# Validation documentation
## *APIs & excipients, solid*

HiperScan GmbH

October 1, 2025

Validation documentation of the chemometrics database of the near-infrared spectrometer *Apo-Ident*.
Report number: **50-2.10-2025-04**

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# Introduction

The unequivocal proof of the identity of pharmaceutical raw materials based on a monograph or traditional alternative methods is work-intense, time-intense and economically often no longer makes sense. Near-infrared spectroscopy (NIR) provides a new means here. It enables relatively easy, fast and nonetheless safe identity testing via the preparation and evaluation of spectra.

The analysis system *Apo-Ident* was developed specially for pharmacy use. Pharmacists have the duty to check the identity of all raw materials for extemporaneous products in their pharmacies. This normally takes place based on the monographs for the respective substances in the European Pharmacopoeia. But also NIR spectroscopy is described in the European Pharmacopoeia as an identification method which, as opposed to the methods incorporated in the respective monographs, is approved for testing [1] (quotation translated)

> *with the prerequisite that the same results ("namely the determination of the identity" [2]),* (quotation translated) *are achieved as with the described methods and instruments.*

The *Apo-Ident* analysis system serves to identify raw materials for prescriptions in the defined manner according to *ApBetrO* [Pharmacies Rules and Regulations] §§ 6 and 11 at pharmacies (NIR spectroscopy as an alternative testing method). *Apo-Ident* consists of three components:

- An *NIR spectrometer*, which records the spectra of non-preprocessed raw materials in a measuring glass in diffuse reflection or transflection.
- The *QuickStep* spectroscopy software controls the instrument and records the spectra and user inputs via a pharmacy-specific software plug-in. It also generates the test protocol for documentation of the testing and storage of the printout to be signed in the pharmacy.
- The software module *IdentModule* incorporates *reference databases*. The spectra from the *QuickStep* software are presented to it for evaluation.

NIR spectroscopy is a very powerful analytical method. It is also able to establish the identity of several chemical compounds and mixes in as far as an appropriate database (technically correct: a chemometric model) was created. Identity testing with *Apo-Ident* is a very safe, very fast and easy to operate analytical method for testing a large number of raw materials.

## Context of this document

The suitability of the instrument, method and database is proven as follows:

- *NIR spectroscopy as a method for identity testing:* The *Ph. Eur.* [3] describes NIR spectroscopy in *Section 2.2.40* as an analytical method which is also suitable for the identification of raw materials. Therefore, validation of the method as such is not necessary.
- *Performance of the instrument:* The *Ph. Eur.* [3] furthermore describes the apparatus and the testing of its performance in *Section 2.2.40*. The document *Erfüllung von 2.2.40 Ph. Eur. durch Apo-Ident* [4] compares the implementation by *Apo-Ident* with this monograph in order to prove that *Apo-Ident* meets the specifications of the Pharmacopoeia. Each individual instrument delivered to a pharmacy is qualified in accordance with the tests described in *"Control of Instrument Performance"*. In this test, the unit consisting of analysis instrument hardware and the *QuickStep* spectroscopy software is assessed. The result is documented in a test protocol which is kept at the pharmacy.
- *Validation of the database* is documented separately for each substance class. The report at hand documents the substance class *APIs & excipients, solid*.

The *Arbeitsgemeinschaft der Pharmazieräte Deutschlands (APD)* [Working Group of German Pharmacy Inspectors] has clarified the following in its resolution dated October 16, 2013 ([5], quotation translated):

> *NIR is a testing method incorporated in the Pharmacopoeia. The testing quality depends on the quality of the database stored. The* APD *views the use of NIR instruments in case of ensured validation of the databases used in conjunction with it as one of several options for identity testing.*

The *APD* defined more precisely ([6], quotation translated) on October 1, 2014:

> *The use of near-infrared is a recognised testing method according to* Ph. Eur. 8. *For the use of NIR instruments in pharmacies for testing the identity of raw materials, sufficient and verifiable validation of the instrument used is required. The quality of the database stored by the instrument manufacturer is decisive for quality. Batch-specific differences with the same original substances must be taken into account if present.*

So NIR is basically suitable. The validity of the reference database is proven with the existing validation documentation.

## Criteria for the inclusion of substances

This validation documentation describes the results of the validation of the reference database for the substance class *APIs & excipients, solid*. Validation documentation is created for each published version of the reference database for all substance classes incorporated.

The reference database is incorporated in the software module *IdentModule*. During identification testing with *Apo-Ident*, spectra which are used for evaluation purposes are presented to it by the *QuickStep* software. In the same manner, the *IdentModule* is presented all validation spectra successively during the validation runs for evaluation purposes. The *IdentModule* responds respectively (without taking the initial assumption into account) with the identified substance or rejects it as unknown. The correctness of this response is checked for each possible initial assumption and counted.

The results are summarised for each substance and reproduced in this document. The core statement of this validation report is that the following criteria must be fulfilled for each database entry, so that *Apo-Ident* offers verification of identity by means of NIR for the relevant substance/substance group:

- The database is exclusively generated from spectra which have been recorded under the control of *HiperScan GmbH* on traceable samples in pharmaceutical quality (for *cannabis flowers*, see *Appendix H*).
  - The samples are procured via typical pharmacy sources (*DAC III.2.: Bezugsquellennachweis für Rezepturbestandteile [reference source for prescription components]* [7]).
  - A valid manufacturer's certificate exists (content, purity and identity of the batch).
  - The identity was confirmed by a certified test laboratory or *HiperScan GmbH*.
- Each version of the reference database (every update) is validated in-full.
  - Calibration spectra (*Type A*), other spectra recorded under the control of *HiperScan GmbH* (*Type B*), and spectra from the field (*Type C*) are presented to the *IdentModule* for evaluation in three separately evaluated validation runs.
  - Here, no single *false positive* result may arise.
  - Here, the various substance classes are also tested for reciprocal rejection, where this is objectively justified (see *Summary* section).
- In the validation with spectra recorded under the control of *HiperScan GmbH*, spectra of at least one independent sample must be considered, i.e. spectra from a batch whose spectra have not been used for the generation of the database. In addition, the set of *Type A* and *Type B* spectra must originate from at least three different batches.
- Spectra of additional substances may be used for the generation of the database even though they will not be offered for identification by this database. The purpose is the reliable distinction from these substances.


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- Any positive result of *Apo-Ident* confirms the identity of the substance/substance group and distinguishes it from all other substances of the database. In the case of substance groups, the result is ambiguous: Distinction from all substances not belonging to the group is proven. The substance is identified as a member of this group. However, within the substance group, it is not possible to reliably classify which substance has been tested.

- The criteria for clear identifiability are a specificity of 100 % (true negative rate) and a minimum distance in the distance matrix. See 2. d) under Model creation procedure and validation runs (for *cannabis flowers*, see *Appendix H*).

## Validation concept

*Chemometrics* is a statistical technique for the extraction of relevant chemical information from spectra. In mathematics, this method is described as *multivariate data analysis*. Chemometrics proceeds here as follows:

1. Collection of spectra for the *calibration sample*. The results (identities) of the calibration sample must be known. The calibration samples must be representative for the samples which are to be evaluated later. Therefore, they must take the various possible (physical) compositions into account. (Therefore, sourcing calibration samples for NIR from the specialist trade is superior to the use of CRS reference substances.)

2. The first mathematical step is *calibration*. Here, the chemometric model is calculated from the *calibration sample spectra* (reference spectra) and limits as well as some parameters are stipulated. The chemometric model is used later to calculate the analysis result (*prediction*).

3. Collection of further spectra for the *validation sample* which should be independent of the *calibration sample*. The results (identities) of the *validation sample* must also be known. The textbook suggests a random sample with a normal scope of 25 % to 50 % of the *calibration sample* [8].

4. The second technical data step is *validation*. Here, the chemometric model created is evaluated based on the spectra of the *validation samples*. As validation parameters for the identification, the *Ph. Eur. Section 2.2.40* [3] specifies the specificity and robustness.

The validation step according to the textbook has the target of estimating the performance capability of the model created based on a random sample. In order to achieve the best possible precision, attention is paid to the calibration sample. In the field of pharmaceuticals, the safety of the method has priority. In order to be able to *validate* the model within the regulatory scope, the validation step must include probative force. For this purpose, the validation sample must be *representative and complete* in order to enable the testing of all cases.

A *sufficient number of batches* must be secured for validation because validation finally proves whether the number of batches in calibration suffices.

Each substance is validated individually. The validation results are documented per substance in this document. Moreover, the documents show how many and which batches have been used for creating the model or model validation.

At least one certificate is taken in for each substance from an accredited test laboratory for the independent testing of identity of the sample. The identification number of the corresponding test certificate is listed in the report, enabling traceability of a substance tested according to the monographs in the Pharmacopoeia.

## Model creation procedure and validation runs

The safety of the chemometric models is guaranteed by several measures during model creation, of which the validation step is the final one. Normally, the procedure is as follows. It is in particular valid for the active pharmaceutical ingredients (APIs) *solid API excipients*, *liquid/semi-solid API excipients (with a test certificate)*, *narcotics - solid medicinal substances* and *cannabis flowers*. If, for individual substance classes, variations are required, they are depicted in the section *Particularities of individual substance classes*.

**1. Collecting the reference spectra (calibration sample)**

a) Procurement of the samples from the same sources from which pharmacies source their raw material for compounding (Caelo, Fagron, Euro-OTC, ..., see also *DAC III.2. Bezugsquellennachweis für Rezepturbestandteile* [Sources of supply for compounding] [7]).

b) Testing the suitability according to *ApBetrO* [Pharmacies Rules and Regulations] §§ 6, 11, that is to say the availability of a valid manufacturer certificates via identity, purity and contents of the batch.

c) Recording standard 40 spectra of the sample in different positions, as a standard on four instruments. Here, handling and presentation of the samples as later in the pharmacy.

d) Visual checking for anomalies in the spectra. In case of indications of measurement errors, measurement must be repeated. If a signature is missing in the spectrum, the substance may be excluded from the start as not promising (the spectra are nonetheless entered in the database validation as independent *Type B* spectra).

e) Testing identity. For each substance, a certificate of correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the respective following substance page of this validation documentation the *Mahalanobis distance* to this reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance. Such samples underline the statistical spread of the original reference substance, but cannot add any new characteristics of the substance.

   *HiperScan GmbH* cooperates with some suppliers as follows: the raw materials supplier takes a sufficiently large sample in his incoming goods area so that part of it can be used for recording the NIR spectra. The remainder of the sample goes to analytics for market approval. The manufacturer's batch certificate emerges from these identity, contents and purity tests, which consequently also prove the correct identity of the NIR reference sample. Therefore, the NIR spectra are suitable for structuring the database *(Type A)* and can also optionally be used for validation *(Type B)*. The samples which this applies to are marked in the validation report with a footnote.

f) If the identity of the new sample is proven, it is declared as a reference sample and the spectra are approved for structuring the database.

**2. Generating the chemometric models (calibration)**

a) Determination of the transformation matrix from the reference spectra using variance maximisation [8, 9]. (*All* reference spectra are always included, even if only a few spectra are added for an update.) All reference spectra receive the same data pre-treatment, which is also later applied to all measurement spectra in the field (in the pharmacies).

b) Checking that the number of principal components used is still sufficient.

c) Calculating the limits for each substance from the spread of the reference spectra. The calculation regulation is identical for each substance in a substance class.

d) Checking the distances between the limits of the separable substances: The distance matrix contains the *Mahalanobis distances* from each substance to each other. The values in a bidirectional manner are different in each case because the spread of the initial substance is included. If a distance is smaller than the minimal distance, the substances are not considered to be reliably separable. The minimal distance is set at 9. The developer of the model may specify a larger minimal distance (one value for the entire *chemometric model*), to increase the selectivity.

e) Verification of the model using the reference spectra. No *false-positive* results are permitted.

f) If one of the criteria is violated (d) *Minimum distance between two substances undershot* or (e) *One substance is identified as another*, the database developers decide which of the following options to apply:


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- They remove both substances from the database. (The spectra remain in the validation and may also be included when generating the model. However, they are not offered for testing.)
- They form a substance group of several substances which cannot be reliably separated. The result is then ambiguous: The chemometric model determines that the sample is one of the substances in the group and not another substance. However, it cannot determine which of the group members it is. In order to determine the clear identity, the user must carry out a suitable additional analysis.
- They create another *chemometric model* with a smaller scope, in which at least all substances of the non-separable substance group are included (second-stage model). Second-stage models are only called up if the first stage has established that only one of the substances included in the second-stage model can be involved. The second-stage models are documented in the appendix *Addition to the second-stage models*.

g) If *chemometric models* that fulfil both criteria (distance matrix and no *false positives*), are available for all substance classes, they are combined with the evaluation algorithms to form an *IdentModule* and encoded. This unit can no longer be changed. Its overall function is checked by the validation.

### 3. Set of validation spectra (validation samples)

The following is provided for validation:

a) *Type A*: The reference spectra = calibration spectra from which the database was generated. These also include spectra from substances which the *chemometric model* should not identify, but were also recorded during generation in order to increase selectivity. (As a result, the model "learns" to differentiate from other substances which are actually unknown to it.)

b) *Type B*: Spectra recorded under the control of *HiperScan GmbH* and not used for the generation of the database. These also include reference spectra of other substance classes, and spectra that are not used as reference spectra. Samples are considered to be independent, if they originate from a batch, of which no spectra have been used for the generation of the database. (Up to *IdentModule 2018-01*, samples were still considered independent if the sampling was done independently, i.e. if they originate from another sales container.)

c) *Type C*: Spectra from the field, which have not been recorded under the control of *HiperScan GmbH* and have not been used for the generation of the database. The spectra include not only substances of the substance class to be tested, but also substances from other classes.

All manufacturers' batches from which spectra are used for the validation are listed by substance in this document: for substances included in the substance class *APIs & excipients, solid* in the respective validation reports; otherwise in attachments *A*, *B* and *C*.

Furthermore remains valid: validation spectra may only be removed if an error in the spectrum can be proven. Here, the spectra are not deleted, but instead placed on a *blacklist* incorporating the reason, date and initials in the commentary.

The section *Particularities of individual substance classes* treats the other substance classes from which *Type B* and *Type C* spectra are cited for validation purposes.

### 4. Validation runs and approval

a) Validation spectra are transferred holistically to the *IdentModule* for evaluation in the same way as the spectroscopy software *QuickStep* transfers measured spectra.

b) Following the provision of each spectrum, the *IdentModule* responds as to whether it has recognised a substance and which substance was recognised.

c) The correctness of this response is checked for each possible initial assumption (each measurable substance with the substance class) and counted according to *true negative*, *false negative*, *true positive* and *false positive*. These figures are provided for each substance and additionally in the section *Summary*, separated according to types *A*, *B* and *C* .

d) No *false positive* results whatsoever are permissible.

e) If the criterion is also met for all substance classes, the *IdentModule* is approved.

## Particularities of individual substance classes

Basically, *HiperScan GmbH* procures and tests the manufacturer's certificate for the batch, commissions external testing of the identity of the sample or carries it out independently and stores the certificates. As described, this process is established for the Pharmacopoeia substances, that is to say for substance classes **APIs & excipients, solid**, **APIs & excipients, liquid/semi-solid (with analysis certificate)**, **Narcotic substances, liquid/semi-solid** and for the most part also *cannabis flowers* (see *Appendix H*). Therefore, *HiperScan GmbH* is able to furnish proof of the identity of the reference samples. In case of manufacturer-specific substance classes and others, individual steps are organised differently in-part:

The substance class **APIs & excipients, liquid/semi-solid (other)** (often described as cosmetics) incorporates substances for which no specification of the requirements of the pharmaceutical quality is determined, neither in a Pharmacopoeia monograph, a DAC/NRF monograph nor via a manufacturer's specification. Consequently, neither the identity nor contents can be tested independently. No certificates whatsoever exist for the reference samples. So here, merely the matching of the sample with former samples of this product is established and confusion with the other substances is ruled-out. (If the manufacturer of such a substance prepares a specification, determines testing methods and provides manufacturer's certificates in accordance with *ApBetrO* [Pharmacies Rules and Regulations] §§ 6, 11, *HiperScan GmbH* can assign the substance to the substance class *APIs & excipients, liquid/semi-solid (with analysis certificate)* again in the future).

Substance class **HCK – nutritional supplements (Hepart)** contains the HCK micro-nutrients from the Swiss company *Hepart AG*. *HiperScan GmbH* receives the reference samples directly from the manufacturer. For each reference sample, *HiperScan GmbH* also receives manufacturer's certificates and keeps these. New checking of the identity of the reference sample is not carried out by *HiperScan GmbH*. The identity of the reference samples is therefore documented by *Hepart AG*. The spectra of all batches provided by *Hepart AG* are recorded under the control of *HiperScan GmbH* and entered in the database.

All the manufacturer's batches are used for the generation and validation of the substance class *HCK*. The expected variation is also represented in the generation and validation if there are less than three batches.

## Significance of testing with *Apo-Ident*

The analysis result is determined using sophisticated statistical methods according to state-of-the-art science and technology. Chemical and pharmaceutical knowledge is applied for the selection of the samples from which the calibration spectra and validation spectra are recorded. Otherwise it does not influence the further steps of model creation.

Verbally, the statement of the analysis result can be expressed as follows. Here *"the spectra match"* means that the criteria *Mahalanobis distance*, *outlier analysis* and *correlation* are met as shown in *Erfüllung von 2.2.40 Ph. Eur. durch Apo-Ident* [4]. "The spectra do not match", on the other hand, means that at least the criterion *Mahalanobis distance* is not met. A different evaluation procedure is only used for *cannabis flowers* (see *Appendix H*).

The positive analysis result *"was identified as . . . "* is very meaningful because both the quantity of substances to be taken into account and the number of underlying samples is very comprehensive.

1. The spectrum of the sample measured matches spectra of the defined substance.

2. The spectrum of the sample measured does not match any spectrum of any other substance in this substance class. Therefore, all other substances can be clearly ruled-out.

3. As the spectra from other substance classes were used for validation, it is proven that no spectrum of one of these other substances matches the defined substance. (All substance classes with which a spectrum comparison is possible and makes sense are used for validation. This is documented for each substance class in the section *Summary*.)


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4. If the defined substance belongs to a *substance group* which in itself is not clearly separable with *Apo-Ident*, matching with the spectra of one or several substances in this group is confirmed. Which of these substances it actually is cannot be determined clearly. All other substances are excluded analogous to 2 and 3.

On the other hand, a negative analysis result *"was not identified as ..."* means:

1. The substance offered could not be recognised based on the spectrum of this sample.
2. The identity of this sample is not confirmed.
3. Testing must be repeated in accordance with the specifications of the Pharmacopoeia.

## Conclusion

NIR spectroscopy is a testing method incorporated in the Pharmacopoeia. In case of successful database validation, it is a possible method for identity testing [5]. *Apo-Ident* meets the criteria of the *European Pharmacopeia* as a near-infrared spectrometer and proves the validity of the reference database with the existing validation documentation. This means that *Apo-Ident* can be used as an alternative testing method for testing raw materials at pharmacies.

# Explanation of terminology

The following section serves to explain or define specialist terminology which is required in order to understand this document. If necessary, definitions for the analysis system *Apo-Ident* are defined more precisely.

**The term database** is used in this document exactly as in the *Ph. Eur. Section 2.2.40* [3] synonymous with chemometric model. In order to differentiate the databases which are relatively independent of each other, *HiperScan GmbH* frequently also uses the term substance class (primarily in the plural). On the other hand, the spectra used to structure the database are termed spectrum collection and not database.

**Substance classes** are units of the organisational structure of the *IdentModule*. The substance classes are substance databases which are also broadly independently subscribable. On the one hand, the liquid and semi-solid substances are separated from the solid powders because they are measured against different references and therefore the spectra cannot be compared. On the other hand, for example the Pharmacopoeia substances are kept separated from the manufacturer-specific database HCK micro-nutrients from the Swiss company *Hepart AG*.

The individual substance classes need only be limited against each other in-part. Often, no risk of confusion exists because they can only be procured from different sources. On the other hand, in several cases we handle substances which need not be distinguished. For example, *Angelica root oil* of the substance class *APIs & excipients, liquid/semi-solid (with analysis certificate* neither needs to be delimited from *Angelica root oil* of the substance class *APIs & excipients, liquid/semi-solid (other)* nor is matching required. Respectively one single chemometric model is behind a substance class. (Even if several reciprocally secured chemometric models would be permissible.) The terms *substance class*, *chemometric model* and *databases* are mostly used here as synonyms.

**A substance group** respectively summarises all the substances within a substance class which cannot safely be distinguished from one another based on their NIR spectra. However, all the other substances in the database can be excluded.

**The formation of subgroups** is mentioned in the *Ph. Eur. Section 2.2.40* [3]. In this manner, technical restrictions in case of extensive databases can be avoided and it is possible to prepare individual subgroups with different spectrum pre-treatment. Validation of the subgroups against each other is required. *HiperScan GmbH* has solved these technical restrictions and doesn't use any subgroups within a substance class any longer.

**Principal component analysis (PCA)** [8, 9] is a multivariate statistics process or multivariate data analysis. It serves to structure, simplify and illustrate comprehensive data records by describing a large number of statistical variables by describing a lower number of linear combinations (the *principal components*) which are as significant as possible. In the *Apo-Ident IdentModule*, *PCA* is used to evaluate the recorded spectrum data (corresponding with *Ph. Eur. 2.2.40* [3]).

**The term validation** is defined in both relevant contexts here with different (even if related) meanings.

Within the sense of the expert discipline of *chemometrics*, validation is a process step when creating a chemometric model: after a transformation matrix, limits and various parameters have been calculated or determined from a set of reference spectra during the course of the calibration step [8, 9], the validation step determines the performance capability of the model (selectivity, precision, ...) based on the validation spectra. Normally, random sampling is planned here. In order for the validation to gain strength of proof, the validation spectrum set must be selected with an appropriately wide scope (*representative* and *complete*). The terms *validation run* and *validation step* always actually mean the process step in this sense.

In the regulatory sense (of pharmaceutical production), validation is the documented proof that a process or system meets the previously specified requirements reproducibly when applied practi-


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cally. In this sense, the *Apo-Ident* databases only become validated databases with the validation documentation, which this document is part of.

The *European Pharmacopeia* uses the term validation in *Section 2.2.40* within the sense of the specialist discipline of *chemometrics* [3].

**The robustness** of a process is the property of only being influenced by environmental fluctuations (e.g. temperature or humidity) a little. A method is robust if the environmental conditions do not or hardly falsify the final result.

**The specificity** of a classification (of a chemometric model) is the true negative rate.

**The recognition rate** (also sensitivity) is the true positive rate. It defines in how many percent of cases a correctly set up substance is actually confirmed.

**The true negative rate** describes the share of spectra correctly classified as non-identity during validation. This is equivalent to correct classification. It means that a substance $A$ within identity checking as substance $B$ is judged as *"not identified"*. The *true negative rate* is equivalent to the conditional frequency

$$h(\text{rejected}|\text{genuinely no identity}) = \frac{r_n}{r_n + f_p}$$

with $r_n$ as the total number of *true negative* classifications and $f_p$ as the total number of *false positive* classifications. For successful validation of an *IdentModule*, all spectra presented belonging to this category must be classified as *not in accordance*.

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of this number. The weight of each spectrum of a substance/substance group $i$ therefore results as

$$w_i = \frac{1}{n_i}$$

with $n_i$ number of spectra in this substance/substance group. This weighting ensures that the overall result cannot be enhanced by adding especially large numbers of spectra from easily separable substances.

**The true positive rate** describes the share of spectra correctly classified as identity during validation. This is equivalent to correct classification. It means that a substance $A$ within identity checking as substance $A$ is judged as *"identified"*. The *true positive rate* is equivalent to the conditional frequency

$$h(\text{identified}|\text{genuine identity}) = \frac{r_p}{r_p + f_n}$$

with $r_p$ as the total number of *true positive* classifications and $f_n$ as the total number of *false negative* classifications. The *true positive* rate is a measure for the recognition rate of the validated *Apo-Ident IdentModule*.
In order to ensure that each substance is received with the same weight, the spectra are weighted as described for the true negative rate.

**The true negative result** describes a spectrum correctly classified as non-identity during validation. It is equivalent to correct classification. It means that a substance $A$ within identity checking as substance $B$ is judged as *"not identified"*.

**The false positive result** describes a spectrum falsely classified as non-identity during validation. This is the most critical type of possible false classification. It means that a substance $A$ within identity checking as substance $B$ is judged as *"identified"*. For successful validation of an *IdentModule*, a number of false positive events of zero are demanded for all spectra entering the validation.

**The true positive result** describes a spectrum correctly classified as identity during validation. It is equivalent to correct classification. It means that a substance $A$ within identity checking as substance $A$ is judged as *"identified"*.

**The false negative result** describes a spectrum falsely classified as non-identity during validation. It is equivalent to false classification. It means that a substance $A$ within identity checking as substance $A$ is judged as *"not identified"*.

**The 'Rule of Three'** says that with a probability of 95 % the next random sample of the same size no more than three false results are to be expected if no false result existed in the existing random sample [10, 11].

The *specificity* and *recognition rate* are determined both globally and from the validation runs for all substances. The information is supplemented with the hypothetical value if there had been three false results more. The percent information is provided in parentheses with the "greater than" symbol '>', e.g. *specificity* 100.000 % (>99.983 %) if 17 567 false spectra have been presented without one single *false positive* result. The larger the statistical basis, the lower the influence of the hypothetical false results.

**The Mahalanobis distance** is a distance measure between two points in $n$-dimensional vector space. Here, the respective direction component of the distance to *standard deviation* [12] of an $n$-dimensional distribution is standardised. In case of the *principal component analysis* [8, 9] this standardisation relates to the distribution of the respective calibration data set for a classification (substance/substance group) in the *principal component space* [8]. The *Mahalanobis distance* of a point (mapping of a spectrum) $\vec{y}$ in the $n$-dimensional principal component space to the expected value of an $n$-dimensional distribution $\mathbf{X}$ then results as

$$d(\mathbf{X}, \vec{y}) = \sqrt{(\bar{\mathbf{X}} - \vec{y})^T \mathbf{S}^{-1} (\bar{\mathbf{X}} - \vec{y})} \qquad \text{with} \qquad \mathbf{X} \in \mathbb{R}^{m \times n}, \vec{y} \in \mathbb{R}^m$$

[13]. Here, $m$ is equivalent to the number of principal components used (dimension of the principal component space) and $n$ the number of measurements existing in the calibration data set (spectra). $\bar{\mathbf{X}}$ is the expected value of the resulting distribution for the calibration data set (the average value of $n$ measurements received). $\mathbf{S}^{-1}$ is the inverse covariance matrix [12] for distribution $\mathbf{X}$.

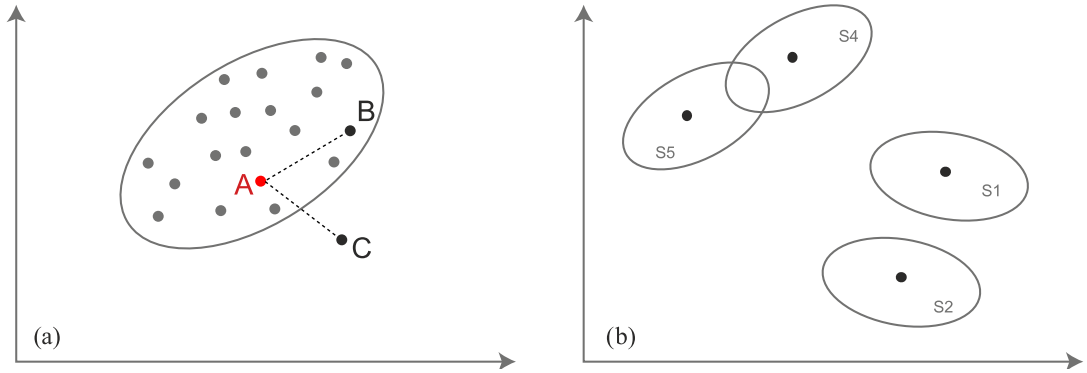



**Figure 1:** (a) The *Mahalanobis distance* from $A$ to $B$ is less than from $A$ to $C$. However, the Euclidean distances are identical. (b) The *Mahalanobis distance* between the two measurement series *S4* and *S5* is smaller than between *S1* and *S2*. However, the Euclidean distances are identical.

The *Mahalanobis distance* offers advantages compared to the *Euclidean distance*: For the calculation of the distance it takes the statistical properties of a data point distribution (measurement series), i.e. average value, variance and covariance of the data points [14] into account. The *Mahalanobis distance* is applied while creating the reference database for evaluating the spectra from different samples of a substance.


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**A chemometric model** is a classifier based on statistical methods [8, 9]. Through the respective algorithm used (e.g. *Principal Component Analysis*, *Cluster Analysis*), a maximum of chemical information is extracted from measurement data. Here, systematical or physical disturbances are eliminated using appropriate data pre-processing [15, 16].

At several places in this document, in order to simplify understanding, the term database is used instead of *chemometric model* – in the same manner as in the *Ph. Eur. Section 2.2.40* [3].

**A sample** (with its own sample ID) refers to substance in a sales container. Repeated sampling from the same sales container is listed under the same sample ID. (The suffix "SI" is not part of the sample ID.) Several samples may originate from the same batch. Samples are called "independent", if they originate from a batch, of which no spectra have been used for the generation of the database. (Up to *IdentModule 2018-01*, samples from different sales packages were considered to be independent.) The information above the list of validation spectra now includes also the number of batches that deliver independent samples for the validation (for both *Type B* and *Type C*).

In case a supplier takes a sample for testing from its incoming goods and splits it to multiple laboratory containers, the substance in all laboratory containers will still be ascribed to the same sample. *HiperScan GmbH* only uses one of the subsamples.

**Reference samples** are used to structure the database. The *reference spectra* originate from these samples. In chemometric technical jargon you would normally say: For *calibration*, a *chemometric model* is generated from the *calibration spectra* recorded from the *calibration samples*, whose quality is subsequently assessed in validation.

*Reference samples* are procured via typical pharmacy sources. Their identity is tested. The *reference spectra* are recorded under the control of *HiperScan GmbH*. The documentation also includes the manufacturer's name and batch number.

*Reference samples* are clearly identified by a sample ID. Samples without sample ID may not be used as *reference samples*.

# Summary

A total of 628 152 spectra from 58 128 different batches for a total of 993 substances were used to validate the substance class *APIs & excipients, solid*.

## Validation samples

The validation samples can be categorised as follows:

**Type A** Calibration spectra. These are the spectra used to generate the chemometric model. They were recorded under the control of *HiperScan GmbH*. Detailed information regarding the batches or samples can be found in the following validation reports under *calibration samples* and under *Type A*. Further information is listed in *Appendix A*.

| Substance class | Substances | Batches | Spectra |
|---|---|---|---|
| APIs & excipients, solid | 397 | 2686 | 143 158 |
| APIs & excipients, solid (BR) | 36 | 59 | 2480 |
| Specific classifier 26188 | 17 | 38 | 1790 |
| Narcotic substances, solid | 13 | 66 | 6000 |
| Drugs | 42 | 109 | 4898 |

From category *A* a total of 158 326 spectra from 2958 batches for a total of 505 substances were taken into account for validation.

**Type B** Spectra from independent samples which are not included in database generation. These spectra were recorded under the control of *HiperScan GmbH*. Detailed information regarding the batches or samples can be found in the following validation reports in the section *Type B* or in *Appendix B*.

| Substance class | Substances | Batches | Spectra |
|---|---|---|---|
| APIs & excipients, solid | 536 | 3529 | 177 169 |
| APIs & excipients, solid (BR) | 58 | 133 | 5900 |
| Drugs | 254 | 533 | 23 532 |
| Specific classifier 26188 | 12 | 23 | 979 |
| Narcotic substances, solid | 17 | 66 | 5040 |
| Chemicals, solid | 8 | 8 | 320 |

From category *B* a total of 212 940 spectra from 4292 batches for a total of 885 substances were taken into account for validation.

**Type C** Spectra from independent samples which are not included in database generation. *ApoIdent* customers carried out the measurements. Detailed information regarding the batches or samples can be found in the following validation reports in the section *Type C* or in *Appendix C*.

| Substance class | Substances | Batches | Spectra |
|---|---|---|---|
| APIs & excipients, solid | 421 | 46 013 | 239 910 |
| Narcotic substances, solid | 15 | 937 | 2553 |
| Drugs | 286 | 6039 | 14 415 |
| Specific classifier 26188 | 3 | 7 | 8 |

From category *C* a total of 256 886 spectra from 52 996 batches for a total of 725 substances were taken into account for validation.

## Validation results

The validation runs checked whether all substances/substance groups in the substance class *APIs & excipients, solid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, the matching of all relevant spectra of various substances with the substances/substance groups in the substance class *APIs & excipients, solid* was checked and the correctness of the results was evaluated. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 142 333 | 55 | 55 430 038 |
| **Type B** | 0 | 161 415 | 244 | 74 579 823 |
| **Type C** | 0 | 234 763 | 2855 | 89 928 580 |

All substances/substance groups in the substance class *APIs & excipients, solid* can be clearly distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.000 00 % (> 99.999 98 %) | 99.975 46 % (> 99.972 57 %) |
| **Type B** | 100.000 00 % (> 99.999 98 %) | 99.732 43 % (> 99.728 17 %) |
| **Type C** | 100.000 00 % (> 99.999 72 %) | 98.777 96 % (> 98.723 35 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **4-Aminobenzoic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005947-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

4-Aminobenzoic acid; Acidum 4-aminobenzoicum

### Special notes

When selecting the *4-Aminobenzoic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| 4-Aminobenzoic acid | 4 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *4-Aminobenzoic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *4-Aminobenzoic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 177.04 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *4-Aminobenzoic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *4-Aminobenzoic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | 4-Aminobenzoic acid | 2111019 | 25867 | 50 | 20211208* |
| Euro OTC | 4-Aminobenzoic acid | 2203029 | 26050 | 40 | 20220408* |
| Euro OTC | 4-Aminobenzoic acid | 2205024 | 26207 | 40 | 20220620* |
| Euro OTC | 4-Aminobenzoic acid | 2205024 | 26207SI | 20 | 20220620* |
| Euro OTC | 4-Aminobenzoic acid | 2302016 | 26754 | 40 | 20230511* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 190 spectra of 5 reference samples from the substance/substance group *4-Aminobenzoic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 136 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 4 reference samples from the substance/substance group *4-Aminobenzoic acid*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | 4-Aminobenzoic acid | 2008012 | 25394 | 40 |
| Euro OTC | 4-Aminobenzoic acid | 2111019 | 25867SI† | 10 |
| Euro OTC | 4-Aminobenzoic acid | 2203029 | 26050SI† | 10 |
| Euro OTC | 4-Aminobenzoic acid | 2302016 | 26754SI† | 20 |

- 212 860 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *4-Aminobenzoic acid*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

### Validation results

The validation runs checked whether the substance/substance group *4-Aminobenzoic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *4-Aminobenzoic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 190 | 0 | 158 136 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *4-Aminobenzoic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.8421 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25867 | 25867 | 0.00 | 298.34 |
| 26050 | 26050 | 0.00 | 299.09 |
| 26207 | 26207 | 0.00 | 299.66 |
| 26754 | 26754 | 0.00 | 298.87 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **5-aminolevulinic acid hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20371-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

5-aminolevulinic acid hydrochloride; Acidum aminolaevulinicum hydrochloricum

### Special notes

When selecting the *5-aminolevulinic acid hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| 5-aminolevulinic acid hydrochloride | 7 | 7 | 86 |

### Second-stage model

For differentiation of the substance/substance group *5-aminolevulinic acid hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *5-aminolevulinic acid hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 101.00 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *5-aminolevulinic acid hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *5-aminolevulinic acid hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | 5-aminolevulinic acid hyd… | 16357904 | 23208 | 40 | 1707616 |
| Caelo | 5-aminolevulinic acid hyd… | 16357904 | 23747 | 40 | 20170324 |
| Caelo | 5-aminolevulinic acid hyd… | 190219 | 24733 | 40 | 20190312* |
| Caelo | 5-aminolevulinic acid hyd… | 192811002 | 25371 | 40 | 20191107 |
| Caelo | 5-aminolevulinic acid hyd… | 20004269 | 25645 | 40 | 20210202* |
| Fagron | 5-aminolevulinic acid hyd… | 13K27-N02 | 21339 | 40 | 20131125 |
| Fagron | 5-aminolevulinic acid hyd… | 17A12-B07-332960 | 23403 | 40 | 20170131 |
| Fagron | 5-aminolevulinic acid hyd… | 17A12-B07-332960 | 23404 | 40 | 20170131 |
| Fagron | 5-aminolevulinic acid hyd… | 19K14-F02-366541 | 25372 | 40 | 20191209 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *5-aminolevulinic acid hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 375 spectra of 12 reference samples from the substance/substance group *5-aminolevulinic acid hydrochloride*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | 5-aminolevulinic acid hyd… | 22003347 | 26505 | 40 |
| Caelo | 5-aminolevulinic acid hyd… | 24000220 | 27558 | 40 |
| Fagron | 5-aminolevulinic acid hyd… | 18C16-B05-347714 | 24099 | 40 |
| Fagron | 5-aminolevulinic acid hyd… | 21G28-B05-216542 | 25843 | 50 |
| Fagron | 5-aminolevulinic acid hyd… | 21L14-B01-220727 | 26082 | 40 |
| Fagron | 5-aminolevulinic acid hyd… | 22B16-B03-218068 | 26297 | 40 |
| Fagron | 5-aminolevulinic acid hyd… | 23B17-B04-227315 | 26685 | 40 |
| Caelo | 5-aminolevulinic acid hyd… | 22003347 | 26505SI | 20 |
| Fagron | 5-aminolevulinic acid hyd… | 21G28-B05-216542 | 25843SI | 15 |
| Fagron | 5-aminolevulinic acid hyd… | 21L14-B01-220727 | 26082SI | 10 |
| Fagron | 5-aminolevulinic acid hyd… | 22B16-B03-218068 | 26297SI | 20 |
| Fagron | 5-aminolevulinic acid hyd… | 23B17-B04-227315 | 26685SI | 20 |

- 212 565 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 120 spectra from 43 *Apo-Ident* customers from 90 batches from the substance/substance group *5-aminolevulinic acid hydrochloride*.

- Among them are spectra of independent samples from 86 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | 5-aminolevulinic acid hyd… | 13C-19-N07 | 1 |
| | 5-aminolevulinic acid hyd… | 22H03-B02-225921 | 1 |
| | 5-aminolevulinic acid hyd… | 23B17-B04-227317 | 1 |
| Biosynth AG / Otto | 5-aminolevulinic acid hyd… | 20563 | 1 |
| Biosynth AG | 5-aminolevulinic acid hyd… | F05-3695208 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 11355616 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 12093205 | 2 |
| Caelo | 5-aminolevulinic acid hyd… | 12093208 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 13017402 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 13017403 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 13K27-N02 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 14145003 | 2 |
| Caelo | 5-aminolevulinic acid hyd… | 14145007 | 3 |
| Caelo | 5-aminolevulinic acid hyd… | 14145011 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 14K04-B01-297971 | 2 |
| Caelo | 5-aminolevulinic acid hyd… | 15254803 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 16357902 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 16357910 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 18026102 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 18C16-B05-347711 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 18C16-B05-37711 | 1 |
| Caelo | 5-aminolevulinic acid hyd… | 19281105 | 1 |
| Caeolo | 5-aminolevulinic acid hyd… | 15254803 | 1 |
| Caesar & Loretz GmbH | 5-aminolevulinic acid hyd… | 192811002 | 1 |
| Caesar & Loretz GmbH | 5-aminolevulinic acid hyd… | 20004269005 | 1 |
| Caesar & Loretz GmbH | 5-aminolevulinic acid hyd… | 22003347002 | 1 |
| Euro OTC | 5-aminolevulinic acid hyd… | 18L03-B01-357231 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 11I30-N01 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 12c23-n05 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 12H20-N01 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 12K26-N05 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 13C19-N05 | 3 |
| Fagron | 5-aminolevulinic acid hyd… | 13G18-B06-355728 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 13H13-N07 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 13J29-N03 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 13K27-N02 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 14802 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 14K13-B01 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 15C06-B02-305245 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 15J23-B06 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 15J23-B06-314284 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16A11-B02 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16A11-B02-316734 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16A11-B02-317459 | 3 |
| Fagron | 5-aminolevulinic acid hyd… | 16A11-B02-318406 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16E17-B08-324962 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 16G27-B10 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16I12-B06 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16I12-B06-326185 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16K17-B09-328197 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 16K17-B09-330371 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17/22-B02-342555 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 1701-b05-342090 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17A12-B07-331744 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17A12-B07-331745 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17F01-B05-338204 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17F01-B06_337165 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | 5-aminolevulinic acid hyd… | 17F01-B06-337163 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 17F01-B06-337164 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 17I22-B02 | 3 |
| Fagron | 5-aminolevulinic acid hyd… | 17I22-B02-343410 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17I22-B02-343411 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17L18-B05-344673 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 17l22-B02-343410 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 18C16-B05 | 4 |
| Fagron | 5-aminolevulinic acid hyd… | 18C16-B05-347714 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 18D10-B02-361711 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 18D17-B02349681 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 18G13-806-352897 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 18G13-B06 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 18G13-B06-355728 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 18L03-B01 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 18L03-B01-360101 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 19G31-B02 | 5 |
| Fagron | 5-aminolevulinic acid hyd… | 19G31-B02-363475 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 19G31-B02-364671 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 19G31-B02-364672 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 19G31-B02-36473 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 19K14-F02-366541 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 19K14-F02-366544 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 19K14-F02-368326 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 20A29-F05-367867 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 20A29-F05-369528 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 20F04-F01-371114 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 20F04-F01-371115 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 20F04-F02-371121 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 21G28-B05-213714 | 2 |
| Fagron | 5-aminolevulinic acid hyd… | 22H03-B02-225921 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 23B17-B04-227315 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 23B17-B04-227317 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 24C22-B01-238799 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 25414 | 1 |
| Fagron | 5-aminolevulinic acid hyd… | 7447 | 1 |
| Fiebig | 5-aminolevulinic acid hyd… | 18c16-b05-347711 | 1 |

- 256 766 spectra from 1666 *Apo-Ident* customers from a total of 52 064 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *5-aminolevulinic acid hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *5-aminolevulinic acid hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 375 | 0 | 212 565 |
| **Type C** | 0 | 118 | 2 | 256 766 |

The substance/substance group *5-aminolevulinic acid hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.3333 % (> 95.8333 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21339 | 23208 | 56.51 | 127.72 |
| 23208 | 23208 | 0.00 | 127.95 |
| 23403 | 23208 | 46.97 | 126.22 |
| 23404 | 23208 | 39.21 | 127.14 |
| 23747 | 23208 | 6.01 | 127.92 |
| 24733 | 24733 | 0.00 | 123.80 |
| 25371 | 23208 | 38.30 | 129.83 |
| 25372 | 23208 | 45.66 | 126.97 |
| 25645 | 25645 | 0.00 | 127.20 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Acacia, dried dispersion** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20457-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Acacia, dried dispersion; Acaciae gummi dispersione desiccatum

### Special notes

When selecting the *Acacia, dried dispersion* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Acacia, dried dispersion | 6 | 3 | 15 |

### Second-stage model

For differentiation of the substance/substance group *Acacia, dried dispersion* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Acacia, dried dispersion* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 24.93 | – |
| SyrSpend® SF pH4 | 31.76 | 14.60 |
| SyrSpend® SF Alka | 37.71 | 24.48 |
| Cannabis flower, CBD-dominant type | 41.39 | – |
| Rice starch | 43.11 | 25.08 |
| SyrSpend® SF pH4 neo (Maize starch) | 44.25 | 16.02 |
| Calcium glycerophosphate | 49.88 | 32.84 |
| ⋮ | ⋮ | ⋮ |
| Wheat starch | >50 | 21.43 |
| Carmellose sodium | >50 | 23.55 |
| Corn starch | >50 | 26.20 |
| Colistin sulfate | >50 | 29.01 |
| Maltodextrin | >50 | 32.61 |
| Polymyxin B sulfate | >50 | 32.69 |
| Potato starch | >50 | 32.88 |
| Cyanocobalamin | >50 | 48.27 |
| Bacitracin | >50 | 53.36 |
| Riboflavin | >50 | 62.74 |
| Amphotericin B | >50 | 75.58 |
| Tosylchloramide sodium | >50 | 84.83 |
| Calcium pantothenate | >50 | 85.37 |
| Nystatin | >50 | 86.65 |
| Oxalic acid | >50 | 93.48 |
| Fructose | >50 | 98.39 |
| Gelatine, white | >50 | 105.35 |
| Hyoscine hydrobromide | >50 | 111.20 |
| alpha-tocopheryl acetate dry concentrate | >50 | 131.61 |
| Triamcinolone | >50 | 133.22 |
| Estradiol hemihydrate | >50 | 136.06 |
| Estriol | >50 | 169.33 |
| Methylcobalamin | >50 | 174.31 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Acacia, dried dispersion* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Acacia, dried dispersion*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Acacia, dried dispersion | 14141901 | 21431 | 120 | AR-15-FG-006809-01 |
| Caelo | Acacia, dried dispersion | 15413201 | 22653 | 40 | AR-17-FG-000844-01 |
| Caelo | Acacia, dried dispersion | 181860 | 24730 | 40 | 20180725* |
| Caelo | Acacia, dried dispersion | 192248013 | 25501 | 40 | 20190828 |
| Caelo | Acacia, dried dispersion | 24001100 | 27261 | 40 | 20240604* |
| Caelo | Acacia, dried dispersion | 24002524 | 27443 | 40 | 20241105* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 6 reference samples from the substance/substance group *Acacia, dried dispersion*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 210 spectra of 7 reference samples from the substance/substance group *Acacia, dried dispersion*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Acacia, dried dispersion | 162331 | 22853 | 40 |
| Caelo | Acacia, dried dispersion | 16233105 | 23443 | 40 |
| Caelo | Acacia, dried dispersion | 21003060 | 25982 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Acacia, dried dispersion | 16233105 | 23444 | 40 |
| Caelo | Acacia, dried dispersion | 21003060 | 25982SI | 10 |
| Caelo | Acacia, dried dispersion | 24001100 | 27261SI† | 20 |
| Caelo | Acacia, dried dispersion | 24002524 | 27443SI† | 20 |

- 212 730 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 18 spectra from 15 *Apo-Ident* customers from 16 batches from the substance/substance group *Acacia, dried dispersion*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Acacia, dried dispersion | 11345715 | 1 |
| Caelo | Acacia, dried dispersion | 12111301 | 1 |
| Caelo | Acacia, dried dispersion | 12138607 | 1 |
| Caelo | Acacia, dried dispersion | 12138612 | 1 |
| Caelo | Acacia, dried dispersion | 12372302 | 1 |
| Caelo | Acacia, dried dispersion | 15086704 | 1 |
| Caelo | Acacia, dried dispersion | 15413201 | 1 |
| Caelo | Acacia, dried dispersion | 15413207 | 1 |
| Caelo | Acacia, dried dispersion | 16233105 | 2 |
| Caelo | Acacia, dried dispersion | 20002146003 | 1 |
| Caelo | Acacia, dried dispersion | 21003060008 | 2 |
| Caelo | Acacia, dried dispersion | 21003060011 | 1 |
| Caelo | Acacia, dried dispersion | 3314A160121 | 1 |
| Caesar & Loretz GmbH | Acacia, dried dispersion | 18186001 | 1 |
| Klenk | Acacia, dried dispersion | 3314A140121 | 1 |
| ROHA | Acacia, dried dispersion | 170190 | 1 |

- 256 868 spectra from 1666 *Apo-Ident* customers from a total of 52 137 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Acacia, dried dispersion* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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purpose, all relevant spectra of the various substances were compared with *Acacia, dried dispersion* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 210 | 0 | 212 730 |
| **Type C** | 0 | 18 | 0 | 256 868 |

The substance/substance group *Acacia, dried dispersion* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.1429 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21431 | 21431 | 0.00 | 42.75 |
| 22653 | 22653 | 0.00 | 39.51 |
| 24730 | 24730 | 0.00 | 41.66 |
| 25501 | 22653 | 6.61 | 39.41 |
| 27261 | 27261 | 0.00 | 39.21 |
| 27443 | 27443 | 0.00 | 39.20 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Acetylcysteine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20040-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Acetylcysteine; Acetylcysteinum

### Special notes

When selecting the *Acetylcysteine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Acetylcysteine | 8 | 17 | 54 |

### Second-stage model

For differentiation of the substance/substance group *Acetylcysteine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Acetylcysteine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 116.17 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Acetylcysteine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Acetylcysteine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Acetylcysteine | 12299020 | 21315 | 40 | 20121026 |
| Caelo | Acetylcysteine | 161398 | 22469 | 60 | 20160520* |
| Euro OTC | Acetylcysteine | 1208026-01 | 21628 | 60 | 20121116 |
| Euro OTC | Acetylcysteine | 1510016 | 22228 | 60 | 20151116* |
| Euro OTC | Acetylcysteine | 1610011 | 22854 | 40 | 20161107* |
| Euro OTC | Acetylcysteine | 2202014 | 26090 | 40 | 20220512* |
| Fagron | Acetylcysteine | 15C16-B06-308039 | 22886 | 40 | 20150402 |
| Fagron | Acetylcysteine | 24I10-B068 | BR20135 | 40 | 20240607* |
| Fagron | Acetylcysteine | 24I10-B068 | BR20135SI | 20 | 20240607* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 9 reference samples from the substance/substance group *Acetylcysteine*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 926 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 810 spectra of 23 reference samples from the substance/substance group *Acetylcysteine*.

- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Acetylcysteine | 163340 | 23035 | 40 |
| Caelo | Acetylcysteine | 20004543008 | 25989 | 40 |
| Caelo | Acetylcysteine | 22001099 | 26240 | 40 |
| Euro OTC | Acetylcysteine | 1801037 | 23956 | 40 |
| Euro OTC | Acetylcysteine | 1809026 | 24302 | 40 |
| Euro OTC | Acetylcysteine | 1907008 | 24837 | 40 |
| Euro OTC | Acetylcysteine | 1911003 | 24981 | 40 |
| Euro OTC | Acetylcysteine | 2003061 | 25315 | 40 |
| Euro OTC | Acetylcysteine | 2010011 | 25524 | 40 |
| Euro OTC | Acetylcysteine | 2208019 | 26340 | 40 |
| Euro OTC | Acetylcysteine | 2301028 | 26600 | 40 |
| Euro OTC | Acetylcysteine | 2411002 | 27465 | 30 |
| Fagron | Acetylcysteine | 18B01-B04-357511 | 24703 | 40 |
| Fagron | Acetylcysteine | 18K06-B02-363236 | 25043 | 40 |
| Fagron | Acetylcysteine | 22G22-B02-227323 | 26984 | 40 |
| Fagron | Acetylcysteine | 25D15-B031 | BR20133 | 40 |
| Fagron | Acetylcysteine | 24H27-B044 | BR20134 | 40 |
| Caelo | Acetylcysteine | 20004543008 | 25989SI | 40 |
| Caelo | Acetylcysteine | 22001099 | 26240SI | 20 |
| Euro OTC | Acetylcysteine | 2202014 | 26090SI† | 20 |
| Euro OTC | Acetylcysteine | 2208019 | 26340SI | 20 |
| Fagron | Acetylcysteine | 25D15-B031 | BR20133SI | 20 |
| Fagron | Acetylcysteine | 24H27-B044 | BR20134SI | 20 |

- 212 130 spectra from a total of 4269 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 101 spectra from 79 *Apo-Ident* customers from 55 batches from the substance/substance group *Acetylcysteine*.
- Among them are spectra of independent samples from 54 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Acetylcysteine | 20004543006 | 1 |
| | Acetylcysteine | 20004543008 | 1 |
| | Acetylcysteine | 22001099002 | 1 |
| | Acetylcysteine | 22001099005 | 2 |
| | Acetylcysteine | 22001099009 | 1 |
| | Acetylcysteine | 22001099011 | 1 |
| | Acetylcysteine | 2208019-03 | 1 |
| Alliance | Acetylcysteine | 22001099005 | 1 |
| Caelo | Acetylcysteine | 1(18180405) | 1 |
| Caelo | Acetylcysteine | 1011171701 | 1 |
| Caelo | Acetylcysteine | 10230713 | 1 |
| Caelo | Acetylcysteine | 12299004 | 1 |
| Caelo | Acetylcysteine | 12299021 | 1 |
| Caelo | Acetylcysteine | 12299027 | 1 |
| Caelo | Acetylcysteine | 130702601 | 1 |
| Caelo | Acetylcysteine | 15114007 | 2 |
| Caelo | Acetylcysteine | 15114013 | 2 |
| Caelo | Acetylcysteine | 16139802 | 2 |
| Caelo | Acetylcysteine | 16139808 | 1 |
| Caelo | Acetylcysteine | 16334006 | 7 |
| Caelo | Acetylcysteine | 16334007 | 1 |
| Caelo | Acetylcysteine | 17357305 | 1 |
| Caelo | Acetylcysteine | 18180402 | 1 |
| Caelo | Acetylcysteine | 18180405 | 3 |
| Caelo | Acetylcysteine | 18180409 | 1 |
| Caelo | Acetylcysteine | 18180412 | 3 |
| Caelo | Acetylcysteine | 18180421 | 1 |
| Caelo | Acetylcysteine | 192757006 | 4 |
| Caelo | Acetylcysteine | 2(18180405) | 1 |
| Caelo | Acetylcysteine | 20004543006 | 1 |
| Caelo | Acetylcysteine | 20004543008 | 1 |
| Caelo | Acetylcysteine | 20004543009 | 1 |
| Caesar & Loretz GmbH... | Acetylcysteine | 18180412 | 1 |
| Caesar & Loretz GmbH/sana | Acetylcysteine | 181804 | 1 |
| Caesar & Loretz GmbH... | Acetylcysteine | 16334006 | 1 |
| Caesar & Loretz GmbH | Acetylcysteine | 18180412 | 2 |
| Caesar & Loretz GmbH | Acetylcysteine | 20004543004 | 1 |
| Caesar & Loretz GmbH | Acetylcysteine | 20004543006 | 1 |
| Caleo/ Noweda | Acetylcysteine | 17357305 | 2 |
| Cealo / Anzag | Acetylcysteine | 221129(20004543008) | 1 |
| EuRho | Acetylcysteine | 2010011-02 | 2 |
| Euro OTC | Acetylcysteine | 120802601 | 2 |
| Euro OTC | Acetylcysteine | 12299010 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Acetylcysteine | 1307026-01 | 1 |
| Euro OTC | Acetylcysteine | 1505011-01 | 1 |
| Euro OTC | Acetylcysteine | 1510016-01 | 3 |
| Euro OTC | Acetylcysteine | 1610011-01 | 1 |
| Euro OTC | Acetylcysteine | 1610011-02 | 1 |
| Euro OTC | Acetylcysteine | 180103701 | 1 |
| Euro OTC | Acetylcysteine | 1809026-01 | 2 |
| Euro OTC | Acetylcysteine | 1911003-02 | 5 |
| Euro OTC | Acetylcysteine | 192757006 | 1 |
| Euro OTC | Acetylcysteine | 2010011-01 | 1 |
| Euro OTC | Acetylcysteine | 2010011-02 | 1 |
| Euro OTC | Acetylcysteine | 2301028-02 | 1 |
| Fagron | Acetylcysteine | 13A22N07 | 1 |
| Fagron | Acetylcysteine | 14C28-B05-292386 | 1 |
| Fagron | Acetylcysteine | 21D22-B04-213886 | 1 |
| Fargon | Acetylcysteine | 20G17-F01-373416 | 3 |
| Farmalabor | Acetylcysteine | P1701913-003 | 1 |
| Gehe | Acetylcysteine | 16139813 | 1 |
| gehe | Acetylcysteine | 190700801 | 1 |
| phar | Acetylcysteine | 1610011-02 | 1 |
| PharmaZell GmbH/Noweda | Acetylcysteine | 1911003-02 | 1 |
| Phoenix 06.06.2014 | Acetylcysteine | 1208026-01 | 1 |
| Phoenix goettin | Acetylcysteine | 1208026-01 | 1 |
| Phönix | Acetylcysteine | 1208026 | 1 |
| Sanacorp 07.03.2016 ... | Acetylcysteine | 15114007 | 1 |
| Sanacorp | Acetylcysteine | 18180405 | 1 |
| Sanacorp | Acetylcysteine | 22001099005 | 1 |
| sanacorp | Acetylcysteine | 22001099012 | 1 |

- 256 785 spectra from 1666 *Apo-Ident* customers from a total of 52 099 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Acetylcysteine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Acetylcysteine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 810 | 0 | 212 130 |
| **Type C** | 0 | 101 | 0 | 256 785 |

The substance/substance group *Acetylcysteine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2593 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 94.0594 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21315 | 22228 | 15.31 | 217.34 |
| 21628 | 22469 | 12.54 | 199.81 |
| 22228 | 22228 | 0.00 | 218.35 |
| 22469 | 22469 | 0.00 | 202.10 |
| 22854 | 22854 | 0.00 | 219.08 |
| 22886 | 22228 | 13.56 | 220.56 |
| 26090 | 26090 | 0.00 | 230.74 |
| BR20135 | BR20135 | 0.00 | 197.77 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Acetylsalicylic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20449-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Acetylsalicylic acid; Acidum acetylsalicylicum

### Special notes

When selecting the *Acetylsalicylic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Acetylsalicylic acid | 7 | 9 | 109 |

### Second-stage model

For differentiation of the substance/substance group *Acetylsalicylic acid* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Acetylsalicylic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Midazolam hydrochloride | 89.05 | – |
| ⋮ | ⋮ | ⋮ |
| Dithranol | >50 | 17.02 |
| Dequalinium chloride | >50 | 52.48 |
| Sodium salicylate | >50 | 69.40 |
| Benzoic acid | >50 | 79.93 |
| Eosin Y | >50 | 252.87 |
| Oxytetracycline hydrochloride | >50 | 357.71 |
| Levothyroxin sodium | >50 | 683.56 |
| Tannin | >50 | 1569.01 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Acetylsalicylic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Acetylsalicylic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Acetylsalicylic acid | 13297509 | 21383 | 40 | 20131014 |
| Caelo | Acetylsalicylic acid | 161316 | 23064 | 40 | 20160825* |
| Euro OTC | Acetylsalicylic acid | 1307024-01 | 21597 | 45 | 20130904 |
| Euro OTC | Acetylsalicylic acid | 1407026-01 | 21637 | 60 | 20140801 |
| Euro OTC | Acetylsalicylic acid | 1601042 | 22377 | 40 | 20160204* |
| Euro OTC | Acetylsalicylic acid | 1608037 | 22820 | 40 | 20160921* |
| Fagron | Acetylsalicylic acid | 14E02-B04-297099 | 22949 | 40 | 20140515 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 305 spectra of 7 reference samples from the substance/substance group *Acetylsalicylic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 021 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 400 spectra of 12 reference samples from the substance/substance group *Acetylsalicylic acid*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Acetylsalicylic acid | 173098 | 23806 | 40 |
| Caelo | Acetylsalicylic acid | 20003902006 | 25929 | 40 |
| Caelo | Acetylsalicylic acid | 22000047 | 26011 | 40 |
| Caelo | Acetylsalicylic acid | 23001248 | 26837 | 40 |
| Caelo | Acetylsalicylic acid | 24002283 | 27427 | 40 |
| Euro OTC | Acetylsalicylic acid | 1703010 | 23388 | 40 |
| Euro OTC | Acetylsalicylic acid | 1805004 | 24120 | 40 |
| Euro OTC | Acetylsalicylic acid | 1805003 | 24127 | 40 |
| Euro OTC | Acetylsalicylic acid | 2007003 | 25345 | 40 |
| Caelo | Acetylsalicylic acid | 20003902006 | 25929SI | 10 |
| Caelo | Acetylsalicylic acid | 22000047 | 26011SI | 10 |
| Caelo | Acetylsalicylic acid | 23001248 | 26837SI | 20 |

- 212 540 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

descend.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 466 spectra from 295 *Apo-Ident* customers from 112 batches from the substance/substance group *Acetylsalicylic acid*.
- Among them are spectra of independent samples from 109 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Acetylsalicylic acid | 2007003-03 | 1 |
| | Acetylsalicylic acid | 2007003-04 | 1 |
| | Acetylsalicylic acid | 22000047006 | 2 |
| | Acetylsalicylic acid | 22000047013 | 2 |
| | Acetylsalicylic acid | 22000047016 | 3 |
| | Acetylsalicylic acid | 22000047018 | 1 |
| | Acetylsalicylic acid | 23001248002 | 1 |
| | Acetylsalicylic acid | 23001248003 | 13 |
| | Acetylsalicylic acid | 23001248004 | 4 |
| | Acetylsalicylic acid | 23003553002 | 3 |
| ACM | Acetylsalicylic acid | KNC2077J14 | 1 |
| ACM | Acetylsalicylic acid | KNC2152J13 | 1 |
| Alliance Healthcare | Acetylsalicylic acid | 18122605 | 1 |
| Alliance | Acetylsalicylic acid | 23001248004 | 1 |
| Anzag | Acetylsalicylic acid | 20003902010 | 1 |
| Anzag | Acetylsalicylic acid | 230918 | 1 |
| Anzag | Acetylsalicylic acid | 240924(23003553002) | 1 |
| Bombastus | Acetylsalicylic acid | 1212005-01 | 1 |
| Bombastus | Acetylsalicylic acid | 17023102 | 1 |
| Caelo | Acetylsalicylic acid | 10099907 | 1 |
| Caelo | Acetylsalicylic acid | 1061117/17023107 | 1 |
| Caelo | Acetylsalicylic acid | 1110417 | 1 |
| Caelo | Acetylsalicylic acid | 11257126 | 1 |
| Caelo | Acetylsalicylic acid | 12212203 | 1 |
| Caelo | Acetylsalicylic acid | 12212219 | 1 |
| Caelo | Acetylsalicylic acid | 12212223 | 3 |
| Caelo | Acetylsalicylic acid | 12212230 | 1 |
| Caelo | Acetylsalicylic acid | 12212233 | 1 |
| Caelo | Acetylsalicylic acid | 12212236 | 2 |
| Caelo | Acetylsalicylic acid | 1307024-01 | 2 |
| Caelo | Acetylsalicylic acid | 13297511 | 1 |
| Caelo | Acetylsalicylic acid | 13324101 | 2 |
| Caelo | Acetylsalicylic acid | 13324105 | 1 |
| Caelo | Acetylsalicylic acid | 13324109 | 3 |
| Caelo | Acetylsalicylic acid | 13324116 | 1 |
| Caelo | Acetylsalicylic acid | 13324118 | 1 |
| Caelo | Acetylsalicylic acid | 13324119 | 1 |
| Caelo | Acetylsalicylic acid | 14189603 | 1 |
| Caelo | Acetylsalicylic acid | 14250101 | 2 |
| Caelo | Acetylsalicylic acid | 15081301 | 3 |
| Caelo | Acetylsalicylic acid | 15081304 | 1 |
| Caelo | Acetylsalicylic acid | 15081308 | 2 |
| Caelo | Acetylsalicylic acid | 15081310 | 1 |
| Caelo | Acetylsalicylic acid | 15122701 | 1 |
| Caelo | Acetylsalicylic acid | 15334902 | 4 |
| Caelo | Acetylsalicylic acid | 15334907 | 7 |
| Caelo | Acetylsalicylic acid | 15334910 | 1 |
| Caelo | Acetylsalicylic acid | 15334914 | 3 |
| Caelo | Acetylsalicylic acid | 15334917 | 4 |
| Caelo | Acetylsalicylic acid | 160104202 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Acetylsalicylic acid | 16131607 | 2 |
| Caelo | Acetylsalicylic acid | 170230107 | 1 |
| Caelo | Acetylsalicylic acid | 17023102 | 11 |
| Caelo | Acetylsalicylic acid | 17023107 | 11 |
| Caelo | Acetylsalicylic acid | 17023108 | 4 |
| Caelo | Acetylsalicylic acid | 17023110 | 18 |
| Caelo | Acetylsalicylic acid | 17023111 | 1 |
| Caelo | Acetylsalicylic acid | 1703010-02 | 1 |
| Caelo | Acetylsalicylic acid | 17309801 | 1 |
| Caelo | Acetylsalicylic acid | 17329204 | 3 |
| Caelo | Acetylsalicylic acid | 1805004-02 | 2 |
| Caelo | Acetylsalicylic acid | 18108303 | 2 |
| Caelo | Acetylsalicylic acid | 18108306 | 2 |
| Caelo | Acetylsalicylic acid | 18108311 | 1 |
| Caelo | Acetylsalicylic acid | 18122601 | 2 |
| Caelo | Acetylsalicylic acid | 18122602 | 13 |
| Caelo | Acetylsalicylic acid | 18122605 | 16 |
| Caelo | Acetylsalicylic acid | 18122612 | 14 |
| Caelo | Acetylsalicylic acid | 18122615 | 3 |
| Caelo | Acetylsalicylic acid | 1911166001 | 1 |
| Caelo | Acetylsalicylic acid | 191166001 | 14 |
| Caelo | Acetylsalicylic acid | 191166003 | 1 |
| Caelo | Acetylsalicylic acid | 191166005 | 9 |
| Caelo | Acetylsalicylic acid | 19116601 | 1 |
| Caelo | Acetylsalicylic acid | 19116602 | 2 |
| Caelo | Acetylsalicylic acid | 19116604 | 16 |
| Caelo | Acetylsalicylic acid | 200003902006 | 1 |
| Caelo | Acetylsalicylic acid | 20003902003 | 15 |
| Caelo | Acetylsalicylic acid | 20003902004 | 2 |
| Caelo | Acetylsalicylic acid | 20003902006 | 9 |
| Caelo | Acetylsalicylic acid | 20003902008 | 1 |
| Caelo | Acetylsalicylic acid | 20003902010 | 4 |
| Caelo | Acetylsalicylic acid | 20003902013 | 7 |
| Caelo | Acetylsalicylic acid | 2000392003 | 2 |
| Caelo | Acetylsalicylic acid | 2000392006 | 3 |
| Caelo | Acetylsalicylic acid | 2000392010 | 1 |
| Caelo | Acetylsalicylic acid | 2003902010 | 1 |
| Caelo | Acetylsalicylic acid | 2003902013 | 1 |
| Caelo | Acetylsalicylic acid | 22000047006 | 3 |
| Caelo | Acetylsalicylic acid | 22000047013 | 7 |
| Caelo | Acetylsalicylic acid | 22000047016 | 6 |
| Caelo | Acetylsalicylic acid | 23001248003 | 1 |
| Caelo | Acetylsalicylic acid | 23003553002 | 1 |
| Caelo | Acetylsalicylic acid | 301115 | 1 |
| Caelo | Acetylsalicylic acid | 54018122612 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 20003902013 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 191166001 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 22000047006 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 20003902003 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 191166005 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 191166001 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 19116604 | 1 |
| Caesar & Loretz GmbH/Gehe | Acetylsalicylic acid | 191166005 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 191166001 | 2 |
| Caesar & Loretz GmbH/Phoe | Acetylsalicylic acid | 20003902003 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 191166001 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 191166005 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 22000047006 | 2 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 22000047016 | 1 |
| Caesar & Loretz GmbH... | Acetylsalicylic acid | 191166001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Sana | Acetylsalicylic acid | 18122612 | 1 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 15334914 | 1 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 15334917 | 1 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 18108311 | 1 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 18122602 | 1 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 18122605 | 4 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 18122612 | 2 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 191166001 | 4 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 191166005 | 3 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 19116604 | 3 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 20003902003 | 9 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 20003902006 | 5 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 20003902010 | 1 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 22000047006 | 4 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 22000047013 | 2 |
| Caesar & Loretz GmbH | Acetylsalicylic acid | 22000047016 | 2 |
| Caesar & Loretz/Geil... | Acetylsalicylic acid | 19116604 | 1 |
| Calo | Acetylsalicylic acid | 15334902 | 1 |
| Cealo | Acetylsalicylic acid | 15334910 | 1 |
| EuRho | Acetylsalicylic acid | 1407025-01 | 1 |
| EuRo Gehe | Acetylsalicylic acid | 147026-01 | 1 |
| Euro OTC | Acetylsalicylic acid | | 1 |
| Euro OTC | Acetylsalicylic acid | 1011015-01 | 1 |
| Euro OTC | Acetylsalicylic acid | 1107007-01 | 1 |
| Euro OTC | Acetylsalicylic acid | 1212005-01 | 3 |
| Euro OTC | Acetylsalicylic acid | 1307024-01 | 6 |
| Euro OTC | Acetylsalicylic acid | 1407025 | 1 |
| Euro OTC | Acetylsalicylic acid | 1407025-01 | 17 |
| Euro OTC | Acetylsalicylic acid | 1501046-01 | 5 |
| Euro OTC | Acetylsalicylic acid | 1601042-02 | 2 |
| Euro OTC | Acetylsalicylic acid | 1703010-03 | 3 |
| Euro OTC | Acetylsalicylic acid | 1805004-01 | 3 |
| Euro OTC | Acetylsalicylic acid | 1805004-02 | 3 |
| Euro OTC | Acetylsalicylic acid | 18122602 | 1 |
| Euro OTC | Acetylsalicylic acid | 20030611-1 | 1 |
| Euro OTC | Acetylsalicylic acid | 2007003-01 | 2 |
| Euro OTC | Acetylsalicylic acid | 2007003-02 | 1 |
| Euro OTC | Acetylsalicylic acid | 3518A-01012 | 1 |
| Euro OTC | Acetylsalicylic acid | 4017Q-01012 | 1 |
| Euro OTC | Acetylsalicylic acid | 815A-01012 | 1 |
| Europharm | Acetylsalicylic acid | 1407025-0 | 1 |
| Fagron | Acetylsalicylic acid | 12212234 | 2 |
| Fagron | Acetylsalicylic acid | 14B10-B02-296841 | 1 |
| Gehe | Acetylsalicylic acid | 10365302 | 1 |
| GEHE | Acetylsalicylic acid | 17023110 | 1 |
| Gehe | Acetylsalicylic acid | 18122602 | 1 |
| Gehe | Acetylsalicylic acid | 18122605 | 2 |
| Gehe | Acetylsalicylic acid | 23001248003 | 1 |
| L12 | Acetylsalicylic acid | 15334917 | 1 |
| Midas Göttingen | Acetylsalicylic acid | 191166001 | 1 |
| Novacyl / Gehe | Acetylsalicylic acid | 191166001 | 1 |
| Noweda | Acetylsalicylic acid | 10040403 | 1 |
| Noweda | Acetylsalicylic acid | 20003902006 | 1 |
| Noweda | Acetylsalicylic acid | 22000047018 | 1 |
| Noweda | Acetylsalicylic acid | 23001248003 | 1 |
| Noweda | Acetylsalicylic acid | 23001248004 | 1 |
| Phoenix/Cealo | Acetylsalicylic acid | 17356301 | 1 |
| Phoenix | Acetylsalicylic acid | 13324107 | 1 |
| Phoenix | Acetylsalicylic acid | 19116604 | 1 |
| Phoenix | Acetylsalicylic acid | 22000047013 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Acetylsalicylic acid | 13324114 | 1 |
| Phönix | Acetylsalicylic acid | 191166005 | 1 |
| Phönix | Acetylsalicylic acid | 23003553002 | 1 |
| Sanacorp | Acetylsalicylic acid | 1307024-01 | 1 |
| Sanacorp | Acetylsalicylic acid | 13324109 | 1 |
| sanacorp | Acetylsalicylic acid | 14250101 | 1 |
| Sanacorp | Acetylsalicylic acid | 17329204 | 1 |
| Sanacorp | Acetylsalicylic acid | 17329205 | 1 |
| Stadt Apo Geesthacht | Acetylsalicylic acid | | 1 |

- 256 420 spectra from 1666 *Apo-Ident* customers from a total of 52 046 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Acetylsalicylic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Acetylsalicylic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 305 | 0 | 158 021 |
| **Type B** | 0 | 400 | 0 | 212 540 |
| **Type C** | 0 | 446 | 20 | 256 420 |

The substance/substance group *Acetylsalicylic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0328 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 95.7082 % (> 95.0644 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21383 | 22377 | 12.35 | 117.68 |
| 21597 | 22377 | 13.50 | 116.42 |
| 21637 | 22377 | 21.98 | 118.73 |
| 22377 | 22377 | 0.00 | 118.26 |
| 22820 | 22820 | 0.00 | 116.93 |
| 22949 | 22377 | 10.70 | 115.34 |
| 23064 | 23064 | 0.00 | 117.18 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Aciclovir** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21677-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Aciclovir; Aciclovirum

### Special notes

When selecting the *Aciclovir* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Aciclovir | 6 | 3 | 27 |

### Second-stage model

For differentiation of the substance/substance group *Aciclovir* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Aciclovir* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 78.21 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Aciclovir* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Aciclovir*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Aciclovir | 13B04-B40-294559 | 21677 | 60 | AR-15-FG-002570-01 |
| Fagron | Aciclovir | 13B04-B40-302333 | 21761 | 60 | 20131217 |
| Fagron | Aciclovir | 14G07-B05-296462 | 21831 | 60 | 20140728 |
| Fagron | Aciclovir | 19I17-F02-366255 | 25064 | 40 | 20191202 |
| Fagron | Aciclovir | 24C11-B01-236108 | 27381 | 40 | 20240418 |
| Gatt-Koller | Aciclovir | 22J01376 | 27099 | 30 | 20220804 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 290 spectra of 6 reference samples from the substance/substance group *Aciclovir*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.
- 158 036 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 220 spectra of 7 reference samples from the substance/substance group *Aciclovir*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Aciclovir | 15A15-B10-323362 | 22938 | 40 |
| Fagron | Aciclovir | 18I18-B04-356027 | 24570 | 40 |
| Fagron | Aciclovir | 22A15-B02-222370 | 26290 | 40 |
| Fagron | Aciclovir | 15A15-B10-323362 | 22939 | 40 |
| Fagron | Aciclovir | 22A15-B02-222370 | 26290SI | 20 |
| Fagron | Aciclovir | 24C11-B01-236108 | 27381SI† | 20 |
| Gatt-Koller | Aciclovir | 22J01376 | 27099SI† | 20 |

- 212 720 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 48 spectra from 32 *Apo-Ident* customers from 29 batches from the substance/substance group *Aciclovir*.
- Among them are spectra of independent samples from 27 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Aciclovir | F02-3709204 | 1 |
| Caelo | Aciclovir | 18118-B04-355420 | 1 |
| Fagron | Aciclovir | 13B04-B40-288651 | 1 |
| Fagron | Aciclovir | 146501524 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Aciclovir | 14g07-b05-296462 | 1 |
| Fagron | Aciclovir | 15A15-B10-307743 | 1 |
| Fagron | Aciclovir | 15A15-B10-315379 | 13 |
| Fagron | Aciclovir | 15A15-B10-323362 | 1 |
| Fagron | Aciclovir | 15AS15-B10-307743 | 1 |
| Fagron | Aciclovir | 16GK09-B05-332754 | 1 |
| Fagron | Aciclovir | 16K09-B05-328196 | 4 |
| Fagron | Aciclovir | 17G11-B01-339460 | 1 |
| Fagron | Aciclovir | 17G11-B01-342081 | 1 |
| Fagron | Aciclovir | 18/18-B04-358573 | 1 |
| Fagron | Aciclovir | 18/18-B24-358573 | 1 |
| Fagron | Aciclovir | 18I18-B04-355420 | 1 |
| Fagron | Aciclovir | 18I18-B04-358573 | 1 |
| Fagron | Aciclovir | 19/17-F02 | 1 |
| Fagron | Aciclovir | 19/17-F02-366256 | 1 |
| Fagron | Aciclovir | 19I17-F02-366255 | 1 |
| Fagron | Aciclovir | 19I17-F02-366256 | 2 |
| Fagron | Aciclovir | 19i17-F02-367853 | 1 |
| Fagron | Aciclovir | 19I17-F02-367853 | 2 |
| Fagron | Aciclovir | 19I17-F02-370924 | 1 |
| Fagron | Aciclovir | 19I17-FO2-366256 | 1 |
| Fagron | Aciclovir | 19l17-F02 | 1 |
| Fagron | Aciclovir | ACV1019008 | 3 |
| Fagron | Aciclovir | ACV1116001 | 1 |
| Fagron | Aciclovir | F02-3678503 | 1 |

- 256 838 spectra from 1666 *Apo-Ident* customers from a total of 52 124 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Aciclovir* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Aciclovir* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 290 | 0 | 158 036 |
| **Type B** | 0 | 220 | 0 | 212 720 |
| **Type C** | 0 | 47 | 1 | 256 838 |

The substance/substance group *Aciclovir* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.9310 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.2727 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.9167 % (> 91.6667 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21677 | 21677 | 0.00 | 204.18 |
| 21761 | 21677 | 7.32 | 201.24 |
| 21831 | 21677 | 17.74 | 202.76 |
| 25064 | 21677 | 14.62 | 199.89 |
| 27099 | 21677 | 14.49 | 202.81 |
| 27381 | 21677 | 8.56 | 199.00 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Albendazole** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21596-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Albendazole; Albendazolum

### Special notes

When selecting the *Albendazole* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Albendazole | 6 | 3 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Albendazole* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Albendazole* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Clonidine hydrochloride | 166.28 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Albendazole* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Albendazole*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Albendazole | 2208010 | 26263 | 40 | 20220831* |
| Euro OTC | Albendazole | 2208010 | 26263SI | 20 | 20220831* |
| Fagron | Albendazole | 12J25-B40-293217 | 21596 | 45 | AR-15-FG-002571-01 |
| Fagron | Albendazole | 16B04-B06-329519 | 23017 | 40 | 20160302 |
| Fagron | Albendazole | 18C21-B04-351586 | 24578 | 40 | 20180625 |
| Fagron | Albendazole | 20B27-F01-373154 | 25714 | 40 | 20200901 |
| Fagron | Albendazole | 22B26-B05-219216 | 26174 | 40 | 20220602 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 265 spectra of 7 reference samples from the substance/substance group *Albendazole*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 061 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 4 reference samples from the substance/substance group *Albendazole*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Albendazole | 14B05-B41-299704 | 21730 | 60 |
| Fagron | Albendazole | 14B05-B41-314321 | 22940 | 40 |
| Fagron | Albendazole | 16B04-B06-322057 | 22968 | 40 |
| Fagron | Albendazole | 22B26-B05-219216 | 26174SI† | 20 |

- 212 780 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 33 spectra from 15 *Apo-Ident* customers from 19 batches from the substance/substance group *Albendazole*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Albendazole | AEA006078A | 4 |
| | Albendazole | B05-0003 | 1 |
| Fagron | Albendazole | 14B05-B41 | 1 |
| Fagron | Albendazole | 14B05-B41-305249 | 1 |
| Fagron | Albendazole | 14B05B41-312959 | 1 |
| Fagron | Albendazole | 14B05-B41-312959 | 1 |
| Fagron | Albendazole | 14b05-b41-314321 | 1 |
| Fagron | Albendazole | 14B05-B41-314321 | 1 |
| Fagron | Albendazole | 16B04-B06-322055 | 2 |
| Fagron | Albendazole | 16B04-B06-329519 | 1 |
| Fagron | Albendazole | 16B04-B06-337998 | 2 |
| Fagron | Albendazole | 18C21-B04 | 1 |
| Fagron | Albendazole | 18C21-B04-350057 | 1 |
| Fagron | Albendazole | 18C21-B04-351584 | 1 |
| Fagron | Albendazole | 18C21-B04-351585 | 3 |
| Fagron | Albendazole | 18C21-B04-351586 | 4 |
| Fagron | Albendazole | 18C21-B04-357034 | 1 |
| Fagron | Albendazole | 18C21-B04x3 | 1 |
| Fagron | Albendazole | 20B27-F01-373151 | 5 |

- 256 853 spectra from 1666 *Apo-Ident* customers from a total of 52 134 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Albendazole* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Albendazole* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 265 | 0 | 158 061 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 33 | 0 | 256 853 |

The substance/substance group *Albendazole* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7358 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 81.8182 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21596 | 21596 | 0.00 | 285.30 |
| 23017 | 26263 | 16.77 | 297.02 |
| 24578 | 26263 | 13.35 | 304.06 |
| 25714 | 26263 | 12.30 | 303.36 |
| 26174 | 26263 | 9.17 | 303.52 |
| 26263 | 26263 | 0.00 | 304.34 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Alfatradiol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20292-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Alfatradiol; Alfatradiolum

### Special notes

When selecting the *Alfatradiol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Alfatradiol | 11 | 18 | 289 |

### Second-stage model

For differentiation of the substance/substance group *Alfatradiol* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Alfatradiol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 82.47 | – |
| ⋮ | ⋮ | ⋮ |
| Capsaicin | >50 | 54.80 |
| Levocarnitine | >50 | 120.89 |
| Prednicarbate | >50 | 133.28 |
| Sodium citrate | >50 | 140.03 |
| Oxybutynin hydrochloride | >50 | 152.03 |
| Norethisterone acetate | >50 | 201.30 |
| Pyridoxal-5-phosphate hydrate | >50 | 221.01 |
| Tetracaine | >50 | 221.07 |
| Cyproterone acetate | >50 | 260.78 |
| Amitriptyline hydrochloride | >50 | 461.81 |
| Quinine hydrochloride dihydrate | >50 | 473.01 |
| Methoxsalen | >50 | 569.87 |
| Heparin sodium | >50 | 615.74 |
| Valine | >50 | 638.24 |
| Ciprofloxacin hydrochloride | >50 | 756.01 |
| Amifampridine | >50 | 1510.77 |
| Triclosan | >50 | 1588.90 |
| Sucrose | >50 | 2023.77 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Alfatradiol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Alfatradiol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Alfatradiol | AP33-16-I-62P2985A | 22935 | 40 | 20161017 |
| Audor Pharma | Alfatradiol | AP33-18-I-68P3620A | 24662 | 40 | 20180804 |

*continued on the next page*


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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Alfatradiol | 13201601 | 21476 | 120 | 20130812 |
| Caelo | Alfatradiol | 13201601 | 21477 | 60 | 20130812 |
| Caelo | Alfatradiol | 191599 | 24747 | 40 | 20190812* |
| Caelo | Alfatradiol | 20004170 | 25553 | 40 | 20210106* |
| Caelo | Alfatradiol | 20004170 | 25553SI | 40 | 20210106* |
| Caelo | Alfatradiol | 20002390 | 25561 | 40 | 20200914* |
| Caelo | Alfatradiol | 20002390 | 25561SI | 40 | 20200914* |
| Euro OTC | Alfatradiol | 1404001-01 | 21714 | 50 | 1509288 |
| Euro OTC | Alfatradiol | 1404001-01 | 21714SI | 60 | 1509288 |
| Euro OTC | Alfatradiol | 1603019 | 22511 | 40 | 20160419* |
| Euro OTC | Alfatradiol | 1603019 | 22511SI | 40 | 20160419* |
| Fagron | Alfatradiol | 13G19-N06 | 20940 | 40 | 1402683 |
| Fagron | Alfatradiol | 15J27-B08-323877 | 22933 | 40 | 20151117 |
| Fagron | Alfatradiol | 15J27-B08-323877 | 22934 | 40 | 20151117 |
| Fagron | Alfatradiol | 15J27-B08-323877 | 22934SI | 40 | 20151117 |
| Fagron | Alfatradiol | 24J10-B12-003450 | 27478 | 40 | 20241105 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 850 spectra of 18 reference samples from the substance/substance group *Alfatradiol*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.
- 157 476 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1695 spectra of 42 reference samples from the substance/substance group *Alfatradiol*.
- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Alfatradiol | 161804 | 23354 | 40 |
| Caelo | Alfatradiol | 191598 | 24738 | 40 |
| Caelo | Alfatradiol | 22000052006 | 26740 | 40 |
| Euro OTC | Alfatradiol | 1902020 | 24621 | 40 |
| Euro OTC | Alfatradiol | 2002017 | 25118 | 40 |
| Euro OTC | Alfatradiol | 2006005 | 25473 | 40 |
| Euro OTC | Alfatradiol | 2103003 | 25689 | 50 |
| Euro OTC | Alfatradiol | 2201003 | 25948 | 40 |
| Euro OTC | Alfatradiol | 2301040 | 26601 | 40 |
| Euro OTC | Alfatradiol | 2305010 | 26755 | 40 |
| Euro OTC | Alfatradiol | 2305011 | 26756 | 30 |
| Euro OTC | Alfatradiol | 2305012 | 26757 | 30 |
| Euro OTC | Alfatradiol | 2305013 | 26758 | 40 |
| Euro OTC | Alfatradiol | 2305014 | 26759 | 40 |
| Euro OTC | Alfatradiol | 2310012 | 26998 | 40 |
| Euro OTC | Alfatradiol | 2409001 | 27388 | 40 |
| Euro OTC | Alfatradiol | 2409008 | 27389 | 40 |
| Fagron | Alfatradiol | 22I06-B02-222372 | 26390 | 40 |
| Audor Pharma | Alfatradiol | AP33-16-I-62P2985A | 22935SI† | 40 |
| Audor Pharma | Alfatradiol | AP33-18-I-68P3620A | 24662SI† | 40 |
| Caelo | Alfatradiol | 13201601 | 21477SI† | 60 |
| Caelo | Alfatradiol | 161804 | 23354SI | 40 |
| Caelo | Alfatradiol | 191598 | 24738SI | 40 |
| Caelo | Alfatradiol | 191599 | 24747SI† | 40 |
| Caelo | Alfatradiol | 22000052006 | 26740SI | 40 |
| Euro OTC | Alfatradiol | 1902020 | 24621SI | 40 |
| Euro OTC | Alfatradiol | 2002017 | 25118SI | 40 |
| Euro OTC | Alfatradiol | 2006005 | 25473SI | 40 |
| Euro OTC | Alfatradiol | 2103003 | 25689SI | 50 |
| Euro OTC | Alfatradiol | 2201003 | 25948SI | 40 |
| Euro OTC | Alfatradiol | 2301040 | 26601SI | 40 |
| Euro OTC | Alfatradiol | 2305010 | 26755SI | 40 |
| Euro OTC | Alfatradiol | 2305011 | 26756SI | 40 |
| Euro OTC | Alfatradiol | 2305012 | 26757SI | 40 |
| Euro OTC | Alfatradiol | 2305013 | 26758SI | 35 |
| Euro OTC | Alfatradiol | 2305014 | 26759SI | 40 |
| Euro OTC | Alfatradiol | 2310012 | 26998SI | 40 |
| Euro OTC | Alfatradiol | 2409001 | 27388SI | 40 |
| Euro OTC | Alfatradiol | 2409008 | 27389SI | 40 |
| Fagron | Alfatradiol | 15J27-B08-323877 | 22933SI† | 40 |
| Fagron | Alfatradiol | 22I06-B02-222372 | 26390SI | 40 |
| Fagron | Alfatradiol | 24J10-B12-003450 | 27478SI† | 40 |

- 211 245 spectra from a total of 4263 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1094 spectra from 500 *Apo-Ident* customers from 299 batches from the substance/substance group *Alfatradiol*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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- Among them are spectra of independent samples from 289 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Alfatradiol | 181023/10 | 1 |
| | Alfatradiol | 19K06-F04-366005 | 1 |
| | Alfatradiol | 2103003-01 | 1 |
| | Alfatradiol | 21D20-F06-379262 | 2 |
| | Alfatradiol | 21D20-F06-379263 | 2 |
| | Alfatradiol | 22000052001 | 10 |
| | Alfatradiol | 22000052002 | 2 |
| | Alfatradiol | 22000052005 | 1 |
| | Alfatradiol | 22000052006 | 1 |
| | Alfatradiol | 22000053007 | 2 |
| | Alfatradiol | 2200052001 | 1 |
| | Alfatradiol | 2201003-01 | 3 |
| | Alfatradiol | 22A10-F02-381369 | 2 |
| | Alfatradiol | 22I06-B02-222372 | 1 |
| | Alfatradiol | 22I06-B02-2223701 | 1 |
| | Alfatradiol | 22I06-B02-222371 | 1 |
| | Alfatradiol | 23000344003 | 3 |
| | Alfatradiol | 23000344004 | 19 |
| | Alfatradiol | 23000346002 | 10 |
| | Alfatradiol | 23000346004 | 6 |
| | Alfatradiol | 23000346006 | 3 |
| | Alfatradiol | 2301040-01 | 2 |
| | Alfatradiol | 23E15-B08-224467 | 2 |
| | Alfatradiol | 23E15-B08-227265 | 1 |
| | Alfatradiol | 23E15-B09-227266 | 1 |
| | Alfatradiol | 23E15-B09-231378 | 1 |
| | Alfatradiol | 23E-B08-227265 | 1 |
| | Alfatradiol | 2409001-01 | 5 |
| | Alfatradiol | 2409008-02 | 9 |
| | Alfatradiol | 24J10-B12-003450 | 1 |
| | Alfatradiol | 24J10-B13-003480 | 7 |
| | Alfatradiol | 25B21-B06-007293 | 1 |
| | Alfatradiol | 25B21-B06-007294 | 2 |
| | Alfatradiol | 35-23-I-07P4758 | 1 |
| | Alfatradiol | 35-23-I-O7P4758 | 1 |
| | Alfatradiol | 5122243 | 1 |
| | Alfatradiol | B09-2313708 | 4 |
| | Alfatradiol | B09-231378 | 1 |
| | Alfatradiol | f02-3813609 | 1 |
| | Alfatradiol | I-07P502007 | 1 |
| | Alfatradiol | I07P5027 | 1 |
| Alliance | Alfatradiol | 19159803 | 1 |
| Anzag / Gehe | Alfatradiol | 14C20-B02-294943 | 1 |
| Audor Pharma | Alfatradiol | 1617M-03305 | 1 |
| Audor Pharma | Alfatradiol | 18C23-B05-352725 | 1 |
| Audor Pharma | Alfatradiol | 2019Q-03305 | 1 |
| Audor Pharma | Alfatradiol | 2818A-03305 | 1 |
| Audor Pharma | Alfatradiol | 33-16-I-62P2985A | 1 |
| Audor Pharma | Alfatradiol | 33-18-I-68P3620A | 1 |
| Audor Pharma | Alfatradiol | AP1404001-01A | 1 |
| Audor Pharma | Alfatradiol | AP1404001-01-A | 1 |
| Audor Pharma | Alfatradiol | AP1504015-01A | 6 |
| Audor Pharma | Alfatradiol | AP21-16-II-14P4511 | 2 |
| Audor Pharma | Alfatradiol | AP21-16II-14P4511A | 1 |
| Audor Pharma | Alfatradiol | AP21-16-II-14P4511A | 10 |
| Audor Pharma | Alfatradiol | ap2116ll14p4511a | 1 |
| Audor Pharma | Alfatradiol | AP33_16_I_62P2985A | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Alfatradiol | AP3316I42P2945A | 1 |
| Audor Pharma | Alfatradiol | AP33-16-I-42P2945A | 4 |
| Audor Pharma | Alfatradiol | AP3316I62P2985A | 1 |
| Audor Pharma | Alfatradiol | AP33-16-I-62P2985A | 4 |
| Audor Pharma | Alfatradiol | AP33-18-I68P3620A | 1 |
| Audor Pharma | Alfatradiol | AP33-18-I-68P3620A | 6 |
| Audor Pharma | Alfatradiol | AP35_17_II_85P3624A | 1 |
| Audor Pharma | Alfatradiol | AP35-17-II-85P3524A | 1 |
| Audor Pharma | Alfatradiol | AP35-17-II-85P3624 | 2 |
| Audor Pharma | Alfatradiol | AP35-17-II-85P3624-1A | 2 |
| Audor Pharma | Alfatradiol | ap35-17-II-85P3624A | 1 |
| Audor Pharma | Alfatradiol | AP35-17-II-85P3624A | 4 |
| Audor Pharma | Alfatradiol | AP5100461A | 2 |
| Audor Pharma | Alfatradiol | AP5104925A | 6 |
| Audor Pharma | Alfatradiol | AP514925A | 1 |
| Audor Pharma | Alfatradiol | APXP103DAA | 2 |
| Audor Pharma | Alfatradiol | APXPC0071A | 2 |
| Bombastus | Alfatradiol | 16G05-B01-335789 | 1 |
| cae | Alfatradiol | 20002390006 | 1 |
| Caelo | Alfatradiol | 10319904 | 1 |
| Caelo | Alfatradiol | 10319909 | 1 |
| Caelo | Alfatradiol | 11061001 | 2 |
| Caelo | Alfatradiol | 11061004 | 1 |
| Caelo | Alfatradiol | 11061005 | 1 |
| Caelo | Alfatradiol | 111161607 | 1 |
| Caelo | Alfatradiol | 11161805 | 4 |
| Caelo | Alfatradiol | 11161807 | 3 |
| Caelo | Alfatradiol | 12164201 | 4 |
| Caelo | Alfatradiol | 12164207 | 7 |
| Caelo | Alfatradiol | 12H29-N05 | 2 |
| Caelo | Alfatradiol | 13130805 | 5 |
| Caelo | Alfatradiol | 13130806 | 2 |
| Caelo | Alfatradiol | 13130808 | 1 |
| Caelo | Alfatradiol | 13201605 | 2 |
| Caelo | Alfatradiol | 14037904 | 3 |
| Caelo | Alfatradiol | 14130104 | 1 |
| Caelo | Alfatradiol | 14139102 | 3 |
| Caelo | Alfatradiol | 14139103 | 6 |
| Caelo | Alfatradiol | 14139104 | 14 |
| Caelo | Alfatradiol | 14139105 | 2 |
| Caelo | Alfatradiol | 14318502 | 2 |
| Caelo | Alfatradiol | 14318509 | 1 |
| Caelo | Alfatradiol | 14318511 | 3 |
| Caelo | Alfatradiol | 14318512 | 3 |
| Caelo | Alfatradiol | 14318514 | 2 |
| Caelo | Alfatradiol | 14C20-B02-294943 | 2 |
| Caelo | Alfatradiol | 14C20-B02-294944 | 1 |
| Caelo | Alfatradiol | 14I22-B30-302019 | 1 |
| Caelo | Alfatradiol | 15356801 | 17 |
| Caelo | Alfatradiol | 15356804 | 8 |
| Caelo | Alfatradiol | 1536801 | 1 |
| Caelo | Alfatradiol | 15380001 | 9 |
| Caelo | Alfatradiol | 15G07-B01-310227 | 1 |
| Caelo | Alfatradiol | 15G07-B01-311881 | 1 |
| Caelo | Alfatradiol | 15J27-B08-318164 | 2 |
| Caelo | Alfatradiol | 16087501 | 12 |
| Caelo | Alfatradiol | 16087502 | 7 |
| Caelo | Alfatradiol | 16087504 | 22 |
| Caelo | Alfatradiol | 16087507 | 1 |
| Caelo | Alfatradiol | 16087510 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Alfatradiol | 160875105728 | 1 |
| Caelo | Alfatradiol | 16087511 | 2 |
| Caelo | Alfatradiol | 16087512 | 10 |
| Caelo | Alfatradiol | 16180406 | 4 |
| Caelo | Alfatradiol | 16180408 | 7 |
| Caelo | Alfatradiol | 16180409 | 19 |
| Caelo | Alfatradiol | 16180412 | 1 |
| Caelo | Alfatradiol | 16180413 | 2 |
| Caelo | Alfatradiol | 16180415 | 2 |
| Caelo | Alfatradiol | 16G05-B01-335789 | 1 |
| Caelo | Alfatradiol | 16G05-B01-337353 | 1 |
| Caelo | Alfatradiol | 16G-B01-328254 | 1 |
| Caelo | Alfatradiol | 17G03-B11-341398 | 1 |
| Caelo | Alfatradiol | 18180409 | 1 |
| Caelo | Alfatradiol | 18C23-B05-354802 | 1 |
| Caelo | Alfatradiol | 19159801 | 4 |
| Caelo | Alfatradiol | 19159802 | 5 |
| Caelo | Alfatradiol | 19159803 | 10 |
| Caelo | Alfatradiol | 19159804 | 20 |
| Caelo | Alfatradiol | 19159805 | 6 |
| Caelo | Alfatradiol | 191599002 | 1 |
| Caelo | Alfatradiol | 191599003 | 10 |
| Caelo | Alfatradiol | 191599005 | 7 |
| Caelo | Alfatradiol | 19A24-B03-360709 | 1 |
| Caelo | Alfatradiol | 19K06-F04 | 1 |
| Caelo | Alfatradiol | 20002390001 | 1 |
| Caelo | Alfatradiol | 20002390003 | 11 |
| Caelo | Alfatradiol | 20002390006 | 14 |
| Caelo | Alfatradiol | 20004170001 | 1 |
| Caelo | Alfatradiol | 20004170003 | 2 |
| Caelo | Alfatradiol | 20004170004 | 9 |
| Caelo | Alfatradiol | 20004170006 | 6 |
| Caelo | Alfatradiol | 20004170009 | 5 |
| Caelo | Alfatradiol | 2000417001 | 1 |
| Caelo | Alfatradiol | 2000417004 | 2 |
| Caelo | Alfatradiol | 2061504 | 1 |
| Caelo | Alfatradiol | 2103003-01 | 3 |
| Caelo | Alfatradiol | 21D20-F06-378303 | 1 |
| Caelo | Alfatradiol | 220000052001 | 1 |
| Caelo | Alfatradiol | 220000053005 | 2 |
| Caelo | Alfatradiol | 22000052001 | 2 |
| Caelo | Alfatradiol | 22000052002 | 8 |
| Caelo | Alfatradiol | 22000053003 | 2 |
| Caelo | Alfatradiol | 22000053004 | 5 |
| Caelo | Alfatradiol | 22000053005 | 16 |
| Caelo | Alfatradiol | 22000053007 | 1 |
| Caelo | Alfatradiol | 23000346006 | 1 |
| Caelo | Alfatradiol | 2830 | 1 |
| Caelo | Alfatradiol | 4318512 | 1 |
| Caelo | Alfatradiol | 5051406 | 1 |
| Caelo | Alfatradiol | 5107516 | 1 |
| Caelo | Alfatradiol | 511211 | 1 |
| Caeol/Noweda | Alfatradiol | 16180410 | 1 |
| Caesar & Loretz GmbH... | Alfatradiol | 19159803 | 1 |
| Caesar & Loretz GmbH... | Alfatradiol | 22000053005 | 1 |
| Caesar & Loretz GmbH... | Alfatradiol | 20002390004 | 1 |
| Caesar & Loretz GmbH... | Alfatradiol | 20002390003 | 1 |
| Caesar & Loretz GmbH/AEP | Alfatradiol | 20002390004 | 1 |
| Caesar & Loretz GmbH/all | Alfatradiol | 191599003 | 1 |
| Caesar & Loretz GmbH/GEHE | Alfatradiol | 20002390006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Alfatradiol | 22000052002 | 1 |
| Caesar & Loretz GmbH… | Alfatradiol | 20004170006 | 1 |
| Caesar & Loretz GmbH… | Alfatradiol | 23000344003 | 1 |
| Caesar & Loretz GmbH/Kehr | Alfatradiol | 22000052002 | 1 |
| Caesar & Loretz GmbH… | Alfatradiol | 19159804 | 1 |
| Caesar & Loretz GmbH… | Alfatradiol | 22000053005 | 1 |
| Caesar & Loretz GmbH/P | Alfatradiol | 19159801 | 1 |
| Caesar & Loretz GmbH/Sa | Alfatradiol | 19159803 | 1 |
| Caesar & Loretz GmbH… | Alfatradiol | 19159805 | 1 |
| Caesar & Loretz GmbH… | Alfatradiol | 20004170004 | 1 |
| Caesar & Loretz GmbH… | Alfatradiol | 22000053005 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 16087512 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 16180407 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 16180408 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 16180409 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 16180413 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 19159801 | 2 |
| Caesar & Loretz GmbH | Alfatradiol | 19159803 | 4 |
| Caesar & Loretz GmbH | Alfatradiol | 19159804 | 2 |
| Caesar & Loretz GmbH | Alfatradiol | 19159805 | 2 |
| Caesar & Loretz GmbH | Alfatradiol | 191599002 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 191599003 | 6 |
| Caesar & Loretz GmbH | Alfatradiol | 191599005 | 7 |
| Caesar & Loretz GmbH | Alfatradiol | 20002390003 | 3 |
| Caesar & Loretz GmbH | Alfatradiol | 20002390004 | 1 |
| Caesar & Loretz GmbH | Alfatradiol | 20002390006 | 3 |
| Caesar & Loretz GmbH | Alfatradiol | 20004170001 | 2 |
| Caesar & Loretz GmbH | Alfatradiol | 20004170004 | 5 |
| Caesar & Loretz GmbH | Alfatradiol | 20004170006 | 5 |
| Caesar & Loretz GmbH | Alfatradiol | 20004170009 | 3 |
| Caesar & Loretz GmbH | Alfatradiol | 22000052002 | 6 |
| Caesar & Loretz GmbH | Alfatradiol | 22000052003 | 2 |
| Caesar & Loretz GmbH | Alfatradiol | 22000053003 | 3 |
| Caesar & Loretz GmbH | Alfatradiol | 22000053004 | 4 |
| Caesar & Loretz GmbH | Alfatradiol | 22000053005 | 5 |
| Caesar & Loretz GmbH | Alfatradiol | AP33-18-I-68P3620A | 1 |
| Caesar & Loretz/Sanacorp | Alfatradiol | 16180409 | 1 |
| Caesar und Loretz GmbH | Alfatradiol | 16087502 | 1 |
| Caesar&Lorenz/Phoenix | Alfatradiol | 16087502 | 1 |
| Caesar&Loretz GmbH/Anzag | Alfatradiol | 12164207 | 1 |
| Caesar/Lorenz | Alfatradiol | 11061001 | 1 |
| carlo | Alfatradiol | 10319903 | 1 |
| Chiracon GmbH | Alfatradiol | AP35-17-II-85P3624 | 1 |
| Chiracon/Phoenix | Alfatradiol | 35-19-I-14P3693 | 1 |
| EuRho | Alfatradiol | 210300-01 | 1 |
| Euro OTC | Alfatradiol | 121696 | 1 |
| Euro OTC | Alfatradiol | 1404001-01 | 2 |
| Euro OTC | Alfatradiol | 1404001-02 | 1 |
| Euro OTC | Alfatradiol | 15356804 | 1 |
| Euro OTC | Alfatradiol | 160301901 | 1 |
| Euro OTC | Alfatradiol | 1603019-03 | 3 |
| Euro OTC | Alfatradiol | 16180410 | 1 |
| Euro OTC | Alfatradiol | 2002017-01 | 1 |
| Euro OTC | Alfatradiol | 200201702 | 1 |
| Euro OTC | Alfatradiol | 2002017-02 | 2 |
| Euro OTC | Alfatradiol | 20060005-01 | 1 |
| Euro OTC | Alfatradiol | 2006005-01 | 3 |
| Euro OTC | Alfatradiol | 2103003-01 | 4 |
| Euro OTC | Alfatradiol | 2201003-01 | 7 |
| Euro OTC | Alfatradiol | 2201830-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Alfatradiol | 2209016-01 | 1 |
| Euro OTC | Alfatradiol | 2301040-01 | 1 |
| Euro OTC | Alfatradiol | AP21-16-II-14P4511A | 1 |
| Euro OTC | Alfatradiol | AP33-16-I-62P2985A | 1 |
| Euro OTC | Alfatradiol | AP33-16-l-62P2985A | 1 |
| Fa.Phönix | Alfatradiol | 22000052002 | 1 |
| Fagron | Alfatradiol | | 2 |
| Fagron | Alfatradiol | 11B07-N05 | 1 |
| Fagron | Alfatradiol | 11D07-N19 | 1 |
| Fagron | Alfatradiol | 11G22-N11 | 2 |
| Fagron | Alfatradiol | 11k25-N01 | 1 |
| Fagron | Alfatradiol | 11K25-N01 | 3 |
| Fagron | Alfatradiol | 12D19-N03 | 6 |
| Fagron | Alfatradiol | 12H29-N05 | 4 |
| Fagron | Alfatradiol | 12J27-B08-314546 | 1 |
| Fagron | Alfatradiol | 12L19-N08 | 9 |
| Fagron | Alfatradiol | 12L19-No8 | 1 |
| Fagron | Alfatradiol | 13201605 | 1 |
| Fagron | Alfatradiol | 1372918 | 1 |
| Fagron | Alfatradiol | 13G19-N06 | 19 |
| Fagron | Alfatradiol | 13G19-N06 | 1 |
| Fagron | Alfatradiol | 13G19-N09 | 1 |
| Fagron | Alfatradiol | 13G19-No6 | 2 |
| Fagron | Alfatradiol | 13L30B32 | 1 |
| Fagron | Alfatradiol | 13L30-B32 | 2 |
| Fagron | Alfatradiol | 13L30-B32-290739 | 1 |
| Fagron | Alfatradiol | 13L30B32-290741 | 1 |
| Fagron | Alfatradiol | 13130b32290742 | 1 |
| Fagron | Alfatradiol | 13L30-B32-290742 | 1 |
| Fagron | Alfatradiol | 14/22-B30-302017 | 3 |
| Fagron | Alfatradiol | 14722-B30-302018 | 1 |
| Fagron | Alfatradiol | 14C20-B02-294943 | 4 |
| Fagron | Alfatradiol | 14C20-B02-294944 | 1 |
| Fagron | Alfatradiol | 14G07-B99 | 1 |
| Fagron | Alfatradiol | 14G07-B99-294942 | 1 |
| Fagron | Alfatradiol | 14G07-B99-294945 | 4 |
| Fagron | Alfatradiol | 14I22-B30 | 1 |
| Fagron | Alfatradiol | 15G07-B01 | 2 |
| Fagron | Alfatradiol | 15G07-B01-310227 | 5 |
| Fagron | Alfatradiol | 15G07-B01-310228 | 3 |
| Fagron | Alfatradiol | 15G07-B01-310229 | 3 |
| Fagron | Alfatradiol | 15G07-B01-311881 | 3 |
| Fagron | Alfatradiol | 15J27-B08 | 1 |
| Fagron | Alfatradiol | 15J27-B08-314546 | 1 |
| Fagron | Alfatradiol | 15J27B08318164 | 1 |
| Fagron | Alfatradiol | 15J27-B08-318164 | 1 |
| Fagron | Alfatradiol | 15J27-B08-318783 | 1 |
| Fagron | Alfatradiol | 15J27-B08-321786 | 2 |
| Fagron | Alfatradiol | 16G05-801 | 1 |
| Fagron | Alfatradiol | 16g05-b01-324614 | 1 |
| Fagron | Alfatradiol | 16G05-B01-324614 | 1 |
| Fagron | Alfatradiol | 16G05-B01-325108 | 1 |
| Fagron | Alfatradiol | 16G05-B01-326866 | 1 |
| Fagron | Alfatradiol | 16G05-B01-328254 | 1 |
| Fagron | Alfatradiol | 16G05-B01-332379 | 4 |
| Fagron | Alfatradiol | 16G05-B01-334055 | 3 |
| Fagron | Alfatradiol | 16G05-B01-335789 | 7 |
| Fagron | Alfatradiol | 16G05-B01-337352 | 3 |
| Fagron | Alfatradiol | 16G05-B01-337353 | 1 |
| Fagron | Alfatradiol | 16G05-Bo1-332379 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Alfatradiol | 16G05-N01-335789 | 1 |
| Fagron | Alfatradiol | 17G03-B11 | 4 |
| Fagron | Alfatradiol | 17G03-B11_348862 | 1 |
| Fagron | Alfatradiol | 17G03-B11-341398 | 2 |
| Fagron | Alfatradiol | 17G03-B11-341399 | 2 |
| Fagron | Alfatradiol | 17G03-B11-345093 | 5 |
| Fagron | Alfatradiol | 17G03-B11-346962 | 1 |
| Fagron | Alfatradiol | 17G03-B11-348862 | 2 |
| Fagron | Alfatradiol | 17G03-B11-348863 | 1 |
| Fagron | Alfatradiol | 18C23-B05 | 2 |
| Fagron | Alfatradiol | 18C23-B05_350996 | 1 |
| Fagron | Alfatradiol | 18C23-B05_354802 | 1 |
| Fagron | Alfatradiol | 18C23-B05-350996 | 4 |
| Fagron | Alfatradiol | 18C23-B05-352724 | 2 |
| Fagron | Alfatradiol | 18C23-B05-352725 | 1 |
| Fagron | Alfatradiol | 18C23-B05-354802 | 9 |
| Fagron | Alfatradiol | 18C23-B05-356316 | 2 |
| Fagron | Alfatradiol | 18C23-B05-4802 | 1 |
| Fagron | Alfatradiol | 19A24-B003360712 | 1 |
| Fagron | Alfatradiol | 19A24-B03 | 3 |
| Fagron | Alfatradiol | 19A24-B03_360710 | 1 |
| Fagron | Alfatradiol | 19A24-B03-360709 | 4 |
| Fagron | Alfatradiol | 19A24-B03-360710 | 13 |
| Fagron | Alfatradiol | 19AB03360709 | 1 |
| Fagron | Alfatradiol | 19K06-F04 | 1 |
| Fagron | Alfatradiol | 19K06F04366005 | 1 |
| Fagron | Alfatradiol | 19K06-F04-366005 | 10 |
| Fagron | Alfatradiol | 19K06-F04-366006 | 2 |
| Fagron | Alfatradiol | 19K06-F04-366007 | 2 |
| Fagron | Alfatradiol | 20122-F02-374255 | 2 |
| Fagron | Alfatradiol | 20122-F02-374256 | 1 |
| Fagron | Alfatradiol | 20F18-F01 | 1 |
| Fagron | Alfatradiol | 20F18F01372918 | 2 |
| Fagron | Alfatradiol | 20F18-F01-372918 | 15 |
| Fagron | Alfatradiol | 20F18-F01372920 | 1 |
| Fagron | Alfatradiol | 20F18-F01-372920 | 4 |
| Fagron | Alfatradiol | 20F8-FD1 | 1 |
| Fagron | Alfatradiol | 20I22-F02-374255 | 3 |
| Fagron | Alfatradiol | 20I22-F02-374256 | 2 |
| Fagron | Alfatradiol | 21D20_F06_379262 | 1 |
| Fagron | Alfatradiol | 21D20-F036-379262 | 1 |
| Fagron | Alfatradiol | 21D20-F06 | 2 |
| Fagron | Alfatradiol | 21D20F06378303 | 2 |
| Fagron | Alfatradiol | 21D20-F06-378303 | 6 |
| Fagron | Alfatradiol | 21D20-F06-378305 | 2 |
| Fagron | Alfatradiol | 21D20-F06-378306 | 2 |
| Fagron | Alfatradiol | 21D20-F06-378476 | 3 |
| Fagron | Alfatradiol | 21d20f06379262 | 1 |
| Fagron | Alfatradiol | 21D20-F06-379262 | 12 |
| Fagron | Alfatradiol | 21D20-F06-379263 | 5 |
| Fagron | Alfatradiol | 22A10-F02-381369 | 10 |
| Fagron | Alfatradiol | 22A10-F02-381420 | 2 |
| Fagron | Alfatradiol | 22A10-F02-381421 | 2 |
| Fagron | Alfatradiol | 23E15-B08-224470 | 1 |
| Fagron | Alfatradiol | 24J10-B13-003480 | 1 |
| Fagron | Alfatradiol | 2735 | 1 |
| Fagron | Alfatradiol | 324614 | 1 |
| Fagron | Alfatradiol | 5102432 | 1 |
| Fagron | Alfatradiol | 5111184 | 3 |
| Fagron | Alfatradiol | 5115018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Alfatradiol | 5119507 | 4 |
| Fagron | Alfatradiol | 5122243 | 6 |
| Fagron | Alfatradiol | 5122244 | 3 |
| Fagron | Alfatradiol | 6882484 | 1 |
| Fagron | Alfatradiol | 700670-0010 | 1 |
| Fagron | Alfatradiol | 9011904 | 1 |
| Fagron | Alfatradiol | F01-3729103 | 1 |
| Fagron | Alfatradiol | F04-3660005 | 1 |
| Fagron | Alfatradiol | F04-3660006 | 1 |
| Fagron | Alfatradiol | F0637926002 | 1 |
| Fagron | Alfatradiol | XP101UT | 1 |
| Fargon/AHD | Alfatradiol | 17G03-B11 | 1 |
| Fargon/Kehr | Alfatradiol | 16G05-B01-332379 | 1 |
| Fargon | Alfatradiol | 21D20-F06-379262 | 1 |
| Fgron / Alliance Healthc. | Alfatradiol | 16G05-B01-328254 | 1 |
| Fiebig/Farago | Alfatradiol | 19A24-B03-360709 | 1 |
| fragon/phonix | Alfatradiol | 17G03-B11-341399 | 1 |
| Gatt-Koller | Alfatradiol | 180077661 | 1 |
| Gatt-Koller | Alfatradiol | 1803210 | 2 |
| Gehe/Fragron | Alfatradiol | 5111184 | 2 |
| Gehe | Alfatradiol | 16087501 | 1 |
| GEHE | Alfatradiol | 16087512 | 1 |
| Gehe | Alfatradiol | 19159801 | 1 |
| Gehe | Alfatradiol | 19159802 | 2 |
| Gehe | Alfatradiol | 22000053007 | 1 |
| Gehe | Alfatradiol | 24J10-B13-003480 | 1 |
| gepepharm/Phoenix | Alfatradiol | 19054203 | 2 |
| Kehr | Alfatradiol | 18C23-B05-350996 | 1 |
| Kehr | Alfatradiol | 19K06-F04-3660055 | 1 |
| kehr | Alfatradiol | 23000346002 | 1 |
| Kwizda | Alfatradiol | 529068 | 1 |
| Noweda am 10.08.2018 | Alfatradiol | 16087510 | 1 |
| Noweda/Fragron | Alfatradiol | 16G05-B01-332379 | 1 |
| Noweda | Alfatradiol | 16G05-B01-324614 | 2 |
| Noweda | Alfatradiol | 19159803 | 1 |
| Noweda | Alfatradiol | 21D20-F06-378303 | 1 |
| Noweda | Alfatradiol | 22000052002 | 1 |
| Noweda | Alfatradiol | 22000053007 | 1 |
| Noweda | Alfatradiol | 22A10-F02-381369 | 1 |
| Noweda | Alfatradiol | 2301040-01 | 2 |
| Phönix | Alfatradiol | 15356801 | 1 |
| Phönix | Alfatradiol | 21D20-F06-378305 | 1 |
| phönix | Alfatradiol | 21D20-F06-379262 | 2 |
| Phönix | Alfatradiol | 22A10-F02381369 | 1 |
| Phönix | Alfatradiol | 23000346002 | 1 |
| Phönix | Alfatradiol | 33-18-1-68P3620A | 1 |
| Phönix | Alfatradiol | APXPC0071A | 1 |
| Phönix | Alfatradiol | B05-3509906 | 1 |
| Proquina / Gehe | Alfatradiol | 15356801 | 1 |
| Proquina / Gehe | Alfatradiol | 19A24-B03-360711 | 1 |
| Proquina / Gehe | Alfatradiol | 5122243 | 1 |
| Proquina / Gehe | Alfatradiol | 6882478 | 1 |
| Proquina / Gehe | Alfatradiol | F04-3660006 | 1 |
| Proquina / Sanacorp | Alfatradiol | F04-3660005 | 1 |
| Sanacorp, 39,57EUR, 27.1.17 | Alfatradiol | 700670-0011 | 1 |
| Sanacorp | Alfatradiol | 13201605 | 1 |
| Sanacorp | Alfatradiol | 15356804 | 1 |
| Sanacorp | Alfatradiol | 19A24B03360710 | 1 |
| Sanacorp | Alfatradiol | 2103003-01 | 1 |
| Sanacorp | Alfatradiol | 21D20-F06-379262 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Alfatradiol | 22A10-F02-381369 | 1 |
| Shandong Northwest M… | Alfatradiol | AEC160522 | 1 |
| Shandong northwest m… | Alfatradiol | AEC151211 | 1 |
| VDL 1.7.14;40.30 euro | Alfatradiol | 13G19-N06 | 1 |

- 255 792 spectra from 1666 *Apo-Ident* customers from a total of 51 858 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Alfatradiol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Alfatradiol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 850 | 0 | 157 476 |
| **Type B** | 0 | 1695 | 0 | 211 245 |
| **Type C** | 0 | 1078 | 16 | 255 792 |

The substance/substance group *Alfatradiol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.2941 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6460 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.5375 % (> 98.2633 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20940 | 20940 | 0.00 | 114.83 |
| 21476 | 22511 | 22.76 | 124.82 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21477 | 22511 | 25.29 | 124.26 |
| 21714 | 21714 | 0.00 | 121.33 |
| 22511 | 22511 | 0.00 | 119.02 |
| 22933 | 22511 | 9.53 | 119.41 |
| 22934 | 22511 | 4.99 | 118.83 |
| 22935 | 25553 | 9.49 | 130.72 |
| 24662 | 24747 | 39.98 | 127.27 |
| 24747 | 24747 | 0.00 | 127.98 |
| 25553 | 25553 | 0.00 | 129.80 |
| 25561 | 25561 | 0.00 | 128.30 |
| 27478 | 24747 | 13.51 | 128.70 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Allantoin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20079-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Allantoin; Allantoinum

### Special notes

When selecting the *Allantoin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Allantoin | 7 | 8 | 127 |

### Second-stage model

For differentiation of the substance/substance group *Allantoin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Allantoin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 110.90 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Allantoin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Allantoin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Allantoin | 162289 | 22756 | 40 | 20160815* |
| Caelo | Allantoin | 172346 | 23629 | 40 | 20171019* |
| Caelo | Allantoin | 172346 | 23635 | 40 | 20171019* |
| Euro OTC | Allantoin | 1406011-01 | 21625 | 60 | 20140718 |
| Euro OTC | Allantoin | 1609012 | 22750 | 40 | 20161006* |
| Euro OTC | Allantoin | 1609012-01 | 22810 | 40 | 20161006 |
| Euro OTC | Allantoin | 1406011-04 | 24095 | 40 | 20170213 |
| Fagron | Allantoin | 13I03-B05 | 21216 | 40 | 20130927 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 340 spectra of 8 reference samples from the substance/substance group *Allantoin*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 986 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 390 spectra of 11 reference samples from the substance/substance group *Allantoin*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Allantoin | 181586 | 24235 | 40 |
| Caelo | Allantoin | 191828 | 24894 | 40 |
| Caelo | Allantoin | 21003135 | 25848 | 50 |
| Caelo | Allantoin | 23000841 | 27337 | 40 |
| Caelo | Allantoin | 25000530 | 27667 | 40 |
| Euro OTC | Allantoin | 1811006 | 24344 | 40 |
| Euro OTC | Allantoin | 2101022 | 25593 | 40 |
| Euro OTC | Allantoin | 2212010 | 26511 | 40 |
| Caelo | Allantoin | 23000841 | 27337SI | 20 |
| Caelo | Allantoin | 25000530 | 27667SI | 20 |
| Euro OTC | Allantoin | 2212010 | 26511SI | 20 |

- 212 550 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 582 spectra from 272 *Apo-Ident* customers from 130 batches from the substance/substance group *Allantoin*.

- Among them are spectra of independent samples from 127 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Allantoin | 20004526005 | 1 |
| | Allantoin | 21003135003 | 1 |
| | Allantoin | 21003135007 | 3 |
| | Allantoin | 21003135015 | 5 |
| | Allantoin | 21003135019 | 2 |
| | Allantoin | 2101022-01 | 1 |
| | Allantoin | 2101022-02 | 1 |
| | Allantoin | 2212010-01 | 1 |
| | Allantoin | LAV-2020060 | 1 |
| ACM Herba | Allantoin | 22J00443 | 1 |
| AHD | Allantoin | 1609012-01 | 1 |
| Anzag;18.03.15;2,76EUR | Allantoin | 14247602 | 1 |
| Caelo | Allantoin | 10064008 | 4 |
| Caelo | Allantoin | 10064012 | 1 |
| Caelo | Allantoin | 10064015 | 1 |
| Caelo | Allantoin | 10318305 | 1 |
| Caelo | Allantoin | 10318312 | 1 |
| Caelo | Allantoin | 10318313 | 2 |
| Caelo | Allantoin | 1113E-01087 | 1 |
| Caelo | Allantoin | 11247504 | 5 |
| Caelo | Allantoin | 11247510 | 2 |
| Caelo | Allantoin | 11247511 | 2 |
| Caelo | Allantoin | 121127 | 1 |
| Caelo | Allantoin | 1225101 | 1 |
| Caelo | Allantoin | 12251501 | 4 |
| Caelo | Allantoin | 12251502 | 2 |
| Caelo | Allantoin | 12251505 | 7 |
| Caelo | Allantoin | 12251510 | 9 |
| Caelo | Allantoin | 12251511 | 1 |
| Caelo | Allantoin | 12374401 | 1 |
| Caelo | Allantoin | 12374403 | 8 |
| Caelo | Allantoin | 12374404 | 2 |
| Caelo | Allantoin | 12374407 | 1 |
| Caelo | Allantoin | 12374408 | 1 |
| Caelo | Allantoin | 12374409 | 15 |
| Caelo | Allantoin | 12374414 | 8 |
| Caelo | Allantoin | 12374415 | 10 |
| Caelo | Allantoin | 12374417 | 1 |
| Caelo | Allantoin | 12374418 | 2 |
| Caelo | Allantoin | 12374422 | 9 |
| Caelo | Allantoin | 12374423 | 2 |
| Caelo | Allantoin | 1251505 | 1 |
| Caelo | Allantoin | 140512 | 1 |
| Caelo | Allantoin | 1406011-05 | 1 |
| Caelo | Allantoin | 14247602 | 6 |
| Caelo | Allantoin | 14247609 | 10 |
| Caelo | Allantoin | 14247610 | 1 |
| Caelo | Allantoin | 1522000 | 1 |
| Caelo | Allantoin | 152200012 | 1 |
| Caelo | Allantoin | 15220004 | 1 |
| Caelo | Allantoin | 15220005 | 2 |
| Caelo | Allantoin | 15220006 | 17 |
| Caelo | Allantoin | 15220007 | 4 |
| Caelo | Allantoin | 15220008 | 11 |
| Caelo | Allantoin | 15220010 | 3 |
| Caelo | Allantoin | 15220011 | 2 |
| Caelo | Allantoin | 15220012 | 11 |
| Caelo | Allantoin | 1522008 | 1 |
| Caelo | Allantoin | 15275302 | 1 |
| Caelo | Allantoin | 15275304 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Allantoin | 15275305 | 3 |
| Caelo | Allantoin | 15275312 | 9 |
| Caelo | Allantoin | 16228903 | 13 |
| Caelo | Allantoin | 16228904 | 1 |
| Caelo | Allantoin | 16228906 | 17 |
| Caelo | Allantoin | 16228913 | 2 |
| Caelo | Allantoin | 16228914 | 3 |
| Caelo | Allantoin | 16228915 | 29 |
| Caelo | Allantoin | 17355901 | 2 |
| Caelo | Allantoin | 17355903 | 20 |
| Caelo | Allantoin | 17355904 | 1 |
| Caelo | Allantoin | 17355905 | 1 |
| Caelo | Allantoin | 1811006-01 | 1 |
| Caelo | Allantoin | 18158602 | 12 |
| Caelo | Allantoin | 18158604 | 12 |
| Caelo | Allantoin | 18158605 | 4 |
| Caelo | Allantoin | 18158606 | 1 |
| Caelo | Allantoin | 18158613 | 3 |
| Caelo | Allantoin | 1918202 | 1 |
| Caelo | Allantoin | 191828002 | 2 |
| Caelo | Allantoin | 19182802 | 1 |
| Caelo | Allantoin | 19182803 | 7 |
| Caelo | Allantoin | 20002009004 | 7 |
| Caelo | Allantoin | 20004518002 | 3 |
| Caelo | Allantoin | 20004518003 | 8 |
| Caelo | Allantoin | 20004526003 | 7 |
| Caelo | Allantoin | 20004526005 | 5 |
| Caelo | Allantoin | 20004526006 | 1 |
| Caelo | Allantoin | 2004526005 | 1 |
| Caelo | Allantoin | 20071202 | 1 |
| Caelo | Allantoin | 20140612-15 | 1 |
| Caelo | Allantoin | 21003135003 | 1 |
| Caelo | Allantoin | 21003135007 | 3 |
| Caelo | Allantoin | 2100315007 | 1 |
| Caelo | Allantoin | 2264594 | 1 |
| Caelo | Allantoin | 2713431 | 1 |
| Caelo | Allantoin | 2713448 | 1 |
| Caelo | Allantoin | 28101702 | 1 |
| Caelo | Allantoin | 4247602 | 1 |
| Caelo | Allantoin | 5051402 | 1 |
| Caelo | Allantoin | 81542099 | 1 |
| Caelo | Allantoin | 81542358 | 2 |
| Caesar & Loretz GmbH... | Allantoin | 17355905 | 2 |
| Caesar & Loretz GmbH... | Allantoin | 191828002 | 1 |
| Caesar & Loretz GmbH... | Allantoin | 18158605 | 1 |
| Caesar & Loretz GmbH... | Allantoin | 191828002 | 1 |
| Caesar & Loretz GmbH... | Allantoin | 20002009004 | 1 |
| Caesar & Loretz GmbH... | Allantoin | 18158604 | 2 |
| Caesar & Loretz GmbH... | Allantoin | 20002009004 | 1 |
| Caesar & Loretz GmbH... | Allantoin | 18158604 | 1 |
| Caesar & Loretz GmbH... | Allantoin | 21003135018 | 1 |
| Caesar & Loretz GmbH | Allantoin | 12251505 | 1 |
| Caesar & Loretz GmbH | Allantoin | 12251510 | 1 |
| Caesar & Loretz GmbH | Allantoin | 12374403 | 1 |
| Caesar & Loretz GmbH | Allantoin | 12374409 | 1 |
| Caesar & Loretz GmbH | Allantoin | 12374415 | 1 |
| Caesar & Loretz GmbH | Allantoin | 12374416 | 1 |
| Caesar & Loretz GmbH | Allantoin | 14247602 | 1 |
| Caesar & Loretz GmbH | Allantoin | 18158602 | 2 |
| Caesar & Loretz GmbH | Allantoin | 18158604 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Allantoin | 18158605 | 1 |
| Caesar & Loretz GmbH | Allantoin | 18158613 | 2 |
| Caesar & Loretz GmbH | Allantoin | 191828002 | 4 |
| Caesar & Loretz GmbH | Allantoin | 19182803 | 4 |
| Caesar & Loretz GmbH | Allantoin | 20004518002 | 1 |
| Caesar & Loretz GmbH | Allantoin | 20004518003 | 1 |
| CAESAR & LORETZ GMBH | Allantoin | 20004526005 | 1 |
| Caesar & Loretz GmbH | Allantoin | 21003135007 | 2 |
| Caesar & Loretz Hilden | Allantoin | 17355903 | 1 |
| Caesar & Loretz | Allantoin | 16228906 | 1 |
| Caesar&Loretz GmbH | Allantoin | 12374409 | 1 |
| Caeser / Gehe | Allantoin | 15220007 | 1 |
| Cealo/Phönix | Allantoin | 18158602 | 1 |
| Cealo | Allantoin | 19182803 | 1 |
| celo/Jenne | Allantoin | 12374403 | 1 |
| Deretil SA / Allianc... | Allantoin | 2101022-01 | 1 |
| DSM Nutritional Prod... | Allantoin | 12251505 | 1 |
| EuRho / Phoenix | Allantoin | 1406011-03 | 1 |
| EuRho | Allantoin | 1406011-04 | 1 |
| Euro OTC | Allantoin | 140104601 | 1 |
| Euro OTC | Allantoin | 1401046-01 | 3 |
| Euro OTC | Allantoin | 1406011 | 2 |
| Euro OTC | Allantoin | 1406011-01 | 7 |
| Euro OTC | Allantoin | 1406011-02 | 3 |
| Euro OTC | Allantoin | 140601103 | 1 |
| Euro OTC | Allantoin | 1406011-04 | 1 |
| Euro OTC | Allantoin | 1406011-05 | 3 |
| Euro OTC | Allantoin | 15220008 | 2 |
| Euro OTC | Allantoin | 1609012-01 | 10 |
| Euro OTC | Allantoin | 160901202 | 1 |
| Euro OTC | Allantoin | 1609012-02 | 3 |
| Euro OTC | Allantoin | 1609012-03 | 2 |
| Euro OTC | Allantoin | 16228915 | 1 |
| Euro OTC | Allantoin | 18110006-01 | 1 |
| Euro OTC | Allantoin | 1811006 | 1 |
| Euro OTC | Allantoin | 1811006-01 | 11 |
| Euro OTC | Allantoin | 181100602 | 1 |
| Euro OTC | Allantoin | 1811006-02 | 12 |
| Euro OTC | Allantoin | 1811006-03 | 8 |
| Euro OTC | Allantoin | 2101022-01 | 9 |
| Euro OTC | Allantoin | 5024-000077 | 1 |
| Euro OTC | Allantoin | K93504015 | 1 |
| Fagron | Allantoin | 11J11-N11 | 3 |
| Fagron | Allantoin | 12374407 | 3 |
| Fagron | Allantoin | 12B09-N09 | 1 |
| Fagron | Allantoin | 12C30-N04 | 1 |
| Fagron | Allantoin | 13A21-N07 | 3 |
| Fagron | Allantoin | 13G16-N07 | 6 |
| Fagron | Allantoin | 13I03-B05-289430 | 1 |
| Fagron | Allantoin | 16228905 | 2 |
| Fagron | Allantoin | 5011E-01087 | 1 |
| Fargron/AHD | Allantoin | 13G16-N07 | 1 |
| Gehe | Allantoin | 12251510 | 1 |
| Gehe | Allantoin | 14247603 | 1 |
| Gehe | Allantoin | 15220008 | 1 |
| Gehe | Allantoin | 15220012 | 1 |
| Gehe | Allantoin | 1609012-02 | 1 |
| Gehe | Allantoin | 17355903 | 1 |
| Gehe | Allantoin | 1811006-02 | 1 |
| Herba Chemosan | Allantoin | 22JOD443 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Ichthyol-Gesellschaft | Allantoin | 16228915 | 1 |
| Kehr | Allantoin | 15220008 | 1 |
| Krieger/Hedinger | Allantoin | 15220006 | 1 |
| Merck | Allantoin | 1406011-05 | 1 |
| Merck | Allantoin | 160901201 | 1 |
| Merck | Allantoin | 1609012-01 | 1 |
| Noweda | Allantoin | 1609012-01 | 1 |
| Noweda | Allantoin | 16228915 | 1 |
| Noweda | Allantoin | 21003135015 | 1 |
| Noweda | Allantoin | 2101022-02 | 1 |
| Phoenix 08.10.14 | Allantoin | 1401046-01 | 1 |
| Sanacorp | Allantoin | 12251501 | 1 |
| Sanacorp | Allantoin | 12251510 | 1 |
| Sanacorp | Allantoin | 12374409 | 2 |
| Sanacorp | Allantoin | 12374422 | 1 |
| Sanacorp | Allantoin | 15275312 | 1 |
| Sanacorp | Allantoin | 1811006-02 | 1 |
| Sanacorp | Allantoin | 21003135015 | 1 |
| Sanacorp | Allantoin | K93504015 | 1 |
| Spinnrad | Allantoin | 1217503012 | 1 |
| VDL 17.10.14 | Allantoin | 12374415 | 1 |

- 256 304 spectra from 1666 *Apo-Ident* customers from a total of 52 023 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Allantoin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Allantoin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 340 | 0 | 157 986 |
| **Type B** | 0 | 390 | 0 | 212 550 |
| **Type C** | 0 | 580 | 2 | 256 304 |

The substance/substance group *Allantoin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2353 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4615 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6564 % (> 99.1409 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to

exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21216 | 22756 | 10.14 | 286.50 |
| 21625 | 22750 | 10.05 | 286.91 |
| 22750 | 22750 | 0.00 | 281.44 |
| 22756 | 22756 | 0.00 | 275.05 |
| 22810 | 22750 | 6.01 | 276.65 |
| 23629 | 23629 | 0.00 | 272.31 |
| 23635 | 23635 | 0.00 | 274.03 |
| 24095 | 22750 | 6.29 | 279.80 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Allopurinol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22243-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Allopurinol; Allopurinolum

### Special notes

When selecting the *Allopurinol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Allopurinol | 4 | 3 | 17 |

### Second-stage model

For differentiation of the substance/substance group *Allopurinol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Allopurinol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 109.56 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Allopurinol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Allopurinol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Allopurinol | 14E15-B05-307746 | 22243 | 60 | AR-16-FG-004367-01 |
| Fagron | Allopurinol | 14E15-B05-315557 | 22345 | 60 | 20140611 |
| Fagron | Allopurinol | 14E15-B05-307746 | 22836 | 40 | 20140611 |
| Fagron | Allopurinol | 22H29-B06-223774 | 26450 | 40 | 20220930 |
| Fagron | Allopurinol | 23D12-B06-228657 | 26818 | 40 | 20230510 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 240 spectra of 5 reference samples from the substance/substance group *Allopurinol*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 086 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 220 spectra of 7 reference samples from the substance/substance group *Allopurinol*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Allopurinol | 14E15-B05-330859 | 23523 | 40 |
| Fagron | Allopurinol | 18E23-B02-357777 | 24577 | 40 |
| Fagron | Allopurinol | 24D16-B11-002853 | 27479 | 40 |
| Fagron | Allopurinol | 14E15-B05-330859 | 23526 | 40 |
| Fagron | Allopurinol | 22H29-B06-223774 | 26450SI† | 20 |
| Fagron | Allopurinol | 23D12-B06-228657 | 26818SI† | 20 |
| Fagron | Allopurinol | 24D16-B11-002853 | 27479SI | 20 |

- 212 720 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 38 spectra from 19 *Apo-Ident* customers from 19 batches from the substance/substance group *Allopurinol*.
- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Allopurinol | 18E23-B02-350905 | 1 |
| Fagron | Allopurinol | 14E15-B05_315557 | 1 |
| Fagron | Allopurinol | 14E15-B05-315557 | 14 |
| Fagron | Allopurinol | 14E15B05-320787 | 1 |
| Fagron | Allopurinol | 14E15-B05-320787 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Allopurinol | 14E15-B05-337862 | 4 |
| Fagron | Allopurinol | 14E15-B08 | 1 |
| Fagron | Allopurinol | 18E23-B02 | 1 |
| Fagron | Allopurinol | 18E23-B02-350905 | 1 |
| Fagron | Allopurinol | 18E23-B02-357777 | 3 |
| Fagron | Allopurinol | 18E23-B02-361600 | 1 |
| Fagron | Allopurinol | 190261502 | 1 |
| Fagron | Allopurinol | 19061206 | 1 |
| Fagron | Allopurinol | 200250306 | 1 |
| Fagron | Allopurinol | 200803107 | 1 |
| Fagron | Allopurinol | 22H29-B06-223774 | 1 |
| Fagron | Allopurinol | B02-3509005 | 1 |
| Fagron | Allopurinol | B02-3577707 | 1 |
| Fagron | Allopurinol | B02-3616000 | 1 |
| Phönix | Allopurinol | 200612506 | 1 |

- 256 848 spectra from 1666 *Apo-Ident* customers from a total of 52 135 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Allopurinol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Allopurinol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 240 | 0 | 158 086 |
| **Type B** | 0 | 220 | 0 | 212 720 |
| **Type C** | 0 | 38 | 0 | 256 848 |

The substance/substance group *Allopurinol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.2727 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 84.2105 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22243 | 22243 | 0.00 | 192.63 |
| 22345 | 22243 | 3.52 | 194.79 |
| 22836 | 22243 | 4.05 | 195.98 |
| 26450 | 22243 | 8.25 | 196.06 |
| 26818 | 22243 | 15.01 | 196.36 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **alpha-tocopheryl acetate dry concentrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20433-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

alpha-tocopheryl acetate dry concentrate; alpha-Tocopherylis acetatis pulvis

### Special notes

When selecting the *alpha-tocopheryl acetate dry concentrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| alpha-tocopheryl acetate dry concentrate | 10 | 12 | 23 |

### Second-stage model

For differentiation of the substance/substance group *alpha-tocopheryl acetate dry concentrate* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *alpha-tocopheryl acetate dry concentrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 26.73 | – |
| Cannabis flower, THC/CBD-intermedia… | 43.56 | – |
| Cannabis flower, CBD-dominant type | 54.69 | – |
| ⋮ | ⋮ | ⋮ |
| Bacitracin | >50 | 19.89 |
| Nystatin | >50 | 26.91 |
| Amphotericin B | >50 | 39.84 |
| Polymyxin B sulfate | >50 | 42.57 |
| Colistin sulfate | >50 | 46.49 |
| Cyanocobalamin | >50 | 57.53 |
| Estriol | >50 | 62.81 |
| Estradiol hemihydrate | >50 | 64.96 |
| Riboflavin | >50 | 69.06 |
| Calcium glycerophosphate | >50 | 86.19 |
| Triamcinolone | >50 | 92.73 |
| Carmellose sodium | >50 | 102.65 |
| Calcium pantothenate | >50 | 124.58 |
| Gelatine, white | >50 | 150.72 |
| Methylcobalamin | >50 | 169.80 |
| SyrSpend® SF Alka | >50 | 180.45 |
| Hyoscine hydrobromide | >50 | 184.05 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 184.55 |
| Tosylchloramide sodium | >50 | 191.83 |
| Rice starch | >50 | 198.14 |
| Corn starch | >50 | 263.38 |
| Oxalic acid | >50 | 282.63 |
| SyrSpend® SF pH4 | >50 | 341.12 |
| Acacia, dried dispersion | >50 | 368.60 |
| Maltodextrin | >50 | 375.11 |
| Wheat starch | >50 | 394.69 |
| Potato starch | >50 | 407.89 |
| Fructose | >50 | 627.71 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *alpha-tocopheryl acetate dry concentrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *alpha-tocopheryl acetate dry concentrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | alpha-tocopheryl acetate ... | 1110021-02 | 20907 | 40 | 20120104 |
| Euro OTC | alpha-tocopheryl acetate ... | 1305032-01 | 21680 | 60 | AR-15-FG-001194-01 |
| Euro OTC | alpha-tocopheryl acetate ... | 1507001 | 21842 | 60 | 20130708* |
| Euro OTC | alpha-tocopheryl acetate ... | 1603046 | 22543 | 40 | 20160429* |
| Euro OTC | alpha-tocopheryl acetate ... | 1907033 | 24841 | 40 | 20190820* |
| Euro OTC | alpha-tocopheryl acetate ... | 2005022 | 25277 | 40 | 20200728* |
| Euro OTC | alpha-tocopheryl acetate ... | 2101019 | 25599 | 40 | 20210323* |
| Fagron | alpha-tocopheryl acetate ... | 13H30-B02-287169 | 21609 | 60 | AR-15-FG-006388-01 |
| Fagron | alpha-tocopheryl acetate ... | 14B03-B04-295113 | 21959 | 60 | 20140224 |
| Fagron | Vitamin E acetate powder 50% | 022402A013 | BR20042 | 40 | 20240919* |
| Fagron | Vitamin E acetate powder 50% | 022402A013 | BR20042SI | 20 | 20240919* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 500 spectra of 11 reference samples from the substance/substance group *alpha-tocopheryl - acetate dry concentrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.
- 157 826 spectra from a total of 2947 batches from further 495 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 590 spectra of 17 reference samples from the substance/substance group *alpha-tocopheryl - acetate dry concentrate*.
- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | alpha-tocopheryl acetate … | 1705003 | 23424 | 40 |
| Euro OTC | alpha-tocopheryl acetate … | 1810024 | 24309 | 40 |
| Euro OTC | alpha-tocopheryl acetate … | 2106013 | 25780 | 50 |
| Euro OTC | alpha-tocopheryl acetate … | 2111015 | 25889 | 50 |
| Euro OTC | alpha-tocopheryl acetate … | 2207013 | 26279 | 40 |
| Euro OTC | alpha-tocopheryl acetate … | 2309007 | 26929 | 40 |
| Euro OTC | alpha-tocopheryl acetate … | 2408017 | 27395 | 40 |
| Euro OTC | alpha-tocopheryl acetate … | 2412003 | 27503 | 40 |
| Fagron | alpha-tocopheryl acetate … | 16H30-B05-326792 | 22948 | 40 |
| Fagron | alpha-tocopheryl acetate … | 24F28-B01-004723 | 27563 | 40 |
| Fagron | Vitamin E acetate powder 50% | 022403A011 | BR20041 | 40 |
| Fagron | Vitamin E acetate powder 50% | 022402A012 | BR20043 | 40 |
| Euro OTC | alpha-tocopheryl acetate … | 2111015 | 25889SI | 10 |
| Euro OTC | alpha-tocopheryl acetate … | 2207013 | 26279SI | 20 |
| Euro OTC | alpha-tocopheryl acetate … | 2309007 | 26929SI | 20 |
| Fagron | Vitamin E acetate powder 50% | 022403A011 | BR20041SI | 20 |
| Fagron | Vitamin E acetate powder 50% | 022402A012 | BR20043SI | 20 |

- 212 350 spectra from a total of 4275 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 44 spectra from 15 *Apo-Ident* customers from 25 batches from the substance/substance group *alpha-tocopheryl acetate dry concentrate*.

- Among them are spectra of independent samples from 23 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | alpha-tocopheryl acetate … | 1507001-02 | 1 |
| Caelo | alpha-tocopheryl acetate … | 1705003-01 | 1 |
| EuRho | alpha-tocopheryl acetate … | 1810024-01 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1110021-02 | 2 |
| Euro OTC | alpha-tocopheryl acetate … | 1507001-01 | 2 |
| Euro OTC | alpha-tocopheryl acetate … | 160304602 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1603046-02 | 3 |
| Euro OTC | alpha-tocopheryl acetate … | 170500301 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1705003-01 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1705003-02 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1705003-04 | 2 |
| Euro OTC | alpha-tocopheryl acetate … | 1705003-05 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 181002401 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1810024-01 | 4 |
| Euro OTC | alpha-tocopheryl acetate … | 190033-01 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1907033-01 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 190703302 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 1907033-02 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 200502201 | 1 |
| Euro OTC | alpha-tocopheryl acetate … | 2005022-01 | 6 |
| Euro OTC | alpha-tocopheryl acetate … | 2106013-01 | 2 |
| Euro OTC | alpha-tocopheryl acetate … | 2111015-01 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | alpha-tocopheryl acetate … | 2207013-01 | 2 |
| Euro/Sanacorp | alpha-tocopheryl acetate … | 150700101 | 1 |
| Fagron | alpha-tocopheryl acetate … | 13H30-B02-287169 | 1 |
| Fagron | alpha-tocopheryl acetate … | 16H30-B05-326792 | 1 |
| Kehr | alpha-tocopheryl acetate … | 1705003-03 | 2 |
| Sanacorp | alpha-tocopheryl acetate … | 1705003-03 | 1 |

- 256 842 spectra from 1666 *Apo-Ident* customers from a total of 52 129 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *alpha-tocopheryl acetate dry concentrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *alpha-tocopheryl acetate dry concentrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 500 | 0 | 157 826 |
| **Type B** | 0 | 550 | 40 | 212 350 |
| **Type C** | 0 | 43 | 1 | 256 842 |

The substance/substance group *alpha-tocopheryl acetate dry concentrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 93.2203 % (> 92.7119 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.7273 % (> 90.9091 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20907 | 21680 | 7.12 | 115.36 |
| 21609 | 21609 | 0.00 | 116.23 |
| 21680 | 21680 | 0.00 | 119.09 |
| 21842 | 21842 | 0.00 | 117.99 |
| 21959 | 21680 | 10.61 | 131.32 |
| 22543 | 22543 | 0.00 | 123.00 |
| 24841 | 24841 | 0.00 | 143.81 |
| 25277 | 25277 | 0.00 | 126.59 |
| 25599 | 25599 | 0.00 | 135.78 |
| BR20042 | BR20042 | 0.00 | 82.47 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Aluminium chloride hexahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20131-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Aluminium chloride hexahydrate; Aluminii chloridum hexahydricum

### Special notes

When selecting the *Aluminium chloride hexahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Aluminium chloride hexahydrate | 6 | 3 | 155 |

### Second-stage model

For differentiation of the substance/substance group *Aluminium chloride hexahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Aluminium chloride hexahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 100.22 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Aluminium chloride hexahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Aluminium chloride hexahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Aluminium chloride hexahydrate | 22002438 | 26556 | 40 | 20221121* |
| Euro OTC | Aluminium chloride hexahydrate | 1911008-03 | 26049 | 40 | 20210630 |
| Euro OTC | Aluminium chloride hexahydrate | 2207005 | 26203 | 40 | 20220726* |
| Euro OTC | Aluminium chloride hexahydrate | 2207005 | 26203SI | 20 | 20220726* |
| Fagron | Aluminium chloride hexahydrate | 21F07-B18-213240 | 26059 | 40 | 20211105 |
| Fagron | Aluminium chloride hexahydrate | 23F22-B08-232244 | 27019 | 40 | 20230705 |
| Fagron | Aluminium chloride hexahydrate | 23K16-B03-234491 | 27059 | 40 | 20231130 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 260 spectra of 7 reference samples from the substance/substance group *Aluminium chloride hexahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 6 reference samples from the substance/substance group *Aluminium chloride hexahydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Aluminium chloride hexahydrate | 21002588 | 26053 | 40 |
| Fagron | Aluminium chloride hexahydrate | 12I27-N01 | 20903 | 40 |
| Fagron | Aluminium chloride hexahydrate | 23C23-B17-227778 | 26670 | 40 |
| Caelo | Aluminium chloride hexahydrate | 21002588 | 26053SI | 10 |
| Euro OTC | Aluminium chloride hexahydrate | 1911008-03 | 26049SI† | 10 |
| Fagron | Aluminium chloride hexahydrate | 21F07-B18-213240 | 26059SI† | 10 |

- 212 790 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 626 spectra from 297 *Apo-Ident* customers from 164 batches from the substance/substance group *Aluminium chloride hexahydrate*.

- Among them are spectra of independent samples from 155 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Aluminium chloride hexahydrate | 191008-04 | 1 |
| | Aluminium chloride hexahydrate | 191023/1 | 1 |
| | Aluminium chloride hexahydrate | 1911008-03 | 3 |
| | Aluminium chloride hexahydrate | 191100804 | 1 |
| | Aluminium chloride hexahydrate | 1911008-04 | 3 |
| | Aluminium chloride hexahydrate | 21002588002 | 1 |
| | Aluminium chloride hexahydrate | 21002588006 | 1 |
| | Aluminium chloride hexahydrate | 21002588007 | 1 |
| | Aluminium chloride hexahydrate | 220002438001 | 1 |
| | Aluminium chloride hexahydrate | 22002438001 | 12 |
| | Aluminium chloride hexahydrate | 22002438002 | 8 |
| | Aluminium chloride hexahydrate | 22002438003 | 1 |
| | Aluminium chloride hexahydrate | 22002438005 | 3 |
| | Aluminium chloride hexahydrate | 22002438006 | 9 |
| | Aluminium chloride hexahydrate | 22002438008 | 4 |
| | Aluminium chloride hexahydrate | 22002438010 | 11 |
| | Aluminium chloride hexahydrate | 22002438012 | 4 |
| | Aluminium chloride hexahydrate | 22002438013 | 4 |
| | Aluminium chloride hexahydrate | 220700-02 | 1 |
| | Aluminium chloride hexahydrate | 220700501 | 1 |
| | Aluminium chloride hexahydrate | 2207005-01 | 33 |
| | Aluminium chloride hexahydrate | 2207005-02 | 7 |
| | Aluminium chloride hexahydrate | 2207005-03 | 1 |
| | Aluminium chloride hexahydrate | 2297005-03 | 1 |
| | Aluminium chloride hexahydrate | 22G29-B04-222933 | 1 |
| | Aluminium chloride hexahydrate | 22G29-B04 | 1 |
| | Aluminium chloride hexahydrate | 22K14-B01-225235 | 1 |
| | Aluminium chloride hexahydrate | 234326412 | 1 |
| | Aluminium chloride hexahydrate | 23c23-b17-227777 | 1 |
| | Aluminium chloride hexahydrate | 23C23-B17-227777 | 3 |
| | Aluminium chloride hexahydrate | 23C23-B17227778 | 1 |
| | Aluminium chloride hexahydrate | 23C23-B17-227778 | 1 |
| | Aluminium chloride hexahydrate | 23k16-b03-234491 | 2 |
| | Aluminium chloride hexahydrate | 23K16-B03-234491 | 1 |
| | Aluminium chloride hexahydrate | 24B20-B06-001195 | 1 |
| | Aluminium chloride hexahydrate | 24B20-B06-006726 | 1 |
| | Aluminium chloride hexahydrate | 24B2O-B06-006726 | 1 |
| | Aluminium chloride hexahydrate | 24F19-B13-006930 | 4 |
| | Aluminium chloride hexahydrate | 24F19-B13-0069300 | 1 |
| | Aluminium chloride hexahydrate | 24L11-B10-008504 | 1 |
| | Aluminium chloride hexahydrate | 7784-13-6 | 1 |
| | Aluminium chloride hexahydrate | AP240229 | 1 |
| | Aluminium chloride hexahydrate | B06-0011905 | 2 |
| | Aluminium chloride hexahydrate | B08-2322404 | 1 |
| | Aluminium chloride hexahydrate | B13-0069300 | 1 |
| | Aluminium chloride hexahydrate | K140A | 1 |
| | Aluminium chloride hexahydrate | O138A | 1 |
| 5,56 | Aluminium chloride hexahydrate | 22002438010 | 1 |
| AHD | Aluminium chloride hexahydrate | 22002438001 | 1 |
| AHD | Aluminium chloride hexahydrate | 22002438002 | 1 |
| AHD | Aluminium chloride hexahydrate | 22002438012 | 1 |
| AHD | Aluminium chloride hexahydrate | 22K14-B01-225218 | 2 |
| Alliance Healthcare | Aluminium chloride hexahydrate | 13D22-N09 | 1 |
| Alliance | Aluminium chloride hexahydrate | 21F07-B18-213240 | 1 |
| Anzag | Aluminium chloride hexahydrate | 1204026-02 | 1 |
| Caelo | Aluminium chloride hexahydrate | | 2 |
| Caelo | Aluminium chloride hexahydrate | 10251307 | 1 |
| Caelo | Aluminium chloride hexahydrate | 10251314 | 1 |
| Caelo | Aluminium chloride hexahydrate | 11229905 | 1 |
| Caelo | Aluminium chloride hexahydrate | 11229906 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Aluminium chloride hexahydrate | 11229907 | 1 |
| Caelo | Aluminium chloride hexahydrate | 11229914 | 1 |
| Caelo | Aluminium chloride hexahydrate | 11229917 | 2 |
| Caelo | Aluminium chloride hexahydrate | 12021303 | 1 |
| Caelo | Aluminium chloride hexahydrate | 120402601 | 1 |
| Caelo | Aluminium chloride hexahydrate | 1204026-01 | 1 |
| Caelo | Aluminium chloride hexahydrate | 1204026-02 | 2 |
| Caelo | Aluminium chloride hexahydrate | 12047503 | 2 |
| Caelo | Aluminium chloride hexahydrate | 12047508 | 3 |
| Caelo | Aluminium chloride hexahydrate | 12047512 | 1 |
| Caelo | Aluminium chloride hexahydrate | 12047514 | 3 |
| Caelo | Aluminium chloride hexahydrate | 1210014-01 | 1 |
| Caelo | Aluminium chloride hexahydrate | 12114902 | 2 |
| Caelo | Aluminium chloride hexahydrate | 12114904 | 2 |
| Caelo | Aluminium chloride hexahydrate | 12114906 | 4 |
| Caelo | Aluminium chloride hexahydrate | 12114908 | 7 |
| Caelo | Aluminium chloride hexahydrate | 12114910 | 5 |
| Caelo | Aluminium chloride hexahydrate | 12114912 | 4 |
| Caelo | Aluminium chloride hexahydrate | 12114918 | 12 |
| Caelo | Aluminium chloride hexahydrate | 12114919 | 1 |
| Caelo | Aluminium chloride hexahydrate | 12114920 | 10 |
| Caelo | Aluminium chloride hexahydrate | 12114922 | 13 |
| Caelo | Aluminium chloride hexahydrate | 12323702 | 11 |
| Caelo | Aluminium chloride hexahydrate | 12323710 | 8 |
| Caelo | Aluminium chloride hexahydrate | 12323711 | 12 |
| Caelo | Aluminium chloride hexahydrate | 12323717 | 4 |
| Caelo | Aluminium chloride hexahydrate | 12C07-N01 | 2 |
| Caelo | Aluminium chloride hexahydrate | 12i27-N01 | 1 |
| Caelo | Aluminium chloride hexahydrate | 12I27-N01 | 1 |
| Caelo | Aluminium chloride hexahydrate | 12l27-N01 | 2 |
| Caelo | Aluminium chloride hexahydrate | 12l27-NO1 | 1 |
| Caelo | Aluminium chloride hexahydrate | 13/13-B03-287298 | 1 |
| Caelo | Aluminium chloride hexahydrate | 13D22-N09 | 3 |
| Caelo | Aluminium chloride hexahydrate | 13G03-N02 | 2 |
| Caelo | Aluminium chloride hexahydrate | 13L13-B03-287298 | 1 |
| Caelo | Aluminium chloride hexahydrate | 15051302 | 1 |
| Caelo | Aluminium chloride hexahydrate | 15080701 | 1 |
| Caelo | Aluminium chloride hexahydrate | 15080715 | 1 |
| Caelo | Aluminium chloride hexahydrate | 18061308 | 1 |
| Caelo | Aluminium chloride hexahydrate | 18261314 | 1 |
| Caelo | Aluminium chloride hexahydrate | 19041302 | 1 |
| Caelo | Aluminium chloride hexahydrate | 23111203 | 1 |
| Caelo | Aluminium chloride hexahydrate | 28121301 | 1 |
| Caelo | Aluminium chloride hexahydrate | 3091205 | 1 |
| Caelo | Aluminium chloride hexahydrate | 3113E-01095 | 1 |
| Caelo | Aluminium chloride hexahydrate | 5081301 | 1 |
| Caelo | Aluminium chloride hexahydrate | 51/AD1 | 1 |
| Caelo | Aluminium chloride hexahydrate | 8031301 | 1 |
| Caelo | Aluminium chloride hexahydrate | 9071303 | 1 |
| Caelo | Aluminium chloride hexahydrate | C181A | 1 |
| Caesar & Loretz GmbH... | Aluminium chloride hexahydrate | 12047508 | 1 |
| Caesar & Loretz GmbH... | Aluminium chloride hexahydrate | 12114906 | 1 |
| Caesar & Loretz GmbH... | Aluminium chloride hexahydrate | 12114918 | 4 |
| Caesar & Loretz GmbH... | Aluminium chloride hexahydrate | 12323702 | 1 |
| Caesar & Loretz GmbH... | Aluminium chloride hexahydrate | 12323711 | 2 |
| Caesar & Loretz GmbH | Aluminium chloride hexahydrate | 12114906 | 1 |
| Caesar & Loretz GmbH | Aluminium chloride hexahydrate | 12114918 | 1 |
| Caesar & Loretz GmbH | Aluminium chloride hexahydrate | 12323702 | 1 |
| Caesar/Lorenz | Aluminium chloride hexahydrate | 12114918 | 1 |
| Eurho / Sanacorp | Aluminium chloride hexahydrate | 12I27-N01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho Pharm | Aluminium chloride hexahydrate | 1109025-02 | 1 |
| EuRho | Aluminium chloride hexahydrate | 1106017-01 | 1 |
| EuRho | Aluminium chloride hexahydrate | 1210014-01 | 3 |
| EuRho | Aluminium chloride hexahydrate | 2512I01095 | 1 |
| EuRho | Aluminium chloride hexahydrate | d024a | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1103007-01 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1109025-01 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1109025-02 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 120402601 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1204026-01 | 18 |
| Euro OTC | Aluminium chloride hexahydrate | 120402602 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1204026-02 | 13 |
| Euro OTC | Aluminium chloride hexahydrate | 12100014-02 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1210012-01 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 121001401 | 2 |
| Euro OTC | Aluminium chloride hexahydrate | 1210014-01 | 20 |
| Euro OTC | Aluminium chloride hexahydrate | 121001402 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1210014-02 | 26 |
| Euro OTC | Aluminium chloride hexahydrate | 1210014-02-336331909 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1213M-01095 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1307011 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1307011-01 | 10 |
| Euro OTC | Aluminium chloride hexahydrate | 1307011-02 | 2 |
| Euro OTC | Aluminium chloride hexahydrate | 1406021-01 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 1507002-01 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 2111Q-01095 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 2207005-01 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | 2207005-03 | 1 |
| Euro OTC | Aluminium chloride hexahydrate | co31a | 1 |
| EUro/AHD | Aluminium chloride hexahydrate | 121001401 | 1 |
| EUro/AHD | Aluminium chloride hexahydrate | 1210014-01 | 1 |
| Euroo/Phoenix | Aluminium chloride hexahydrate | 120014-02 | 1 |
| Fagron | Aluminium chloride hexahydrate | | 1 |
| Fagron | Aluminium chloride hexahydrate | 105282-0001 | 1 |
| Fagron | Aluminium chloride hexahydrate | 11/23-N06 | 1 |
| Fagron | Aluminium chloride hexahydrate | 11/23-N06B206A | 1 |
| Fagron | Aluminium chloride hexahydrate | 11G05-N02 | 1 |
| Fagron | Aluminium chloride hexahydrate | 11G05-No2 | 1 |
| Fagron | Aluminium chloride hexahydrate | 11l23-N06 | 3 |
| Fagron | Aluminium chloride hexahydrate | 12/11-No3 | 1 |
| Fagron | Aluminium chloride hexahydrate | 12/27/N01 | 1 |
| Fagron | Aluminium chloride hexahydrate | 12/27-n01 | 1 |
| Fagron | Aluminium chloride hexahydrate | 12/27-N01 | 6 |
| Fagron | Aluminium chloride hexahydrate | 12047512 | 1 |
| Fagron | Aluminium chloride hexahydrate | 1207211095 | 1 |
| Fagron | Aluminium chloride hexahydrate | 12082013D | 1 |
| Fagron | Aluminium chloride hexahydrate | 12323702 | 2 |
| Fagron | Aluminium chloride hexahydrate | 12323711 | 1 |
| Fagron | Aluminium chloride hexahydrate | 12C07-N01 | 4 |
| Fagron | Aluminium chloride hexahydrate | 12G05-N10 | 21 |
| Fagron | Aluminium chloride hexahydrate | 12i27-N01 | 1 |
| Fagron | Aluminium chloride hexahydrate | 12I27-N01 | 9 |
| Fagron | Aluminium chloride hexahydrate | 12L11-N03 | 2 |
| Fagron | Aluminium chloride hexahydrate | 12l27-N01 | 2 |
| Fagron | Aluminium chloride hexahydrate | 13126-N13 | 1 |
| Fagron | Aluminium chloride hexahydrate | 13D22N09 | 2 |
| Fagron | Aluminium chloride hexahydrate | 13D22-N09 | 19 |
| Fagron | Aluminium chloride hexahydrate | 13d22no9 | 1 |
| Fagron | Aluminium chloride hexahydrate | 13G03-N02 | 19 |
| Fagron | Aluminium chloride hexahydrate | 13I26-N13 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Aluminium chloride hexahydrate | 13J31-B06-287615 | 1 |
| Fagron | Aluminium chloride hexahydrate | 17F26-B01-340253 | 1 |
| Fagron | Aluminium chloride hexahydrate | 1910211095 | 1 |
| Fagron | Aluminium chloride hexahydrate | 20122013E | 1 |
| Fagron | Aluminium chloride hexahydrate | 2013U-01095 | 1 |
| Fagron | Aluminium chloride hexahydrate | 2913U1095 | 1 |
| Fagron | Aluminium chloride hexahydrate | 5213A1095 | 1 |
| Fagron | Aluminium chloride hexahydrate | 8547287 | 1 |
| Fagron | Aluminium chloride hexahydrate | C012A | 1 |
| Fagron | Aluminium chloride hexahydrate | C145A | 1 |
| Fagron | Aluminium chloride hexahydrate | C181A | 1 |
| Fargon | Aluminium chloride hexahydrate | 11/23-N06 | 1 |
| Faron | Aluminium chloride hexahydrate | 13I13-B03-287298 | 1 |
| Fiebig | Aluminium chloride hexahydrate | 2200248013 | 2 |
| Fragon | Aluminium chloride hexahydrate | 13D22-N09 | 1 |
| Gehe | Aluminium chloride hexahydrate | 11229917 | 1 |
| Gehe | Aluminium chloride hexahydrate | 120402601 | 1 |
| Gehe | Aluminium chloride hexahydrate | 12047512 | 1 |
| Gehe | Aluminium chloride hexahydrate | 12114902 | 1 |
| Gehe | Aluminium chloride hexahydrate | 12114908 | 1 |
| Gehe | Aluminium chloride hexahydrate | 12114922 | 1 |
| Gehe | Aluminium chloride hexahydrate | 12323711 | 2 |
| Gehe | Aluminium chloride hexahydrate | 130701102 | 1 |
| Gehe | Aluminium chloride hexahydrate | 1911008-04 | 1 |
| Gehe | Aluminium chloride hexahydrate | 21002588009 | 1 |
| Gehe | Aluminium chloride hexahydrate | 22002438001 | 1 |
| Gehe | Aluminium chloride hexahydrate | 22002438005 | 1 |
| Gehe | Aluminium chloride hexahydrate | 2202438005 | 1 |
| Gehe | Aluminium chloride hexahydrate | 2207005-01 | 1 |
| Gehe | Aluminium chloride hexahydrate | 23C23-B17-227777 | 1 |
| Honeywell | Aluminium chloride hexahydrate | 1210014-02 | 1 |
| Ichthyol-Gesellschaf... | Aluminium chloride hexahydrate | 12114918 | 1 |
| Infectopharm/Phönix | Aluminium chloride hexahydrate | 12G05-N10 | 2 |
| Krömpke | Aluminium chloride hexahydrate | 1204026-01 | 1 |
| Noweda | Aluminium chloride hexahydrate | 1109025-02 | 1 |
| Noweda | Aluminium chloride hexahydrate | 12114910 | 2 |
| Noweda | Aluminium chloride hexahydrate | 191008-04 | 1 |
| Noweda | Aluminium chloride hexahydrate | 21K26-B04-216815 | 1 |
| Noweda | Aluminium chloride hexahydrate | 22002438001 | 2 |
| NOWEDA | Aluminium chloride hexahydrate | 22002438001 | 1 |
| Noweda | Aluminium chloride hexahydrate | 22002438006 | 1 |
| NOWEDA | Aluminium chloride hexahydrate | 22002438006 | 1 |
| Noweda | Aluminium chloride hexahydrate | 2207005-01 | 6 |
| Noweda | Aluminium chloride hexahydrate | 22G29-B04-220831 | 1 |
| Noweda | Aluminium chloride hexahydrate | 22K14-B01-225219 | 1 |
| Noweda | Aluminium chloride hexahydrate | 23C23-B17-227777 | 1 |
| Noweda | Aluminium chloride hexahydrate | 23C23-B17-227778 | 2 |
| Noweda | Aluminium chloride hexahydrate | 23K16-B03-234491 | 1 |
| Phoenix | Aluminium chloride hexahydrate | 1210014-01 | 1 |
| Phoenix | Aluminium chloride hexahydrate | 13D22-N09 | 1 |
| Phoenix | Aluminium chloride hexahydrate | 2207005-01 | 1 |
| Phönix Gotha | Aluminium chloride hexahydrate | 1210014-02 | 1 |
| Phönix | Aluminium chloride hexahydrate | 12/27-N01 | 1 |
| Phönix | Aluminium chloride hexahydrate | 1204026-02 | 1 |
| Phönix | Aluminium chloride hexahydrate | 1210014-02 | 1 |
| Phönix | Aluminium chloride hexahydrate | 12L11-N03 | 1 |
| Phönix | Aluminium chloride hexahydrate | 22002438001 | 1 |
| Phönix | Aluminium chloride hexahydrate | 22002438010 | 3 |
| Phönix | Aluminium chloride hexahydrate | 2207005-01 | 1 |
| Phönix | Aluminium chloride hexahydrate | 2207005-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Aluminium chloride hexahydrate | 1210014-02 | 1 |
| Sanacorp | Aluminium chloride hexahydrate | 12114920 | 1 |
| Sanacorp | Aluminium chloride hexahydrate | 12323717 | 1 |
| Sanacorp | Aluminium chloride hexahydrate | 12C07-N01 | 1 |
| Sanacorp | Aluminium chloride hexahydrate | 22002438001 | 1 |
| Sanacorp | Aluminium chloride hexahydrate | 22002438006 | 2 |
| Sanacorp | Aluminium chloride hexahydrate | 22002438010 | 1 |
| Sanacorp | Aluminium chloride hexahydrate | 2207005-01 | 2 |
| Sanacorp | Aluminium chloride hexahydrate | 22G29-B04-220832 | 1 |
| Sanacorp | Aluminium chloride hexahydrate | 24B20-B06-001195 | 1 |
| vdL | Aluminium chloride hexahydrate | 2207005-01 | 1 |

- 256 260 spectra from 1666 *Apo-Ident* customers from a total of 51 991 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Aluminium chloride hexahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Aluminium chloride hexahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 622 | 4 | 256 260 |

The substance/substance group *Aluminium chloride hexahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.3610 % (> 98.8818 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26049 | 26556 | 14.47 | 175.30 |
| 26059 | 26556 | 11.99 | 182.76 |
| 26203 | 26203 | 0.00 | 175.65 |
| 26556 | 26556 | 0.00 | 184.36 |
| 27019 | 26203 | 7.57 | 180.05 |
| 27059 | 26203 | 11.18 | 184.96 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ambroxol hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20742-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ambroxol hydrochloride; Ambroxoli hydrochloridum

### Special notes

When selecting the *Ambroxol hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ambroxol hydrochloride | 10 | 18 | 198 |

### Second-stage model

For differentiation of the substance/substance group *Ambroxol hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ambroxol hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 63.98 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ambroxol hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ambroxol hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ambroxol hydrochloride | 161996 | 22636 | 40 | 20160810* |
| Caelo | Ambroxol hydrochloride | 171582 | 23344 | 40 | 20170607* |
| Euro OTC | Ambroxol hydrochloride | 11110008-01 | 20742 | 40 | 1401146 |
| Euro OTC | Ambroxol hydrochloride | 1311032-01 | 21244 | 40 | 20131219 |
| Euro OTC | Ambroxol hydrochloride | 1509032 | 21942 | 60 | 20151027* |
| Euro OTC | Ambroxol hydrochloride | 1601008 | 22298 | 60 | 20160119* |
| Euro OTC | Ambroxol hydrochloride | 1602015 | 22347 | 60 | 20160217* |
| Euro OTC | Ambroxol hydrochloride | 1604035 | 22550 | 40 | 20160428* |
| Fagron | Ambroxol hydrochloride | 13I24-N02 | 21230 | 40 | 20131017 |
| Fagron | Ambroxol hydrochloride | 19E01-B02-361735 | 24821 | 40 | 20190606 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 460 spectra of 10 reference samples from the substance/substance group *Ambroxol hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 866 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 760 spectra of 21 reference samples from the substance/substance group *Ambroxol hydrochloride*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ambroxol hydrochloride | 172860 | 23801 | 40 |
| Caelo | Ambroxol hydrochloride | 190618 | 24524 | 40 |
| Caelo | Ambroxol hydrochloride | 22000044 | 26000 | 40 |
| Caelo | Ambroxol hydrochloride | 23000573 | 26842 | 40 |
| Caelo | Ambroxol hydrochloride | 23003608 | 27246 | 40 |
| Caelo | Ambroxol hydrochloride | 24001656 | 27433 | 40 |
| Euro OTC | Ambroxol hydrochloride | 1609002 | 22800 | 40 |
| Euro OTC | Ambroxol hydrochloride | 1702004 | 23155 | 40 |
| Euro OTC | Ambroxol hydrochloride | 1711021 | 23894 | 40 |
| Euro OTC | Ambroxol hydrochloride | 1806009 | 24155 | 40 |
| Euro OTC | Ambroxol hydrochloride | 1811039 | 24423 | 40 |
| Euro OTC | Ambroxol hydrochloride | 1904001 | 24623 | 40 |
| Euro OTC | Ambroxol hydrochloride | 1911002 | 24969 | 40 |
| Euro OTC | Ambroxol hydrochloride | 2011004 | 25463 | 40 |
| Euro OTC | Ambroxol hydrochloride | 2201029 | 25943 | 40 |
| Euro OTC | Ambroxol hydrochloride | 2210020 | 26440 | 40 |
| Euro OTC | Ambroxol hydrochloride | 2402033 | 27289 | 40 |
| Fagron | Ambroxol hydrochloride | 23I29-B08-002374 | 27414 | 40 |
| Caelo | Ambroxol hydrochloride | 22000044 | 26000SI | 10 |
| Caelo | Ambroxol hydrochloride | 23000573 | 26842SI | 20 |
| Euro OTC | Ambroxol hydrochloride | 2201029 | 25943SI | 10 |

- 212 180 spectra from a total of 4269 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1743 spectra from 617 *Apo-Ident* customers from 199 batches from the substance/substance group *Ambroxol hydrochloride*.
- Among them are spectra of independent samples from 198 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ambroxol hydrochloride | 1702004-01 | 2 |
| | Ambroxol hydrochloride | 1904001-01 | 2 |
| | Ambroxol hydrochloride | 20003999003 | 1 |
| | Ambroxol hydrochloride | 211020-01 | 1 |
| | Ambroxol hydrochloride | 21I29-B02-215601 | 1 |
| | Ambroxol hydrochloride | 22000044002 | 5 |
| | Ambroxol hydrochloride | 22000044003 | 1 |
| | Ambroxol hydrochloride | 22000044011 | 1 |
| | Ambroxol hydrochloride | 22000044012 | 1 |
| | Ambroxol hydrochloride | 22000044016 | 8 |
| | Ambroxol hydrochloride | 22000044021 | 21 |
| | Ambroxol hydrochloride | 22000044022 | 3 |
| | Ambroxol hydrochloride | 2201029-03 | 4 |
| | Ambroxol hydrochloride | 22100 | 1 |
| | Ambroxol hydrochloride | 2210020-01 | 22 |
| | Ambroxol hydrochloride | 22100200179/23P | 1 |
| | Ambroxol hydrochloride | 2210020-02 | 10 |
| | Ambroxol hydrochloride | 2210020-03 | 5 |
| | Ambroxol hydrochloride | 22J31-B01-224227 | 1 |
| | Ambroxol hydrochloride | 23000573001 | 4 |
| | Ambroxol hydrochloride | 23000573002 | 1 |
| | Ambroxol hydrochloride | 23000573003 | 25 |
| | Ambroxol hydrochloride | 2300057300303/24P | 1 |
| | Ambroxol hydrochloride | 2300057300330/24P | 1 |
| | Ambroxol hydrochloride | 23003608002 | 3 |
| | Ambroxol hydrochloride | 23003608003 | 21 |
| | Ambroxol hydrochloride | 23003608004 | 4 |
| | Ambroxol hydrochloride | 23003608005 | 5 |
| | Ambroxol hydrochloride | 2300360800521/25P | 1 |
| | Ambroxol hydrochloride | 24001656003 | 7 |
| | Ambroxol hydrochloride | 2402033 | 2 |
| | Ambroxol hydrochloride | 240203301 | 2 |
| | Ambroxol hydrochloride | 2402033-01 | 9 |
| | Ambroxol hydrochloride | 2402033-02 | 6 |
| | Ambroxol hydrochloride | ame90010124 | 1 |
| | Ambroxol hydrochloride | AXL0747202207 | 1 |
| | Ambroxol hydrochloride | CEPABX001L21 | 1 |
| AEP | Ambroxol hydrochloride | 24001656003 | 1 |
| AHD/EuRho | Ambroxol hydrochloride | 2011004-01 | 1 |
| AHD | Ambroxol hydrochloride | 2201029-03 | 2 |
| AHD | Ambroxol hydrochloride | 2210020-01 | 2 |
| AHD | Ambroxol hydrochloride | 2210020-03 | 1 |
| AHD | Ambroxol hydrochloride | 23003608001 | 3 |
| AHD | Ambroxol hydrochloride | 233608001 | 1 |
| Alliance Healthcare | Ambroxol hydrochloride | 1911002-02 | 1 |
| Alliance Healthcare | Ambroxol hydrochloride | 20003999017 | 1 |
| Alliance Healthcare | Ambroxol hydrochloride | 23003608005 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| alliance | Ambroxol hydrochloride | 2210020-01 | 1 |
| Anuh Phama Limited | Ambroxol hydrochloride | 2201029-03 | 1 |
| Anuh Pharma ltd | Ambroxol hydrochloride | 2201029-01 | 1 |
| Anzag | Ambroxol hydrochloride | 15G15-B01-316109 | 1 |
| Anzag | Ambroxol hydrochloride | 22000044002 | 1 |
| Anzag | Ambroxol hydrochloride | 2210020-01 | 4 |
| Anzag | Ambroxol hydrochloride | 230515(2210020-01) | 1 |
| Anzag | Ambroxol hydrochloride | 231113(22000044021) | 1 |
| APO IDENT | Ambroxol hydrochloride | 1711021-02 | 2 |
| APO IDENT | Ambroxol hydrochloride | 1806009-01 | 2 |
| apo-ident | Ambroxol hydrochloride | 1806009-01 | 1 |
| Audor Pharma | Ambroxol hydrochloride | 1911002-02 | 2 |
| Caedo | Ambroxol hydrochloride | 192983012 | 1 |
| Caelo | Ambroxol hydrochloride | 1602015-02 | 1 |
| Caelo | Ambroxol hydrochloride | 1609002-01 | 3 |
| Caelo | Ambroxol hydrochloride | 1609002-02 | 2 |
| Caelo | Ambroxol hydrochloride | 16199602 | 1 |
| Caelo | Ambroxol hydrochloride | 16199603 | 2 |
| Caelo | Ambroxol hydrochloride | 16309201 | 2 |
| Caelo | Ambroxol hydrochloride | 17002902 | 2 |
| Caelo | Ambroxol hydrochloride | 17002904 | 1 |
| Caelo | Ambroxol hydrochloride | 17002905 | 1 |
| Caelo | Ambroxol hydrochloride | 1702004-02 | 2 |
| Caelo | Ambroxol hydrochloride | 170522AH/16309201 | 1 |
| Caelo | Ambroxol hydrochloride | 171102101 | 1 |
| Caelo | Ambroxol hydrochloride | 1711021-02 | 4 |
| Caelo | Ambroxol hydrochloride | 17158201 | 3 |
| Caelo | Ambroxol hydrochloride | 17158202 | 6 |
| Caelo | Ambroxol hydrochloride | 17158203 | 2 |
| Caelo | Ambroxol hydrochloride | 17158204 | 2 |
| Caelo | Ambroxol hydrochloride | 17286001 | 8 |
| Caelo | Ambroxol hydrochloride | 1801306 | 1 |
| Caelo | Ambroxol hydrochloride | 18013201 | 11 |
| Caelo | Ambroxol hydrochloride | 18013202 | 2 |
| Caelo | Ambroxol hydrochloride | 18013202/P-23041821 | 1 |
| Caelo | Ambroxol hydrochloride | 18013205 | 11 |
| Caelo | Ambroxol hydrochloride | 18013206 | 1 |
| Caelo | Ambroxol hydrochloride | 18013208 | 4 |
| Caelo | Ambroxol hydrochloride | 18013209 | 1 |
| Caelo | Ambroxol hydrochloride | 18013211 | 24 |
| Caelo | Ambroxol hydrochloride | 18013214 | 1 |
| Caelo | Ambroxol hydrochloride | 18013216 | 1 |
| Caelo | Ambroxol hydrochloride | 18013219 | 7 |
| Caelo | Ambroxol hydrochloride | 18013221 | 1 |
| Caelo | Ambroxol hydrochloride | 1806009-01 | 1 |
| Caelo | Ambroxol hydrochloride | 1811039-01 | 2 |
| Caelo | Ambroxol hydrochloride | 1904001-01 | 5 |
| Caelo | Ambroxol hydrochloride | 19061803 | 14 |
| Caelo | Ambroxol hydrochloride | 19061804 | 27 |
| Caelo | Ambroxol hydrochloride | 19061805 | 1 |
| Caelo | Ambroxol hydrochloride | 19061809 | 18 |
| Caelo | Ambroxol hydrochloride | 19061813 | 4 |
| Caelo | Ambroxol hydrochloride | 19061815 | 30 |
| Caelo | Ambroxol hydrochloride | 1911002-01 | 4 |
| Caelo | Ambroxol hydrochloride | 1911002-02 | 1 |
| Caelo | Ambroxol hydrochloride | 192983001 | 25 |
| Caelo | Ambroxol hydrochloride | 192983002 | 4 |
| Caelo | Ambroxol hydrochloride | 192983003 | 3 |
| Caelo | Ambroxol hydrochloride | 192983006 | 21 |
| Caelo | Ambroxol hydrochloride | 192983008 | 25 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ambroxol hydrochloride | 192983011 | 3 |
| Caelo | Ambroxol hydrochloride | 192983012 | 17 |
| Caelo | Ambroxol hydrochloride | 20003996011 | 1 |
| Caelo | Ambroxol hydrochloride | 20003998002 | 4 |
| Caelo | Ambroxol hydrochloride | 20003999002 | 31 |
| Caelo | Ambroxol hydrochloride | 20003999003 | 25 |
| Caelo | Ambroxol hydrochloride | 20003999008 | 3 |
| Caelo | Ambroxol hydrochloride | 20003999011 | 15 |
| Caelo | Ambroxol hydrochloride | 20003999014 | 2 |
| Caelo | Ambroxol hydrochloride | 20003999015 | 3 |
| Caelo | Ambroxol hydrochloride | 20003999017 | 17 |
| Caelo | Ambroxol hydrochloride | 2000399915 | 1 |
| Caelo | Ambroxol hydrochloride | 200039999003 | 1 |
| Caelo | Ambroxol hydrochloride | 2011004-01 | 1 |
| Caelo | Ambroxol hydrochloride | 2021904 | 1 |
| Caelo | Ambroxol hydrochloride | 2100086001 | 1 |
| Caelo | Ambroxol hydrochloride | 21001184001 | 1 |
| Caelo | Ambroxol hydrochloride | 210518/1 | 1 |
| Caelo | Ambroxol hydrochloride | 22000044001 | 2 |
| Caelo | Ambroxol hydrochloride | 22000044002 | 16 |
| Caelo | Ambroxol hydrochloride | 22000044003 | 15 |
| Caelo | Ambroxol hydrochloride | 220000440116 | 1 |
| Caelo | Ambroxol hydrochloride | 22000044012 | 1 |
| Caelo | Ambroxol hydrochloride | 22000044016 | 8 |
| Caelo | Ambroxol hydrochloride | 2200044003 | 2 |
| Caelo | Ambroxol hydrochloride | 2200044016 | 1 |
| Caelo | Ambroxol hydrochloride | 2201029-01 | 1 |
| Caelo | Ambroxol hydrochloride | 2201029-03 | 2 |
| Caelo | Ambroxol hydrochloride | 23000573003 | 2 |
| Caelo | Ambroxol hydrochloride | 26011902 | 1 |
| Caelo | Ambroxol hydrochloride | 27101707 | 1 |
| Caelo | Ambroxol hydrochloride | AXL0512201612 | 1 |
| Caeolo/Gehe | Ambroxol hydrochloride | 1702004-02 | 2 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 22000044003 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 22000044016 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 20003999011 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 192983008 | 1 |
| Caesar & Loretz GmbH/AHD | Ambroxol hydrochloride | 20003999002 | 3 |
| Caesar & Loretz GmbH/G | Ambroxol hydrochloride | 19061809 | 3 |
| Caesar & Loretz GmbH/G | Ambroxol hydrochloride | 20003999002 | 1 |
| Caesar & Loretz GmbH/gehe | Ambroxol hydrochloride | 19061804 | 1 |
| Caesar & Loretz GmbH/Gehe | Ambroxol hydrochloride | 19061815 | 1 |
| Caesar & Loretz GmbH/Gehe | Ambroxol hydrochloride | 192983008 | 14 |
| Caesar & Loretz GmbH/Gehe | Ambroxol hydrochloride | 192983012 | 2 |
| Caesar & Loretz GmbH/Gehe | Ambroxol hydrochloride | 20003999002 | 5 |
| Caesar & Loretz GmbH/Gehe | Ambroxol hydrochloride | 20003999011 | 1 |
| Caesar & Loretz GmbH/Gehe | Ambroxol hydrochloride | 22000044002 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 20003999017 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 22000044002 | 1 |
| Caesar & Loretz GmbH/Kehr | Ambroxol hydrochloride | 19061804 | 1 |
| Caesar & Loretz GmbH/Kehr | Ambroxol hydrochloride | 22000044003 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 20003999002 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 20003999017 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 20003999017 | 2 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 22000044002 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 19061802 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 192983008 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 20003999002 | 2 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 22000044003 | 1 |
| Caesar & Loretz GmbH... | Ambroxol hydrochloride | 20003999015 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 17286001 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 18013205 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 18013211 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 18013219 | 3 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 19061803 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 19061804 | 6 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 19061805 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 19061809 | 3 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 19061815 | 10 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983001 | 7 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983002 | 2 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983003 | 4 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983006 | 6 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983008 | 8 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983010 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983011 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 192983012 | 8 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 20003998002 | 5 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 20003999002 | 16 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 20003999003 | 10 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 20003999008 | 3 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 20003999011 | 9 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 20003999014 | 3 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 20003999017 | 11 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 21001184001 | 4 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 22000044002 | 6 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 22000044003 | 18 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 22000044012 | 1 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 22000044016 | 4 |
| Caesar & Loretz GmbH | Ambroxol hydrochloride | 22000044021 | 1 |
| Caesar & Loretz | Ambroxol hydrochloride | 19061809 | 1 |
| Cealo/Gehe | Ambroxol hydrochloride | 171158204 | 1 |
| Cealo/Sanacorp | Ambroxol hydrochloride | 22000044003 | 1 |
| Chem & Pharma | Ambroxol hydrochloride | AXL0361201310 | 1 |
| Ebert & Jacobi | Ambroxol hydrochloride | 1806009-01 | 1 |
| Ensbona/Eimermacher | Ambroxol hydrochloride | 1711021-02 | 1 |
| E-plus | Ambroxol hydrochloride | 1711021-02 | 1 |
| Eu Rho | Ambroxol hydrochloride | 1911002-02 | 1 |
| Eurho / GEHE | Ambroxol hydrochloride | 2011004-01 | 1 |
| EuRho- Phoenix | Ambroxol hydrochloride | 2201029-02 | 1 |
| EuRho/ Anzag | Ambroxol hydrochloride | 220504(2201029-01) | 1 |
| EuRho/ NOWEDA | Ambroxol hydrochloride | 1806009-01 | 1 |
| EuRho/ NOWEDA | Ambroxol hydrochloride | 1811039-01 | 1 |
| Eurho/AHD | Ambroxol hydrochloride | 2011004-01 | 1 |
| Eurho/Anzag | Ambroxol hydrochloride | 1811039-01 | 1 |
| EuRho/Fiebig | Ambroxol hydrochloride | 1811039-01 | 1 |
| EuRho/Fiebig | Ambroxol hydrochloride | 20212004-01 | 1 |
| EuRho/Gehe | Ambroxol hydrochloride | 1911002-02 | 1 |
| EuRho/Gehe | Ambroxol hydrochloride | 2011004-02 | 1 |
| EuRho/Jenne | Ambroxol hydrochloride | 3(190400101) | 1 |
| Eurho/Noweda | Ambroxol hydrochloride | 1911002-02 | 1 |
| EuRho/Noweda | Ambroxol hydrochloride | 2201029-03 | 1 |
| EuRho/ph | Ambroxol hydrochloride | 1911002-01 | 1 |
| Eurho/Phoenix | Ambroxol hydrochloride | 190400101 | 1 |
| EuRho | Ambroxol hydrochloride | 1602015-02 | 2 |
| EuRho | Ambroxol hydrochloride | 1711021-02 | 1 |
| EuRho | Ambroxol hydrochloride | 1811039-01 | 1 |
| EuRho | Ambroxol hydrochloride | 1911002-01 | 3 |
| euRho | Ambroxol hydrochloride | 1911002-02 | 1 |
| EuRho | Ambroxol hydrochloride | 1911002-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Ambroxol hydrochloride | 2011001-01 | 1 |
| EuRho | Ambroxol hydrochloride | 2011004-01 | 7 |
| EuRho | Ambroxol hydrochloride | 2011004-03 | 1 |
| EuRho | Ambroxol hydrochloride | 2201029-01 | 2 |
| EuRho | Ambroxol hydrochloride | 2201029-03 | 2 |
| Euro OCT/ | Ambroxol hydrochloride | 1904001-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1(1806009-01) | 1 |
| Euro OTC | Ambroxol hydrochloride | 111039-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1311032-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1509032-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1601015-2 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1602015-02 | 2 |
| Euro OTC | Ambroxol hydrochloride | 160215-02 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1604032-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1604035-01 | 3 |
| Euro OTC | Ambroxol hydrochloride | 1604035-02 | 13 |
| Euro OTC | Ambroxol hydrochloride | 1609002-01 | 15 |
| Euro OTC | Ambroxol hydrochloride | 1609002-02 | 21 |
| Euro OTC | Ambroxol hydrochloride | 170192 | 1 |
| Euro OTC | Ambroxol hydrochloride | 170200401 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1702004-01 | 12 |
| Euro OTC | Ambroxol hydrochloride | 170200402 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1702004-02 | 13 |
| Euro OTC | Ambroxol hydrochloride | 171102-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 171102101 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1711021-01 | 21 |
| Euro OTC | Ambroxol hydrochloride | 1711021-01/P-030518 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1711021-02 | 29 |
| Euro OTC | Ambroxol hydrochloride | 1806009 | 2 |
| Euro OTC | Ambroxol hydrochloride | 1806009-01 | 34 |
| Euro OTC | Ambroxol hydrochloride | 1806009-1 | 1 |
| Euro OTC | Ambroxol hydrochloride | 181103901 | 3 |
| Euro OTC | Ambroxol hydrochloride | 1811039-01 | 45 |
| Euro OTC | Ambroxol hydrochloride | 190400-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1904001 | 2 |
| Euro OTC | Ambroxol hydrochloride | 1904001-0 | 1 |
| Euro OTC | Ambroxol hydrochloride | 190400101 | 2 |
| Euro OTC | Ambroxol hydrochloride | 1904001-01 | 77 |
| Euro OTC | Ambroxol hydrochloride | 19040101 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1904401 | 1 |
| Euro OTC | Ambroxol hydrochloride | 191002-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 191100-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 19110002-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1911001-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1911001-02 | 1 |
| Euro OTC | Ambroxol hydrochloride | 191100201 | 2 |
| Euro OTC | Ambroxol hydrochloride | 1911002-01 | 44 |
| Euro OTC | Ambroxol hydrochloride | 191100202 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1911002-02 | 41 |
| Euro OTC | Ambroxol hydrochloride | 1911002-42 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1911008-04 | 1 |
| Euro OTC | Ambroxol hydrochloride | 191102-02 | 2 |
| Euro OTC | Ambroxol hydrochloride | 1911022-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 1L2001 | 1 |
| Euro OTC | Ambroxol hydrochloride | 2(1904001-01) | 1 |
| Euro OTC | Ambroxol hydrochloride | 201100401 | 2 |
| Euro OTC | Ambroxol hydrochloride | 2011004-01 | 69 |
| Euro OTC | Ambroxol hydrochloride | 2011004-02 | 13 |
| Euro OTC | Ambroxol hydrochloride | 2011004-03 | 11 |
| Euro OTC | Ambroxol hydrochloride | 2011004-04 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Ambroxol hydrochloride | 201104-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | 201104-03 | 1 |
| Euro OTC | Ambroxol hydrochloride | 2201029-002 | 1 |
| Euro OTC | Ambroxol hydrochloride | 220102901 | 1 |
| Euro OTC | Ambroxol hydrochloride | 2201029-01 | 55 |
| Euro OTC | Ambroxol hydrochloride | 2201029-02 | 9 |
| Euro OTC | Ambroxol hydrochloride | 2201029-03 | 6 |
| Euro OTC | Ambroxol hydrochloride | 220109-02 | 1 |
| Euro OTC | Ambroxol hydrochloride | 220715(2201029-01) | 1 |
| Euro OTC | Ambroxol hydrochloride | 221002001 | 1 |
| Euro OTC | Ambroxol hydrochloride | 2210020-01 | 7 |
| Euro OTC | Ambroxol hydrochloride | 2210020-02 | 2 |
| Euro OTC | Ambroxol hydrochloride | 2402033-01 | 2 |
| Euro OTC | Ambroxol hydrochloride | 27061702 | 1 |
| Euro OTC | Ambroxol hydrochloride | 3111805 | 1 |
| Euro OTC | Ambroxol hydrochloride | 811030-01 | 1 |
| Euro OTC | Ambroxol hydrochloride | ax10492201608 | 1 |
| Euro OTC | Ambroxol hydrochloride | AXL056201709 | 1 |
| Euro OTC | Ambroxol hydrochloride | AXL0592201803 | 2 |
| Euro OTC | Ambroxol hydrochloride | AXL0601201807 | 1 |
| Euro OTC | Ambroxol hydrochloride | CEPABIX001L21 | 1 |
| Euro OTC | Ambroxol hydrochloride | CEPABX001L21 | 1 |
| Euro/Noweda | Ambroxol hydrochloride | 1509032-01 | 1 |
| Euro/Noweda | Ambroxol hydrochloride | 181103901 | 1 |
| Euro/Phönix | Ambroxol hydrochloride | 1904001-01 | 1 |
| Euro/Phönix | Ambroxol hydrochloride | 2201029-01 | 2 |
| Euroo/Gehe | Ambroxol hydrochloride | 1702004-02 | 1 |
| EuroTOC | Ambroxol hydrochloride | 1602015-01 | 1 |
| EurRho | Ambroxol hydrochloride | 2011004-01 | 1 |
| Fagron | Ambroxol hydrochloride | 12K12-N02 | 1 |
| Fagron | Ambroxol hydrochloride | 1602015-01 | 1 |
| Fagron | Ambroxol hydrochloride | 16G12-B06-326184 | 1 |
| Fagron | Ambroxol hydrochloride | 16G12-B06-333330 | 2 |
| Fagron | Ambroxol hydrochloride | 17K30-B04-352348 | 1 |
| Fiebig | Ambroxol hydrochloride | 1911002-01 | 2 |
| Fiebig | Ambroxol hydrochloride | 2300368005 | 1 |
| Gatt-Koller | Ambroxol hydrochloride | 180600901 | 1 |
| Gatt-Koller | Ambroxol hydrochloride | 181103901 | 2 |
| Gehe amax | Ambroxol hydrochloride | 1904001-01 | 1 |
| Gehe | Ambroxol hydrochloride | 16199602 | 1 |
| GEHE | Ambroxol hydrochloride | 1702004-02 | 1 |
| GEHE | Ambroxol hydrochloride | 1711021-01 | 1 |
| Gehe | Ambroxol hydrochloride | 18013211 | 1 |
| GEHE | Ambroxol hydrochloride | 1904001-01 | 3 |
| Gehe | Ambroxol hydrochloride | 19061804 | 2 |
| Gehe | Ambroxol hydrochloride | 1911002-01 | 3 |
| Gehe | Ambroxol hydrochloride | 192983001 | 1 |
| Gehe | Ambroxol hydrochloride | 20003999002 | 1 |
| Gehe | Ambroxol hydrochloride | 20003999011 | 1 |
| Gehe | Ambroxol hydrochloride | 2011004 | 1 |
| Gehe | Ambroxol hydrochloride | 2011004-02 | 3 |
| Gehe | Ambroxol hydrochloride | 22000044002 | 1 |
| Gehe | Ambroxol hydrochloride | 22000044020 | 5 |
| Gehe | Ambroxol hydrochloride | 22000044021 | 1 |
| Gehe | Ambroxol hydrochloride | 2200044020 | 1 |
| Gehe | Ambroxol hydrochloride | 2201029-01 | 1 |
| Gehe | Ambroxol hydrochloride | 2201029-02 | 1 |
| Gehe | Ambroxol hydrochloride | 2210020-01 | 1 |
| Gehe | Ambroxol hydrochloride | 2300057001 | 1 |
| Gehe | Ambroxol hydrochloride | 23000573001 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Ambroxol hydrochloride | 23000573002 | 1 |
| Gehe | Ambroxol hydrochloride | 23003608003 | 1 |
| Gehe | Ambroxol hydrochloride | 2402033-01 | 2 |
| Hanse/Sanacorp | Ambroxol hydrochloride | 22000044001 | 1 |
| Jenne | Ambroxol hydrochloride | 2210020-01 | 2 |
| Jenne | Ambroxol hydrochloride | 23003608002 | 2 |
| Jenne | Ambroxol hydrochloride | 240514(23000573003) | 1 |
| Jenne | Ambroxol hydrochloride | 250722(24001656004) | 1 |
| Kehr | Ambroxol hydrochloride | 18013201 | 1 |
| Kehr | Ambroxol hydrochloride | 2210020-01 | 2 |
| Midas | Ambroxol hydrochloride | 2011004-01 | 1 |
| Noweda 23.07.2019 | Ambroxol hydrochloride | 19061804 | 1 |
| Noweda Taucha | Ambroxol hydrochloride | 2011004-03 | 2 |
| Noweda/ Caesar&Loren… | Ambroxol hydrochloride | 192983001 | 1 |
| Noweda/EuRo | Ambroxol hydrochloride | 1609002-02 | 1 |
| Noweda | Ambroxol hydrochloride | 1711021-01 | 1 |
| Noweda | Ambroxol hydrochloride | 17158201 | 2 |
| Noweda | Ambroxol hydrochloride | 19061804 | 1 |
| Noweda | Ambroxol hydrochloride | 19061815 | 5 |
| Noweda | Ambroxol hydrochloride | 1911002-02 | 1 |
| Noweda | Ambroxol hydrochloride | 192983012 | 1 |
| Noweda | Ambroxol hydrochloride | 20003999002 | 2 |
| Noweda | Ambroxol hydrochloride | 20003999011 | 1 |
| Noweda | Ambroxol hydrochloride | 20003999017 | 1 |
| Noweda | Ambroxol hydrochloride | 21001184001 | 1 |
| Noweda | Ambroxol hydrochloride | 22000044016 | 2 |
| Noweda | Ambroxol hydrochloride | 22000044021 | 1 |
| Noweda | Ambroxol hydrochloride | 2210020-01 | 2 |
| Noweda | Ambroxol hydrochloride | 2210020-02 | 1 |
| Noweda | Ambroxol hydrochloride | 23003608003 | 4 |
| Noweda | Ambroxol hydrochloride | 23003608005 | 1 |
| Noweda | Ambroxol hydrochloride | 2402033-01 | 1 |
| Noweda | Ambroxol hydrochloride | AXL0747202207 | 1 |
| Noweda | Ambroxol hydrochloride | CEPABX001L21 | 1 |
| phoenix /eurho | Ambroxol hydrochloride | 1911002-01 | 1 |
| Phoenix 09.10.2017 | Ambroxol hydrochloride | 1702004-02 | 2 |
| Phoenix 21.6.2019, 17,35EUR | Ambroxol hydrochloride | 1811039-01 | 1 |
| Phoenix | Ambroxol hydrochloride | 1604035-02 | 1 |
| Phoenix | Ambroxol hydrochloride | 200003999011 | 1 |
| Phoenix | Ambroxol hydrochloride | 20003999017 | 1 |
| Phoenix | Ambroxol hydrochloride | 22000044016 | 3 |
| Phoenix | Ambroxol hydrochloride | 3188 | 1 |
| Phoenix | Ambroxol hydrochloride | 3198 | 1 |
| PHÖNIX | Ambroxol hydrochloride | 1702004-01 | 1 |
| Phönix | Ambroxol hydrochloride | 1904001-01 | 1 |
| PHÖNIX | Ambroxol hydrochloride | 2011004-01 | 1 |
| Phönix | Ambroxol hydrochloride | 22000044002 | 1 |
| Phönix | Ambroxol hydrochloride | 22000044003 | 1 |
| phönix | Ambroxol hydrochloride | 2210020-01 | 3 |
| Phönix | Ambroxol hydrochloride | 2210020-0167/23P | 1 |
| Phönix | Ambroxol hydrochloride | 2210020-02 | 4 |
| Phönix | Ambroxol hydrochloride | 23003608003 | 3 |
| Phönix | Ambroxol hydrochloride | 23003608005 | 1 |
| Phönix | Ambroxol hydrochloride | AXL0747202207 | 1 |
| Sana/Hanse | Ambroxol hydrochloride | 23003608002 | 7 |
| Sanacorb | Ambroxol hydrochloride | 22000044021 | 1 |
| Sanacorp EURO | Ambroxol hydrochloride | 1806009-01 | 1 |
| Sanacorp/EuRho | Ambroxol hydrochloride | 1806009-01 | 3 |
| Sanacorp/EuRho | Ambroxol hydrochloride | 1904001-01 | 1 |
| Sanacorp | Ambroxol hydrochloride | 170204-02 | 1 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Ambroxol hydrochloride | 1711021-01 | 2 |
| Sanacorp | Ambroxol hydrochloride | 18013219 | 2 |
| Sanacorp | Ambroxol hydrochloride | 1811039-01 | 1 |
| SANACORP | Ambroxol hydrochloride | 1811039-01 | 2 |
| SANACORP | Ambroxol hydrochloride | 19061802 | 1 |
| Sanacorp | Ambroxol hydrochloride | 1911002-01 | 1 |
| Sanacorp | Ambroxol hydrochloride | 192983001 | 2 |
| Sanacorp | Ambroxol hydrochloride | 20003999003 | 1 |
| Sanacorp | Ambroxol hydrochloride | 21001184001 | 1 |
| Sanacorp | Ambroxol hydrochloride | 22000044002 | 1 |
| Sanacorp | Ambroxol hydrochloride | 22000044015 | 1 |
| Sanacorp | Ambroxol hydrochloride | 22000044016 | 1 |
| Sanacorp | Ambroxol hydrochloride | 22000044021 | 3 |
| Sanacorp | Ambroxol hydrochloride | 2201029-01 | 1 |
| Sanacorp | Ambroxol hydrochloride | 2201029-02 | 1 |
| Sanacorp | Ambroxol hydrochloride | 2201029-03 | 1 |
| Sanacorp | Ambroxol hydrochloride | 23000573003 | 1 |
| Sanacorp | Ambroxol hydrochloride | 23003608002 | 3 |
| Sanacorp | Ambroxol hydrochloride | 23003608003 | 2 |
| Sanacorp | Ambroxol hydrochloride | 2402033-01 | 1 |
| Sanacorp | Ambroxol hydrochloride | 720220007 | 1 |
| synthetisch | Ambroxol hydrochloride | 2201029-01 | 2 |
| Ven Petro | Ambroxol hydrochloride | 1911002-01 | 1 |
| Ven Petrochem&Pharma… | Ambroxol hydrochloride | 18013205 | 1 |
| Ven Petrochem&Pharma/Gehe | Ambroxol hydrochloride | 18013211 | 2 |
| Ven Petro-Chem | Ambroxol hydrochloride | 1806009-01 | 1 |

- 255 143 spectra from 1666 *Apo-Ident* customers from a total of 51 963 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ambroxol hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ambroxol hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 460 | 0 | 157 866 |
| **Type B** | 0 | 760 | 0 | 212 180 |
| **Type C** | 0 | 1731 | 12 | 255 143 |

The substance/substance group *Ambroxol hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6957 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2105 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.3115 % (> 99.1394 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several

new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20742 | 20742 | 0.00 | 124.20 |
| 21230 | 21942 | 10.95 | 142.81 |
| 21244 | 22550 | 5.87 | 132.74 |
| 21942 | 21942 | 0.00 | 143.13 |
| 22298 | 22298 | 0.00 | 133.19 |
| 22347 | 22347 | 0.00 | 130.07 |
| 22550 | 22550 | 0.00 | 130.69 |
| 22636 | 22636 | 0.00 | 125.64 |
| 23344 | 23344 | 0.00 | 129.05 |
| 24821 | 21942 | 11.02 | 143.86 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Amifampridine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20317-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Amifampridine; Amifampridinum

### Special notes

When selecting the *Amifampridine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Amifampridine | 6 | 8 | 50 |

### Second-stage model

For differentiation of the substance/substance group *Amifampridine* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Amifampridine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 124.08 | – |
| ⋮ | ⋮ | ⋮ |
| Sodium citrate | >50 | 180.36 |
| Heparin sodium | >50 | 191.42 |
| Capsaicin | >50 | 236.97 |
| Sucrose | >50 | 499.34 |
| Levocarnitine | >50 | 562.72 |
| Oxybutynin hydrochloride | >50 | 580.61 |
| Alfatradiol | >50 | 607.14 |
| Prednicarbate | >50 | 607.97 |
| Quinine hydrochloride dihydrate | >50 | 662.52 |
| Pyridoxal-5-phosphate hydrate | >50 | 738.28 |
| Tetracaine | >50 | 803.16 |
| Methoxsalen | >50 | 917.79 |
| Triclosan | >50 | 950.13 |
| Ciprofloxacin hydrochloride | >50 | 1106.82 |
| Cyproterone acetate | >50 | 1317.03 |
| Norethisterone acetate | >50 | 1417.61 |
| Amitriptyline hydrochloride | >50 | 2559.22 |
| Valine | >50 | 3917.29 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Amifampridine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Amifampridine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Amifampridine | 17251208 | 24177 | 40 | 20171117 |
| Caelo | Amifampridine | 19180701 | 25392 | 40 | 2104347 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Amifampridine | 13F05-N01 | 20901 | 41 | 20130606 |
| Fagron | Amifampridine | 16A22-B04-317264 | 22321 | 60 | 20160204 |
| Fagron | Amifampridine | 19K01-F01-366966 | 25175 | 40 | 20191219 |
| Inresa | Amifampridine | 33-15-IV-56P2749B | 22848 | 40 | 20160822 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 261 spectra of 6 reference samples from the substance/substance group *Amifampridine*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 065 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 390 spectra of 12 reference samples from the substance/substance group *Amifampridine*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Amifampridine | 22000776004 | 26308 | 40 |
| Caelo | Amifampridine | 24001153001 | 27576 | 40 |
| Euro OTC | Amifampridine | 2108004 | 25818 | 50 |
| Euro OTC | Amifampridine | 2201034 | 25951 | 40 |
| Fagron | Amifampridine | 17J11-B01-340962 | 23766 | 40 |
| Fagron | Amifampridine | 22A22-B04-219578 | 26136 | 40 |
| Fagron | Amifampridine | 24G03-B01-001048 | 27378 | 40 |
| Inresa | Amifampridine | 33-16-I-77P3018 | 23723 | 40 |
| Caelo | Amifampridine | 22000776004 | 26308SI | 20 |
| Euro OTC | Amifampridine | 2108004 | 25818SI | 10 |
| Euro OTC | Amifampridine | 2201034 | 25951SI | 10 |
| Fagron | Amifampridine | 22A22-B04-219578 | 26136SI | 20 |

- 212 550 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 114 spectra from 26 *Apo-Ident* customers from 52 batches from the substance/substance group *Amifampridine*.

- Among them are spectra of independent samples from 50 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Amifampridine | 21003139001 | 2 |
| | Amifampridine | 22000776003 | 2 |
| | Amifampridine | 23000580001 | 1 |
| | Amifampridine | 23A27-B02-228660 | 1 |
| | Amifampridine | 23E10-B10-228658 | 2 |
| | Amifampridine | 24L02-B03-005437 | 1 |
| | Amifampridine | 33-24-I-29P5324 | 2 |
| | Amifampridine | B02-2237706 | 2 |
| Caelo | Amifampridine | 13f05-n01 | 1 |
| Caelo | Amifampridine | 14H11-B06-298447 | 2 |
| Caelo | Amifampridine | 17251206 | 6 |
| Caelo | Amifampridine | 17251207 | 1 |
| Caelo | Amifampridine | 17251209 | 3 |
| Caelo | Amifampridine | 17251210 | 4 |
| Caelo | Amifampridine | 19180702 | 3 |
| Caelo | Amifampridine | 19180703 | 1 |
| Caelo | Amifampridine | 193070001 | 3 |
| Caelo | Amifampridine | 193070002 | 2 |
| Caelo | Amifampridine | 19307001 | 1 |
| Caelo | Amifampridine | 21003139002 | 4 |
| Caelo | Amifampridine | 22000776002 | 2 |
| Caelo | Amifampridine | 22000776003 | 2 |
| Caelo | Amifampridine | 33-15-IV-56P2749 | 1 |
| Caelo | Amifampridine | 33-15IV-56P2749B | 1 |
| Caesar & Loretz GmbH... | Amifampridine | 21003139002 | 1 |
| Caesar & Loretz GmbH/Gehe | Amifampridine | 22000776002 | 1 |
| Caesar & Loretz GmbH | Amifampridine | 19180702 | 1 |
| Fagron | Amifampridine | 11/14-N03 | 1 |
| Fagron | Amifampridine | 11K07-N02 | 1 |
| Fagron | Amifampridine | 13F07-N07 | 1 |
| Fagron | Amifampridine | 13K14-M01 | 1 |
| Fagron | Amifampridine | 13L12-M03 | 1 |
| Fagron | Amifampridine | 13L12-M06 | 2 |
| Fagron | Amifampridine | 14H11-B06 | 3 |
| Fagron | Amifampridine | 15B20-B02 | 2 |
| Fagron | Amifampridine | 16D05-B01 | 1 |
| Fagron | Amifampridine | 16D05-B01-318216 | 1 |
| Fagron | Amifampridine | 16K15-B03-330546 | 1 |
| Fagron | Amifampridine | 17J11-B01-343013 | 1 |
| Fagron | Amifampridine | 17L19-B02-352347 | 1 |
| Fagron | Amifampridine | 18G04-B14-353053 | 3 |
| Fagron | Amifampridine | 20J13-F01 | 1 |
| Fagron | Amifampridine | 21C17-F01-377439 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Amifampridine | 13F07-N07 | 1 |
| Inresa Arzneimittel GmbH | Amifampridine | 33-16-I-77P3018/1307 | 1 |
| Inresa | Amifampridine | 33-15-IV-56P2749 | 2 |
| Inresa | Amifampridine | 33-15-IV-56P2749B | 3 |
| Inresa | Amifampridine | 33-15-IV-56P2749B/22 | 3 |
| Inresa | Amifampridine | 33-16-I-77P3018 | 3 |
| Inresa | Amifampridine | 33-16-I-77P3018/1307 | 2 |
| Inresa | Amifampridine | 3316I77P301816022018 | 1 |
| Inresa | Amifampridine | 508670001 | 1 |
| inresa | Amifampridine | 58010001 | 1 |
| inresa | Amifampridine | 580710001 | 2 |
| Inresa | Amifampridine | 580710001 | 7 |
| inresa | Amifampridine | 58710001 | 2 |
| inresa | Amifampridine | 631350001 | 1 |
| Inresa | Amifampridine | 631350001 | 3 |
| Inresa | Amifampridine | 63150001 | 1 |
| Loba Feinchemie | Amifampridine | 580710001 | 2 |
| Phönix | Amifampridine | 22000776003 | 1 |
| Phönix | Amifampridine | 23000580001 | 1 |
| Sanacorp | Amifampridine | 20L14-F03-376279 | 1 |

- 256 772 spectra from 1666 *Apo-Ident* customers from a total of 52 102 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Amifampridine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Amifampridine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 261 | 0 | 158 065 |
| **Type B** | 0 | 390 | 0 | 212 550 |
| **Type C** | 0 | 114 | 0 | 256 772 |

The substance/substance group *Amifampridine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7011 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4615 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 94.7368 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20901 | 25392 | 9.55 | 314.19 |
| 22321 | 25392 | 9.09 | 314.61 |
| 22848 | 25392 | 12.31 | 312.86 |
| 24177 | 25392 | 6.45 | 316.39 |
| 25175 | 25392 | 6.43 | 315.69 |
| 25392 | 25392 | 0.00 | 318.68 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Amiloride hydrochloride dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21879-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Amiloride hydrochloride dihydrate; Amiloridi hydrochloridum dihydricum

### Special notes

When selecting the *Amiloride hydrochloride dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Amiloride hydrochloride dihydrate | 5 | 3 | 9 |

### Second-stage model

For differentiation of the substance/substance group *Amiloride hydrochloride dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Amiloride hydrochloride dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 77.41 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Amiloride hydrochloride dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Amiloride hydrochloride dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Amiloride hydrochloride d… | 13J08-B04-288620 | 21879 | 60 | AR-16-FG-008919-01 |
| Fagron | Amiloride hydrochloride d… | 13J08-B04-304547 | 22339 | 60 | 20131024 |
| Fagron | Amiloride hydrochloride d… | 17F02-B06-335953 | 23525 | 40 | 20170630 |
| Fagron | Amiloride hydrochloride d… | 23E30-B10-229440 | 26985 | 40 | 20230624 |
| Fagron | Amiloride hydrochloride d… | 23E30-B10-229440 | 26985SI | 20 | 20230624 |
| Fagron | Amiloride hydrochloride d… | 23L12-B13-235070 | 27168 | 40 | 20240123 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 6 reference samples from the substance/substance group *Amiloride hydrochloride dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.
- 158 066 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 5 reference samples from the substance/substance group *Amiloride hydrochloride dihydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Amiloride hydrochloride d… | 15C25-B05-325653 | 22834 | 40 |
| Fagron | Amiloride hydrochloride d… | 16K07-B02-329114 | 23119 | 40 |
| Fagron | Amiloride hydrochloride d… | 21D20-F01-379327 | 25904 | 40 |
| Fagron | Amiloride hydrochloride d… | 21D20-F01-379327 | 25904SI | 10 |
| Fagron | Amiloride hydrochloride d… | 23L12-B13-235070 | 27168SI† | 20 |

- 212 790 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 10 spectra from 4 *Apo-Ident* customers from 9 batches from the substance/substance group *Amiloride hydrochloride dihydrate*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Ebert 04.04.2014 | Amiloride hydrochloride d… | 13J08-B04 | 1 |
| Fagron | Amiloride hydrochloride d… | 17J02-B04 | 1 |
| Fagron | Amiloride hydrochloride d… | 17J02-B04-341175 | 2 |
| Fagron | Amiloride hydrochloride d… | 18C08-B03-353047 | 1 |
| Fagron | Amiloride hydrochloride d… | 18K16-B01-360014 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Amiloride hydrochloride d… | 20h25-f03-373607 | 1 |
| Fagron | Amiloride hydrochloride d… | 3100/07/15 | 1 |
| Fagron | Amiloride hydrochloride d… | 3100-03-12 | 1 |
| Fagron | Amiloride hydrochloride d… | 3100-07-15 | 1 |

- 256 876 spectra from 1666 *Apo-Ident* customers from a total of 52 144 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Amiloride hydrochloride dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Amiloride hydrochloride dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 10 | 0 | 256 876 |

The substance/substance group *Amiloride hydrochloride dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21879 | 21879 | 0.00 | 142.07 |
| 22339 | 21879 | 5.42 | 142.37 |

*continued on the next page*


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23525 | 21879 | 49.04 | 147.30 |
| 26985 | 21879 | 29.00 | 140.79 |
| 27168 | 21879 | 20.75 | 141.60 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Amitriptyline hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22844-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Amitriptyline hydrochloride; Amitriptylini hydrochloridum

### Special notes

When selecting the *Amitriptyline hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Amitriptyline hydrochloride | 6 | 3 | 88 |

### Second-stage model

For differentiation of the substance/substance group *Amitriptyline hydrochloride* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Amitriptyline hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Doxepin hydrochloride | 98.93 | – |
| ⋮ | ⋮ | ⋮ |
| Cyproterone acetate | >50 | 69.12 |
| Prednicarbate | >50 | 122.50 |
| Oxybutynin hydrochloride | >50 | 123.82 |
| Levocarnitine | >50 | 194.34 |
| Capsaicin | >50 | 215.54 |
| Tetracaine | >50 | 226.36 |
| Sodium citrate | >50 | 236.93 |
| Valine | >50 | 311.64 |
| Methoxsalen | >50 | 349.16 |
| Norethisterone acetate | >50 | 424.44 |
| Alfatradiol | >50 | 471.87 |
| Pyridoxal-5-phosphate hydrate | >50 | 472.97 |
| Quinine hydrochloride dihydrate | >50 | 542.09 |
| Ciprofloxacin hydrochloride | >50 | 582.28 |
| Heparin sodium | >50 | 651.95 |
| Triclosan | >50 | 1724.29 |
| Amifampridine | >50 | 2346.09 |
| Sucrose | >50 | 2648.16 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Amitriptyline hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Amitriptyline hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Amitriptyline hydrochloride | 16C31-B01-325540 | 22844 | 40 | 20160425 |
| Fagron | Amitriptyline hydrochloride | 18A16-B06-348643 | 24180 | 40 | 1909242 |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Amitriptyline hydrochloride | 21G23-B03-213920 | 25842 | 50 | 20210906 |
| Fagron | Amitriptyline hydrochloride | 23C04-B07-227329 | 26663 | 30 | 20230327 |
| Inresa | Amitriptyline hydrochloride | 005669/17112016 | 22845 | 40 | 1705099 |
| Inresa | Amitriptyline hydrochloride | 005669/06022017 | 23078 | 40 | 20160524 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 240 spectra of 6 reference samples from the substance/substance group *Amitriptyline hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 086 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 170 spectra of 6 reference samples from the substance/substance group *Amitriptyline hydrochloride*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Amitriptyline hydrochloride | 17E11-B02-335098 | 23528 | 40 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-362280 | 24689 | 40 |
| Fagron | Amitriptyline hydrochloride | 22F28-B04-222454 | 26282 | 40 |
| Fagron | Amitriptyline hydrochloride | 21G23-B03-213920 | 25842SI† | 10 |
| Fagron | Amitriptyline hydrochloride | 22F28-B04-222454 | 26282SI | 20 |
| Fagron | Amitriptyline hydrochloride | 23C04-B07-227329 | 26663SI† | 20 |

- 212 770 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by

this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 298 spectra from 134 *Apo-Ident* customers from 98 batches from the substance/substance group *Amitriptyline hydrochloride*.
- Among them are spectra of independent samples from 86 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Amitriptyline hydrochloride | | 1 |
| | Amitriptyline hydrochloride | 2113440 | 2 |
| | Amitriptyline hydrochloride | 22B10-B04 | 1 |
| | Amitriptyline hydrochloride | 22B10-B04-217981 | 4 |
| | Amitriptyline hydrochloride | 2301192 | 1 |
| | Amitriptyline hydrochloride | 23C04-B07-227328 | 6 |
| | Amitriptyline hydrochloride | 23C04-B07-227329 | 8 |
| | Amitriptyline hydrochloride | 23C04-B07-231756 | 6 |
| | Amitriptyline hydrochloride | 23C04-B07-227329 | 1 |
| | Amitriptyline hydrochloride | 23I19-B17-236163 | 1 |
| | Amitriptyline hydrochloride | 23L04-B09-236162 | 1 |
| | Amitriptyline hydrochloride | 23L04-B09-236162 | 1 |
| | Amitriptyline hydrochloride | 2401534 | 1 |
| | Amitriptyline hydrochloride | 24A31-B09-000800 | 2 |
| | Amitriptyline hydrochloride | 24A31-B09-00800 | 3 |
| | Amitriptyline hydrochloride | 24A31-B09-237260 | 2 |
| | Amitriptyline hydrochloride | 24i09-B03-004637 | 1 |
| | Amitriptyline hydrochloride | 24I09-B03-004637 | 9 |
| | Amitriptyline hydrochloride | B07-2317506 | 13 |
| | Amitriptyline hydrochloride | B09-2361602 | 3 |
| | Amitriptyline hydrochloride | B17-2361603 | 1 |
| AEP | Amitriptyline hydrochloride | 23C04-B07-231756 | 1 |
| Alliance Healthcare | Amitriptyline hydrochloride | 23C04-B07-227329 | 1 |
| Alliance Healthcare | Amitriptyline hydrochloride | 23C04-B07-231756 | 2 |
| Alliance Healthcare | Amitriptyline hydrochloride | 24A31-B09-237260 | 1 |
| Anzag | Amitriptyline hydrochloride | 23I19-B17-236163 | 1 |
| Anzag | Amitriptyline hydrochloride | 24I09-B03-004637 | 1 |
| Caelo | Amitriptyline hydrochloride | 19C08-b02-368626 | 1 |
| Caelo | Amitriptyline hydrochloride | 22B10B04217981 | 1 |
| Euro OTC | Amitriptyline hydrochloride | | 1 |
| Euro OTC | Amitriptyline hydrochloride | 1019Q-03993 | 1 |
| Euro OTC | Amitriptyline hydrochloride | 1506024 | 2 |
| Euro OTC | Amitriptyline hydrochloride | 19C08-B02-362280 | 1 |
| Euro OTC | Amitriptyline hydrochloride | 2715E-07209 | 1 |
| Fagron | Amitriptyline hydrochloride | 1(1901746) | 1 |
| Fagron | Amitriptyline hydrochloride | 12496176 | 1 |
| Fagron | Amitriptyline hydrochloride | 12C29-B03-211252 | 1 |
| Fagron | Amitriptyline hydrochloride | 17E-11-B02-335096 | 1 |
| Fagron | Amitriptyline hydrochloride | 17E11-B02-337699 | 1 |
| Fagron | Amitriptyline hydrochloride | 17E11-B02-340187 | 3 |
| Fagron | Amitriptyline hydrochloride | 18A16-B06 | 2 |
| Fagron | Amitriptyline hydrochloride | 18A16-B06-344853 | 3 |
| Fagron | Amitriptyline hydrochloride | 18A16-B06-348642 | 4 |
| Fagron | Amitriptyline hydrochloride | 18A16-B06-348643 | 2 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Amitriptyline hydrochloride | 18A16-B06-353064 | 1 |
| Fagron | Amitriptyline hydrochloride | 18A16-B06-353065 | 2 |
| Fagron | Amitriptyline hydrochloride | 18A16-B06_346046 | 1 |
| Fagron | Amitriptyline hydrochloride | 1901746 | 5 |
| Fagron | Amitriptyline hydrochloride | 19c08-802-368627 | 1 |
| Fagron | Amitriptyline hydrochloride | 19c08-802372547 | 1 |
| Fagron | Amitriptyline hydrochloride | 19c08-b02 | 1 |
| Fagron | Amitriptyline hydrochloride | 19c08-B02 | 1 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02 | 8 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-362279 | 3 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-362280 | 4 |
| Fagron | Amitriptyline hydrochloride | 19C-08-B02-362280 | 1 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-362281 | 4 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-363377 | 1 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-363378 | 5 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-365573 | 1 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-365574 | 5 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-367679 | 4 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-3686207 | 1 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-368627 | 7 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-370336 | 6 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-372647 | 6 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-374309 | 4 |
| Fagron | Amitriptyline hydrochloride | 19C08-B02-370336 | 1 |
| Fagron | Amitriptyline hydrochloride | 2012315 | 1 |
| Fagron | Amitriptyline hydrochloride | 2012436 | 4 |
| Fagron | Amitriptyline hydrochloride | 21C29-803 | 1 |
| Fagron | Amitriptyline hydrochloride | 21C29-B03 | 4 |
| Fagron | Amitriptyline hydrochloride | 21C29-B03-211251 | 2 |
| Fagron | Amitriptyline hydrochloride | 21C29-B03-211252 | 6 |
| Fagron | Amitriptyline hydrochloride | 21G23-B03 | 2 |
| Fagron | Amitriptyline hydrochloride | 21G23-B03-213919 | 1 |
| Fagron | Amitriptyline hydrochloride | 21G23-B03-21392 | 1 |
| Fagron | Amitriptyline hydrochloride | 21G23B03213920 | 1 |
| Fagron | Amitriptyline hydrochloride | 21G23-B03-213920 | 12 |
| Fagron | Amitriptyline hydrochloride | 22810-804-217981 | 1 |
| Fagron | Amitriptyline hydrochloride | 22B10-B04 | 4 |
| Fagron | Amitriptyline hydrochloride | 22B10-B04-2113440 | 2 |
| Fagron | Amitriptyline hydrochloride | 22b10-b04-21791 | 1 |
| Fagron | Amitriptyline hydrochloride | 22B10-B04-217981 | 28 |
| Fagron | Amitriptyline hydrochloride | 22B10-B04-2179891 | 1 |
| Fagron | Amitriptyline hydrochloride | 22B10-B04-218072 | 3 |
| Fagron | Amitriptyline hydrochloride | 22B10-B04-217981 | 1 |
| Fagron | Amitriptyline hydrochloride | 2301192 | 3 |
| Fagron | Amitriptyline hydrochloride | 2-36862007 | 1 |
| Fagron | Amitriptyline hydrochloride | 23C04-B07-227329 | 1 |
| Fagron | Amitriptyline hydrochloride | B02-3686207 | 1 |
| Fagron | Amitriptyline hydrochloride | B02-3703306 | 1 |
| Fagron | Amitriptyline hydrochloride | B03-2112502 | 2 |
| Fagron | Amitriptyline hydrochloride | B03-2139109 | 1 |
| Fagron | Amitriptyline hydrochloride | B03-2139200 | 1 |
| Fagron | Amitriptyline hydrochloride | BO3-2139200 | 1 |
| Fagron | Amitriptyline hydrochloride | Fagron | 1 |
| Fischar/Gehe | Amitriptyline hydrochloride | B03-2112502 | 1 |
| Fragon Gehe | Amitriptyline hydrochloride | 22B10-B04-217981 | 1 |
| Fragon/Sanacorp | Amitriptyline hydrochloride | 1901746 | 1 |
| Gehe Rostock | Amitriptyline hydrochloride | 19C08-B02 | 2 |
| Gehe Rostock | Amitriptyline hydrochloride | 22B10-B04-217981 | 2 |
| GEHE | Amitriptyline hydrochloride | 17E11-B02 | 1 |
| Gehe | Amitriptyline hydrochloride | 19C08-B02-368627 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Amitriptyline hydrochloride | 21C29-B03-211252 | 1 |
| Gehe | Amitriptyline hydrochloride | 23C04-B07-231756 | 1 |
| INRESA/INRESA | Amitriptyline hydrochloride | | 1 |
| Inresa | Amitriptyline hydrochloride | 17112016/P-17031721 | 1 |
| Inresa | Amitriptyline hydrochloride | 5945/12102017 | 1 |
| Inresa | Amitriptyline hydrochloride | 5945/13122017 | 1 |
| jenne | Amitriptyline hydrochloride | 23c04-b07-231756 | 1 |
| Jenne | Amitriptyline hydrochloride | 250428(24I09-B03-004637) | 1 |
| Kehr | Amitriptyline hydrochloride | 22B10-B04 | 2 |
| Kehr | Amitriptyline hydrochloride | 23C04-B07-227329 | 1 |
| Kehr | Amitriptyline hydrochloride | 23C04-Bo7-227329 | 1 |
| Kehr | Amitriptyline hydrochloride | 23C04-B07-227329 | 1 |
| Noweda | Amitriptyline hydrochloride | 22B10-B04-217981 | 1 |
| Noweda | Amitriptyline hydrochloride | 23/19-B17-236163 | 1 |
| Noweda | Amitriptyline hydrochloride | 23C04-B07-227329 | 1 |
| Noweda | Amitriptyline hydrochloride | 23C04-B07-231756 | 1 |
| Noweda | Amitriptyline hydrochloride | 24A31-B09-000800 | 3 |
| Sanacorp | Amitriptyline hydrochloride | 17e11-b02 | 1 |
| SANACORP | Amitriptyline hydrochloride | 19C08-B02 | 1 |
| Sanacorp | Amitriptyline hydrochloride | 22b10-b04-217981 | 1 |
| Sanacorp | Amitriptyline hydrochloride | 23C04-B07-227329 | 1 |

- 256 588 spectra from 1666 *Apo-Ident* customers from a total of 52 057 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Amitriptyline hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Amitriptyline hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 240 | 0 | 158 086 |
| **Type B** | 0 | 170 | 0 | 212 770 |
| **Type C** | 0 | 298 | 0 | 256 588 |

The substance/substance group *Amitriptyline hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.4706 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.9866 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to


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exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22844 | 24180 | 10.32 | 160.11 |
| 22845 | 22845 | 0.00 | 153.40 |
| 23078 | 22845 | 3.86 | 151.96 |
| 24180 | 24180 | 0.00 | 164.63 |
| 25842 | 24180 | 13.44 | 168.21 |
| 26663 | 22845 | 9.93 | 165.20 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Amlodipine besilate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005976-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Amlodipine besilate; Amlodipini besilas

### Special notes

When selecting the *Amlodipine besilate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Amlodipine besilate | 4 | 1 | 2 |

### Second-stage model

For differentiation of the substance/substance group *Amlodipine besilate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Amlodipine besilate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 123.77 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Amlodipine besilate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Amlodipine besilate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Amlodipine besilate | 21J12-B20-217787 | 26064 | 40 | 2301087 |
| Fagron | Amlodipine besilate | 23F02-B01-233301 | 26980 | 40 | 20230705 |
| Fagron | Amlodipine besilate | 23K14-B07-233516 | 27176 | 40 | 20231205 |
| Hetero Dru... | Amlodipine besilate | AL22090086 | 26403 | 40 | 20220929 |
| Hetero Dru... | Amlodipine besilate | AL22090086 | 26403SI | 20 | 20220929 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 180 spectra of 5 reference samples from the substance/substance group *Amlodipine besilate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 146 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 3 reference samples from the substance/substance group *Amlodipine besilate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Amlodipine besilate | 21L15-B03-220098 | 26073 | 40 |
| Fagron | Amlodipine besilate | 21J12-B20-217787 | 26064SI† | 10 |
| Fagron | Amlodipine besilate | 21L15-B03-220098 | 26073SI | 10 |

- 212 880 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 5 spectra from 5 *Apo-Ident* customers from 4 batches from the substance/substance group *Amlodipine besilate*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Amlodipine besilate | 21AM001 | 1 |
| | Amlodipine besilate | 21J12-B20-217787 | 1 |
| | Amlodipine besilate | 21L15-B03-220098 | 2 |
| | Amlodipine besilate | 23K14-B07-233516 | 1 |

- 256 881 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are docu-

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

mented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Amlodipine besilate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Amlodipine besilate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 60 | 0 | 212 880 |
| **Type C** | 0 | 5 | 0 | 256 881 |

The substance/substance group *Amlodipine besilate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26064 | 26064 | 0.00 | 283.63 |
| 26403 | 26064 | 8.77 | 281.95 |
| 26980 | 26064 | 7.33 | 278.88 |
| 27176 | 26064 | 5.51 | 279.02 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ammonium hydrogen carbonate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20166-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ammonium hydrogen carbonate; Ammonii hydrogencarbonas

### Special notes

When selecting the *Ammonium hydrogen carbonate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ammonium hydrogen carbonate | 2 | 1 | 13 |

### Second-stage model

For differentiation of the substance/substance group *Ammonium hydrogen carbonate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ammonium hydrogen carbonate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 111.66 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ammonium hydrogen carbonate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ammonium hydrogen carbonate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ammonium hydrogen carbonate | 182108 | 24268 | 40 | 20180926* |
| Caelo | Ammonium hydrogen carbonate | 23002439 | 27078 | 31 | 20230929* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 71 spectra of 2 reference samples from the substance/substance group *Ammonium hydrogen carbonate*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.
- 158 255 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 70 spectra of 2 reference samples from the substance/substance group *Ammonium hydrogen carbonate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ammonium hydrogen carbonate | 21001324 | 25811 | 50 |
| Caelo | Ammonium hydrogen carbonate | 23002439 | 27078SI† | 20 |

- 212 870 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 15 spectra from 11 *Apo-Ident* customers from 13 batches from the substance/substance group *Ammonium hydrogen carbonate*.
- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ammonium hydrogen carbonate | 11145612 | 2 |
| Caelo | Ammonium hydrogen carbonate | 12022308 | 2 |
| Caelo | Ammonium hydrogen carbonate | 12322201 | 1 |
| Caelo | Ammonium hydrogen carbonate | 12322204 | 1 |
| Caelo | Ammonium hydrogen carbonate | 13104601 | 1 |
| Caelo | Ammonium hydrogen carbonate | 13104611 | 1 |
| Caelo | Ammonium hydrogen carbonate | 23011404 | 1 |
| Caelo | Ammonium hydrogen carbonate | 24101202 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ammonium hydrogen carbonate | 25111308 | 1 |
| Caelo | Ammonium hydrogen carbonate | 3091204 | 1 |
| Caelo | Ammonium hydrogen carbonate | 3712Q-01103 | 1 |
| Caelo | Ammonium hydrogen carbonate | 72715338 | 1 |
| Caelo | Ammonium hydrogen carbonate | 9139402 | 1 |

- 256 871 spectra from 1666 *Apo-Ident* customers from a total of 52 140 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ammonium hydrogen carbonate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ammonium hydrogen carbonate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 71 | 0 | 158 255 |
| **Type B** | 0 | 50 | 20 | 212 870 |
| **Type C** | 0 | 15 | 0 | 256 871 |

The substance/substance group *Ammonium hydrogen carbonate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 91.5493 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 71.4286 % (> 67.1429 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24268 | 24268 | 0.00 | 202.75 |
| 27078 | 27078 | 0.00 | 212.18 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Amoxicillin trihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006096-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Amoxicillin trihydrate; Amoxicillinum trihydricum

### Special notes

When selecting the *Amoxicillin trihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Amoxicillin trihydrate | 5 | 2 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Amoxicillin trihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Amoxicillin trihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 64.00 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Amoxicillin trihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Amoxicillin trihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Amoxicillin trihydrate | 2301017 | 26570 | 40 | 20230223* |
| Euro OTC | Amoxicillin trihydrate | 2301052 | 26571 | 40 | 20230228* |
| Euro OTC | Amoxicillin trihydrate | 2305004 | 26764 | 40 | 20230703* |
| Euro OTC | Amoxicillin trihydrate | 2306006 | 26765 | 40 | 20230712* |
| Fagron | Amoxicillin trihydrate | 23F29-F01-384940 | 27023 | 40 | 20230703 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 5 reference samples from the substance/substance group *Amoxicillin trihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 126 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 5 reference samples from the substance/substance group *Amoxicillin trihydrate*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Amoxicillin trihydrate | 2304002 | 26662 | 40 |
| Gatt-Koller | Amoxicillin trihydrate | 23J00336 | 26624 | 40 |
| Euro OTC | Amoxicillin trihydrate | 2301017 | 26570SI† | 20 |
| Euro OTC | Amoxicillin trihydrate | 2301052 | 26571SI† | 20 |
| Gatt-Koller | Amoxicillin trihydrate | 23J00336 | 26624SI | 20 |

- 212 800 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6 spectra from 6 *Apo-Ident* customers from 3 batches from the substance/substance group *Amoxicillin trihydrate*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Amoxicillin trihydrate | 221213182 | 2 |
| | Amoxicillin trihydrate | 2305004-01 | 2 |
| | Amoxicillin trihydrate | 2306006-01 | 1 |
| Sanacorp | Amoxicillin trihydrate | 2306006-01 | 1 |

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 256 880 spectra from 1666 *Apo-Ident* customers from a total of 52 151 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Amoxicillin trihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Amoxicillin trihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 136 | 4 | 212 800 |
| **Type C** | 0 | 6 | 0 | 256 880 |

The substance/substance group *Amoxicillin trihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 97.1429 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26570 | 26570 | 0.00 | 135.99 |
| 26571 | 26571 | 0.00 | 134.91 |
| 26764 | 26764 | 0.00 | 135.39 |
| 26765 | 26765 | 0.00 | 135.62 |
| 27023 | 26570 | 12.26 | 136.32 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at


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least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Amphotericin B** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20933-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Amphotericin B; Amphotericinum B

### Special notes

When selecting the *Amphotericin B* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Amphotericin B | 6 | 9 | 8 |

### Second-stage model

For differentiation of the substance/substance group *Amphotericin B* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Amphotericin B* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 43.63 | 18.75 |
| Bacitracin | 76.02 | 16.72 |
| ⋮ | ⋮ | ⋮ |
| Nystatin | >50 | 20.20 |
| Colistin sulfate | >50 | 26.80 |
| Cyanocobalamin | >50 | 28.52 |
| Riboflavin | >50 | 47.67 |
| Calcium pantothenate | >50 | 59.85 |
| alpha-tocopheryl acetate dry concentrate | >50 | 63.70 |
| Estradiol hemihydrate | >50 | 68.26 |
| Triamcinolone | >50 | 71.64 |
| Calcium glycerophosphate | >50 | 75.85 |
| Methylcobalamin | >50 | 76.27 |
| Estriol | >50 | 81.81 |
| Gelatine, white | >50 | 83.79 |
| Hyoscine hydrobromide | >50 | 129.59 |
| Carmellose sodium | >50 | 131.00 |
| SyrSpend® SF Alka | >50 | 139.48 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 147.12 |
| Tosylchloramide sodium | >50 | 147.67 |
| Rice starch | >50 | 183.76 |
| Corn starch | >50 | 238.68 |
| Oxalic acid | >50 | 240.63 |
| SyrSpend® SF pH4 | >50 | 298.07 |
| Acacia, dried dispersion | >50 | 340.06 |
| Wheat starch | >50 | 360.20 |
| Maltodextrin | >50 | 365.96 |
| Potato starch | >50 | 374.16 |
| Fructose | >50 | 475.55 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Amphotericin B* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Amphotericin B*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Amphotericin B | 1305033-02 | 20933 | 40 | 1403224 |
| Euro OTC | Amphotericin B | 1512026-01 | 22813 | 40 | 20160121 |
| Euro OTC | Amphotericin B | 2008028 | 25397 | 40 | 20200930* |
| Euro OTC | Amphotericin B | 2105013 | 25761 | 50 | 20210826* |
| Fagron | Amphotericin B | 13I16-N02 | 21338 | 40 | 1508271 |
| Fagron | Amphotericin B | 13I16-N02 | 21951 | 60 | 20130911 |
| Fagron | Amphotericin B | 16L06-B04-333234 | 23530 | 40 | 20170103 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 310 spectra of 7 reference samples from the substance/substance group *Amphotericin B*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.
- 158 016 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 420 spectra of 12 reference samples from the substance/substance group *Amphotericin B*.
- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Amphotericin B | 1803036 | 24065 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Amphotericin B | 1903002 | 24614 | 40 |
| Euro OTC | Amphotericin B | 2202018 | 26031 | 40 |
| Euro OTC | Amphotericin B | 2203033 | 26089 | 40 |
| Euro OTC | Amphotericin B | 2209011 | 26433 | 40 |
| Euro OTC | Amphotericin B | 2301050 | 26939 | 40 |
| Euro OTC | Amphotericin B | 2401018 | 27157 | 40 |
| Fagron | Amphotericin B | 20G16-F06-373576 | 25715 | 50 |
| Fagron | Amphotericin B | 22C16-B01-227326 | 26538 | 40 |
| Euro OTC | Amphotericin B | 2202018 | 26031SI | 10 |
| Euro OTC | Amphotericin B | 2203033 | 26089SI | 20 |
| Fagron | Amphotericin B | 22C16-B01-227326 | 26538SI | 20 |

- 212 520 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 21 spectra from 12 *Apo-Ident* customers from 9 batches from the substance/substance group *Amphotericin B*.
- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Amphotericin B | 1305033-03 | 12 |
| Euro OTC | Amphotericin B | 1803036-01 | 1 |
| Euro OTC | Amphotericin B | 1903002-01 | 2 |
| Fagron | Amphotericin B | 16D05-B04 | 1 |
| Fagron | Amphotericin B | 16106-b04-333234 | 1 |
| Fagron | Amphotericin B | 18Job-B02-358370 | 1 |
| Fagron | Amphotericin B | 20C03-F01-371264 | 1 |
| Fagron | Amphotericin B | 20F10-F03-372701 | 1 |
| Fagron | Amphotericin B | 5173 | 1 |

- 256 865 spectra from 1666 *Apo-Ident* customers from a total of 52 144 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Amphotericin B* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Amphotericin B* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 310 | 0 | 158 016 |
| **Type B** | 0 | 420 | 0 | 212 520 |
| **Type C** | 0 | 21 | 0 | 256 865 |

The substance/substance group *Amphotericin B* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0645 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5714 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | 100.0000 % (> 71.4286 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20933 | 20933 | 0.00 | 77.07 |
| 21338 | 21338 | 0.00 | 80.32 |
| 21951 | 21338 | 10.62 | 81.63 |
| 22813 | 20933 | 9.11 | 76.02 |
| 23530 | 20933 | 13.16 | 76.71 |
| 25397 | 25397 | 0.00 | 77.69 |
| 25761 | 25761 | 0.00 | 77.83 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Arginine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20391-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Arginine; Argininum

### Special notes

When selecting the *Arginine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Arginine | 8 | 11 | 62 |

### Second-stage model

For differentiation of the substance/substance group *Arginine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Arginine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Trometamol | 80.01 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Arginine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Arginine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Arginine | 1604003 | 22514 | 40 | 20160425* |
| Euro OTC | Arginine | 1608031 | 22801 | 40 | 20160916* |
| Euro OTC | Arginine | 1702014 | 23154 | 40 | 20170316* |
| Euro OTC | Arginine | 2001001 | 25092 | 40 | 20200122* |
| Euro OTC | Arginine | 2208024 | 26533 | 40 | 20230119* |
| Euro OTC | Arginine | 2208024 | 26533SI | 20 | 20230119* |
| Fagron | Arginine | 13J28-B02 | 21226 | 40 | AR-15-FG-008045-01 |
| Fagron | Arginine | 16H24-B04-335673 | 23748 | 40 | 20161010 |
| Fagron | Arginine | 21L16-B02-220332 | 26132 | 40 | 20220401 |
| Fagron | Arginine | 21L16-B02-220332 | 26132SI | 20 | 20220401 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 10 reference samples from the substance/substance group *Arginine*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 966 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 460 spectra of 12 reference samples from the substance/substance group *Arginine*.

- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Arginine | 1710010 | 23774 | 40 |
| Euro OTC | Arginine | 1806010 | 24154 | 40 |
| Euro OTC | Arginine | 1902024 | 24478 | 40 |
| Euro OTC | Arginine | 1909005 | 24856 | 40 |
| Euro OTC | Arginine | 2008003 | 25477 | 40 |
| Euro OTC | Arginine | 2107003 | 25774 | 50 |
| Euro OTC | Arginine | 2203019 | 26030 | 40 |
| Euro OTC | Arginine | 2307009 | 26867 | 40 |
| Euro OTC | Arginine | 2402021 | 27141 | 40 |
| Euro OTC | Arginine | 2501028 | 27621 | 40 |
| Fagron | Arginine | 24A10-B07-235268 | 27170 | 40 |
| Euro OTC | Arginine | 2203019 | 26030SI | 10 |

- 212 480 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 124 spectra from 30 *Apo-Ident* customers from 64 batches from the substance/substance group *Arginine*.

- Among them are spectra of independent samples from 62 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Arginine | 21L-16-B02-220332 | 4 |
| | Arginine | 22G19-B03-221821 | 2 |
| | Arginine | 24A10-B07-235268 | 5 |
| Caelo | Arginine | 13J28-B02-290463 | 1 |
| Caelo | Arginine | 14l24-B08-303720 | 1 |
| Caelo | Arginine | 15C10-B03-314547 | 1 |
| Caelo | Arginine | 15C10-B03-318785 | 1 |
| Caelo | Arginine | 17G10-B07-347888 | 1 |
| Euro OTC | Arginine | 1105040-01 | 1 |
| Euro OTC | Arginine | 1604003-01 | 1 |
| Euro OTC | Arginine | 1710010-01 | 2 |
| Euro OTC | Arginine | 17122746 | 1 |
| Euro OTC | Arginine | 1902024-01 | 6 |
| Euro OTC | Arginine | 1909005-01 | 5 |
| Euro OTC | Arginine | 2001001-01 | 3 |
| Euro OTC | Arginine | 2001001-1 | 1 |
| Euro OTC | Arginine | 2008003-01 | 2 |
| Euro OTC | Arginine | 2009040-01 | 3 |
| Euro OTC | Arginine | 20113317 | 1 |
| Euro OTC | Arginine | L1206006-01 | 1 |
| Fagron | Arginine | 12C21-N04 | 1 |
| Fagron | Arginine | 13031801 | 1 |
| Fagron | Arginine | 13F14-N02 | 2 |
| Fagron | Arginine | 13J28-B02-290463 | 6 |
| Fagron | Arginine | 14/24-B08-303720 | 4 |
| Fagron | Arginine | 14/24-B08-303721 | 2 |
| Fagron | Arginine | 14/24-B08-303901 | 1 |
| Fagron | Arginine | 14062019 | 1 |
| Fagron | Arginine | 14092035 | 2 |
| Fagron | Arginine | 1424-B08-303720 | 1 |
| Fagron | Arginine | 14B25-B04 | 2 |
| Fagron | Arginine | 14B25-B04-295749 | 1 |
| Fagron | Arginine | 14I24-B08-303901 | 1 |
| Fagron | Arginine | 14I24-B-303720 | 1 |
| Fagron | Arginine | 15102258 | 1 |
| Fagron | Arginine | 15C10-B03-318784 | 1 |
| Fagron | Arginine | 16032361 | 1 |
| Fagron | Arginine | 16D11-B01-322156 | 1 |
| Fagron | Arginine | 16D11-B01-323566 | 2 |
| Fagron | Arginine | 16H24-B04-328914 | 1 |
| Fagron | Arginine | 16H24-B04-331399 | 1 |
| Fagron | Arginine | 16H24-B04-334063 | 2 |
| Fagron | Arginine | 16H24-B04-335673 | 3 |
| Fagron | Arginine | 16H24-B04-335674 | 8 |
| Fagron | Arginine | 16H24-B04-341855 | 1 |
| Fagron | Arginine | 17022585 | 1 |
| Fagron | Arginine | 17G10-B07 | 1 |
| Fagron | Arginine | 17G10-B07-345399 | 2 |
| Fagron | Arginine | 17G10-B07-347888 | 1 |
| Fagron | Arginine | 17G10-B07-349772 | 3 |
| Fagron | Arginine | 17G10-B07-352495 | 1 |
| Fagron | Arginine | 17G10-B07-354908 | 1 |
| Fagron | Arginine | 18072859 | 1 |
| Fagron | Arginine | 18J04-B03-357823 | 5 |
| Fagron | Arginine | 18J04-B03-357824 | 2 |
| Fagron | Arginine | 19G04-B05-363253 | 1 |
| Fagron | Arginine | 19g04-b05-364722 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Arginine | 19G04-B05-364722 | 1 |
| Fagron | Arginine | 20A16-F07-368384 | 2 |
| Fagron | Arginine | 20E08-F09-370773 | 1 |
| Fagron | Arginine | 21F14-B11-213620 | 3 |
| Fagron | Arginine | 701743-0006 | 1 |
| Fagron | Arginine | B05-3647202 | 1 |
| Fargon | Arginine | 121429 | 1 |
| GEHE | Arginine | 17G10-B07-341856 | 2 |
| Phönix | Arginine | L1302006-01 | 1 |

- 256 762 spectra from 1666 *Apo-Ident* customers from a total of 52 090 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Arginine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Arginine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 460 | 0 | 212 480 |
| **Type C** | 0 | 124 | 0 | 256 762 |

The substance/substance group *Arginine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6957 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 95.1613 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21226 | 21226 | 0.00 | 170.81 |
| 22514 | 22514 | 0.00 | 157.68 |
| 22801 | 22801 | 0.00 | 146.82 |
| 23154 | 23154 | 0.00 | 151.91 |
| 23748 | 25092 | 6.02 | 168.10 |
| 25092 | 25092 | 0.00 | 172.60 |
| 26132 | 25092 | 5.90 | 171.72 |
| 26533 | 26533 | 0.00 | 167.57 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Arginine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20657-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Arginine hydrochloride; Arginini hydrochloridum

### Special notes

When selecting the *Arginine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Arginine hydrochloride | 9 | 10 | 26 |

### Second-stage model

For differentiation of the substance/substance group *Arginine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Arginine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 79.20 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Arginine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Arginine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Arginine hydrochloride | 1306023-01 | 21776 | 60 | AR-15-FG-008412-01 |
| Euro OTC | Arginine hydrochloride | 1603033 | 22512 | 40 | 20160425* |
| Euro OTC | Arginine hydrochloride | 1610042 | 22877 | 40 | 20161128* |
| Euro OTC | Arginine hydrochloride | 1904014 | 24628 | 40 | 20190509* |
| Euro OTC | Arginine hydrochloride | 2008024 | 25338 | 40 | 20200909* |
| Euro OTC | Arginine hydrochloride | 2105005 | 25673 | 40 | 20210531* |
| Euro OTC | Arginine hydrochloride | 2206021 | 26424 | 40 | 20221206* |
| Fagron | Arginine hydrochloride | 22B28-B04-220548 | 26163 | 40 | 20220602 |
| Fagron | Arginine hydrochloride | 22B28-B04-220548 | 26163SI | 20 | 20220602 |
| Fagron | L-Arginine hydrochloride | 24I02-B011 | BR20148 | 40 | 20240330* |
| Fagron | L-Arginine hydrochloride | 24I02-B011 | BR20148SI | 20 | 20240330* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 11 reference samples from the substance/substance group *Arginine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 906 spectra from a total of 2948 batches from further 495 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 470 spectra of 14 reference samples from the substance/substance group *Arginine hydrochloride*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Arginine hydrochloride | 1711014 | 23875 | 40 |
| Euro OTC | Arginine hydrochloride | 1809012 | 24313 | 40 |
| Euro OTC | Arginine hydrochloride | 1909026 | 24937 | 40 |
| Euro OTC | Arginine hydrochloride | 2004004 | 25141 | 40 |
| Euro OTC | Arginine hydrochloride | 2011006 | 25460 | 40 |
| Euro OTC | Arginine hydrochloride | 2201019 | 25922 | 40 |
| Euro OTC | Arginine hydrochloride | 2402022 | 27147 | 40 |
| Fagron | Arginine hydrochloride | 24A10-B09-236592 | 27179 | 40 |
| Fagron | L-Arginine hydrochloride | 24I16-B011 | BR20149 | 40 |
| Fagron | L-Arginine hydrochloride | 24I16-B010 | BR20150 | 40 |
| Euro OTC | Arginine hydrochloride | 2201019 | 25922SI | 10 |
| Euro OTC | Arginine hydrochloride | 2402022 | 27147SI | 20 |
| Fagron | L-Arginine hydrochloride | 24I16-B011 | BR20149SI | 20 |
| Fagron | L-Arginine hydrochloride | 24I16-B010 | BR20150SI | 20 |

- 212 470 spectra from a total of 4277 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 52 spectra from 12 *Apo-Ident* customers from 27 batches from the substance/substance group *Arginine hydrochloride*.

- Among them are spectra of independent samples from 26 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Arginine hydrochloride | 2402022-01 | 1 |
| EuRho | Arginine hydrochloride | 1306023-01 | 1 |
| Euro OTC | Arginine hydrochloride | 1306023-01 | 1 |
| Euro OTC | Arginine hydrochloride | 1603033-01 | 1 |
| Euro OTC | Arginine hydrochloride | 1610042-01 | 1 |
| Euro OTC | Arginine hydrochloride | 1610042-02 | 1 |
| Euro OTC | Arginine hydrochloride | 1711014-01 | 2 |
| Euro OTC | Arginine hydrochloride | 1909026-01 | 1 |
| Euro OTC | Arginine hydrochloride | 2004004-01 | 2 |
| Euro OTC | Arginine hydrochloride | 2008024-01 | 1 |
| Euro OTC | Arginine hydrochloride | 2011006-01 | 2 |
| Euro OTC | Arginine hydrochloride | 21011967 | 1 |
| Euro OTC | Arginine hydrochloride | 2105005-01 | 8 |
| Euro OTC | Arginine hydrochloride | 2105005-02 | 2 |
| Euro OTC | Arginine hydrochloride | 2201019-01 | 6 |
| Euro OTC | Arginine hydrochloride | 2202019-01 | 1 |
| Euro OTC | Arginine hydrochloride | L1212009-01 | 3 |
| Euro OTC | Arginine hydrochloride | L1407040-01 | 1 |
| Euro OTC | Arginine hydrochloride | L1407040-02 | 3 |
| Euro OTC | Arginine hydrochloride | L1506023-01 | 3 |
| Fagron | Arginine hydrochloride | 12C20-N08 | 1 |
| Fagron | Arginine hydrochloride | 13J28-B03 | 2 |
| Fagron | Arginine hydrochloride | 13J28-B03-287766 | 1 |
| Fagron | Arginine hydrochloride | 13j28-b03-287768 | 1 |
| Fagron | Arginine hydrochloride | 13j28-B03-287768 | 1 |
| Fagron | Arginine hydrochloride | 13J28-B032x | 1 |
| Hirundo Products Ver… | Arginine hydrochloride | 6412784-152 | 2 |
| Pure encapsulations | Arginine hydrochloride | 50152421 | 1 |

- 256 834 spectra from 1666 *Apo-Ident* customers from a total of 52 126 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Arginine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Arginine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 470 | 0 | 212 470 |
| **Type C** | 0 | 52 | 0 | 256 834 |

The substance/substance group *Arginine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7234 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 88.4615 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21776 | 21776 | 0.00 | 180.58 |
| 22512 | 22512 | 0.00 | 181.68 |
| 22877 | 22877 | 0.00 | 182.74 |
| 24628 | 24628 | 0.00 | 182.91 |
| 25338 | 25338 | 0.00 | 183.85 |
| 25673 | 25673 | 0.00 | 182.79 |
| 26163 | 24628 | 7.63 | 182.56 |
| 26424 | 26424 | 0.00 | 178.39 |
| BR20148 | BR20148 | 0.00 | 176.68 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ascorbic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20394-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ascorbic acid; Acidum ascorbicum

### Special notes

When selecting the *Ascorbic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ascorbic acid | 9 | 23 | 147 |

### Second-stage model

For differentiation of the substance/substance group *Ascorbic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ascorbic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 83.28 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ascorbic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ascorbic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ascorbic acid | 12350011 | 21317 | 40 | 20121122 |
| Caelo | Ascorbic acid | 163452 | 23062 | 40 | 20170125* |
| Caelo | Ascorbic acid | 171358 | 23288 | 40 | 20170524* |
| Caelo | Ascorbic acid | 171358 | 23293 | 40 | 20170524* |
| Euro OTC | Ascorbic acid | 1607025 | 22672 | 40 | 20160801* |
| Euro OTC | Ascorbic acid | 1605024 | 22680 | 40 | 20160617* |
| Euro OTC | Ascorbic acid | 1609015 | 22789 | 40 | 20161006* |
| Euro OTC | Ascorbic acid | 1612018 | 22918 | 40 | 20170109* |
| Euro OTC | Ascorbic acid | 1911012 | 24936 | 40 | 20191204* |
| Fagron | Ascorbic acid | 13G29-B07 | 21229 | 40 | 1410500 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 10 reference samples from the substance/substance group *Ascorbic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 926 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1040 spectra of 29 reference samples from the substance/substance group *Ascorbic acid*.

- Among them are spectra of independent samples from 23 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ascorbic acid | 190262 | 24508 | 40 |
| Caelo | Ascorbic acid | 192143 | 24893 | 40 |
| Caelo | Ascorbic acid | 22001801 | 26257 | 40 |
| Caelo | Ascorbic acid | 24000579 | 27132 | 40 |
| Euro OTC | Ascorbic acid | 1703040 | 23128 | 40 |
| Euro OTC | Ascorbic acid | 1703025 | 23144 | 40 |
| Euro OTC | Ascorbic acid | 1707005 | 23553 | 40 |
| Euro OTC | Ascorbic acid | 1708026 | 23701 | 40 |
| Euro OTC | Ascorbic acid | 1710032 | 23891 | 40 |
| Euro OTC | Ascorbic acid | 1901044 | 24462 | 40 |
| Euro OTC | Ascorbic acid | 1903008 | 24634 | 40 |
| Euro OTC | Ascorbic acid | 1909018 | 24848 | 40 |
| Euro OTC | Ascorbic acid | 1911013 | 24975 | 40 |
| Euro OTC | Ascorbic acid | 2002022 | 25126 | 40 |
| Euro OTC | Ascorbic acid | 2002023 | 25154 | 40 |
| Euro OTC | Ascorbic acid | 2307032 | 26868 | 40 |
| Euro OTC | Ascorbic acid | 2307033 | 26874 | 40 |
| Fagron | Ascorbic acid | 19G18-B03-194674 | 25041 | 40 |
| Fagron | Ascorbic acid | 22A21-B05-218612 | 26155 | 40 |
| Fagron | Ascorbic acid | 24C07-B16-235947 | 27386 | 40 |
| Fagron | Vitamin C coated powder | 25C07-B046 | BR20121 | 40 |
| Fagron | Vitamin C coated powder | 25C07-B044 | BR20122 | 40 |
| Fagron | Vitamin C coated powder | 25C07-B042 | BR20123 | 40 |
| Caelo | Ascorbic acid | 22001801 | 26257SI | 20 |
| Euro OTC | Ascorbic acid | 2307032 | 26868SI | 20 |
| Fagron | Ascorbic acid | 22A21-B05-218612 | 26155SI | 20 |
| Fagron | Vitamin C coated powder | 25C07-B046 | BR20121SI | 20 |
| Fagron | Vitamin C coated powder | 25C07-B044 | BR20122SI | 20 |
| Fagron | Vitamin C coated powder | 25C07-B042 | BR20123SI | 20 |

- 211 900 spectra from a total of 4264 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 376 spectra from 259 *Apo-Ident* customers from 154 batches from the substance/substance group *Ascorbic acid*.

- Among them are spectra of independent samples from 146 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ascorbic acid | 1210142074 | 1 |
| | Ascorbic acid | 22001801006 | 7 |
| | Ascorbic acid | 23000894001 | 10 |
| | Ascorbic acid | 23000894006 | 8 |
| | Ascorbic acid | 23003218001 | 4 |
| | Ascorbic acid | 2307032-01 | 2 |
| | Ascorbic acid | 2307033-01 | 5 |
| | Ascorbic acid | CH1210142074 | 1 |
| | Ascorbic acid | VC2302 | 1 |
| | Ascorbic acid | VC2315 | 1 |
| ACM Herba | Ascorbic acid | KNC0385J21 | 3 |
| ACM | Ascorbic acid | Knc1035j16 | 1 |
| ACM | Ascorbic acid | KNC1035J16 | 2 |
| ACM | Ascorbic acid | KNC1488J14 | 6 |
| Alliance Healthcare | Ascorbic acid | 192143005 | 1 |
| alliance | Ascorbic acid | 23000894001 | 1 |
| Amos Vital GmbH/Alli... | Ascorbic acid | L1711004 | 1 |
| Amos Vital GmbH | Ascorbic acid | L1411003 | 1 |
| Amos Vital | Ascorbic acid | L1120454 | 1 |
| Amos vital | Ascorbic acid | L1501004 | 1 |
| Amosvital GMBH | Ascorbic acid | 201084 | 1 |
| Amosvital/Fiebig | Ascorbic acid | L1509002 | 1 |
| apoday | Ascorbic acid | HPB1804126 | 1 |
| apo-ident | Ascorbic acid | DY0261921073 | 1 |
| Apolda/Noweda | Ascorbic acid | 15021548 | 1 |
| Atlantic chemicals | Ascorbic acid | DY0261921097 | 2 |
| Caealo/phoen | Ascorbic acid | 2223806007 | 1 |
| Caelo | Ascorbic acid | 1071404 | 1 |
| Caelo | Ascorbic acid | 11208606 | 1 |
| Caelo | Ascorbic acid | 1121010320 | 1 |
| Caelo | Ascorbic acid | 12272601/1 | 1 |
| Caelo | Ascorbic acid | 123456 | 2 |
| Caelo | Ascorbic acid | 1234567 | 1 |
| Caelo | Ascorbic acid | 12349909 | 1 |
| Caelo | Ascorbic acid | 12350003 | 1 |
| Caelo | Ascorbic acid | 12350005 | 2 |
| Caelo | Ascorbic acid | 12350011 | 1 |
| Caelo | Ascorbic acid | 123test | 3 |
| Caelo | Ascorbic acid | 123Test | 2 |
| Caelo | Ascorbic acid | 12456 | 1 |
| Caelo | Ascorbic acid | 13341803/3 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ascorbic acid | 14044701/3 | 1 |
| Caelo | Ascorbic acid | 14123809 | 3 |
| Caelo | Ascorbic acid | 14123910 | 1 |
| Caelo | Ascorbic acid | 14123915 | 2 |
| Caelo | Ascorbic acid | 14214403 | 1 |
| Caelo | Ascorbic acid | 15084503 | 1 |
| Caelo | Ascorbic acid | 15084507 | 1 |
| Caelo | Ascorbic acid | 151214588 | 1 |
| Caelo | Ascorbic acid | 153000 | 1 |
| Caelo | Ascorbic acid | 15300002 | 5 |
| Caelo | Ascorbic acid | 15300007 | 8 |
| Caelo | Ascorbic acid | 15359003 | 2 |
| Caelo | Ascorbic acid | 16050403 | 4 |
| Caelo | Ascorbic acid | 16345202 | 5 |
| Caelo | Ascorbic acid | 16345204 | 1 |
| Caelo | Ascorbic acid | 16345205 | 6 |
| Caelo | Ascorbic acid | 17135803 | 6 |
| Caelo | Ascorbic acid | 17233201 | 1 |
| Caelo | Ascorbic acid | 17360301 | 8 |
| Caelo | Ascorbic acid | 17360308 | 3 |
| Caelo | Ascorbic acid | 17564875 | 1 |
| Caelo | Ascorbic acid | 18030501 | 1 |
| Caelo | Ascorbic acid | 18030503 | 1 |
| Caelo | Ascorbic acid | 18127801 | 4 |
| Caelo | Ascorbic acid | 18127805 | 6 |
| Caelo | Ascorbic acid | 18127811 | 4 |
| Caelo | Ascorbic acid | 1812805 | 1 |
| Caelo | Ascorbic acid | 19026202 | 6 |
| Caelo | Ascorbic acid | 192143002 | 4 |
| Caelo | Ascorbic acid | 192143005 | 7 |
| Caelo | Ascorbic acid | 192143006 | 1 |
| Caelo | Ascorbic acid | 200003806007 | 1 |
| Caelo | Ascorbic acid | 20000988002 | 1 |
| Caelo | Ascorbic acid | 20001112002 | 1 |
| Caelo | Ascorbic acid | 20001112003 | 4 |
| Caelo | Ascorbic acid | 20001112033 | 1 |
| Caelo | Ascorbic acid | 20003806003 | 3 |
| Caelo | Ascorbic acid | 20003806005 | 2 |
| Caelo | Ascorbic acid | 20003806007 | 4 |
| Caelo | Ascorbic acid | 20003806018 | 4 |
| Caelo | Ascorbic acid | 2061203 | 1 |
| Caelo | Ascorbic acid | 21001355002 | 1 |
| Caelo | Ascorbic acid | 22101302 | 1 |
| Caelo | Ascorbic acid | 23000894001 | 1 |
| Caelo | Ascorbic acid | 23003218001 | 1 |
| Caelo | Ascorbic acid | 3819Q-01016 | 1 |
| Caelo | Ascorbic acid | 4116E-01016 | 1 |
| Caelo | Ascorbic acid | 4565487978 | 1 |
| Caelo | Ascorbic acid | Test | 1 |
| Caesar & Loretz GmbH/AHD | Ascorbic acid | 192143005 | 1 |
| Caesar & Loretz GmbH... | Ascorbic acid | 20003806007 | 1 |
| Caesar & Loretz GmbH/Gehe | Ascorbic acid | 192143005 | 1 |
| Caesar & Loretz GmbH/Gehe | Ascorbic acid | 20003806003 | 4 |
| Caesar & Loretz GmbH... | Ascorbic acid | 20003806018 | 1 |
| Caesar & Loretz GmbH... | Ascorbic acid | 20003806003 | 1 |
| Caesar & Loretz GmbH... | Ascorbic acid | 20003806007 | 1 |
| Caesar & Loretz GmbH/sana | Ascorbic acid | 19026202 | 1 |
| Caesar & Loretz GmbH | Ascorbic acid | 11208606 | 1 |
| Caesar & Loretz GmbH | Ascorbic acid | 12m1253 | 1 |
| Caesar & Loretz GmbH | Ascorbic acid | 1542134 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Ascorbic acid | 18114802 | 1 |
| Caesar & Loretz GmbH | Ascorbic acid | 18127801 | 1 |
| Caesar & Loretz GmbH | Ascorbic acid | 18127811 | 5 |
| Caesar & Loretz GmbH | Ascorbic acid | 19026202 | 4 |
| Caesar & Loretz GmbH | Ascorbic acid | 192143005 | 2 |
| Caesar & Loretz GmbH | Ascorbic acid | 20001112003 | 4 |
| Caesar & Loretz GmbH | Ascorbic acid | 20003806003 | 5 |
| Caesar & Loretz GmbH | Ascorbic acid | 20003806005 | 5 |
| Caesar & Loretz GmbH | Ascorbic acid | 20003806007 | 4 |
| Caesar & Loretz GmbH | Ascorbic acid | 20003806018 | 2 |
| Caesar & Loretz | Ascorbic acid | 15300007 | 1 |
| Caesar und Loretz | Ascorbic acid | 19026202 | 1 |
| caleo | Ascorbic acid | 16345205 | 1 |
| Canea Pharma/ Phönix | Ascorbic acid | VC2014 | 1 |
| Canea Pharma | Ascorbic acid | VC1740 | 1 |
| Canea/Gehe/21.10.19 | Ascorbic acid | VC1846 | 1 |
| Cealo/Gehe | Ascorbic acid | 17360301 | 1 |
| CSPC Weisheng | Ascorbic acid | 1211170065 | 1 |
| EuRho | Ascorbic acid | 1710032-01 | 1 |
| Euro OTC | Ascorbic acid | 10071418 | 1 |
| Euro OTC | Ascorbic acid | 11121302 | 1 |
| Euro OTC | Ascorbic acid | 12061408 | 1 |
| Euro OTC | Ascorbic acid | 1607025 | 1 |
| Euro OTC | Ascorbic acid | 17011404 | 1 |
| Euro OTC | Ascorbic acid | 17041406 | 1 |
| Euro OTC | Ascorbic acid | 1710032_01 | 1 |
| Euro OTC | Ascorbic acid | 1710032-01 | 2 |
| Euro OTC | Ascorbic acid | 1901044-01 | 1 |
| Euro OTC | Ascorbic acid | 1909018-01 | 2 |
| Euro OTC | Ascorbic acid | 191101201 | 1 |
| Euro OTC | Ascorbic acid | 200202201 | 2 |
| Euro OTC | Ascorbic acid | 2002022-01 | 10 |
| Euro OTC | Ascorbic acid | 200202202 | 1 |
| Euro OTC | Ascorbic acid | 2002022-02 | 6 |
| Euro OTC | Ascorbic acid | 20020222-02 | 1 |
| Euro OTC | Ascorbic acid | 2002023 | 1 |
| Euro OTC | Ascorbic acid | 2002023_01 | 1 |
| Euro OTC | Ascorbic acid | 2002023-01 | 3 |
| Euro OTC | Ascorbic acid | 2307032-01 | 1 |
| Euro OTC | Ascorbic acid | 28081303 | 1 |
| Euro OTC | Ascorbic acid | DY0261921072 | 1 |
| Euro OTC | Ascorbic acid | L1202011-02 | 1 |
| Euro OTC | Ascorbic acid | L1708004 | 1 |
| Euro OTC | Ascorbic acid | L60502801 | 1 |
| Fagron | Ascorbic acid | 123456 | 1 |
| Fagron | Ascorbic acid | 16345205 | 1 |
| Fagron | Ascorbic acid | 2002022-01 | 1 |
| Fagron | Ascorbic acid | 20D14-B06-201123 | 1 |
| Gatt-Koller | Ascorbic acid | 18020406 | 1 |
| Gatt-Koller | Ascorbic acid | 1802406 | 2 |
| Gehe/Canea | Ascorbic acid | VC2012 | 1 |
| Gehe/Gehe | Ascorbic acid | L1505001 | 1 |
| Gehe | Ascorbic acid | 16345202 | 1 |
| Gehe | Ascorbic acid | 16345205 | 1 |
| GEHE | Ascorbic acid | 16345205 | 1 |
| GEHE | Ascorbic acid | 18127805 | 1 |
| Gehe | Ascorbic acid | 20003806018 | 1 |
| gehe | Ascorbic acid | 23000894001 | 1 |
| Gehe | Ascorbic acid | 23000894001 | 1 |
| Gehe | Ascorbic acid | 23000894006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Ge-Hh | Ascorbic acid | 192143005 | 1 |
| Gesundform | Ascorbic acid | L1110704 | 1 |
| Hanse/Sana | Ascorbic acid | 233218001 | 1 |
| Hänseler | Ascorbic acid | | 1 |
| Internet | Ascorbic acid | X00162LAML | 1 |
| iuhj | Ascorbic acid | ouhoh | 1 |
| Kehr | Ascorbic acid | 17360301 | 1 |
| Kehr | Ascorbic acid | 22001801006 | 1 |
| kehr | Ascorbic acid | 23000894001 | 1 |
| KÖGL | Ascorbic acid | 1900900 | 1 |
| Nachprüfung | Ascorbic acid | VC1242 | 2 |
| Ningxia | Ascorbic acid | 201114-C01-A | 1 |
| Ningxia | Ascorbic acid | 201115-C01-A | 1 |
| Northeast Pharmaceut… | Ascorbic acid | DY02622000007 | 1 |
| Northeast Pharmaceut… | Ascorbic acid | DY02622100178 | 2 |
| Noweda | Ascorbic acid | 180608-C02 | 1 |
| Noweda | Ascorbic acid | 1909018-01 | 1 |
| Noweda | Ascorbic acid | 23000894001 | 1 |
| Phoenix | Ascorbic acid | 123456789 | 1 |
| Phoenix | Ascorbic acid | 19026202 | 1 |
| Phönix | Ascorbic acid | 18127805 | 1 |
| Phönix | Ascorbic acid | 20003806003 | 1 |
| PHÖNIX | Ascorbic acid | v002 | 1 |
| Probe aus China | Ascorbic acid | DY02622000011 | 1 |
| Runika | Ascorbic acid | 23/10 | 1 |
| Sanacorp/ Ph.Peter | Ascorbic acid | VC2143 | 1 |
| Sanacorp | Ascorbic acid | 20003806003 | 1 |
| SANACORP | Ascorbic acid | 201401318 | 1 |
| Sanacorp | Ascorbic acid | 2300089401 | 1 |
| Shandong Luwei | Ascorbic acid | 1210111073 | 1 |
| Taoasis | Ascorbic acid | 810049 | 1 |
| Wep apot | Ascorbic acid | | 1 |
| wepa Apoday | Ascorbic acid | 2616110375431 | 1 |
| Wepa Paulus | Ascorbic acid | 11406201 | 1 |
| WEPA/Sanacorp | Ascorbic acid | 170623-C01 | 1 |
| Wepa/Wepa | Ascorbic acid | 1121010319 | 1 |
| wepa | Ascorbic acid | 1210142074 | 1 |
| Wepa | Ascorbic acid | 170322-c01 | 1 |
| Wepa | Ascorbic acid | 170322-C01 | 1 |
| Wepa | Ascorbic acid | 180316-C01 | 1 |
| wepa | Ascorbic acid | 180608-c02 | 1 |
| wepa | Ascorbic acid | 180608-C02 | 1 |
| Wepa | Ascorbic acid | 261120415 | 1 |
| Wepa | Ascorbic acid | VC2005013 | 1 |
| Zentiva/Alliance Hea… | Ascorbic acid | 15300007 | 1 |

- 256 510 spectra from 1666 *Apo-Ident* customers from a total of 52 007 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ascorbic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ascorbic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following

table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 1040 | 0 | 211 900 |
| **Type C** | 0 | 375 | 1 | 256 510 |

The substance/substance group *Ascorbic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4231 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7340 % (> 98.9362 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21229 | 21229 | 0.00 | 188.56 |
| 21317 | 21229 | 5.28 | 186.63 |
| 22672 | 22672 | 0.00 | 191.35 |
| 22680 | 22680 | 0.00 | 190.99 |
| 22789 | 22789 | 0.00 | 199.48 |
| 22918 | 22918 | 0.00 | 197.19 |
| 23062 | 23062 | 0.00 | 192.88 |
| 23288 | 23288 | 0.00 | 188.58 |
| 23293 | 23293 | 0.00 | 189.16 |
| 24936 | 24936 | 0.00 | 204.09 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ascorbyl palmitate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21053-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ascorbyl palmitate; Ascorbylis palmitas

### Special notes

When selecting the *Ascorbyl palmitate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ascorbyl palmitate | 7 | 5 | 226 |

### Second-stage model

For differentiation of the substance/substance group *Ascorbyl palmitate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ascorbyl palmitate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Estriol | 85.53 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ascorbyl palmitate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ascorbyl palmitate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ascorbyl palmitate | 13K04-N01 | 21053 | 40 | 1403226 |
| Fagron | Ascorbyl palmitate | 13C06-B40-291206 | 21665 | 60 | 20140306 |
| Fagron | Ascorbyl palmitate | 15F01-B99-309774 | 21851 | 60 | 20150615 |
| Fagron | Ascorbyl palmitate | 17E18-B06-335527 | 23520 | 40 | 20170606 |
| Fagron | Ascorbyl palmitate | 17E18-B06-335527 | 23520SI | 40 | 20170606 |
| Fagron | Ascorbyl palmitate | 19D25-B04-361254 | 24665 | 40 | 20190517 |
| Fagron | Ascorbyl palmitate | 20L07-F01-375723 | 25583 | 40 | 20201223 |
| Fagron | Ascorbyl palmitate | 20L07-F01-375723 | 25583SI | 40 | 20201223 |
| Fagron | Ascorbyl palmitate | 24I26-B11-004333 | 27471 | 40 | 20241007 |
| Fagron | Ascorbyl palmitate | 24I26-B11-004333 | 27471SI | 40 | 20241007 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 440 spectra of 10 reference samples from the substance/substance group *Ascorbyl palmitate*. These samples are listed above in the *calibration samples* section. The reference samples come


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from 7 different batches.

- 157 886 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 440 spectra of 11 reference samples from the substance/substance group *Ascorbyl palmitate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Ascorbyl palmitate | 17H04-B01-338484 | 23987 | 40 |
| Fagron | Ascorbyl palmitate | 18A10-B03-344364 | 24098 | 40 |
| Fagron | Ascorbyl palmitate | 21G17-B04-213672 | 26058 | 40 |
| Fagron | Ascorbyl palmitate | 22F07-B01-222885 | 26604 | 40 |
| Fagron | Ascorbyl palmitate | 23A09-B04-228316 | 26605 | 40 |
| Fagron | Ascorbyl palmitate | 17H04-B01-338484 | 23987SI | 40 |
| Fagron | Ascorbyl palmitate | 18A10-B03-344364 | 24098SI | 40 |
| Fagron | Ascorbyl palmitate | 19D25-B04-361254 | 24665SI† | 40 |
| Fagron | Ascorbyl palmitate | 21G17-B04-213672 | 26058SI | 40 |
| Fagron | Ascorbyl palmitate | 22F07-B01-222885 | 26604SI | 40 |
| Fagron | Ascorbyl palmitate | 23A09-B04-228316 | 26605SI | 40 |

- 212 500 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 754 spectra from 375 *Apo-Ident* customers from 245 batches from the substance/substance group *Ascorbyl palmitate*.

- Among them are spectra of independent samples from 224 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ascorbyl palmitate | 18B12-B09-525889 | 1 |
| | Ascorbyl palmitate | 21E10-F02-526523 | 1 |
| | Ascorbyl palmitate | 21G17-B04-213672 | 1 |
| | Ascorbyl palmitate | 21L16-B09-217351 | 1 |
| | Ascorbyl palmitate | 21L16-B09-221849 | 1 |
| | Ascorbyl palmitate | 22F07-B01 | 1 |
| | Ascorbyl palmitate | 22F07-B01-222885 | 12 |
| | Ascorbyl palmitate | 23a09-B04-228316 | 1 |
| | Ascorbyl palmitate | 23A09-B04-228316 | 17 |
| | Ascorbyl palmitate | 23Ao9-B04-228316 | 1 |
| | Ascorbyl palmitate | 24C13-B08-235298 | 9 |
| | Ascorbyl palmitate | 24I26-B11-004333 | 3 |
| | Ascorbyl palmitate | 24L05-B05-008731 | 1 |
| | Ascorbyl palmitate | 700259-0001 | 1 |
| | Ascorbyl palmitate | B11-0087300 | 1 |
| | Ascorbyl palmitate | UQ20916092 | 1 |
| | Ascorbyl palmitate | UQ30716153 | 1 |
| 18J22-B03-525911 | Ascorbyl palmitate | Fagron | 1 |
| AHC | Ascorbyl palmitate | 23A09-B04-228316 | 1 |
| AHD | Ascorbyl palmitate | 23A09-B04-228316 | 1 |
| Anzag | Ascorbyl palmitate | 240709(24C13-B08-235298) | 1 |
| Bionorica Ethics/ Noweda | Ascorbyl palmitate | 85532 | 2 |
| Bionorica Ethics/Noweda | Ascorbyl palmitate | 82275 | 2 |
| Bionorica Ethics | Ascorbyl palmitate | 82275 | 1 |
| Bionorica ethics | Ascorbyl palmitate | 85532 | 2 |
| Bionorica EthicsGmbH... | Ascorbyl palmitate | 74736 | 1 |
| Bionorica/Noweda | Ascorbyl palmitate | 77773 | 2 |
| Bionorica/Noweda | Ascorbyl palmitate | 82275 | 1 |
| Bionorica/Noweda | Ascorbyl palmitate | 85532 | 2 |
| Bionorica | Ascorbyl palmitate | 74736 | 1 |
| Bionorica | Ascorbyl palmitate | 74962 | 1 |
| Bionorica | Ascorbyl palmitate | 82275 | 1 |
| Bionorica | Ascorbyl palmitate | 85532 | 1 |
| Bombastus | Ascorbyl palmitate | 525526 | 1 |
| Caelo | Ascorbyl palmitate | 15F01-B99-525121 | 1 |
| Caelo | Ascorbyl palmitate | 16810-B04525199 | 1 |
| Caelo | Ascorbyl palmitate | 16B10-B04324111 | 1 |
| Caelo | Ascorbyl palmitate | 16B10-B04-525199 | 1 |
| Caelo | Ascorbyl palmitate | 16B-B04-525283 | 1 |
| Caelo | Ascorbyl palmitate | 16I30-B03-525489 | 1 |
| Caelo | Ascorbyl palmitate | 16l30-B03-525358 | 2 |
| Caelo | Ascorbyl palmitate | 17E18-B06 | 1 |
| Caelo | Ascorbyl palmitate | 17E18-B06-334914 | 1 |
| Caelo | Ascorbyl palmitate | 17H04-B01-525632 | 1 |
| Caelo | Ascorbyl palmitate | 18A10-B03 | 1 |
| Caelo | Ascorbyl palmitate | 18A10-B03-344364 | 2 |
| Caelo | Ascorbyl palmitate | 18B12-B09-525720 | 1 |
| Caelo | Ascorbyl palmitate | 18B12-B09-525721 | 1 |
| Caelo | Ascorbyl palmitate | 18J22-B03-355582 | 1 |
| Caelo | Ascorbyl palmitate | 19D25-B04-361254 | 2 |
| Caelo | Ascorbyl palmitate | 20I01-F04-52693 | 1 |
| Caelo | Ascorbyl palmitate | B04-2136007 | 1 |
| Caelo | Ascorbyl palmitate | K50264890 | 1 |
| DSM Nutritional GmbH | Ascorbyl palmitate | 20L07-F01-526513 | 1 |
| DSM Nutritional Prod... | Ascorbyl palmitate | UQ11216148 | 1 |
| Euro OTC | Ascorbyl palmitate | 16I30-B03 | 1 |
| Euro OTC | Ascorbyl palmitate | 17H04-B0152632 | 1 |
| Fagrin/Noweda | Ascorbyl palmitate | 18B12-B09525720 | 1 |
| Fagron | Ascorbyl palmitate | | 7 |
| Fagron | Ascorbyl palmitate | 10061708 | 1 |

*continued on the next page*



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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Ascorbyl palmitate | 137-66-6 | 2 |
| Fagron | Ascorbyl palmitate | 13C06-B40-291206 | 2 |
| Fagron | Ascorbyl palmitate | 14I03-N01 | 1 |
| Fagron | Ascorbyl palmitate | 15F01-B99 | 3 |
| Fagron | Ascorbyl palmitate | 15f01-b99-309774 | 1 |
| Fagron | Ascorbyl palmitate | 15F01-B99-52063 | 1 |
| Fagron | Ascorbyl palmitate | 15F01-B99-525063 | 1 |
| Fagron | Ascorbyl palmitate | 15F01-B99-525121 | 1 |
| Fagron | Ascorbyl palmitate | 15F01-B99-525122 | 2 |
| Fagron | Ascorbyl palmitate | 16/30-B03 | 1 |
| Fagron | Ascorbyl palmitate | 16/30-B03-329375 | 1 |
| Fagron | Ascorbyl palmitate | 16/30-B03-330625 | 3 |
| Fagron | Ascorbyl palmitate | 1630-B03-525489 | 1 |
| Fagron | Ascorbyl palmitate | 16B10-B04-525199 | 2 |
| Fagron | Ascorbyl palmitate | 16B10-B04-525228 | 1 |
| Fagron | Ascorbyl palmitate | 16B10-B04-525283 | 1 |
| Fagron | Ascorbyl palmitate | 16I30-B03 | 3 |
| Fagron | Ascorbyl palmitate | 16I30-B03-326543 | 1 |
| Fagron | Ascorbyl palmitate | 16I30-B03-329375 | 1 |
| Fagron | Ascorbyl palmitate | 16I30-B03-330625 | 1 |
| Fagron | Ascorbyl palmitate | 16I30-B03-332623 | 5 |
| Fagron | Ascorbyl palmitate | 16I30-B03-525358 | 3 |
| Fagron | Ascorbyl palmitate | 16I30-B03-525380 | 2 |
| Fagron | Ascorbyl palmitate | 16I30-B03-525425 | 1 |
| Fagron | Ascorbyl palmitate | 16I30-B03-525426 | 1 |
| Fagron | Ascorbyl palmitate | 16I30-B03-525489 | 1 |
| Fagron | Ascorbyl palmitate | 16L30-B03-332623 | 1 |
| Fagron | Ascorbyl palmitate | 17e18-b06 | 2 |
| Fagron | Ascorbyl palmitate | 17E18-B06 | 1 |
| Fagron | Ascorbyl palmitate | 17e18b06334914 | 1 |
| Fagron | Ascorbyl palmitate | 17E18-B06-334914 | 2 |
| Fagron | Ascorbyl palmitate | 17E18-B06-335527 | 3 |
| Fagron | Ascorbyl palmitate | 17E18-B06-336731 | 2 |
| Fagron | Ascorbyl palmitate | 17E18-B06-525514 | 1 |
| Fagron | Ascorbyl palmitate | 17E18-B06-5255225 | 1 |
| Fagron | Ascorbyl palmitate | 17E18-B06-525524 | 4 |
| Fagron | Ascorbyl palmitate | 17E18-B06-525525 | 1 |
| Fagron | Ascorbyl palmitate | 17E18-B06-525526 | 2 |
| Fagron | Ascorbyl palmitate | 17H04-B01 | 1 |
| Fagron | Ascorbyl palmitate | 17H04B01338484 | 1 |
| Fagron | Ascorbyl palmitate | 17H04-B01-338484 | 8 |
| Fagron | Ascorbyl palmitate | 17H04B01340474 | 2 |
| Fagron | Ascorbyl palmitate | 17H04-B01-340474 | 3 |
| Fagron | Ascorbyl palmitate | 17h04-b01-525632 | 1 |
| Fagron | Ascorbyl palmitate | 17H04-B01-525632 | 4 |
| Fagron | Ascorbyl palmitate | 18812b09348867 | 1 |
| Fagron | Ascorbyl palmitate | 18812-B09-525719 | 2 |
| Fagron | Ascorbyl palmitate | 18812-B09-525720 | 3 |
| Fagron | Ascorbyl palmitate | 18812-B09-525721 | 1 |
| Fagron | Ascorbyl palmitate | 188B12-B09-525721 | 1 |
| Fagron | Ascorbyl palmitate | 18A10_B03_344364 | 1 |
| Fagron | Ascorbyl palmitate | 18A10-B03 | 1 |
| Fagron | Ascorbyl palmitate | 18A10B03344364 | 1 |
| Fagron | Ascorbyl palmitate | 18A10-B03-344364 | 24 |
| Fagron | Ascorbyl palmitate | 18A10-B03-525701 | 7 |
| Fagron | Ascorbyl palmitate | 18A10-B23-525701 | 1 |
| Fagron | Ascorbyl palmitate | 18B12-B09 | 3 |
| Fagron | Ascorbyl palmitate | 18B-12-B09-001 | 1 |
| Fagron | Ascorbyl palmitate | 18B12-B09-348867 | 14 |
| Fagron | Ascorbyl palmitate | 18B12-B09-3488670092 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Ascorbyl palmitate | 18B12B09525719 | 1 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525719 | 9 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525720 | 5 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525721 | 5 |
| Fagron | Ascorbyl palmitate | 18b12-B09-525799 | 1 |
| Fagron | Ascorbyl palmitate | 18B12-B09525799 | 1 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525799 | 4 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525820 | 2 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525836 | 3 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525888 | 2 |
| Fagron | Ascorbyl palmitate | 18B12-B09-525889 | 2 |
| Fagron | Ascorbyl palmitate | 18B12-B09-52889 | 1 |
| Fagron | Ascorbyl palmitate | 18B12-B09-528899 | 1 |
| Fagron | Ascorbyl palmitate | 18I22-B03-525911 | 1 |
| Fagron | Ascorbyl palmitate | 18I22-B03-525967 | 1 |
| Fagron | Ascorbyl palmitate | 18J22-B03 | 9 |
| Fagron | Ascorbyl palmitate | 18J22-B03_525967 | 1 |
| Fagron | Ascorbyl palmitate | 18j22-b03-355582 | 2 |
| Fagron | Ascorbyl palmitate | 18J22-B03-355582 | 6 |
| Fagron | Ascorbyl palmitate | 18J22-B03-357638 | 3 |
| Fagron | Ascorbyl palmitate | 18J22-B03-361032 | 1 |
| Fagron | Ascorbyl palmitate | 18J22-B03-525911 | 1 |
| Fagron | Ascorbyl palmitate | 18J22-B03525967 | 1 |
| Fagron | Ascorbyl palmitate | 18J22-B03-525967 | 5 |
| Fagron | Ascorbyl palmitate | 18J22-B03-526006 | 3 |
| Fagron | Ascorbyl palmitate | 18J22-B03-529967 | 1 |
| Fagron | Ascorbyl palmitate | 19/12-F02 | 1 |
| Fagron | Ascorbyl palmitate | 19112-F02-526151 | 1 |
| Fagron | Ascorbyl palmitate | 1912-F02 | 1 |
| Fagron | Ascorbyl palmitate | 19-12F02 | 1 |
| Fagron | Ascorbyl palmitate | 1912-F02364765 | 1 |
| Fagron | Ascorbyl palmitate | 1912-F02-521699 | 1 |
| Fagron | Ascorbyl palmitate | 19D25 | 1 |
| Fagron | Ascorbyl palmitate | 19D25-B04 | 18 |
| Fagron | Ascorbyl palmitate | 19d25b04361254 | 1 |
| Fagron | Ascorbyl palmitate | 19D25-B04-361254 | 24 |
| Fagron | Ascorbyl palmitate | 19D25-B04-361255 | 1 |
| Fagron | Ascorbyl palmitate | 19D25-B04-362604 | 7 |
| Fagron | Ascorbyl palmitate | 19D25-B04-526038 | 10 |
| Fagron | Ascorbyl palmitate | 19D25-B04-526062 | 8 |
| Fagron | Ascorbyl palmitate | 19D25-B04-526080 | 1 |
| Fagron | Ascorbyl palmitate | 19D25-B04-526092 | 6 |
| Fagron | Ascorbyl palmitate | 19D25-Bo4-361254 | 1 |
| Fagron | Ascorbyl palmitate | 19I12-F02 | 4 |
| Fagron | Ascorbyl palmitate | 19I12-F02-364756 | 1 |
| Fagron | Ascorbyl palmitate | 19I12-F02-364765 | 9 |
| Fagron | Ascorbyl palmitate | 19I12F02526151 | 1 |
| Fagron | Ascorbyl palmitate | 19I12-F02-526151 | 2 |
| Fagron | Ascorbyl palmitate | 19I12-F02-526152 | 4 |
| Fagron | Ascorbyl palmitate | 19I12F02526170 | 1 |
| Fagron | Ascorbyl palmitate | 19I12-F02-526199 | 1 |
| Fagron | Ascorbyl palmitate | 19K12-K03 | 1 |
| Fagron | Ascorbyl palmitate | 19l12-F02 | 1 |
| Fagron | Ascorbyl palmitate | 19O25-B04 | 1 |
| Fagron | Ascorbyl palmitate | 20/01-F04-373583 | 1 |
| Fagron | Ascorbyl palmitate | 2001-F04 | 2 |
| Fagron | Ascorbyl palmitate | 20101-F04-33584 | 1 |
| Fagron | Ascorbyl palmitate | 20101-F04-373584 | 1 |
| Fagron | Ascorbyl palmitate | 20101-F04-526393 | 1 |
| Fagron | Ascorbyl palmitate | 20A17F02 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Ascorbyl palmitate | 20A17-F02 | 13 |
| Fagron | Ascorbyl palmitate | 20A17-F02-256273 | 1 |
| Fagron | Ascorbyl palmitate | 20A17F02368100 | 3 |
| Fagron | Ascorbyl palmitate | 20A17-F02-368100 | 20 |
| Fagron | Ascorbyl palmitate | 20A17-F02-526247 | 8 |
| Fagron | Ascorbyl palmitate | 20A17-F02-526273 | 12 |
| Fagron | Ascorbyl palmitate | 20A17-F02-526362 | 2 |
| Fagron | Ascorbyl palmitate | 20A17-FO2-526273 | 1 |
| Fagron | Ascorbyl palmitate | 20I01-04 | 1 |
| Fagron | Ascorbyl palmitate | 20I01-F04 | 7 |
| Fagron | Ascorbyl palmitate | 20I01-F04-373583 | 6 |
| Fagron | Ascorbyl palmitate | 20I01-F04-373584 | 4 |
| Fagron | Ascorbyl palmitate | 20I01-F04-526393 | 5 |
| Fagron | Ascorbyl palmitate | 20I0-F04-373584 | 1 |
| Fagron | Ascorbyl palmitate | 20l01-F04 | 1 |
| Fagron | Ascorbyl palmitate | 20l01-F04-373583 | 1 |
| Fagron | Ascorbyl palmitate | 20L07-F01 | 4 |
| Fagron | Ascorbyl palmitate | 20l07-f01-375723 | 1 |
| Fagron | Ascorbyl palmitate | 20L07-F01-375723 | 9 |
| Fagron | Ascorbyl palmitate | 20L07-F01-526454 | 1 |
| Fagron | Ascorbyl palmitate | 20L07-F01-526513 | 1 |
| Fagron | Ascorbyl palmitate | 20LO-F01-375723 | 1 |
| Fagron | Ascorbyl palmitate | 21E10-F02 | 11 |
| Fagron | Ascorbyl palmitate | 21E10-F02-378353 | 8 |
| Fagron | Ascorbyl palmitate | 21E10-F02-526522 | 5 |
| Fagron | Ascorbyl palmitate | 21E10-F02-526523 | 3 |
| Fagron | Ascorbyl palmitate | 21E10-F02-526524 | 1 |
| Fagron | Ascorbyl palmitate | 21E10-F02-526525 | 1 |
| Fagron | Ascorbyl palmitate | 21E10-F02-526570 | 2 |
| Fagron | Ascorbyl palmitate | 21E10-FO2-526625 | 1 |
| Fagron | Ascorbyl palmitate | 21E1O-259-0010 | 1 |
| Fagron | Ascorbyl palmitate | 21G17-804 | 1 |
| Fagron | Ascorbyl palmitate | 21G17-B04 | 5 |
| Fagron | Ascorbyl palmitate | 21G17-B04-213672 | 26 |
| Fagron | Ascorbyl palmitate | 21G17-BO4 | 1 |
| Fagron | Ascorbyl palmitate | 21G17-BO4-213672 | 1 |
| Fagron | Ascorbyl palmitate | 21L16-B09 | 1 |
| Fagron | Ascorbyl palmitate | 21L16B09217351 | 1 |
| Fagron | Ascorbyl palmitate | 21L16-B09-217351 | 7 |
| Fagron | Ascorbyl palmitate | 21L16-B09-221849 | 4 |
| Fagron | Ascorbyl palmitate | 21L16-B09W-217351 | 1 |
| Fagron | Ascorbyl palmitate | 21L16-Bo9-217351 | 1 |
| Fagron | Ascorbyl palmitate | 21L16-BO9-217351 | 1 |
| Fagron | Ascorbyl palmitate | 22F07-B01 | 1 |
| Fagron | Ascorbyl palmitate | 22F07-B01-22285 | 1 |
| Fagron | Ascorbyl palmitate | 22F07-B01-222885 | 6 |
| Fagron | Ascorbyl palmitate | 230123(22F07-B01-222885) | 1 |
| Fagron | Ascorbyl palmitate | 23061810 | 1 |
| Fagron | Ascorbyl palmitate | 24C13-B08-235298 | 2 |
| Fagron | Ascorbyl palmitate | 25/10/19Fr | 1 |
| Fagron | Ascorbyl palmitate | 2OIO1-F04-373584 | 1 |
| Fagron | Ascorbyl palmitate | 2OIOF-F04-373583 | 1 |
| Fagron | Ascorbyl palmitate | 2OLO7-F01-375723 | 1 |
| Fagron | Ascorbyl palmitate | 525426 | 1 |
| Fagron | Ascorbyl palmitate | 525489 | 1 |
| Fagron | Ascorbyl palmitate | 525524 | 1 |
| Fagron | Ascorbyl palmitate | 525525 | 1 |
| Fagron | Ascorbyl palmitate | 925749 | 1 |
| Fagron | Ascorbyl palmitate | A17-F02-368100 | 1 |
| Fagron | Ascorbyl palmitate | BO4-2136702 | 1 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Ascorbyl palmitate | F01-3757203 | 3 |
| Fagron | Ascorbyl palmitate | F02-3681000 | 1 |
| Fagron | Ascorbyl palmitate | F02-3783503 | 3 |
| Fagron | Ascorbyl palmitate | F02-5265203 | 1 |
| Fagron | Ascorbyl palmitate | F03-5265804 | 1 |
| Fagron | Ascorbyl palmitate | F04-3735803 | 2 |
| Fagron | Ascorbyl palmitate | F04-3735804 | 2 |
| Fagron | Ascorbyl palmitate | Fagron | 1 |
| Fagron | Ascorbyl palmitate | K45532790 | 2 |
| Fagron | Ascorbyl palmitate | K47747490 | 1 |
| Fagron | Ascorbyl palmitate | K48951290 | 1 |
| Fagron | Ascorbyl palmitate | K48951390 | 2 |
| Fagron | Ascorbyl palmitate | K49421190 | 6 |
| Fagron | Ascorbyl palmitate | K50642890 | 4 |
| Fagron | Ascorbyl palmitate | K50642890/19D25-B04 | 1 |
| Fagron | Ascorbyl palmitate | k51125490 | 1 |
| Fagron | Ascorbyl palmitate | K51125490 | 4 |
| Fagron | Ascorbyl palmitate | UQ90606133 | 1 |
| Fagron | Ascorbyl palmitate | UQ91006215 | 6 |
| Fangro/4 | Ascorbyl palmitate | 19I12F02364765 | 1 |
| Fargon/GEHE | Ascorbyl palmitate | 19/12-F02-364765 | 1 |
| Fargon/Noweda | Ascorbyl palmitate | 18J22-B03-355582 | 1 |
| Fargon/Sanacorp | Ascorbyl palmitate | 19D25-B04-361254 | 1 |
| Fargon | Ascorbyl palmitate | 18A10-B03-344364 | 1 |
| Fargon | Ascorbyl palmitate | 19D25-B04-361254 | 1 |
| Fargon | Ascorbyl palmitate | 21E10-F02-526523 | 2 |
| Fargon | Ascorbyl palmitate | 21E10-F02-526625 | 1 |
| Fiebig | Ascorbyl palmitate | 20I01-F04-373584 | 1 |
| Gehe | Ascorbyl palmitate | 18B12-B09-348867 | 1 |
| Gehe | Ascorbyl palmitate | 19I12-F02 | 1 |
| GEHE | Ascorbyl palmitate | 22F07-B01-222885 | 2 |
| L12 | Ascorbyl palmitate | 18B12-B09 | 1 |
| Merck | Ascorbyl palmitate | 16130-B03 | 1 |
| Merck | Ascorbyl palmitate | 17E18-B06-334914 | 1 |
| Merck | Ascorbyl palmitate | 18J22-B03-357638 | 1 |
| Merck | Ascorbyl palmitate | K50642890 | 1 |
| Noweda / Fargon | Ascorbyl palmitate | 20A17-F02-368100 | 1 |
| Noweda 27.12.2019 | Ascorbyl palmitate | 19D25-B04-526062 | 1 |
| Noweda | Ascorbyl palmitate | 18J22-B03-525697 | 1 |
| Noweda | Ascorbyl palmitate | 18J22-B03-525943 | 1 |
| Noweda | Ascorbyl palmitate | 19D25-B04-362604 | 1 |
| Noweda | Ascorbyl palmitate | 20A17-F02-368100 | 1 |
| Noweda | Ascorbyl palmitate | 22F07-B01-222885 | 1 |
| Noweda | Ascorbyl palmitate | 23A09-B04-228316 | 1 |
| Noweda | Ascorbyl palmitate | 23A09-B04-228316 | 1 |
| Noweda | Ascorbyl palmitate | K50642890 | 1 |
| Noweda_22.01.2020 | Ascorbyl palmitate | 19D25-B04-526038 | 1 |
| PHOENIX 30.06.2014 | Ascorbyl palmitate | UQ21206229 | 1 |
| Phoenix | Ascorbyl palmitate | 18B12-B09 | 2 |
| Phoenix | Ascorbyl palmitate | 18J22-B03-357638 | 1 |
| Phoenix | Ascorbyl palmitate | 20I01-F04-526393 | 2 |
| Phoenix | Ascorbyl palmitate | 21L16-B09-221849 | 1 |
| Phoenix | Ascorbyl palmitate | 23A09-B04-228316 | 1 |
| Phoenix | Ascorbyl palmitate | 24C13-B08-235298 | 1 |
| Phoenix | Ascorbyl palmitate | F04-3735803 | 1 |
| Phönix/Bionorica | Ascorbyl palmitate | 18A10-B03-344364 | 1 |
| Phönix | Ascorbyl palmitate | 17H04-B01-52632 | 1 |
| Phönix | Ascorbyl palmitate | 18812-B09-525720 | 2 |
| PHÖNIX | Ascorbyl palmitate | 18a10-B03-344364 | 1 |
| Phönix | Ascorbyl palmitate | 20101-F04-373583 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Ascorbyl palmitate | 21L16-B09-221849 | 1 |
| Phönix | Ascorbyl palmitate | 23A09-B04-228316 | 1 |
| Sanacorp | Ascorbyl palmitate | 137-66-6 | 1 |
| Sanacorp | Ascorbyl palmitate | 17H04-B01 | 1 |
| Sanacorp | Ascorbyl palmitate | 18B12-B09 | 1 |
| Sanacorp | Ascorbyl palmitate | 19D25-B04-361254 | 2 |
| Sanacorp | Ascorbyl palmitate | 21g17-b04-213672 | 1 |
| Sanacorp | Ascorbyl palmitate | 22F07-B01-222885 | 1 |

- 256 132 spectra from 1665 *Apo-Ident* customers from a total of 51 910 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ascorbyl palmitate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ascorbyl palmitate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 440 | 0 | 212 500 |
| **Type C** | 0 | 744 | 10 | 256 132 |

The substance/substance group *Ascorbyl palmitate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6364 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.6737 % (> 98.2759 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21053 | 21053 | 0.00 | 87.03 |
| 21665 | 21053 | 39.17 | 85.53 |
| 21851 | 21053 | 43.95 | 86.78 |
| 23520 | 21053 | 27.29 | 87.81 |
| 24665 | 21053 | 18.68 | 87.67 |
| 25583 | 21053 | 37.91 | 87.64 |
| 27471 | 21053 | 46.19 | 87.53 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Aspartic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005413-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Aspartic acid; Acidum asparticum

### Special notes

When selecting the *Aspartic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Aspartic acid | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Aspartic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Aspartic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glutamic acid | 47.03 | – |
| Glycine | 84.69 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Aspartic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Aspartic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Aspartic acid | 2108022 | 25775 | 50 | 20210906* |
| Euro OTC | Aspartic acid | 2402020 | 27156 | 30 | 20240322* |
| Euro OTC | Aspartic acid | 2402020 | 27156SI | 20 | 20240322* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 100 spectra of 3 reference samples from the substance/substance group *Aspartic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 226 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 2 reference samples from the substance/substance group *Aspartic acid*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Aspartic acid | 2307035 | 26873 | 40 |
| Euro OTC | Aspartic acid | 2307035 | 26873SI | 20 |

- 212 880 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Aspartic acid*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Aspartic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Aspartic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 100 | 0 | 158 226 |
| **Type B** | 0 | 60 | 0 | 212 880 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Aspartic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 94.0000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25775 | 25775 | 0.00 | 101.67 |
| 27156 | 27156 | 0.00 | 133.10 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Atropine sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20653-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Atropine sulfate; Atropine sulphate; Atropini sulfas

### Special notes

When selecting the *Atropine sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Atropine sulfate | 7 | 6 | 33 |

### Second-stage model

For differentiation of the substance/substance group *Atropine sulfate* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Atropine sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 79.96 | – |
| ⋮ | ⋮ | ⋮ |
| Mometasone furoate | >50 | 42.04 |
| Potassium sorbate | >50 | 110.49 |
| Propranolol hydrochloride | >50 | 160.28 |
| Magnesium hydrogen citrate | >50 | 180.34 |
| Hydrocortisone | >50 | 228.65 |
| Quinoline yellow | >50 | 258.08 |
| Saccharin sodium | >50 | 282.40 |
| Phenytoin | >50 | 296.05 |
| Calcium orotate dihydrate | >50 | 473.73 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Atropine sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Atropine sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Atropine sulfate | 11180602 | 20653 | 30 | 1405538 |
| Caelo | Atropine sulfate | 13173808 | 21088 | 40 | 1403483 |
| Caelo | Atropine sulfate | 13357405 | 21551 | 50 | 1504594 |
| Caelo | Atropine sulfate | 14336806 | 21719 | 60 | 1510209 |
| Caelo | Atropine sulfate | 14336806 | 21719SI | 60 | 1510209 |
| Caelo | Atropine sulfate | 15301601 | 21920 | 60 | 20150930 |
| Caelo | Atropine sulfate | 15301601 | 21920SI | 60 | 20150930 |
| Caelo | Atropine sulfate | 172732 | 23682 | 40 | 20171020* |
| Fagron | Atropine sulfate | 16G20-B06-328437 | 22932 | 40 | 20160823 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 440 spectra of 9 reference samples from the substance/substance group *Atropine sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 886 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 550 spectra of 14 reference samples from the substance/substance group *Atropine sulfate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Atropine sulfate | 16326802 | 22952 | 40 |
| Caelo | Atropine sulfate | 170264 | 23367 | 40 |
| Caelo | Atropine sulfate | 22002311 | 26353 | 40 |
| Caelo | Atropine sulfate | 23002005 | 26949 | 40 |
| Fagron | Atropine sulfate | 22E05-B03-220032 | 26298 | 40 |
| Fagron | Atropine sulfate | 23J24-B05-233615 | 27241 | 40 |
| Caelo | Atropine sulfate | 16326802 | 22952SI | 40 |
| Caelo | Atropine sulfate | 170264 | 23367SI | 40 |
| Caelo | Atropine sulfate | 172732 | 23682SI† | 30 |
| Caelo | Atropine sulfate | 22002311 | 26353SI | 40 |
| Caelo | Atropine sulfate | 23002005 | 26949SI | 40 |
| Fagron | Atropine sulfate | 16G20-B06-328437 | 22932SI† | 40 |
| Fagron | Atropine sulfate | 22E05-B03-220032 | 26298SI | 40 |
| Fagron | Atropine sulfate | 23J24-B05-233615 | 27241SI | 40 |

- 212 390 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 111 spectra from 79 *Apo-Ident* customers from 34 batches from the substance/substance group *Atropine sulfate*.
- Among them are spectra of independent samples from 33 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Atropine sulfate | 22000757003 | 1 |
| | Atropine sulfate | 23000208003 | 8 |
| | Atropine sulfate | 23002005004 | 6 |
| | Atropine sulfate | 23J24-B05-233615 | 1 |
| | Atropine sulfate | 24002145003 | 5 |
| AHD | Atropine sulfate | 23000208003 | 1 |
| ATS 200005 | Atropine sulfate | 21000738004 | 1 |
| Caelo | Atropine sulfate | 13173809 | 1 |
| Caelo | Atropine sulfate | 13357403 | 1 |
| Caelo | Atropine sulfate | 13357405 | 1 |
| Caelo | Atropine sulfate | 14336807 | 1 |
| Caelo | Atropine sulfate | 15115201 | 3 |
| Caelo | Atropine sulfate | 16326802 | 3 |
| Caelo | Atropine sulfate | 16c15b03-319166 | 1 |
| Caelo | Atropine sulfate | 17273202 | 1 |
| Caelo | Atropine sulfate | 18099107 | 1 |
| Caelo | Atropine sulfate | 18099111 | 3 |
| Caelo | Atropine sulfate | 18276501 | 1 |
| Caelo | Atropine sulfate | 18276510 | 2 |
| Caelo | Atropine sulfate | 192937003 | 1 |
| Caelo | Atropine sulfate | 192937007 | 4 |
| Caelo | Atropine sulfate | 21000146001 | 1 |
| Caelo | Atropine sulfate | 21000738001 | 7 |
| Caelo | Atropine sulfate | 21000738004 | 4 |
| Caelo | Atropine sulfate | 21000738007 | 2 |
| Caelo | Atropine sulfate | 22000757003 | 3 |
| Caelo | Atropine sulfate | 22002311003 | 7 |
| Caelo | Atropine sulfate | 23002005004 | 1 |
| Caelo | Atropine sulfate | 70446207 | 1 |
| Caelo | Atropine sulfate | 738001 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 18276501 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 192937007 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 21000738004 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 18099111 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 22000757003 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 182765 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 192937 | 1 |
| Caesar & Loretz GmbH... | Atropine sulfate | 192937007 | 1 |
| Caesar & Loretz GmbH | Atropine sulfate | 192937003 | 2 |
| Caesar & Loretz GmbH | Atropine sulfate | 192937007 | 4 |
| Caesar & Loretz GmbH | Atropine sulfate | 21000738001 | 2 |
| Caesar & Loretz GmbH | Atropine sulfate | 22000757003 | 4 |
| Caesar & Loretz GmbH | Atropine sulfate | 22002311003 | 3 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH2 | Atropine sulfate | 22002311003 | 1 |
| fargon | Atropine sulfate | 13K01-N01 | 1 |
| Gehe | Atropine sulfate | 16326802 | 1 |
| GEHE | Atropine sulfate | 17273202 | 1 |
| Noweda | Atropine sulfate | 12250403 | 1 |
| Noweda | Atropine sulfate | 18276510 | 1 |
| Noweda | Atropine sulfate | 23000208002 | 1 |
| Noweda | Atropine sulfate | 23002005004 | 1 |
| Noweda | Atropine sulfate | 24002145003 | 2 |
| Parthe Apotheke | Atropine sulfate | 120/20 | 1 |
| Parthe Apotheke | Atropine sulfate | 50/21 | 1 |
| Phönix | Atropine sulfate | 15301607 | 1 |
| Sanacorp | Atropine sulfate | 23000208003 | 1 |

- 256 775 spectra from 1666 *Apo-Ident* customers from a total of 52 119 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Atropine sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Atropine sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 550 | 0 | 212 390 |
| **Type C** | 0 | 108 | 3 | 256 775 |

The substance/substance group *Atropine sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.9091 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.2973 % (> 94.5946 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested

reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20653 | 20653 | 0.00 | 215.21 |
| 21088 | 21088 | 0.00 | 202.80 |
| 21551 | 21551 | 0.00 | 213.08 |
| 21719 | 21719 | 0.00 | 158.49 |
| 21920 | 21719 | 21.12 | 178.73 |
| 22932 | 21088 | 17.68 | 195.22 |
| 23682 | 23682 | 0.00 | 162.11 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Bacitracin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20851-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Bacitracin; Bacitracinum

### Special notes

When selecting the *Bacitracin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Bacitracin | 6 | 4 | 103 |

### Second-stage model

For differentiation of the substance/substance group *Bacitracin* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Bacitracin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 36.45 | 22.85 |
| Colistin sulfate | 59.66 | 20.74 |
| ⋮ | ⋮ | ⋮ |
| Amphotericin B | >50 | 54.68 |
| Cyanocobalamin | >50 | 56.60 |
| Calcium pantothenate | >50 | 56.93 |
| Methylcobalamin | >50 | 71.58 |
| alpha-tocopheryl acetate dry concentrate | >50 | 71.70 |
| Gelatine, white | >50 | 72.83 |
| Nystatin | >50 | 72.99 |
| Triamcinolone | >50 | 73.69 |
| Estriol | >50 | 79.88 |
| Estradiol hemihydrate | >50 | 109.54 |
| Riboflavin | >50 | 127.80 |
| Calcium glycerophosphate | >50 | 185.53 |
| Carmellose sodium | >50 | 211.16 |
| Hyoscine hydrobromide | >50 | 222.17 |
| SyrSpend® SF Alka | >50 | 259.58 |
| Tosylchloramide sodium | >50 | 267.25 |
| Rice starch | >50 | 338.40 |
| Oxalic acid | >50 | 362.80 |
| Corn starch | >50 | 431.76 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 447.10 |
| Acacia, dried dispersion | >50 | 472.53 |
| SyrSpend® SF pH4 | >50 | 537.39 |
| Maltodextrin | >50 | 601.32 |
| Wheat starch | >50 | 632.89 |
| Potato starch | >50 | 664.90 |
| Fructose | >50 | 710.96 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Bacitracin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Bacitracin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Bacitracin | 13A-03-N11 | 20851 | 40 | 1401189 |
| Fagron | Bacitracin | 14A21-B09-292909 | 21657 | 60 | 1511741 |
| Fagron | Bacitracin | 14E23-B03-296243 | 21686 | 60 | 1503715 |
| Fagron | Bacitracin | 15C12-B06-309185 | 21898 | 60 | 20150324 |
| Fagron | Bacitracin | 15C12-B06-309185 | 21986 | 60 | 9466 |
| Fagron | Bacitracin | 16B17-B03-322939 | 22739 | 40 | 20160421 |
| Fagron | Bacitracin | 20E-14-F01-373034 | 25374 | 40 | 20200828 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 360 spectra of 7 reference samples from the substance/substance group *Bacitracin*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 966 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 5 reference samples from the substance/substance group *Bacitracin*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Bacitracin | 16I12-B03-334194 | 23531 | 40 |
| Fagron | Bacitracin | 17L11-B02-343685 | 23933 | 40 |
| Fagron | Bacitracin | 18K14-B04-358690 | 24815 | 40 |
| Fagron | Bacitracin | 23A04-B07-225071 | 26603 | 40 |
| Fagron | Bacitracin | 23A04-B07-225071 | 26603SI | 20 |

- 212 760 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 326 spectra from 185 *Apo-Ident* customers from 115 batches from the substance/substance group *Bacitracin*.

- Among them are spectra of independent samples from 103 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Bacitracin | 21H03-B04 | 2 |
| | Bacitracin | 21H03-B04-216119 | 1 |
| | Bacitracin | 21H03-B04-216120 | 1 |
| | Bacitracin | 21H03-B04-220048 | 3 |
| | Bacitracin | 23A04-B07-225070 | 6 |
| | Bacitracin | 23A04-B07-225071 | 1 |
| | Bacitracin | B0722507000 | 1 |
| 18K14-B04-367499 | Bacitracin | Fagron | 1 |
| AHD | Bacitracin | 17L11-B02-344244 | 1 |
| Bombastus | Bacitracin | 17L11-B02-354799 | 1 |
| Caelo | Bacitracin | 14A21-B09-292908 | 1 |
| Caelo | Bacitracin | 14E23-B03-296243 | 2 |
| Caelo | Bacitracin | 15080605 | 1 |
| Caelo | Bacitracin | 15C12-B06-317782 | 1 |
| Caelo | Bacitracin | 16/12-B03 | 1 |
| Caelo | Bacitracin | 16B17-B03 | 1 |
| Caelo | Bacitracin | 16B17-B03-322891 | 2 |
| Caelo | Bacitracin | 16I12-B03-331152 | 1 |
| Caelo | Bacitracin | 17L11-B02-343685 | 1 |
| Caelo | Bacitracin | 17L11-B02-354799 | 1 |
| Caelo | Bacitracin | 17L11-B02-357635 | 1 |
| Caelo | Bacitracin | C2280092 | 1 |
| Euro OTC | Bacitracin | 17L11-B02-348461 | 1 |
| Fa.Phönix | Bacitracin | c2280111 | 1 |
| fag | Bacitracin | 17L11-B02-346531 | 1 |
| Fagraon | Bacitracin | 14E23-B03-303424 | 1 |
| Fagron | Bacitracin | | 1 |
| Fagron | Bacitracin | 11J17-N01 | 2 |
| Fagron | Bacitracin | 12G12-N17 | 1 |
| Fagron | Bacitracin | 13A03-N11 | 1 |
| Fagron | Bacitracin | 13B25-B01 | 1 |
| Fagron | Bacitracin | 13C13-N10 | 1 |
| Fagron | Bacitracin | 13D26-N08 | 1 |
| Fagron | Bacitracin | 14A21-B09 | 2 |
| Fagron | Bacitracin | 14A21-B09-290643 | 2 |
| Fagron | Bacitracin | 14A21-B09-290645 | 2 |
| Fagron | Bacitracin | 14A21-B09-292908 | 2 |
| Fagron | Bacitracin | 14E23-B03 | 3 |
| Fagron | Bacitracin | 14e23-b03-296243 | 1 |
| Fagron | Bacitracin | 14E23-B03-296243 | 6 |
| Fagron | Bacitracin | 14E23-B03-296245 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Bacitracin | 14E23B03303424 | 1 |
| Fagron | Bacitracin | 14E23B03-303424 | 1 |
| Fagron | Bacitracin | 14E23-B03-303424 | 3 |
| Fagron | Bacitracin | 14E23-B03-333424 | 1 |
| Fagron | Bacitracin | 15C12-B06 | 1 |
| Fagron | Bacitracin | 15C12-B06-309185 | 1 |
| Fagron | Bacitracin | 15C12-B06-317782 | 1 |
| Fagron | Bacitracin | 16/12-B03-329401 | 3 |
| Fagron | Bacitracin | 16/12-B03-331152 | 1 |
| Fagron | Bacitracin | 16/12-B03-334052 | 3 |
| Fagron | Bacitracin | 16/12-B03-334701 | 1 |
| Fagron | Bacitracin | 16/12B03335331 | 1 |
| Fagron | Bacitracin | 16/12-B03-335331 | 1 |
| Fagron | Bacitracin | 1612-B033-334052 | 1 |
| Fagron | Bacitracin | 16B17-B03 | 2 |
| Fagron | Bacitracin | 16B17-B03-321315 | 1 |
| Fagron | Bacitracin | 16b17-b03-322891 | 1 |
| Fagron | Bacitracin | 16B17-b03-322891 | 1 |
| Fagron | Bacitracin | 16B17-B03-322891 | 8 |
| Fagron | Bacitracin | 16b17-b03-322939 | 1 |
| Fagron | Bacitracin | 16B17-B03-322939 | 1 |
| Fagron | Bacitracin | 16B17-B03-323876 | 1 |
| Fagron | Bacitracin | 16B17b03325856 | 1 |
| Fagron | Bacitracin | 16B17B03325856 | 1 |
| Fagron | Bacitracin | 16B17-B03-325856 | 1 |
| Fagron | Bacitracin | 16I12-B03 | 3 |
| Fagron | Bacitracin | 16I12-B03-329401 | 1 |
| Fagron | Bacitracin | 16i12-b03-334052 | 1 |
| Fagron | Bacitracin | 16I12-B03-334052 | 5 |
| Fagron | Bacitracin | 16I12-B03-335331 | 3 |
| Fagron | Bacitracin | 17L11-802 | 1 |
| Fagron | Bacitracin | 17L11-B02 | 9 |
| Fagron | Bacitracin | 17L11-B02_357635 | 1 |
| Fagron | Bacitracin | 17L11-B02-343685 | 14 |
| Fagron | Bacitracin | 17L11-B02-343686 | 1 |
| Fagron | Bacitracin | 17L11-B02-346531 | 3 |
| Fagron | Bacitracin | 17L11-B02-346961 | 2 |
| Fagron | Bacitracin | 17L11B02348461 | 1 |
| Fagron | Bacitracin | 17L11-B02-348461 | 11 |
| Fagron | Bacitracin | 17L11-B02-35400 | 1 |
| Fagron | Bacitracin | 17L11-B02-354799 | 8 |
| Fagron | Bacitracin | 17L11B02357635 | 1 |
| Fagron | Bacitracin | 17L11-B02-357635 | 7 |
| Fagron | Bacitracin | 17L11-B02-357980 | 1 |
| Fagron | Bacitracin | 18K14-B04 | 10 |
| Fagron | Bacitracin | 18k14-B04-358690 | 1 |
| Fagron | Bacitracin | 18K14-B04-358690 | 17 |
| Fagron | Bacitracin | 18K14-B04-358692 | 1 |
| Fagron | Bacitracin | 18K14B04363373 | 1 |
| Fagron | Bacitracin | 18K14-B04363373 | 1 |
| Fagron | Bacitracin | 18K14-B04-363373 | 7 |
| Fagron | Bacitracin | 18K14-B04-367499 | 5 |
| Fagron | Bacitracin | 18K14-B04-368113 | 1 |
| Fagron | Bacitracin | 18K14-B0463373 | 1 |
| Fagron | Bacitracin | 18K14-B04-363374 | 1 |
| Fagron | Bacitracin | 20E14-F01 | 5 |
| Fagron | Bacitracin | 20E14-F01-373033 | 1 |
| Fagron | Bacitracin | 20E14-F01-373258 | 7 |
| Fagron | Bacitracin | 20K20-F02-376064 | 1 |
| Fagron | Bacitracin | 211531 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Bacitracin | 21H03_B04_220048 | 1 |
| Fagron | Bacitracin | 21H03-804-216119 | 1 |
| Fagron | Bacitracin | 21H03-B04-216119 | 3 |
| Fagron | Bacitracin | 21H03-B04-216120 | 1 |
| Fagron | Bacitracin | 21H03-B04-220048 | 4 |
| Fagron | Bacitracin | 28051509 | 1 |
| Fagron | Bacitracin | 2917M-03314 | 1 |
| Fagron | Bacitracin | 31071503 | 1 |
| Fagron | Bacitracin | 358690 | 1 |
| Fagron | Bacitracin | B04-3633703 | 2 |
| Fagron | Bacitracin | B04-3633704 | 2 |
| Fagron | Bacitracin | B04-3674909 | 2 |
| Fagron | Bacitracin | B04-3681103 | 1 |
| Fagron | Bacitracin | C2208111 | 2 |
| Fagron | Bacitracin | C2280017 | 3 |
| Fagron | Bacitracin | C2280054 | 1 |
| Fagron | Bacitracin | C2280065 | 3 |
| Fagron | Bacitracin | C2280092 | 3 |
| Fagron | Bacitracin | C2280111 | 8 |
| Fagron | Bacitracin | C2280138 | 3 |
| Fagron | Bacitracin | F01-3730303 | 2 |
| Fagron | Bacitracin | F01-3732508 | 7 |
| Fargon - Alliance He... | Bacitracin | 21H03-B04-216119 | 1 |
| Fargon/Gehe | Bacitracin | C2280092 | 1 |
| Fargon/Phönix | Bacitracin | 15C12-B06-312975 | 1 |
| Fargon/Phönix | Bacitracin | 18K14-B04 | 1 |
| Fargon | Bacitracin | 16B17-B03-325856 | 2 |
| fargon | Bacitracin | 17L11-B02-357635 | 1 |
| Fargron | Bacitracin | 16/14-b03-334701 | 1 |
| Fragon/ Gehe | Bacitracin | 17L11-B02 | 1 |
| Fragon/Phönix | Bacitracin | 16/12-B03-329401 | 1 |
| Gehe | Bacitracin | 16/12-B03-331185 | 1 |
| Gehe | Bacitracin | 16B17-B03-322891 | 1 |
| Gehe | Bacitracin | 17L11-B02-343685 | 1 |
| Gehe | Bacitracin | 17L11-B02-346531 | 1 |
| Gehe | Bacitracin | 17L11-B02-348461 | 1 |
| gehe | Bacitracin | 21H03-B04-216120 | 2 |
| Gehe | Bacitracin | C2280065 | 1 |
| Geibo/ Fargron | Bacitracin | 16B17-B03-322891 | 1 |
| Geilenkirchen | Bacitracin | 16/12-B03-329401 | 1 |
| Kehr | Bacitracin | 16B17-B03-322891 | 1 |
| Noweda | Bacitracin | 17L11-B02-346961 | 2 |
| Noweda | Bacitracin | 17L11-B02-354800 | 3 |
| Noweda | Bacitracin | 18K14-B04-363373 | 1 |
| Phönix Gotha | Bacitracin | C2280010 | 1 |
| Phönix | Bacitracin | c2280065 | 1 |
| Sanacorp | Bacitracin | 18K14-B04 | 1 |
| Sanacorp | Bacitracin | 20E14-F01-373258 | 1 |
| Sanacorp | Bacitracin | 21H03-B04-220048 | 1 |
| Sanacorp | Bacitracin | 21h03-b04-220074 | 1 |
| sanacorp | Bacitracin | 2280111 | 1 |
| Sanacorp | Bacitracin | 23A04-B07-225070 | 1 |

- 256 560 spectra from 1666 *Apo-Ident* customers from a total of 52 040 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Bacitracin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Bacitracin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 324 | 2 | 256 560 |

The substance/substance group *Bacitracin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.3865 % (> 98.4663 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20851 | 20851 | 0.00 | 61.23 |
| 21657 | 21657 | 0.00 | 64.95 |
| 21686 | 21686 | 0.00 | 69.02 |
| 21898 | 21986 | 12.78 | 69.88 |
| 21986 | 21986 | 0.00 | 68.25 |
| 22739 | 20851 | 14.68 | 66.25 |
| 25374 | 21686 | 21.73 | 76.99 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Baclofen** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 23375-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Baclofen; Baclofenum

### Special notes

When selecting the *Baclofen* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Baclofen | 6 | 3 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Baclofen* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Baclofen* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dithranol | 128.39 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Baclofen* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Baclofen*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Baclofen | 21D09-F05-377817 | 25716 | 50 | 20210503 |
| Fagron | Baclofen | 21K12-B21-221120 | 26177 | 40 | 20211222 |
| Fagron | Baclofen | 21K12-B21-221120 | 26177SI | 20 | 20211222 |
| Fagron | Baclofen | 22K19-B06-225423 | 26463 | 40 | 20221201 |
| Fagron | Baclofen | 23K24-B02-234668 | 27046 | 40 | 20231129 |
| Fagron | Baclofen | 23K24-B02-234668 | 27046SI | 20 | 20231129 |
| Fagron | Baclofen | 24E21-B01-238856 | 27300 | 40 | 20240613 |
| Inresa | Baclofen | 206031617/09062017 | 23376 | 40 | AR-17-FG-018577-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 290 spectra of 8 reference samples from the substance/substance group *Baclofen*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 036 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Baclofen*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Baclofen | 18I28-B02-356294 | 24444 | 40 |
| Fagron | Baclofen | 20J01-F06-374476 | 25489 | 40 |
| Fagron | Baclofen | 23G19-B03-230417 | 26912 | 40 |
| Fagron | Baclofen | 23G19-B03-230417 | 26912SI | 20 |

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 51 spectra from 40 *Apo-Ident* customers from 18 batches from the substance/substance group *Baclofen*.
- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Baclofen | | 1 |
| | Baclofen | 1234567890 | 1 |
| | Baclofen | 201062126 | 1 |
| | Baclofen | 201072217 | 2 |
| | Baclofen | 21K12-B21-221120 | 4 |
| | Baclofen | 22K19-B06-225423 | 6 |
| | Baclofen | 23K24-B02-234668 | 4 |
| | Baclofen | 24E21-B01-238856 | 1 |
| | Baclofen | 24E21-B01-2388506 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Baclofen | AP231114-02 | 1 |
| | Baclofen | B01-2388506 | 2 |
| Alliance Healthcare | Baclofen | 23K24-B02-234668 | 1 |
| Anzag | Baclofen | 23K24-B02-234668 | 1 |
| Fagron | Baclofen | 202022126 | 2 |
| Fagron | Baclofen | 21D09-F05 | 3 |
| Fagron | Baclofen | 21d09-f05-377817 | 1 |
| Fagron | Baclofen | 21D09-F05377817 | 1 |
| Fagron | Baclofen | 21D09-F05-377817 | 13 |
| Gehe | Baclofen | 23G19-B03-230417 | 1 |
| Noweda | Baclofen | 24E21-B01_238856 | 1 |
| Pharmac. works Polph... | Baclofen | 201062126 | 1 |
| Phoenix | Baclofen | 23K24-B02-234668 | 1 |
| Phoenix | Baclofen | 24E21-B01-238856 | 1 |

- 256 835 spectra from 1666 *Apo-Ident* customers from a total of 52 135 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Baclofen* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Baclofen* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 290 | 0 | 158 036 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 51 | 0 | 256 835 |

The substance/substance group *Baclofen* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.9310 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 88.2353 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23376 | 23376 | 0.00 | 206.99 |
| 25716 | 23376 | 7.83 | 214.32 |
| 26177 | 23376 | 10.04 | 213.67 |
| 26463 | 23376 | 16.09 | 201.73 |
| 27046 | 23376 | 12.72 | 213.63 |
| 27300 | 23376 | 7.95 | 211.75 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Beclometasone dipropionate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21046-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Beclometasone dipropionate; Beclometasoni dipropionas

### Special notes

When selecting the *Beclometasone dipropionate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Beclometasone dipropionate | 6 | 4 | 47 |

### Second-stage model

For differentiation of the substance/substance group *Beclometasone dipropionate* the following second-stage model is used:

- Submodel 15

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Beclometasone dipropionate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Clobetasol propionate | 53.08 | 58.11 |
| ⋮ | ⋮ | ⋮ |
| Betamethasone dipropionate | >50 | 33.20 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Beclometasone dipropionate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Beclometasone dipropionate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Beclometasone dipropionate | 1203022-03 | 21634 | 55 | 1509281 |
| Euro OTC | Beclometasone dipropionate | 1203022-03 | 21995 | 60 | 20120424 |
| Euro OTC | Beclometasone dipropionate | 1502032 | 22989 | 40 | 20150327* |
| Euro OTC | Beclometasone dipropionate | 1502032 | 22989SI | 30 | 20150327* |
| Euro OTC | Beclometasone dipropionate | 1502032 | 24869 | 40 | 20190828* |
| Fagron | Beclometasone dipropionate | 13I05-N03 | 21046 | 60 | 1511689 |
| Fagron | Beclometasone dipropionate | 13E02-B40-293328 | 21554 | 40 | 20140508 |
| Fagron | Beclometasone dipropionate | 13E02-B40-296353 | 21977 | 60 | 20140508 |
| Fagron | Beclometasone dipropionate | 13E02-B40-296353 | 21977SI | 29 | 20140508 |
| Fagron | Beclometasone dipropionate | 20C17-F03-376057 | 25743 | 40 | 20200518 |
| Fagron | Beclometasone dipropionate | 20C17-F03-376057 | 25743SI | 32 | 20200518 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 486 spectra of 11 reference samples from the substance/substance group *Beclometasone dipropionate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 840 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 359 spectra of 11 reference samples from the substance/substance group *Beclometasone dipropionate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Beclometasone dipropionate | 15F29-B09-314376 | 23104 | 40 |
| Fagron | Beclometasone dipropionate | 16B16-B03-342082 | 23930 | 40 |
| Fagron | Beclometasone dipropionate | 19J02-F03-374146 | 25717 | 50 |
| Fagron | Beclometasone dipropionate | 21K15-B03-230979 | 27177 | 40 |
| Euro OTC | Beclometasone dipropionate | 1203022-03 | 21634† | 5 |
| Euro OTC | Beclometasone dipropionate | 1203022-03 | 21995SI† | 28 |
| Euro OTC | Beclometasone dipropionate | 1502032 | 24869SI† | 31 |
| Fagron | Beclometasone dipropionate | 15F29-B09-314376 | 23104SI | 20 |
| Fagron | Beclometasone dipropionate | 16B16-B03-342082 | 23930SI | 25 |
| Fagron | Beclometasone dipropionate | 19J02-F03-374146 | 25717SI | 40 |
| Fagron | Beclometasone dipropionate | 21K15-B03-230979 | 27177SI | 40 |

- 212 581 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 98 spectra from 39 *Apo-Ident* customers from 52 batches from the substance/substance group *Beclometasone dipropionate*.
- Among them are spectra of independent samples from 46 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Beclometasone dipropionate | 18C05-B01-347367 | 2 |
| | Beclometasone dipropionate | 21K15-B03-226134 | 3 |
| | Beclometasone dipropionate | B03-2309709 | 1 |
| Caelo | Beclometasone dipropionate | 13E02-B40-293326 | 1 |
| Caelo | Beclometasone dipropionate | 18c05b01358707 | 1 |
| Caelo | Beclometasone dipropionate | 21K15-B03-213640 | 1 |
| Euro OTC | Beclometasone dipropionate | 1203022-01 | 2 |
| Euro OTC | Beclometasone dipropionate | 1203022-03 | 1 |
| Euro OTC | Beclometasone dipropionate | 1502032 | 1 |
| Euro OTC | Beclometasone dipropionate | 1502032-01 | 1 |
| Euro OTC | Beclometasone dipropionate | 1502032-02 | 3 |
| Euro OTC | Beclometasone dipropionate | 1502032-03 | 2 |
| Euro OTC | Beclometasone dipropionate | 18041820 | 1 |
| Euro OTC | Beclometasone dipropionate | C0783111020 | 1 |
| Fagro/Noweda | Beclometasone dipropionate | 14D04-B04-302335 | 1 |
| Fagron | Beclometasone dipropionate | | 1 |
| Fagron | Beclometasone dipropionate | 11F28-N02 | 2 |
| Fagron | Beclometasone dipropionate | 11L01-N03 | 1 |
| Fagron | Beclometasone dipropionate | 12D12-N03 | 4 |
| Fagron | Beclometasone dipropionate | 12G04-N11 | 3 |
| Fagron | Beclometasone dipropionate | 13/05-N03 | 1 |
| Fagron | Beclometasone dipropionate | 13/05-NO3 | 1 |
| Fagron | Beclometasone dipropionate | 13E02-B40 | 1 |
| Fagron | Beclometasone dipropionate | 13E02-B40-293327 | 4 |
| Fagron | Beclometasone dipropionate | 13E02-B40-293328 | 2 |
| Fagron | Beclometasone dipropionate | 13E02-B40-296353 | 1 |
| Fagron | Beclometasone dipropionate | 13E02-B40-296354 | 2 |
| Fagron | Beclometasone dipropionate | 13I05N03 | 1 |
| Fagron | Beclometasone dipropionate | 13I05-N03 | 3 |
| Fagron | Beclometasone dipropionate | 14D04-B04-302335 | 1 |
| Fagron | Beclometasone dipropionate | 14D04-B04302336 | 1 |
| Fagron | Beclometasone dipropionate | 14D04-B04-302336 | 3 |
| Fagron | Beclometasone dipropionate | 15F29-B09-314376 | 1 |
| Fagron | Beclometasone dipropionate | 16B16-B03-318877 | 3 |
| Fagron | Beclometasone dipropionate | 16B16-B03-322517 | 2 |
| Fagron | Beclometasone dipropionate | 16B16-B03-333670 | 2 |
| Fagron | Beclometasone dipropionate | 16B16-B03-342082 | 1 |
| Fagron | Beclometasone dipropionate | 18C05-B01-347367 | 1 |
| Fagron | Beclometasone dipropionate | 18C05-B01-347369 | 5 |
| Fagron | Beclometasone dipropionate | 18C05-B01-351434 | 2 |
| Fagron | Beclometasone dipropionate | 18C05-B01-358708 | 1 |
| Fagron | Beclometasone dipropionate | 19J02-F03 | 3 |
| Fagron | Beclometasone dipropionate | 19J02-F03-365513 | 1 |
| Fagron | Beclometasone dipropionate | 19j02f03365514 | 2 |
| Fagron | Beclometasone dipropionate | 19JO2-F03-365513 | 1 |
| Fagron | Beclometasone dipropionate | 21K15-B03-213638 | 5 |
| Fagron | Beclometasone dipropionate | 21k15b03213639 | 1 |
| Fagron | Beclometasone dipropionate | 21K15-B03-213640 | 6 |
| Fagron | Beclometasone dipropionate | 21K15-B03-226133 | 1 |
| Fagron | Beclometasone dipropionate | BMD/M/021/19 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Beclometasone dipropionate | C0783/112020 | 1 |
| Fagron | Beclometasone dipropionate | F03-3741405 | 2 |
| Fagron | Beclometasone dipropionate | P-26061721/322517 | 1 |
| fragon | Beclometasone dipropionate | 700721-0004 | 1 |

- 256 788 spectra from 1666 *Apo-Ident* customers from a total of 52 101 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Beclometasone dipropionate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Beclometasone dipropionate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 486 | 0 | 157 840 |
| **Type B** | 0 | 359 | 0 | 212 581 |
| **Type C** | 0 | 96 | 2 | 256 788 |

The substance/substance group *Beclometasone dipropionate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7654 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.3287 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.9592 % (> 94.8980 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21046 | 21046 | 0.00 | 63.92 |
| 21554 | 21634 | 5.21 | 57.30 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21634 | 21634 | 0.00 | 57.54 |
| 21977 | 24869 | 5.15 | 61.70 |
| 21995 | 21634 | 6.98 | 62.14 |
| 22989 | 22989 | 0.00 | 60.29 |
| 24869 | 24869 | 0.00 | 60.47 |
| 25743 | 24869 | 5.37 | 62.07 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Benzocaine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20211-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Benzocaine; Benzocainum

### Special notes

When selecting the *Benzocaine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Benzocaine | 9 | 11 | 207 |

### Second-stage model

For differentiation of the substance/substance group *Benzocaine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Benzocaine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 175.12 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Benzocaine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Benzocaine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Benzocaine | 12341904 | 20843 | 40 | 1411055 |
| Caelo | Benzocaine | 13213509 | 21563 | 60 | 1706017 |
| Caelo | Benzocaine | 20000972 | 25195 | 40 | 20200513* |
| Caelo | Benzocaine | 22002349 | 26493 | 40 | 20221011* |
| Caelo | Benzocaine | 22002349 | 26493SI | 20 | 20221011* |
| Euro OTC | Benzocaine | 2207016 | 26346 | 40 | 20221013* |
| Euro OTC | Benzocaine | 2207016 | 26346SI | 20 | 20221013* |
| Fagron | Benzocaine | 12E04-N06 | 21083 | 30 | 20120607 |
| Fagron | Benzocaine | 14G02-B01-306980 | 23569 | 40 | 20140723 |
| Fagron | Benzocaine | 16D13-B01-342411 | 23986 | 40 | 1807429 |
| Fagron | Benzocaine | 19J11-B11-195266 | 25172 | 40 | 20191031 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 410 spectra of 11 reference samples from the substance/substance group *Benzocaine*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 916 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 490 spectra of 13 reference samples from the substance/substance group *Benzocaine*.

- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Benzocaine | 161740 | 22641 | 40 |
| Caelo | Benzocaine | 172174 | 23628 | 40 |
| Caelo | Benzocaine | 182778 | 24378 | 40 |
| Caelo | Benzocaine | 190220 | 24531 | 40 |
| Caelo | Benzocaine | 20002741 | 25616 | 40 |
| Caelo | Benzocaine | 210001141 | 25642 | 40 |
| Caelo | Benzocaine | 21003052 | 25854 | 50 |
| Caelo | Benzocaine | 24000752 | 27221 | 40 |
| Fagron | Benzocaine | 22A15-B10-220491 | 26183 | 40 |
| Fagron | Benzocaine | 23H08-B12-239118 | 27190 | 40 |
| Fagron | Benzocaine | 24K19-B26-009750 | 27645 | 40 |
| Fagron | Benzocaine | 22A15-B10-220491 | 26183SI | 20 |
| Fagron | Benzocaine | 24K19-B26-009750 | 27645SI | 20 |

- 212 450 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 869 spectra from 445 *Apo-Ident* customers from 222 batches from the substance/substance group *Benzocaine*.

- Among them are spectra of independent samples from 207 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Benzocaine | 1231909 | 1 |
| | Benzocaine | 21003052004 | 2 |
| | Benzocaine | 21003052005 | 5 |
| | Benzocaine | 21003052007 | 2 |
| | Benzocaine | 21003052013 | 3 |
| | Benzocaine | 21J21-B01-216131 | 1 |
| | Benzocaine | 22002349001 | 12 |
| | Benzocaine | 22002349005 | 4 |
| | Benzocaine | 22002349007 | 3 |
| | Benzocaine | 22002349008 | 2 |
| | Benzocaine | 22002349010 | 2 |
| | Benzocaine | 22002349011 | 3 |
| | Benzocaine | 22G25-B01-222567 | 1 |
| | Benzocaine | 22G25-B01-227344 | 4 |
| | Benzocaine | 22H30-B01-231909 | 1 |
| | Benzocaine | 23H08-B12-239118 | 1 |
| | Benzocaine | 24000752002 | 1 |
| | Benzocaine | 24000752003 | 7 |
| | Benzocaine | 24002905002 | 2 |
| | Benzocaine | 24K19-B26-006056 | 1 |
| | Benzocaine | 24K19-B26-009750 | 1 |
| | Benzocaine | B01-2319009 | 1 |
| | Benzocaine | B26-0060506 | 1 |
| | Benzocaine | C0012201014 | 2 |
| ACM | Benzocaine | KNC1643J15 | 1 |
| AHD | Benzocaine | 16174001 | 1 |
| Alliance | Benzocaine | 22002349001 | 1 |
| Anzag / Noweda | Benzocaine | 1321351 | 1 |
| apomix | Benzocaine | 190911 | 1 |
| Beiersdorf | Benzocaine | 15227314 | 1 |
| Bombastus | Benzocaine | B02-2007200 | 2 |
| Caelo | Benzocaine | | 1 |
| Caelo | Benzocaine | 1(19022001) | 1 |
| Caelo | Benzocaine | 10072603 | 3 |
| Caelo | Benzocaine | 11031703 | 1 |
| Caelo | Benzocaine | 11127506 | 1 |
| Caelo | Benzocaine | 11127508 | 1 |
| Caelo | Benzocaine | 1119E-01118 | 1 |
| Caelo | Benzocaine | 12115007 | 5 |
| Caelo | Benzocaine | 12115008 | 2 |
| Caelo | Benzocaine | 12115011 | 3 |
| Caelo | Benzocaine | 12341904 | 6 |
| Caelo | Benzocaine | 12341906 | 1 |
| Caelo | Benzocaine | 13213502 | 5 |
| Caelo | Benzocaine | 13213509 | 8 |
| Caelo | Benzocaine | 13213515 | 4 |
| Caelo | Benzocaine | 13213516 | 1 |
| Caelo | Benzocaine | 13213518 | 1 |
| Caelo | Benzocaine | 13L06-B02 | 1 |
| Caelo | Benzocaine | 13L06-B02-294112 | 2 |
| Caelo | Benzocaine | 14277502 | 4 |
| Caelo | Benzocaine | 1515I-01118 | 1 |
| Caelo | Benzocaine | 15227301 | 2 |
| Caelo | Benzocaine | 15227302 | 13 |
| Caelo | Benzocaine | 15227307 | 4 |
| Caelo | Benzocaine | 15227311 | 3 |
| Caelo | Benzocaine | 15227312 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Benzocaine | 15227313 | 1 |
| Caelo | Benzocaine | 15227314 | 4 |
| Caelo | Benzocaine | 15227315 | 8 |
| Caelo | Benzocaine | 15227315I-201016-1 | 1 |
| Caelo | Benzocaine | 15227317 | 2 |
| Caelo | Benzocaine | 15C19-B04-322019 | 1 |
| Caelo | Benzocaine | 15c19-b04-325359 | 1 |
| Caelo | Benzocaine | 16030403 | 2 |
| Caelo | Benzocaine | 16174001 | 8 |
| Caelo | Benzocaine | 16174001I-290517 | 1 |
| Caelo | Benzocaine | 16174005 | 2 |
| Caelo | Benzocaine | 16174007 | 9 |
| Caelo | Benzocaine | 161740075429 | 1 |
| Caelo | Benzocaine | 161740077 | 1 |
| Caelo | Benzocaine | 16174008 | 1 |
| Caelo | Benzocaine | 16174014 | 16 |
| Caelo | Benzocaine | 16174015 | 1 |
| Caelo | Benzocaine | 16174017 | 6 |
| Caelo | Benzocaine | 16174019 | 12 |
| Caelo | Benzocaine | 161740195459 | 1 |
| Caelo | Benzocaine | 16174020 | 1 |
| Caelo | Benzocaine | 16D13-B01_348062 | 1 |
| Caelo | Benzocaine | 16D13-B01-334195 | 2 |
| Caelo | Benzocaine | 16D13-B01-342411 | 1 |
| Caelo | Benzocaine | 16D13-B01-345969 | 1 |
| Caelo | Benzocaine | 16D13-B01-348062 | 1 |
| Caelo | Benzocaine | 18018801 | 14 |
| Caelo | Benzocaine | 18018804 | 12 |
| Caelo | Benzocaine | 18018805 | 1 |
| Caelo | Benzocaine | 18018806 | 1 |
| Caelo | Benzocaine | 18018808 | 7 |
| Caelo | Benzocaine | 18018810 | 2 |
| Caelo | Benzocaine | 18041803 | 1 |
| Caelo | Benzocaine | 18277801 | 7 |
| Caelo | Benzocaine | 18277802 | 14 |
| Caelo | Benzocaine | 18277805 | 2 |
| Caelo | Benzocaine | 18277806 | 1 |
| Caelo | Benzocaine | 18F-B07-190519 | 1 |
| Caelo | Benzocaine | 1902004 | 1 |
| Caelo | Benzocaine | 19022001 | 10 |
| Caelo | Benzocaine | 19022004 | 11 |
| Caelo | Benzocaine | 19022006 | 3 |
| Caelo | Benzocaine | 19031301 | 1 |
| Caelo | Benzocaine | 19210006 | 1 |
| Caelo | Benzocaine | 192710002 | 2 |
| Caelo | Benzocaine | 192710003 | 23 |
| Caelo | Benzocaine | 192710004 | 3 |
| Caelo | Benzocaine | 192710006 | 24 |
| Caelo | Benzocaine | 19271003 | 1 |
| Caelo | Benzocaine | 19271006 | 1 |
| Caelo | Benzocaine | 192829002 | 1 |
| Caelo | Benzocaine | 20000972003 | 13 |
| Caelo | Benzocaine | 20004054001 | 3 |
| Caelo | Benzocaine | 20004055001 | 17 |
| Caelo | Benzocaine | 20004055005 | 1 |
| Caelo | Benzocaine | 21000114002 | 1 |
| Caelo | Benzocaine | 21000114004 | 10 |
| Caelo | Benzocaine | 21000114005 | 9 |
| Caelo | Benzocaine | 21000114006 | 1 |
| Caelo | Benzocaine | 21003052004 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Benzocaine | 21003052005 | 3 |
| Caelo | Benzocaine | 21003052007 | 8 |
| Caelo | Benzocaine | 21003052013 | 1 |
| Caelo | Benzocaine | 21J21-B01-216131 | 1 |
| Caelo | Benzocaine | 22002349008 | 1 |
| Caelo | Benzocaine | 24002905002 | 1 |
| Caelo | Benzocaine | 2412M-01118 | 1 |
| Caelo | Benzocaine | 3784947 | 1 |
| Caelo | Benzocaine | 5021401 | 1 |
| Caelo | Benzocaine | 6031501 | 1 |
| Caelo | Benzocaine | 718E-01118 | 1 |
| Caelo | Benzocaine | 91062169 | 1 |
| Caesaer/Jenne | Benzocaine | 16174019 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 18277801 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 16174019 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 1927100 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 20004055001 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 192710006 | 1 |
| Caesar & Loretz GmbH/GEHE | Benzocaine | 192710006 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 18277801 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 19022001 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 21000114005 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 21003052004 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 192710003 | 1 |
| Caesar & Loretz GmbH... | Benzocaine | 20000972003 | 2 |
| Caesar & Loretz GmbH... | Benzocaine | 21000114002 | 2 |
| Caesar & Loretz GmbH... | Benzocaine | 505500001 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 18018808 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 18277801 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 18277802 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 18277806 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 19022001 | 3 |
| Caesar & Loretz GmbH | Benzocaine | 19022004 | 4 |
| Caesar & Loretz GmbH | Benzocaine | 19022006 | 3 |
| Caesar & Loretz GmbH | Benzocaine | 192710003 | 17 |
| Caesar & Loretz GmbH | Benzocaine | 192710006 | 4 |
| Caesar & Loretz GmbH | Benzocaine | 20000972003 | 5 |
| Caesar & Loretz GmbH | Benzocaine | 20004054001 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 20004055001 | 12 |
| Caesar & Loretz GmbH | Benzocaine | 21000114002 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 21000114004 | 6 |
| Caesar & Loretz GmbH | Benzocaine | 21000114005 | 2 |
| Caesar & Loretz GmbH | Benzocaine | 21003052004 | 5 |
| Caesar & Loretz GmbH | Benzocaine | 21003052007 | 6 |
| Caesar & Loretz GmbH | Benzocaine | 22002349001 | 1 |
| Caesar & Loretz GmbH | Benzocaine | 22002349005 | 1 |
| Caesar & Loretz Hild... | Benzocaine | 192710003 | 1 |
| Caesar & Loretz Hilden | Benzocaine | 18277801 | 1 |
| Caesar & Loretz/Geil... | Benzocaine | 192710003 | 1 |
| Caesar & Loretz/Geil... | Benzocaine | 20004055001 | 1 |
| Caesar & Loretz/Geil... | Benzocaine | 21000114004 | 1 |
| Caesar Loretz | Benzocaine | 192710006 | 1 |
| Caleo/Phoenix | Benzocaine | 20004055001 | 1 |
| Cealo | Benzocaine | 21000114002 | 1 |
| Changzhou Sunlight P... | Benzocaine | 192710003 | 1 |
| Changzhou/Noweda | Benzocaine | C0011905005 | 1 |
| Euro OTC | Benzocaine | 13L06-B02-297505 | 1 |
| Euro OTC | Benzocaine | 15227313 | 1 |
| Euro OTC | Benzocaine | 15227314 | 1 |
| Fa.Phönix | Benzocaine | 21003052007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagrin/Gehe | Benzocaine | 15C19-B04 | 1 |
| Fagron | Benzocaine | | 1 |
| Fagron | Benzocaine | 104210-0001 | 1 |
| Fagron | Benzocaine | 10K02-N01 | 1 |
| Fagron | Benzocaine | 11/22-N03 | 1 |
| Fagron | Benzocaine | 11/22-N3 | 1 |
| Fagron | Benzocaine | 11K08-B40 | 4 |
| Fagron | Benzocaine | 11K08-B40-291840 | 1 |
| Fagron | Benzocaine | 11k08-b40-291841 | 1 |
| Fagron | Benzocaine | 11k08-B40-291841 | 1 |
| Fagron | Benzocaine | 11K08-B40-291841 | 6 |
| Fagron | Benzocaine | 12341904 | 1 |
| Fagron | Benzocaine | 12E014-N06 | 1 |
| Fagron | Benzocaine | 12E04-N06 | 9 |
| Fagron | Benzocaine | 12H10-N06 | 3 |
| Fagron | Benzocaine | 13F06N10 | 1 |
| Fagron | Benzocaine | 13F06-N10 | 1 |
| Fagron | Benzocaine | 13L06-B02 | 4 |
| Fagron | Benzocaine | 13L06-B02_297505 | 1 |
| Fagron | Benzocaine | 13L06-B02-294100 | 2 |
| Fagron | Benzocaine | 13L06-B02-294112 | 4 |
| Fagron | Benzocaine | 13L06-B02-300480 | 2 |
| Fagron | Benzocaine | 13l06-B02-300494 | 1 |
| Fagron | Benzocaine | 13L06-B02-300494 | 5 |
| Fagron | Benzocaine | 13L06Bo2 | 1 |
| Fagron | Benzocaine | 14G02-B01-306980 | 1 |
| Fagron | Benzocaine | 14G02-B01-310324 | 8 |
| Fagron | Benzocaine | 14G02B01318318 | 1 |
| Fagron | Benzocaine | 14G02-B01-318318 | 3 |
| Fagron | Benzocaine | 15227307 | 1 |
| Fagron | Benzocaine | 15C19-B04 | 1 |
| Fagron | Benzocaine | 15C19-B04-308254 | 1 |
| Fagron | Benzocaine | 15C19-B04-316239 | 3 |
| Fagron | Benzocaine | 15C19-B04-322019 | 7 |
| Fagron | Benzocaine | 15c19-b04-325359 | 1 |
| Fagron | Benzocaine | 15C19-B04-325359 | 3 |
| Fagron | Benzocaine | 15C-19-B04-325359 | 1 |
| Fagron | Benzocaine | 16D113-B01-345969 | 1 |
| Fagron | Benzocaine | 16D13 | 1 |
| Fagron | Benzocaine | 16D13_B01_348062 | 1 |
| Fagron | Benzocaine | 16D13-B01 | 2 |
| Fagron | Benzocaine | 16D13B01330168 | 1 |
| Fagron | Benzocaine | 16D13-B01-330168 | 1 |
| Fagron | Benzocaine | 16D13-b01-334195 | 1 |
| Fagron | Benzocaine | 16D13-B01-334195 | 3 |
| Fagron | Benzocaine | 16D13-B01-337264 | 4 |
| Fagron | Benzocaine | 16D13B01341861 | 2 |
| Fagron | Benzocaine | 16D13-B01-341861 | 2 |
| Fagron | Benzocaine | 16d13-b01-342411 | 1 |
| Fagron | Benzocaine | 16D13-B01-342411 | 5 |
| Fagron | Benzocaine | 16D13B01345969 | 1 |
| Fagron | Benzocaine | 16D13-B01-345969 | 2 |
| Fagron | Benzocaine | 16D13-B01-348062 | 6 |
| Fagron | Benzocaine | 18F18-B50 | 2 |
| Fagron | Benzocaine | 18F18B50352167 | 1 |
| Fagron | Benzocaine | 18F18-B50-352167 | 2 |
| Fagron | Benzocaine | 18F18B50352171 | 1 |
| Fagron | Benzocaine | 18F18-B50-352171 | 6 |
| Fagron | Benzocaine | 18F18B50-353577 | 1 |
| Fagron | Benzocaine | 18F18-B50-353577 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Benzocaine | 18F18-B50-35377 | 1 |
| Fagron | Benzocaine | 18F18B50355282 | 1 |
| Fagron | Benzocaine | 18F29-B07 | 1 |
| Fagron | Benzocaine | 18F29-B07_190519 | 1 |
| Fagron | Benzocaine | 18f29b07190519 | 1 |
| Fagron | Benzocaine | 18F29B07190519 | 1 |
| Fagron | Benzocaine | 18F29-B07-190519 | 19 |
| Fagron | Benzocaine | 18F-B50 | 1 |
| Fagron | Benzocaine | 18J31-B02 | 2 |
| Fagron | Benzocaine | 18J31-B02-193431 | 10 |
| Fagron | Benzocaine | 18J31-BO2 | 1 |
| Fagron | Benzocaine | 19G02-B04 | 1 |
| Fagron | Benzocaine | 19J11-011-195266 | 1 |
| Fagron | Benzocaine | 19J11-B11 | 1 |
| Fagron | Benzocaine | 19J11-B11-195266 | 8 |
| Fagron | Benzocaine | 19J11-B11-2000500 | 1 |
| Fagron | Benzocaine | 19J11-B11-200500 | 5 |
| Fagron | Benzocaine | 202522/1 | 1 |
| Fagron | Benzocaine | 20817-801-201337 | 1 |
| Fagron | Benzocaine | 20B17B01201337 | 1 |
| Fagron | Benzocaine | 20B17-B01-201337 | 1 |
| Fagron | Benzocaine | 20C09-B02 | 2 |
| Fagron | Benzocaine | 20C09-B02-200720 | 8 |
| Fagron | Benzocaine | 20C09B02-2007200 | 1 |
| Fagron | Benzocaine | 20G27-B05-201740 | 1 |
| Fagron | Benzocaine | 21A26-B18 | 1 |
| Fagron | Benzocaine | 21A26-B18-204192 | 2 |
| Fagron | Benzocaine | 21D13-B03-210845 | 3 |
| Fagron | Benzocaine | 21G17-B07-214449 | 1 |
| Fagron | Benzocaine | 21J21-B01 | 1 |
| Fagron | Benzocaine | 21J21-B01-216131 | 1 |
| Fagron | Benzocaine | 21J21-B01-218075 | 3 |
| Fagron | Benzocaine | 21J21-BO1-216131 | 1 |
| Fagron | Benzocaine | 22G25-B01-222567 | 1 |
| Fagron | Benzocaine | 2OG27-BO5-201740 | 1 |
| Fagron | Benzocaine | 400313 | 1 |
| Fagron | Benzocaine | 4413E-01118 | 1 |
| Fagron | Benzocaine | 581015 | 2 |
| Fagron | Benzocaine | B01-2005307 | 1 |
| Fagron | Benzocaine | B02-2007200 | 2 |
| Fagron | Benzocaine | B071905109 | 1 |
| Fagron | Benzocaine | B11-1952606 | 1 |
| Fagron | Benzocaine | B11-2005000 | 1 |
| Fagron | Benzocaine | BZ-08/11-12 | 1 |
| Fagron | Benzocaine | BZ-27/1112 | 1 |
| Fagron | Benzocaine | C0011803001 | 1 |
| Fagron | Benzocaine | C0011911003 | 1 |
| Fagron | Benzocaine | C0012106001 | 3 |
| Fargon/Sana | Benzocaine | 11K08-290049 | 1 |
| Fargon/Sanacorp | Benzocaine | 20C09-B02_200720 | 1 |
| Fargon | Benzocaine | 12H10-N06 | 1 |
| Fargron | Benzocaine | 13L06-B02-294112 | 1 |
| Fiebig | Benzocaine | 13L06-B02-300494 | 1 |
| Fiebig | Benzocaine | 15C19-B04-325359 | 1 |
| Fiebig | Benzocaine | 18018801 | 1 |
| Fragon | Benzocaine | B02-2007200 | 1 |
| Gehe | Benzocaine | 111214 | 1 |
| Gehe | Benzocaine | 15C19-B04 | 1 |
| Gehe | Benzocaine | 16D13-B01-337264 | 1 |
| Gehe | Benzocaine | 18018801 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Benzocaine | 18018808 | 1 |
| Gehe | Benzocaine | 18277801 | 1 |
| Gehe | Benzocaine | 18J31-B02-193431 | 1 |
| Gehe | Benzocaine | 20004055001 | 1 |
| Gehe | Benzocaine | 22002349005 | 1 |
| Gehe | Benzocaine | 22002349007 | 1 |
| Gehe | Benzocaine | 22G25-B01-227344 | 1 |
| Geibo | Benzocaine | 22G25-B01-227344 | 1 |
| Jenne / Fargon | Benzocaine | 16D13-B01-337264 | 1 |
| Jenne | Benzocaine | 21003052004 | 1 |
| Jenne | Benzocaine | 22002349001 | 1 |
| Kehr | Benzocaine | 15C19-B04-325359 | 1 |
| Kehr | Benzocaine | 16D13-B01-330168 | 1 |
| Kehr | Benzocaine | 22002349001 | 1 |
| L12 | Benzocaine | 16D13-B01-348062 | 1 |
| Mömerzheim | Benzocaine | 18018804 | 2 |
| Noweda | Benzocaine | 15227313 | 1 |
| Noweda | Benzocaine | 18018804 | 1 |
| Noweda | Benzocaine | 192710003 | 2 |
| Noweda | Benzocaine | 20000972003 | 1 |
| Noweda | Benzocaine | 21000114005 | 2 |
| noweda | Benzocaine | 21003052005 | 1 |
| Noweda | Benzocaine | 22002349007 | 2 |
| Noweda | Benzocaine | 22G25-B01-227344 | 1 |
| Noweda | Benzocaine | 22H30-B01-231909 | 1 |
| Noweda | Benzocaine | 23H08-B12-239118 | 1 |
| Noweda | Benzocaine | 24000752003 | 1 |
| otto geilenkirchen | Benzocaine | 192710006 | 1 |
| Phoenix | Benzocaine | 12H10-N06 | 1 |
| Phoenix | Benzocaine | 19022001 | 2 |
| Phoenix | Benzocaine | 19022006 | 1 |
| Phoenix | Benzocaine | 192710006 | 1 |
| Phönix | Benzocaine | 13F06-N10 | 1 |
| Phönix | Benzocaine | 20004055001 | 1 |
| s.Prüfprotokoll | Benzocaine | | 1 |
| Sanacorp W.E:07.01.1… | Benzocaine | 13213502 | 1 |
| Sanacorp | Benzocaine | 13213502 | 1 |
| Sanacorp | Benzocaine | 13213506 | 1 |
| Sanacorp | Benzocaine | 18018801 | 1 |

- 256 017 spectra from 1666 *Apo-Ident* customers from a total of 51 935 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Benzocaine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Benzocaine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 410 | 0 | 157 916 |
| **Type B** | 0 | 490 | 0 | 212 450 |
| **Type C** | 0 | 866 | 3 | 256 017 |

The substance/substance group *Benzocaine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5366 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7755 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6548 % (> 99.3096 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20843 | 20843 | 0.00 | 262.90 |
| 21083 | 21563 | 57.00 | 264.52 |
| 21563 | 21563 | 0.00 | 262.74 |
| 23569 | 23986 | 6.57 | 261.80 |
| 23986 | 23986 | 0.00 | 261.99 |
| 25172 | 21563 | 11.26 | 260.78 |
| 25195 | 25195 | 0.00 | 262.07 |
| 26346 | 26346 | 0.00 | 261.53 |
| 26493 | 26493 | 0.00 | 261.37 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Benzoic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | `20041-2025-09-30` |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Benzoic acid; Acidum benzoicum

### Special notes

When selecting the *Benzoic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Benzoic acid | 4 | 2 | 30 |

### Second-stage model

For differentiation of the substance/substance group *Benzoic acid* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Benzoic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dithranol | 73.31 | 13.34 |
| ⋮ | ⋮ | ⋮ |
| Sodium salicylate | >50 | 33.73 |
| Dequalinium chloride | >50 | 54.06 |
| Acetylsalicylic acid | >50 | 62.25 |
| Eosin Y | >50 | 220.87 |
| Oxytetracycline hydrochloride | >50 | 328.66 |
| Levothyroxin sodium | >50 | 661.20 |
| Tannin | >50 | 1493.00 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Benzoic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Benzoic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Benzoic acid | 13391310 | 21458 | 60 | 20131216 |
| Caelo | Benzoic acid | 15084614 | 22664 | 40 | 20150318 |
| Caelo | Benzoic acid | 15084611 | 23095 | 40 | 20150318 |
| Caelo | Benzoic acid | 15084614 | 23096 | 40 | 1707644 |
| Caelo | Benzoic acid | 15084614 | 23726 | 40 | 20150318 |
| Caelo | Benzoic acid | 23001052 | 26693 | 40 | 20230601* |
| Caelo | Benzoic acid | 23001052 | 26693SI | 20 | 20230601* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 280 spectra of 7 reference samples from the substance/substance group *Benzoic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

- 158 046 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 2 reference samples from the substance/substance group *Benzoic acid*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Benzoic acid | 162701 | 24027 | 40 |
| Caelo | Benzoic acid | 190752 | 24532 | 40 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 104 spectra from 74 *Apo-Ident* customers from 32 batches from the substance/substance group *Benzoic acid*.

- Among them are spectra of independent samples from 30 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Benzoic acid | 20003734013 | 1 |
| | Benzoic acid | 22001605009 | 1 |
| ACM | Benzoic acid | KNC0396J17 | 1 |
| ACM | Benzoic acid | KNC0558J15 | 1 |
| Anza | Benzoic acid | 16001702 | 1 |
| Anzag | Benzoic acid | 16001708 | 1 |
| Caelo | Benzoic acid | 10156104 | 1 |
| Caelo | Benzoic acid | 13074605 | 5 |
| Caelo | Benzoic acid | 13074610 | 4 |
| Caelo | Benzoic acid | 1339120 | 1 |
| Caelo | Benzoic acid | 13391310 | 1 |
| Caelo | Benzoic acid | 13391314 | 1 |
| Caelo | Benzoic acid | 13391320 | 1 |
| Caelo | Benzoic acid | 15084603 | 3 |
| Caelo | Benzoic acid | 15084607 | 4 |
| Caelo | Benzoic acid | 15084614 | 2 |
| Caelo | Benzoic acid | 15084701 | 1 |
| Caelo | Benzoic acid | 16001702 | 2 |
| Caelo | Benzoic acid | 16001708 | 2 |
| Caelo | Benzoic acid | 16001714 | 7 |
| Caelo | Benzoic acid | 17327003 | 2 |
| Caelo | Benzoic acid | 17327004 | 1 |
| Caelo | Benzoic acid | 17327006 | 1 |
| Caelo | Benzoic acid | 17327009 | 2 |
| Caelo | Benzoic acid | 1732701 | 1 |
| Caelo | Benzoic acid | 17327013 | 6 |
| Caelo | Benzoic acid | 17327101 | 10 |
| Caelo | Benzoic acid | 190752005 | 1 |
| Caelo | Benzoic acid | 190752007 | 6 |
| Caelo | Benzoic acid | 20003734002 | 5 |
| Caelo | Benzoic acid | 20003734004 | 1 |
| Caelo | Benzoic acid | 20003734006 | 4 |
| Caesar & Loretz GmbH... | Benzoic acid | 17327013 | 2 |
| Caesar & Loretz GmbH/Gehe | Benzoic acid | 20003734004 | 1 |
| Caesar & Loretz GmbH | Benzoic acid | 17327003 | 2 |
| Caesar & Loretz GmbH | Benzoic acid | 17327006 | 2 |
| Caesar & Loretz GmbH | Benzoic acid | 17327009 | 1 |
| Caesar & Loretz GmbH | Benzoic acid | 17327013 | 1 |
| Caesar & Loretz GmbH | Benzoic acid | 190752007 | 1 |
| Caesar & Loretz GmbH | Benzoic acid | 20003734004 | 1 |
| Caesar & Loretz GmbH | Benzoic acid | 20003734006 | 1 |
| Caesar & Loretz GmbH | Benzoic acid | 20003734013 | 1 |
| Caleo/Phoenix | Benzoic acid | 15084607 | 1 |
| Cealo, GEHE | Benzoic acid | 20003734002 | 1 |
| Cealo | Benzoic acid | 13391314 | 1 |
| Fresenius | Benzoic acid | 80715102 | 1 |
| Gatt-Koller / Phoenix | Benzoic acid | 2992/07131314 | 2 |
| Gehe | Benzoic acid | 22001605009 | 1 |
| Phönix | Benzoic acid | 16001714 | 1 |
| Phönix | Benzoic acid | 17327003 | 1 |
| Sanacorp | Benzoic acid | 16001714 | 1 |

- 256 782 spectra from 1666 *Apo-Ident* customers from a total of 52 121 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Benzoic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Benzoic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 104 | 0 | 256 782 |

The substance/substance group *Benzoic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 94.2308 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21458 | 23096 | 17.65 | 118.43 |
| 22664 | 26693 | 16.12 | 118.27 |
| 23095 | 26693 | 15.05 | 117.82 |
| 23096 | 23096 | 0.00 | 121.45 |
| 23726 | 23096 | 7.92 | 121.21 |
| 26693 | 26693 | 0.00 | 122.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Benzydamine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20624-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Benzydamine hydrochloride; Benzydamini hydrochloridum

### Special notes

When selecting the *Benzydamine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Benzydamine hydrochloride | 6 | 7 | 95 |

### Second-stage model

For differentiation of the substance/substance group *Benzydamine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Benzydamine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Doxepin hydrochloride | 52.40 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Benzydamine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Benzydamine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Benzydamine hydrochloride | AP300111801004B | 24411 | 40 | 20180418 |
| Euro OTC | Benzydamine hydrochloride | 2011014 | 25596 | 40 | 20210310* |
| Euro OTC | Benzydamine hydrochloride | 2011014-01 | 25781 | 50 | 20210317 |
| Fagron | Benzydamine hydrochloride | 14I30-B04-300713 | 21699 | 45 | AR-15-FG-015977-01 |
| Fagron | Benzydamine hydrochloride | 15I17-B02-315060 | 22268 | 60 | 20151211 |
| Fagron | Benzydamine hydrochloride | 20K16-F04-375883 | 25718 | 50 | 20210105 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 285 spectra of 6 reference samples from the substance/substance group *Benzydamine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 041 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 370 spectra of 11 reference samples from the substance/substance group *Benzydamine hydrochloride*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Benzydamine hydrochloride | 2201027 | 25967 | 40 |
| Euro OTC | Benzydamine hydrochloride | 2301015 | 26587 | 40 |
| Euro OTC | Benzydamine hydrochloride | 2401026 | 27372 | 40 |
| Euro OTC | Benzydamine hydrochloride | 2409005 | 27387 | 40 |
| Fagron | Benzydamine hydrochloride | 16D05-B50-332333 | 23203 | 40 |
| Fagron | Benzydamine hydrochloride | 17H01-B03-345050 | 23942 | 40 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-355663 | 24445 | 40 |
| Euro OTC | Benzydamine hydrochloride | 2201027 | 25967SI | 10 |
| Euro OTC | Benzydamine hydrochloride | 2301015 | 26587SI | 20 |
| Euro OTC | Benzydamine hydrochloride | 2401026 | 27372SI | 20 |
| Fagron | Benzydamine hydrochloride | 16D05-B50-332333 | 23204 | 40 |

- 212 570 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 267 spectra from 217 *Apo-Ident* customers from 103 batches from the substance/substance group *Benzydamine hydrochloride*.

- Among them are spectra of independent samples from 94 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Benzydamine hydrochloride | 12406002 | 1 |
| | Benzydamine hydrochloride | 2103302P | 1 |
| | Benzydamine hydrochloride | 21G10-B09-213933 | 1 |
| | Benzydamine hydrochloride | 21G10-B10-213932 | 5 |
| | Benzydamine hydrochloride | 21G10B10219520 | 1 |
| | Benzydamine hydrochloride | 21G10-B10-219520 | 4 |
| | Benzydamine hydrochloride | 21G10-B10-223829 | 4 |
| | Benzydamine hydrochloride | 2201027-01 | 1 |
| | Benzydamine hydrochloride | 2201027-02 | 4 |
| | Benzydamine hydrochloride | 2409005-01 | 4 |
| | Benzydamine hydrochloride | 24A11-B11-228722 | 4 |
| 20E13-F02_373489 | Benzydamine hydrochloride | Fagron | 1 |
| Anzag/ Audov | Benzydamine hydrochloride | AP300111801004B | 1 |
| Audor Pharma | Benzydamine hydrochloride | 19K25-F01 | 1 |
| Audor Pharma | Benzydamine hydrochloride | 300111702007 | 1 |
| Audor Pharma | Benzydamine hydrochloride | 300111702007b | 1 |
| Audor Pharma | Benzydamine hydrochloride | 300111702007B | 1 |
| Audor Pharma | Benzydamine hydrochloride | 300111801004B | 3 |
| Audor Pharma | Benzydamine hydrochloride | AP3000111801004B | 1 |
| Audor Pharma | Benzydamine hydrochloride | AP300111702007 | 1 |
| Audor Pharma | Benzydamine hydrochloride | AP300111702007B | 6 |
| Audor Pharma | Benzydamine hydrochloride | AP300111801004 | 1 |
| Audor Pharma | Benzydamine hydrochloride | AP300111801004B | 6 |
| Bal Pharma | Benzydamine hydrochloride | AP300111801004B | 1 |
| Caelo | Benzydamine hydrochloride | 12K07-N16 | 1 |
| Caelo | Benzydamine hydrochloride | 17H01-B03-345050 | 2 |
| Caelo | Benzydamine hydrochloride | 1803309P | 1 |
| Caelo | Benzydamine hydrochloride | 18H29B02355663 | 1 |
| Caelo | Benzydamine hydrochloride | 18H29B02-358710 | 1 |
| Caelo | Benzydamine hydrochloride | 18H29-B02-358710 | 2 |
| Caelo | Benzydamine hydrochloride | 1903303P | 1 |
| Centaur / Gehe | Benzydamine hydrochloride | 18H29-B02-361603 | 1 |
| Euro OTC | Benzydamine hydrochloride | 2001026-01 | 1 |
| Euro OTC | Benzydamine hydrochloride | 2011014-01 | 1 |
| Fagron | Benzydamine hydrochloride | | 1 |
| Fagron | Benzydamine hydrochloride | 12C20-N02 | 1 |
| Fagron | Benzydamine hydrochloride | 12J10-N03 | 1 |
| Fagron | Benzydamine hydrochloride | 12K07-N16 | 1 |
| Fagron | Benzydamine hydrochloride | 13A15-N03 | 1 |
| Fagron | Benzydamine hydrochloride | 13H19_N06 | 1 |
| Fagron | Benzydamine hydrochloride | 13H19-N06 | 1 |
| Fagron | Benzydamine hydrochloride | 14B25-B01-294054 | 1 |
| Fagron | Benzydamine hydrochloride | 1503309P | 1 |
| Fagron | Benzydamine hydrochloride | 1503313P | 1 |
| Fagron | Benzydamine hydrochloride | 1503315P | 1 |
| Fagron | Benzydamine hydrochloride | 15A14-B05 | 2 |
| Fagron | Benzydamine hydrochloride | 15A14-B05-303068 | 1 |
| Fagron | Benzydamine hydrochloride | 15A14-B05-307102 | 1 |
| Fagron | Benzydamine hydrochloride | 15A14-B05-307103 | 1 |
| Fagron | Benzydamine hydrochloride | 15I17-B02 | 1 |
| Fagron | Benzydamine hydrochloride | 16B09-B05-318272 | 3 |
| Fagron | Benzydamine hydrochloride | 16B09-B05-318273 | 2 |
| Fagron | Benzydamine hydrochloride | 16B09-B05-320007 | 2 |
| Fagron | Benzydamine hydrochloride | 16d05-b50-332333 | 1 |
| Fagron | Benzydamine hydrochloride | 16D05-B50-332333 | 1 |
| Fagron | Benzydamine hydrochloride | 16D05-b50-332334 | 1 |
| Fagron | Benzydamine hydrochloride | 16D05-B50-332334 | 3 |
| Fagron | Benzydamine hydrochloride | 1703305P | 1 |
| Fagron | Benzydamine hydrochloride | 17H01-B03 | 1 |
| Fagron | Benzydamine hydrochloride | 17H01-B03_34641 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Benzydamine hydrochloride | 17H01-B03-345050 | 5 |
| Fagron | Benzydamine hydrochloride | 17H01-B03-345051 | 2 |
| Fagron | Benzydamine hydrochloride | 17H01-B03-348469 | 4 |
| Fagron | Benzydamine hydrochloride | 17H01-B03-348470 | 1 |
| Fagron | Benzydamine hydrochloride | 1803309P | 4 |
| Fagron | Benzydamine hydrochloride | 18H29-02-358710 | 1 |
| Fagron | Benzydamine hydrochloride | 18H29-B02 | 2 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-354329 | 5 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-354330 | 2 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-355318 | 1 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-355663 | 4 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-357424 | 1 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-358710 | 4 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-358711 | 1 |
| Fagron | Benzydamine hydrochloride | 18H29-B02-361603 | 3 |
| Fagron | Benzydamine hydrochloride | 18H29-B-357424 | 1 |
| Fagron | Benzydamine hydrochloride | 1903303P | 2 |
| Fagron | Benzydamine hydrochloride | 19K25-F01 | 3 |
| Fagron | Benzydamine hydrochloride | 19K25-F01_366695 | 1 |
| Fagron | Benzydamine hydrochloride | 19K25-F01-366695 | 10 |
| Fagron | Benzydamine hydrochloride | 19K25-F01-366697 | 2 |
| Fagron | Benzydamine hydrochloride | 19K25-F01-366699 | 6 |
| Fagron | Benzydamine hydrochloride | 19K25-F01-366695 | 1 |
| Fagron | Benzydamine hydrochloride | 19K25-F01-366699 | 1 |
| Fagron | Benzydamine hydrochloride | 2003305P | 3 |
| Fagron | Benzydamine hydrochloride | 200330SP | 1 |
| Fagron | Benzydamine hydrochloride | 2003311P | 2 |
| Fagron | Benzydamine hydrochloride | 20E13-F02 | 9 |
| Fagron | Benzydamine hydrochloride | 20E13-F02-2373489 | 1 |
| Fagron | Benzydamine hydrochloride | 20E13-F02-373391 | 1 |
| Fagron | Benzydamine hydrochloride | 20E13-F02-373489 | 18 |
| Fagron | Benzydamine hydrochloride | 20E13-F02-373491 | 1 |
| Fagron | Benzydamine hydrochloride | 20K16-F04 | 1 |
| Fagron | Benzydamine hydrochloride | 2103302P | 2 |
| Fagron | Benzydamine hydrochloride | 21G10_B10 | 1 |
| Fagron | Benzydamine hydrochloride | 21G10-810-213932 | 2 |
| Fagron | Benzydamine hydrochloride | 21G10-B10 | 2 |
| Fagron | Benzydamine hydrochloride | 21G10-B10_213932 | 1 |
| Fagron | Benzydamine hydrochloride | 21G10-B10-2103932 | 1 |
| Fagron | Benzydamine hydrochloride | 21g10b10213932 | 1 |
| Fagron | Benzydamine hydrochloride | 21g10-b10-213932 | 1 |
| Fagron | Benzydamine hydrochloride | 21G10-B10-213932 | 20 |
| Fagron | Benzydamine hydrochloride | 21G10-B10-213932fagr | 1 |
| Fagron | Benzydamine hydrochloride | 21G10-B10-219520 | 1 |
| Fagron | Benzydamine hydrochloride | 220830(21G10-B10-213932) | 1 |
| Fagron | Benzydamine hydrochloride | 25021710 | 1 |
| Fagron | Benzydamine hydrochloride | 3280417 | 1 |
| Fagron | Benzydamine hydrochloride | F02-3734809 | 5 |
| Fagron | Benzydamine hydrochloride | F04-3758803 | 1 |
| Fargon/Noweda | Benzydamine hydrochloride | 19K25-F01-366695 | 1 |
| Fargon | Benzydamine hydrochloride | 21G10-B10-213932 | 1 |
| Fragron | Benzydamine hydrochloride | 18H29-B02-358711 | 1 |
| Fresenius | Benzydamine hydrochloride | 30062015099 | 1 |
| Gehe | Benzydamine hydrochloride | 18H29-B02-354329 | 1 |
| Gehe | Benzydamine hydrochloride | 200417115744 | 1 |
| Gehe | Benzydamine hydrochloride | 21G10-B10-219520 | 1 |
| Gehe | Benzydamine hydrochloride | 21G10-B10-223829 | 1 |
| Gehe | Benzydamine hydrochloride | AP300111801004B | 1 |
| GUMO | Benzydamine hydrochloride | 19k25-f01 | 1 |
| Noweda | Benzydamine hydrochloride | 21G10-B10-219520 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Benzydamine hydrochloride | 21G10-B10-223829 | 1 |
| Noweda | Benzydamine hydrochloride | 2201027-02 | 1 |
| Phönix | Benzydamine hydrochloride | 19K25-F01-366695 | 1 |
| Phönix | Benzydamine hydrochloride | 2003305P | 1 |
| Phönix | Benzydamine hydrochloride | f02-3734809 | 1 |
| Sanacorp | Benzydamine hydrochloride | 18H29-B02 | 1 |
| SANACORP | Benzydamine hydrochloride | 18H29-B02 | 1 |
| Sanacorp | Benzydamine hydrochloride | 18H29-Bo2-355663 | 1 |
| Sanacorp | Benzydamine hydrochloride | 20E13-F02-3734809 | 1 |
| Sanacorp | Benzydamine hydrochloride | 21G10-B10-213932 | 1 |

- 256 619 spectra from 1666 *Apo-Ident* customers from a total of 52 052 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Benzydamine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Benzydamine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 285 | 0 | 158 041 |
| **Type B** | 0 | 370 | 0 | 212 570 |
| **Type C** | 0 | 247 | 20 | 256 619 |

The substance/substance group *Benzydamine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8947 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.3784 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 92.5094 % (> 91.3858 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21699 | 21699 | 0.00 | 122.46 |
| 22268 | 21699 | 5.25 | 117.50 |
| 24411 | 25596 | 8.07 | 122.46 |
| 25596 | 25596 | 0.00 | 121.42 |
| 25718 | 21699 | 22.83 | 127.69 |
| 25781 | 25596 | 15.81 | 123.88 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Betaine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006496-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Betaine hydrochloride; Betaini hydrochloridum

### Special notes

When selecting the *Betaine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Betaine hydrochloride | 5 | 1 | 11 |

### Second-stage model

For differentiation of the substance/substance group *Betaine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Betaine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Methacholine chloride | 131.31 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Betaine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Betaine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Betaine hydrochloride | 2201015 | 25942 | 40 | 20220309* |
| Euro OTC | Betaine hydrochloride | 2309009 | 26992 | 40 | 20231027* |
| Euro OTC | Betaine hydrochloride | 2309009 | 26992SI | 20 | 20231027* |
| Fagron | Betaine hydrochloride | 13H13-N02 | 20969 | 40 | 1402684 |
| Fagron | Betaine hydrochloride | BH20240119 | BR20011 | 40 | 20240118* |
| Gatt-Koller | Betaine hydrochloride | 23J02134 | 27301 | 40 | 20231121 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 220 spectra of 6 reference samples from the substance/substance group *Betaine hydrochloride*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

- 158 106 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 90 spectra of 4 reference samples from the substance/substance group *Betaine hydrochloride*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Betaine hydrochloride | 2503004 | 27627 | 40 |
| Euro OTC | Betaine hydrochloride | 2201015 | 25942SI† | 10 |
| Fagron | Betaine hydrochloride | BH20240119 | BR20011SI† | 20 |
| Gatt-Koller | Betaine hydrochloride | 23J02134 | 27301SI† | 20 |

- 212 850 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 12 spectra from 9 *Apo-Ident* customers from 11 batches from the substance/substance group *Betaine hydrochloride*.
- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Betaine hydrochloride | 1202008-01 | 1 |
| Euro OTC | Betaine hydrochloride | 1305027-01 | 2 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Betaine hydrochloride | 1510011-02 | 1 |
| Euro OTC | Betaine hydrochloride | L1412019-01 | 1 |
| Euro OTC | Betaine hydrochloride | L1510011-03 | 1 |
| Euro OTC | Betaine hydrochloride | L1701040-01 | 1 |
| Fagron | Betaine hydrochloride | 12C20-N09 | 1 |
| Fagron | Betaine hydrochloride | 13G29-B02-294870 | 1 |
| Fagron | Betaine hydrochloride | 15121401 | 1 |
| Fagron | Betaine hydrochloride | 24091301 | 1 |
| Gatt-Koller | Betaine hydrochloride | 2970/07102910 | 1 |

- 256 874 spectra from 1666 *Apo-Ident* customers from a total of 52 142 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Betaine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Betaine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 220 | 0 | 158 106 |
| **Type B** | 0 | 90 | 0 | 212 850 |
| **Type C** | 0 | 12 | 0 | 256 874 |

The substance/substance group *Betaine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.2727 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 93.3333 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20969 | 20969 | 0.00 | 221.90 |
| 25942 | 25942 | 0.00 | 212.56 |
| 26992 | 26992 | 0.00 | 221.87 |
| 27301 | 26992 | 4.25 | 221.56 |
| BR20011 | BR20011 | 0.00 | 209.71 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Betaine monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20498-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Betaine monohydrate; Betainum monohydricum

### Special notes

When selecting the *Betaine monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Betaine monohydrate | 4 | 1 | 4 |

### Second-stage model

For differentiation of the substance/substance group *Betaine monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Betaine monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 134.20 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Betaine monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Betaine monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Betaine monohydrate | 12336602 | 20991 | 40 | 1403327 |
| Fagron | Betaine monohydrate | 14I26-B06-309878 | 21956 | 60 | 20141212 |
| Fagron | Betaine monohydrate | 18H13-B01-355585 | 24585 | 40 | 20180907 |
| Fagron | Betaine monohydrate | 20J26-B02-201459 | 25480 | 40 | 20201104 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 180 spectra of 4 reference samples from the substance/substance group *Betaine monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 146 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by


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this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 2 reference samples from the substance/substance group *Betaine monohydrate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Betaine monohydrate | 16H03-B04-330370 | 23092 | 40 |
| Fagron | Betaine monohydrate | 16H03-B04-330370 | 23378 | 40 |

- 212 860 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4 spectra from 3 *Apo-Ident* customers from 4 batches from the substance/substance group *Betaine monohydrate*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betaine monohydrate | 14A14-B02-292983 | 1 |
| Caelo | Betaine monohydrate | 4312172831 | 1 |
| Fagron | Betaine monohydrate | 16H03-B04 | 1 |
| Fagron | Betaine monohydrate | 16H03-B04-330370 | 1 |

- 256 882 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Betaine monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Betaine monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 4 | 0 | 256 882 |

The substance/substance group *Betaine monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20991 | 20991 | 0.00 | 272.04 |
| 21956 | 20991 | 6.49 | 271.65 |
| 24585 | 20991 | 11.25 | 267.02 |
| 25480 | 20991 | 13.85 | 272.16 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Betamethasone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20943-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Betamethasone; Betamethasonum

### Special notes

When selecting the *Betamethasone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Betamethasone | 5 | 3 | 38 |

### Second-stage model

For differentiation of the substance/substance group *Betamethasone* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Betamethasone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 91.40 | – |
| ⋮ | ⋮ | ⋮ |
| Methylprednisolone | >50 | 52.42 |
| Dexamethasone | >50 | 57.14 |
| Fluocinolone acetonide | >50 | 58.62 |
| Triamcinolone acetonide | >50 | 64.54 |
| Prednisolone | >50 | 67.35 |
| Tyrothricin | >50 | 90.23 |
| Gramicidin | >50 | 153.50 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Betamethasone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Betamethasone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Betamethasone | 12D26-N08 | 20943 | 40 | 1402096 |
| Fagron | Betamethasone | 13H08-N06 | 21579 | 60 | 1411037 |
| Fagron | Betamethasone | 11H31-B06-288219 | 22493 | 40 | 1608324 |
| Fagron | Betamethasone | 20A27-F07-368847 | 25173 | 40 | 20200320 |
| Fagron | Betamethasone | 23F15-B13-227908 | 26981 | 40 | 20230817 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:


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**Type A** All calibration spectra.

- 220 spectra of 5 reference samples from the substance/substance group *Betamethasone*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

- 158 106 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 4 reference samples from the substance/substance group *Betamethasone*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Betamethasone | 14C13-B02-296165 | 22897 | 40 |
| Fagron | Betamethasone | 15L09-B05-324091 | 22904 | 40 |
| Fagron | Betamethasone | 21K15-B08-213853 | 26062 | 40 |
| Fagron | Betamethasone | 21K15-B08-213853 | 26062SI | 40 |

- 212 780 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 53 spectra from 38 *Apo-Ident* customers from 40 batches from the substance/substance group *Betamethasone*.

- Among them are spectra of independent samples from 38 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| BASF/Phönix | Betamethasone | ZBtBY13004 | 1 |
| Caelo | Betamethasone | 11/14-N02 | 1 |
| Caelo | Betamethasone | 16l07-B01-341871 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone | 11/14-N02 | 1 |
| Fagron | Betamethasone | 11H31-B06-288217 | 1 |
| Fagron | Betamethasone | 12B20-N05 | 2 |
| Fagron | Betamethasone | 12D26-N08 | 1 |
| Fagron | Betamethasone | 12D26-NO8 | 1 |
| Fagron | Betamethasone | 12J01-N02 | 1 |
| Fagron | Betamethasone | 14C13-B02 | 2 |
| Fagron | Betamethasone | 14C13-B02-296154 | 1 |
| Fagron | Betamethasone | 14C13-B02-296164 | 2 |
| Fagron | Betamethasone | 14C13-B02-305561 | 1 |
| Fagron | Betamethasone | 14c13-bo2-305561 | 1 |
| Fagron | Betamethasone | 15L09-B05 | 1 |
| Fagron | Betamethasone | 15L09-B05_322119 | 1 |
| Fagron | Betamethasone | 16I07-B01-341871 | 3 |
| Fagron | Betamethasone | 1810B02-353535 | 1 |
| Fagron | Betamethasone | 18I10-B02-353535 | 1 |
| Fagron | Betamethasone | 18I10-B02-353536 | 2 |
| Fagron | Betamethasone | 18I10-B02-355063 | 2 |
| Fagron | Betamethasone | 18I10-B02-357418 | 1 |
| Fagron | Betamethasone | 18l10-B02-355063 | 1 |
| Fagron | Betamethasone | 20A27-F07 | 1 |
| Fagron | Betamethasone | 20A27-F07-368846 | 2 |
| Fagron | Betamethasone | 20A27-F07-368847 | 1 |
| Fagron | Betamethasone | 20A27-F07-370552 | 1 |
| Fagron | Betamethasone | 21K15-B08-213852 | 1 |
| Fagron | Betamethasone | 9071304 | 1 |
| Fagron | Betamethasone | 9J26-N08 | 1 |
| Fagron | Betamethasone | 9K25-N13 | 1 |
| Fagron | Betamethasone | BT-191101 | 1 |
| Fagron | Betamethasone | F07-3705501 | 1 |
| Fagron | Betamethasone | ZBTBY15002 | 1 |
| Fargon | Betamethasone | 20A27-F07-370551 | 1 |
| Fiebig | Betamethasone | 12J01-120301-m1 | 1 |
| Gehe amax | Betamethasone | 18/10-B02-353535 | 1 |
| Gehe | Betamethasone | 15L09-B05-319353 | 1 |
| Huan Yuxin Pharmaceutics | Betamethasone | 20A27-F07-370551 | 1 |
| Hunan Yuxin Pharmace… | Betamethasone | 20A27-F07-372113 | 1 |
| Noweda | Betamethasone | 12B20-N05 | 1 |
| Noweda | Betamethasone | M-XO1-120301m1 | 1 |
| Phönix | Betamethasone | 12B20-N05 | 1 |
| Symbiotec Pharmalab … | Betamethasone | 14C13-B02 | 1 |
| Unisan | Betamethasone | Retest09K25-N13 | 1 |

- 256 833 spectra from 1666 *Apo-Ident* customers from a total of 52 113 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Betamethasone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Betamethasone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 220 | 0 | 158 106 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 48 | 5 | 256 833 |

The substance/substance group *Betamethasone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.2727 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 90.5660 % (> 84.9057 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20943 | 20943 | 0.00 | 115.27 |
| 21579 | 21579 | 0.00 | 128.15 |
| 22493 | 22493 | 0.00 | 126.65 |
| 25173 | 21579 | 26.30 | 133.21 |
| 26981 | 21579 | 22.02 | 134.68 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Betamethasone dipropionate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20930-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Betamethasone dipropionate; Betamethasoni dipropionas

### Special notes

When selecting the *Betamethasone dipropionate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.

2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.

3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Betamethasone dipropionate | 7 | 15 | 303 |

### Second-stage model

For differentiation of the substance/substance group *Betamethasone dipropionate* the following second-stage model is used:

- Submodel 15

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Betamethasone dipropionate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Beclometasone dipropionate | 37.17 | 33.36 |
| Clobetasol propionate | 38.48 | 53.00 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Betamethasone dipropionate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Betamethasone dipropionate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Betamethasone dipropionate | 13372501 | 21250 | 40 | AR-15-FG-005428-01 |
| Caelo | Betamethasone dipropionate | 13236803 | 21366 | 50 | 20130730 |
| Caelo | Betamethasone dipropionate | 13236803 | 21367 | 40 | 20130730 |
| Euro OTC | Betamethasone dipropionate | 1311023-01 | 21716 | 60 | 1505455 |
| Euro OTC | Betamethasone dipropionate | 1601034 | 22372 | 45 | 20160204* |
| Euro OTC | Betamethasone dipropionate | 2102001 | 25691 | 50 | 20210528* |
| Euro OTC | Betamethasone dipropionate | 2102001 | 25691SI | 50 | 20210528* |
| Fagron | Betamethasone dipropionate | 13I17-N05 | 20930 | 40 | 1401377 |
| Fagron | Betamethasone dipropionate | 13I17-N05 | 20952 | 80 | 20130926 |
| Fagron | Betamethasone dipropionate | 16C04-B03-324513 | 22898 | 40 | 20160421 |
| Fagron | Betamethasone dipropionate | 16C04-B03-324513 | 22898SI | 39 | 20160421 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 534 spectra of 11 reference samples from the substance/substance group *Betamethasone dipropionate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 792 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1373 spectra of 35 reference samples from the substance/substance group *Betamethasone dipropionate*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Betamethasone dipropionate | 171059 | 23342 | 40 |
| Caelo | Betamethasone dipropionate | 173536 | 23839 | 40 |
| Caelo | Betamethasone dipropionate | 22001649001 | 26313 | 40 |
| Euro OTC | Betamethasone dipropionate | 1610014 | 22851 | 40 |
| Euro OTC | Betamethasone dipropionate | 1705020 | 23539 | 40 |
| Euro OTC | Betamethasone dipropionate | 1801045 | 24090 | 40 |
| Euro OTC | Betamethasone dipropionate | 1811007 | 24343 | 40 |
| Euro OTC | Betamethasone dipropionate | 1907034 | 24796 | 40 |
| Euro OTC | Betamethasone dipropionate | 2003057 | 25309 | 40 |
| Euro OTC | Betamethasone dipropionate | 2110005 | 25914 | 40 |
| Euro OTC | Betamethasone dipropionate | 2208030 | 26345 | 40 |
| Euro OTC | Betamethasone dipropionate | 2301013 | 26573 | 40 |
| Euro OTC | Betamethasone dipropionate | 2406016 | 27350 | 40 |
| Fagron | Betamethasone dipropionate | 21K24-B04-216140 | 26178 | 40 |
| Fagron | Betamethasone dipropionate | 25C07-B07-008829 | 27609 | 40 |
| Caelo | Betamethasone dipropionate | 13372501 | 21250SI† | 45 |
| Caelo | Betamethasone dipropionate | 13236803 | 21366SI† | 46 |
| Caelo | Betamethasone dipropionate | 13236803 | 21367SI† | 60 |
| Caelo | Betamethasone dipropionate | 171059 | 23342SI | 20 |
| Caelo | Betamethasone dipropionate | 173536 | 23839SI | 25 |
| Caelo | Betamethasone dipropionate | 22001649001 | 26313SI | 40 |
| Euro OTC | Betamethasone dipropionate | 1311023-01 | 21716SI† | 46 |
| Euro OTC | Betamethasone dipropionate | 1601034 | 22372SI† | 45 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Betamethasone dipropionate | 1610014 | 22851SI | 30 |
| Euro OTC | Betamethasone dipropionate | 1705020 | 23539SI | 27 |
| Euro OTC | Betamethasone dipropionate | 1801045 | 24090SI | 39 |
| Euro OTC | Betamethasone dipropionate | 1811007 | 24343SI | 30 |
| Euro OTC | Betamethasone dipropionate | 1907034 | 24796SI | 40 |
| Euro OTC | Betamethasone dipropionate | 2003057 | 25309SI | 40 |
| Euro OTC | Betamethasone dipropionate | 2110005 | 25914SI | 40 |
| Euro OTC | Betamethasone dipropionate | 2208030 | 26345SI | 40 |
| Euro OTC | Betamethasone dipropionate | 2301013 | 26573SI | 40 |
| Euro OTC | Betamethasone dipropionate | 2406016 | 27350SI | 40 |
| Fagron | Betamethasone dipropionate | 21K24-B04-216140 | 26178SI | 40 |
| Fagron | Betamethasone dipropionate | 25C07-B07-008829 | 27609SI | 40 |

- 211 567 spectra from a total of 4268 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1777 spectra from 718 *Apo-Ident* customers from 321 batches from the substance/substance group *Betamethasone dipropionate*.

- Among them are spectra of independent samples from 303 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Betamethasone dipropionate | | 1 |
| | Betamethasone dipropionate | 13/17-N05 | 2 |
| | Betamethasone dipropionate | 19000537003 | 1 |
| | Betamethasone dipropionate | 19000537007 | 1 |
| | Betamethasone dipropionate | 2110005-01 | 1 |
| | Betamethasone dipropionate | 21H18-B04-213656 | 1 |
| | Betamethasone dipropionate | 21K24-B04 | 1 |
| | Betamethasone dipropionate | 21K24-B04-220120 | 2 |
| | Betamethasone dipropionate | 21K24-B04-222402 | 2 |
| | Betamethasone dipropionate | 21K24-B04-222404 | 1 |
| | Betamethasone dipropionate | 21K24-B04-224485 | 1 |
| | Betamethasone dipropionate | 21K24-B04-227289 | 6 |
| | Betamethasone dipropionate | 21K24-B04-227290 | 1 |
| | Betamethasone dipropionate | 22001649001 | 2 |
| | Betamethasone dipropionate | 22001649002 | 2 |
| | Betamethasone dipropionate | 22001649003 | 1 |
| | Betamethasone dipropionate | 22001649005 | 2 |
| | Betamethasone dipropionate | 22001649007 | 4 |
| | Betamethasone dipropionate | 22001649008 | 8 |
| | Betamethasone dipropionate | 22001649009 | 2 |
| | Betamethasone dipropionate | 22003962001 | 10 |
| | Betamethasone dipropionate | 22003962002 | 22 |
| | Betamethasone dipropionate | 22003962004 | 1 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Betamethasone dipropionate | 22003962007 | 8 |
| | Betamethasone dipropionate | 2203962002 | 2 |
| | Betamethasone dipropionate | 2208030-01 | 10 |
| | Betamethasone dipropionate | 228030-01 | 1 |
| | Betamethasone dipropionate | 23003250001 | 6 |
| | Betamethasone dipropionate | 23003250005 | 3 |
| | Betamethasone dipropionate | 2301013 | 1 |
| | Betamethasone dipropionate | 2301013-01 | 11 |
| | Betamethasone dipropionate | 2301013-02 | 1 |
| | Betamethasone dipropionate | BDP004/0821 | 1 |
| | Betamethasone dipropionate | BDP104/0622 | 1 |
| AHD/Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648013 | 1 |
| AHD | Betamethasone dipropionate | 18B06-B05-346219 | 1 |
| AHD | Betamethasone dipropionate | 22003962004 | 1 |
| Alliance Health 24.0... | Betamethasone dipropionate | 13/17-N05 | 1 |
| Alliance | Betamethasone dipropionate | 22003962001 | 2 |
| Anzag | Betamethasone dipropionate | 12114513 | 2 |
| Apo-ident | Betamethasone dipropionate | 1601034-01 | 3 |
| apo-ident | Betamethasone dipropionate | 1907034 | 1 |
| Bombastus | Betamethasone dipropionate | 12B27N08 | 1 |
| cae | Betamethasone dipropionate | 17353601 | 1 |
| Cae | Betamethasone dipropionate | 18293408 | 1 |
| Caelo | Betamethasone dipropionate | | 2 |
| Caelo | Betamethasone dipropionate | 1210020-01 | 1 |
| Caelo | Betamethasone dipropionate | 12114501 | 1 |
| Caelo | Betamethasone dipropionate | 12114506 | 1 |
| Caelo | Betamethasone dipropionate | 12114507 | 2 |
| Caelo | Betamethasone dipropionate | 12114512 | 1 |
| Caelo | Betamethasone dipropionate | 12114513 | 1 |
| Caelo | Betamethasone dipropionate | 13023001 | 3 |
| Caelo | Betamethasone dipropionate | 13023002 | 5 |
| Caelo | Betamethasone dipropionate | 13023002NP | 1 |
| Caelo | Betamethasone dipropionate | 13023005 | 7 |
| Caelo | Betamethasone dipropionate | 1303006-01 | 1 |
| Caelo | Betamethasone dipropionate | 13125701 | 3 |
| Caelo | Betamethasone dipropionate | 13125703 | 5 |
| Caelo | Betamethasone dipropionate | 13236801 | 4 |
| Caelo | Betamethasone dipropionate | 13236801ok | 1 |
| Caelo | Betamethasone dipropionate | 13236802 | 4 |
| Caelo | Betamethasone dipropionate | 13236803 | 1 |
| Caelo | Betamethasone dipropionate | 13236805 | 5 |
| Caelo | Betamethasone dipropionate | 13236806 | 3 |
| Caelo | Betamethasone dipropionate | 1325702 | 1 |
| Caelo | Betamethasone dipropionate | 13372501 | 3 |
| Caelo | Betamethasone dipropionate | 13372503 | 7 |
| Caelo | Betamethasone dipropionate | 13372504 | 5 |
| Caelo | Betamethasone dipropionate | 13372512 | 1 |
| Caelo | Betamethasone dipropionate | 13372514 | 12 |
| Caelo | Betamethasone dipropionate | 13372515 | 3 |
| Caelo | Betamethasone dipropionate | 13372516 | 4 |
| Caelo | Betamethasone dipropionate | 13372520 | 2 |
| Caelo | Betamethasone dipropionate | 140507 | 1 |
| Caelo | Betamethasone dipropionate | 14C03-B06-296837 | 1 |
| Caelo | Betamethasone dipropionate | 1503003-01 | 2 |
| Caelo | Betamethasone dipropionate | 1503003-02 | 1 |
| Caelo | Betamethasone dipropionate | 150605BD | 1 |
| Caelo | Betamethasone dipropionate | 15163204 | 1 |
| Caelo | Betamethasone dipropionate | 15163301 | 15 |
| Caelo | Betamethasone dipropionate | 15163302 | 6 |
| Caelo | Betamethasone dipropionate | 15163303 | 12 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone dipropionate | 15163304 | 18 |
| Caelo | Betamethasone dipropionate | 15163305 | 1 |
| Caelo | Betamethasone dipropionate | 15238701 | 32 |
| Caelo | Betamethasone dipropionate | 15412901 | 1 |
| Caelo | Betamethasone dipropionate | 15412903 | 2 |
| Caelo | Betamethasone dipropionate | 15412905 | 1 |
| Caelo | Betamethasone dipropionate | 15412906 | 12 |
| Caelo | Betamethasone dipropionate | 15412907 | 5 |
| Caelo | Betamethasone dipropionate | 15412909 | 1 |
| Caelo | Betamethasone dipropionate | 15412910 | 7 |
| Caelo | Betamethasone dipropionate | 15412913 | 1 |
| Caelo | Betamethasone dipropionate | 15412914 | 7 |
| Caelo | Betamethasone dipropionate | 15412915 | 2 |
| Caelo | Betamethasone dipropionate | 15412916 | 1 |
| Caelo | Betamethasone dipropionate | 15H28-B06 | 1 |
| Caelo | Betamethasone dipropionate | 15H28B06313088 | 1 |
| Caelo | Betamethasone dipropionate | 15H28-B06-313088 | 1 |
| Caelo | Betamethasone dipropionate | 15-H28-B06-313088 | 1 |
| Caelo | Betamethasone dipropionate | 17015905 | 1 |
| Caelo | Betamethasone dipropionate | 1705020-01 | 1 |
| Caelo | Betamethasone dipropionate | 17105901 | 19 |
| Caelo | Betamethasone dipropionate | 17105902 | 17 |
| Caelo | Betamethasone dipropionate | 17105903 | 1 |
| Caelo | Betamethasone dipropionate | 17105905 | 4 |
| Caelo | Betamethasone dipropionate | 17105906 | 16 |
| Caelo | Betamethasone dipropionate | 17105907 | 10 |
| Caelo | Betamethasone dipropionate | 17105909 | 3 |
| Caelo | Betamethasone dipropionate | 17105911 | 6 |
| Caelo | Betamethasone dipropionate | 17353601 | 20 |
| Caelo | Betamethasone dipropionate | 17353603 | 16 |
| Caelo | Betamethasone dipropionate | 1735601 | 1 |
| Caelo | Betamethasone dipropionate | 17B16-B04 | 1 |
| Caelo | Betamethasone dipropionate | 17B16-B04-332220 | 1 |
| Caelo | Betamethasone dipropionate | 17E22-B06-336993 | 1 |
| Caelo | Betamethasone dipropionate | 17H16B04340537 | 1 |
| Caelo | Betamethasone dipropionate | 1801045-01 | 3 |
| Caelo | Betamethasone dipropionate | 18041819 | 1 |
| Caelo | Betamethasone dipropionate | 18090601 | 7 |
| Caelo | Betamethasone dipropionate | 18090602 | 7 |
| Caelo | Betamethasone dipropionate | 18090603 | 13 |
| Caelo | Betamethasone dipropionate | 18090606 | 22 |
| Caelo | Betamethasone dipropionate | 18090607 | 14 |
| Caelo | Betamethasone dipropionate | 18090608 | 15 |
| Caelo | Betamethasone dipropionate | 1811007-01 | 2 |
| Caelo | Betamethasone dipropionate | 18121306 | 1 |
| Caelo | Betamethasone dipropionate | 18127B03357221 | 1 |
| Caelo | Betamethasone dipropionate | 18292406 | 1 |
| Caelo | Betamethasone dipropionate | 18293402 | 12 |
| Caelo | Betamethasone dipropionate | 18293404 | 14 |
| Caelo | Betamethasone dipropionate | 182934046 | 1 |
| Caelo | Betamethasone dipropionate | 18293406 | 26 |
| Caelo | Betamethasone dipropionate | 18293407 | 4 |
| Caelo | Betamethasone dipropionate | 18293408 | 26 |
| Caelo | Betamethasone dipropionate | 18294306 | 1 |
| Caelo | Betamethasone dipropionate | 18B06B05350473 | 1 |
| Caelo | Betamethasone dipropionate | 18B06-B05-350473 | 2 |
| Caelo | Betamethasone dipropionate | 18B06-B05-352731 | 1 |
| Caelo | Betamethasone dipropionate | 18I27B03357221 | 1 |
| Caelo | Betamethasone dipropionate | 19000537003 | 10 |
| Caelo | Betamethasone dipropionate | 19000537007 | 24 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone dipropionate | 19000537008 | 5 |
| Caelo | Betamethasone dipropionate | 19000537010 | 11 |
| Caelo | Betamethasone dipropionate | 1900537008 | 1 |
| Caelo | Betamethasone dipropionate | 1900537010 | 1 |
| Caelo | Betamethasone dipropionate | 1907034-01 | 1 |
| Caelo | Betamethasone dipropionate | 20003997001 | 7 |
| Caelo | Betamethasone dipropionate | 20003997002 | 8 |
| Caelo | Betamethasone dipropionate | 20003997005 | 14 |
| Caelo | Betamethasone dipropionate | 2000648010 | 1 |
| Caelo | Betamethasone dipropionate | 2100064013 | 1 |
| Caelo | Betamethasone dipropionate | 21000645001 | 2 |
| Caelo | Betamethasone dipropionate | 21000648001 | 1 |
| Caelo | Betamethasone dipropionate | 21000648002 | 4 |
| Caelo | Betamethasone dipropionate | 21000648003 | 5 |
| Caelo | Betamethasone dipropionate | 21000648004 | 6 |
| Caelo | Betamethasone dipropionate | 21000648006 | 8 |
| Caelo | Betamethasone dipropionate | 21000648007 | 13 |
| Caelo | Betamethasone dipropionate | 21000648010 | 15 |
| Caelo | Betamethasone dipropionate | 21000648012 | 2 |
| Caelo | Betamethasone dipropionate | 21000648013 | 10 |
| Caelo | Betamethasone dipropionate | 21000648014 | 5 |
| Caelo | Betamethasone dipropionate | 2100648006 | 1 |
| Caelo | Betamethasone dipropionate | 2109DMOB00111322 | 1 |
| Caelo | Betamethasone dipropionate | 21648004 | 1 |
| Caelo | Betamethasone dipropionate | 22001649001 | 14 |
| Caelo | Betamethasone dipropionate | 22001649002 | 13 |
| Caelo | Betamethasone dipropionate | 22001649003 | 1 |
| Caelo | Betamethasone dipropionate | 22001649005 | 4 |
| Caelo | Betamethasone dipropionate | 220016490054 | 1 |
| Caelo | Betamethasone dipropionate | 22001649007 | 2 |
| Caelo | Betamethasone dipropionate | 22001649008 | 1 |
| Caelo | Betamethasone dipropionate | 22003962002 | 1 |
| Caelo | Betamethasone dipropionate | 220621(21000648014) | 1 |
| Caelo | Betamethasone dipropionate | 3170717 | 1 |
| Caelo | Betamethasone dipropionate | 700216-0001 | 1 |
| Caelo | Betamethasone dipropionate | 8K03-N13 | 1 |
| Caelo | Betamethasone dipropionate | AKD11 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18293406 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18293402 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18293408 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18090603 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 22001649005 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 20003997001 | 2 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18293408 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 22001649005 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 21000648013 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 21000648007 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 19000537003 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18293408 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone dipropionate | 18090606 | 2 |
| Caesar & Loretz GmbH/Gehe | Betamethasone dipropionate | 19000537003 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone dipropionate | 20003997001 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone dipropionate | 21000648006 | 2 |
| Caesar & Loretz GmbH/Gehe | Betamethasone dipropionate | 21000648010 | 1 |
| Caesar & Loretz GmbH/K | Betamethasone dipropionate | 21000648013 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18090602 | 2 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 19000537010 | 2 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 20003997005 | 2 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 20003997002 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 21000648004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/S | Betamethasone dipropionate | 21000648007 | 1 |
| Caesar & Loretz GmbH/S | Betamethasone dipropionate | 22001649002 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 18293406 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 20003997005 | 2 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 21000648007 | 1 |
| Caesar & Loretz GmbH... | Betamethasone dipropionate | 21000648014 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 17105902 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 17353605 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 18090606 | 2 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 18090608 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 18293402 | 3 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 18293404 | 5 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 18293406 | 10 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 18293407 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 18293408 | 7 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 19000537003 | 4 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 19000537007 | 6 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 19000537008 | 2 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 19000537010 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 20003997001 | 7 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 20003997002 | 3 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 20003997005 | 9 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648001 | 2 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648002 | 7 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648003 | 3 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648004 | 4 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648006 | 4 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648007 | 2 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648010 | 5 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648012 | 3 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648013 | 2 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 21000648014 | 3 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 2100648006 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 22001649001 | 9 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 22001649002 | 4 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 22001649005 | 1 |
| Caesar & Loretz GmbH | Betamethasone dipropionate | 22001649007 | 3 |
| Caesar & Loretz Hild... | Betamethasone dipropionate | 18293408 | 1 |
| Caesar & Loretz Hilden | Betamethasone dipropionate | 18293404 | 1 |
| Caesar & Loretz Hilden | Betamethasone dipropionate | 18293406 | 1 |
| Caesar & Loretz Hilden | Betamethasone dipropionate | 19000537007 | 1 |
| Caesar & Loretz | Betamethasone dipropionate | 22001649002 | 1 |
| Caesar & Loretz | Betamethasone dipropionate | 22001649005 | 1 |
| Cealo / Otto Geilenk... | Betamethasone dipropionate | 18293402 | 1 |
| Cealo/ AHD | Betamethasone dipropionate | 18293402 | 1 |
| Cealo/Sanacorp | Betamethasone dipropionate | 13125701 | 1 |
| Cealo | Betamethasone dipropionate | 17353601 | 1 |
| Crystal Pharma / Ebert | Betamethasone dipropionate | 15163301 | 1 |
| Crystal Pharma / Gehe | Betamethasone dipropionate | 17105906 | 1 |
| Delta | Betamethasone dipropionate | 18B06-B05-346219 | 1 |
| EU RHO/GEHE | Betamethasone dipropionate | 2003057-01 | 1 |
| EuRho/ Noweda | Betamethasone dipropionate | 2003057-01 | 1 |
| EuRho/ Noweda | Betamethasone dipropionate | 2208030-01 | 1 |
| EuRho/Alliance | Betamethasone dipropionate | 2003057-01 | 1 |
| EuRho/Fiebig | Betamethasone dipropionate | 1811007-01 | 1 |
| EuRho/Noweda | Betamethasone dipropionate | 1907034-01 | 2 |
| EuRho/Phoenix | Betamethasone dipropionate | 2102001-01 | 1 |
| Eurho/Phönix | Betamethasone dipropionate | | 1 |
| EuRho/Phönix | Betamethasone dipropionate | 2003057-01 | 1 |
| euro AHD | Betamethasone dipropionate | 1801045-015715 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| euro AHD | Betamethasone dipropionate | 1801045-015787 | 1 |
| Euro OTC | Betamethasone dipropionate | 102001-012 | 1 |
| Euro OTC | Betamethasone dipropionate | 111007-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 121002001 | 1 |
| Euro OTC | Betamethasone dipropionate | 12114511 | 2 |
| Euro OTC | Betamethasone dipropionate | 1303006/01 | 1 |
| Euro OTC | Betamethasone dipropionate | 1303006-01 | 2 |
| Euro OTC | Betamethasone dipropionate | 1303006-02 | 1 |
| Euro OTC | Betamethasone dipropionate | 1305041-01 | 10 |
| Euro OTC | Betamethasone dipropionate | 1305041-02 | 3 |
| Euro OTC | Betamethasone dipropionate | 130541-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 131023-02 | 1 |
| Euro OTC | Betamethasone dipropionate | 131102301 | 2 |
| Euro OTC | Betamethasone dipropionate | 1311023-01 | 11 |
| Euro OTC | Betamethasone dipropionate | 1311023-02 | 5 |
| Euro OTC | Betamethasone dipropionate | 13125702 | 1 |
| Euro OTC | Betamethasone dipropionate | 13372501 | 1 |
| Euro OTC | Betamethasone dipropionate | 1503003-01 | 10 |
| Euro OTC | Betamethasone dipropionate | 150300302 | 1 |
| Euro OTC | Betamethasone dipropionate | 1503003-02 | 12 |
| Euro OTC | Betamethasone dipropionate | 1506016-02 | 1 |
| Euro OTC | Betamethasone dipropionate | 15163304 | 1 |
| Euro OTC | Betamethasone dipropionate | 153003-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 160103401 | 1 |
| Euro OTC | Betamethasone dipropionate | 1601034-01 | 22 |
| Euro OTC | Betamethasone dipropionate | 1610014-01 | 37 |
| Euro OTC | Betamethasone dipropionate | 1610014-015308 | 1 |
| Euro OTC | Betamethasone dipropionate | 17050-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 170502001 | 1 |
| Euro OTC | Betamethasone dipropionate | 1705020-01 | 27 |
| Euro OTC | Betamethasone dipropionate | 17B16-B04-332218 | 1 |
| Euro OTC | Betamethasone dipropionate | 180104501 | 3 |
| Euro OTC | Betamethasone dipropionate | 1801045-01 | 27 |
| Euro OTC | Betamethasone dipropionate | 180808185 | 1 |
| Euro OTC | Betamethasone dipropionate | 1811007 | 1 |
| Euro OTC | Betamethasone dipropionate | 181100701 | 2 |
| Euro OTC | Betamethasone dipropionate | 1811007-01 | 26 |
| Euro OTC | Betamethasone dipropionate | 19070324-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 1907034 | 1 |
| Euro OTC | Betamethasone dipropionate | 190703401 | 1 |
| Euro OTC | Betamethasone dipropionate | 1907034-01 | 33 |
| Euro OTC | Betamethasone dipropionate | 1907234-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 20030057-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 2003024-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 200305-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 2003057 | 1 |
| Euro OTC | Betamethasone dipropionate | 2003057-01 | 35 |
| Euro OTC | Betamethasone dipropionate | 2102001-01 | 22 |
| Euro OTC | Betamethasone dipropionate | 211000-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 2110005-01 | 16 |
| Euro OTC | Betamethasone dipropionate | 2110005-02 | 10 |
| Euro OTC | Betamethasone dipropionate | 2208030-01 | 9 |
| Euro OTC | Betamethasone dipropionate | 2208030-1 | 1 |
| Euro OTC | Betamethasone dipropionate | 2208630-01 | 1 |
| Euro OTC | Betamethasone dipropionate | 2301013-01 | 1 |
| Euro OTC | Betamethasone dipropionate | BDP102/0817 | 1 |
| Euro OTC | Betamethasone dipropionate | C0044/1A170130 | 1 |
| euro//Noweda | Betamethasone dipropionate | 1705030-01 | 1 |
| EUro/AHD | Betamethasone dipropionate | 1303006-01 | 3 |
| Euro/Gehe | Betamethasone dipropionate | 1601034-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro/Gehe | Betamethasone dipropionate | 2102001 | 1 |
| Euro/Krieger | Betamethasone dipropionate | 1801045-01 | 1 |
| Euro/Phönix | Betamethasone dipropionate | 2208030-01 | 1 |
| Euro/Sanacorp | Betamethasone dipropionate | 1503003-02 | 1 |
| Fagon/Noweda | Betamethasone dipropionate | 18I27-B03 | 1 |
| Fagron | Betamethasone dipropionate | | 7 |
| Fagron | Betamethasone dipropionate | 10E19-N03 | 1 |
| Fagron | Betamethasone dipropionate | 11D26-N06 | 2 |
| Fagron | Betamethasone dipropionate | 11I02-N01 | 1 |
| Fagron | Betamethasone dipropionate | 11K28-N10 | 2 |
| Fagron | Betamethasone dipropionate | 12827-N08 | 1 |
| Fagron | Betamethasone dipropionate | 12B27-N08 | 6 |
| Fagron | Betamethasone dipropionate | 12C21-N13 | 1 |
| Fagron | Betamethasone dipropionate | 13/17-n05 | 1 |
| Fagron | Betamethasone dipropionate | 13/17-N05 | 15 |
| Fagron | Betamethasone dipropionate | 13023004 | 1 |
| Fagron | Betamethasone dipropionate | 1317-N05 | 1 |
| Fagron | Betamethasone dipropionate | 13i17-N05 | 1 |
| Fagron | Betamethasone dipropionate | 13I17-N05 | 12 |
| Fagron | Betamethasone dipropionate | 13j16-B01-291844 | 1 |
| Fagron | Betamethasone dipropionate | 13j16-b01-291845 | 1 |
| Fagron | Betamethasone dipropionate | 13J16-B01-291845 | 2 |
| Fagron | Betamethasone dipropionate | 14C03-B03-296838 | 1 |
| Fagron | Betamethasone dipropionate | 14C03-B06 | 2 |
| Fagron | Betamethasone dipropionate | 14C03-B06-296837 | 10 |
| Fagron | Betamethasone dipropionate | 15H25-B06-313088 | 1 |
| Fagron | Betamethasone dipropionate | 15H28B06313088 | 1 |
| Fagron | Betamethasone dipropionate | 15H28-B06-313088 | 4 |
| Fagron | Betamethasone dipropionate | 1601034-01 | 1 |
| Fagron | Betamethasone dipropionate | 16C04-B03 | 1 |
| Fagron | Betamethasone dipropionate | 16C04-B03-320850 | 5 |
| Fagron | Betamethasone dipropionate | 16C04-B03-320851 | 1 |
| Fagron | Betamethasone dipropionate | 16C04-B03-320852 | 1 |
| Fagron | Betamethasone dipropionate | 17816B04332224 | 1 |
| Fagron | Betamethasone dipropionate | 17B16-B04 | 1 |
| Fagron | Betamethasone dipropionate | 17B16-B04-332217 | 9 |
| Fagron | Betamethasone dipropionate | 17b16b04332218 | 1 |
| Fagron | Betamethasone dipropionate | 17B16-B04-332219-201 | 1 |
| Fagron | Betamethasone dipropionate | 17B16-B04-332224 | 4 |
| Fagron | Betamethasone dipropionate | 17B6-B04-332217 | 1 |
| Fagron | Betamethasone dipropionate | 17E22-B06-335244 | 3 |
| Fagron | Betamethasone dipropionate | 17E22-B06-336705 | 2 |
| Fagron | Betamethasone dipropionate | 17E22B06336993 | 1 |
| Fagron | Betamethasone dipropionate | 17E22-B06-336993 | 5 |
| Fagron | Betamethasone dipropionate | 17H16-B04-340537 | 1 |
| Fagron | Betamethasone dipropionate | 18/27-B03-357221 | 2 |
| Fagron | Betamethasone dipropionate | 1801045-01 | 1 |
| Fagron | Betamethasone dipropionate | 1811007-01 | 1 |
| Fagron | Betamethasone dipropionate | 18127-B03-362601 | 2 |
| Fagron | Betamethasone dipropionate | 18127-B03-362603 | 1 |
| Fagron | Betamethasone dipropionate | 1827-b03-362601 | 1 |
| Fagron | Betamethasone dipropionate | 18B06-B05 | 5 |
| Fagron | Betamethasone dipropionate | 18B06-B05_350473 | 1 |
| Fagron | Betamethasone dipropionate | 18B06-B05-346218 | 5 |
| Fagron | Betamethasone dipropionate | 18B06-B05-346219 | 1 |
| Fagron | Betamethasone dipropionate | 18B06B05347338 | 1 |
| Fagron | Betamethasone dipropionate | 18B06-B05-347338 | 5 |
| Fagron | Betamethasone dipropionate | 18B06B0534996 | 1 |
| Fagron | Betamethasone dipropionate | 18b06-b05-350473 | 1 |
| Fagron | Betamethasone dipropionate | 18B06-B05-350473 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone dipropionate | 18B06-B05-350474 | 1 |
| Fagron | Betamethasone dipropionate | 18B06B05352731 | 2 |
| Fagron | Betamethasone dipropionate | 18B06-B05-352731 | 5 |
| Fagron | Betamethasone dipropionate | 18B06B05354807 | 1 |
| Fagron | Betamethasone dipropionate | 18B06-B05-354807 | 6 |
| Fagron | Betamethasone dipropionate | 18B06-B05-354808 | 3 |
| Fagron | Betamethasone dipropionate | 18Bo6-B0o5-352731 | 1 |
| Fagron | Betamethasone dipropionate | 18I127-B03-357222 | 1 |
| Fagron | Betamethasone dipropionate | 18I27-B03 | 8 |
| Fagron | Betamethasone dipropionate | 18I27-B03-357221 | 4 |
| Fagron | Betamethasone dipropionate | 18I27-B03-357222 | 3 |
| Fagron | Betamethasone dipropionate | 18I27-B03-358725 | 3 |
| Fagron | Betamethasone dipropionate | 18I27-B03-358726 | 1 |
| Fagron | Betamethasone dipropionate | 18I27-B03-358727 | 1 |
| Fagron | Betamethasone dipropionate | 18I27-B03-3626001 | 1 |
| Fagron | Betamethasone dipropionate | 18I27-B03-362601 | 10 |
| Fagron | Betamethasone dipropionate | 18I27-B03-362602 | 3 |
| Fagron | Betamethasone dipropionate | 18I27-BO3-362602 | 1 |
| Fagron | Betamethasone dipropionate | 18l27-B03-358725 | 1 |
| Fagron | Betamethasone dipropionate | 19041706 | 1 |
| Fagron | Betamethasone dipropionate | 19J31-F02 | 1 |
| Fagron | Betamethasone dipropionate | 19J31-F02-3666808 | 1 |
| Fagron | Betamethasone dipropionate | 19J31F02-366807 | 1 |
| Fagron | Betamethasone dipropionate | 19J31-F02-366807 | 8 |
| Fagron | Betamethasone dipropionate | 19J31-F02-366808 | 9 |
| Fagron | Betamethasone dipropionate | 19J31-F02-366809 | 1 |
| Fagron | Betamethasone dipropionate | 19J31-F02-366810 | 2 |
| Fagron | Betamethasone dipropionate | 20171127Ma5 | 1 |
| Fagron | Betamethasone dipropionate | 20C10_F02372115 | 1 |
| Fagron | Betamethasone dipropionate | 20C10-F02 | 1 |
| Fagron | Betamethasone dipropionate | 20C10-F02372115 | 1 |
| Fagron | Betamethasone dipropionate | 20C10-F02-372115 | 4 |
| Fagron | Betamethasone dipropionate | 2109DM0B0011322 | 1 |
| Fagron | Betamethasone dipropionate | 21C002-F01-377438 | 1 |
| Fagron | Betamethasone dipropionate | 21C02-F01-3774308 | 1 |
| Fagron | Betamethasone dipropionate | 21C02-F01-377438 | 1 |
| Fagron | Betamethasone dipropionate | 21H18-B04-213656 | 9 |
| Fagron | Betamethasone dipropionate | 21J12-B09-216139 | 7 |
| Fagron | Betamethasone dipropionate | 21K24B04216140 | 2 |
| Fagron | Betamethasone dipropionate | 21K24-B04-216140 | 1 |
| Fagron | Betamethasone dipropionate | 21K24B04220120 | 1 |
| Fagron | Betamethasone dipropionate | 21K24-B04-220120 | 2 |
| Fagron | Betamethasone dipropionate | 21K24-B04-222402 | 2 |
| Fagron | Betamethasone dipropionate | 21K24-B04-227289 | 2 |
| Fagron | Betamethasone dipropionate | 8K03-N13 | 1 |
| Fagron | Betamethasone dipropionate | 9J05-N09 | 1 |
| Fagron | Betamethasone dipropionate | B03-3587205 | 1 |
| Fagron | Betamethasone dipropionate | BDP003/0521 | 2 |
| Fagron | Betamethasone dipropionate | BDP004/0821 | 1 |
| Fagron | Betamethasone dipropionate | BDP101/0417 | 1 |
| Fagron | Betamethasone dipropionate | BDP101/0419 | 2 |
| Fagron | Betamethasone dipropionate | BDP102/0817 | 3 |
| Fagron | Betamethasone dipropionate | F01-3774308 | 1 |
| Fagron | Betamethasone dipropionate | F02-0668007 | 1 |
| Fagron | Betamethasone dipropionate | F02-3668007 | 1 |
| Fagron | Betamethasone dipropionate | F02-3721105 | 1 |
| Fargon/ Noweda | Betamethasone dipropionate | 13/17-N05 | 1 |
| Fargon/AllianceH. | Betamethasone dipropionate | 17H16B04-340537 | 1 |
| Fargon | Betamethasone dipropionate | 16C04-B033-24513 | 1 |
| Fargon | Betamethasone dipropionate | 17b16-b04-332224 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fiebig | Betamethasone dipropionate | 21K24-B04-227289 | 1 |
| Fiebig | Betamethasone dipropionate | 22003962001 | 1 |
| Fischer/Gehe | Betamethasone dipropionate | 13/17-N05 | 2 |
| Fragon/ Gehe | Betamethasone dipropionate | 18B06-B05 | 1 |
| Fragon | Betamethasone dipropionate | 18B06-B05-352731 | 1 |
| Gehe amax | Betamethasone dipropionate | 1610014-01 | 1 |
| Gehe amax | Betamethasone dipropionate | 17B16-B04-332217 | 1 |
| Gehe | Betamethasone dipropionate | 1311023-01 | 1 |
| Gehe | Betamethasone dipropionate | 15238701 | 1 |
| GEHE | Betamethasone dipropionate | 15412914 | 1 |
| Gehe | Betamethasone dipropionate | 1705020-01 | 1 |
| Gehe | Betamethasone dipropionate | 17E22B06-336993 | 1 |
| Gehe | Betamethasone dipropionate | 18293404 | 1 |
| GEHE | Betamethasone dipropionate | 20003997005 | 1 |
| Gehe | Betamethasone dipropionate | 21000648001 | 1 |
| Gehe | Betamethasone dipropionate | 21000648010 | 1 |
| Gehe | Betamethasone dipropionate | 21000648012 | 1 |
| Gehe | Betamethasone dipropionate | 21k24-B04 | 1 |
| Hirsch | Betamethasone dipropionate | 1303006-01 | 1 |
| Kehr | Betamethasone dipropionate | 1705020-01 | 1 |
| Kehr | Betamethasone dipropionate | 220039602001 | 1 |
| Klosterring | Betamethasone dipropionate | 17B16-B04-332219 | 2 |
| Nachprüfung | Betamethasone dipropionate | 17B16-B04-332217 | 1 |
| Noweda/ Caesar&Loren… | Betamethasone dipropionate | 19000537003 | 1 |
| Noweda | Betamethasone dipropionate | 13125703 | 1 |
| Noweda | Betamethasone dipropionate | 13236802 | 1 |
| Noweda | Betamethasone dipropionate | 13236803 | 1 |
| Noweda | Betamethasone dipropionate | 1811007-01 | 1 |
| Noweda | Betamethasone dipropionate | 21C02-F01-377438 | 1 |
| Noweda | Betamethasone dipropionate | 22001649008 | 1 |
| noweda | Betamethasone dipropionate | 22003962002 | 1 |
| Noweda | Betamethasone dipropionate | 22003962007 | 1 |
| Noweda | Betamethasone dipropionate | 23011013-01 | 1 |
| Noweda | Betamethasone dipropionate | BDP014/1115 | 1 |
| Noweda | Betamethasone dipropionate | BDP102/0817 | 1 |
| Ph/Euro | Betamethasone dipropionate | 2110005-01 | 1 |
| Phoenix 03.04.20147 | Betamethasone dipropionate | 13236805 | 1 |
| Phoenix | Betamethasone dipropionate | 13236806 | 1 |
| Phoenix | Betamethasone dipropionate | 1610014-01 | 1 |
| Phoenix | Betamethasone dipropionate | 1705020-01 | 1 |
| Phoenix | Betamethasone dipropionate | 1811007-01 | 1 |
| Phoenix | Betamethasone dipropionate | 21000648006 | 1 |
| Phoenix | Betamethasone dipropionate | 2301013-01 | 2 |
| Phönix Gotha | Betamethasone dipropionate | 1811007-01 | 1 |
| phönix | Betamethasone dipropionate | 15163304 | 1 |
| Phönix | Betamethasone dipropionate | 1705020-01 | 1 |
| PHÖNIX | Betamethasone dipropionate | 17353603 | 1 |
| Phönix | Betamethasone dipropionate | 2003057-01 | 1 |
| phönix | Betamethasone dipropionate | 21000648014 | 1 |
| Phönix | Betamethasone dipropionate | 22001649005 | 1 |
| Phönix | Betamethasone dipropionate | 2208030-01 | 1 |
| Phönix | Betamethasone dipropionate | 2301013-0173/23P | 1 |
| sanacorb | Betamethasone dipropionate | 12B27-No8 | 1 |
| Sanacorp WE: 12.08.1… | Betamethasone dipropionate | 15238701 | 1 |
| Sanacorp | Betamethasone dipropionate | 13236801 | 2 |
| Sanacorp | Betamethasone dipropionate | 15412910 | 1 |
| Sanacorp | Betamethasone dipropionate | 1610014-01 | 1 |
| Sanacorp | Betamethasone dipropionate | 170502001 | 1 |
| Sanacorp | Betamethasone dipropionate | 1705020-01 | 1 |
| Sanacorp | Betamethasone dipropionate | 17105911 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Betamethasone dipropionate | 17B16-B04-332217 | 2 |
| Sanacorp | Betamethasone dipropionate | 18090607 | 1 |
| SANACORP | Betamethasone dipropionate | 18293404 | 1 |
| Sanacorp | Betamethasone dipropionate | 18B06-B05-346218 | 1 |
| Sanacorp | Betamethasone dipropionate | 19000537010 | 1 |
| Sanacorp | Betamethasone dipropionate | 19J31-F02 | 2 |
| Sanacorp | Betamethasone dipropionate | 21000648010 | 1 |
| Sanacorp | Betamethasone dipropionate | 22001649008 | 1 |
| Sanacorp | Betamethasone dipropionate | 2208030-01 | 3 |
| Sanacorp | Betamethasone dipropionate | 2406016-01 | 2 |
| Sanacorp | Betamethasone dipropionate | BDP102/0817 | 1 |
| Symbiotica Spec. | Betamethasone dipropionate | 18B06-B05-350473 | 1 |
| Symbiotica/Noweda | Betamethasone dipropionate | BDP102/0817 | 1 |
| Symbiotica | Betamethasone dipropionate | 2208030-01 | 1 |
| Symbiotica | Betamethasone dipropionate | BDP103/1019 | 1 |
| WE:09.12.2016 | Betamethasone dipropionate | 15163301 | 1 |

- 255 109 spectra from 1666 *Apo-Ident* customers from a total of 51 838 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Betamethasone dipropionate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Betamethasone dipropionate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 534 | 0 | 157 792 |
| **Type B** | 0 | 1373 | 0 | 211 567 |
| **Type C** | 0 | 1701 | 76 | 255 109 |

The substance/substance group *Betamethasone dipropionate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8764 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.5630 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 95.7231 % (> 95.5543 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20930 | 20930 | 0.00 | 39.66 |
| 20952 | 22372 | 8.46 | 38.34 |
| 21250 | 21250 | 0.00 | 38.18 |
| 21366 | 21250 | 5.38 | 38.51 |
| 21367 | 21250 | 6.01 | 39.21 |
| 21716 | 21716 | 0.00 | 39.03 |
| 22372 | 22372 | 0.00 | 37.17 |
| 22898 | 22372 | 7.87 | 39.42 |
| 25691 | 25691 | 0.00 | 42.16 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Betamethasone valerate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20026-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Betamethasone valerate; Betamethasoni valeras

### Special notes

When selecting the *Betamethasone valerate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Betamethasone valerate | 10 | 12 | 875 |

### Second-stage model

For differentiation of the substance/substance group *Betamethasone valerate* the following second-stage model is used:

- Submodel 07

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Betamethasone valerate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 80.54 | – |
| ⋮ | ⋮ | ⋮ |
| Budesonide | >50 | 34.77 |
| Erythromycin | >50 | 35.66 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Betamethasone valerate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Betamethasone valerate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Betamethasone valerate | 13091213 | 21215 | 40 | 20130506 |
| Caelo | Betamethasone valerate | 13225507 | 21588 | 54 | 1706018 |
| Euro OTC | Betamethasone valerate | 1208014-01 | 20920 | 40 | 20120928 |
| Euro OTC | Betamethasone valerate | 1406019-01 | 21645 | 60 | 20140725 |
| Euro OTC | Betamethasone valerate | 1510037 | 22249 | 60 | 20151215* |
| Euro OTC | Betamethasone valerate | 1510037 | 22249SI | 30 | 20151215* |
| Euro OTC | Betamethasone valerate | 1610010 | 22861 | 40 | 20161116* |
| Euro OTC | Betamethasone valerate | 1811008 | 24349 | 40 | 20181207* |
| Euro OTC | Betamethasone valerate | 1811008 | 24349SI | 30 | 20181207* |
| Fagron | Betamethasone valerate | 12K07-N23 | 20887 | 40 | 20121119 |
| Fagron | Betamethasone valerate | 13K29-B32-288243 | 21566 | 60 | 20131210 |
| Fagron | Betamethasone valerate | 13K05-B08-292651 | 21674 | 60 | 1511154 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 554 spectra of 12 reference samples from the substance/substance group *Betamethasone valerate*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 772 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 881 spectra of 26 reference samples from the substance/substance group *Betamethasone valerate*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Betamethasone valerate | 170787 | 23332 | 40 |
| Caelo | Betamethasone valerate | 172716 | 23683 | 40 |
| Caelo | Betamethasone valerate | 22001101 | 26127 | 38 |
| Caelo | Betamethasone valerate | 23002259 | 26968 | 40 |
| Euro OTC | Betamethasone valerate | 1606023 | 22716 | 40 |
| Euro OTC | Betamethasone valerate | 1704019 | 23396 | 40 |
| Euro OTC | Betamethasone valerate | 1801024 | 23967 | 40 |
| Euro OTC | Betamethasone valerate | 1911001 | 24982 | 40 |
| Euro OTC | Betamethasone valerate | 2102010 | 25540 | 40 |
| Euro OTC | Betamethasone valerate | 2202016 | 26035 | 40 |
| Euro OTC | Betamethasone valerate | 2309023 | 27009 | 30 |
| Fagron | Betamethasone valerate | 21K09-B05-217898 | 26171 | 40 |
| Caelo | Betamethasone valerate | 13225507 | 21588† | 6 |
| Caelo | Betamethasone valerate | 170787 | 23332SI | 20 |
| Caelo | Betamethasone valerate | 172716 | 23683SI | 20 |
| Caelo | Betamethasone valerate | 22001101 | 26127SI | 30 |
| Caelo | Betamethasone valerate | 23002259 | 26968SI | 34 |
| Euro OTC | Betamethasone valerate | 1606023 | 22716SI | 34 |
| Euro OTC | Betamethasone valerate | 1610010 | 22861SI† | 30 |
| Euro OTC | Betamethasone valerate | 1704019 | 23396SI | 29 |
| Euro OTC | Betamethasone valerate | 1801024 | 23967SI | 40 |
| Euro OTC | Betamethasone valerate | 1911001 | 24982SI | 40 |
| Euro OTC | Betamethasone valerate | 2102010 | 25540SI | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Betamethasone valerate | 2202016 | 26035SI | 10 |
| Euro OTC | Betamethasone valerate | 2309023 | 27009SI | 40 |
| Fagron | Betamethasone valerate | 21K09-B05-217898 | 26171SI | 40 |

- 212 059 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6065 spectra from 1367 *Apo-Ident* customers from 930 batches from the substance/substance group *Betamethasone valerate*.

- Among them are spectra of independent samples from 871 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Betamethasone valerate | | 3 |
| | Betamethasone valerate | 1208014-04 | 1 |
| | Betamethasone valerate | 17G31-B04-338575 | 2 |
| | Betamethasone valerate | 181108-01 | 1 |
| | Betamethasone valerate | 20E14-F02-371690 | 1 |
| | Betamethasone valerate | 21000036021 | 3 |
| | Betamethasone valerate | 2102010-01 | 1 |
| | Betamethasone valerate | 2102010-02 | 1 |
| | Betamethasone valerate | 2102010-03 | 3 |
| | Betamethasone valerate | 2102010-1 | 1 |
| | Betamethasone valerate | 21G28-B02-213663 | 1 |
| | Betamethasone valerate | 21K09-B05-217891 | 1 |
| | Betamethasone valerate | 21K09-B05-217898 | 1 |
| | Betamethasone valerate | 21K09-B05-218287 | 1 |
| | Betamethasone valerate | 21K09-B05-22018 | 1 |
| | Betamethasone valerate | 21K09-B05-220180 | 1 |
| | Betamethasone valerate | 21K09-B05-220365 | 1 |
| | Betamethasone valerate | 21K09-B05-220493 | 1 |
| | Betamethasone valerate | 21K09-B05-222185 | 7 |
| | Betamethasone valerate | 21k09-B05-222192 | 1 |
| | Betamethasone valerate | 21K09-B05-222192 | 9 |
| | Betamethasone valerate | 21K09-B05-222194 | 1 |
| | Betamethasone valerate | 2200101016 | 1 |
| | Betamethasone valerate | 22001101003 | 5 |
| | Betamethasone valerate | 22001101004 | 1 |
| | Betamethasone valerate | 22001101005 | 2 |
| | Betamethasone valerate | 22001101008 | 5 |
| | Betamethasone valerate | 22001101009 | 7 |
| | Betamethasone valerate | 22001101014 | 2 |
| | Betamethasone valerate | 22001101015 | 12 |
| | Betamethasone valerate | 22001101016 | 15 |
| | Betamethasone valerate | 22001101017 | 5 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.



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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Betamethasone valerate | 22001101018 | 20 |
| | Betamethasone valerate | 22001101020 | 38 |
| | Betamethasone valerate | 2200110102032/24P | 1 |
| | Betamethasone valerate | 2200110102055/24P | 1 |
| | Betamethasone valerate | 22001101021 | 13 |
| | Betamethasone valerate | 22001101024 | 1 |
| | Betamethasone valerate | 22001101025 | 3 |
| | Betamethasone valerate | 22001102021 | 1 |
| | Betamethasone valerate | 2201101021 | 1 |
| | Betamethasone valerate | 2202015-51 | 1 |
| | Betamethasone valerate | 2202016-01 | 34 |
| | Betamethasone valerate | 2202016-02 | 9 |
| | Betamethasone valerate | 221101020 | 1 |
| | Betamethasone valerate | 22H23-B07-227236 | 1 |
| | Betamethasone valerate | 22H25B07223527 | 4 |
| | Betamethasone valerate | 22H25-B07-223527 | 7 |
| | Betamethasone valerate | 22H25-B07-227224 | 1 |
| | Betamethasone valerate | 22H25-B07-227226 | 1 |
| | Betamethasone valerate | 22H25-B07-227236 | 9 |
| | Betamethasone valerate | 22H25-B07-227293 | 2 |
| | Betamethasone valerate | 22HB07223527 | 1 |
| | Betamethasone valerate | 22K07-B08-227496 | 2 |
| | Betamethasone valerate | 22K07-B08-229282 | 2 |
| | Betamethasone valerate | 22K07B08229283 | 1 |
| | Betamethasone valerate | 22K07-B08-229283 | 4 |
| | Betamethasone valerate | 22K07-B08-229284 | 1 |
| | Betamethasone valerate | 22K07-B08-231551 | 1 |
| | Betamethasone valerate | 22K07-B08-233606 | 2 |
| | Betamethasone valerate | 23003251002 | 2 |
| | Betamethasone valerate | 23003251004 | 3 |
| | Betamethasone valerate | 23003251005 | 6 |
| | Betamethasone valerate | 23003251102 | 1 |
| | Betamethasone valerate | 23003252001 | 6 |
| | Betamethasone valerate | 23003252003 | 14 |
| | Betamethasone valerate | 2300325200302/25P | 1 |
| | Betamethasone valerate | 23003252005 | 1 |
| | Betamethasone valerate | 2309023 | 1 |
| | Betamethasone valerate | 2309023-01 | 31 |
| | Betamethasone valerate | 230902302 | 1 |
| | Betamethasone valerate | 2309023-02 | 1 |
| | Betamethasone valerate | 23E29-B03-238320 | 3 |
| | Betamethasone valerate | 23E29-B03-238762 | 1 |
| | Betamethasone valerate | 23E29-BO3-238762 | 1 |
| | Betamethasone valerate | 2409004-01 | 1 |
| | Betamethasone valerate | 24A30-B08-005167 | 1 |
| | Betamethasone valerate | 24A30-B08-238302 | 1 |
| | Betamethasone valerate | 24A30-B08-238319 | 4 |
| | Betamethasone valerate | 24A30-BOB-238319 | 1 |
| | Betamethasone valerate | 24K07-B14-008088 | 1 |
| | Betamethasone valerate | 3238320 | 1 |
| | Betamethasone valerate | B08-2336006 | 1 |
| | Betamethasone valerate | BO7-2272306 | 1 |
| | Betamethasone valerate | BO8-2292802 | 1 |
| | Betamethasone valerate | BV004/0721 | 2 |
| | Betamethasone valerate | BV005/1221 | 1 |
| | Betamethasone valerate | BV006/1123 | 1 |
| | Betamethasone valerate | F02-3649801 | 1 |
| /Sanacorp | Betamethasone valerate | 17078701 | 1 |
| 03110031 | Betamethasone valerate | 17271603 | 1 |
| A.H.D. | Betamethasone valerate | 13D03-N07 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AEP | Betamethasone valerate | 22001101014 | 1 |
| Aep | Betamethasone valerate | 22001101018 | 1 |
| AEP | Betamethasone valerate | 22K07-B08-229282 | 1 |
| AEP | Betamethasone valerate | F02-3737908 | 1 |
| agron/Krieger | Betamethasone valerate | 12B2B-N01 | 1 |
| AHC 01.07.13 EK 48,05 | Betamethasone valerate | 12K07-N23 | 1 |
| AHD / Caesar & Loret… | Betamethasone valerate | 1912012-01 | 1 |
| AHD 04.10.17 E.k:18,47 | Betamethasone valerate | 16270514 | 1 |
| AHD 15.06.16 EK:18,44 | Betamethasone valerate | 15398505 | 1 |
| AHD 17.11.14 EK 18,11 | Betamethasone valerate | 13091205 | 1 |
| AHD/Euro | Betamethasone valerate | 181100801 | 1 |
| AHD/Fargon | Betamethasone valerate | 14H28-Bo1-302865 | 1 |
| AHD | Betamethasone valerate | 1406019-02 | 2 |
| AHD | Betamethasone valerate | 15262607 | 1 |
| AHD | Betamethasone valerate | 15398515 | 1 |
| AHD | Betamethasone valerate | 17078714 | 1 |
| AHD | Betamethasone valerate | 18199902 | 1 |
| AHD | Betamethasone valerate | 22001101015 | 1 |
| AHD | Betamethasone valerate | 2202016-01 | 1 |
| AHD | Betamethasone valerate | 2309023-01 | 1 |
| AHDE / Cael 17.02.2015 | Betamethasone valerate | 13225516 | 1 |
| AHL | Betamethasone valerate | 15398501 | 1 |
| ALH | Betamethasone valerate | 15398512 | 1 |
| Alliance Haelthcare | Betamethasone valerate | 21K09-B05-220180 | 1 |
| Alliance Health 06.0… | Betamethasone valerate | 13091207 | 1 |
| Alliance healthcare | Betamethasone valerate | 13D03-N07 | 1 |
| Alliance Healthcare | Betamethasone valerate | 1610010-01 | 1 |
| Alliance Healthcare | Betamethasone valerate | 2309023-01 | 1 |
| Alliance/EurRho | Betamethasone valerate | 1912012-01 | 1 |
| Alliance | Betamethasone valerate | 22001101003 | 2 |
| Alliance | Betamethasone valerate | 22001101017 | 1 |
| Alliance | Betamethasone valerate | 22001101021 | 1 |
| alliance | Betamethasone valerate | 2202016-01 | 1 |
| Alliance | Betamethasone valerate | 2309023-01 | 1 |
| Allianz Healthcare 2… | Betamethasone valerate | 15075802 | 1 |
| Anzag | Betamethasone valerate | 12L11-N01 | 1 |
| Anzag | Betamethasone valerate | 1819908 | 1 |
| Anzag | Betamethasone valerate | 22001101008 | 1 |
| Anzag | Betamethasone valerate | 22001101018 | 1 |
| Anzag | Betamethasone valerate | 23003252002 | 1 |
| Anzag | Betamethasone valerate | 23003252003 | 1 |
| Audor Pharma | Betamethasone valerate | APBV010/0516B | 5 |
| Biomed / Gehe | Betamethasone valerate | 1510037-01 | 1 |
| Bombastus | Betamethasone valerate | 12L11-N01 | 1 |
| Bombastus | Betamethasone valerate | 1510037-01 | 1 |
| Bombastus | Betamethasone valerate | 16E23-B03-327350 | 2 |
| Bombastus | Betamethasone valerate | 1704019-01 | 2 |
| Bombastus | Betamethasone valerate | 17329015 | 2 |
| cae | Betamethasone valerate | 16270502 | 1 |
| Cael Sanacorp 05.02.2016 | Betamethasone valerate | 14H28-B01-302864 | 1 |
| Caello/Sanacorp | Betamethasone valerate | 15075803 | 1 |
| Caelo | Betamethasone valerate | | 3 |
| Caelo | Betamethasone valerate | 10296701 | 1 |
| Caelo | Betamethasone valerate | 10296705 | 2 |
| Caelo | Betamethasone valerate | 10296707 | 1 |
| Caelo | Betamethasone valerate | 1108045-03 | 1 |
| Caelo | Betamethasone valerate | 1113 | 1 |
| Caelo | Betamethasone valerate | 11131905 | 1 |
| Caelo | Betamethasone valerate | 11131909 | 1 |
| Caelo | Betamethasone valerate | 11131914 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone valerate | 11131917 | 2 |
| Caelo | Betamethasone valerate | 1131914 | 1 |
| Caelo | Betamethasone valerate | 1199932 | 1 |
| Caelo | Betamethasone valerate | 12003402 | 1 |
| Caelo | Betamethasone valerate | 12003403 | 7 |
| Caelo | Betamethasone valerate | 12003404 | 1 |
| Caelo | Betamethasone valerate | 12003405 | 8 |
| Caelo | Betamethasone valerate | 12003406 | 6 |
| Caelo | Betamethasone valerate | 12003407 | 1 |
| Caelo | Betamethasone valerate | 12003409 | 1 |
| Caelo | Betamethasone valerate | 12003410 | 1 |
| Caelo | Betamethasone valerate | 12003411 | 3 |
| Caelo | Betamethasone valerate | 1208014-01 | 1 |
| Caelo | Betamethasone valerate | 1208014-03 | 1 |
| Caelo | Betamethasone valerate | 12207004 | 1 |
| Caelo | Betamethasone valerate | 12229802 | 3 |
| Caelo | Betamethasone valerate | 12229804 | 4 |
| Caelo | Betamethasone valerate | 12229805 | 9 |
| Caelo | Betamethasone valerate | 12229806 | 6 |
| Caelo | Betamethasone valerate | 12229808 | 12 |
| Caelo | Betamethasone valerate | 12229809 | 2 |
| Caelo | Betamethasone valerate | 12229810 | 4 |
| Caelo | Betamethasone valerate | 12229811 | 7 |
| Caelo | Betamethasone valerate | 12229812 | 9 |
| Caelo | Betamethasone valerate | 12229813 | 2 |
| Caelo | Betamethasone valerate | 123345 | 1 |
| Caelo | Betamethasone valerate | 129711-5471 | 1 |
| Caelo | Betamethasone valerate | 12B28-N01 | 1 |
| Caelo | Betamethasone valerate | 12g09-n07 | 1 |
| Caelo | Betamethasone valerate | 12G09-N07 | 1 |
| Caelo | Betamethasone valerate | 12K07-N23 | 1 |
| Caelo | Betamethasone valerate | 12L11-N01 | 1 |
| Caelo | Betamethasone valerate | 13012015C | 1 |
| Caelo | Betamethasone valerate | 13091201 | 2 |
| Caelo | Betamethasone valerate | 13091203 | 12 |
| Caelo | Betamethasone valerate | 13091204 | 4 |
| Caelo | Betamethasone valerate | 13091205 | 11 |
| Caelo | Betamethasone valerate | 13091206 | 1 |
| Caelo | Betamethasone valerate | 13091207 | 8 |
| Caelo | Betamethasone valerate | 13091209 | 4 |
| Caelo | Betamethasone valerate | 13091210 | 3 |
| Caelo | Betamethasone valerate | 13091211 | 3 |
| Caelo | Betamethasone valerate | 13091212 | 6 |
| Caelo | Betamethasone valerate | 13091213 | 6 |
| Caelo | Betamethasone valerate | 13225502 | 2 |
| Caelo | Betamethasone valerate | 13225503 | 9 |
| Caelo | Betamethasone valerate | 13225504 | 9 |
| Caelo | Betamethasone valerate | 13225505 | 12 |
| Caelo | Betamethasone valerate | 13225507 | 2 |
| Caelo | Betamethasone valerate | 13225508 | 9 |
| Caelo | Betamethasone valerate | 13225509 | 2 |
| Caelo | Betamethasone valerate | 13225515 | 9 |
| Caelo | Betamethasone valerate | 13225516 | 10 |
| Caelo | Betamethasone valerate | 13225607 | 1 |
| Caelo | Betamethasone valerate | 13923 | 1 |
| Caelo | Betamethasone valerate | 13D03-N07 | 3 |
| Caelo | Betamethasone valerate | 13G19-N01 | 1 |
| Caelo | Betamethasone valerate | 13K05_B08_292652 | 1 |
| Caelo | Betamethasone valerate | 13K29-B32-288247 | 1 |
| Caelo | Betamethasone valerate | 14031407 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone valerate | 1406019-01 | 1 |
| Caelo | Betamethasone valerate | 1406019-02 | 3 |
| Caelo | Betamethasone valerate | 140601903 | 1 |
| Caelo | Betamethasone valerate | 1406019-03 | 4 |
| Caelo | Betamethasone valerate | 14188602 | 2 |
| Caelo | Betamethasone valerate | 14188603 | 5 |
| Caelo | Betamethasone valerate | 14188604 | 8 |
| Caelo | Betamethasone valerate | 14188605 | 1 |
| Caelo | Betamethasone valerate | 14188606 | 1 |
| Caelo | Betamethasone valerate | 14188608 | 8 |
| Caelo | Betamethasone valerate | 14188609 | 5 |
| Caelo | Betamethasone valerate | 14188610 | 7 |
| Caelo | Betamethasone valerate | 14188617 | 3 |
| Caelo | Betamethasone valerate | 14188619 | 3 |
| Caelo | Betamethasone valerate | 1488609 | 1 |
| Caelo | Betamethasone valerate | 1488610 | 1 |
| Caelo | Betamethasone valerate | 14C19-B02-292653 | 1 |
| Caelo | Betamethasone valerate | 14G30-B05 | 1 |
| Caelo | Betamethasone valerate | 14G30-B05-296173 | 2 |
| Caelo | Betamethasone valerate | 14G30-B05-309520 | 1 |
| Caelo | Betamethasone valerate | 14H28-B01-302865 | 1 |
| Caelo | Betamethasone valerate | 15/16-B07-317416 | 1 |
| Caelo | Betamethasone valerate | 15/16-B07-317417 | 1 |
| Caelo | Betamethasone valerate | 15/16-B07-319228 | 2 |
| Caelo | Betamethasone valerate | 15075802 | 22 |
| Caelo | Betamethasone valerate | 150758022 | 1 |
| Caelo | Betamethasone valerate | 15075803 | 9 |
| Caelo | Betamethasone valerate | 150758036 | 1 |
| Caelo | Betamethasone valerate | 15075804 | 8 |
| Caelo | Betamethasone valerate | 15075805 | 8 |
| Caelo | Betamethasone valerate | 15075809 | 4 |
| Caelo | Betamethasone valerate | 15075810 | 9 |
| Caelo | Betamethasone valerate | 15075811 | 1 |
| Caelo | Betamethasone valerate | 15075812 | 3 |
| Caelo | Betamethasone valerate | 1510037-01 | 2 |
| Caelo | Betamethasone valerate | 1516-B07-319228 | 1 |
| Caelo | Betamethasone valerate | 1526213 | 1 |
| Caelo | Betamethasone valerate | 15262602 | 8 |
| Caelo | Betamethasone valerate | 15262603 | 15 |
| Caelo | Betamethasone valerate | 15262604 | 14 |
| Caelo | Betamethasone valerate | 15262606 | 4 |
| Caelo | Betamethasone valerate | 15262607 | 7 |
| Caelo | Betamethasone valerate | 15262609 | 3 |
| Caelo | Betamethasone valerate | 15262610 | 4 |
| Caelo | Betamethasone valerate | 15262612 | 1 |
| Caelo | Betamethasone valerate | 15262613 | 1 |
| Caelo | Betamethasone valerate | 1526604 | 1 |
| Caelo | Betamethasone valerate | 1538506 | 1 |
| Caelo | Betamethasone valerate | 15395512 | 1 |
| Caelo | Betamethasone valerate | 15398501 | 23 |
| Caelo | Betamethasone valerate | 15398502 | 1 |
| Caelo | Betamethasone valerate | 15398503 | 2 |
| Caelo | Betamethasone valerate | 15398504 | 3 |
| Caelo | Betamethasone valerate | 15398505 | 18 |
| Caelo | Betamethasone valerate | 15398506 | 30 |
| Caelo | Betamethasone valerate | 15398512 | 22 |
| Caelo | Betamethasone valerate | 15398513 | 4 |
| Caelo | Betamethasone valerate | 15398514 | 3 |
| Caelo | Betamethasone valerate | 15398515 | 27 |
| Caelo | Betamethasone valerate | 15B24-B04 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone valerate | 15B24-B04-307016 | 1 |
| Caelo | Betamethasone valerate | 15F16-B04-314054 | 1 |
| Caelo | Betamethasone valerate | 15F16-B04-315327 | 1 |
| Caelo | Betamethasone valerate | 15L21-B03-318663 | 1 |
| Caelo | Betamethasone valerate | 160216BV | 1 |
| Caelo | Betamethasone valerate | 160501 | 1 |
| Caelo | Betamethasone valerate | 160503 | 1 |
| Caelo | Betamethasone valerate | 1606023-01 | 4 |
| Caelo | Betamethasone valerate | 1610010-01 | 5 |
| Caelo | Betamethasone valerate | 161125BV/15398512 | 1 |
| Caelo | Betamethasone valerate | 16270501 | 18 |
| Caelo | Betamethasone valerate | 16270502 | 37 |
| Caelo | Betamethasone valerate | 16270503 | 18 |
| Caelo | Betamethasone valerate | 16270504 | 1 |
| Caelo | Betamethasone valerate | 16270505 | 16 |
| Caelo | Betamethasone valerate | 16270508 | 2 |
| Caelo | Betamethasone valerate | 16270509 | 9 |
| Caelo | Betamethasone valerate | 1627051 | 1 |
| Caelo | Betamethasone valerate | 16270511 | 26 |
| Caelo | Betamethasone valerate | 16270513 | 22 |
| Caelo | Betamethasone valerate | 16270514 | 9 |
| Caelo | Betamethasone valerate | 16720513 | 1 |
| Caelo | Betamethasone valerate | 16B18-B02-320971 | 2 |
| Caelo | Betamethasone valerate | 16B18-B02-322121 | 2 |
| Caelo | Betamethasone valerate | 16B18-B02-324798 | 1 |
| Caelo | Betamethasone valerate | 16E23-B03 | 1 |
| Caelo | Betamethasone valerate | 16E23-B03-324799 | 2 |
| Caelo | Betamethasone valerate | 16E23-B03-324800 | 1 |
| Caelo | Betamethasone valerate | 16e23-b03-328128 | 1 |
| Caelo | Betamethasone valerate | 16E23-B03-328128 | 5 |
| Caelo | Betamethasone valerate | 16h22-b06-330523 | 2 |
| Caelo | Betamethasone valerate | 16H22-B06-331273 | 1 |
| Caelo | Betamethasone valerate | 16H22B06332351 | 1 |
| Caelo | Betamethasone valerate | 16H22-B06-332351 | 1 |
| Caelo | Betamethasone valerate | 17/251/Bv | 1 |
| Caelo | Betamethasone valerate | 170401901 | 4 |
| Caelo | Betamethasone valerate | 1704019-01 | 21 |
| Caelo | Betamethasone valerate | 17078103 | 1 |
| Caelo | Betamethasone valerate | 1707814 | 1 |
| Caelo | Betamethasone valerate | 1707815 | 2 |
| Caelo | Betamethasone valerate | 1707819 | 1 |
| Caelo | Betamethasone valerate | 17078701 | 25 |
| Caelo | Betamethasone valerate | 17078702 | 1 |
| Caelo | Betamethasone valerate | 17078703 | 33 |
| Caelo | Betamethasone valerate | 17078704 | 7 |
| Caelo | Betamethasone valerate | 17078705 | 1 |
| Caelo | Betamethasone valerate | 17078707 | 1 |
| Caelo | Betamethasone valerate | 17078711 | 7 |
| Caelo | Betamethasone valerate | 17078712 | 13 |
| Caelo | Betamethasone valerate | 17078713 | 21 |
| Caelo | Betamethasone valerate | 17078714 | 17 |
| Caelo | Betamethasone valerate | 17078715 | 16 |
| Caelo | Betamethasone valerate | 17078716 | 1 |
| Caelo | Betamethasone valerate | 17078719 | 18 |
| Caelo | Betamethasone valerate | 17078720 | 26 |
| Caelo | Betamethasone valerate | 1708701 | 1 |
| Caelo | Betamethasone valerate | 17196001 | 1 |
| Caelo | Betamethasone valerate | 17271601 | 7 |
| Caelo | Betamethasone valerate | 17271602 | 1 |
| Caelo | Betamethasone valerate | 17271603 | 29 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone valerate | 17271604 | 9 |
| Caelo | Betamethasone valerate | 1729002 | 1 |
| Caelo | Betamethasone valerate | 17329001 | 29 |
| Caelo | Betamethasone valerate | 17329002 | 39 |
| Caelo | Betamethasone valerate | 17329003 | 17 |
| Caelo | Betamethasone valerate | 17329004 | 4 |
| Caelo | Betamethasone valerate | 17329008 | 10 |
| Caelo | Betamethasone valerate | 17329011 | 7 |
| Caelo | Betamethasone valerate | 17329015 | 11 |
| Caelo | Betamethasone valerate | 17329017 | 10 |
| Caelo | Betamethasone valerate | 17329018 | 76 |
| Caelo | Betamethasone valerate | 1732901803110025 | 1 |
| Caelo | Betamethasone valerate | 17329019 | 4 |
| Caelo | Betamethasone valerate | 173296011 | 1 |
| Caelo | Betamethasone valerate | 1739002 | 3 |
| Caelo | Betamethasone valerate | 17C29-B04 | 2 |
| Caelo | Betamethasone valerate | 17C29-B04-334329 | 1 |
| Caelo | Betamethasone valerate | 17c29-b04-335657 | 2 |
| Caelo | Betamethasone valerate | 17C29-B04-335676 | 2 |
| Caelo | Betamethasone valerate | 17G31B04338575 | 1 |
| Caelo | Betamethasone valerate | 17G31-B04-338575 | 1 |
| Caelo | Betamethasone valerate | 17G31-B04-341576 | 1 |
| Caelo | Betamethasone valerate | 17K16-B0/8-347310 | 1 |
| Caelo | Betamethasone valerate | 17K16-B08 | 1 |
| Caelo | Betamethasone valerate | 17K16-B08-345541 | 3 |
| Caelo | Betamethasone valerate | 17K16-B08-347309 | 2 |
| Caelo | Betamethasone valerate | 17K16-B08-347912 | 4 |
| Caelo | Betamethasone valerate | 1801024-01 | 12 |
| Caelo | Betamethasone valerate | 18071403 | 1 |
| Caelo | Betamethasone valerate | 1811008 | 1 |
| Caelo | Betamethasone valerate | 181100801 | 1 |
| Caelo | Betamethasone valerate | 1811008-01 | 3 |
| Caelo | Betamethasone valerate | 18121206 | 1 |
| Caelo | Betamethasone valerate | 18189907 | 1 |
| Caelo | Betamethasone valerate | 1819908 | 1 |
| Caelo | Betamethasone valerate | 1819918 | 3 |
| Caelo | Betamethasone valerate | 1819924 | 1 |
| Caelo | Betamethasone valerate | 1819932 | 1 |
| Caelo | Betamethasone valerate | 181999007 | 1 |
| Caelo | Betamethasone valerate | 18199902 | 43 |
| Caelo | Betamethasone valerate | 18199903 | 2 |
| Caelo | Betamethasone valerate | 18199906 | 10 |
| Caelo | Betamethasone valerate | 18199907 | 36 |
| Caelo | Betamethasone valerate | 1819990705/2023 | 1 |
| Caelo | Betamethasone valerate | 18199908 | 15 |
| Caelo | Betamethasone valerate | 18199914 | 4 |
| Caelo | Betamethasone valerate | 18199915 | 4 |
| Caelo | Betamethasone valerate | 18199916 | 23 |
| Caelo | Betamethasone valerate | 18199918 | 51 |
| Caelo | Betamethasone valerate | 18199923P-200116-2 | 1 |
| Caelo | Betamethasone valerate | 18199924 | 19 |
| Caelo | Betamethasone valerate | 18199926 | 4 |
| Caelo | Betamethasone valerate | 18199930 | 8 |
| Caelo | Betamethasone valerate | 18199932 | 46 |
| Caelo | Betamethasone valerate | 18199933 | 37 |
| Caelo | Betamethasone valerate | 18199937 | 2 |
| Caelo | Betamethasone valerate | 18199938 | 8 |
| Caelo | Betamethasone valerate | 18G03B03351731 | 1 |
| Caelo | Betamethasone valerate | 18G03-B03-351731 | 1 |
| Caelo | Betamethasone valerate | 18I27-B05-354880 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone valerate | 1912012-01 | 2 |
| Caelo | Betamethasone valerate | 19220009 | 1 |
| Caelo | Betamethasone valerate | 1922070003 | 1 |
| Caelo | Betamethasone valerate | 192207001 | 18 |
| Caelo | Betamethasone valerate | 192207002 | 43 |
| Caelo | Betamethasone valerate | 192207003 | 32 |
| Caelo | Betamethasone valerate | 192207004 | 4 |
| Caelo | Betamethasone valerate | 192207006 | 11 |
| Caelo | Betamethasone valerate | 192207009 | 28 |
| Caelo | Betamethasone valerate | 192207010 | 20 |
| Caelo | Betamethasone valerate | 192207012 | 21 |
| Caelo | Betamethasone valerate | 19220702 | 34 |
| Caelo | Betamethasone valerate | 19220703 | 7 |
| Caelo | Betamethasone valerate | 19220704 | 28 |
| Caelo | Betamethasone valerate | 19220705 | 44 |
| Caelo | Betamethasone valerate | 19220706 | 1 |
| Caelo | Betamethasone valerate | 19220707012 | 1 |
| Caelo | Betamethasone valerate | 19g30-b02-363673 | 1 |
| Caelo | Betamethasone valerate | 19g30-b02-363693 | 1 |
| Caelo | Betamethasone valerate | 19K11-F07-366785 | 1 |
| Caelo | Betamethasone valerate | 20002685001 | 4 |
| Caelo | Betamethasone valerate | 20B18-F07-370009 | 2 |
| Caelo | Betamethasone valerate | 20B18-F07-370010 | 1 |
| Caelo | Betamethasone valerate | 21000026003 | 2 |
| Caelo | Betamethasone valerate | 210000360010 | 2 |
| Caelo | Betamethasone valerate | 21000036003 | 59 |
| Caelo | Betamethasone valerate | 21000036004 | 22 |
| Caelo | Betamethasone valerate | 210000360063 | 1 |
| Caelo | Betamethasone valerate | 21000036007 | 2 |
| Caelo | Betamethasone valerate | 21000036008 | 11 |
| Caelo | Betamethasone valerate | 21000036010 | 34 |
| Caelo | Betamethasone valerate | 21000036011 | 2 |
| Caelo | Betamethasone valerate | 21000036013 | 1 |
| Caelo | Betamethasone valerate | 21000036015 | 1 |
| Caelo | Betamethasone valerate | 21000036016 | 19 |
| Caelo | Betamethasone valerate | 21000036017 | 47 |
| Caelo | Betamethasone valerate | 21000036018 | 2 |
| Caelo | Betamethasone valerate | 21000036019 | 1 |
| Caelo | Betamethasone valerate | 21000036020 | 19 |
| Caelo | Betamethasone valerate | 21000036021 | 21 |
| Caelo | Betamethasone valerate | 21000036022 | 3 |
| Caelo | Betamethasone valerate | 2100003610 | 1 |
| Caelo | Betamethasone valerate | 2100036003 | 4 |
| Caelo | Betamethasone valerate | 2100036004 | 1 |
| Caelo | Betamethasone valerate | 2100036010 | 2 |
| Caelo | Betamethasone valerate | 2100036016 | 1 |
| Caelo | Betamethasone valerate | 2100036017 | 1 |
| Caelo | Betamethasone valerate | 2100036020 | 1 |
| Caelo | Betamethasone valerate | 2100036021 | 1 |
| Caelo | Betamethasone valerate | 210003610 | 1 |
| Caelo | Betamethasone valerate | 210112 | 1 |
| Caelo | Betamethasone valerate | 210201001 | 1 |
| Caelo | Betamethasone valerate | 2102010-02 | 1 |
| Caelo | Betamethasone valerate | 21G28-B02-213516 | 1 |
| Caelo | Betamethasone valerate | 2200/101003 | 1 |
| Caelo | Betamethasone valerate | 220011009 | 1 |
| Caelo | Betamethasone valerate | 22001101003 | 3 |
| Caelo | Betamethasone valerate | 22001101004 | 4 |
| Caelo | Betamethasone valerate | 22001101005 | 15 |
| Caelo | Betamethasone valerate | 22001101005103/22P | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Betamethasone valerate | 22001101009 | 6 |
| Caelo | Betamethasone valerate | 22001101015 | 2 |
| Caelo | Betamethasone valerate | 22001101016 | 3 |
| Caelo | Betamethasone valerate | 22001101018 | 2 |
| Caelo | Betamethasone valerate | 23003252001 | 1 |
| Caelo | Betamethasone valerate | 2x12229813 | 1 |
| Caelo | Betamethasone valerate | 31(17329018) | 1 |
| Caelo | Betamethasone valerate | 311002517078712 | 1 |
| Caelo | Betamethasone valerate | 32(192207002) | 1 |
| Caelo | Betamethasone valerate | 3303 | 1 |
| Caelo | Betamethasone valerate | 534210000363 | 1 |
| Caelo | Betamethasone valerate | 5348210000368 | 1 |
| Caelo | Betamethasone valerate | 8081502 | 1 |
| Caelo | Betamethasone valerate | 922070101 | 1 |
| Caelo | Betamethasone valerate | APPV010/0516B | 1 |
| Caelo | Betamethasone valerate | B03041205 | 1 |
| Caelo | Betamethasone valerate | BV018/0715 | 2 |
| Caelo | Betamethasone valerate | BV109/0519 | 1 |
| Caelo | Betamethasone valerate | BV-BLT225/0514 | 1 |
| Caelo | Betamethasone valerate | C0073/1 | 3 |
| Caelo | Betamethasone valerate | F07-3667709 | 1 |
| Caelo | Betamethasone valerate | NT0597M | 1 |
| Caeolo /Sana | Betamethasone valerate | 18199903 | 1 |
| Caesar & Lorenz GmbH | Betamethasone valerate | 15075805 | 1 |
| Caesar & Lorenz GmbH | Betamethasone valerate | 16270501 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036020 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199924 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207001 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036021 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 19220702 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036004 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207010 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036003 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 2100036017 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199938 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101005 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036011 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 120801402 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 10296707 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 11131914 | 3 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 12003404 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 12003409 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 12229809 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 13091206 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 13091211 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101005 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036008 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101005 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199915 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101015 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199916 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101009 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101005 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199902 | 1 |
| Caesar & Loretz GmbH/ | Betamethasone valerate | 17329018 | 1 |
| Caesar & Loretz GmbH/AEP | Betamethasone valerate | 18199924 | 1 |
| Caesar & Loretz GmbH/E | Betamethasone valerate | 18199938 | 1 |
| Caesar & Loretz GmbH/E | Betamethasone valerate | 21000036016 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 20002685001 | 2 |
| Caesar & Loretz GmbH/Gehe | Betamethasone valerate | 18199903 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Betamethasone valerate | 18199908 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone valerate | 18199916 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone valerate | 19220702 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone valerate | 21000036010 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone valerate | 21000036016 | 1 |
| Caesar & Loretz GmbH/Gehe | Betamethasone valerate | 22001101021 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036010 | 1 |
| Caesar & Loretz GmbH/Gö | Betamethasone valerate | 21000036021 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199918 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207010 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036003 | 3 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199918 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199933 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207010 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 19220705 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036016 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101004 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101015 | 1 |
| Caesar & Loretz GmbH/K | Betamethasone valerate | 19220702 | 1 |
| Caesar & Loretz GmbH/Kehr | Betamethasone valerate | 21000036021 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199918 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036010 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036017 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 17078712 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199907 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199908 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199918 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199933 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207002 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207010 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 19220705 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036003 | 3 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036010 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036021 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199915 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199924 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18G03-B03-352460 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 20002685001 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036003 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036004 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036017 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | BV116/0819 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199918 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207002 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 192207009 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 19220705 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036003 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101005 | 4 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 22001101015 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199915 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 18199932 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 19220702 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 19220703 | 1 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036004 | 2 |
| Caesar & Loretz GmbH... | Betamethasone valerate | 21000036017 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 13225504 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 16270511 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 17078701 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 17329001 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 17329002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Betamethasone valerate | 17329004 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 17329015 | 3 |
| Caesar & Loretz GmbH | Betamethasone valerate | 17329018 | 5 |
| Caesar & Loretz GmbH | Betamethasone valerate | 17K16B08345555 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 1811008-01 | 2 |
| Caesar & Loretz GmbH | Betamethasone valerate | 1819930 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199902 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199903 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199906 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199907 | 10 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199908 | 3 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199914 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199915 | 4 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199916 | 3 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199918 | 15 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199923 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199924 | 6 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199930 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199932 | 7 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199933 | 14 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199937 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18199938 | 5 |
| Caesar & Loretz GmbH | Betamethasone valerate | 18G03-B03 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207001 | 8 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207002 | 14 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207003 | 8 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207004 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207005 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207006 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207009 | 7 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207010 | 7 |
| Caesar & Loretz GmbH | Betamethasone valerate | 192207012 | 11 |
| Caesar & Loretz GmbH | Betamethasone valerate | 19220702 | 12 |
| Caesar & Loretz GmbH | Betamethasone valerate | 19220703 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 19220704 | 11 |
| Caesar & Loretz GmbH | Betamethasone valerate | 19220705 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 19220706 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 19220707 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 1922207002 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 20002685001 | 2 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036001 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036003 | 18 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036004 | 14 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036007 | 2 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036008 | 6 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036010 | 9 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036011 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036015 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036016 | 14 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036017 | 19 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036018 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036019 | 3 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036020 | 9 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036021 | 8 |
| Caesar & Loretz GmbH | Betamethasone valerate | 21000036023 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101002 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101004 | 2 |
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101005 | 4 |
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101009 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101015 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101016 | 4 |
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101020 | 1 |
| Caesar & Loretz GmbH | Betamethasone valerate | 22001101023 | 2 |
| Caesar & Loretz/Gehe | Betamethasone valerate | 18199932 | 1 |
| Caesar & Loretz/Geil... | Betamethasone valerate | 192207001 | 1 |
| Caesar & Loretz | Betamethasone valerate | 17329016 | 1 |
| Caesar & Loretz | Betamethasone valerate | 21000036008 | 1 |
| Caesar &Loretz GmbH | Betamethasone valerate | 11131917 | 1 |
| Caesar Loretz | Betamethasone valerate | 192207010 | 1 |
| Caesar und Loretz | Betamethasone valerate | 15075803 | 1 |
| Caesar&Lorenz | Betamethasone valerate | 21000036016 | 1 |
| Caesar&Loretz GmbH,P... | Betamethasone valerate | 16270509 | 1 |
| Caesar&Loretz GmbH/Anzag | Betamethasone valerate | 15075802 | 1 |
| Caesar&Loretz GmbH | Betamethasone valerate | 15262609 | 1 |
| caesar&loretz,phönix | Betamethasone valerate | 14188606 | 1 |
| Caesar/Lorenz | Betamethasone valerate | 12003403 | 1 |
| Caleo/Phönix | Betamethasone valerate | 1522609 | 1 |
| Carlo/Gehe | Betamethasone valerate | 19220702 | 1 |
| Carlo/Phönix/46,64 | Betamethasone valerate | 18199924 | 1 |
| Cealo/Gehe | Betamethasone valerate | 17329002 | 1 |
| Cealo/Gehe | Betamethasone valerate | 1739002 | 1 |
| Cealo/Gehe | Betamethasone valerate | 1801024-01 | 1 |
| Cealo/Noweda | Betamethasone valerate | 16270509 | 2 |
| Cealo | Betamethasone valerate | 17078716 | 1 |
| Crystal PH/Oberlinde... | Betamethasone valerate | C0073/114040 | 1 |
| Dr. Aug. Wolff GmbH ... | Betamethasone valerate | 192207012 | 1 |
| E Plus | Betamethasone valerate | 16270502 | 1 |
| E Plus | Betamethasone valerate | 17329002 | 1 |
| Ebert & Jacobi | Betamethasone valerate | 14188606 | 1 |
| Ebert & Jacobi | Betamethasone valerate | 15075810 | 1 |
| Ebert u. Jacobi 1... | Betamethasone valerate | 15/16-B07-317417 | 1 |
| Eigenherstellung | Betamethasone valerate | 9070313 | 1 |
| EuRho / Phoenix | Betamethasone valerate | 1704019-01 | 1 |
| EuRho /Gumo | Betamethasone valerate | 1911001-01 | 1 |
| EuRho/Noweda 02.06.2022 | Betamethasone valerate | 2102010 | 1 |
| EuRho/Noweda 11.11.2020 | Betamethasone valerate | 1912012-01 | 1 |
| EuRho/Phönix | Betamethasone valerate | 2102010-01 | 1 |
| EuRho/Sanacorp | Betamethasone valerate | 1911001-01 | 1 |
| EuRho | Betamethasone valerate | 1208014-01 | 2 |
| EuRho | Betamethasone valerate | 1208014-02 | 1 |
| EuRho | Betamethasone valerate | 1406019-03 | 3 |
| EuRho | Betamethasone valerate | 1610010-01 | 2 |
| Eurho | Betamethasone valerate | 1801024-01 | 1 |
| EuRho | Betamethasone valerate | 180102401 | 1 |
| EuRho | Betamethasone valerate | 1801024-01 | 4 |
| EuRho | Betamethasone valerate | 181008-01 | 1 |
| euRho | Betamethasone valerate | 1811008-01 | 1 |
| Eurho | Betamethasone valerate | 1811008-01 | 1 |
| Eurho | Betamethasone valerate | 1911001-01 | 1 |
| EuRho | Betamethasone valerate | 1911001-01 | 1 |
| EuRho | Betamethasone valerate | 1911001-02 | 1 |
| EuRho | Betamethasone valerate | 1912012-01 | 1 |
| euRho | Betamethasone valerate | 2102010-01 | 1 |
| EuRho | Betamethasone valerate | 2102010-01 | 2 |
| Euro / Gehe | Betamethasone valerate | 1912012-12 | 1 |
| Euro OTC | Betamethasone valerate | | 1 |
| Euro OTC | Betamethasone valerate | 1031707 | 1 |
| Euro OTC | Betamethasone valerate | 110804-02 | 1 |
| Euro OTC | Betamethasone valerate | 1108045-01 | 2 |
| Euro OTC | Betamethasone valerate | 1108045-02 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Betamethasone valerate | 110804503 | 1 |
| Euro OTC | Betamethasone valerate | 1108045-03 | 10 |
| Euro OTC | Betamethasone valerate | 1206014-02 | 1 |
| Euro OTC | Betamethasone valerate | 1208014-01 | 12 |
| Euro OTC | Betamethasone valerate | 120801402 | 2 |
| Euro OTC | Betamethasone valerate | 1208014-02 | 12 |
| Euro OTC | Betamethasone valerate | 120801403 | 1 |
| Euro OTC | Betamethasone valerate | 1208014-03 | 4 |
| Euro OTC | Betamethasone valerate | 120801404 | 1 |
| Euro OTC | Betamethasone valerate | 1208014-04 | 4 |
| Euro OTC | Betamethasone valerate | 120812-02 | 1 |
| Euro OTC | Betamethasone valerate | 12L11-N01 | 1 |
| Euro OTC | Betamethasone valerate | 1311039 | 1 |
| Euro OTC | Betamethasone valerate | 131103901 | 1 |
| Euro OTC | Betamethasone valerate | 1311039-01 | 22 |
| Euro OTC | Betamethasone valerate | 131139-01 | 1 |
| Euro OTC | Betamethasone valerate | 13D03-N07 | 1 |
| Euro OTC | Betamethasone valerate | 13K29-B32-289364 | 1 |
| Euro OTC | Betamethasone valerate | 1406011903 | 1 |
| Euro OTC | Betamethasone valerate | 140601901 | 1 |
| Euro OTC | Betamethasone valerate | 1406019-01 | 30 |
| Euro OTC | Betamethasone valerate | 140601902 | 1 |
| Euro OTC | Betamethasone valerate | 1406019-02 | 23 |
| Euro OTC | Betamethasone valerate | 140601903 | 2 |
| Euro OTC | Betamethasone valerate | 1406019-03 | 32 |
| Euro OTC | Betamethasone valerate | 15/16-B07-319228 | 1 |
| Euro OTC | Betamethasone valerate | 1510037 | 1 |
| Euro OTC | Betamethasone valerate | 151003701 | 1 |
| Euro OTC | Betamethasone valerate | 1510037-01 | 24 |
| Euro OTC | Betamethasone valerate | 1510037-07 | 1 |
| Euro OTC | Betamethasone valerate | 1516B07317416 | 1 |
| Euro OTC | Betamethasone valerate | 15398501 | 1 |
| Euro OTC | Betamethasone valerate | 15F16/B04-314054 | 1 |
| Euro OTC | Betamethasone valerate | 1606023-01 | 43 |
| Euro OTC | Betamethasone valerate | 160623-01 | 1 |
| Euro OTC | Betamethasone valerate | 16100100-01 | 1 |
| Euro OTC | Betamethasone valerate | 161001001 | 1 |
| Euro OTC | Betamethasone valerate | 1610010-01 | 55 |
| Euro OTC | Betamethasone valerate | 1610010-03 | 1 |
| Euro OTC | Betamethasone valerate | 16270505 | 1 |
| Euro OTC | Betamethasone valerate | 16E23-B03-328128 | 1 |
| Euro OTC | Betamethasone valerate | 1704018-01 | 1 |
| Euro OTC | Betamethasone valerate | 1704019 | 2 |
| Euro OTC | Betamethasone valerate | 1704019_01 | 1 |
| Euro OTC | Betamethasone valerate | 1704019-0 | 1 |
| Euro OTC | Betamethasone valerate | 170401901 | 5 |
| Euro OTC | Betamethasone valerate | 1704019-01 | 142 |
| Euro OTC | Betamethasone valerate | 1704019-1 | 1 |
| Euro OTC | Betamethasone valerate | 1704021-04 | 1 |
| Euro OTC | Betamethasone valerate | 170419-01 | 1 |
| Euro OTC | Betamethasone valerate | 17078701 | 1 |
| Euro OTC | Betamethasone valerate | 17078703 | 1 |
| Euro OTC | Betamethasone valerate | 17078720 | 1 |
| Euro OTC | Betamethasone valerate | 17271603 | 3 |
| Euro OTC | Betamethasone valerate | 17329001 | 1 |
| Euro OTC | Betamethasone valerate | 1739002 | 1 |
| Euro OTC | Betamethasone valerate | 1740419-01 | 1 |
| Euro OTC | Betamethasone valerate | 17C29-B04-336434 | 1 |
| Euro OTC | Betamethasone valerate | 17K16-B08-345541 | 1 |
| Euro OTC | Betamethasone valerate | 17o4019-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Betamethasone valerate | 18010024-01 | 1 |
| Euro OTC | Betamethasone valerate | 1801024 | 1 |
| Euro OTC | Betamethasone valerate | 1801024_01 | 1 |
| Euro OTC | Betamethasone valerate | 180102401 | 2 |
| Euro OTC | Betamethasone valerate | 1801024-01 | 137 |
| Euro OTC | Betamethasone valerate | 180104-01 | 1 |
| Euro OTC | Betamethasone valerate | 181008-01 | 1 |
| Euro OTC | Betamethasone valerate | 1811008 | 1 |
| Euro OTC | Betamethasone valerate | 181100801 | 5 |
| Euro OTC | Betamethasone valerate | 1811008-01 | 129 |
| Euro OTC | Betamethasone valerate | 1811008-1 | 2 |
| Euro OTC | Betamethasone valerate | 1811024-01 | 1 |
| Euro OTC | Betamethasone valerate | 18199902 | 1 |
| Euro OTC | Betamethasone valerate | 18199907 | 1 |
| Euro OTC | Betamethasone valerate | 190451504 | 1 |
| Euro OTC | Betamethasone valerate | 191001-01 | 2 |
| Euro OTC | Betamethasone valerate | 191100101 | 1 |
| Euro OTC | Betamethasone valerate | 1911001-01 | 153 |
| Euro OTC | Betamethasone valerate | 1911001-02 | 6 |
| Euro OTC | Betamethasone valerate | 191101-01 | 1 |
| Euro OTC | Betamethasone valerate | 1911011-01 | 1 |
| Euro OTC | Betamethasone valerate | 1912012-01 | 21 |
| Euro OTC | Betamethasone valerate | 2014Q1181 | 1 |
| Euro OTC | Betamethasone valerate | 20906 | 1 |
| Euro OTC | Betamethasone valerate | 2102010 | 3 |
| Euro OTC | Betamethasone valerate | 2102010-01 | 74 |
| Euro OTC | Betamethasone valerate | 2102010-02 | 22 |
| Euro OTC | Betamethasone valerate | 210210-01 | 1 |
| Euro OTC | Betamethasone valerate | 2202016-01 | 17 |
| Euro OTC | Betamethasone valerate | 2202016-02 | 1 |
| Euro OTC | Betamethasone valerate | 2309023-01 | 5 |
| Euro OTC | Betamethasone valerate | 2507211181 | 1 |
| Euro OTC | Betamethasone valerate | 29061805 | 1 |
| Euro OTC | Betamethasone valerate | 3313U-01181 | 1 |
| Euro OTC | Betamethasone valerate | 7071802 | 1 |
| Euro OTC | Betamethasone valerate | BV116/1117 | 1 |
| Euro OTC | Betamethasone valerate | BV-BLT221/0314 | 1 |
| Euro Pharma/Noweda | Betamethasone valerate | 1912012-01 | 6 |
| euro//Noweda | Betamethasone valerate | 1801024-01 | 2 |
| Euro/Alliance Healthcare | Betamethasone valerate | 1510037-01 | 1 |
| Euro/direkt | Betamethasone valerate | 1704019-01 | 1 |
| Euro/Gehe | Betamethasone valerate | 1704019-01 | 1 |
| Euro/Noweda | Betamethasone valerate | 1801024-01 | 2 |
| Euro | Betamethasone valerate | 1801024-01 | 2 |
| Euroo | Betamethasone valerate | 1406019-03 | 1 |
| Europ Ots Pharma | Betamethasone valerate | 12111-N01 | 1 |
| EurRho/Gehe | Betamethasone valerate | 1610010-01 | 1 |
| Fa.Phönix | Betamethasone valerate | 192207009 | 1 |
| Fa.Phönix | Betamethasone valerate | 21000036003 | 1 |
| Fa.Phönix | Betamethasone valerate | 21000036021 | 1 |
| Fa.Phönix | Betamethasone valerate | 22001101009 | 1 |
| Fagon / Noweda | Betamethasone valerate | 21G-28-B02-213663 | 1 |
| Fagon/Gehe | Betamethasone valerate | 24A30-B08-238302 | 1 |
| Fagon/Noweda | Betamethasone valerate | F07-3667806 | 1 |
| Fagron | Betamethasone valerate | | 3 |
| Fagron | Betamethasone valerate | 1018E-01181 | 1 |
| Fagron | Betamethasone valerate | 11A04-N02 | 1 |
| Fagron | Betamethasone valerate | 11E18-N03 | 3 |
| Fagron | Betamethasone valerate | 11K18-N09 | 3 |
| Fagron | Betamethasone valerate | 11K-18-N09 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone valerate | 120801402 | 1 |
| Fagron | Betamethasone valerate | 123649978B | 1 |
| Fagron | Betamethasone valerate | 12B28-N01 | 8 |
| Fagron | Betamethasone valerate | 12G09-N07 | 25 |
| Fagron | Betamethasone valerate | 12K07N23 | 1 |
| Fagron | Betamethasone valerate | 12K07-N23 | 6 |
| Fagron | Betamethasone valerate | 12L11-N01 | 18 |
| Fagron | Betamethasone valerate | 12L11-NO1 | 1 |
| Fagron | Betamethasone valerate | 13/17-B08-292649 | 2 |
| Fagron | Betamethasone valerate | 1311039-01 | 1 |
| Fagron | Betamethasone valerate | 13d03-n07 | 3 |
| Fagron | Betamethasone valerate | 13D03-N07 | 40 |
| Fagron | Betamethasone valerate | 13g19-n01 | 2 |
| Fagron | Betamethasone valerate | 13G19N01 | 1 |
| Fagron | Betamethasone valerate | 13G19-N01 | 49 |
| Fagron | Betamethasone valerate | 13G19-NO1 | 1 |
| Fagron | Betamethasone valerate | 13K05-B08 | 2 |
| Fagron | Betamethasone valerate | 13K05-B08-092652 | 1 |
| Fagron | Betamethasone valerate | 13K05-B08-291663 | 3 |
| Fagron | Betamethasone valerate | 13K05-B08-292647 | 2 |
| Fagron | Betamethasone valerate | 13K05-B08-292651 | 1 |
| Fagron | Betamethasone valerate | 13K05-B08-292652 | 2 |
| Fagron | Betamethasone valerate | 13K29-B12-288247 | 1 |
| Fagron | Betamethasone valerate | 13K29-B23-288246 | 1 |
| Fagron | Betamethasone valerate | 13K29B32 | 1 |
| Fagron | Betamethasone valerate | 13K29-B32 | 6 |
| Fagron | Betamethasone valerate | 13K29-B32-28824 | 1 |
| Fagron | Betamethasone valerate | 13K29B32288243 | 1 |
| Fagron | Betamethasone valerate | 13K29-B32-288244 | 2 |
| Fagron | Betamethasone valerate | 13K29-B32-288245 | 1 |
| Fagron | Betamethasone valerate | 13K29-B32-288246 | 5 |
| Fagron | Betamethasone valerate | 13k29b32288247 | 1 |
| Fagron | Betamethasone valerate | 13K29-B32-288247 | 20 |
| Fagron | Betamethasone valerate | 13K29-B32-288248 | 3 |
| Fagron | Betamethasone valerate | 13K29-B32-288250 | 4 |
| Fagron | Betamethasone valerate | 13117-B08-292649 | 2 |
| Fagron | Betamethasone valerate | 1406019-03 | 1 |
| Fagron | Betamethasone valerate | 14188603 | 1 |
| Fagron | Betamethasone valerate | 14C19B02 | 1 |
| Fagron | Betamethasone valerate | 14C19-B02 | 3 |
| Fagron | Betamethasone valerate | 14C19-B02-292646 | 2 |
| Fagron | Betamethasone valerate | 14C19-B02-292648 | 1 |
| Fagron | Betamethasone valerate | 14c19-b02-292650 | 1 |
| Fagron | Betamethasone valerate | 14C19-B02-292650 | 6 |
| Fagron | Betamethasone valerate | 14C19-B02-292653 | 6 |
| Fagron | Betamethasone valerate | 14C19B02296168 | 1 |
| Fagron | Betamethasone valerate | 14C19-B02-296168 | 4 |
| Fagron | Betamethasone valerate | 14c19-b02-296169 | 1 |
| Fagron | Betamethasone valerate | 14C19-B02-296169 | 1 |
| Fagron | Betamethasone valerate | 14G30-B05 | 4 |
| Fagron | Betamethasone valerate | 14G30-B05-29617 | 1 |
| Fagron | Betamethasone valerate | 14G30-B05-296170 | 1 |
| Fagron | Betamethasone valerate | 14G30B05296172 | 1 |
| Fagron | Betamethasone valerate | 14G30-B05-296172 | 3 |
| Fagron | Betamethasone valerate | 14G30-B05-296173 | 12 |
| Fagron | Betamethasone valerate | 14G30-B05-296175 | 3 |
| Fagron | Betamethasone valerate | 14G30-B05-309518 | 2 |
| Fagron | Betamethasone valerate | 14G30B05309519 | 1 |
| Fagron | Betamethasone valerate | 14G30-B05-309519 | 1 |
| Fagron | Betamethasone valerate | 14G30-B05-309520 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone valerate | 14G30-B05-309521 | 1 |
| Fagron | Betamethasone valerate | 14G30-B05-309528 | 1 |
| Fagron | Betamethasone valerate | 14G30-Bo5-296172 | 1 |
| Fagron | Betamethasone valerate | 14G31-B04-342639 | 1 |
| Fagron | Betamethasone valerate | 14H28B01 | 1 |
| Fagron | Betamethasone valerate | 14H28-B01 | 3 |
| Fagron | Betamethasone valerate | 14H28-B01-302683 | 1 |
| Fagron | Betamethasone valerate | 14H28-B01-302863 | 5 |
| Fagron | Betamethasone valerate | 14H28B01302864 | 1 |
| Fagron | Betamethasone valerate | 14H28-B01-302864 | 6 |
| Fagron | Betamethasone valerate | 14H28-B01-302864/201 | 1 |
| Fagron | Betamethasone valerate | 14h28-b01-302865 | 2 |
| Fagron | Betamethasone valerate | 14H28-B01-302865 | 13 |
| Fagron | Betamethasone valerate | 14H28-b01-302866 | 1 |
| Fagron | Betamethasone valerate | 14H28-B01-302866 | 7 |
| Fagron | Betamethasone valerate | 14H28-B01-302877 | 3 |
| Fagron | Betamethasone valerate | 14H28-B01-305470 | 2 |
| Fagron | Betamethasone valerate | 15/16-B07 | 1 |
| Fagron | Betamethasone valerate | 15/16-B07-317416 | 5 |
| Fagron | Betamethasone valerate | 15/16-B07-317417 | 2 |
| Fagron | Betamethasone valerate | 15/16-B07-317428 | 3 |
| Fagron | Betamethasone valerate | 15/16-B07-319228 | 3 |
| Fagron | Betamethasone valerate | 15/16-B07-319831 | 1 |
| Fagron | Betamethasone valerate | 15/16-B07-319832 | 1 |
| Fagron | Betamethasone valerate | 15075802 | 1 |
| Fagron | Betamethasone valerate | 15116-B07 | 1 |
| Fagron | Betamethasone valerate | 1516-B07-317416 | 1 |
| Fagron | Betamethasone valerate | 1526260 | 1 |
| Fagron | Betamethasone valerate | 15398515 | 1 |
| Fagron | Betamethasone valerate | 15824-B04 | 1 |
| Fagron | Betamethasone valerate | 15B24-B04 | 2 |
| Fagron | Betamethasone valerate | 15B24-B04-307015 | 4 |
| Fagron | Betamethasone valerate | 15B24-B04-307016 | 14 |
| Fagron | Betamethasone valerate | 15F16-804-314054 | 1 |
| Fagron | Betamethasone valerate | 15F16-B04 | 4 |
| Fagron | Betamethasone valerate | 15F16-B04-215327 | 1 |
| Fagron | Betamethasone valerate | 15f16-b04314054 | 1 |
| Fagron | Betamethasone valerate | 15F16-B04-314054 | 5 |
| Fagron | Betamethasone valerate | 15F16-B04-314054/201 | 1 |
| Fagron | Betamethasone valerate | 15F16-B04-314055 | 1 |
| Fagron | Betamethasone valerate | 15F16-B04-314882 | 1 |
| Fagron | Betamethasone valerate | 15F16-B04-315328 | 3 |
| Fagron | Betamethasone valerate | 15I16-B07 | 1 |
| Fagron | Betamethasone valerate | 15I16-B07-317416 | 1 |
| Fagron | Betamethasone valerate | 15I16B07317417 | 1 |
| Fagron | Betamethasone valerate | 15I16-B07-317417 | 1 |
| Fagron | Betamethasone valerate | 15I16-B07-319228 | 3 |
| Fagron | Betamethasone valerate | 15I16-B07-319832 | 3 |
| Fagron | Betamethasone valerate | 15I16-Bo7-319832 | 1 |
| Fagron | Betamethasone valerate | 15l16-B07-319832 | 2 |
| Fagron | Betamethasone valerate | 16270511 | 1 |
| Fagron | Betamethasone valerate | 16270513 | 1 |
| Fagron | Betamethasone valerate | 16818-B02-320971 | 1 |
| Fagron | Betamethasone valerate | 16818-B02-323033 | 1 |
| Fagron | Betamethasone valerate | 16B18_B02-322111 | 1 |
| Fagron | Betamethasone valerate | 16B18-B02 | 6 |
| Fagron | Betamethasone valerate | 16B18-B02-320606 | 1 |
| Fagron | Betamethasone valerate | 16B18B02320971 | 1 |
| Fagron | Betamethasone valerate | 16B18-B02320971 | 2 |
| Fagron | Betamethasone valerate | 16B18-B02-320971 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone valerate | 16B18-B02-322109 | 5 |
| Fagron | Betamethasone valerate | 16B18-B02-322111 | 2 |
| Fagron | Betamethasone valerate | 16B18-B02-322121 | 4 |
| Fagron | Betamethasone valerate | 16B18-B02-323033 | 1 |
| Fagron | Betamethasone valerate | 16b18-b02-323034 | 1 |
| Fagron | Betamethasone valerate | 16B18-B02-323034 | 4 |
| Fagron | Betamethasone valerate | 16b18-b02-324798 | 1 |
| Fagron | Betamethasone valerate | 16B18-B02-324798 | 3 |
| Fagron | Betamethasone valerate | 16E23-B03 | 8 |
| Fagron | Betamethasone valerate | 16E23-B03-324799 | 8 |
| Fagron | Betamethasone valerate | 16E23-B03-3247990855 | 1 |
| Fagron | Betamethasone valerate | 16e23b03324800 | 1 |
| Fagron | Betamethasone valerate | 16e23-b03-324800 | 1 |
| Fagron | Betamethasone valerate | 16E23-B03-324800 | 13 |
| Fagron | Betamethasone valerate | 16E23-B03-327350 | 3 |
| Fagron | Betamethasone valerate | 16E23-B03-327354 | 3 |
| Fagron | Betamethasone valerate | 16E23-b03-328128 | 1 |
| Fagron | Betamethasone valerate | 16E23B03328128 | 1 |
| Fagron | Betamethasone valerate | 16E23-B03-328128 | 11 |
| Fagron | Betamethasone valerate | 16E23-B03-328129 | 2 |
| Fagron | Betamethasone valerate | 16H22-B06 | 3 |
| Fagron | Betamethasone valerate | 16H22-B06-329223 | 6 |
| Fagron | Betamethasone valerate | 16H22-B06-329231 | 5 |
| Fagron | Betamethasone valerate | 16H22-B06-330522 | 2 |
| Fagron | Betamethasone valerate | 16H22-B06-330523 | 4 |
| Fagron | Betamethasone valerate | 16H22B06330524 | 2 |
| Fagron | Betamethasone valerate | 16H22-B06-330524 | 6 |
| Fagron | Betamethasone valerate | 16h22b06330584 | 1 |
| Fagron | Betamethasone valerate | 16h22-b06-331273 | 1 |
| Fagron | Betamethasone valerate | 16H22-B06-331273 | 1 |
| Fagron | Betamethasone valerate | 16H22-B06-332351 | 11 |
| Fagron | Betamethasone valerate | 16H22-B06-3332351 | 1 |
| Fagron | Betamethasone valerate | 170401901 | 1 |
| Fagron | Betamethasone valerate | 1704019-01 | 2 |
| Fagron | Betamethasone valerate | 17078701 | 1 |
| Fagron | Betamethasone valerate | 17078703 | 2 |
| Fagron | Betamethasone valerate | 17271604 | 2 |
| Fagron | Betamethasone valerate | 17329001 | 1 |
| Fagron | Betamethasone valerate | 17329008 | 1 |
| Fagron | Betamethasone valerate | 17329016 | 1 |
| Fagron | Betamethasone valerate | 17B14-B04 | 1 |
| Fagron | Betamethasone valerate | 17C29-335654 | 1 |
| Fagron | Betamethasone valerate | 17C29-B04 | 7 |
| Fagron | Betamethasone valerate | 17C29-B04_336434 | 1 |
| Fagron | Betamethasone valerate | 17C29-B04-33368 | 1 |
| Fagron | Betamethasone valerate | 17C29-B04-333688 | 1 |
| Fagron | Betamethasone valerate | 17C29-B04-334329 | 10 |
| Fagron | Betamethasone valerate | 17c29-b04-335654 | 1 |
| Fagron | Betamethasone valerate | 17C29-B04-335654 | 3 |
| Fagron | Betamethasone valerate | 17C29-B04-335657 | 11 |
| Fagron | Betamethasone valerate | 17C29B043356575581 | 1 |
| Fagron | Betamethasone valerate | 17C29-B04-335658 | 1 |
| Fagron | Betamethasone valerate | 17C29-B04-335676 | 6 |
| Fagron | Betamethasone valerate | 17C29-B04-336434 | 6 |
| Fagron | Betamethasone valerate | 17G31-B04 | 5 |
| Fagron | Betamethasone valerate | 17G31-B-04 | 1 |
| Fagron | Betamethasone valerate | 17g31-b04-338575 | 2 |
| Fagron | Betamethasone valerate | 17G31B04338575 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-338575 | 9 |
| Fagron | Betamethasone valerate | 17G31-B04-339784 | 15 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone valerate | 17G-31-B04-339784 | 1 |
| Fagron | Betamethasone valerate | 17G31B04339785 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-339785 | 4 |
| Fagron | Betamethasone valerate | 17G31-B04-341303 | 1 |
| Fagron | Betamethasone valerate | 17g31-b04-341576 | 3 |
| Fagron | Betamethasone valerate | 17G31B04341576 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-341576 | 12 |
| Fagron | Betamethasone valerate | 17G-31-B04-341576 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-341576-201 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-3415765 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-342639 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-344457 | 1 |
| Fagron | Betamethasone valerate | 17G31-B04-344757 | 2 |
| Fagron | Betamethasone valerate | 17K16_B08-348042 | 1 |
| Fagron | Betamethasone valerate | 17k16-b08 | 1 |
| Fagron | Betamethasone valerate | 17K16B08 | 1 |
| Fagron | Betamethasone valerate | 17K16-B08 | 11 |
| Fagron | Betamethasone valerate | 17K16-B08-344754 | 3 |
| Fagron | Betamethasone valerate | 17k16-b08-345541 | 4 |
| Fagron | Betamethasone valerate | 17K16-B08-345541 | 11 |
| Fagron | Betamethasone valerate | 17K16-B08-345542 | 1 |
| Fagron | Betamethasone valerate | 17K16-B08-345555 | 5 |
| Fagron | Betamethasone valerate | 17k16-B08-347309 | 1 |
| Fagron | Betamethasone valerate | 17K16-B08-347309 | 9 |
| Fagron | Betamethasone valerate | 17K-16-B08-347309 | 2 |
| Fagron | Betamethasone valerate | 17k16-b08-347310 | 1 |
| Fagron | Betamethasone valerate | 17K16-B08-347310 | 4 |
| Fagron | Betamethasone valerate | 17k16-b08-347912 | 1 |
| Fagron | Betamethasone valerate | 17k16-B08-347912 | 1 |
| Fagron | Betamethasone valerate | 17K16-B08-347912 | 8 |
| Fagron | Betamethasone valerate | 17K16-B08-348042 | 14 |
| Fagron | Betamethasone valerate | 17K16-B08-348538 | 2 |
| Fagron | Betamethasone valerate | 17K16-B08-349755 | 9 |
| Fagron | Betamethasone valerate | 17K16-B08-349774 | 1 |
| Fagron | Betamethasone valerate | 17K16-B09-345541 | 1 |
| Fagron | Betamethasone valerate | 17k16-bo8-347309 | 1 |
| Fagron | Betamethasone valerate | 17K16-BOB-345541 | 1 |
| Fagron | Betamethasone valerate | 18/26-B05-356852 | 1 |
| Fagron | Betamethasone valerate | 18/27-B05 | 1 |
| Fagron | Betamethasone valerate | 18/27-B05-354880 | 1 |
| Fagron | Betamethasone valerate | 18/27-B05-356570 | 2 |
| Fagron | Betamethasone valerate | 18/27-B05-356571 | 5 |
| Fagron | Betamethasone valerate | 18/27-B05-356584 | 1 |
| Fagron | Betamethasone valerate | 18/27-b05-357770 | 1 |
| Fagron | Betamethasone valerate | 18/27-B05-357770 | 1 |
| Fagron | Betamethasone valerate | 18/27-B05-358065 | 5 |
| Fagron | Betamethasone valerate | 18/27-B05-360081 | 1 |
| Fagron | Betamethasone valerate | 18/27-B05-356570 | 1 |
| Fagron | Betamethasone valerate | 1811008-01 | 1 |
| Fagron | Betamethasone valerate | 18127-B05-358065 | 1 |
| Fagron | Betamethasone valerate | 1817-B05-360082 | 1 |
| Fagron | Betamethasone valerate | 18199907 | 1 |
| Fagron | Betamethasone valerate | 18G03-03-351731 | 1 |
| Fagron | Betamethasone valerate | 18G03-B03 | 6 |
| Fagron | Betamethasone valerate | 18G03-B03_351731 | 1 |
| Fagron | Betamethasone valerate | 18G03-B03-351450 | 12 |
| Fagron | Betamethasone valerate | 18G03-B03-351451 | 1 |
| Fagron | Betamethasone valerate | 18G03-B03-351513 | 3 |
| Fagron | Betamethasone valerate | 18G03-B03-351730 | 2 |
| Fagron | Betamethasone valerate | 18G03-B03-351731 | 22 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone valerate | 18G03-B03-351731 | 1 |
| Fagron | Betamethasone valerate | 18G03-B03-352458 | 1 |
| Fagron | Betamethasone valerate | 18G03-B03-352460 | 7 |
| Fagron | Betamethasone valerate | 18G03-B03-353212 | 13 |
| Fagron | Betamethasone valerate | 18I07-B05-356584 | 1 |
| Fagron | Betamethasone valerate | 18I27-B05 | 3 |
| Fagron | Betamethasone valerate | 18I27-B05_356571 | 1 |
| Fagron | Betamethasone valerate | 18I27-B05-354898 | 1 |
| Fagron | Betamethasone valerate | 18I27-B05-356570 | 2 |
| Fagron | Betamethasone valerate | 18i27B05356571 | 1 |
| Fagron | Betamethasone valerate | 18I27-B05356571 | 1 |
| Fagron | Betamethasone valerate | 18I27-B05-356571 | 5 |
| Fagron | Betamethasone valerate | 18I27-B05-356852 | 1 |
| Fagron | Betamethasone valerate | 18I27-B05-357770 | 2 |
| Fagron | Betamethasone valerate | 18I27-b05-358065 | 1 |
| Fagron | Betamethasone valerate | 18I27-B05-358065 | 5 |
| Fagron | Betamethasone valerate | 18I27-B5-356571 | 1 |
| Fagron | Betamethasone valerate | 18l27-B05 | 1 |
| Fagron | Betamethasone valerate | 18l27-B05-356584 | 1 |
| Fagron | Betamethasone valerate | 18l27-B05-357770 | 1 |
| Fagron | Betamethasone valerate | 19/26-F02-364980 | 1 |
| Fagron | Betamethasone valerate | 19/26-F02-364981 | 2 |
| Fagron | Betamethasone valerate | 19126-F02-364980 | 1 |
| Fagron | Betamethasone valerate | 19G03-B02-363670 | 1 |
| Fagron | Betamethasone valerate | 19G30-B02 | 17 |
| Fagron | Betamethasone valerate | 19G30B02363672 | 1 |
| Fagron | Betamethasone valerate | 19G30-B02-363672 | 8 |
| Fagron | Betamethasone valerate | 19g30-b02-363673 | 1 |
| Fagron | Betamethasone valerate | 19G30-B02-363673 | 5 |
| Fagron | Betamethasone valerate | 19G30-B02-363681 | 1 |
| Fagron | Betamethasone valerate | 19g30-b02-363682 | 1 |
| Fagron | Betamethasone valerate | 19G30-B02-363682 | 17 |
| Fagron | Betamethasone valerate | 19G30-B02-363686 | 5 |
| Fagron | Betamethasone valerate | 19G30-B02-363692 | 9 |
| Fagron | Betamethasone valerate | 19G30-B02-363693 | 16 |
| Fagron | Betamethasone valerate | 19G30-B03-363692 | 1 |
| Fagron | Betamethasone valerate | 19G30-BO2-363673 | 1 |
| Fagron | Betamethasone valerate | 19G30-Bo2-363693 | 1 |
| Fagron | Betamethasone valerate | 19GB0-B02-363693 | 1 |
| Fagron | Betamethasone valerate | 19I26-F02 | 4 |
| Fagron | Betamethasone valerate | 19I26F02364980 | 1 |
| Fagron | Betamethasone valerate | 19I26-F02-364980 | 4 |
| Fagron | Betamethasone valerate | 19I26-F02-364981 | 6 |
| Fagron | Betamethasone valerate | 19I26-F02-364982 | 1 |
| Fagron | Betamethasone valerate | 19I26-F02-364987 | 6 |
| Fagron | Betamethasone valerate | 19I86-F02-364987 | 1 |
| Fagron | Betamethasone valerate | 19J26-F02-364987 | 1 |
| Fagron | Betamethasone valerate | 19K11-07-366784 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07 | 7 |
| Fagron | Betamethasone valerate | 19K11-F07-366779 | 3 |
| Fagron | Betamethasone valerate | 19k11-f07-366780 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-366780 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-3667807 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-3667809 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-366782 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-366784 | 1 |
| Fagron | Betamethasone valerate | 19k11-F07-366785 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-366785 | 17 |
| Fagron | Betamethasone valerate | 19k11f07366786 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-366786 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone valerate | 19K11-F07-3667860 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-366787 | 7 |
| Fagron | Betamethasone valerate | 19K11-F07-366788 | 3 |
| Fagron | Betamethasone valerate | 19K11-F07-366788 | 1 |
| Fagron | Betamethasone valerate | 19K11-F07-366789 | 3 |
| Fagron | Betamethasone valerate | 19K11-Fo7-366785 | 1 |
| Fagron | Betamethasone valerate | 19K11-FO7-366785 | 1 |
| Fagron | Betamethasone valerate | 19K-F0-366786 | 1 |
| Fagron | Betamethasone valerate | 19126-F02 | 3 |
| Fagron | Betamethasone valerate | 19126-F02-364981 | 1 |
| Fagron | Betamethasone valerate | 19126-F02-364986 | 1 |
| Fagron | Betamethasone valerate | 19UI26-F02-364981 | 1 |
| Fagron | Betamethasone valerate | 2000036016 | 1 |
| Fagron | Betamethasone valerate | 20101012-1 | 1 |
| Fagron | Betamethasone valerate | 20818-F07 | 1 |
| Fagron | Betamethasone valerate | 20B18-F07 | 6 |
| Fagron | Betamethasone valerate | 20B18-F07-3696704 | 2 |
| Fagron | Betamethasone valerate | 20B18-F07-369671 | 3 |
| Fagron | Betamethasone valerate | 20B18-F07-369673 | 17 |
| Fagron | Betamethasone valerate | 20B18-F07-369674 | 1 |
| Fagron | Betamethasone valerate | 20B18-F07-369676 | 4 |
| Fagron | Betamethasone valerate | 20b18f0736976 | 1 |
| Fagron | Betamethasone valerate | 20B18-F07-3700009 | 1 |
| Fagron | Betamethasone valerate | 20B18-F07-370009 | 6 |
| Fagron | Betamethasone valerate | 20B18-F07-370010 | 3 |
| Fagron | Betamethasone valerate | 20B18F07370013 | 1 |
| Fagron | Betamethasone valerate | 20B18-F07-370013 | 3 |
| Fagron | Betamethasone valerate | 20B18-F07-37009 | 1 |
| Fagron | Betamethasone valerate | 20E14-F02 | 3 |
| Fagron | Betamethasone valerate | 20E14-F02-371690 | 14 |
| Fagron | Betamethasone valerate | 20E14-F02-372350 | 7 |
| Fagron | Betamethasone valerate | 20G17-F02 | 3 |
| Fagron | Betamethasone valerate | 20G17-F02-3737909 | 1 |
| Fagron | Betamethasone valerate | 20G17-F02-373798 | 7 |
| Fagron | Betamethasone valerate | 20G17-F02-373799 | 5 |
| Fagron | Betamethasone valerate | 21000036020 | 1 |
| Fagron | Betamethasone valerate | 2152-44-5 | 1 |
| Fagron | Betamethasone valerate | 21D09-F03 | 3 |
| Fagron | Betamethasone valerate | 21D09-F03-377824 | 9 |
| Fagron | Betamethasone valerate | 21D09-F03-377825 | 4 |
| Fagron | Betamethasone valerate | 21D09-F03377843 | 1 |
| Fagron | Betamethasone valerate | 21D09-F03-377843 | 1 |
| Fagron | Betamethasone valerate | 21G28-B02 | 1 |
| Fagron | Betamethasone valerate | 21G28-B02-213513 | 1 |
| Fagron | Betamethasone valerate | 21G28-b02-213516 | 1 |
| Fagron | Betamethasone valerate | 21G28-B02-213516 | 12 |
| Fagron | Betamethasone valerate | 21G28-B02-213517 | 6 |
| Fagron | Betamethasone valerate | 21G28-B02-213518 | 6 |
| Fagron | Betamethasone valerate | 21G28-B02-213663 | 2 |
| Fagron | Betamethasone valerate | 21G28-B08-213517 | 1 |
| Fagron | Betamethasone valerate | 21G28-BO2-213518 | 1 |
| Fagron | Betamethasone valerate | 21-J09-B05-222192 | 1 |
| Fagron | Betamethasone valerate | 21K09_B05_218135 | 1 |
| Fagron | Betamethasone valerate | 21K09B05 | 1 |
| Fagron | Betamethasone valerate | 21K09-B05 | 1 |
| Fagron | Betamethasone valerate | 21K09-B05-217883 | 9 |
| Fagron | Betamethasone valerate | 21K09B05217891 | 1 |
| Fagron | Betamethasone valerate | 21K09-B05-217891 | 4 |
| Fagron | Betamethasone valerate | 21K09-B05-217898 | 2 |
| Fagron | Betamethasone valerate | 21K09-B05-218135 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Betamethasone valerate | 21K09-B05-220180 | 12 |
| Fagron | Betamethasone valerate | 21K09B05220215 | 1 |
| Fagron | Betamethasone valerate | 21K09-B05-220215 | 6 |
| Fagron | Betamethasone valerate | 21K09-B05-220334 | 3 |
| Fagron | Betamethasone valerate | 21K09-B05-220335 | 1 |
| Fagron | Betamethasone valerate | 21K09-B05-220365 | 2 |
| Fagron | Betamethasone valerate | 21K09-B05-2221193 | 1 |
| Fagron | Betamethasone valerate | 21K09-B05-222192 | 5 |
| Fagron | Betamethasone valerate | 21K09-B05-222194 | 2 |
| Fagron | Betamethasone valerate | 21K09-B5-217883 | 1 |
| Fagron | Betamethasone valerate | 21K09-BO5-222192 | 1 |
| Fagron | Betamethasone valerate | 22H25B07 | 1 |
| Fagron | Betamethasone valerate | 22H25-B07 | 1 |
| Fagron | Betamethasone valerate | 22H25-B07-223527 | 8 |
| Fagron | Betamethasone valerate | 22H25-B07-223537 | 1 |
| Fagron | Betamethasone valerate | 22H25B072235527 | 1 |
| Fagron | Betamethasone valerate | 292652 | 1 |
| Fagron | Betamethasone valerate | 2B28-N01 | 1 |
| Fagron | Betamethasone valerate | 2K09-805 | 1 |
| Fagron | Betamethasone valerate | 2OB18-F07-370009 | 1 |
| Fagron | Betamethasone valerate | 309520 | 1 |
| Fagron | Betamethasone valerate | 364979 | 1 |
| Fagron | Betamethasone valerate | 612211181 | 1 |
| Fagron | Betamethasone valerate | 700103-0002 | 3 |
| Fagron | Betamethasone valerate | 700103-0003 | 1 |
| Fagron | Betamethasone valerate | 700103-0004 | 2 |
| Fagron | Betamethasone valerate | 90616-2 | 1 |
| Fagron | Betamethasone valerate | B02-3636307 | 1 |
| Fagron | Betamethasone valerate | b02-3636702 | 1 |
| Fagron | Betamethasone valerate | B02-3636802 | 1 |
| Fagron | Betamethasone valerate | B05-217898 | 1 |
| Fagron | Betamethasone valerate | B05-2203305 | 1 |
| Fagron | Betamethasone valerate | B07-317416 | 1 |
| Fagron | Betamethasone valerate | BO5-2203305 | 1 |
| Fagron | Betamethasone valerate | BV004/0721 | 2 |
| Fagron | Betamethasone valerate | BV008/0415 | 1 |
| Fagron | Betamethasone valerate | BV008/045 | 1 |
| Fagron | Betamethasone valerate | BV008/0516 | 1 |
| Fagron | Betamethasone valerate | BV009/0117 | 1 |
| Fagron | Betamethasone valerate | BV019/0514 | 3 |
| Fagron | Betamethasone valerate | BV036/1215 | 1 |
| Fagron | Betamethasone valerate | BV102/0420 | 6 |
| Fagron | Betamethasone valerate | BV106/0717 | 2 |
| Fagron | Betamethasone valerate | BV109/0117 | 2 |
| Fagron | Betamethasone valerate | BV109/0519 | 6 |
| Fagron | Betamethasone valerate | BV110/0818 | 1 |
| Fagron | Betamethasone valerate | BV123/0120 | 2 |
| Fagron | Betamethasone valerate | BV124/0118 | 2 |
| Fagron | Betamethasone valerate | BV127/0120 | 1 |
| Fagron | Betamethasone valerate | BV-BLT225/0514 | 1 |
| Fagron | Betamethasone valerate | BV-BLT250/0616 | 2 |
| Fagron | Betamethasone valerate | F02-3649807 | 2 |
| Fagron | Betamethasone valerate | F02-3716900 | 1 |
| Fagron | Betamethasone valerate | F02-3723500 | 1 |
| Fagron | Betamethasone valerate | F02-3737908 | 1 |
| Fagron | Betamethasone valerate | F02-3737909 | 2 |
| Fagron | Betamethasone valerate | F03377824 | 1 |
| Fagron | Betamethasone valerate | F07-3667805 | 1 |
| Fagron | Betamethasone valerate | F07-3667808 | 1 |
| Fagron | Betamethasone valerate | F07-3696703 | 1 |

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|---|---|---|---|
| Fagron | Betamethasone valerate | F07-3700100 | 1 |
| Fagron | Betamethasone valerate | F073700103 | 1 |
| Fagron | Betamethasone valerate | fagron | 1 |
| Fagron | Betamethasone valerate | NP1351M | 1 |
| Fagron | Betamethasone valerate | NS0706M | 3 |
| Fagron | Betamethasone valerate | NS2072M | 1 |
| Fagron | Betamethasone valerate | NT0597M | 4 |
| Fagron | Betamethasone valerate | NT059M | 1 |
| Fagron | Betamethasone valerate | Op07062022B | 1 |
| Fargon, Noweda 07.11.2017 | Betamethasone valerate | 16H22-B06-329223 | 1 |
| Fargon/AHD | Betamethasone valerate | 18/27-B05 | 1 |
| Fargon/Alliance HC | Betamethasone valerate | 13K29-B32-288247 | 1 |
| Fargon/Alliance HC | Betamethasone valerate | 16B18-B02-322111 | 1 |
| Fargon/Anzag | Betamethasone valerate | 13G19-N01 | 1 |
| Fargon/Anzag | Betamethasone valerate | 16B18-B02-320971 | 1 |
| Fargon/Noweda | Betamethasone valerate | 18I27-B05-354898 | 1 |
| Fargon | Betamethasone valerate | 13k29-b32-289364 | 1 |
| Fargon | Betamethasone valerate | 18g03-b03-351731 | 1 |
| Fargon | Betamethasone valerate | 19G30-B08-36393 | 1 |
| Fargon | Betamethasone valerate | 20G17-F02-373798 | 1 |
| Fargon | Betamethasone valerate | 21K09-B05-217883 | 1 |
| Fargon | Betamethasone valerate | 7890 | 1 |
| Fargron | Betamethasone valerate | 13G19-N01 | 1 |
| Fargron | Betamethasone valerate | 13K29-B32-288246 | 1 |
| Farmabios S. p. A./ ... | Betamethasone valerate | 17078715 | 1 |
| Farmabios S.p.A., IT | Betamethasone valerate | 2109VM00012222 | 1 |
| Farmabios spa | Betamethasone valerate | 19220704 | 1 |
| Farmabios/Noweda | Betamethasone valerate | 2109VM0B0011722 | 1 |
| Farmabios/Noweda | Betamethasone valerate | 2109VMOB0011722 | 1 |
| Farmabios/Phoenix | Betamethasone valerate | 2109VMOC00011922 | 1 |
| Farmabios | Betamethasone valerate | 17271603 | 1 |
| Fiebig 27.06.13 EK47,81 | Betamethasone valerate | B9/131 | 1 |
| Fiebig ek: 45,65EUR | Betamethasone valerate | 12B28-N01 | 1 |
| Fiebig/Farago | Betamethasone valerate | 19G30-B02-363692 | 1 |
| Fiebig | Betamethasone valerate | 14H28-B01 | 1 |
| Fiebig | Betamethasone valerate | 15B24-B04-307016 | 1 |
| Fiebig | Betamethasone valerate | 16B18-B02-322111 | 1 |
| Fiebig | Betamethasone valerate | 17271603 | 1 |
| Fiebig | Betamethasone valerate | 2102010-02 | 1 |
| Fiebig | Betamethasone valerate | 22001101021 | 1 |
| Fiebig | Betamethasone valerate | 2202016-01 | 1 |
| FIEBIG | Betamethasone valerate | F17-3696703 | 1 |
| Fragon/ Gehe | Betamethasone valerate | 19K11-F07-366785 | 1 |
| Fragon/Alliance | Betamethasone valerate | 17k16-B08 | 1 |
| Fragon/Phönix | Betamethasone valerate | 17G31-B04-341576 | 1 |
| Fragon/Sanacorp | Betamethasone valerate | 17K16-B08-340842 | 1 |
| Fragon | Betamethasone valerate | 16G03-B03-353212 | 1 |
| Fragon | Betamethasone valerate | 19K11-F07-366784 | 1 |
| Fragron | Betamethasone valerate | BV-BLT225/0514 | 2 |
| Galderma/ Noweda | Betamethasone valerate | C0023/115040 | 1 |
| Gatt-Koller | Betamethasone valerate | 1800117 | 1 |
| GEHE 17.06.2014 | Betamethasone valerate | 13225503 | 1 |
| Gehe am 03.02.2014 | Betamethasone valerate | 13091210 | 3 |
| Gehe amax | Betamethasone valerate | 18199930 | 1 |
| Gehe | Betamethasone valerate | 12003403 | 1 |
| Gehe | Betamethasone valerate | 12003409 | 1 |
| Gehe | Betamethasone valerate | 1208014-04 | 1 |
| Gehe | Betamethasone valerate | 12229809 | 1 |
| Gehe | Betamethasone valerate | 13091211 | 1 |
| Gehe | Betamethasone valerate | 14H25-B01-302863 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Betamethasone valerate | 14H28-B01-302863 | 1 |
| Gehe | Betamethasone valerate | 15075804 | 1 |
| Gehe | Betamethasone valerate | 15075811 | 1 |
| Gehe | Betamethasone valerate | 15398501 | 1 |
| Gehe | Betamethasone valerate | 15398512 | 1 |
| Gehe | Betamethasone valerate | 1610010-01 | 1 |
| GEHE | Betamethasone valerate | 16270501 | 1 |
| Gehe | Betamethasone valerate | 16270505 | 1 |
| Gehe | Betamethasone valerate | 16H22-B06 | 1 |
| Gehe | Betamethasone valerate | 16H22-B06-330524 | 1 |
| GEHE | Betamethasone valerate | 17078701 | 2 |
| Gehe | Betamethasone valerate | 17078703 | 1 |
| Gehe | Betamethasone valerate | 17078712 | 1 |
| GEHE | Betamethasone valerate | 17078719 | 1 |
| GEHE | Betamethasone valerate | 17078720 | 1 |
| Gehe | Betamethasone valerate | 1712E-01181 | 1 |
| Gehe | Betamethasone valerate | 17271603 | 1 |
| Gehe | Betamethasone valerate | 17329002 | 1 |
| Gehe | Betamethasone valerate | 17329015 | 1 |
| Gehe | Betamethasone valerate | 17329018 | 1 |
| Gehe | Betamethasone valerate | 17G31-B04 | 1 |
| Gehe | Betamethasone valerate | 17K16-B08 | 1 |
| Gehe | Betamethasone valerate | 17K16-B08-347309 | 1 |
| Gehe | Betamethasone valerate | 17K16-B08-348042 | 1 |
| Gehe | Betamethasone valerate | 1811008-01 | 1 |
| GEHE | Betamethasone valerate | 18199902 | 2 |
| Gehe | Betamethasone valerate | 18199908 | 1 |
| Gehe | Betamethasone valerate | 18199924 | 1 |
| gehe | Betamethasone valerate | 18199937 | 1 |
| Gehe | Betamethasone valerate | 18G03-B03-351731 | 1 |
| Gehe | Betamethasone valerate | 18I27-B05 | 1 |
| Gehe | Betamethasone valerate | 192207001 | 2 |
| Gehe | Betamethasone valerate | 192207002 | 1 |
| Gehe | Betamethasone valerate | 19220702 | 1 |
| Gehe | Betamethasone valerate | 21K09-b05 | 1 |
| gehe | Betamethasone valerate | 21K09-B05-220180 | 1 |
| Gehe | Betamethasone valerate | 21K09-B05-22192 | 1 |
| GEHE | Betamethasone valerate | 22001101015 | 1 |
| Gehe | Betamethasone valerate | 22001101016 | 1 |
| Gehe | Betamethasone valerate | 22001101020 | 1 |
| Gehe | Betamethasone valerate | 22001101021 | 1 |
| Gehe | Betamethasone valerate | 2202016-01 | 3 |
| Gehe | Betamethasone valerate | 2202016-02 | 1 |
| gehe | Betamethasone valerate | 22H25B07227237 | 1 |
| Gehe | Betamethasone valerate | 22K07-B08-229283 | 1 |
| Gehe | Betamethasone valerate | 22K07-B08-233606 | 1 |
| Gehe | Betamethasone valerate | 23003251005 | 1 |
| Gehe | Betamethasone valerate | 23003252003 | 2 |
| Gehe | Betamethasone valerate | 2309023-01 | 1 |
| Gehe | Betamethasone valerate | 23E29-B03-235955 | 1 |
| Gehe | Betamethasone valerate | 23E29-B03-238320 | 1 |
| Gehe | Betamethasone valerate | BV001/0322 | 1 |
| Geilenkirchen | Betamethasone valerate | 16270513 | 1 |
| Geilenkirchen | Betamethasone valerate | 17078701 | 1 |
| Geilenkirchen | Betamethasone valerate | 18199918 | 1 |
| Hedinger / Noweda | Betamethasone valerate | 16270505 | 1 |
| Hedinger | Betamethasone valerate | 14H28-B01-302877 | 1 |
| henry lamotte/gehe | Betamethasone valerate | 17C29-B04-333688 | 2 |
| Hirsch | Betamethasone valerate | 13G19-No1 | 1 |
| Holdermann | Betamethasone valerate | 1208014-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Holdermann | Betamethasone valerate | 120801402 | 1 |
| Ichthyol/Noweda | Betamethasone valerate | 17329004 | 2 |
| Ichthyol-Gesellschaft | Betamethasone valerate | 13k29-B32-288247 | 1 |
| Ichthyol-Gesellschaft | Betamethasone valerate | 17078720 | 1 |
| jenne/eurho | Betamethasone valerate | 2102010-01 | 1 |
| Jenne | Betamethasone valerate | 17078712 | 1 |
| Jenne | Betamethasone valerate | 18199918 | 1 |
| Jenne | Betamethasone valerate | 18199933 | 1 |
| Jenne | Betamethasone valerate | 18I27-B05-358065 | 1 |
| Jenne | Betamethasone valerate | 21000036017 | 1 |
| Jenne | Betamethasone valerate | 22001101004 | 1 |
| Jenne | Betamethasone valerate | 22001101008 | 1 |
| Jenne | Betamethasone valerate | 22001101020 | 1 |
| Jenne | Betamethasone valerate | 23003252001 | 1 |
| Jenne | Betamethasone valerate | 240429(23003252003) | 1 |
| Kehr | Betamethasone valerate | 1801024-01 | 1 |
| Kehr | Betamethasone valerate | 22001101015 | 1 |
| Kehr | Betamethasone valerate | 22001101020 | 1 |
| kehr | Betamethasone valerate | 2200201601 | 1 |
| Kehr | Betamethasone valerate | 2202016-01 | 1 |
| Kehr | Betamethasone valerate | 22H25-07-227224 | 1 |
| Kehr | Betamethasone valerate | 23003251006 | 1 |
| Klenk | Betamethasone valerate | 16623-01 | 1 |
| Klenk | Betamethasone valerate | 17078713 | 1 |
| Klenk | Betamethasone valerate | 17078714 | 1 |
| Krieger | Betamethasone valerate | 192207010 | 1 |
| krieger | Betamethasone valerate | 20G17-F02-373798 | 1 |
| L12 | Betamethasone valerate | 16E23-B03-324799 | 2 |
| L12 | Betamethasone valerate | 17C29-B04-334329 | 2 |
| L12 | Betamethasone valerate | 17K16-B08-345541 | 1 |
| Lamotte/Noweda | Betamethasone valerate | 17K16-B08-349755 | 1 |
| Max Jenne | Betamethasone valerate | 22001101021 | 1 |
| Midas | Betamethasone valerate | 16270503 | 1 |
| Midas | Betamethasone valerate | 16270513 | 1 |
| Midas | Betamethasone valerate | 17078720 | 1 |
| Midas | Betamethasone valerate | 17329001 | 2 |
| Midas | Betamethasone valerate | 17329018 | 1 |
| Midas | Betamethasone valerate | 17G31-B04-338575 | 2 |
| Mömerzheim | Betamethasone valerate | 17329008 | 1 |
| NEWCHEM | Betamethasone valerate | 1311039-01 | 1 |
| Noveda | Betamethasone valerate | 1311039-01 | 1 |
| Noveda | Betamethasone valerate | 192207002 | 1 |
| Noweda/ Infecto Pharm | Betamethasone valerate | 16270505 | 1 |
| Noweda/cealo | Betamethasone valerate | 17329002 | 1 |
| Noweda/Ceasar Lorenz | Betamethasone valerate | 14188606 | 1 |
| Noweda | Betamethasone valerate | 11131902 | 1 |
| Noweda | Betamethasone valerate | 11B21-N02 | 1 |
| Noweda | Betamethasone valerate | 1208014-01 | 1 |
| Noweda | Betamethasone valerate | 1208014-02 | 2 |
| noweda | Betamethasone valerate | 1208014-04 | 1 |
| Noweda | Betamethasone valerate | 12229832 | 1 |
| Noweda | Betamethasone valerate | 12G09-N07 | 1 |
| Noweda | Betamethasone valerate | 13091203 | 1 |
| Noweda | Betamethasone valerate | 13091205 | 1 |
| noweda | Betamethasone valerate | 1406019-01 | 1 |
| Noweda | Betamethasone valerate | 1406019-03 | 2 |
| Noweda | Betamethasone valerate | 14H28B01302863 | 1 |
| Noweda | Betamethasone valerate | 15075812 | 1 |
| Noweda | Betamethasone valerate | 161001001 | 1 |
| Noweda | Betamethasone valerate | 16270511 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Betamethasone valerate | 1704019-01 | 1 |
| Noweda | Betamethasone valerate | 17078701 | 1 |
| Noweda | Betamethasone valerate | 17271601 | 2 |
| Noweda | Betamethasone valerate | 17329018 | 2 |
| Noweda | Betamethasone valerate | 17g31-b04-338575 | 1 |
| Noweda | Betamethasone valerate | 1801024-01 | 2 |
| Noweda | Betamethasone valerate | 1811008-01 | 2 |
| Noweda | Betamethasone valerate | 18199918 | 1 |
| Noweda | Betamethasone valerate | 18199932 | 3 |
| Noweda | Betamethasone valerate | 18199933 | 1 |
| Noweda | Betamethasone valerate | 18127-B05-354880 | 1 |
| Noweda | Betamethasone valerate | 1912012-01 | 1 |
| Noweda | Betamethasone valerate | 19220704 | 2 |
| Noweda | Betamethasone valerate | 19220705 | 2 |
| Noweda | Betamethasone valerate | 19I26-F02-364981 | 1 |
| Noweda | Betamethasone valerate | 20G17-F02-373798 | 1 |
| Noweda | Betamethasone valerate | 21000036003 | 1 |
| Noweda | Betamethasone valerate | 21000036020 | 1 |
| Noweda | Betamethasone valerate | 2102010-03 | 2 |
| Noweda | Betamethasone valerate | 21K09-B05 | 1 |
| Noweda | Betamethasone valerate | 21K09-B05-222192 | 6 |
| Noweda | Betamethasone valerate | 2200110016 | 1 |
| Noweda | Betamethasone valerate | 22001101002 | 2 |
| Noweda | Betamethasone valerate | 22001101003 | 1 |
| Noweda | Betamethasone valerate | 22001101018 | 1 |
| Noweda | Betamethasone valerate | 22001101020 | 1 |
| Noweda | Betamethasone valerate | 2202016-01 | 7 |
| Noweda | Betamethasone valerate | 22H25-B07-227236 | 2 |
| Noweda | Betamethasone valerate | 22K07-08-229283 | 1 |
| Noweda | Betamethasone valerate | 23003252003 | 3 |
| Noweda | Betamethasone valerate | 2309023 | 1 |
| noweda | Betamethasone valerate | 2309023-01 | 1 |
| Noweda | Betamethasone valerate | 2309023-01 | 4 |
| Noweda | Betamethasone valerate | 24A30-B08-238319 | 1 |
| Noweda | Betamethasone valerate | BV01090117 | 1 |
| Noweda | Betamethasone valerate | F07-3700100 | 1 |
| Oberlinden Apotheke | Betamethasone valerate | C0073/115040 | 3 |
| Oberlinden Apotheke | Betamethasone valerate | c073/115040 | 1 |
| Pheonix | Betamethasone valerate | 23003251005 | 1 |
| Phoenix 15.1.2014 | Betamethasone valerate | 1208014-04 | 1 |
| Phoenix 13.12.2017 | Betamethasone valerate | 16H22-B06-330524 | 1 |
| Phoenix 22.01.2019 | Betamethasone valerate | 1801021-01 | 1 |
| Phoenix 30.10.19 19,34EUR | Betamethasone valerate | 18/27-B05-358065 | 1 |
| Phoenix Goettin | Betamethasone valerate | 13225508 | 1 |
| Phoenix/ Fagro | Betamethasone valerate | 18G03-B03-351731 | 1 |
| Phoenix | Betamethasone valerate | 12003409 | 2 |
| Phoenix | Betamethasone valerate | 16270513 | 1 |
| Phoenix | Betamethasone valerate | 170401901 | 1 |
| Phoenix | Betamethasone valerate | 17329002 | 1 |
| Phoenix | Betamethasone valerate | 17329018 | 1 |
| Phoenix | Betamethasone valerate | 17C29-B04-334329 | 1 |
| Phoenix | Betamethasone valerate | 17K16-B08-348042 | 2 |
| Phoenix | Betamethasone valerate | 1801024-01 | 1 |
| Phoenix | Betamethasone valerate | 1811008-01 | 2 |
| Phoenix | Betamethasone valerate | 18127-B05-358065 | 1 |
| Phoenix | Betamethasone valerate | 191201201 | 1 |
| Phoenix | Betamethasone valerate | 192207003 | 1 |
| Phoenix | Betamethasone valerate | 192207009 | 1 |
| Phoenix | Betamethasone valerate | 19220705 | 1 |
| Phoenix | Betamethasone valerate | 19G30-B02-363672 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Betamethasone valerate | 19G30-B02-363682 | 1 |
| Phoenix | Betamethasone valerate | 19K11-F07 | 1 |
| Phoenix | Betamethasone valerate | 19l26-F02-3649800 | 1 |
| Phoenix | Betamethasone valerate | 200592406 | 1 |
| Phoenix | Betamethasone valerate | 2102010-01 | 1 |
| phoenix | Betamethasone valerate | 22001101021 | 1 |
| Phoenix | Betamethasone valerate | 220201601 | 1 |
| Phoenix | Betamethasone valerate | 22K07-B08-229283 | 1 |
| Phoenix | Betamethasone valerate | 23003251005 | 2 |
| Phoenix | Betamethasone valerate | 23003252003 | 1 |
| Phoenix | Betamethasone valerate | 23003252100508/25P | 1 |
| Phoenix | Betamethasone valerate | 2309023-01 | 3 |
| Phoenix | Betamethasone valerate | 3105 | 1 |
| Phoenix | Betamethasone valerate | 3364 | 1 |
| Phönix 26.11.2019 | Betamethasone valerate | 1811008-01 | 3 |
| Phönix Gotha | Betamethasone valerate | 12229808 | 1 |
| Phönix Gotha | Betamethasone valerate | 13091213 | 1 |
| Phönix Gotha | Betamethasone valerate | 14188608 | 1 |
| Phönix Gotha | Betamethasone valerate | 1704019-01 | 1 |
| Phönix Gotha | Betamethasone valerate | 1811008-01 | 1 |
| Phönix WE:16.07.2016. . . | Betamethasone valerate | 1510037-01 | 1 |
| Phönix | Betamethasone valerate | 12229807 | 1 |
| Phönix | Betamethasone valerate | 13091209 | 2 |
| Phönix | Betamethasone valerate | 13091212 | 2 |
| Phönix | Betamethasone valerate | 13D03-N07 | 1 |
| Phonix | Betamethasone valerate | 13K29-B32 | 1 |
| phönix | Betamethasone valerate | 15/16B07-319228 | 1 |
| Phönix | Betamethasone valerate | 15075804 | 1 |
| Phönix | Betamethasone valerate | 1507804 | 1 |
| phönix | Betamethasone valerate | 15398515 | 1 |
| Phönix | Betamethasone valerate | 16270503 | 1 |
| phönix | Betamethasone valerate | 16e23-b03-327350 | 1 |
| Phönix | Betamethasone valerate | 16H22-B06-330522 | 1 |
| Phönix | Betamethasone valerate | 17078712 | 1 |
| Phönix | Betamethasone valerate | 17329001 | 1 |
| Phönix | Betamethasone valerate | 18199907 | 1 |
| Phönix | Betamethasone valerate | 18199918 | 1 |
| Phönix | Betamethasone valerate | 18199933 | 1 |
| Phönix | Betamethasone valerate | 1911001-01 | 2 |
| Phönix | Betamethasone valerate | 192207009 | 1 |
| Phönix | Betamethasone valerate | 19220705 | 1 |
| Phönix | Betamethasone valerate | 19g30-b02-363672 | 1 |
| Phönix | Betamethasone valerate | 19G30-B02-363693 | 1 |
| Phönix | Betamethasone valerate | 19I26-F02-0364979 | 2 |
| Phönix | Betamethasone valerate | 19I26-F02-364981 | 1 |
| Phönix | Betamethasone valerate | 19K11-F07-366779 | 1 |
| PHÖNIX | Betamethasone valerate | 19K11-F07-366785 | 1 |
| Phönix | Betamethasone valerate | 19K11-F07-366786 | 1 |
| Phönix | Betamethasone valerate | 19K11-F07-366789 | 1 |
| Phönix | Betamethasone valerate | 20E14-F02-371690 | 1 |
| phönix | Betamethasone valerate | 2102010-01 | 2 |
| Phönix | Betamethasone valerate | 2102010-01 | 1 |
| Phönix | Betamethasone valerate | 21K09-B05-220180 | 2 |
| Phönix | Betamethasone valerate | 21K09-B05-220215 | 1 |
| Phönix | Betamethasone valerate | 21K09-B05-222192 | 1 |
| Phönix | Betamethasone valerate | 22001101009 | 1 |
| Phönix | Betamethasone valerate | 22001101016 | 2 |
| Phönix | Betamethasone valerate | 2200110101634/23P | 1 |
| Phönix | Betamethasone valerate | 2200110101644/23P | 1 |
| Phönix | Betamethasone valerate | 22001101018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Betamethasone valerate | 22001101020 | 3 |
| Phönix | Betamethasone valerate | 2200110102069/23P | 1 |
| Phönix | Betamethasone valerate | 22001101021 | 1 |
| Phönix | Betamethasone valerate | 2201101018 | 1 |
| Phönix | Betamethasone valerate | 2202016-01 | 1 |
| Phönix | Betamethasone valerate | 2202016-02 | 1 |
| Phönix | Betamethasone valerate | 22H25-B07-227237 | 1 |
| Phönix | Betamethasone valerate | 22K07-B08-227496 | 2 |
| Phönix | Betamethasone valerate | 23003251005 | 1 |
| Phönix | Betamethasone valerate | 2309023-01 | 1 |
| Phönix | Betamethasone valerate | 24A30-B08-238319 | 1 |
| Phönix | Betamethasone valerate | B02-3636802 | 1 |
| Phönix | Betamethasone valerate | BV110/0818 | 1 |
| Phönix | Betamethasone valerate | BV-BLT186/0512 | 1 |
| Phönix | Betamethasone valerate | F07-3696701 | 1 |
| Sanacorp W.E: 18.01.... | Betamethasone valerate | 1704019-01 | 1 |
| Sanacorp | Betamethasone valerate | | 1 |
| Sanacorp | Betamethasone valerate | 12G09-N07 | 1 |
| Sanacorp | Betamethasone valerate | 13091201 | 2 |
| Sanacorp | Betamethasone valerate | 13091210 | 1 |
| Sanacorp | Betamethasone valerate | 13225503 | 1 |
| Sanacorp | Betamethasone valerate | 14188602 | 1 |
| Sanacorp | Betamethasone valerate | 14G30-B05-296173 | 1 |
| Sanacorp | Betamethasone valerate | 16H22-B06-330522 | 1 |
| Sanacorp | Betamethasone valerate | 1704019-01 | 1 |
| Sanacorp | Betamethasone valerate | 17078715 | 1 |
| Sanacorp | Betamethasone valerate | 17078719 | 1 |
| Sanacorp | Betamethasone valerate | 17C29-B04 | 1 |
| Sanacorp | Betamethasone valerate | 1801024-01 | 4 |
| Sanacorp | Betamethasone valerate | 1811008 | 2 |
| Sanacorp | Betamethasone valerate | 1811008-01 | 7 |
| Sanacorp | Betamethasone valerate | 18199918 | 2 |
| Sanacorp | Betamethasone valerate | 192207010 | 1 |
| Sanacorp | Betamethasone valerate | 19220705 | 1 |
| Sanacorp | Betamethasone valerate | 19G30-B02-3636706 | 1 |
| Sanacorp | Betamethasone valerate | 19G30-B02-3636806 | 1 |
| Sanacorp | Betamethasone valerate | 19I26f02364981 | 1 |
| Sanacorp | Betamethasone valerate | 21000036017 | 1 |
| Sanacorp | Betamethasone valerate | 21000036019 | 1 |
| Sanacorp | Betamethasone valerate | 2100036021 | 1 |
| Sanacorp | Betamethasone valerate | 2102010-02 | 1 |
| sanacorp | Betamethasone valerate | 21K09-B05-217891 | 4 |
| Sanacorp | Betamethasone valerate | 22001101014 | 1 |
| Sanacorp | Betamethasone valerate | 22001101020 | 5 |
| Sanacorp | Betamethasone valerate | 22K07-B08-233606 | 1 |
| Sanacorp | Betamethasone valerate | 2300251005 | 1 |
| Sanacorp | Betamethasone valerate | 23003252003 | 4 |
| Sanacorp | Betamethasone valerate | 2309023-01 | 1 |
| Sanacorp | Betamethasone valerate | 30051201 | 1 |
| Sanacorp | Betamethasone valerate | F07-3700100 | 1 |
| Spangro | Betamethasone valerate | 17078714 | 1 |
| Symbiotica / Gehe | Betamethasone valerate | 18I27-B05-354898 | 2 |
| Symbiotica / Gehe | Betamethasone valerate | BV018/0715 | 1 |
| Symbiotica / Gehe | Betamethasone valerate | BV036/1215 | 1 |
| Symbiotica Spec. | Betamethasone valerate | 1208014-04 | 1 |
| Symbiotica Spec. | Betamethasone valerate | 17G31-B04-338575 | 1 |
| Symbiotica/ Phönix | Betamethasone valerate | 210201001 | 2 |
| Symbiotica/Gehe | Betamethasone valerate | 1912012-01 | 1 |
| Symbiotica | Betamethasone valerate | 14H28B01302863 | 1 |
| Symbiotica | Betamethasone valerate | 1610010-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Symbotica Spec/Noweda | Betamethasone valerate | 1208014-04 | 1 |
| vdl | Betamethasone valerate | 12003411 | 1 |

- 250 821 spectra from 1666 *Apo-Ident* customers from a total of 51 238 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Betamethasone valerate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Betamethasone valerate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 554 | 0 | 157 772 |
| **Type B** | 0 | 881 | 0 | 212 059 |
| **Type C** | 0 | 5982 | 83 | 250 821 |

The substance/substance group *Betamethasone valerate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9170 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3190 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.6315 % (> 98.5820 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20887 | 22249 | 9.00 | 104.88 |
| 20920 | 22249 | 10.25 | 115.65 |
| 21215 | 22249 | 8.72 | 114.16 |
| 21566 | 22249 | 7.72 | 112.59 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21588 | 21588 | 0.00 | 109.19 |
| 21645 | 22249 | 6.86 | 109.94 |
| 21674 | 21674 | 0.00 | 142.14 |
| 22249 | 22249 | 0.00 | 112.62 |
| 22861 | 22861 | 0.00 | 115.81 |
| 24349 | 24349 | 0.00 | 107.69 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Bifonazole** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20810-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Bifonazole; Bifonazolum

### Special notes

When selecting the *Bifonazole* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Bifonazole | 8 | 5 | 81 |

### Second-stage model

For differentiation of the substance/substance group *Bifonazole* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Bifonazole* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Clotrimazole | 29.61 | – |
| Methoxsalen | 145.12 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Bifonazole* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Bifonazole*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Bifonazole | 15152701 | 22906 | 40 | 20150703 |
| Caelo | Bifonazole | 15152702 | 22907 | 40 | 20150703 |
| Caelo | Bifonazole | 15152702 | 22955 | 40 | 20150703 |
| Caelo | Bifonazole | 151527 | 23364 | 40 | 20150703* |
| Euro OTC | Bifonazole | 1206027-01 | 20810 | 40 | 1312397 |
| Euro OTC | Bifonazole | 1401031-01 | 21631 | 60 | 20140220 |
| Euro OTC | Bifonazole | 1510001 | 22253 | 60 | 20151203* |
| Fagron | Bifonazole | 12G11-N09 | 20820 | 40 | 20120807 |
| Fagron | Bifonazole | 16D07-B10-324381 | 22941 | 40 | 20160419 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 9 reference samples from the substance/substance group *Bifonazole*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 926 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 7 reference samples from the substance/substance group *Bifonazole*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Bifonazole | 182771 | 24365 | 40 |
| Caelo | Bifonazole | 22001498 | 26738 | 40 |
| Euro OTC | Bifonazole | 1703041 | 23395 | 40 |
| Euro OTC | Bifonazole | 1806008 | 24161 | 40 |
| Fagron | Bifonazole | 22C23-B03-219763 | 26376 | 40 |
| Caelo | Bifonazole | 22001498 | 26738SI | 20 |
| Fagron | Bifonazole | 22C23-B03-219763 | 26376SI | 20 |

- 212 700 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 227 spectra from 89 *Apo-Ident* customers from 90 batches from the substance/substance group *Bifonazole*.

- Among them are spectra of independent samples from 81 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Bifonazole | 21B18-B03-228686 | 2 |
| | Bifonazole | 22001498010 | 1 |
| | Bifonazole | 22C23-B03-223797 | 2 |
| | Bifonazole | 22L06-B10-223798 | 4 |
| | Bifonazole | 22L06-B10-228687 | 1 |
| | Bifonazole | 24000099002 | 2 |
| | Bifonazole | 2400099002 | 1 |
| | Bifonazole | B10-2330708 | 1 |
| Caelo | Bifonazole | 13I09-N07 | 1 |
| Caelo | Bifonazole | 14k10-B01-312067 | 1 |
| Caelo | Bifonazole | 15152701 | 6 |
| Caelo | Bifonazole | 16J03-B08-331029 | 1 |
| Caelo | Bifonazole | 18009702 | 9 |
| Caelo | Bifonazole | 18009704 | 4 |
| Caelo | Bifonazole | 18009705 | 1 |
| Caelo | Bifonazole | 18277103 | 1 |
| Caelo | Bifonazole | 18277104 | 1 |
| Caelo | Bifonazole | 19287504 | 1 |
| Caelo | Bifonazole | 19287505 | 2 |
| Caelo | Bifonazole | 20003802002 | 2 |
| Caesar & Loretz GmbH... | Bifonazole | 18277104 | 1 |
| Caesar & Loretz GmbH... | Bifonazole | 19287505 | 1 |
| Caesar & Loretz GmbH... | Bifonazole | 20003802009 | 1 |
| Caesar & Loretz GmbH | Bifonazole | 18277104 | 1 |
| Caesar & Loretz GmbH | Bifonazole | 19287505 | 2 |
| Caesar & Loretz GmbH | Bifonazole | 20003802002 | 2 |
| Erregierre S.p.A | Bifonazole | A200003 | 2 |
| Euro OTC | Bifonazole | 1206027-01 | 2 |
| Euro OTC | Bifonazole | 1206027-02 | 1 |
| Euro OTC | Bifonazole | 13G10N02 | 1 |
| Euro OTC | Bifonazole | 1510001-02 | 6 |
| Euro OTC | Bifonazole | 16703-B08-333937 | 1 |
| Euro OTC | Bifonazole | 170304101 | 1 |
| Euro OTC | Bifonazole | 1703041-01 | 7 |
| Euro OTC | Bifonazole | 18041814 | 1 |
| Euro OTC | Bifonazole | 1806008-01 | 12 |
| Euro OTC | Bifonazole | 18065008-01 | 1 |
| Euro Rho/Jenne | Bifonazole | 1806008-011 | 1 |
| Fagron | Bifonazole | | 2 |
| Fagron | Bifonazole | 11F20-N06 | 1 |
| Fagron | Bifonazole | 12D17-N02 | 3 |
| Fagron | Bifonazole | 12E29-N03 | 5 |
| Fagron | Bifonazole | 12G11-N09 | 2 |
| Fagron | Bifonazole | 13G10-N02 | 2 |
| Fagron | Bifonazole | 14C28-B03-292388 | 1 |
| Fagron | Bifonazole | 14C28-B03-292389 | 1 |
| Fagron | Bifonazole | 14K10-B01-300541 | 6 |
| Fagron | Bifonazole | 14K10-B01-306783 | 5 |
| Fagron | Bifonazole | 14K10-B01-308349 | 2 |
| Fagron | Bifonazole | 14K10-B01-312067 | 2 |
| Fagron | Bifonazole | 14K10-B01-316618 | 1 |
| Fagron | Bifonazole | 15/18-B04-320085 | 1 |
| Fagron | Bifonazole | 1518-B04-316619 | 1 |
| Fagron | Bifonazole | 15I18-B04-316619 | 1 |
| Fagron | Bifonazole | 1607-B10-324380 | 1 |
| Fagron | Bifonazole | 16D07-B10-321576 | 2 |
| Fagron | Bifonazole | 16D07-B10-324380 | 3 |
| Fagron | Bifonazole | 16D07-B10-324381 | 6 |
| Fagron | Bifonazole | 16D07-B10-32480 | 1 |
| Fagron | Bifonazole | 16j03-b08-327046 | 2 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Bifonazole | 16J03-B08-327046 | 4 |
| Fagron | Bifonazole | 16J03-B08-331029 | 2 |
| Fagron | Bifonazole | 16J03-B08-333936 | 2 |
| Fagron | Bifonazole | 16J03-B08-333937 | 6 |
| Fagron | Bifonazole | 18A15-B05 | 1 |
| Fagron | Bifonazole | 18A15-B05_344514 | 1 |
| Fagron | Bifonazole | 18A15-B05-344515 | 4 |
| Fagron | Bifonazole | 18A15-B05-347176 | 2 |
| Fagron | Bifonazole | 18A15-B05-350644 | 1 |
| Fagron | Bifonazole | 18A15-B05-353060 | 2 |
| Fagron | Bifonazole | 18A15-B05-357230 | 1 |
| Fagron | Bifonazole | 18A15-B05-357781 | 2 |
| Fagron | Bifonazole | 18A15-B05-358736 | 2 |
| Fagron | Bifonazole | 18A15-B05-362358 | 1 |
| Fagron | Bifonazole | 18A15-B5-34716 | 1 |
| Fagron | Bifonazole | 19E06B01363093 | 1 |
| Fagron | Bifonazole | 19E06-B01-363093 | 7 |
| Fagron | Bifonazole | 19E06-B01-367109 | 2 |
| Fagron | Bifonazole | 19L04-F02-369242 | 8 |
| Fagron | Bifonazole | 19L-F02-369242 | 1 |
| Fagron | Bifonazole | 20L03-F03-375885 | 8 |
| Fagron | Bifonazole | 20L03-F03-375887 | 1 |
| Fagron | Bifonazole | 21B18-B03-215543 | 2 |
| Fagron | Bifonazole | 22C23-B03-223797 | 1 |
| Fagron | Bifonazole | A160002 | 1 |
| Fagron | Bifonazole | A170003 | 1 |
| Fagron | Bifonazole | A190005 | 1 |
| Fagron | Bifonazole | A200003 | 1 |
| Fagron | Bifonazole | A210002 | 1 |
| Fagron | Bifonazole | B05-3623508 | 1 |
| Fagron | Bifonazole | f02-3671100 | 2 |
| Fargon | Bifonazole | 14k10-b01-300541 | 1 |
| Gehe | Bifonazole | 13D12-N11 | 1 |
| Gehe | Bifonazole | 15152703 | 1 |
| Gehe | Bifonazole | 19L04-F02-369242 | 1 |
| Gehe | Bifonazole | 20003802002 | 2 |
| Gehe | Bifonazole | 20003802009 | 1 |
| Noweda | Bifonazole | 18A15-B05-344514 | 1 |
| Noweda | Bifonazole | 21B18-B03-215543 | 2 |
| Sanacorp | Bifonazole | 19287505 | 1 |
| Sanacorp | Bifonazole | 19E06-B01 | 1 |
| Sanacorp | Bifonazole | 20L03-F03-375887 | 4 |
| Sanacorp | Bifonazole | 21B18-B03-215543 | 1 |

- 256 659 spectra from 1666 *Apo-Ident* customers from a total of 52 063 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Bifonazole* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Bifonazole* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 224 | 3 | 256 659 |

The substance/substance group *Bifonazole* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.6784 % (> 97.3568 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20810 | 20810 | 0.00 | 63.44 |
| 20820 | 23364 | 12.35 | 60.71 |
| 21631 | 20810 | 9.01 | 66.44 |
| 22253 | 22253 | 0.00 | 66.38 |
| 22906 | 22253 | 6.49 | 60.86 |
| 22907 | 23364 | 4.83 | 63.05 |
| 22941 | 23364 | 4.42 | 62.51 |
| 22955 | 23364 | 3.06 | 62.81 |
| 23364 | 23364 | 0.00 | 63.74 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Biotin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20414-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Biotin; Biotinum

### Special notes

When selecting the *Biotin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Biotin | 9 | 19 | 59 |

### Second-stage model

For differentiation of the substance/substance group *Biotin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Biotin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 112.43 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Biotin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Biotin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Biotin | 16164313 | 22901 | 40 | 20160616 |
| Caelo | Biotin | 16164313 | 22902 | 40 | 20160216 |
| Caelo | Biotin | 163432 | 23029 | 40 | 20170119* |
| Caelo | Biotin | 163432 | 23063 | 40 | 20170119* |
| Euro OTC | Biotin | 1402028-01 | 21632 | 60 | 20140404 |
| Euro OTC | Biotin | 1508030 | 21904 | 60 | 20150925* |
| Euro OTC | Biotin | 1610003 | 22855 | 40 | 20161110* |
| Euro OTC | Biotin | 2009044 | 25536 | 40 | 20210215* |
| Fagron | Biotin | 13K29-N02 | 21221 | 40 | 20131204 |
| Fagron | Biotin | 17K20-B03-351524 | 24694 | 40 | 20180108 |
| Fagron | Biotin | 25D10-B022 | BR20128 | 40 | 20250121* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 480 spectra of 11 reference samples from the substance/substance group *Biotin*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 846 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 890 spectra of 25 reference samples from the substance/substance group *Biotin*.

- Among them are spectra of independent samples from 19 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Biotin | 173152 | 23829 | 40 |
| Caelo | Biotin | 183009 | 24372 | 40 |
| Caelo | Biotin | 21003208 | 25850 | 50 |
| Caelo | Biotin | 24000895 | 27224 | 40 |
| Caelo | Biotin | 23003236 | 27228 | 40 |
| Caelo | Biotin | 24000895001 | 27575 | 40 |
| Euro OTC | Biotin | 1603017 | 22507 | 40 |
| Euro OTC | Biotin | 1708007 | 23728 | 40 |
| Euro OTC | Biotin | 1802022 | 23955 | 40 |
| Euro OTC | Biotin | 1903020 | 24612 | 40 |
| Euro OTC | Biotin | 1903019 | 24631 | 40 |
| Euro OTC | Biotin | 2005032 | 25420 | 40 |
| Euro OTC | Biotin | 2110003 | 25875 | 50 |
| Euro OTC | Biotin | 2306005 | 26934 | 40 |
| Euro OTC | Biotin | 2311005 | 27146 | 40 |
| Fagron | Biotin | 22C02-B01-217682 | 26157 | 40 |
| Fagron | Biotin | 24D08-B01-236877 | 27374 | 40 |
| Fagron | Biotin | 25C14-B003 | BR20127 | 40 |
| Fagron | Biotin | 24J02-B015 | BR20129 | 40 |
| Euro OTC | Biotin | 2110003 | 25875SI | 10 |
| Euro OTC | Biotin | 2306005 | 26934SI | 20 |
| Fagron | Biotin | 22C02-B01-217682 | 26157SI | 20 |
| Fagron | Biotin | 25C14-B003 | BR20127SI | 20 |
| Fagron | Biotin | 25D10-B022 | BR20128SI† | 20 |
| Fagron | Biotin | 24J02-B015 | BR20129SI | 20 |

- 212 050 spectra from a total of 4267 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 130 spectra from 40 *Apo-Ident* customers from 63 batches from the substance/substance group *Biotin*.
- Among them are spectra of independent samples from 59 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Biotin | 2009044-03 | 1 |
| | Biotin | 21002482008 | 1 |
| | Biotin | 22C02-B01-224530 | 1 |
| | Biotin | 22C02-B01-217682 | 1 |
| | Biotin | 2306005-01 | 2 |
| | Biotin | 2306005-02 | 3 |
| | Biotin | 2311005-01 | 1 |
| | Biotin | 2311005-02 | 2 |
| | Biotin | 24000895001 | 1 |
| Caelo | Biotin | 12A23-N03 | 1 |
| Caelo | Biotin | 13K29-N02 | 2 |
| Caelo | Biotin | 1402028-01 | 2 |
| Caelo | Biotin | 1610003-02 | 1 |
| Caelo | Biotin | 1708007-01 | 2 |
| Caelo | Biotin | 17D28-B07-334630 | 1 |
| EuRho | Biotin | 1802022-01 | 1 |
| Euro OTC | Biotin | 10061709 | 1 |
| Euro OTC | Biotin | 1111039-02 | 1 |
| Euro OTC | Biotin | 1301026-01 | 3 |
| Euro OTC | Biotin | 1402028-01 | 2 |
| Euro OTC | Biotin | 1411047-01 | 3 |
| Euro OTC | Biotin | 1508030-01 | 2 |
| Euro OTC | Biotin | 1603017-01 | 1 |
| Euro OTC | Biotin | 161000301 | 1 |
| Euro OTC | Biotin | 1610003-01 | 6 |
| Euro OTC | Biotin | 170800701 | 1 |
| Euro OTC | Biotin | 1708007-01 | 8 |
| Euro OTC | Biotin | 180202201 | 6 |
| Euro OTC | Biotin | 1802022-01 | 4 |
| Euro OTC | Biotin | 1802022-02 | 3 |
| Euro OTC | Biotin | 1802022-03 | 1 |
| Euro OTC | Biotin | 1903019-01 | 5 |
| Euro OTC | Biotin | 190302001 | 1 |
| Euro OTC | Biotin | 1903020-01 | 4 |
| Euro OTC | Biotin | 2009044-01 | 14 |
| Euro OTC | Biotin | 2009044-02 | 1 |
| Euro OTC | Biotin | 2041517 | 1 |
| Euro OTC | Biotin | 2110003 | 1 |
| Euro OTC | Biotin | 2110003-01 | 9 |
| Euro OTC | Biotin | 24011801 | 1 |
| Euro OTC | Biotin | 2417Q-01100 | 1 |
| Euro OTC | Biotin | 28071506 | 1 |
| Euro OTC | Biotin | 2818Q-01100 | 1 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Biotin | 3021501 | 1 |
| Euro OTC | Biotin | 5121812 | 1 |
| Fagron | Biotin | 12111302 | 1 |
| Fagron | Biotin | 12A23-N03 | 1 |
| Fagron | Biotin | 12C14-N01 | 1 |
| Fagron | Biotin | 13081203 | 1 |
| Fagron | Biotin | 13111202 | 1 |
| Fagron | Biotin | 14d04-b07-292963 | 1 |
| Fagron | Biotin | 17k20-B03-351524 | 1 |
| Fagron | Biotin | 17K20-B03-351524 | 1 |
| Fagron | Biotin | 19E22-B01-363404 | 1 |
| Fagron | Biotin | 20110634 | 1 |
| Fagron | Biotin | 20K09-F02-375271 | 1 |
| Fagron | Biotin | 20K09-F02-375272 | 1 |
| Fagron | Biotin | 22C02-B01-217682 | 1 |
| Fagron | Biotin | F03-3775400 | 1 |
| Fagron | Biotin | UE01704007 | 1 |
| Fagron | Biotin | UE01807006 | 1 |
| Fagron | Biotin | UE02005010 | 1 |
| Fagron | Biotin | UE02005015 | 1 |
| Gatt-Koller | Biotin | 1634211 | 1 |
| kögl | Biotin | 17315206 | 1 |
| KÖGL | Biotin | 17315212 | 1 |
| privat | Biotin | 20171208-05-100 | 1 |

- 256 756 spectra from 1666 *Apo-Ident* customers from a total of 52 091 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Biotin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Biotin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 890 | 0 | 212 050 |
| **Type C** | 0 | 130 | 0 | 256 756 |

The substance/substance group *Biotin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3258 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 95.3846 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21221 | 21904 | 13.81 | 157.19 |
| 21632 | 21904 | 6.46 | 160.25 |
| 21904 | 21904 | 0.00 | 162.32 |
| 22855 | 22855 | 0.00 | 163.61 |
| 22901 | 21904 | 4.34 | 163.75 |
| 22902 | 21904 | 4.90 | 164.25 |
| 23029 | 23029 | 0.00 | 165.44 |
| 23063 | 23063 | 0.00 | 164.70 |
| 24694 | 23029 | 11.44 | 166.00 |
| 25536 | 25536 | 0.00 | 164.23 |
| BR20128 | BR20128 | 0.00 | 164.78 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Bismuth gallath, basic** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21252-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Bismuth gallath, basic; Bismuthi subgallas

### Special notes

When selecting the *Bismuth gallath, basic* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Bismuth gallath, basic | 6 | 5 | 257 |

### Second-stage model

For differentiation of the substance/substance group *Bismuth gallath, basic* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Bismuth gallath, basic* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 68.46 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Bismuth gallath, basic* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Bismuth gallath, basic*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Bismuth gallath, basic | 13179105 | 21252 | 40 | 1412254 |
| Caelo | Bismuth gallath, basic | 13179105 | 21553 | 60 | 20130701 |
| Caelo | Bismuth gallath, basic | 170041 | 23359 | 40 | 20170214* |
| Caelo | Bismuth gallath, basic | 17004102 | 23372 | 40 | 20170214 |
| Caelo | Bismuth gallath, basic | 20000903 | 25204 | 40 | 20200331* |
| Fagron | Bismuth gallath, basic | 15B02-B04-309481 | 22597 | 40 | 20150226 |
| Fagron | Bismuth gallath, basic | 15J26-B02-317883 | 22598 | 40 | 20151102 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 7 reference samples from the substance/substance group *Bismuth gallath, basic*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 026 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 230 spectra of 6 reference samples from the substance/substance group *Bismuth gallath, basic*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Bismuth gallath, basic | 191063 | 24714 | 40 |
| Caelo | Bismuth gallath, basic | 21003110 | 25845 | 50 |
| Fagron | Bismuth gallath, basic | 16K17-B04-335597 | 23570 | 40 |
| Fagron | Bismuth gallath, basic | 19K28-B02-196432 | 25186 | 40 |
| Fagron | Bismuth gallath, basic | 22I21-B04-223756 | 26617 | 40 |
| Fagron | Bismuth gallath, basic | 22I21-B04-223756 | 26617SI | 20 |

- 212 710 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 946 spectra from 476 *Apo-Ident* customers from 276 batches from the substance/substance group *Bismuth gallath, basic*.

- Among them are spectra of independent samples from 257 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Bismuth gallath, basic | 2022003849 | 3 |
| | Bismuth gallath, basic | 2023001183 | 1 |
| | Bismuth gallath, basic | 202300183 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Bismuth gallath, basic | 2023004222 | 1 |
| | Bismuth gallath, basic | 2100310013 | 1 |
| | Bismuth gallath, basic | 21003110002 | 1 |
| | Bismuth gallath, basic | 21003110005 | 1 |
| | Bismuth gallath, basic | 21003110009 | 2 |
| | Bismuth gallath, basic | 21003110010 | 5 |
| | Bismuth gallath, basic | 21003110013 | 4 |
| | Bismuth gallath, basic | 21003110015 | 2 |
| | Bismuth gallath, basic | 21003110017 | 4 |
| | Bismuth gallath, basic | 21G21-B03-213570 | 2 |
| | Bismuth gallath, basic | 221-B04-223683 | 1 |
| | Bismuth gallath, basic | 22I21-B04-223756 | 2 |
| | Bismuth gallath, basic | 22I21-B04-228625 | 3 |
| | Bismuth gallath, basic | 22l21-B04-228625 | 1 |
| | Bismuth gallath, basic | 23c31-b07-228539 | 1 |
| | Bismuth gallath, basic | 23C31-B07-228539 | 3 |
| | Bismuth gallath, basic | 23C31-B07-233045 | 5 |
| | Bismuth gallath, basic | 23K07-B12-237501 | 3 |
| | Bismuth gallath, basic | 24000112002 | 1 |
| | Bismuth gallath, basic | B02-3369608 | 1 |
| | Bismuth gallath, basic | B04-2286205 | 4 |
| 5N Plus GmbH / Ebert | Bismuth gallath, basic | 18040801 | 1 |
| 5N Plus GmbH/Phoenix | Bismuth gallath, basic | 2020000872 | 1 |
| ahd/lamotte | Bismuth gallath, basic | 13718_b13_292058 | 1 |
| Alliance H. | Bismuth gallath, basic | 15080602 | 1 |
| Alliance Healthcare | Bismuth gallath, basic | 13D19-N02 | 2 |
| Alliance | Bismuth gallath, basic | 12172402 | 1 |
| Allianz Healthcare | Bismuth gallath, basic | 15200911 | 1 |
| Allianz Healthcare | Bismuth gallath, basic | 17259517 | 1 |
| Anzag | Bismuth gallath, basic | 2012000059 | 2 |
| apomix | Bismuth gallath, basic | 13D19-N02 | 1 |
| Bombastus | Bismuth gallath, basic | 13/18-B13-292058 | 1 |
| Bombastus | Bismuth gallath, basic | 13G10-N12 | 1 |
| Caelo | Bismuth gallath, basic | | 1 |
| Caelo | Bismuth gallath, basic | 10135109 | 1 |
| Caelo | Bismuth gallath, basic | 10D23-N05 | 1 |
| Caelo | Bismuth gallath, basic | 11127101 | 1 |
| Caelo | Bismuth gallath, basic | 11127104 | 1 |
| Caelo | Bismuth gallath, basic | 1127203 | 1 |
| Caelo | Bismuth gallath, basic | 12166901 | 2 |
| Caelo | Bismuth gallath, basic | 1217240 | 1 |
| Caelo | Bismuth gallath, basic | 12172401 | 1 |
| Caelo | Bismuth gallath, basic | 12172402 | 4 |
| Caelo | Bismuth gallath, basic | 12172409 | 6 |
| Caelo | Bismuth gallath, basic | 12172412 | 5 |
| Caelo | Bismuth gallath, basic | 12c13-n03 | 1 |
| Caelo | Bismuth gallath, basic | 12C13-N03 | 1 |
| Caelo | Bismuth gallath, basic | 12c13-no3 | 1 |
| Caelo | Bismuth gallath, basic | 12E16-N03 | 1 |
| Caelo | Bismuth gallath, basic | 12I13-N11 | 1 |
| Caelo | Bismuth gallath, basic | 13/18-B13-292057 | 1 |
| Caelo | Bismuth gallath, basic | 13/18-B13-292058 | 1 |
| Caelo | Bismuth gallath, basic | 13179101 | 2 |
| Caelo | Bismuth gallath, basic | 13179105 | 1 |
| Caelo | Bismuth gallath, basic | 13179111 | 6 |
| Caelo | Bismuth gallath, basic | 13D19-N02 | 2 |
| Caelo | Bismuth gallath, basic | 13I18-B13 | 1 |
| Caelo | Bismuth gallath, basic | 13I18-B13-294108 | 2 |
| Caelo | Bismuth gallath, basic | 14224103 | 4 |
| Caelo | Bismuth gallath, basic | 14224105 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Bismuth gallath, basic | 15080602 | 3 |
| Caelo | Bismuth gallath, basic | 15080603 | 1 |
| Caelo | Bismuth gallath, basic | 15080606 | 10 |
| Caelo | Bismuth gallath, basic | 15200904 | 3 |
| Caelo | Bismuth gallath, basic | 15200905 | 1 |
| Caelo | Bismuth gallath, basic | 15200907 | 1 |
| Caelo | Bismuth gallath, basic | 15200910 | 2 |
| Caelo | Bismuth gallath, basic | 15200911 | 7 |
| Caelo | Bismuth gallath, basic | 15200913 | 4 |
| Caelo | Bismuth gallath, basic | 1520910 | 1 |
| Caelo | Bismuth gallath, basic | 1520913 | 1 |
| Caelo | Bismuth gallath, basic | 15B02-B04-304408 | 1 |
| Caelo | Bismuth gallath, basic | 15B02B04304413 | 1 |
| Caelo | Bismuth gallath, basic | 15B02-B04-309481 | 2 |
| Caelo | Bismuth gallath, basic | 15J26_B02-321313 | 1 |
| Caelo | Bismuth gallath, basic | 15J26-B02-320473 | 1 |
| Caelo | Bismuth gallath, basic | 15J26-B02-320479 | 1 |
| Caelo | Bismuth gallath, basic | 1603810 | 1 |
| Caelo | Bismuth gallath, basic | 16038308 | 8 |
| Caelo | Bismuth gallath, basic | 16038310 | 8 |
| Caelo | Bismuth gallath, basic | 16038312 | 9 |
| Caelo | Bismuth gallath, basic | 16K17-B04-335597 | 1 |
| Caelo | Bismuth gallath, basic | 17/26-B01-340556 | 1 |
| Caelo | Bismuth gallath, basic | 17004102 | 10 |
| Caelo | Bismuth gallath, basic | 17004106 | 10 |
| Caelo | Bismuth gallath, basic | 17004107 | 5 |
| Caelo | Bismuth gallath, basic | 17004109 | 9 |
| Caelo | Bismuth gallath, basic | 17004112 | 4 |
| Caelo | Bismuth gallath, basic | 1725909 | 1 |
| Caelo | Bismuth gallath, basic | 17259503 | 2 |
| Caelo | Bismuth gallath, basic | 17259505 | 4 |
| Caelo | Bismuth gallath, basic | 17259509 | 6 |
| Caelo | Bismuth gallath, basic | 17259510 | 3 |
| Caelo | Bismuth gallath, basic | 17259513 | 5 |
| Caelo | Bismuth gallath, basic | 17259517 | 8 |
| Caelo | Bismuth gallath, basic | 17259519 | 3 |
| Caelo | Bismuth gallath, basic | 17E16-B02-336992 | 1 |
| Caelo | Bismuth gallath, basic | 17-E16-B02-336992 | 1 |
| Caelo | Bismuth gallath, basic | 17I26-B01-341866 | 1 |
| Caelo | Bismuth gallath, basic | 18040801 | 11 |
| Caelo | Bismuth gallath, basic | 18A29-B06 | 1 |
| Caelo | Bismuth gallath, basic | 18A29-B06-346305 | 2 |
| Caelo | Bismuth gallath, basic | 18A29-B346305 | 1 |
| Caelo | Bismuth gallath, basic | 191063002 | 23 |
| Caelo | Bismuth gallath, basic | 191063004 | 6 |
| Caelo | Bismuth gallath, basic | 191063005 | 1 |
| Caelo | Bismuth gallath, basic | 191063006 | 8 |
| Caelo | Bismuth gallath, basic | 19106301 | 8 |
| Caelo | Bismuth gallath, basic | 19106302 | 6 |
| Caelo | Bismuth gallath, basic | 19B05-B09-191019 | 1 |
| Caelo | Bismuth gallath, basic | 20004232001 | 5 |
| Caelo | Bismuth gallath, basic | 20004232002 | 2 |
| Caelo | Bismuth gallath, basic | 20004232004 | 3 |
| Caelo | Bismuth gallath, basic | 2004232006 | 1 |
| Caelo | Bismuth gallath, basic | 2012006724 | 1 |
| Caelo | Bismuth gallath, basic | 2017002570 | 1 |
| Caelo | Bismuth gallath, basic | 21000126001 | 5 |
| Caelo | Bismuth gallath, basic | 21003110002 | 7 |
| Caelo | Bismuth gallath, basic | 21003110005 | 3 |
| Caelo | Bismuth gallath, basic | 21003110006 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Bismuth gallath, basic | 21003110009 | 2 |
| Caelo | Bismuth gallath, basic | 21003110010 | 3 |
| Caelo | Bismuth gallath, basic | 21003110013 | 2 |
| Caelo | Bismuth gallath, basic | 220511(21000126001) | 1 |
| Caelo | Bismuth gallath, basic | 23121410 | 1 |
| Caelo | Bismuth gallath, basic | 2414E-01185 | 1 |
| Caelo | Bismuth gallath, basic | 26011903 | 1 |
| Caelo | Bismuth gallath, basic | 5208I-01185 | 1 |
| Caelo | Bismuth gallath, basic | 62183516 | 1 |
| Caelo | Bismuth gallath, basic | 81297468 | 5 |
| Caelo | Bismuth gallath, basic | 8129768 | 1 |
| Caelo | Bismuth gallath, basic | 9205701 | 1 |
| Caelo | Bismuth gallath, basic | 9205703 | 2 |
| Caelo | Bismuth gallath, basic | 92057409 | 1 |
| Caelo | Bismuth gallath, basic | B02-1964302 | 2 |
| Caelo | Bismuth gallath, basic | B-150513-1 | 1 |
| Caesar & Loretz GmbH... | Bismuth gallath, basic | 21003110006 | 1 |
| Caesar & Loretz GmbH... | Bismuth gallath, basic | 21003110002 | 1 |
| Caesar & Loretz GmbH... | Bismuth gallath, basic | 17259505 | 1 |
| Caesar & Loretz GmbH/Gehe | Bismuth gallath, basic | 17259509 | 1 |
| Caesar & Loretz GmbH/Gehe | Bismuth gallath, basic | 191063006 | 1 |
| Caesar & Loretz GmbH/Gehe | Bismuth gallath, basic | 19106301 | 1 |
| Caesar & Loretz GmbH/Gehe | Bismuth gallath, basic | 21000126001 | 2 |
| Caesar & Loretz GmbH... | Bismuth gallath, basic | 20004232004 | 1 |
| Caesar & Loretz GmbH... | Bismuth gallath, basic | 191063006 | 1 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 16038312 | 2 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 17004102 | 1 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 17259509 | 2 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 17259510 | 5 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 17259513 | 3 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 191063002 | 4 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 191063004 | 4 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 191063006 | 6 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 19106301 | 3 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 20004232001 | 3 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 20004232004 | 2 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 21000126001 | 6 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 21003110002 | 5 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 21003110006 | 8 |
| Caesar & Loretz GmbH | Bismuth gallath, basic | 21003110009 | 1 |
| Caesar/Ebert | Bismuth gallath, basic | 17259509 | 1 |
| Euro OTC | Bismuth gallath, basic | 16K17-B04-335597 | 3 |
| Fagro/Gehe | Bismuth gallath, basic | 2018005145 | 1 |
| Fagron | Bismuth gallath, basic | | 3 |
| Fagron | Bismuth gallath, basic | 10H31-N01 | 1 |
| Fagron | Bismuth gallath, basic | 114101-0003 | 1 |
| Fagron | Bismuth gallath, basic | 11F15-N03 | 1 |
| Fagron | Bismuth gallath, basic | 12/13-N11 | 1 |
| Fagron | Bismuth gallath, basic | 12B02-B04-304408 | 1 |
| Fagron | Bismuth gallath, basic | 12C13-N03 | 4 |
| Fagron | Bismuth gallath, basic | 12E16-N03 | 1 |
| Fagron | Bismuth gallath, basic | 12K26-N01 | 3 |
| Fagron | Bismuth gallath, basic | 13/18-B13-292057 | 2 |
| Fagron | Bismuth gallath, basic | 13/18-B-13-292057 | 1 |
| Fagron | Bismuth gallath, basic | 13/18-B13-292058 | 3 |
| Fagron | Bismuth gallath, basic | 13/18-B13294098 | 1 |
| Fagron | Bismuth gallath, basic | 13/18-B13-294098 | 2 |
| Fagron | Bismuth gallath, basic | 13/18-B13-294108 | 3 |
| Fagron | Bismuth gallath, basic | 13179111 | 1 |
| Fagron | Bismuth gallath, basic | 1318-B13-292057 | 2 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Bismuth gallath, basic | 1318b13292058 | 1 |
| Fagron | Bismuth gallath, basic | 1318B1329409 | 1 |
| Fagron | Bismuth gallath, basic | 1318B13294108 | 1 |
| Fagron | Bismuth gallath, basic | 13D19-N02 | 3 |
| Fagron | Bismuth gallath, basic | 13E21-N03 | 2 |
| Fagron | Bismuth gallath, basic | 13F10-N12 | 1 |
| Fagron | Bismuth gallath, basic | 13G10-N12 | 4 |
| Fagron | Bismuth gallath, basic | 13I18-B13 | 5 |
| Fagron | Bismuth gallath, basic | 13I18-b13-292057 | 1 |
| Fagron | Bismuth gallath, basic | 13I18-B13-292057 | 2 |
| Fagron | Bismuth gallath, basic | 13I18-B13-292058 | 1 |
| Fagron | Bismuth gallath, basic | 13I18-B13-294098 | 4 |
| Fagron | Bismuth gallath, basic | 13i18-b13-294108 | 1 |
| Fagron | Bismuth gallath, basic | 13I18-B13-294108 | 6 |
| Fagron | Bismuth gallath, basic | 13K08-N03 | 4 |
| Fagron | Bismuth gallath, basic | 14H13-B07 | 1 |
| Fagron | Bismuth gallath, basic | 14H13B07303639 | 1 |
| Fagron | Bismuth gallath, basic | 14H13-B07-303639 | 6 |
| Fagron | Bismuth gallath, basic | 15/26-B02-320473 | 1 |
| Fagron | Bismuth gallath, basic | 15/26-B02-321313 | 1 |
| Fagron | Bismuth gallath, basic | 15126-B02-321313 | 1 |
| Fagron | Bismuth gallath, basic | 15B02-B04 | 3 |
| Fagron | Bismuth gallath, basic | 15B02-B04-209481 | 1 |
| Fagron | Bismuth gallath, basic | 15b02b04304408 | 1 |
| Fagron | Bismuth gallath, basic | 15B02-B04-304408 | 9 |
| Fagron | Bismuth gallath, basic | 15B02-B04-304413 | 5 |
| Fagron | Bismuth gallath, basic | 15b02-B04-309481 | 1 |
| Fagron | Bismuth gallath, basic | 15B02B04309481 | 1 |
| Fagron | Bismuth gallath, basic | 15B02-B04-309481 | 4 |
| Fagron | Bismuth gallath, basic | 15B02-B04-311878 | 1 |
| Fagron | Bismuth gallath, basic | 15C27-B02-311879 | 1 |
| Fagron | Bismuth gallath, basic | 15H05-B07 | 1 |
| Fagron | Bismuth gallath, basic | 15h05-b07-311880 | 1 |
| Fagron | Bismuth gallath, basic | 15H05-B07-311880 | 5 |
| Fagron | Bismuth gallath, basic | 15I26-B02-325472 | 1 |
| Fagron | Bismuth gallath, basic | 15J26-B02 | 5 |
| Fagron | Bismuth gallath, basic | 15J26-B022 | 1 |
| Fagron | Bismuth gallath, basic | 15J26-B02-317883 | 10 |
| Fagron | Bismuth gallath, basic | 15J26-B02-320473 | 5 |
| Fagron | Bismuth gallath, basic | 15j26-b02-321313 | 1 |
| Fagron | Bismuth gallath, basic | 15J26-B02-321313 | 7 |
| Fagron | Bismuth gallath, basic | 15J26-B02-325450 | 1 |
| Fagron | Bismuth gallath, basic | 15J26-B02-325472 | 9 |
| Fagron | Bismuth gallath, basic | 15J26-B02-321313 | 2 |
| Fagron | Bismuth gallath, basic | 16K17B04 | 1 |
| Fagron | Bismuth gallath, basic | 16K17-B04 | 1 |
| Fagron | Bismuth gallath, basic | 16K17-B04-3355593 | 1 |
| Fagron | Bismuth gallath, basic | 16K17B04335597 | 2 |
| Fagron | Bismuth gallath, basic | 16K17-B04-335597 | 12 |
| Fagron | Bismuth gallath, basic | 17/26-B01-340556 | 4 |
| Fagron | Bismuth gallath, basic | 17/26-B01-341866 | 1 |
| Fagron | Bismuth gallath, basic | 1726B01341866 | 1 |
| Fagron | Bismuth gallath, basic | 17E16-B02 | 4 |
| Fagron | Bismuth gallath, basic | 17E16-B02-336968 | 1 |
| Fagron | Bismuth gallath, basic | 17E16-B02-336992 | 3 |
| Fagron | Bismuth gallath, basic | 17G06-B10-355772 | 1 |
| Fagron | Bismuth gallath, basic | 17i26-B01 | 1 |
| Fagron | Bismuth gallath, basic | 17I26-B01-340552 | 4 |
| Fagron | Bismuth gallath, basic | 17I26-B01-340556 | 6 |
| Fagron | Bismuth gallath, basic | 17I26-B01-341866 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Bismuth gallath, basic | 180307BB/2016006984 | 1 |
| Fagron | Bismuth gallath, basic | 180808186 | 1 |
| Fagron | Bismuth gallath, basic | 18A29-B06 | 2 |
| Fagron | Bismuth gallath, basic | 18A29-B06-3460303 | 1 |
| Fagron | Bismuth gallath, basic | 18A29-B06-346303 | 1 |
| Fagron | Bismuth gallath, basic | 18A29B06-346305 | 1 |
| Fagron | Bismuth gallath, basic | 18A29-B06-346305 | 9 |
| Fagron | Bismuth gallath, basic | 18A29-BO6-346305 | 1 |
| Fagron | Bismuth gallath, basic | 18G06-B10 | 2 |
| Fagron | Bismuth gallath, basic | 18G06-B10-352463 | 4 |
| Fagron | Bismuth gallath, basic | 18G06-B10-352486 | 3 |
| Fagron | Bismuth gallath, basic | 18G06-B10-353902 | 2 |
| Fagron | Bismuth gallath, basic | 18G06-B10-353916 | 6 |
| Fagron | Bismuth gallath, basic | 18G06B10355772 | 2 |
| Fagron | Bismuth gallath, basic | 18G06-B10-355772 | 6 |
| Fagron | Bismuth gallath, basic | 18K29-B06-346303 | 1 |
| Fagron | Bismuth gallath, basic | 191022 | 1 |
| Fagron | Bismuth gallath, basic | 19B05-B09-191019 | 4 |
| Fagron | Bismuth gallath, basic | 19B05-B09-191022 | 8 |
| Fagron | Bismuth gallath, basic | 19k28-B02 | 1 |
| Fagron | Bismuth gallath, basic | 19K28-B02 | 5 |
| Fagron | Bismuth gallath, basic | 19K28-B02-196431 | 12 |
| Fagron | Bismuth gallath, basic | 19k28b02196432 | 1 |
| Fagron | Bismuth gallath, basic | 19K28-B02-196432 | 18 |
| Fagron | Bismuth gallath, basic | 19k28-B02-201353 | 1 |
| Fagron | Bismuth gallath, basic | 19K28-B02-201353 | 2 |
| Fagron | Bismuth gallath, basic | 19K28Bo2-196432 | 1 |
| Fagron | Bismuth gallath, basic | 2010002685 | 2 |
| Fagron | Bismuth gallath, basic | 20114b10202382 | 1 |
| Fagron | Bismuth gallath, basic | 2012000059 | 3 |
| Fagron | Bismuth gallath, basic | 2012006724 | 2 |
| Fagron | Bismuth gallath, basic | 2013006220 | 1 |
| Fagron | Bismuth gallath, basic | 2014006082 | 1 |
| Fagron | Bismuth gallath, basic | 2015000361 | 3 |
| Fagron | Bismuth gallath, basic | 2015000866 | 1 |
| Fagron | Bismuth gallath, basic | 2015007568 | 4 |
| Fagron | Bismuth gallath, basic | 2016006984 | 1 |
| Fagron | Bismuth gallath, basic | 2017002570 | 1 |
| Fagron | Bismuth gallath, basic | 2017006945 | 4 |
| Fagron | Bismuth gallath, basic | 2018000237 | 2 |
| Fagron | Bismuth gallath, basic | 2018005145 | 7 |
| Fagron | Bismuth gallath, basic | 2019001542 | 11 |
| Fagron | Bismuth gallath, basic | 2020004951 | 2 |
| Fagron | Bismuth gallath, basic | 2021001320 | 1 |
| Fagron | Bismuth gallath, basic | 20I14_B10-202382 | 1 |
| Fagron | Bismuth gallath, basic | 20I14-B10 | 1 |
| Fagron | Bismuth gallath, basic | 20i14-B10-2023802 | 1 |
| Fagron | Bismuth gallath, basic | 20I14-B10-202382 | 4 |
| Fagron | Bismuth gallath, basic | 21F11-B99 | 2 |
| Fagron | Bismuth gallath, basic | 21F11-B99-215303 | 1 |
| Fagron | Bismuth gallath, basic | 21f11-b99-215304 | 1 |
| Fagron | Bismuth gallath, basic | 21F11-B99-215304 | 5 |
| Fagron | Bismuth gallath, basic | 21G21-B03 | 2 |
| Fagron | Bismuth gallath, basic | 21g21b0321213570 | 1 |
| Fagron | Bismuth gallath, basic | 21G21-B03-213244 | 3 |
| Fagron | Bismuth gallath, basic | 21G21-B03-213570 | 11 |
| Fagron | Bismuth gallath, basic | 21G21-B03-215370 | 1 |
| Fagron | Bismuth gallath, basic | 22121-B04-223756 | 1 |
| Fagron | Bismuth gallath, basic | 22I21-B04-223756 | 2 |
| Fagron | Bismuth gallath, basic | 22l21-B04-223756 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Bismuth gallath, basic | 23K07-B12-237501 | 1 |
| Fagron | Bismuth gallath, basic | 26-B01-340552 | 1 |
| Fagron | Bismuth gallath, basic | 325472 | 1 |
| Fagron | Bismuth gallath, basic | 411092-3-P | 1 |
| Fagron | Bismuth gallath, basic | 5121 | 1 |
| Fagron | Bismuth gallath, basic | 8551389 | 1 |
| Fagron | Bismuth gallath, basic | 9K26-N10 | 2 |
| Fagron | Bismuth gallath, basic | B02-1964302 | 1 |
| Fagron | Bismuth gallath, basic | B02-2013503 | 1 |
| Fagron | Bismuth gallath, basic | B02-201353 | 1 |
| Fagron | Bismuth gallath, basic | b03-2135700 | 1 |
| Fagron | Bismuth gallath, basic | B09-1910109 | 2 |
| Fagron | Bismuth gallath, basic | B10-2023802 | 1 |
| Fagron | Bismuth gallath, basic | BO2-1964302 | 1 |
| Fagron | Bismuth gallath, basic | BO3-2135700 | 1 |
| Fargon GmbH & Co.KG | Bismuth gallath, basic | 15J26-B02-321313 | 2 |
| Fargon/ Noweda | Bismuth gallath, basic | 15B02-B04-309481 | 1 |
| Fargon/ Sanacorp | Bismuth gallath, basic | 19K28-BO2-196432 | 1 |
| Fargon/Sanacorp | Bismuth gallath, basic | 18A29-B06-346305 | 1 |
| Fargon | Bismuth gallath, basic | 13/18-B13-294108 | 1 |
| Fargron | Bismuth gallath, basic | 13D19-N02 | 1 |
| Fargron | Bismuth gallath, basic | 16k17-b04-335597 | 1 |
| Frago/Noweda | Bismuth gallath, basic | 16K17-B04-335597 | 1 |
| Fragon/Sanacorp | Bismuth gallath, basic | 16K17-B04-335593 | 1 |
| Fragon/Sanacorp | Bismuth gallath, basic | 17/26-B01-340552 | 1 |
| Fragon/Sanacorp | Bismuth gallath, basic | 18A-29-B06-346303 | 1 |
| Fragon | Bismuth gallath, basic | 19B05-B09-191022 | 1 |
| Fragon | Bismuth gallath, basic | 19K28-B02-19643 | 1 |
| Fragon | Bismuth gallath, basic | 19K28-B02-1964301 | 1 |
| Fragon | Bismuth gallath, basic | 19K28-B02-196431 | 2 |
| Fragon | Bismuth gallath, basic | 19K28-B02-196432 | 1 |
| Gehe amax | Bismuth gallath, basic | 15J26-B02-325450 | 1 |
| Gehe | Bismuth gallath, basic | 12172401 | 1 |
| Gehe | Bismuth gallath, basic | 15080607 | 1 |
| Gehe | Bismuth gallath, basic | 15J26-B02-317883 | 1 |
| GEHE | Bismuth gallath, basic | 17259509 | 1 |
| Gehe | Bismuth gallath, basic | 17E16-B02-336992 | 1 |
| GEHE | Bismuth gallath, basic | 18040801 | 1 |
| GEHE | Bismuth gallath, basic | 18A29-B06 | 2 |
| Gehe | Bismuth gallath, basic | 2015007568 | 1 |
| Hedinger | Bismuth gallath, basic | 16038310 | 1 |
| Infectopharm | Bismuth gallath, basic | 14224103 | 1 |
| Jenne | Bismuth gallath, basic | 21003110017 | 1 |
| Kehr | Bismuth gallath, basic | 17I26-B01-341866 | 1 |
| Klenk | Bismuth gallath, basic | 12E16-N03 | 1 |
| L12 | Bismuth gallath, basic | 16038308 | 1 |
| Martinus Apotheke | Bismuth gallath, basic | keine | 1 |
| Noweda | Bismuth gallath, basic | 17/26-B01-341866 | 1 |
| Noweda | Bismuth gallath, basic | 18A29-B06-346303 | 1 |
| Noweda | Bismuth gallath, basic | 19K28-B02-196431 | 1 |
| Noweda | Bismuth gallath, basic | 19K28-B02-196432 | 1 |
| Noweda | Bismuth gallath, basic | 19K28-B02-201353 | 1 |
| Noweda | Bismuth gallath, basic | 20004232001 | 1 |
| Noweda | Bismuth gallath, basic | 21003110002 | 1 |
| Noweda | Bismuth gallath, basic | 21003110010 | 1 |
| Noweda | Bismuth gallath, basic | 22I21-B04-223683 | 2 |
| Noweda | Bismuth gallath, basic | 22I21-B04-228625 | 1 |
| Noweda | Bismuth gallath, basic | 23K07-B12-237501 | 1 |
| Noweda | Bismuth gallath, basic | 24000112003 | 1 |
| Noweda | Bismuth gallath, basic | 24B07-B09-237423 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| PHOENIX am 17.01.2014 | Bismuth gallath, basic | 2012006724 | 1 |
| Phoenix, Jembke | Bismuth gallath, basic | 10135101 | 1 |
| Phoenix | Bismuth gallath, basic | 1520913 | 1 |
| Phoenix | Bismuth gallath, basic | 191063002 | 1 |
| Phönix | Bismuth gallath, basic | 12-13-N11 | 1 |
| Phönix | Bismuth gallath, basic | 12E16-N03 | 1 |
| phönix | Bismuth gallath, basic | 15J26-B02-325450 | 1 |
| Phönix | Bismuth gallath, basic | 17259505 | 2 |
| Phönix | Bismuth gallath, basic | 19K28-B02 | 1 |
| Phönix | Bismuth gallath, basic | 19K28-B02-196432 | 1 |
| Phönix | Bismuth gallath, basic | 21g21-b03-213570 | 1 |
| Sanacorp 03.01.22 23,00EUR | Bismuth gallath, basic | 220103BE | 1 |
| Sanacorp 28.06.2017 ... | Bismuth gallath, basic | 2015007568 | 1 |
| Sanacorp | Bismuth gallath, basic | 12/13-N11 | 1 |
| sanacorp | Bismuth gallath, basic | 13/1818B13-292057 | 1 |
| Sanacorp | Bismuth gallath, basic | 13D19-N02 | 1 |
| Sanacorp | Bismuth gallath, basic | 18A29-B06-346305 | 1 |
| Sanacorp | Bismuth gallath, basic | 19K28-B02-2013503 | 1 |
| Sanacorp | Bismuth gallath, basic | 2018005145 | 1 |
| Sanacorp | Bismuth gallath, basic | 2019001542-B02-201353 | 1 |
| Sanacorp | Bismuth gallath, basic | B02-2013503 | 1 |
| Sidonia | Bismuth gallath, basic | 15200904 | 1 |
| Sidonia | Bismuth gallath, basic | 15J-26-B02-325450 | 1 |
| Sidonia | Bismuth gallath, basic | 17004107 | 3 |
| Sidonia | Bismuth gallath, basic | 17004112 | 7 |
| siehe WE-Prüfprotokoll | Bismuth gallath, basic | 4/09 | 1 |

- 255 940 spectra from 1666 *Apo-Ident* customers from a total of 51 878 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Bismuth gallath, basic* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Bismuth gallath, basic* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 230 | 0 | 212 710 |
| **Type C** | 0 | 943 | 3 | 255 940 |

The substance/substance group *Bismuth gallath, basic* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.3913 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6829 % (> 99.3658 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21252 | 21252 | 0.00 | 72.39 |
| 21553 | 21252 | 5.84 | 71.08 |
| 22597 | 25204 | 10.41 | 69.66 |
| 22598 | 25204 | 9.65 | 70.15 |
| 23359 | 23359 | 0.00 | 71.28 |
| 23372 | 21252 | 9.22 | 68.80 |
| 25204 | 25204 | 0.00 | 72.00 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Boric acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20182-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Boric acid; Acidum boricum

### Special notes

When selecting the *Boric acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Boric acid | 6 | 5 | 44 |

### Second-stage model

For differentiation of the substance/substance group *Boric acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Boric acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 93.92 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Boric acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Boric acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Boric acid | 14133119 | 21804 | 60 | 20140509 |
| Caelo | Boric acid | 15425112 | 22964 | 40 | 20160104 |
| Caelo | Boric acid | 170613 | 23286 | 40 | 20170316* |
| Caelo | Boric acid | 193010 | 25210 | 40 | 20200113* |
| Fagron | Boric acid | 13I04-N06 | 21228 | 40 | 20130920 |
| Fagron | Boric acid | 15L09-B07-322988 | 23746 | 40 | 20151222 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 6 reference samples from the substance/substance group *Boric acid*. These

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 6 reference samples from the substance/substance group *Boric acid*.
- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Boric acid | 15242903 | 22965 | 40 |
| Caelo | Boric acid | 191943 | 24741 | 40 |
| Caelo | Boric acid | 21001289 | 25698 | 50 |
| Caelo | Boric acid | 21000784 | 25701 | 50 |
| Caelo | Boric acid | 24001235 | 27258 | 40 |
| Caelo | Boric acid | 24001235 | 27258SI | 20 |

- 212 700 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 82 spectra from 58 *Apo-Ident* customers from 49 batches from the substance/substance group *Boric acid*.
- Among them are spectra of independent samples from 44 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Boric acid | 10227913 | 1 |
| Caelo | Boric acid | 11D13-N08 | 1 |
| Caelo | Boric acid | 12238901 | 1 |
| Caelo | Boric acid | 12260502 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Boric acid | 14095202 | 1 |
| Caelo | Boric acid | 14133113 | 2 |
| Caelo | Boric acid | 14133119 | 1 |
| Caelo | Boric acid | 15095103 | 2 |
| Caelo | Boric acid | 15158901 | 1 |
| Caelo | Boric acid | 15158903 | 1 |
| Caelo | Boric acid | 15242906 | 1 |
| Caelo | Boric acid | 15242909 | 1 |
| Caelo | Boric acid | 15425101 | 5 |
| Caelo | Boric acid | 15425108 | 2 |
| Caelo | Boric acid | 15425112 | 2 |
| Caelo | Boric acid | 15425114 | 2 |
| Caelo | Boric acid | 15425118 | 3 |
| Caelo | Boric acid | 16291001 | 1 |
| Caelo | Boric acid | 17327901 | 4 |
| Caelo | Boric acid | 17327907 | 5 |
| Caelo | Boric acid | 17327912 | 2 |
| Caelo | Boric acid | 17327917 | 3 |
| Caelo | Boric acid | 193010003 | 1 |
| Caelo | Boric acid | 19301003 | 1 |
| Caelo | Boric acid | 20000508002 | 2 |
| Caelo | Boric acid | 20000508005 | 2 |
| Caelo | Boric acid | 200041/5001 | 1 |
| Caelo | Boric acid | 20004175001 | 1 |
| Caelo | Boric acid | 21000784001 | 1 |
| Caelo | Boric acid | 5425114 | 1 |
| Caelo | Boric acid | 80303AB | 1 |
| Caelo | Boric acid | 9324021 | 1 |
| Caelo | Boric acid | 9324036 | 1 |
| Caelo | Boric acid | 9324043 | 1 |
| Caesar & Loretz GmbH… | Boric acid | 20000508002 | 1 |
| Caesar & Loretz GmbH/Kehr | Boric acid | 17327916 | 1 |
| Caesar & Loretz GmbH | Boric acid | 17327912 | 2 |
| Caesar & Loretz GmbH | Boric acid | 17327916 | 1 |
| Caesar & Loretz GmbH | Boric acid | 19194301 | 1 |
| Caesar & Loretz GmbH | Boric acid | 20000508002 | 2 |
| Caesar & Loretz GmbH | Boric acid | 20004175001 | 1 |
| E Plus | Boric acid | 15425108 | 1 |
| Fagron | Boric acid | 11d13-n08 | 1 |
| Fagron | Boric acid | 11I26-n05 | 1 |
| Fagron | Boric acid | 12f01-n08 | 1 |
| Fagron | Boric acid | 12G04-N10 | 1 |
| Fagron | Boric acid | 13A21-N06 | 1 |
| Fagron | Boric acid | 13I04-N06 | 2 |
| Fagron | Boric acid | 14133101 | 1 |
| Fagron | Boric acid | 14B07-B02-295752 | 1 |
| Fagron | Boric acid | 9082012B | 1 |
| Gatt-Koller | Boric acid | 1803542 | 1 |
| Labor | Boric acid | 159095 | 1 |
| Nachprüfung | Boric acid | | 1 |
| Phoenix | Boric acid | 21000784001 | 1 |
| Sanacorp | Boric acid | 1/AKD3 | 1 |

- 256 804 spectra from 1666 *Apo-Ident* customers from a total of 52 105 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Boric acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Boric acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 82 | 0 | 256 804 |

The substance/substance group *Boric acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.6829 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21228 | 25210 | 10.85 | 167.19 |
| 21804 | 25210 | 3.85 | 164.79 |
| 22964 | 23286 | 15.66 | 178.82 |
| 23286 | 23286 | 0.00 | 199.21 |
| 23746 | 25210 | 9.95 | 168.95 |
| 25210 | 25210 | 0.00 | 171.27 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Budesonide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20569-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Budesonide; Budesonidum

### Special notes

When selecting the *Budesonide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Budesonide | 8 | 13 | 192 |

### Second-stage model

For differentiation of the substance/substance group *Budesonide* the following second-stage model is used:

- Submodel 07

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Budesonide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 73.16 | – |
| ⋮ | ⋮ | ⋮ |
| Betamethasone valerate | >50 | 20.70 |
| Erythromycin | >50 | 34.26 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Budesonide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Budesonide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Budesonide | 11351704 | 20808 | 40 | AR-15-FG-005286-01 |
| Caelo | Budesonide | 161431 | 22627 | 40 | 20160606* |
| Caelo | Budesonide | 161431 | 22627SI | 25 | 20160606* |
| Caelo | Budesonide | 15344004 | 22649 | 40 | 20151116 |
| Caelo | Budesonide | 15344004 | 22649SI | 23 | 20151116 |
| Euro OTC | Budesonide | 1311022-01 | 21620 | 60 | 20140113 |
| Euro OTC | Budesonide | 1311022-01 | 21620SI | 37 | 20140113 |
| Euro OTC | Budesonide | 1604018 | 22537 | 40 | 20160509* |
| Euro OTC | Budesonide | 1604018 | 22537SI | 23 | 20160509* |
| Euro OTC | Budesonide | 2010006 | 25475 | 40 | 20201202* |
| Fagron | Budesonide | 16J04-B01-326581 | 22841 | 40 | 20161026 |
| Fagron | Budesonide | 16J04-B01-326581 | 22888 | 40 | 20161026 |
| Fagron | Budesonide | 16J04-B01-326581 | 22888SI | 30 | 20161026 |
| Fagron | Budesonide | 18C15-B03-355399 | 24699 | 40 | 20180409 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 518 spectra of 14 reference samples from the substance/substance group *Budesonide*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 808 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1021 spectra of 30 reference samples from the substance/substance group *Budesonide*.

- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Budesonide | 170788 | 23279 | 40 |
| Caelo | Budesonide | 180749 | 24026 | 40 |
| Caelo | Budesonide | 191381 | 24737 | 40 |
| Caelo | Budesonide | 20002391 | 25636 | 30 |
| Caelo | Budesonide | 23000636 | 26710 | 40 |
| Euro OTC | Budesonide | 1709022 | 23778 | 40 |
| Euro OTC | Budesonide | 1904004 | 24619 | 40 |
| Euro OTC | Budesonide | 2003043 | 25251 | 40 |
| Euro OTC | Budesonide | 2103025 | 25690 | 50 |
| Euro OTC | Budesonide | 2203005 | 26088 | 40 |
| Euro OTC | Budesonide | 2301044 | 26590 | 30 |
| Euro OTC | Budesonide | 2402017 | 27150 | 40 |
| Fagron | Budesonide | 22A12-B01-213702 | 26378 | 40 |
| Caelo | Budesonide | 15344004 | 22649SI† | 7 |
| Caelo | Budesonide | 170788 | 23279SI | 20 |
| Caelo | Budesonide | 180749 | 24026SI | 20 |
| Caelo | Budesonide | 191381 | 24737SI | 24 |
| Caelo | Budesonide | 20002391 | 25636SI | 30 |
| Caelo | Budesonide | 23000636 | 26710SI | 30 |
| Euro OTC | Budesonide | 1709022 | 23778SI | 20 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Budesonide | 1904004 | 24619SI | 40 |
| Euro OTC | Budesonide | 2003043 | 25251SI | 40 |
| Euro OTC | Budesonide | 2010006 | 25475SI† | 39 |
| Euro OTC | Budesonide | 2103025 | 25690SI | 50 |
| Euro OTC | Budesonide | 2203005 | 26088SI | 40 |
| Euro OTC | Budesonide | 2301044 | 26590SI | 32 |
| Euro OTC | Budesonide | 2402017 | 27150SI | 30 |
| Fagron | Budesonide | 16J04-B01-326581 | 22841SI† | 24 |
| Fagron | Budesonide | 18C15-B03-355399 | 24699SI† | 35 |
| Fagron | Budesonide | 22A12-B01-213702 | 26378SI | 30 |

- 211 919 spectra from a total of 4270 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 905 spectra from 273 *Apo-Ident* customers from 201 batches from the substance/substance group *Budesonide*.
- Among them are spectra of independent samples from 192 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Budesonide | 20004092009 | 1 |
| | Budesonide | 20004092016 | 1 |
| | Budesonide | 20004092018 | 1 |
| | Budesonide | 20004092024 | 2 |
| | Budesonide | 20004092026 | 3 |
| | Budesonide | 21I20-B03-215349 | 2 |
| | Budesonide | 2203005-01 | 6 |
| | Budesonide | 22A12-B01-213702 | 1 |
| | Budesonide | 22A12-B01-228674 | 1 |
| | Budesonide | 23000636001 | 3 |
| | Budesonide | 23000636002 | 3 |
| | Budesonide | 23000636003 | 10 |
| | Budesonide | 23000636004 | 5 |
| | Budesonide | 23000636006 | 1 |
| | Budesonide | 23000636009 | 2 |
| | Budesonide | 23000636010 | 2 |
| | Budesonide | 2301044-01 | 3 |
| | Budesonide | 24000137005 | 1 |
| | Budesonide | 701248 | 1 |
| Anzag | Budesonide | 19138101 | 1 |
| Bombastus | Budesonide | 21100M1A0021321 | 1 |
| Caelo | Budesonide | 10061705 | 1 |
| Caelo | Budesonide | 11175014 | 2 |
| Caelo | Budesonide | 11175015 | 1 |
| Caelo | Budesonide | 11351701 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Budesonide | 11351703 | 1 |
| Caelo | Budesonide | 11351706 | 5 |
| Caelo | Budesonide | 11351707 | 3 |
| Caelo | Budesonide | 11351713 | 1 |
| Caelo | Budesonide | 12295103 | 1 |
| Caelo | Budesonide | 12295105 | 1 |
| Caelo | Budesonide | 12295106 | 2 |
| Caelo | Budesonide | 12295108 | 1 |
| Caelo | Budesonide | 12295109 | 2 |
| Caelo | Budesonide | 12295110 | 4 |
| Caelo | Budesonide | 12295111 | 5 |
| Caelo | Budesonide | 1305004-01 | 2 |
| Caelo | Budesonide | 1407116 | 1 |
| Caelo | Budesonide | 140711707 | 1 |
| Caelo | Budesonide | 14071701 | 2 |
| Caelo | Budesonide | 14071702 | 9 |
| Caelo | Budesonide | 14071706 | 1 |
| Caelo | Budesonide | 14071707 | 4 |
| Caelo | Budesonide | 14071713 | 1 |
| Caelo | Budesonide | 14071714 | 6 |
| Caelo | Budesonide | 14071716 | 2 |
| Caelo | Budesonide | 14071717 | 3 |
| Caelo | Budesonide | 1471707 | 1 |
| Caelo | Budesonide | 15044002 | 1 |
| Caelo | Budesonide | 15173802 | 4 |
| Caelo | Budesonide | 15173803 | 6 |
| Caelo | Budesonide | 15173804 | 3 |
| Caelo | Budesonide | 15173806 | 4 |
| Caelo | Budesonide | 15173807 | 3 |
| Caelo | Budesonide | 15173810 | 1 |
| Caelo | Budesonide | 15173811 | 8 |
| Caelo | Budesonide | 15344002 | 4 |
| Caelo | Budesonide | 15344003 | 7 |
| Caelo | Budesonide | 15344004 | 1 |
| Caelo | Budesonide | 15344005 | 4 |
| Caelo | Budesonide | 15344006 | 2 |
| Caelo | Budesonide | 15344008 | 8 |
| Caelo | Budesonide | 15344009 | 2 |
| Caelo | Budesonide | 15344010 | 3 |
| Caelo | Budesonide | 15344012 | 4 |
| Caelo | Budesonide | 15344013 | 1 |
| Caelo | Budesonide | 15344014 | 1 |
| Caelo | Budesonide | 16143101 | 7 |
| Caelo | Budesonide | 16143102 | 2 |
| Caelo | Budesonide | 16143103 | 3 |
| Caelo | Budesonide | 16143105 | 2 |
| Caelo | Budesonide | 16143106 | 3 |
| Caelo | Budesonide | 16143107 | 5 |
| Caelo | Budesonide | 16143108 | 10 |
| Caelo | Budesonide | 16143110 | 2 |
| Caelo | Budesonide | 16143112 | 2 |
| Caelo | Budesonide | 170078801 | 1 |
| Caelo | Budesonide | 170078808 | 1 |
| Caelo | Budesonide | 17078801 | 17 |
| Caelo | Budesonide | 17078803 | 3 |
| Caelo | Budesonide | 17078804 | 7 |
| Caelo | Budesonide | 17078805 | 16 |
| Caelo | Budesonide | 17078808 | 9 |
| Caelo | Budesonide | 17078809 | 6 |
| Caelo | Budesonide | 1709022 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Budesonide | 17342902 | 5 |
| Caelo | Budesonide | 18074901 | 5 |
| Caelo | Budesonide | 18074902 | 11 |
| Caelo | Budesonide | 18074903 | 11 |
| Caelo | Budesonide | 18074905 | 7 |
| Caelo | Budesonide | 18074907 | 10 |
| Caelo | Budesonide | 18074908 | 11 |
| Caelo | Budesonide | 18074909 | 1 |
| Caelo | Budesonide | 181720608 | 1 |
| Caelo | Budesonide | 18172601 | 3 |
| Caelo | Budesonide | 18172603 | 14 |
| Caelo | Budesonide | 18172604 | 19 |
| Caelo | Budesonide | 18172606 | 6 |
| Caelo | Budesonide | 18172607 | 13 |
| Caelo | Budesonide | 18172608 | 10 |
| Caelo | Budesonide | 18172609 | 5 |
| Caelo | Budesonide | 18172610 | 3 |
| Caelo | Budesonide | 18172611 | 13 |
| Caelo | Budesonide | 18172614 | 4 |
| Caelo | Budesonide | 191381002 | 3 |
| Caelo | Budesonide | 191381004 | 13 |
| Caelo | Budesonide | 191381005 | 2 |
| Caelo | Budesonide | 19138101 | 22 |
| Caelo | Budesonide | 19138101P-200511-1 | 1 |
| Caelo | Budesonide | 19138101P-200709-1 | 1 |
| Caelo | Budesonide | 19138101P-200727-2 | 1 |
| Caelo | Budesonide | 19138102 | 21 |
| Caelo | Budesonide | 19138103 | 12 |
| Caelo | Budesonide | 200004092007 | 1 |
| Caelo | Budesonide | 200004092016 | 1 |
| Caelo | Budesonide | 20001092012 | 1 |
| Caelo | Budesonide | 2000402008 | 2 |
| Caelo | Budesonide | 20004092001 | 4 |
| Caelo | Budesonide | 20004092002 | 2 |
| Caelo | Budesonide | 20004092003 | 6 |
| Caelo | Budesonide | 20004092005 | 7 |
| Caelo | Budesonide | 20004092006 | 5 |
| Caelo | Budesonide | 20004092007 | 11 |
| Caelo | Budesonide | 20004092008 | 4 |
| Caelo | Budesonide | 20004092009 | 9 |
| Caelo | Budesonide | 20004092011 | 5 |
| Caelo | Budesonide | 20004092012 | 2 |
| Caelo | Budesonide | 20004092013 | 3 |
| Caelo | Budesonide | 20004092014 | 1 |
| Caelo | Budesonide | 20004092015 | 5 |
| Caelo | Budesonide | 20004092016 | 2 |
| Caelo | Budesonide | 20004092017 | 1 |
| Caelo | Budesonide | 20004092018 | 2 |
| Caelo | Budesonide | 20004092019 | 1 |
| Caelo | Budesonide | 20004092022 | 6 |
| Caelo | Budesonide | 20004092023 | 2 |
| Caelo | Budesonide | 20004092024 | 1 |
| Caelo | Budesonide | 20004092026 | 4 |
| Caelo | Budesonide | 20004092028 | 1 |
| Caelo | Budesonide | 20i17-f07-374500 | 1 |
| Caelo | Budesonide | 21100M1 | 1 |
| Caelo | Budesonide | 23000636003 | 1 |
| Caelo | Budesonide | 774865 | 1 |
| Caelo | Budesonide | B-240619-2 | 1 |
| Caelo | Budesonide | ChB14071717 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caeolo , | Budesonide | 17078809 | 1 |
| Caesar & Lorenz GmbH | Budesonide | 18172607 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 191381002 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 20004092002 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 19138101 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 19138102 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 20004092003 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 20004092018 | 1 |
| Caesar & Loretz GmbH/Gehe | Budesonide | 18172607 | 1 |
| Caesar & Loretz GmbH/Gehe | Budesonide | 20004092001 | 1 |
| Caesar & Loretz GmbH/Gehe | Budesonide | 20004092003 | 1 |
| Caesar & Loretz GmbH/Gehe | Budesonide | 20004092009 | 1 |
| Caesar & Loretz GmbH/Gehe | Budesonide | 20004092014 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 191381002 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 19138102 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 20004092003 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 20004092006 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 19138102 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 18172606 | 1 |
| Caesar & Loretz GmbH/Sana | Budesonide | 18172610 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 18172603 | 1 |
| Caesar & Loretz GmbH... | Budesonide | 20004092009 | 1 |
| Caesar & Loretz GmbH | Budesonide | 17078808 | 1 |
| Caesar & Loretz GmbH | Budesonide | 17342902 | 1 |
| Caesar & Loretz GmbH | Budesonide | 18074905 | 5 |
| Caesar & Loretz GmbH | Budesonide | 18172603 | 1 |
| Caesar & Loretz GmbH | Budesonide | 18172604 | 2 |
| Caesar & Loretz GmbH | Budesonide | 18172606 | 5 |
| Caesar & Loretz GmbH | Budesonide | 18172608 | 4 |
| Caesar & Loretz GmbH | Budesonide | 18172610 | 1 |
| Caesar & Loretz GmbH | Budesonide | 18172611 | 1 |
| Caesar & Loretz GmbH | Budesonide | 18172614 | 2 |
| Caesar & Loretz GmbH | Budesonide | 1913810 | 1 |
| Caesar & Loretz GmbH | Budesonide | 191381002 | 8 |
| Caesar & Loretz GmbH | Budesonide | 191381004 | 3 |
| Caesar & Loretz GmbH | Budesonide | 191381005 | 3 |
| Caesar & Loretz GmbH | Budesonide | 19138101 | 11 |
| Caesar & Loretz GmbH | Budesonide | 19138102 | 20 |
| Caesar & Loretz GmbH | Budesonide | 19138103 | 6 |
| Caesar & Loretz GmbH | Budesonide | 2000402007 | 1 |
| Caesar & Loretz GmbH | Budesonide | 20004092001 | 1 |
| Caesar & Loretz GmbH | Budesonide | 20004092002 | 5 |
| Caesar & Loretz GmbH | Budesonide | 20004092003 | 2 |
| Caesar & Loretz GmbH | Budesonide | 20004092005 | 2 |
| Caesar & Loretz GmbH | Budesonide | 20004092006 | 2 |
| Caesar & Loretz GmbH | Budesonide | 20004092007 | 7 |
| Caesar & Loretz GmbH | Budesonide | 20004092008 | 6 |
| Caesar & Loretz GmbH | Budesonide | 20004092011 | 2 |
| Caesar & Loretz GmbH | Budesonide | 20004092012 | 3 |
| Caesar & Loretz GmbH | Budesonide | 20004092013 | 1 |
| Caesar & Loretz GmbH | Budesonide | 20004092015 | 2 |
| Caesar & Loretz GmbH | Budesonide | 20004092017 | 3 |
| Caesar & Loretz GmbH | Budesonide | 20004092018 | 4 |
| Caesar & Loretz GmbH | Budesonide | 20004092019 | 1 |
| Caesar & Loretz GmbH | Budesonide | 20004092022 | 2 |
| Caesar & Loretz GmbH | Budesonide | 20004092024 | 3 |
| Cealo / Otto Geilenk... | Budesonide | 19138101 | 1 |
| Cealo/Gehe | Budesonide | 19138103 | 1 |
| Cealo/Sanacorp | Budesonide | 20004092006 | 1 |
| Cealo | Budesonide | 17078804 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Ceolo/Spangro | Budesonide | 191381002 | 1 |
| Euro OTC | Budesonide | 1311022-01 | 5 |
| Euro OTC | Budesonide | 1604018-01 | 2 |
| Euro OTC | Budesonide | 1709022-01 | 2 |
| Euro OTC | Budesonide | 1709022-02 | 4 |
| Euro OTC | Budesonide | 18172609 | 1 |
| Euro OTC | Budesonide | 1904004-01 | 2 |
| Euro OTC | Budesonide | 2203005-01 | 1 |
| Euro OTC | Budesonide | 709022-02 | 1 |
| Fa.Alliance Healtc. | Budesonide | 12295111 | 1 |
| Fagron | Budesonide | | 2 |
| Fagron | Budesonide | 12D03-N03 | 1 |
| Fagron | Budesonide | 12G23-N01 | 2 |
| Fagron | Budesonide | 13A07-N09 | 1 |
| Fagron | Budesonide | 13H22-N03 | 2 |
| Fagron | Budesonide | 14A30-B09_291366 | 1 |
| Fagron | Budesonide | 14A30-B09-291366 | 2 |
| Fagron | Budesonide | 14H15-B02 | 3 |
| Fagron | Budesonide | 14H15-B02-297926 | 1 |
| Fagron | Budesonide | 14H15-B02-301971 | 2 |
| Fagron | Budesonide | 14H15-B02-301972 | 1 |
| Fagron | Budesonide | 15344012 | 1 |
| Fagron | Budesonide | 15E27_B10 | 1 |
| Fagron | Budesonide | 15E27-B01-308321 | 1 |
| Fagron | Budesonide | 15e27-b10-308321 | 1 |
| Fagron | Budesonide | 15E27-B10-308321 | 1 |
| Fagron | Budesonide | 15e27-b10-308322 | 1 |
| Fagron | Budesonide | 15E27-B10-308322 | 1 |
| Fagron | Budesonide | 15E27-B10-315704 | 1 |
| Fagron | Budesonide | 16J04-B01 | 1 |
| Fagron | Budesonide | 16j04-b01-326583 | 3 |
| Fagron | Budesonide | 17a17-b01 | 1 |
| Fagron | Budesonide | 17A17-B01 | 1 |
| Fagron | Budesonide | 17A17-B01-331248 | 1 |
| Fagron | Budesonide | 17A17-B01-331448 | 4 |
| Fagron | Budesonide | 17F28-B04-345016 | 2 |
| Fagron | Budesonide | 18074901 | 1 |
| Fagron | Budesonide | 18172601 | 1 |
| Fagron | Budesonide | 18C15-B03-350266 | 4 |
| Fagron | Budesonide | 18C15-B03-353058 | 2 |
| Fagron | Budesonide | 18C15-B03-355399 | 3 |
| Fagron | Budesonide | 19/27-F02-366343 | 1 |
| Fagron | Budesonide | 19F06-B06 | 2 |
| Fagron | Budesonide | 19f06-B06-363444 | 1 |
| Fagron | Budesonide | 19F06-B06-363447 | 1 |
| Fagron | Budesonide | 19F-06-B06-363447 | 1 |
| Fagron | Budesonide | 19I27-F02-366344 | 1 |
| Fagron | Budesonide | 1B001192001 | 1 |
| Fagron | Budesonide | 1B00119201 | 1 |
| Fagron | Budesonide | 1B003202001 | 2 |
| Fagron | Budesonide | 20/17-F07 | 1 |
| Fagron | Budesonide | 20G17-F03-372894 | 1 |
| Fagron | Budesonide | 20G17-F03-372894 | 1 |
| Fagron | Budesonide | 20I17-F07 | 1 |
| Fagron | Budesonide | 20I17-F07-374499 | 2 |
| Fagron | Budesonide | 20l17-F07-374500 | 1 |
| Fagron | Budesonide | 21b05_b17-213703 | 1 |
| Fagron | Budesonide | 21B05-B17 | 1 |
| Fagron | Budesonide | 21I20-B03-215348 | 1 |
| Fagron | Budesonide | 21I20-B03-215664 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Budesonide | 21120-B03-215664 | 1 |
| Fagron | Budesonide | C2280092 | 1 |
| Fargon/Kehr | Budesonide | 16J04-B01-326583 | 1 |
| Farmabios/Noweda | Budesonide | 21100M1B0031821 | 2 |
| Farmabios/Phoenix | Budesonide | 21100M1B0021821 | 1 |
| Gehe | Budesonide | 14071714 | 1 |
| Gehe | Budesonide | 16143103 | 1 |
| Gehe | Budesonide | 16143107 | 1 |
| Gehe | Budesonide | 17078801 | 1 |
| GEHE | Budesonide | 18074901 | 1 |
| Gehe | Budesonide | 18074902 | 3 |
| GEHE | Budesonide | 18172601 | 2 |
| Gehe | Budesonide | 18172604 | 1 |
| Gehe | Budesonide | 20004092024 | 1 |
| Geibo/ Fargron | Budesonide | 15E27-B10-315704 | 1 |
| Geibo/ Fargron | Budesonide | 17A17-b01-331448 | 1 |
| Jenne | Budesonide | 20004092024 | 1 |
| L10 | Budesonide | 15344012 | 1 |
| Noweda/Caesar & Lore... | Budesonide | 19138101 | 1 |
| Noweda | Budesonide | 1604018-01 | 1 |
| Noweda | Budesonide | 16143108 | 1 |
| Noweda | Budesonide | 16143110 | 1 |
| Noweda | Budesonide | 17078803 | 1 |
| Noweda | Budesonide | 18074903 | 1 |
| Noweda | Budesonide | 18172608 | 1 |
| Noweda | Budesonide | 191381004 | 1 |
| Noweda | Budesonide | 19138102 | 2 |
| Noweda | Budesonide | 20004092012 | 1 |
| Noweda | Budesonide | 20004092022 | 1 |
| Noweda | Budesonide | 20004092026 | 1 |
| Noweda | Budesonide | 20004092028 | 1 |
| Noweda | Budesonide | 23000633010 | 1 |
| Noweda | Budesonide | 23000636001 | 2 |
| Noweda | Budesonide | 23000636003 | 1 |
| Noweda | Budesonide | 23000636004 | 1 |
| Otto Geilenkirchen | Budesonide | 23000636003 | 1 |
| Phoenix | Budesonide | 15344013 | 1 |
| phoenix | Budesonide | 19138103 | 1 |
| Phoenix | Budesonide | 23000636009 | 1 |
| Phönix | Budesonide | 18074907 | 1 |
| Phönix | Budesonide | 18172607 | 1 |
| Phönix | Budesonide | 191381004 | 1 |
| Sanacorp /Fargron | Budesonide | 17A17-B01-331448 | 1 |
| Sanacorp, | Budesonide | 16143103 | 1 |
| sanacorp | Budesonide | 14071701 | 1 |
| Sanacorp | Budesonide | 17078801 | 1 |
| Sanacorp | Budesonide | 17078805 | 1 |
| Sanacorp | Budesonide | 18074902 | 1 |
| Sanacorp | Budesonide | 18074907 | 1 |
| sanacorp | Budesonide | 191381004 | 1 |
| Sanacorp | Budesonide | 20004092024 | 1 |
| Sanacorp | Budesonide | 20004092029 | 1 |
| Sanacorp | Budesonide | 23000636003 | 1 |
| Sanacorp | Budesonide | 23000636004 | 1 |
| Übungszwecke | Budesonide | 15344006 | 2 |
| VDl 23.10.14 19,50 euro | Budesonide | 14071707 | 1 |

- 255 981 spectra from 1666 *Apo-Ident* customers from a total of 51 956 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are docu-

mented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Budesonide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Budesonide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 518 | 0 | 157 808 |
| **Type B** | 0 | 1021 | 0 | 211 919 |
| **Type C** | 0 | 855 | 50 | 255 981 |

The substance/substance group *Budesonide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8417 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4123 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 94.4751 % (> 94.1436 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20808 | 20808 | 0.00 | 139.19 |
| 21620 | 20808 | 5.26 | 133.18 |
| 22537 | 22537 | 0.00 | 119.60 |
| 22627 | 22627 | 0.00 | 125.36 |
| 22649 | 22537 | 7.75 | 122.82 |
| 22841 | 22627 | 4.38 | 126.39 |
| 22888 | 22627 | 7.98 | 126.68 |
| 24699 | 25475 | 8.00 | 124.32 |
| 25475 | 25475 | 0.00 | 128.61 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by


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laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Bupivacaine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24435-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Bupivacaine hydrochloride; Bupivacaini hydrochloridum

### Special notes

When selecting the *Bupivacaine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Bupivacaine hydrochloride | 4 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Bupivacaine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Bupivacaine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 86.51 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Bupivacaine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Bupivacaine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Bupivacaine hydrochloride | 17E22-B08-345817 | 24435 | 40 | 1905513 |
| Fagron | Bupivacaine hydrochloride | 21J11-B06-219298 | 26464 | 40 | 20211202 |
| Fagron | Bupivacaine hydrochloride | 23A04-B09-233749 | 27026 | 40 | 20230209 |
| Fagron | Bupivacaine hydrochloride | 23A04-B09-233749 | 27026SI | 20 | 20230209 |
| Fagron | Bupivacaine hydrochloride | 24A03-B11-006771 | 27591 | 40 | 20240222 |
| Fagron | Bupivacaine hydrochloride | 24A03-B11-006771 | 27591SI | 20 | 20240222 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 6 reference samples from the substance/substance group *Bupivacaine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 126 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 2 reference samples from the substance/substance group *Bupivacaine hydrochloride*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Bupivacaine hydrochloride | 17L05-B04-358735 | 24594 | 40 |
| Fagron | Bupivacaine hydrochloride | 21J11-B06-219298 | 26464SI† | 20 |

- 212 880 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Bupivacaine hydrochloride*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Bupivacaine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

purpose, all relevant spectra of the various substances were compared with *Bupivacaine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 60 | 0 | 212 880 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Bupivacaine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24435 | 24435 | 0.00 | 207.46 |
| 26464 | 24435 | 56.13 | 196.90 |
| 27026 | 24435 | 20.46 | 204.78 |
| 27591 | 24435 | 32.41 | 202.03 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Butylated hydroxytoluene** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21307-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Butylated hydroxytoluene; Butylhydroxytoluenum

### Special notes

When selecting the *Butylated hydroxytoluene* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Butylated hydroxytoluene | 6 | 4 | 89 |

### Second-stage model

For differentiation of the substance/substance group *Butylated hydroxytoluene* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Butylated hydroxytoluene* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 88.14 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Butylated hydroxytoluene* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Butylated hydroxytoluene*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Butylated hydroxytoluene | 13354602 | 21307 | 40 | 20131105 |
| Caelo | Butylated hydroxytoluene | 13354604 | 21355 | 40 | AR-15-FG-007846-02 |
| Caelo | Butylated hydroxytoluene | 15172103 | 21911 | 60 | 20150529 |
| Caelo | Butylated hydroxytoluene | 15172103 | 22281 | 60 | 20150529 |
| Caelo | Butylated hydroxytoluene | 15172103 | 22350 | 60 | 20150529 |
| Caelo | Butylated hydroxytoluene | 190749 | 24554 | 40 | 20190405* |
| Caelo | Butylated hydroxytoluene | 20000734 | 25552 | 40 | 20200324* |
| Caelo | Butylated hydroxytoluene | 23000635 | 27322 | 40 | 20230503* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 380 spectra of 8 reference samples from the substance/substance group *Butylated hydroxytoluene*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 946 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 210 spectra of 7 reference samples from the substance/substance group *Butylated hydroxytoluene*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Butylated hydroxytoluene | 163163 | 23356 | 40 |
| Caelo | Butylated hydroxytoluene | 180291 | 24019 | 40 |
| Caelo | Butylated hydroxytoluene | 21004127 | 25999 | 40 |
| Caelo | Butylated hydroxytoluene | 24002119 | 27440 | 40 |
| Caelo | Butylated hydroxytoluene | 21004127 | 25999SI | 10 |
| Caelo | Butylated hydroxytoluene | 23000635 | 27322SI† | 20 |
| Caelo | Butylated hydroxytoluene | 24002119 | 27440SI | 20 |

- 212 730 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 924 spectra from 591 *Apo-Ident* customers from 92 batches from the substance/substance group *Butylated hydroxytoluene*.

- Among them are spectra of independent samples from 89 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Butylated hydroxytoluene | 16316304 | 1 |
| | Butylated hydroxytoluene | 21004127001 | 2 |
| | Butylated hydroxytoluene | 22002085003 | 20 |
| | Butylated hydroxytoluene | 23000635001 | 19 |
| | Butylated hydroxytoluene | 23000635003 | 9 |
| | Butylated hydroxytoluene | 23001370001 | 1 |
| | Butylated hydroxytoluene | 2300635003 | 1 |
| | Butylated hydroxytoluene | 24000147001 | 11 |
| | Butylated hydroxytoluene | 24002119001 | 7 |
| AHC | Butylated hydroxytoluene | 23000635001 | 1 |
| AHD | Butylated hydroxytoluene | 18029102 | 1 |
| Allianz Healthcare | Butylated hydroxytoluene | 19074902 | 1 |
| Anzag | Butylated hydroxytoluene | 240321(23000635001) | 1 |
| Apo Ident/ Noweda | Butylated hydroxytoluene | 18029104 | 1 |
| Bombastus | Butylated hydroxytoluene | 13354604 | 1 |
| Caelo | Butylated hydroxytoluene | 11(18029107) | 1 |
| Caelo | Butylated hydroxytoluene | 11131006 | 1 |
| Caelo | Butylated hydroxytoluene | 12(20000734001) | 1 |
| Caelo | Butylated hydroxytoluene | 12158201 | 3 |
| Caelo | Butylated hydroxytoluene | 12158204 | 5 |
| Caelo | Butylated hydroxytoluene | 12207005 | 3 |
| Caelo | Butylated hydroxytoluene | 1220705 | 1 |
| Caelo | Butylated hydroxytoluene | 122080206 | 1 |
| Caelo | Butylated hydroxytoluene | 12280201 | 2 |
| Caelo | Butylated hydroxytoluene | 12280203 | 5 |
| Caelo | Butylated hydroxytoluene | 12280206 | 4 |
| Caelo | Butylated hydroxytoluene | 1228203 | 1 |
| Caelo | Butylated hydroxytoluene | 123823 | 1 |
| Caelo | Butylated hydroxytoluene | 12382302 | 5 |
| Caelo | Butylated hydroxytoluene | 12382304 | 7 |
| Caelo | Butylated hydroxytoluene | 12382307 | 1 |
| Caelo | Butylated hydroxytoluene | 12382309 | 8 |
| Caelo | Butylated hydroxytoluene | 12382312 | 1 |
| Caelo | Butylated hydroxytoluene | 13354602 | 4 |
| Caelo | Butylated hydroxytoluene | 13354604 | 8 |
| Caelo | Butylated hydroxytoluene | 13354609 | 2 |
| Caelo | Butylated hydroxytoluene | 13354611 | 4 |
| Caelo | Butylated hydroxytoluene | 1400501 | 1 |
| Caelo | Butylated hydroxytoluene | 1426801 | 1 |
| Caelo | Butylated hydroxytoluene | 143004502 | 1 |
| Caelo | Butylated hydroxytoluene | 14300501 | 11 |
| Caelo | Butylated hydroxytoluene | 14300502 | 8 |
| Caelo | Butylated hydroxytoluene | 14300503 | 2 |
| Caelo | Butylated hydroxytoluene | 14300505 | 6 |
| Caelo | Butylated hydroxytoluene | 14300506 | 2 |
| Caelo | Butylated hydroxytoluene | 15094501 | 9 |
| Caelo | Butylated hydroxytoluene | 15172101 | 11 |
| Caelo | Butylated hydroxytoluene | 15172103 | 22 |
| Caelo | Butylated hydroxytoluene | 15172105 | 12 |
| Caelo | Butylated hydroxytoluene | 15426801 | 13 |
| Caelo | Butylated hydroxytoluene | 1542680118029105 | 1 |
| Caelo | Butylated hydroxytoluene | 15426807 | 17 |
| Caelo | Butylated hydroxytoluene | 1631301 | 1 |
| Caelo | Butylated hydroxytoluene | 1631601 | 1 |
| Caelo | Butylated hydroxytoluene | 16316301 | 23 |
| Caelo | Butylated hydroxytoluene | 16316304 | 19 |
| Caelo | Butylated hydroxytoluene | 16316304-20180619Ma5 | 1 |
| Caelo | Butylated hydroxytoluene | 16316305 | 16 |
| Caelo | Butylated hydroxytoluene | 163163055402 | 1 |
| Caelo | Butylated hydroxytoluene | 16316307 | 29 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Butylated hydroxytoluene | 18029102 | 22 |
| Caelo | Butylated hydroxytoluene | 18029104 | 8 |
| Caelo | Butylated hydroxytoluene | 18029105 | 44 |
| Caelo | Butylated hydroxytoluene | 18029107 | 24 |
| Caelo | Butylated hydroxytoluene | 18029108 | 13 |
| Caelo | Butylated hydroxytoluene | 1802915 | 1 |
| Caelo | Butylated hydroxytoluene | 18048701 | 20 |
| Caelo | Butylated hydroxytoluene | 18229102 | 1 |
| Caelo | Butylated hydroxytoluene | 190749001 | 40 |
| Caelo | Butylated hydroxytoluene | 19074901 | 20 |
| Caelo | Butylated hydroxytoluene | 19074902 | 28 |
| Caelo | Butylated hydroxytoluene | 20000734001 | 28 |
| Caelo | Butylated hydroxytoluene | 2000734001 | 2 |
| Caelo | Butylated hydroxytoluene | 20161112-1 | 1 |
| Caelo | Butylated hydroxytoluene | 21000037001 | 43 |
| Caelo | Butylated hydroxytoluene | 21000037004 | 6 |
| Caelo | Butylated hydroxytoluene | 2100037001 | 1 |
| Caelo | Butylated hydroxytoluene | 21004127001 | 32 |
| Caelo | Butylated hydroxytoluene | 21004127002 | 11 |
| Caelo | Butylated hydroxytoluene | 2100427001 | 1 |
| Caelo | Butylated hydroxytoluene | 2113U02851 | 1 |
| Caelo | Butylated hydroxytoluene | 2170717 | 1 |
| Caelo | Butylated hydroxytoluene | 22002082001 | 1 |
| Caelo | Butylated hydroxytoluene | 22002085001 | 2 |
| Caelo | Butylated hydroxytoluene | 22002085003 | 7 |
| Caelo | Butylated hydroxytoluene | 220804(21004127001) | 1 |
| Caelo | Butylated hydroxytoluene | 23000635001 | 1 |
| Caelo | Butylated hydroxytoluene | 23000635003 | 1 |
| Caelo | Butylated hydroxytoluene | 231115BHT | 1 |
| Caelo | Butylated hydroxytoluene | 24000147001 | 1 |
| Caelo | Butylated hydroxytoluene | 2749 | 1 |
| Caelo | Butylated hydroxytoluene | 5426807 | 1 |
| Caelo | Butylated hydroxytoluene | 6316301 | 1 |
| Caelo | Butylated hydroxytoluene | 7031403 | 1 |
| Caelo | Butylated hydroxytoluene | 716M-02851 | 1 |
| Caelo | Butylated hydroxytoluene | BT28112013 | 1 |
| Caesar & Loretz /Gehe | Butylated hydroxytoluene | 19074902 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 18029105 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21000037001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 190749001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 18029108 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 18029107 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21000037001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21000037004 | 1 |
| Caesar & Loretz GmbH/AHD | Butylated hydroxytoluene | 19074902 | 1 |
| Caesar & Loretz GmbH/AHD | Butylated hydroxytoluene | 21000037004 | 1 |
| Caesar & Loretz GmbH/Gehe | Butylated hydroxytoluene | 19074902 | 2 |
| Caesar & Loretz GmbH/GEHE | Butylated hydroxytoluene | 19074902 | 1 |
| Caesar & Loretz GmbH/Gehe | Butylated hydroxytoluene | 21000037001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 190749001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 19074902 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21000037001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21004127001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21004127001 | 2 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21000037001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 18029107 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 19074902 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 20000734001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21000037001 | 1 |
| Caesar & Loretz GmbH... | Butylated hydroxytoluene | 21004127002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 18029102 | 1 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 18029105 | 4 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 18029107 | 3 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 18029108 | 3 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 190749001 | 10 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 19074901 | 9 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 19074902 | 8 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 20000734001 | 15 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 21000037001 | 12 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 21000037004 | 6 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 21004127001 | 13 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 21004127002 | 8 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 22002085001 | 1 |
| Caesar & Loretz GmbH | Butylated hydroxytoluene | 22002085003 | 4 |
| Caesar & Loretz Hilden | Butylated hydroxytoluene | 18029105 | 1 |
| Caesar & Loretz/Noweda | Butylated hydroxytoluene | 21000037001 | 1 |
| Caesar & Loretz | Butylated hydroxytoluene | 15426801 | 1 |
| Caesar & Loretz | Butylated hydroxytoluene | 16316307 | 1 |
| Caesar Loretz | Butylated hydroxytoluene | 190749001 | 1 |
| Caesar&Loretz | Butylated hydroxytoluene | 190749001 | 1 |
| Cealo / Otto Geilenk... | Butylated hydroxytoluene | 18029108 | 1 |
| Cealo/Sanacorp | Butylated hydroxytoluene | 21004127001 | 1 |
| Celo | Butylated hydroxytoluene | 15426801 | 1 |
| Euro OTC | Butylated hydroxytoluene | 15094501 | 3 |
| Euro OTC | Butylated hydroxytoluene | 15172105 | 1 |
| Euro OTC | Butylated hydroxytoluene | 15426807 | 1 |
| Euro OTC | Butylated hydroxytoluene | 18029107 | 1 |
| Fagron | Butylated hydroxytoluene | 11308701 | 1 |
| Fagron | Butylated hydroxytoluene | 15426801 | 1 |
| Fagron | Butylated hydroxytoluene | 16316304 | 1 |
| Fiebig | Butylated hydroxytoluene | 15426807 | 1 |
| Fiebig | Butylated hydroxytoluene | 18029105 | 1 |
| Gehe | Butylated hydroxytoluene | 15426807 | 1 |
| Gehe | Butylated hydroxytoluene | 18029105 | 3 |
| GEHE | Butylated hydroxytoluene | 18029105 | 1 |
| Gehe | Butylated hydroxytoluene | 18029107 | 1 |
| Gehe | Butylated hydroxytoluene | 19074901 | 1 |
| Gehe | Butylated hydroxytoluene | 20000734001 | 2 |
| Gehe | Butylated hydroxytoluene | 23000635001 | 1 |
| Jenne | Butylated hydroxytoluene | 250612(24002119001) | 1 |
| Jenne | Butylated hydroxytoluene | 250709(24002119001) | 1 |
| Krieger | Butylated hydroxytoluene | 16316301 | 1 |
| Krieger | Butylated hydroxytoluene | 18029108 | 1 |
| L12 | Butylated hydroxytoluene | 15426807 | 1 |
| L12 | Butylated hydroxytoluene | 16316307 | 1 |
| Nachprüfung | Butylated hydroxytoluene | 123456 | 1 |
| Noweda | Butylated hydroxytoluene | 12158201 | 1 |
| Noweda | Butylated hydroxytoluene | 12382304 | 1 |
| Noweda | Butylated hydroxytoluene | 15172103 | 1 |
| Noweda | Butylated hydroxytoluene | 15426807 | 1 |
| Noweda | Butylated hydroxytoluene | 16316305 | 1 |
| Noweda | Butylated hydroxytoluene | 18029105 | 2 |
| Noweda | Butylated hydroxytoluene | 21000037001 | 1 |
| Noweda | Butylated hydroxytoluene | 21004127002 | 1 |
| Noweda | Butylated hydroxytoluene | 22002085001 | 2 |
| Noweda | Butylated hydroxytoluene | 22002085003 | 1 |
| Noweda | Butylated hydroxytoluene | 23000635003 | 2 |
| Phoenix | Butylated hydroxytoluene | 12382305 | 1 |
| Phoenix | Butylated hydroxytoluene | 13354609 | 1 |
| Phoenix | Butylated hydroxytoluene | 15426801 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Butylated hydroxytoluene | 16316301 | 1 |
| Phoenix | Butylated hydroxytoluene | 20000734001 | 1 |
| Phoenix | Butylated hydroxytoluene | 21000037001 | 1 |
| Phoenix | Butylated hydroxytoluene | 22002085003 | 1 |
| Phoenix | Butylated hydroxytoluene | 3111201 | 1 |
| Phönix/Caesar&Lorenz… | Butylated hydroxytoluene | 22002085003 | 1 |
| PHÖNIX | Butylated hydroxytoluene | 16316304 | 1 |
| Phönix | Butylated hydroxytoluene | 16316307 | 1 |
| Phönix | Butylated hydroxytoluene | 18029102 | 1 |
| Phönix | Butylated hydroxytoluene | 190749001 | 1 |
| Phönix | Butylated hydroxytoluene | 19074901 | 1 |
| PHÖNIX | Butylated hydroxytoluene | 20000734001 | 1 |
| Sanacorp | Butylated hydroxytoluene | 13354609 | 1 |
| Sanacorp | Butylated hydroxytoluene | 14300505 | 1 |
| sanacorp | Butylated hydroxytoluene | 15172103 | 1 |
| Sanacorp | Butylated hydroxytoluene | 15172103 | 1 |
| Sanacorp | Butylated hydroxytoluene | 16316305 | 1 |
| Sanacorp | Butylated hydroxytoluene | 18029105 | 1 |
| Sanacorp | Butylated hydroxytoluene | 2100037004 | 1 |
| Sanacorp | Butylated hydroxytoluene | 22002085003 | 1 |
| Sanacorp | Butylated hydroxytoluene | 23000635001 | 3 |
| SanacorpWE:04.01.18 … | Butylated hydroxytoluene | 16316304 | 1 |

- 255 962 spectra from 1666 *Apo-Ident* customers from a total of 52 064 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Butylated hydroxytoluene* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Butylated hydroxytoluene* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 210 | 0 | 212 730 |
| **Type C** | 0 | 917 | 7 | 255 962 |

The substance/substance group *Butylated hydroxytoluene* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.1429 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.2424 % (> 98.9177 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to

exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21307 | 21355 | 7.81 | 230.32 |
| 21355 | 21355 | 0.00 | 235.61 |
| 21911 | 21355 | 9.17 | 234.75 |
| 22281 | 21355 | 6.02 | 239.42 |
| 22350 | 21355 | 7.07 | 235.11 |
| 24554 | 24554 | 0.00 | 247.54 |
| 25552 | 25552 | 0.00 | 238.69 |
| 27322 | 27322 | 0.00 | 244.87 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Caffeine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20962-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Caffeine; Coffeinum

### Special notes

When selecting the *Caffeine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Caffeine | 7 | 10 | 105 |

### Second-stage model

For differentiation of the substance/substance group *Caffeine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Caffeine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Caffeine citrate | 142.46 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Caffeine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Caffeine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Caffeine | 12317911 | 21089 | 40 | 20121113 |
| Caelo | Caffeine | 12317911 | 21205 | 40 | 20121113 |
| Caelo | Caffeine | 13233105 | 21456 | 60 | 20131008 |
| Caelo | Caffeine | 13233104 | 21548 | 60 | 20131008 |
| Euro OTC | Caffeine | 1211012-01 | 20962 | 40 | 1412248 |
| Euro OTC | Caffeine | 1808017 | 24199 | 40 | 20180905* |
| Euro OTC | Caffeine | 1909022 | 24980 | 40 | 20191022* |
| Fagron | Caffeine | 22A19-B05-219102 | 26161 | 40 | 20220531 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 360 spectra of 8 reference samples from the substance/substance group *Caffeine*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 470 spectra of 13 reference samples from the substance/substance group *Caffeine*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Caffeine | 15082303 | 22823 | 40 |
| Caelo | Caffeine | 21001749 | 25798 | 50 |
| Caelo | Caffeine | 23000642 | 26711 | 40 |
| Euro OTC | Caffeine | 1603009 | 22517 | 40 |
| Euro OTC | Caffeine | 1703006 | 23140 | 40 |
| Euro OTC | Caffeine | 1907006 | 24784 | 40 |
| Euro OTC | Caffeine | 2001041 | 25079 | 40 |
| Euro OTC | Caffeine | 2205020 | 26201 | 40 |
| Euro OTC | Caffeine | 2311014 | 27068 | 40 |
| Fagron | Caffeine | 24K22-B13-008784 | 27650 | 40 |
| Caelo | Caffeine | 23000642 | 26711SI | 20 |
| Euro OTC | Caffeine | 2205020 | 26201SI | 20 |
| Fagron | Caffeine | 22A19-B05-219102 | 26161SI† | 20 |

- 212 470 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 517 spectra from 304 *Apo-Ident* customers from 110 batches from the substance/substance group *Caffeine*.

- Among them are spectra of independent samples from 104 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Caffeine | 1808017-02 | 2 |
| | Caffeine | 19000754003 | 1 |
| | Caffeine | 20014041-02 | 1 |
| | Caffeine | 21052089 | 1 |
| | Caffeine | 220002096010 | 1 |
| | Caffeine | 22002096001 | 5 |
| | Caffeine | 22002096010 | 13 |
| | Caffeine | 220103008 | 1 |
| | Caffeine | 2205020-01 | 1 |
| | Caffeine | 2205020-02 | 2 |
| | Caffeine | 2205020-03 | 6 |
| | Caffeine | 2205050-03 | 1 |
| | Caffeine | 23000642003 | 7 |
| | Caffeine | 23003554003 | 2 |
| | Caffeine | 2311014-01 | 7 |
| ACM | Caffeine | KNC1294J14 | 2 |
| AHD | Caffeine | 2205020-03 | 1 |
| Alliance Healthcare | Caffeine | 18011911 | 1 |
| Alliance Healthcare | Caffeine | 18011928 | 1 |
| apo-ident | Caffeine | 1808017-01 | 1 |
| Bombastus | Caffeine | 1307049-01 | 1 |
| Caelo | Caffeine | 11076807 | 2 |
| Caelo | Caffeine | 11111111 | 1 |
| Caelo | Caffeine | 12093410 | 2 |
| Caelo | Caffeine | 12093418 | 2 |
| Caelo | Caffeine | 1211012-01 | 1 |
| Caelo | Caffeine | 12317902 | 1 |
| Caelo | Caffeine | 12317904 | 2 |
| Caelo | Caffeine | 12317906 | 1 |
| Caelo | Caffeine | 12317909 | 8 |
| Caelo | Caffeine | 12317914 | 2 |
| Caelo | Caffeine | 13233105 | 4 |
| Caelo | Caffeine | 13233111 | 6 |
| Caelo | Caffeine | 1503020-01 | 2 |
| Caelo | Caffeine | 15054704 | 3 |
| Caelo | Caffeine | 15054709 | 3 |
| Caelo | Caffeine | 15082304 | 1 |
| Caelo | Caffeine | 15082311 | 1 |
| Caelo | Caffeine | 15082315 | 1 |
| Caelo | Caffeine | 15372012 | 1 |
| Caelo | Caffeine | 15375006 | 4 |
| Caelo | Caffeine | 15375007 | 6 |
| Caelo | Caffeine | 15375012 | 6 |
| Caelo | Caffeine | 15375013 | 1 |
| Caelo | Caffeine | 1703006-01 | 1 |
| Caelo | Caffeine | 17133704 | 1 |
| Caelo | Caffeine | 17173704 | 10 |
| Caelo | Caffeine | 17173705 | 10 |
| Caelo | Caffeine | 17173707 | 5 |
| Caelo | Caffeine | 180119001 | 1 |
| Caelo | Caffeine | 180119002 | 3 |
| Caelo | Caffeine | 18011901 | 6 |
| Caelo | Caffeine | 18011902 | 6 |
| Caelo | Caffeine | 18011906 | 9 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Caffeine | 18011911 | 38 |
| Caelo | Caffeine | 18011915 | 9 |
| Caelo | Caffeine | 18011920 | 14 |
| Caelo | Caffeine | 18011928 | 8 |
| Caelo | Caffeine | 180119911 | 1 |
| Caelo | Caffeine | 18077906 | 1 |
| Caelo | Caffeine | 1808017-01 | 1 |
| Caelo | Caffeine | 19000754002 | 13 |
| Caelo | Caffeine | 1907006-01 | 1 |
| Caelo | Caffeine | 21000088004 | 27 |
| Caelo | Caffeine | 21000088006 | 1 |
| Caelo | Caffeine | 21001749004 | 2 |
| Caelo | Caffeine | 21001749006 | 3 |
| Caelo | Caffeine | 21001749014 | 2 |
| Caelo | Caffeine | 21001749015 | 4 |
| Caelo | Caffeine | 22002096001 | 4 |
| Caelo | Caffeine | 23000642003 | 1 |
| Caelo | Caffeine | 291001903 | 2 |
| Caelo | Caffeine | 3212E-01281 | 1 |
| Caelo | Caffeine | 9301807 | 1 |
| Caesar & Lorenz | Caffeine | 22002096001 | 1 |
| Caesar & Loretz GmbH… | Caffeine | 21001749002 | 1 |
| Caesar & Loretz GmbH… | Caffeine | 21001749004 | 1 |
| Caesar & Loretz GmbH… | Caffeine | 19000754002 | 3 |
| Caesar & Loretz GmbH… | Caffeine | 180119002 | 1 |
| Caesar & Loretz GmbH | Caffeine | 180119001 | 1 |
| Caesar & Loretz GmbH | Caffeine | 180119002 | 3 |
| Caesar & Loretz GmbH | Caffeine | 18011912 | 2 |
| Caesar & Loretz GmbH | Caffeine | 18011915 | 2 |
| Caesar & Loretz GmbH | Caffeine | 18011920 | 2 |
| Caesar & Loretz GmbH | Caffeine | 18011928 | 2 |
| Caesar & Loretz GmbH | Caffeine | 19000754002 | 4 |
| Caesar & Loretz GmbH | Caffeine | 21000088004 | 2 |
| Caesar & Loretz GmbH | Caffeine | 21000088006 | 2 |
| Caesar & Loretz GmbH | Caffeine | 21001749002 | 1 |
| Caesar & Loretz GmbH | Caffeine | 21001749004 | 1 |
| Caesar & Loretz GmbH | Caffeine | 21001749006 | 3 |
| Caesar & Loretz GmbH | Caffeine | 21001749014 | 1 |
| Caesar & Loretz GmbH | Caffeine | 21001749015 | 1 |
| Caesar & Loretz GmbH | Caffeine | 22002096001 | 1 |
| Caesar&Loretz GmbH | Caffeine | 21001749006 | 1 |
| EuRho | Caffeine | 17030006-02 | 2 |
| EuRho | Caffeine | 1808017-02 | 1 |
| Euro OTC | Caffeine | | 1 |
| Euro OTC | Caffeine | 1109017-01 | 1 |
| Euro OTC | Caffeine | 1211012-01 | 1 |
| Euro OTC | Caffeine | 1211012-02 | 1 |
| Euro OTC | Caffeine | 1307049-01 | 4 |
| Euro OTC | Caffeine | 1404026-01 | 1 |
| Euro OTC | Caffeine | 1411015-01 | 4 |
| Euro OTC | Caffeine | 1503020-01 | 7 |
| Euro OTC | Caffeine | 1503020-02 | 8 |
| Euro OTC | Caffeine | 1603009/01 | 1 |
| Euro OTC | Caffeine | 160300901 | 2 |
| Euro OTC | Caffeine | 1603009-01 | 2 |
| Euro OTC | Caffeine | 1603009-02 | 4 |
| Euro OTC | Caffeine | 163009-01 | 1 |
| Euro OTC | Caffeine | 16462119 | 1 |
| Euro OTC | Caffeine | 1703006 | 1 |
| Euro OTC | Caffeine | 1703006-01 | 28 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Caffeine | 1703006-02 | 9 |
| Euro OTC | Caffeine | 17173704 | 1 |
| Euro OTC | Caffeine | 1808017 | 3 |
| Euro OTC | Caffeine | 1808017_01 | 1 |
| Euro OTC | Caffeine | 1808017-01 | 7 |
| Euro OTC | Caffeine | 180801702 | 1 |
| Euro OTC | Caffeine | 1808017-02 | 6 |
| Euro OTC | Caffeine | 180881701 | 1 |
| Euro OTC | Caffeine | 1818017-02 | 1 |
| Euro OTC | Caffeine | 18212023 | 1 |
| Euro OTC | Caffeine | 18808017-01 | 1 |
| Euro OTC | Caffeine | 1907006-01 | 6 |
| Euro OTC | Caffeine | 1907006-1 | 1 |
| Euro OTC | Caffeine | 1909022-01 | 5 |
| Euro OTC | Caffeine | 2001041-01 | 3 |
| Euro OTC | Caffeine | 2001041-02 | 13 |
| Euro OTC | Caffeine | 2205020-01 | 1 |
| Euro OTC | Caffeine | 2205020-02 | 4 |
| Euro OTC | Caffeine | 26081406 | 1 |
| Euro OTC | Caffeine | 31071701 | 1 |
| Euro OTC | Caffeine | 325241AX20 | 1 |
| Euro OTC | Caffeine | 5101701 | 1 |
| EUro/AHD | Caffeine | 121012-01 | 1 |
| EUro/AHD | Caffeine | 1307049-01 | 1 |
| Euro/Noweda | Caffeine | 1703006-01 | 1 |
| Fa.Phönix | Caffeine | 1909022-01 | 1 |
| Fagron | Caffeine | 12093402 | 2 |
| Fagron | Caffeine | 123456 | 1 |
| Fagron | Caffeine | 15H11-B02 | 1 |
| Fagron | Caffeine | 17173704 | 1 |
| Gatt-Koller / Phoenix | Caffeine | 5898/12135213 | 2 |
| Gatt-Koller | Caffeine | 1803747 | 1 |
| Gehe | Caffeine | 18011915 | 2 |
| GEHE | Caffeine | 22002096001 | 1 |
| Gehe | Caffeine | 2205020-01 | 1 |
| Gehe | Caffeine | 23000642002 | 1 |
| Gehe | Caffeine | 23000642003 | 3 |
| Klenk | Caffeine | 1411015-01 | 1 |
| Merck | Caffeine | MerckReagenziensatz | 1 |
| Noweda/Caesar & Lore... | Caffeine | 21001749014 | 1 |
| Noweda | Caffeine | 1404026-01 | 1 |
| Noweda | Caffeine | 2001041-01 | 1 |
| Noweda | Caffeine | 23000642003 | 1 |
| Phoenix | Caffeine | 1808017-01 | 1 |
| Phönix | Caffeine | 1603009-02 | 1 |
| Phönix | Caffeine | 23000642003 | 1 |
| Reagenz | Caffeine | | 1 |
| Sanacorp | Caffeine | | 2 |
| Sanacorp | Caffeine | 19000754002 | 1 |
| Sanacorp | Caffeine | 23000642003 | 1 |
| siegfried pharma che... | Caffeine | 1909022-01 | 1 |
| Siegfried PharmaChem... | Caffeine | 1808017-01 | 1 |

- 256 369 spectra from 1666 *Apo-Ident* customers from a total of 52 046 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Caffeine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Caffeine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 470 | 0 | 212 470 |
| **Type C** | 0 | 504 | 13 | 256 369 |

The substance/substance group *Caffeine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7234 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.4855 % (> 96.9052 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20962 | 20962 | 0.00 | 233.09 |
| 21089 | 24199 | 7.19 | 240.19 |
| 21205 | 24199 | 6.44 | 239.17 |
| 21456 | 24980 | 8.01 | 237.27 |
| 21548 | 20962 | 10.43 | 226.62 |
| 24199 | 24199 | 0.00 | 242.20 |
| 24980 | 24980 | 0.00 | 246.88 |
| 26161 | 24199 | 23.75 | 257.12 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Caffeine citrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20701-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Caffeine citrate; Coffeini citras

### Special notes

When selecting the *Caffeine citrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Caffeine citrate | 5 | 2 | 30 |

### Second-stage model

For differentiation of the substance/substance group *Caffeine citrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Caffeine citrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 112.65 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Caffeine citrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Caffeine citrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Caffeine citrate | 12C16-N03 | 20701 | 40 | 1403477 |
| Fagron | Caffeine citrate | 15A05-B03-318006 | 22530 | 40 | 20150115 |
| Fagron | Caffeine citrate | 15A05-B03-318006 | 22531 | 40 | 20150115 |
| Gatt-Koller | Caffeine citrate | 1783/05140715 | 21844 | 60 | AR-15-FG-014994-01 |
| Gatt-Koller | Caffeine citrate | 22J00881 | 26626 | 40 | 20220718 |
| Gatt-Koller | Caffeine citrate | 23J02625 | 27092 | 40 | 20240130 |
| Gatt-Koller | Caffeine citrate | 23J02625 | 27092SI | 20 | 20240130 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 280 spectra of 7 reference samples from the substance/substance group *Caffeine citrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.


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- 158 046 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 4 reference samples from the substance/substance group *Caffeine citrate*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Caffeine citrate | 15A05-B03-302746 | 21734 | 60 |
| Gatt-Koller | Caffeine citrate | 4065/11164916 | 23112 | 40 |
| Fagron | Caffeine citrate | 15A05-B03-302746 | 22729 | 40 |
| Gatt-Koller | Caffeine citrate | 22J00881 | 26626SI† | 20 |

- 212 780 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 82 spectra from 55 *Apo-Ident* customers from 34 batches from the substance/substance group *Caffeine citrate*.
- Among them are spectra of independent samples from 30 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AHD | Caffeine citrate | 13B08-N02 | 1 |
| Caelo | Caffeine citrate | 11F21-N05 | 1 |
| Caelo | Caffeine citrate | 13D30-N02 | 1 |
| Caelo | Caffeine citrate | 15A05-B03-302746 | 1 |
| Caelo | Caffeine citrate | 15A05-B03-307309 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Caffeine citrate | 15A05-B03-318006 | 2 |
| Fagron | Caffeine citrate | 10c23-n02 | 1 |
| Fagron | Caffeine citrate | 10H02-N02 | 2 |
| Fagron | Caffeine citrate | 11082015A | 1 |
| Fagron | Caffeine citrate | 11C29-N04 | 2 |
| Fagron | Caffeine citrate | 12C16-N03 | 1 |
| Fagron | Caffeine citrate | 12J05-N06 | 3 |
| Fagron | Caffeine citrate | 12J05-N06 | 1 |
| Fagron | Caffeine citrate | 13B08N02 | 1 |
| Fagron | Caffeine citrate | 13B08-N02 | 1 |
| Fagron | Caffeine citrate | 13D30-N02 | 9 |
| Fagron | Caffeine citrate | 13D30-No2 | 1 |
| Fagron | Caffeine citrate | 15A05B03 | 1 |
| Fagron | Caffeine citrate | 15A05-B03 | 3 |
| Fagron | Caffeine citrate | 15a05-b03-302746 | 1 |
| Fagron | Caffeine citrate | 15A05-B03-302746 | 11 |
| Fagron | Caffeine citrate | 15A05-B03-307135 | 3 |
| Fagron | Caffeine citrate | 15a05-b03-318006 | 1 |
| Fagron | Caffeine citrate | 15A05-B03-318006 | 11 |
| Fagron | Caffeine citrate | 2002311282 | 1 |
| Fagron | Caffeine citrate | 204311282 | 1 |
| Fagron | Caffeine citrate | 26021401 | 1 |
| Fagron | Caffeine citrate | 2714E-01282 | 1 |
| Fagron | Caffeine citrate | 2813E1282 | 1 |
| Fagron | Caffeine citrate | 3314E-01282 | 1 |
| Fagron | Caffeine citrate | 3513I-01282 | 1 |
| Fagron | Caffeine citrate | 3914U-01282 | 1 |
| Fagron | Caffeine citrate | 4213U01282 | 1 |
| Fagron | Caffeine citrate | 5013U01282 | 1 |
| Fagron | Caffeine citrate | CCC1205 | 1 |
| Fagron | Caffeine citrate | CCD-1401 | 3 |
| Fargon/Phoenix | Caffeine citrate | 15A05-B03-302746 | 1 |
| Fargon | Caffeine citrate | 12J05-N06 | 1 |
| Fgron | Caffeine citrate | 2013Q-01282 | 1 |
| Gehe | Caffeine citrate | 13B08-N02 | 1 |
| Noweda | Caffeine citrate | CCC-1101 | 1 |
| Phoenix | Caffeine citrate | 15A05-B03 | 1 |
| Rondell Apotheke | Caffeine citrate | 15A05-B03-307309 | 1 |

- 256 804 spectra from 1666 *Apo-Ident* customers from a total of 52 119 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Caffeine citrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Caffeine citrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 72 | 10 | 256 804 |


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The substance/substance group *Caffeine citrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 87.8049 % (> 84.1463 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20701 | 20701 | 0.00 | 338.87 |
| 21844 | 21844 | 0.00 | 278.06 |
| 22530 | 20701 | 24.35 | 339.16 |
| 22531 | 20701 | 29.34 | 339.88 |
| 26626 | 21844 | 102.93 | 263.29 |
| 27092 | 21844 | 101.38 | 293.67 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Calcium ascorbate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20393-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Calcium ascorbate dihydrate; Calcii ascorbas dihydricus

### Special notes

When selecting the *Calcium ascorbate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Calcium ascorbate dihydrate | 9 | 14 | 18 |

### Second-stage model

For differentiation of the substance/substance group *Calcium ascorbate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Calcium ascorbate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 84.10 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Calcium ascorbate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Calcium ascorbate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Calcium ascorbate dihydrate | 13105624 | 21313 | 40 | 20130620 |
| Caelo | Calcium ascorbate dihydrate | 163111 | 23060 | 40 | 20161207* |
| Caelo | Calcium ascorbate dihydrate | 16311101 | 23518 | 40 | 20161207 |
| Caelo | Calcium ascorbate dihydrate | 20003812 | 25625 | 40 | 20201211* |
| Euro OTC | Calcium ascorbate dihydrate | 1612003 | 22916 | 40 | 20170110* |
| Euro OTC | Calcium ascorbate dihydrate | 1709005 | 23609 | 40 | 20170914* |
| Euro OTC | Calcium ascorbate dihydrate | 1709004 | 23611 | 40 | 20170914* |
| Euro OTC | Calcium ascorbate dihydrate | 1801010 | 23884 | 40 | 20180115* |
| Euro OTC | Calcium ascorbate dihydrate | 2201040 | 26093 | 40 | 20220211* |
| Euro OTC | Calcium ascorbate dihydrate | 2201040 | 26093SI | 20 | 20220211* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 380 spectra of 10 reference samples from the substance/substance group *Calcium ascorbate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 946 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 590 spectra of 16 reference samples from the substance/substance group *Calcium ascorbate dihydrate*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Calcium ascorbate dihydrate | 183226 | 24373 | 40 |
| Caelo | Calcium ascorbate dihydrate | 19000538 | 25223 | 40 |
| Caelo | Calcium ascorbate dihydrate | 22000185 | 26014 | 30 |
| Euro OTC | Calcium ascorbate dihydrate | 1607033-01 | 22812 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 1807032 | 24194 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 1901003 | 24470 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 1904010 | 24626 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 1910003 | 24979 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 2003025 | 25149 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 2007012 | 25336 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 2101005 | 25538 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 2105006 | 25768 | 50 |
| Euro OTC | Calcium ascorbate dihydrate | 2305017 | 26881 | 40 |
| Euro OTC | Calcium ascorbate dihydrate | 2403007 | 27345 | 40 |
| Caelo | Calcium ascorbate dihydrate | 22000185 | 26014SI | 10 |
| Euro OTC | Calcium ascorbate dihydrate | 2305017 | 26881SI | 20 |

- 212 350 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 28 spectra from 12 *Apo-Ident* customers from 21 batches from the substance/substance group *Calcium ascorbate dihydrate*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Calcium ascorbate dihydrate | 2305017-01 | 2 |
| Arktis | Calcium ascorbate dihydrate | 7339/4617 | 1 |
| Arktis | Calcium ascorbate dihydrate | 733P/1518 | 1 |
| Burton Feingold | Calcium ascorbate dihydrate | L008415 | 1 |
| Caelo | Calcium ascorbate dihydrate | 13105608 | 1 |
| Caelo | Calcium ascorbate dihydrate | 14340907 | 1 |
| Caelo | Calcium ascorbate dihydrate | 15324702 | 1 |
| Caelo | Calcium ascorbate dihydrate | 15324708 | 2 |
| Caelo | Calcium ascorbate dihydrate | 16311101 | 1 |
| Caelo | Calcium ascorbate dihydrate | 16311105 | 1 |
| Euro OTC | Calcium ascorbate dihydrate | 1709004-01 | 1 |
| Euro OTC | Calcium ascorbate dihydrate | 1709005 | 1 |
| Euro OTC | Calcium ascorbate dihydrate | 1801010 | 1 |
| Euro OTC | Calcium ascorbate dihydrate | 1901003-01 | 1 |
| Euro OTC | Calcium ascorbate dihydrate | 1904010-01 | 3 |
| Euro OTC | Calcium ascorbate dihydrate | 1910003-01 | 3 |
| Euro OTC | Calcium ascorbate dihydrate | 2007012-01 | 2 |
| Euro OTC | Calcium ascorbate dihydrate | 2105006-01 | 1 |
| Euro OTC | Calcium ascorbate dihydrate | 220104001 | 1 |
| Farmalabor / Farmalabor | Calcium ascorbate dihydrate | P1104931-000A | 1 |
| Gatt-Koller | Calcium ascorbate dihydrate | 1900123 | 1 |

- 256 858 spectra from 1666 *Apo-Ident* customers from a total of 52 132 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Calcium ascorbate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Calcium ascorbate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 590 | 0 | 212 350 |
| **Type C** | 0 | 28 | 0 | 256 858 |

The substance/substance group *Calcium ascorbate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.9831 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 78.5714 %) |


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In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21313 | 23060 | 9.76 | 206.76 |
| 22916 | 22916 | 0.00 | 205.13 |
| 23060 | 23060 | 0.00 | 204.03 |
| 23518 | 25625 | 4.02 | 202.62 |
| 23609 | 23609 | 0.00 | 203.95 |
| 23611 | 23611 | 0.00 | 203.08 |
| 23884 | 23884 | 0.00 | 202.79 |
| 25625 | 25625 | 0.00 | 205.05 |
| 26093 | 26093 | 0.00 | 207.40 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Calcium citrate tetrahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20013-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Calcium citrate tetrahydrate; Calcii citras tetrahydricus

### Special notes

When selecting the *Calcium citrate tetrahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Calcium citrate tetrahydrate | 9 | 10 | 136 |

### Second-stage model

For differentiation of the substance/substance group *Calcium citrate tetrahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Calcium citrate tetrahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 73.79 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Calcium citrate tetrahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Calcium citrate tetrahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Calcium citrate tetrahydrate | 13391203 | 21320 | 40 | 20131205 |
| Caelo | Calcium citrate tetrahydrate | 13391203 | 21486 | 40 | 20131205 |
| Caelo | Calcium citrate tetrahydrate | 171768 | 23651 | 40 | 20170713* |
| Caelo | Calcium citrate tetrahydrate | 24002963 | 27552 | 40 | 20250219* |
| Euro OTC | Calcium citrate tetrahydrate | 1305018-01 | 21249 | 40 | 20130528 |
| Euro OTC | Calcium citrate tetrahydrate | 1509039 | 21931 | 60 | 20151013* |
| Euro OTC | Calcium citrate tetrahydrate | 1509039-01 | 22255 | 60 | 20151013 |
| Euro OTC | Calcium citrate tetrahydrate | 1701001 | 22995 | 40 | 20170124* |
| Euro OTC | Calcium citrate tetrahydrate | 2206009 | 26184 | 40 | 20220624* |
| Euro OTC | Calcium citrate tetrahydrate | 2206009 | 26184SI | 20 | 20220624* |
| Euro OTC | Calcium citrate tetrahydrate | 2305020 | 26748 | 40 | 20230607* |
| Euro OTC | Calcium citrate tetrahydrate | 2305020 | 26748SI | 20 | 20230607* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 480 spectra of 12 reference samples from the substance/substance group *Calcium citrate tetrahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 846 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 430 spectra of 11 reference samples from the substance/substance group *Calcium citrate tetrahydrate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Calcium citrate tetrahydrate | 181608 | 24230 | 40 |
| Caelo | Calcium citrate tetrahydrate | 20002273 | 25287 | 40 |
| Caelo | Calcium citrate tetrahydrate | 21004151 | 26124 | 40 |
| Caelo | Calcium citrate tetrahydrate | 24001206 | 27230 | 40 |
| Euro OTC | Calcium citrate tetrahydrate | 1606001 | 22681 | 40 |
| Euro OTC | Calcium citrate tetrahydrate | 1707025 | 23606 | 40 |
| Euro OTC | Calcium citrate tetrahydrate | 1803031 | 24077 | 40 |
| Euro OTC | Calcium citrate tetrahydrate | 1901002 | 24514 | 40 |
| Euro OTC | Calcium citrate tetrahydrate | 1912013 | 25075 | 40 |
| Euro OTC | Calcium citrate tetrahydrate | 2105004 | 25769 | 50 |
| Caelo | Calcium citrate tetrahydrate | 21004151 | 26124SI | 20 |

- 212 510 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 342 spectra from 155 *Apo-Ident* customers from 142 batches from the substance/substance group *Calcium citrate tetrahydrate*.

- Among them are spectra of independent samples from 136 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Calcium citrate tetrahydrate | 21004151003 | 2 |
| | Calcium citrate tetrahydrate | 21004151004 | 2 |
| | Calcium citrate tetrahydrate | 21004151008 | 1 |
| | Calcium citrate tetrahydrate | 21004151009 | 1 |
| | Calcium citrate tetrahydrate | 2206009-02 | 2 |
| | Calcium citrate tetrahydrate | 2305020-02 | 1 |
| | Calcium citrate tetrahydrate | 2305020-03 | 2 |
| | Calcium citrate tetrahydrate | 231130 | 1 |
| | Calcium citrate tetrahydrate | 24001206004 | 1 |
| 8,35Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 20002273013 | 1 |
| ACM | Calcium citrate tetrahydrate | KNC0740J15 | 1 |
| Alliance Health 23.1... | Calcium citrate tetrahydrate | 1402003-01 | 1 |
| Caelo | Calcium citrate tetrahydrate | | 2 |
| Caelo | Calcium citrate tetrahydrate | 11061402 | 1 |
| Caelo | Calcium citrate tetrahydrate | 11168803 | 1 |
| Caelo | Calcium citrate tetrahydrate | 11168806 | 3 |
| Caelo | Calcium citrate tetrahydrate | 11168813 | 1 |
| Caelo | Calcium citrate tetrahydrate | 1119E-01209 | 1 |
| Caelo | Calcium citrate tetrahydrate | 11349301 | 1 |
| Caelo | Calcium citrate tetrahydrate | 11349304 | 2 |
| Caelo | Calcium citrate tetrahydrate | 11349309 | 2 |
| Caelo | Calcium citrate tetrahydrate | 11349313 | 2 |
| Caelo | Calcium citrate tetrahydrate | 11349318 | 3 |
| Caelo | Calcium citrate tetrahydrate | 11349320 | 1 |
| Caelo | Calcium citrate tetrahydrate | 11349325 | 2 |
| Caelo | Calcium citrate tetrahydrate | 1168806 | 1 |
| Caelo | Calcium citrate tetrahydrate | 1168813 | 1 |
| Caelo | Calcium citrate tetrahydrate | 12310401 | 1 |
| Caelo | Calcium citrate tetrahydrate | 12310402 | 2 |
| Caelo | Calcium citrate tetrahydrate | 12310403 | 3 |
| Caelo | Calcium citrate tetrahydrate | 12310406 | 5 |
| Caelo | Calcium citrate tetrahydrate | 12310407 | 2 |
| Caelo | Calcium citrate tetrahydrate | 12310411 | 2 |
| Caelo | Calcium citrate tetrahydrate | 12310413 | 4 |
| Caelo | Calcium citrate tetrahydrate | 12310417 | 3 |
| Caelo | Calcium citrate tetrahydrate | 12310418 | 2 |
| Caelo | Calcium citrate tetrahydrate | 13391203 | 4 |
| Caelo | Calcium citrate tetrahydrate | 133912042x | 1 |
| Caelo | Calcium citrate tetrahydrate | 13391205 | 5 |
| Caelo | Calcium citrate tetrahydrate | 1408017-01 | 1 |
| Caelo | Calcium citrate tetrahydrate | 14133303 | 1 |
| Caelo | Calcium citrate tetrahydrate | 14133307 | 1 |
| Caelo | Calcium citrate tetrahydrate | 14133310 | 1 |
| Caelo | Calcium citrate tetrahydrate | 1509039-01 | 1 |
| Caelo | Calcium citrate tetrahydrate | 1509039-02 | 1 |
| Caelo | Calcium citrate tetrahydrate | 15177701 | 1 |
| Caelo | Calcium citrate tetrahydrate | 15177702 | 2 |
| Caelo | Calcium citrate tetrahydrate | 15177703 | 8 |
| Caelo | Calcium citrate tetrahydrate | 15375702 | 6 |
| Caelo | Calcium citrate tetrahydrate | 15375703 | 1 |
| Caelo | Calcium citrate tetrahydrate | 15375707 | 1 |
| Caelo | Calcium citrate tetrahydrate | 15375712 | 2 |
| Caelo | Calcium citrate tetrahydrate | 15375713 | 6 |
| Caelo | Calcium citrate tetrahydrate | 1600565 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Calcium citrate tetrahydrate | 16021502 | 1 |
| Caelo | Calcium citrate tetrahydrate | 16056501 | 1 |
| Caelo | Calcium citrate tetrahydrate | 16056504 | 4 |
| Caelo | Calcium citrate tetrahydrate | 16056505 | 3 |
| Caelo | Calcium citrate tetrahydrate | 16056510 | 2 |
| Caelo | Calcium citrate tetrahydrate | 1606001-02 | 1 |
| Caelo | Calcium citrate tetrahydrate | 1705038-01 | 1 |
| Caelo | Calcium citrate tetrahydrate | 1707025-01 | 2 |
| Caelo | Calcium citrate tetrahydrate | 1716803 | 1 |
| Caelo | Calcium citrate tetrahydrate | 1716808 | 1 |
| Caelo | Calcium citrate tetrahydrate | 17176803 | 6 |
| Caelo | Calcium citrate tetrahydrate | 17176805 | 1 |
| Caelo | Calcium citrate tetrahydrate | 17176806 | 6 |
| Caelo | Calcium citrate tetrahydrate | 17176808 | 7 |
| Caelo | Calcium citrate tetrahydrate | 17176812 | 3 |
| Caelo | Calcium citrate tetrahydrate | 17176816 | 1 |
| Caelo | Calcium citrate tetrahydrate | 17176818 | 1 |
| Caelo | Calcium citrate tetrahydrate | 18160802 | 3 |
| Caelo | Calcium citrate tetrahydrate | 18160803 | 1 |
| Caelo | Calcium citrate tetrahydrate | 18160805 | 1 |
| Caelo | Calcium citrate tetrahydrate | 18160811 | 1 |
| Caelo | Calcium citrate tetrahydrate | 18160813 | 2 |
| Caelo | Calcium citrate tetrahydrate | 19010002-01 | 1 |
| Caelo | Calcium citrate tetrahydrate | 19061315 | 1 |
| Caelo | Calcium citrate tetrahydrate | 20002273004 | 2 |
| Caelo | Calcium citrate tetrahydrate | 20002273009 | 2 |
| Caelo | Calcium citrate tetrahydrate | 20002273010 | 1 |
| Caelo | Calcium citrate tetrahydrate | 20002273013 | 2 |
| Caelo | Calcium citrate tetrahydrate | 2000227306 | 1 |
| Caelo | Calcium citrate tetrahydrate | 2001377004 | 1 |
| Caelo | Calcium citrate tetrahydrate | 2016Q-01209 | 1 |
| Caelo | Calcium citrate tetrahydrate | 21001377004 | 1 |
| Caelo | Calcium citrate tetrahydrate | 21004151002 | 1 |
| Caelo | Calcium citrate tetrahydrate | 2114M1209 | 1 |
| Caelo | Calcium citrate tetrahydrate | 3512U-01209 | 1 |
| Caelo | Calcium citrate tetrahydrate | 71356168 | 1 |
| Caelo | Calcium citrate tetrahydrate | 92192429 | 1 |
| Caelo | Calcium citrate tetrahydrate | 92457399 | 1 |
| Caesar & Loretz GmbH… | Calcium citrate tetrahydrate | 20002273013 | 1 |
| Caesar & Loretz GmbH… | Calcium citrate tetrahydrate | 18160811 | 1 |
| Caesar & Loretz GmbH… | Calcium citrate tetrahydrate | 181608002 | 3 |
| Caesar & Loretz GmbH… | Calcium citrate tetrahydrate | 21001377004 | 1 |
| Caesar & Loretz GmbH… | Calcium citrate tetrahydrate | 21004151002 | 2 |
| Caesar & Loretz GmbH/OG | Calcium citrate tetrahydrate | 20002273002 | 1 |
| Caesar & Loretz GmbH… | Calcium citrate tetrahydrate | 20002273010 | 1 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 17176814 | 1 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 181608002 | 3 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 18160802 | 3 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 18160804 | 3 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 18160811 | 1 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 18160812 | 3 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 18160813 | 1 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 20002273002 | 2 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 20002273004 | 3 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 20002273009 | 3 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 20002273013 | 1 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 21001377004 | 1 |
| Caesar & Loretz GmbH | Calcium citrate tetrahydrate | 21001377009 | 1 |
| Caesar & Loretz | Calcium citrate tetrahydrate | 16056509 | 1 |
| Cealo | Calcium citrate tetrahydrate | 12310401 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Dr.Lohmann | Calcium citrate tetrahydrate | 3042527 | 1 |
| EuRho/Jenne | Calcium citrate tetrahydrate | 1211007-01 | 1 |
| EuRho | Calcium citrate tetrahydrate | 1502012-02 | 1 |
| euro ct | Calcium citrate tetrahydrate | 1912013-01 | 5 |
| Euro OTC | Calcium citrate tetrahydrate | 1009030-01 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1058904 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1207006-01 | 3 |
| Euro OTC | Calcium citrate tetrahydrate | 1211007-01 | 2 |
| Euro OTC | Calcium citrate tetrahydrate | 13031204 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1305018-01 | 3 |
| Euro OTC | Calcium citrate tetrahydrate | 1305018-02 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1402003-01 | 2 |
| Euro OTC | Calcium citrate tetrahydrate | 140801701 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1408017-01 | 4 |
| Euro OTC | Calcium citrate tetrahydrate | 1502012-01 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1502021-02 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1509039-01 | 4 |
| Euro OTC | Calcium citrate tetrahydrate | 1509039-02 | 6 |
| Euro OTC | Calcium citrate tetrahydrate | 15177704 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1606001-01 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1606001-02 | 2 |
| Euro OTC | Calcium citrate tetrahydrate | 1701001-01 | 2 |
| Euro OTC | Calcium citrate tetrahydrate | 1701001-02 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1707025-01 | 3 |
| Euro OTC | Calcium citrate tetrahydrate | 1707025-02 | 2 |
| Euro OTC | Calcium citrate tetrahydrate | 1707025-41 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1710007-01 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1803031-01 | 3 |
| Euro OTC | Calcium citrate tetrahydrate | 1803031-02 | 7 |
| Euro OTC | Calcium citrate tetrahydrate | 190100201 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1901002-01 | 6 |
| Euro OTC | Calcium citrate tetrahydrate | 1901002-02 | 4 |
| Euro OTC | Calcium citrate tetrahydrate | 191201301 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 1912013-01 | 12 |
| Euro OTC | Calcium citrate tetrahydrate | 1912013-02 | 6 |
| Euro OTC | Calcium citrate tetrahydrate | 1912013-13 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 2105004-01 | 3 |
| Euro OTC | Calcium citrate tetrahydrate | 2817U-01209 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 3006222 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 3037086 | 1 |
| Euro OTC | Calcium citrate tetrahydrate | 3842527 | 1 |
| Fagron | Calcium citrate tetrahydrate | 13d16-n06 | 1 |
| Fagron | Calcium citrate tetrahydrate | 13D16-N06 | 1 |
| Fagron | Calcium citrate tetrahydrate | 150903901 | 1 |
| Gehe Kassel | Calcium citrate tetrahydrate | 14133307 | 1 |
| Gehe | Calcium citrate tetrahydrate | 18160806 | 1 |
| Gehe | Calcium citrate tetrahydrate | 21001377009 | 1 |
| Kögl | Calcium citrate tetrahydrate | 1802139 | 3 |
| Krieger | Calcium citrate tetrahydrate | 17176808 | 1 |
| L12 | Calcium citrate tetrahydrate | 1606001-03 | 1 |
| lohmann | Calcium citrate tetrahydrate | 3045397 | 1 |
| Noweda | Calcium citrate tetrahydrate | 1509039-01 | 1 |
| Noweda | Calcium citrate tetrahydrate | 17176803 | 1 |
| Noweda | Calcium citrate tetrahydrate | 17176808 | 1 |
| Noweda | Calcium citrate tetrahydrate | 18160804 | 1 |
| Noweda | Calcium citrate tetrahydrate | 18160813 | 1 |
| Noweda | Calcium citrate tetrahydrate | 20002273004 | 1 |
| Phönix | Calcium citrate tetrahydrate | 1305018-01 | 1 |
| Sanacorp WE: 12.08.1... | Calcium citrate tetrahydrate | 711105 | 1 |
| Sanacorp | Calcium citrate tetrahydrate | 1211007-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Calcium citrate tetrahydrate | 14133310 | 1 |
| Sanacorp | Calcium citrate tetrahydrate | 20002273002 | 1 |
| Sanacorp | Calcium citrate tetrahydrate | 20002273006 | 2 |
| Sanacorp | Calcium citrate tetrahydrate | 3129920 | 1 |

- 256 544 spectra from 1666 *Apo-Ident* customers from a total of 52 014 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Calcium citrate tetrahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Calcium citrate tetrahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 430 | 0 | 212 510 |
| **Type C** | 0 | 342 | 0 | 256 544 |

The substance/substance group *Calcium citrate tetrahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6047 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 98.2456 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21249 | 22995 | 6.06 | 104.59 |
| 21320 | 22995 | 7.57 | 108.24 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21486 | 22995 | 7.33 | 108.96 |
| 21931 | 21931 | 0.00 | 99.48 |
| 22255 | 21931 | 4.73 | 100.50 |
| 22995 | 22995 | 0.00 | 104.01 |
| 23651 | 23651 | 0.00 | 104.94 |
| 26184 | 26184 | 0.00 | 104.98 |
| 26748 | 26748 | 0.00 | 104.87 |
| 27552 | 27552 | 0.00 | 106.05 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Calcium gluconate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20871-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Calcium gluconate; Calcii gluconas

### Special notes

When selecting the *Calcium gluconate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Calcium gluconate | 6 | 9 | 83 |

### Second-stage model

For differentiation of the substance/substance group *Calcium gluconate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Calcium gluconate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 68.86 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Calcium gluconate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Calcium gluconate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Calcium gluconate | 12236502 | 20871 | 40 | 1401575 |
| Caelo | Calcium gluconate | 12335829 | 21312 | 40 | 20121121 |
| Euro OTC | Calcium gluconate | 1304012-01 | 21283 | 40 | AR-15-FG-008127-01 |
| Euro OTC | Calcium gluconate | 1407041-01 | 21821 | 60 | 20140818 |
| Euro OTC | Calcium gluconate | 1712007 | 23873 | 40 | 20171220* |
| Euro OTC | Calcium gluconate | 1911017 | 25086 | 40 | 20200123* |
| Euro OTC | Calcium gluconate | 1712007 | 25106 | 40 | 20200203* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 7 reference samples from the substance/substance group *Calcium gluconate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 026 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 410 spectra of 12 reference samples from the substance/substance group *Calcium gluconate*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Calcium gluconate | 154356 | 23360 | 40 |
| Caelo | Calcium gluconate | 181010 | 24017 | 40 |
| Caelo | Calcium gluconate | 190240 | 24566 | 40 |
| Caelo | Calcium gluconate | 20004137011 | 25986 | 40 |
| Caelo | Calcium gluconate | 22001257 | 26250 | 40 |
| Caelo | Calcium gluconate | 24000791 | 27223 | 40 |
| Euro OTC | Calcium gluconate | 1606034 | 22699 | 40 |
| Euro OTC | Calcium gluconate | 1905015 | 24791 | 40 |
| Fagron | Calcium gluconate | 22D13-B03-229458 | 26666 | 40 |
| Caelo | Calcium gluconate | 20004137011 | 25986SI | 10 |
| Caelo | Calcium gluconate | 22001257 | 26250SI | 20 |
| Fagron | Calcium gluconate | 22D13-B03-229458 | 26666SI | 20 |

- 212 530 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 290 spectra from 170 *Apo-Ident* customers from 86 batches from the substance/substance group *Calcium gluconate*.

- Among them are spectra of independent samples from 83 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Calcium gluconate | 171200-02 | 1 |
| | Calcium gluconate | 1905015-01 | 1 |
| | Calcium gluconate | 21003557009 | 1 |
| | Calcium gluconate | 22001257002 | 2 |
| | Calcium gluconate | 22001257006 | 6 |
| | Calcium gluconate | 22001257008 | 1 |
| | Calcium gluconate | 22001257009 | 2 |
| AHD | Calcium gluconate | 1911017-03 | 1 |
| AHD | Calcium gluconate | 21003557007 | 1 |
| AHD | Calcium gluconate | 22001257003 | 5 |
| apomix | Calcium gluconate | 1905015-02 | 1 |
| Berkel AHK | Calcium gluconate | 14085407 | 2 |
| Caelo | Calcium gluconate | 1000041-01 | 1 |
| Caelo | Calcium gluconate | 12335810 | 1 |
| Caelo | Calcium gluconate | 12335813 | 1 |
| Caelo | Calcium gluconate | 1407041-01 | 1 |
| Caelo | Calcium gluconate | 140704102 | 1 |
| Caelo | Calcium gluconate | 1407041-02 | 1 |
| Caelo | Calcium gluconate | 14085405 | 1 |
| Caelo | Calcium gluconate | 14230706 | 1 |
| Caelo | Calcium gluconate | 15126301 | 1 |
| Caelo | Calcium gluconate | 15324806 | 1 |
| Caelo | Calcium gluconate | 15324807 | 1 |
| Caelo | Calcium gluconate | 15435601 | 2 |
| Caelo | Calcium gluconate | 15435607 | 2 |
| Caelo | Calcium gluconate | 15435610 | 1 |
| Caelo | Calcium gluconate | 15435611 | 1 |
| Caelo | Calcium gluconate | 15435613 | 1 |
| Caelo | Calcium gluconate | 15435619 | 4 |
| Caelo | Calcium gluconate | 15435620 | 2 |
| Caelo | Calcium gluconate | 15435622 | 2 |
| Caelo | Calcium gluconate | 1543601 | 1 |
| Caelo | Calcium gluconate | 1606034 | 1 |
| Caelo | Calcium gluconate | 1606034-01 | 1 |
| Caelo | Calcium gluconate | 16603401 | 1 |
| Caelo | Calcium gluconate | 171200-01 | 1 |
| Caelo | Calcium gluconate | 1712007_02 | 1 |
| Caelo | Calcium gluconate | 1712007-02 | 1 |
| Caelo | Calcium gluconate | 1712007-03 | 1 |
| Caelo | Calcium gluconate | 18101003 | 2 |
| Caelo | Calcium gluconate | 18101004 | 3 |
| Caelo | Calcium gluconate | 18101006 | 2 |
| Caelo | Calcium gluconate | 18101010 | 2 |
| Caelo | Calcium gluconate | 18106202 | 2 |
| Caelo | Calcium gluconate | 1900240002 | 1 |
| Caelo | Calcium gluconate | 190240001 | 2 |
| Caelo | Calcium gluconate | 190240002 | 10 |
| Caelo | Calcium gluconate | 19024006 | 5 |
| Caelo | Calcium gluconate | 19024009 | 2 |
| Caelo | Calcium gluconate | 190240096 | 1 |
| Caelo | Calcium gluconate | 1905015-01 | 1 |
| Caelo | Calcium gluconate | 190772007 | 1 |
| Caelo | Calcium gluconate | 19240002 | 1 |
| Caelo | Calcium gluconate | 20004137002 | 5 |
| Caelo | Calcium gluconate | 20004137004 | 1 |
| Caelo | Calcium gluconate | 20004137006 | 3 |
| Caelo | Calcium gluconate | 21003557007 | 2 |
| Caelo | Calcium gluconate | 22001257003 | 1 |
| Caelo | Calcium gluconate | 4(18101004) | 1 |
| Caesar & Loretz GmbH/Gehe | Calcium gluconate | 21003557007 | 2 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Calcium gluconate | 19024006 | 2 |
| Caesar & Loretz GmbH | Calcium gluconate | 19024009 | 1 |
| Caesar & Loretz GmbH | Calcium gluconate | 20004137002 | 2 |
| Caesar & Loretz GmbH | Calcium gluconate | 20004137005 | 1 |
| Caesar & Loretz GmbH | Calcium gluconate | 20004137006 | 3 |
| Caesar & Loretz GmbH | Calcium gluconate | 20004137011 | 2 |
| Caesar & Loretz GmbH | Calcium gluconate | 21003557007 | 1 |
| Caesar&Lorenz/AHD | Calcium gluconate | 19024009 | 1 |
| Caleo/ Noweda | Calcium gluconate | 18101004 | 2 |
| Eurho/Sns | Calcium gluconate | 1209006-01 | 1 |
| EuRho | Calcium gluconate | 12090006-01 | 1 |
| EuRho | Calcium gluconate | 1209006-01 | 2 |
| EuRho | Calcium gluconate | 1304012-01 | 3 |
| Euro OTC | Calcium gluconate | 1105027-01 | 1 |
| Euro OTC | Calcium gluconate | 1105027-02 | 3 |
| Euro OTC | Calcium gluconate | 115027-01 | 1 |
| Euro OTC | Calcium gluconate | 1209006-01 | 8 |
| Euro OTC | Calcium gluconate | 1210001287 | 1 |
| Euro OTC | Calcium gluconate | 1304012-01 | 4 |
| Euro OTC | Calcium gluconate | 130401202 | 1 |
| Euro OTC | Calcium gluconate | 1304012-02 | 2 |
| Euro OTC | Calcium gluconate | 140704101 | 1 |
| Euro OTC | Calcium gluconate | 1407041-01 | 6 |
| Euro OTC | Calcium gluconate | 140704102 | 1 |
| Euro OTC | Calcium gluconate | 1407041-02 | 9 |
| Euro OTC | Calcium gluconate | 1602001644 | 3 |
| Euro OTC | Calcium gluconate | 1606034-01 | 20 |
| Euro OTC | Calcium gluconate | 1606034-02 | 10 |
| Euro OTC | Calcium gluconate | 1702000290 | 1 |
| Euro OTC | Calcium gluconate | 1712007 | 1 |
| Euro OTC | Calcium gluconate | 1712007-01 | 11 |
| Euro OTC | Calcium gluconate | 1712007-02 | 11 |
| Euro OTC | Calcium gluconate | 1712007-03 | 1 |
| Euro OTC | Calcium gluconate | 1712007-04 | 11 |
| Euro OTC | Calcium gluconate | 1905015-01 | 17 |
| Euro OTC | Calcium gluconate | 1905015-02 | 11 |
| Euro OTC | Calcium gluconate | 1911017-01 | 1 |
| Euro OTC | Calcium gluconate | 20270912-1 | 1 |
| Euro OTC | Calcium gluconate | 513-Q1211 | 1 |
| Euro/Gehe | Calcium gluconate | 1304012-01 | 1 |
| Fagron | Calcium gluconate | 10G22-N12 | 1 |
| Fagron | Calcium gluconate | 12D17-N01 | 1 |
| Fagron | Calcium gluconate | 14D11-B04 | 1 |
| Fagron | Calcium gluconate | 14D11-B04-294136 | 2 |
| Fagron | Calcium gluconate | 15D13-B98-307445 | 1 |
| Fagron | Calcium gluconate | 17E30-B02-343011 | 1 |
| Finze | Calcium gluconate | 917857359 | 1 |
| Gatt-Koller / Phoenix | Calcium gluconate | 550/03141214 | 1 |
| Gehe/EuRo | Calcium gluconate | 1712007-01 | 1 |
| GEHE | Calcium gluconate | 15435619 | 1 |
| Gehe | Calcium gluconate | 19024009 | 1 |
| Gehe | Calcium gluconate | 20004137011 | 1 |
| L12 | Calcium gluconate | 15435627 | 1 |
| Noweda | Calcium gluconate | 15435627 | 1 |
| Noweda | Calcium gluconate | 22001257009 | 1 |
| Pharmachem | Calcium gluconate | 18101003 | 1 |
| Phönix/Euro | Calcium gluconate | 1606034-01 | 1 |
| Phönix | Calcium gluconate | 1606034-01 | 1 |
| sanacorp | Calcium gluconate | 1407041-01 | 1 |
| Sidonia | Calcium gluconate | 18101004 | 1 |

- 256 596 spectra from 1666 *Apo-Ident* customers from a total of 52 068 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Calcium gluconate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Calcium gluconate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 410 | 0 | 212 530 |
| **Type C** | 0 | 290 | 0 | 256 596 |

The substance/substance group *Calcium gluconate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5366 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.9310 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20871 | 20871 | 0.00 | 149.95 |
| 21283 | 21283 | 0.00 | 142.44 |
| 21312 | 20871 | 11.03 | 150.69 |
| 21821 | 23873 | 3.92 | 141.32 |
| 23873 | 23873 | 0.00 | 141.16 |
| 25086 | 25086 | 0.00 | 154.16 |
| 25106 | 25106 | 0.00 | 144.16 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Calcium glycerophosphate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20352-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Calcium glycerophosphate; Calcii glycerophosphas

### Special notes

When selecting the *Calcium glycerophosphate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Calcium glycerophosphate | 7 | 4 | 71 |

### Second-stage model

For differentiation of the substance/substance group *Calcium glycerophosphate* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Calcium glycerophosphate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 27.42 | – |
| Cannabis flower, CBD-dominant type | 28.53 | – |
| Cannabis flower, THC/CBD-intermedia… | 42.38 | – |
| Sodium cromoglicate | 45.25 | – |
| Polymyxin B sulfate | 46.86 | 18.44 |
| Riboflavin sodium phosphate hydrate | 65.52 | – |
| ⋮ | ⋮ | ⋮ |
| Colistin sulfate | >50 | 22.68 |
| Bacitracin | >50 | 35.09 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 37.87 |
| Calcium pantothenate | >50 | 41.16 |
| Amphotericin B | >50 | 45.34 |
| Riboflavin | >50 | 47.73 |
| Nystatin | >50 | 49.09 |
| SyrSpend® SF Alka | >50 | 54.44 |
| Carmellose sodium | >50 | 62.99 |
| Rice starch | >50 | 66.55 |
| Cyanocobalamin | >50 | 72.36 |
| SyrSpend® SF pH4 | >50 | 80.88 |
| Gelatine, white | >50 | 81.02 |
| Tosylchloramide sodium | >50 | 81.37 |
| alpha-tocopheryl acetate dry concentrate | >50 | 83.45 |
| Estradiol hemihydrate | >50 | 85.56 |
| Triamcinolone | >50 | 90.02 |
| Hyoscine hydrobromide | >50 | 91.01 |
| Corn starch | >50 | 93.19 |
| Methylcobalamin | >50 | 94.61 |
| Acacia, dried dispersion | >50 | 94.71 |
| Wheat starch | >50 | 104.72 |
| Potato starch | >50 | 118.60 |
| Oxalic acid | >50 | 118.69 |
| Estriol | >50 | 130.18 |
| Maltodextrin | >50 | 135.46 |
| Fructose | >50 | 153.76 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the sub-


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stance/substance group *Calcium glycerophosphate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Calcium glycerophosphate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Calcium glycerophosphate | 13007912 | 21311 | 40 | 20130124 |
| Caelo | Calcium glycerophosphate | 14341007 | 21969 | 60 | AR-16-FG-005932-01 |
| Caelo | Calcium glycerophosphate | 191007 | 24538 | 40 | 20190502* |
| Caelo | Calcium glycerophosphate | 20000551 | 25228 | 40 | 20200708* |
| Caelo | Calcium glycerophosphate | 21000588 | 25634 | 40 | 20210217* |
| Caelo | Calcium glycerophosphate | 20004507 | 26309 | 30 | 20210108 |
| Fagron | Calcium glycerophosphate | 13I17-N04 | 21234 | 40 | 20131016 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 290 spectra of 7 reference samples from the substance/substance group *Calcium glycerophosphate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.
- 158 036 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 5 reference samples from the substance/substance group *Calcium glycerophosphate*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Calcium glycerophosphate | 12012411 | 20679 | 40 |
| Caelo | Calcium glycerophosphate | 12012417 | 20771 | 40 |
| Caelo | Calcium glycerophosphate | 162310 | 23361 | 40 |
| Fagron | Calcium glycerophosphate | 15B03-B03-305050 | 21978 | 60 |
| Caelo | Calcium glycerophosphate | 20004507 | 26309SI† | 20 |

- 212 740 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 223 spectra from 133 *Apo-Ident* customers from 73 batches from the substance/substance group *Calcium glycerophosphate*.
- Among them are spectra of independent samples from 71 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Calcium glycerophosphate | B03-2224201 | 1 |
| AHD | Calcium glycerophosphate | 20004507016 | 1 |
| Alliance Healthcare | Calcium glycerophosphate | 19100703 | 1 |
| Caelo | Calcium glycerophosphate | 12012406 | 1 |
| Caelo | Calcium glycerophosphate | 12012413 | 2 |
| Caelo | Calcium glycerophosphate | 13007902 | 1 |
| Caelo | Calcium glycerophosphate | 13007908 | 1 |
| Caelo | Calcium glycerophosphate | 13007912 | 2 |
| Caelo | Calcium glycerophosphate | 13007914 | 1 |
| Caelo | Calcium glycerophosphate | 13A18-No2 | 1 |
| Caelo | Calcium glycerophosphate | 14341007 | 5 |
| Caelo | Calcium glycerophosphate | 14341009 | 1 |
| Caelo | Calcium glycerophosphate | 14341010 | 1 |
| Caelo | Calcium glycerophosphate | 14341013 | 1 |
| Caelo | Calcium glycerophosphate | 14341015 | 1 |
| Caelo | Calcium glycerophosphate | 14347101 | 2 |
| Caelo | Calcium glycerophosphate | 14B10-B02-296841 | 1 |
| Caelo | Calcium glycerophosphate | 15B03B03305050 | 1 |
| Caelo | Calcium glycerophosphate | 15B03-B03-305050 | 1 |
| Caelo | Calcium glycerophosphate | 162310 | 1 |
| Caelo | Calcium glycerophosphate | 16231001 | 3 |
| Caelo | Calcium glycerophosphate | 16231004 | 3 |
| Caelo | Calcium glycerophosphate | 16231005 | 1 |
| Caelo | Calcium glycerophosphate | 16231006 | 4 |
| Caelo | Calcium glycerophosphate | 16231007 | 2 |
| Caelo | Calcium glycerophosphate | 16231008 | 2 |
| Caelo | Calcium glycerophosphate | 16231010 | 5 |
| Caelo | Calcium glycerophosphate | 17250703 | 5 |
| Caelo | Calcium glycerophosphate | 17359101 | 14 |
| Caelo | Calcium glycerophosphate | 17359101P-180122-1 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Calcium glycerophosphate | 17359106 | 8 |
| Caelo | Calcium glycerophosphate | 17359107 | 9 |
| Caelo | Calcium glycerophosphate | 17359107P-181218-2 | 1 |
| Caelo | Calcium glycerophosphate | 17359110 | 1 |
| Caelo | Calcium glycerophosphate | 17359111 | 1 |
| Caelo | Calcium glycerophosphate | 180918A | 1 |
| Caelo | Calcium glycerophosphate | 190762007 | 1 |
| Caelo | Calcium glycerophosphate | 191007001 | 3 |
| Caelo | Calcium glycerophosphate | 19100701 | 2 |
| Caelo | Calcium glycerophosphate | 19100702 | 5 |
| Caelo | Calcium glycerophosphate | 19100703 | 18 |
| Caelo | Calcium glycerophosphate | 19100707 | 6 |
| Caelo | Calcium glycerophosphate | 20000551002 | 1 |
| Caelo | Calcium glycerophosphate | 20000551003 | 4 |
| Caelo | Calcium glycerophosphate | 20004507001 | 2 |
| Caelo | Calcium glycerophosphate | 20004507004 | 3 |
| Caelo | Calcium glycerophosphate | 20004507005 | 2 |
| Caelo | Calcium glycerophosphate | 20004507007 | 2 |
| Caelo | Calcium glycerophosphate | 20004507014 | 2 |
| Caelo | Calcium glycerophosphate | 20004507016 | 2 |
| Caelo | Calcium glycerophosphate | 2004507001 | 1 |
| Caelo | Calcium glycerophosphate | 2004507017 | 1 |
| Caesar & Loretz GmbH... | Calcium glycerophosphate | 20004507017 | 1 |
| Caesar & Loretz GmbH/Gehe | Calcium glycerophosphate | 20004507016 | 2 |
| Caesar & Loretz GmbH... | Calcium glycerophosphate | 20004507001 | 2 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 191007001 | 2 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 19100703 | 1 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 19100707 | 1 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 20000551003 | 2 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 20004507001 | 2 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 20004507004 | 3 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 20004507007 | 5 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 20004507014 | 2 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 20004507017 | 1 |
| Caesar & Loretz GmbH | Calcium glycerophosphate | 21000588001 | 2 |
| Caesar&Lorenz/AHD | Calcium glycerophosphate | 16231010 | 1 |
| Cealo/Sanacorp | Calcium glycerophosphate | 17359101 | 1 |
| Fagron | Calcium glycerophosphate | 11G19-N05 | 1 |
| Fagron | Calcium glycerophosphate | 1216000005 | 1 |
| Fagron | Calcium glycerophosphate | 12I18-N06 | 3 |
| Fagron | Calcium glycerophosphate | 1314000019 | 1 |
| Fagron | Calcium glycerophosphate | 1317-N04 | 2 |
| Fagron | Calcium glycerophosphate | 13A18N02 | 2 |
| Fagron | Calcium glycerophosphate | 13A18-N02 | 7 |
| Fagron | Calcium glycerophosphate | 14B10B02 | 1 |
| Fagron | Calcium glycerophosphate | 14B10-B02 | 1 |
| Fagron | Calcium glycerophosphate | 14B10-B02-291642 | 1 |
| Fagron | Calcium glycerophosphate | 14B10-B02-296841 | 4 |
| Fagron | Calcium glycerophosphate | 15B03B03 | 1 |
| Fagron | Calcium glycerophosphate | 15B03-B03 | 1 |
| Fagron | Calcium glycerophosphate | 15B03-B03-305050 | 3 |
| Fagron | Calcium glycerophosphate | 17J17-B07-3583 | 1 |
| Fagron | Calcium glycerophosphate | 19J10-F06-366452 | 3 |
| Fagron | Calcium glycerophosphate | 2417Q-01212 | 1 |
| Fagron | Calcium glycerophosphate | 3115A-01212 | 1 |
| Fagron | Calcium glycerophosphate | 5212M-01212 | 1 |
| Fagron | Calcium glycerophosphate | 700338-0002 | 1 |
| Gatt-Koller/Kwizda | Calcium glycerophosphate | 4007/09123812 | 1 |
| Gehe | Calcium glycerophosphate | 16231006 | 1 |
| Gehe | Calcium glycerophosphate | 17359108 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Calcium glycerophosphate | 19100703 | 1 |
| Gehe | Calcium glycerophosphate | 20004507016 | 1 |
| Phönix | Calcium glycerophosphate | 20004507004 | 1 |
| Sanacorp | Calcium glycerophosphate | 16231008 | 1 |
| Sanacorp | Calcium glycerophosphate | 17359102 | 1 |
| Sanacorp | Calcium glycerophosphate | 19100701 | 2 |
| Sanacorp | Calcium glycerophosphate | 20000551002 | 1 |
| Sanacorp | Calcium glycerophosphate | 20004507007 | 1 |
| Sanacorp | Calcium glycerophosphate | 20004507017 | 2 |
| Sidonia | Calcium glycerophosphate | 17250703 | 1 |

- 256 663 spectra from 1666 *Apo-Ident* customers from a total of 52 081 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Calcium glycerophosphate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Calcium glycerophosphate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 290 | 0 | 158 036 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 221 | 2 | 256 663 |

The substance/substance group *Calcium glycerophosphate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.9310 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.1031 % (> 97.7578 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21234 | 21969 | 14.95 | 50.62 |
| 21311 | 21969 | 9.54 | 49.25 |
| 21969 | 21969 | 0.00 | 50.39 |
| 24538 | 24538 | 0.00 | 46.36 |
| 25228 | 25228 | 0.00 | 42.36 |
| 25634 | 25634 | 0.00 | 44.43 |
| 26309 | 24538 | 9.18 | 48.12 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Calcium hydrogen phosphate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20129-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Calcium hydrogen phosphate dihydrate; Calcii hydrogenphosphas dihydricus

### Special notes

When selecting the *Calcium hydrogen phosphate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Calcium hydrogen phosphate dihydrate | 3 | 1 | 21 |

### Second-stage model

For differentiation of the substance/substance group *Calcium hydrogen phosphate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Calcium hydrogen phosphate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 37.94 | – |
| Riboflavin sodium phosphate hydrate | 58.37 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Calcium hydrogen phosphate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Calcium hydrogen phosphate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Calcium hydrogen phosphat… | 181117 | 24225 | 40 | 20180528* |
| Caelo | Calcium hydrogen phosphat… | 22001222 | 26566 | 40 | 20220607* |
| Caelo | Calcium hydrogen phosphat… | 22001222 | 26566SI | 20 | 20220607* |
| Caelo | Calcium hydrogen phosphat… | 25000297 | 27657 | 40 | 20250312* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 140 spectra of 4 reference samples from the substance/substance group *Calcium hydrogen phosphate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 186 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Calcium hydrogen phosphate dihydrate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Calcium hydrogen phosphat… | 23002987 | 27080 | 40 |
| Caelo | Calcium hydrogen phosphat… | 23002987 | 27080SI | 20 |
| Caelo | Calcium hydrogen phosphat… | 25000297 | 27657SI† | 20 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 38 spectra from 26 *Apo-Ident* customers from 21 batches from the substance/substance group *Calcium hydrogen phosphate dihydrate*.

- Among them are spectra of independent samples from 21 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Calcium hydrogen phosphat… | 101352009 | 1 |
| Caelo | Calcium hydrogen phosphat… | 10135201 | 1 |
| Caelo | Calcium hydrogen phosphat… | 10135216 | 1 |
| Caelo | Calcium hydrogen phosphat… | 10135223 | 1 |
| Caelo | Calcium hydrogen phosphat… | 10135228 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Calcium hydrogen phosphat… | 11287501 | 1 |
| Caelo | Calcium hydrogen phosphat… | 11287503 | 2 |
| Caelo | Calcium hydrogen phosphat… | 11287509 | 2 |
| Caelo | Calcium hydrogen phosphat… | 11287510 | 1 |
| Caelo | Calcium hydrogen phosphat… | 12212804 | 5 |
| Caelo | Calcium hydrogen phosphat… | 12212806 | 1 |
| Caelo | Calcium hydrogen phosphat… | 12212807 | 1 |
| Caelo | Calcium hydrogen phosphat… | 12212811 | 4 |
| Caelo | Calcium hydrogen phosphat… | 12212812 | 2 |
| Caelo | Calcium hydrogen phosphat… | 12212813 | 1 |
| Caelo | Calcium hydrogen phosphat… | 12212816 | 1 |
| Caelo | Calcium hydrogen phosphat… | 12212822 | 1 |
| Caelo | Calcium hydrogen phosphat… | 13170701 | 6 |
| Caelo | Calcium hydrogen phosphat… | 13170704 | 1 |
| Caelo | Calcium hydrogen phosphat… | 14011401 | 1 |
| Caelo | Calcium hydrogen phosphat… | 14085301 | 1 |
| Cealo | Calcium hydrogen phosphat… | 12212811 | 1 |
| Phönix 12.12.2013 | Calcium hydrogen phosphat… | 13170704 | 1 |

- 256 848 spectra from 1666 *Apo-Ident* customers from a total of 52 132 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Calcium hydrogen phosphate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Calcium hydrogen phosphate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 140 | 0 | 158 186 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 36 | 2 | 256 848 |

The substance/substance group *Calcium hydrogen phosphate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.7143 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 94.7368 % (> 86.8421 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24225 | 24225 | 0.00 | 110.44 |
| 26566 | 26566 | 0.00 | 109.77 |
| 27657 | 27657 | 0.00 | 104.94 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Calcium lactate pentahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20745-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Calcium lactate pentahydrate; Calcii lactas pentahydricus

### Special notes

When selecting the *Calcium lactate pentahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Calcium lactate pentahydrate | 7 | 5 | 47 |

### Second-stage model

For differentiation of the substance/substance group *Calcium lactate pentahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Calcium lactate pentahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 45.79 | – |
| Polymyxin B sulfate | 48.84 | – |
| Cannabis flower, CBD-dominant type | 51.90 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Calcium lactate pentahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Calcium lactate pentahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Calcium lactate pentahydrate | 15101401 | 21909 | 60 | 20150407 |
| Caelo | Calcium lactate pentahydrate | 15101405 | 22263 | 60 | 20150407 |
| Caelo | Calcium lactate pentahydrate | 161313 | 22445 | 60 | 20160513* |
| Caelo | Calcium lactate pentahydrate | 20000512 | 25225 | 40 | 20200320* |
| Caelo | Calcium lactate pentahydrate | 23002025 | 26971 | 40 | 20230918* |
| Caelo | Calcium lactate pentahydrate | 23002025 | 26971SI | 20 | 20230918* |
| Fagron | Calcium lactate pentahydrate | 12E10-N03 | 20745 | 40 | 20120704 |
| Fagron | Calcium lactate pentahydrate | 12I12-N06 | 21232 | 40 | AR-15-FG-007939-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 8 reference samples from the substance/substance group *Calcium lactate pentahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 7 reference samples from the substance/substance group *Calcium lactate pentahydrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Calcium lactate pentahydrate | 171377 | 23642 | 40 |
| Caelo | Calcium lactate pentahydrate | 180734 | 24035 | 40 |
| Caelo | Calcium lactate pentahydrate | 24002487 | 27428 | 40 |
| Fagron | Calcium lactate pentahydrate | 14H01-B05-323830 | 23566 | 40 |
| Fagron | Calcium lactate pentahydrate | 23C16-B11-234646 | 27036 | 40 |
| Caelo | Calcium lactate pentahydrate | 24002487 | 27428SI | 20 |
| Fagron | Calcium lactate pentahydrate | 23C16-B11-234646 | 27036SI | 20 |

- 212 700 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 80 spectra from 39 *Apo-Ident* customers from 49 batches from the substance/substance group *Calcium lactate pentahydrate*.

- Among them are spectra of independent samples from 47 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Calcium lactate pentahydrate | 21L065-B03-216728 | 1 |
| Caelo | Calcium lactate pentahydrate | 11369606 | 1 |
| Caelo | Calcium lactate pentahydrate | 11369610 | 1 |
| Caelo | Calcium lactate pentahydrate | 11369614 | 2 |
| Caelo | Calcium lactate pentahydrate | 11369618 | 1 |
| Caelo | Calcium lactate pentahydrate | 12C15-N02 | 1 |
| Caelo | Calcium lactate pentahydrate | 12E10-N03 | 1 |
| Caelo | Calcium lactate pentahydrate | 13080802 | 2 |
| Caelo | Calcium lactate pentahydrate | 13080804 | 2 |
| Caelo | Calcium lactate pentahydrate | 13080805 | 2 |
| Caelo | Calcium lactate pentahydrate | 14H01B05300502 | 1 |
| Caelo | Calcium lactate pentahydrate | 15101409 | 1 |
| Caelo | Calcium lactate pentahydrate | 15101411 | 2 |
| Caelo | Calcium lactate pentahydrate | 15101412 | 3 |
| Caelo | Calcium lactate pentahydrate | 15227804 | 2 |
| Caelo | Calcium lactate pentahydrate | 16131302 | 1 |
| Caelo | Calcium lactate pentahydrate | 16131307 | 1 |
| Caelo | Calcium lactate pentahydrate | 16131312 | 1 |
| Caelo | Calcium lactate pentahydrate | 16333106 | 4 |
| Caelo | Calcium lactate pentahydrate | 16333111 | 4 |
| Caelo | Calcium lactate pentahydrate | 16333113 | 1 |
| Caelo | Calcium lactate pentahydrate | 17137707 | 2 |
| Caelo | Calcium lactate pentahydrate | 17355503 | 2 |
| Caelo | Calcium lactate pentahydrate | 17J18-B01-350892 | 1 |
| Caelo | Calcium lactate pentahydrate | 18073406 | 2 |
| Caelo | Calcium lactate pentahydrate | 18073413 | 2 |
| Caelo | Calcium lactate pentahydrate | 18073415 | 2 |
| Caelo | Calcium lactate pentahydrate | 19042208 | 1 |
| Caelo | Calcium lactate pentahydrate | 20000512004 | 1 |
| Caelo | Calcium lactate pentahydrate | 20003749002 | 1 |
| Caelo | Calcium lactate pentahydrate | 20003749008 | 1 |
| Caesar & Loretz GmbH | Calcium lactate pentahydrate | 19042203 | 2 |
| Fagron | Calcium lactate pentahydrate | 12/12-N06 | 1 |
| Fagron | Calcium lactate pentahydrate | 12C15-N02 | 1 |
| Fagron | Calcium lactate pentahydrate | 12I12-N01 | 1 |
| Fagron | Calcium lactate pentahydrate | 12I12-N06 | 2 |
| Fagron | Calcium lactate pentahydrate | 13L18B04 | 1 |
| Fagron | Calcium lactate pentahydrate | 13L18-B04-295541 | 3 |
| Fagron | Calcium lactate pentahydrate | 14H01-B05 | 1 |
| Fagron | Calcium lactate pentahydrate | 14H01-B05-334588 | 2 |
| Fagron | Calcium lactate pentahydrate | 17J18-B01-343387 | 1 |
| Fagron | Calcium lactate pentahydrate | 17J18-B01-347174 | 1 |
| Fagron | Calcium lactate pentahydrate | 1806000537 | 1 |
| Fagron | Calcium lactate pentahydrate | 1901001645 | 1 |
| Fagron | Calcium lactate pentahydrate | 19B26-B05 | 1 |
| Fagron | Calcium lactate pentahydrate | 20C31-B02-201355 | 2 |
| Fagron | Calcium lactate pentahydrate | 21B23-B02-210092 | 2 |
| Fagron | Calcium lactate pentahydrate | 21B23-B02-210092 | 1 |
| Fagron | Calcium lactate pentahydrate | 21F09-B02-215877 | 3 |
| Phönix | Calcium lactate pentahydrate | 14H01-B05 | 1 |
| phönix | Calcium lactate pentahydrate | 15101411 | 1 |
| Shop | Calcium lactate pentahydrate | 1111001829 | 1 |

- 256 806 spectra from 1666 *Apo-Ident* customers from a total of 52 104 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Calcium lactate pentahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Calcium lactate pentahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 80 | 0 | 256 806 |

The substance/substance group *Calcium lactate pentahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.5000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20745 | 22445 | 7.66 | 139.88 |
| 21232 | 21232 | 0.00 | 137.02 |
| 21909 | 22445 | 8.26 | 141.56 |
| 22263 | 22445 | 6.79 | 139.54 |
| 22445 | 22445 | 0.00 | 142.29 |
| 25225 | 25225 | 0.00 | 139.10 |
| 26971 | 26971 | 0.00 | 144.53 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Calcium pantothenate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20395-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Calcium pantothenate; Calcii pantothenas

### Special notes

When selecting the *Calcium pantothenate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Calcium pantothenate | 11 | 11 | 82 |

### Second-stage model

For differentiation of the substance/substance group *Calcium pantothenate* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Calcium pantothenate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 18.40 | 13.02 |
| Colistin sulfate | 53.30 | 16.63 |
| ⋮ | ⋮ | ⋮ |
| Bacitracin | 59.56 | 15.69 |
| Methylcobalamin | >50 | 33.81 |
| Amphotericin B | >50 | 42.84 |
| Cyanocobalamin | >50 | 54.66 |
| Gelatine, white | >50 | 55.51 |
| Nystatin | >50 | 56.03 |
| Riboflavin | >50 | 60.80 |
| Triamcinolone | >50 | 69.22 |
| alpha-tocopheryl acetate dry concentrate | >50 | 78.84 |
| Estradiol hemihydrate | >50 | 85.89 |
| Calcium glycerophosphate | >50 | 100.50 |
| Estriol | >50 | 108.88 |
| Carmellose sodium | >50 | 126.80 |
| Hyoscine hydrobromide | >50 | 130.39 |
| SyrSpend® SF Alka | >50 | 155.51 |
| Tosylchloramide sodium | >50 | 163.80 |
| Rice starch | >50 | 189.45 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 224.91 |
| Oxalic acid | >50 | 250.73 |
| Acacia, dried dispersion | >50 | 261.46 |
| Corn starch | >50 | 274.57 |
| SyrSpend® SF pH4 | >50 | 304.27 |
| Potato starch | >50 | 374.02 |
| Wheat starch | >50 | 383.25 |
| Maltodextrin | >50 | 384.59 |
| Fructose | >50 | 402.85 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Calcium pantothenate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Calcium pantothenate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Calcium pantothenate | 14208012 | 21765 | 60 | 20140722 |
| Caelo | Calcium pantothenate | 173352 | 24045 | 40 | 20180202* |
| Euro OTC | Calcium pantothenate | 1305034-01 | 21243 | 40 | 20130617 |
| Euro OTC | Calcium pantothenate | 1509024 | 21901 | 60 | 20151005* |
| Euro OTC | Calcium pantothenate | 1603042 | 22551 | 40 | 20160429* |
| Euro OTC | Calcium pantothenate | 1607023 | 22691 | 40 | 20160809* |
| Euro OTC | Calcium pantothenate | 1702018 | 23153 | 40 | 20170330* |
| Euro OTC | Calcium pantothenate | 1711003 | 23890 | 40 | 20171123* |
| Euro OTC | Calcium pantothenate | 2008019 | 25296 | 40 | 20200921* |
| Euro OTC | Calcium pantothenate | 2101037 | 25592 | 40 | 20210304* |
| Fagron | Calcium pantothenate | 13H28-N11 | 21233 | 40 | 20130916 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 480 spectra of 11 reference samples from the substance/substance group *Calcium pantothenate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.
- 157 846 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 490 spectra of 14 reference samples from the substance/substance group *Calcium pantothenate*.
- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Calcium pantothenate | 162516 | 23363 | 40 |
| Caelo | Calcium pantothenate | 15344217 | 23717 | 40 |
| Caelo | Calcium pantothenate | 21003241008 | 26303 | 30 |
| Caelo | Calcium pantothenate | 23000511 | 26724 | 40 |
| Euro OTC | Calcium pantothenate | 1803014 | 24081 | 40 |
| Euro OTC | Calcium pantothenate | 1809014 | 24312 | 40 |
| Euro OTC | Calcium pantothenate | 1902032 | 24479 | 40 |
| Euro OTC | Calcium pantothenate | 2003007 | 25241 | 40 |
| Euro OTC | Calcium pantothenate | 2111014 | 25873 | 50 |
| Euro OTC | Calcium pantothenate | 2311018 | 27070 | 40 |
| Euro OTC | Calcium pantothenate | 2408016 | 27513 | 40 |
| Caelo | Calcium pantothenate | 21003241008 | 26303SI | 20 |
| Caelo | Calcium pantothenate | 23000511 | 26724SI | 20 |
| Euro OTC | Calcium pantothenate | 2111014 | 25873SI | 10 |

- 212 450 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 213 spectra from 87 *Apo-Ident* customers from 86 batches from the substance/substance group *Calcium pantothenate*.

- Among them are spectra of independent samples from 82 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Calcium pantothenate | 21003241008 | 6 |
| | Calcium pantothenate | 21003241015 | 1 |
| | Calcium pantothenate | 2111014-01 | 1 |
| | Calcium pantothenate | 22002458007 | 5 |
| | Calcium pantothenate | 22002458008 | 1 |
| | Calcium pantothenate | 23000511 | 1 |
| | Calcium pantothenate | 2301036-01 | 5 |
| | Calcium pantothenate | 2311018-01 | 1 |
| | Calcium pantothenate | 24002648003 | 1 |
| | Calcium pantothenate | 2408016-01 | 1 |
| AHD | Calcium pantothenate | 15344221 | 1 |
| Anzag/Anzag 26.07.18 | Calcium pantothenate | 1803017-01 | 1 |
| Caelo | Calcium pantothenate | | 1 |
| Caelo | Calcium pantothenate | 1013Q-03022 | 1 |
| Caelo | Calcium pantothenate | 11105731 | 1 |
| Caelo | Calcium pantothenate | 12236622 | 1 |
| Caelo | Calcium pantothenate | 12340808 | 3 |
| Caelo | Calcium pantothenate | 12340809 | 1 |
| Caelo | Calcium pantothenate | 12340819 | 2 |
| Caelo | Calcium pantothenate | 12340832 | 1 |
| Caelo | Calcium pantothenate | 12340846 | 1 |
| Caelo | Calcium pantothenate | 12340859 | 1 |
| Caelo | Calcium pantothenate | 1410011-01 | 1 |
| Caelo | Calcium pantothenate | 1410011-02 | 1 |
| Caelo | Calcium pantothenate | 14208004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Calcium pantothenate | 1509024-01 | 1 |
| Caelo | Calcium pantothenate | 15344207 | 1 |
| Caelo | Calcium pantothenate | 15344214 | 1 |
| Caelo | Calcium pantothenate | 1603042-01 | 1 |
| Caelo | Calcium pantothenate | 1607023-01 | 2 |
| Caelo | Calcium pantothenate | 16251608 | 2 |
| Caelo | Calcium pantothenate | 1711003-01 | 1 |
| Caelo | Calcium pantothenate | 17335208 | 5 |
| Caelo | Calcium pantothenate | 17335209 | 3 |
| Caelo | Calcium pantothenate | 18174608 | 1 |
| Caelo | Calcium pantothenate | 19057402 | 1 |
| Caelo | Calcium pantothenate | 19067402 | 2 |
| Caelo | Calcium pantothenate | 19067404 | 1 |
| Caelo | Calcium pantothenate | 19067405 | 2 |
| Caelo | Calcium pantothenate | 190751002 | 5 |
| Caelo | Calcium pantothenate | 190751004 | 3 |
| Caelo | Calcium pantothenate | 192718003 | 3 |
| Caelo | Calcium pantothenate | 192718004 | 5 |
| Caelo | Calcium pantothenate | 20004234001 | 3 |
| Caelo | Calcium pantothenate | 20004234003 | 1 |
| Caelo | Calcium pantothenate | 20004252009 | 1 |
| Caelo | Calcium pantothenate | 21003241008 | 3 |
| Caelo | Calcium pantothenate | 27111303 | 1 |
| Caelo | Calcium pantothenate | 8041407 | 1 |
| Caesar & Loretz GmbH... | Calcium pantothenate | 20004252012 | 1 |
| Caesar & Loretz GmbH... | Calcium pantothenate | 19067404 | 1 |
| Caesar & Loretz GmbH/Phoe | Calcium pantothenate | 20004234001 | 2 |
| Caesar & Loretz GmbH... | Calcium pantothenate | 190751002 | 1 |
| Caesar & Loretz GmbH... | Calcium pantothenate | 190751002 | 4 |
| Caesar & Loretz GmbH... | Calcium pantothenate | 192718004 | 1 |
| Caesar & Loretz GmbH | Calcium pantothenate | 17335209 | 2 |
| Caesar & Loretz GmbH | Calcium pantothenate | 19067404 | 1 |
| Caesar & Loretz GmbH | Calcium pantothenate | 190751002 | 1 |
| Caesar & Loretz GmbH | Calcium pantothenate | 192718003 | 1 |
| Caesar & Loretz GmbH | Calcium pantothenate | 192718004 | 2 |
| Caesar & Loretz GmbH | Calcium pantothenate | 20004252009 | 2 |
| EuRho/sanacorp | Calcium pantothenate | 1803014-01 | 1 |
| Euro OTC | Calcium pantothenate | 10021505 | 1 |
| Euro OTC | Calcium pantothenate | 1111025-01 | 1 |
| Euro OTC | Calcium pantothenate | 1209022-01 | 1 |
| Euro OTC | Calcium pantothenate | 1209022-02 | 1 |
| Euro OTC | Calcium pantothenate | 1209022-02pzn | 1 |
| Euro OTC | Calcium pantothenate | 130503401 | 2 |
| Euro OTC | Calcium pantothenate | 1305034-01 | 4 |
| Euro OTC | Calcium pantothenate | 1312027-01 | 3 |
| Euro OTC | Calcium pantothenate | 1410011-01 | 1 |
| Euro OTC | Calcium pantothenate | 1410011-02 | 3 |
| Euro OTC | Calcium pantothenate | 1509024-01 | 3 |
| Euro OTC | Calcium pantothenate | 1603042-01 | 4 |
| Euro OTC | Calcium pantothenate | 1607023-01 | 3 |
| Euro OTC | Calcium pantothenate | 1702018-01 | 3 |
| Euro OTC | Calcium pantothenate | 17021401 | 1 |
| Euro OTC | Calcium pantothenate | 1711003-01 | 7 |
| Euro OTC | Calcium pantothenate | 1803014-01 | 4 |
| Euro OTC | Calcium pantothenate | 1809014-01 | 2 |
| Euro OTC | Calcium pantothenate | 18111707 | 1 |
| Euro OTC | Calcium pantothenate | 1902023-01 | 1 |
| Euro OTC | Calcium pantothenate | 190203201 | 1 |
| Euro OTC | Calcium pantothenate | 1902032-01 | 2 |
| Euro OTC | Calcium pantothenate | 190203202 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Calcium pantothenate | 1902032-02 | 4 |
| Euro OTC | Calcium pantothenate | 2001037-01 | 1 |
| Euro OTC | Calcium pantothenate | 200300701 | 1 |
| Euro OTC | Calcium pantothenate | 2003007-01 | 6 |
| Euro OTC | Calcium pantothenate | 2008019-01 | 8 |
| Euro OTC | Calcium pantothenate | 201037-01 | 1 |
| Euro OTC | Calcium pantothenate | 2101037-01 | 6 |
| Euro OTC | Calcium pantothenate | 2111014-01 | 7 |
| Euro OTC | Calcium pantothenate | 2111014-02 | 1 |
| Euro OTC | Calcium pantothenate | 2301036-01 | 1 |
| Euro OTC | Calcium pantothenate | 5121405 | 1 |
| Euro OTC | Calcium pantothenate | 99142536W0 | 1 |
| Euroo/Anzag | Calcium pantothenate | 1509024-01 | 2 |
| Fagron | Calcium pantothenate | 1111025-01 | 1 |
| Fagron | Calcium pantothenate | 1111110405 | 1 |
| Fagron | Calcium pantothenate | 12F19-N07 | 1 |
| Fagron | Calcium pantothenate | 13H28-N11 | 1 |
| Fagron | Calcium pantothenate | 14G02-B10-297373 | 1 |
| Gehe Pharma Handel | Calcium pantothenate | 22002458006 | 1 |
| Gehe | Calcium pantothenate | 1004024-01 | 1 |
| Nachprüfung | Calcium pantothenate | 123456 | 1 |
| Noweda | Calcium pantothenate | 14208012 | 1 |
| Noweda | Calcium pantothenate | TL017107823 | 1 |
| Sanacorp | Calcium pantothenate | 17335203 | 1 |

- 256 673 spectra from 1666 *Apo-Ident* customers from a total of 52 070 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Calcium pantothenate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Calcium pantothenate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 490 | 0 | 212 450 |
| **Type C** | 0 | 213 | 0 | 256 673 |

The substance/substance group *Calcium pantothenate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7755 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.1831 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)


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In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21233 | 23890 | 20.13 | 60.37 |
| 21243 | 24045 | 15.96 | 58.24 |
| 21765 | 24045 | 11.64 | 58.23 |
| 21901 | 21901 | 0.00 | 59.56 |
| 22551 | 22551 | 0.00 | 35.90 |
| 22691 | 22691 | 0.00 | 40.56 |
| 23153 | 23153 | 0.00 | 59.40 |
| 23890 | 23890 | 0.00 | 59.78 |
| 24045 | 24045 | 0.00 | 55.98 |
| 25296 | 25296 | 0.00 | 63.40 |
| 25592 | 25592 | 0.00 | 48.24 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Camphor, racemic/D-Camphor** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 25048-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Camphor, racemic/D-Camphor; Camphor, racemic; Camphora racemica; D-Camphor; D-Camphora

### Special notes

When selecting the *Camphor, racemic/D-Camphor* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Camphor, racemic/D-Camphor | 10 | 12 | 91 |

### Second-stage model

For differentiation of the substance/substance group *Camphor, racemic/D-Camphor* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Camphor, racemic/D-Camphor* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Spironolactone | 76.78 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Camphor, racemic/D-Camphor* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Camphor, racemic/D-Camphor*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Camphor, racemic | 15316801 | 25049 | 60 | 20151029 |
| Caelo | Camphor, racemic | 170043 | 25051 | 40 | 20170220* |
| Caelo | Camphor, racemic | 192762 | 25562 | 40 | 20200127* |
| Caelo | Camphor, racemic | 21002072014 | 25977 | 40 | 20210817 |
| Euro OTC | Camphor, racemic | 1406029-01 | 25048 | 60 | 20140708 |
| Fagron | Camphor, racemic | 14E19-B07-300365 | 25050 | 60 | 20140527 |
| Fagron | Camphor, racemic | 16E23-B08-336937 | 25053 | 40 | 20160627 |
| Caelo | D-Camphor | 162354 | 24680 | 40 | 20160809* |
| Caelo | D-Camphor | 23000933 | 27262 | 40 | 20230505* |
| Gatt-Koller | D-Camphor | 23J02066 | 27091 | 40 | 20231109 |
| Gatt-Koller | D-Camphor | 23J02066 | 27091SI | 20 | 20231109 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 480 spectra of 11 reference samples from the substance/substance group *Camphor, racemic/D-Camphor*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 846 spectra from a total of 2947 batches from further 495 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 540 spectra of 16 reference samples from the substance/substance group *Camphor, racemic/D-Camphor*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Camphor, racemic | 183279 | 24728 | 40 |
| Caelo | Camphor, racemic | 192454 | 24876 | 40 |
| Caelo | Camphor, racemic | 16209309 | 25052 | 40 |
| Caelo | Camphor, racemic | 172883 | 25054 | 40 |
| Caelo | Camphor, racemic | 180198 | 25055 | 40 |
| Caelo | Camphor, racemic | 21003662 | 25994 | 40 |
| Caelo | Camphor, racemic | 23001930 | 26947 | 40 |
| Caelo | Camphor, racemic | 24001181 | 27259 | 40 |
| Fagron | Camphor, racemic | 21K27-B05-226181 | 26462 | 40 |
| Fagron | Camphor, racemic | 24J30-B01-007663 | 27590 | 40 |
| Gatt-Koller | Camphor, racemic | 21J02080 | 26704 | 40 |
| Caelo | D-Camphor | 190097 | 24681 | 40 |
| Caelo | Camphor, racemic | 21002072014 | 25977SI† | 10 |
| Caelo | Camphor, racemic | 21003662 | 25994SI | 10 |
| Fagron | Camphor, racemic | 21K27-B05-226181 | 26462SI | 20 |
| Caelo | D-Camphor | 23000933 | 27262SI† | 20 |

- 212 400 spectra from a total of 4273 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 435 spectra from 291 *Apo-Ident* customers from 92 batches from the substance/substance group *Camphor, racemic/D-Camphor*.
- Among them are spectra of independent samples from 91 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Camphor, racemic | 16235408 | 1 |
| | Camphor, racemic | 20220617 | 1 |
| | Camphor, racemic | 21000070022 | 1 |
| | Camphor, racemic | 21003662006 | 3 |
| | Camphor, racemic | 21003662010 | 6 |
| | Camphor, racemic | 21003662011 | 1 |
| | Camphor, racemic | 22001161005 | 2 |
| | Camphor, racemic | 22003278003 | 2 |
| | Camphor, racemic | 22003278004 | 3 |
| | Camphor, racemic | 22003278007 | 15 |
| | Camphor, racemic | 22003444004 | 1 |
| | Camphor, racemic | 2203278007 | 1 |
| | Camphor, racemic | 24000001002 | 3 |
| | Camphor, racemic | 2400008010 | 1 |
| | Camphor, racemic | 24000108001 | 9 |
| | Camphor, racemic | 24000108004 | 7 |
| | Camphor, racemic | 24000108010 | 6 |
| | Camphor, racemic | 24000108013 | 2 |
| AEP | Camphor, racemic | 24000108004 | 1 |
| AHD | Camphor, racemic | 192762005 | 1 |
| AHD | Camphor, racemic | 24000108001 | 1 |
| Alliance Healthcare | Camphor, racemic | 18196907 | 2 |
| Alliance Healthcare | Camphor, racemic | 21002072010 | 1 |
| Alliance Healthcare | Camphor, racemic | 22001161003 | 1 |
| Caelo | Camphor, racemic | 17004301 | 1 |
| Caelo | Camphor, racemic | 17050605 | 2 |
| Caelo | Camphor, racemic | 17288306 | 3 |
| Caelo | Camphor, racemic | 17288307 | 2 |
| Caelo | Camphor, racemic | 18019806 | 5 |
| Caelo | Camphor, racemic | 18066404 | 1 |
| Caelo | Camphor, racemic | 18108904 | 1 |
| Caelo | Camphor, racemic | 18196906 | 5 |
| Caelo | Camphor, racemic | 18196907 | 8 |
| Caelo | Camphor, racemic | 183279001 | 1 |
| Caelo | Camphor, racemic | 183279002 | 10 |
| Caelo | Camphor, racemic | 18327901 | 1 |
| Caelo | Camphor, racemic | 18327903 | 5 |
| Caelo | Camphor, racemic | 18327905 | 13 |
| Caelo | Camphor, racemic | 18327909 | 20 |
| Caelo | Camphor, racemic | 18327910 | 1 |
| Caelo | Camphor, racemic | 19009704 | 4 |
| Caelo | Camphor, racemic | 19245003 | 1 |
| Caelo | Camphor, racemic | 192454002 | 1 |
| Caelo | Camphor, racemic | 192454003 | 1 |
| Caelo | Camphor, racemic | 192454004 | 6 |
| Caelo | Camphor, racemic | 192454006 | 9 |
| Caelo | Camphor, racemic | 19262009 | 1 |
| Caelo | Camphor, racemic | 192762002 | 1 |
| Caelo | Camphor, racemic | 192762004 | 3 |
| Caelo | Camphor, racemic | 192762005 | 8 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Camphor, racemic | 192762007 | 2 |
| Caelo | Camphor, racemic | 192762009 | 16 |
| Caelo | Camphor, racemic | 192823001 | 1 |
| Caelo | Camphor, racemic | 192823004 | 1 |
| Caelo | Camphor, racemic | 200003828001 | 1 |
| Caelo | Camphor, racemic | 20003828001 | 10 |
| Caelo | Camphor, racemic | 20003828002 | 3 |
| Caelo | Camphor, racemic | 20003828003 | 1 |
| Caelo | Camphor, racemic | 20003828006 | 3 |
| Caelo | Camphor, racemic | 20004261006 | 6 |
| Caelo | Camphor, racemic | 20004261007 | 3 |
| Caelo | Camphor, racemic | 21000070001 | 1 |
| Caelo | Camphor, racemic | 21000070003 | 1 |
| Caelo | Camphor, racemic | 21000070008 | 1 |
| Caelo | Camphor, racemic | 21000070011 | 1 |
| Caelo | Camphor, racemic | 21000070022 | 1 |
| Caelo | Camphor, racemic | 210020720009 | 1 |
| Caelo | Camphor, racemic | 21002072001 | 5 |
| Caelo | Camphor, racemic | 21002072002 | 10 |
| Caelo | Camphor, racemic | 21002072009 | 5 |
| Caelo | Camphor, racemic | 21002072013 | 1 |
| Caelo | Camphor, racemic | 21002072014 | 9 |
| Caelo | Camphor, racemic | 210020722002 | 1 |
| Caelo | Camphor, racemic | 21003662002 | 8 |
| Caelo | Camphor, racemic | 21003662003 | 1 |
| Caelo | Camphor, racemic | 21003662006 | 9 |
| Caelo | Camphor, racemic | 21003662010 | 6 |
| Caelo | Camphor, racemic | 2102072002 | 1 |
| Caelo | Camphor, racemic | 22003278007 | 1 |
| Caelo | Camphor, racemic | 220927(22001161003) | 1 |
| Caelo | Camphor, racemic | 5218Q-01221 | 1 |
| Caelo | Camphor, racemic | 63(192454004) | 1 |
| Caelo | Camphor, racemic | Caelo | 1 |
| Caelo | Camphor, racemic | Nachreichen | 1 |
| Caesar & Lorenz GmbH | Camphor, racemic | 192762005 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 21002072002 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 18327901 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 21002072002 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 21002072014 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 21003662010 | 1 |
| Caesar & Loretz GmbH/AHD | Camphor, racemic | 21002072014 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 20003828001 | 1 |
| Caesar & Loretz GmbH/Gehe | Camphor, racemic | 183279 | 1 |
| Caesar & Loretz GmbH/Now | Camphor, racemic | 20003828001 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 183279002 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 18327905 | 1 |
| Caesar & Loretz GmbH/Otto | Camphor, racemic | 192762005 | 1 |
| Caesar & Loretz GmbH/Ph | Camphor, racemic | 18327910 | 3 |
| Caesar & Loretz GmbH… | Camphor, racemic | 20004261007 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 192762007 | 1 |
| Caesar & Loretz GmbH/Sa | Camphor, racemic | 18327901 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 18327909 | 1 |
| Caesar & Loretz GmbH… | Camphor, racemic | 21003662010 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 17288306 | 3 |
| Caesar & Loretz GmbH | Camphor, racemic | 18019807 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 18019811 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 18196906 | 2 |
| Caesar & Loretz GmbH | Camphor, racemic | 18196907 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 183279002 | 2 |
| Caesar & Loretz GmbH | Camphor, racemic | 18327903 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Camphor, racemic | 18327905 | 3 |
| Caesar & Loretz GmbH | Camphor, racemic | 18327909 | 5 |
| Caesar & Loretz GmbH | Camphor, racemic | 18327910 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 192454001 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 192454004 | 7 |
| Caesar & Loretz GmbH | Camphor, racemic | 192454006 | 3 |
| Caesar & Loretz GmbH | Camphor, racemic | 192454007 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 192762001 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 192762005 | 2 |
| Caesar & Loretz GmbH | Camphor, racemic | 192762009 | 8 |
| Caesar & Loretz GmbH | Camphor, racemic | 20003828001 | 8 |
| Caesar & Loretz GmbH | Camphor, racemic | 20003828002 | 2 |
| Caesar & Loretz GmbH | Camphor, racemic | 20003828006 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 20004261002 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 20004261005 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 20004261006 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 20004261007 | 2 |
| Caesar & Loretz GmbH | Camphor, racemic | 21002072001 | 2 |
| Caesar & Loretz GmbH | Camphor, racemic | 21002072002 | 2 |
| Caesar & Loretz GmbH | Camphor, racemic | 21002072009 | 4 |
| Caesar & Loretz GmbH | Camphor, racemic | 21002072012 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 21002072013 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 21002072014 | 3 |
| Caesar & Loretz GmbH | Camphor, racemic | 21003662002 | 3 |
| Caesar & Loretz GmbH | Camphor, racemic | 21003662003 | 1 |
| Caesar & Loretz GmbH | Camphor, racemic | 21003662006 | 4 |
| Caesar&Loretz GmbH | Camphor, racemic | 192454004 | 1 |
| Caleo/Phoenix | Camphor, racemic | 21002072009 | 1 |
| campher racemischer | Camphor, racemic | 21003662010 | 1 |
| EuRho/Phönix | Camphor, racemic | 21002072002 | 1 |
| Euro OTC | Camphor, racemic | 1202021 | 1 |
| FIEBIG | Camphor, racemic | 110-01 | 1 |
| Gehe | Camphor, racemic | 21003662010 | 1 |
| Gehe | Camphor, racemic | 22003278007 | 1 |
| Gehe | Camphor, racemic | 24000108001 | 1 |
| Gehe | Camphor, racemic | 240805(22003444004) | 1 |
| Kehr | Camphor, racemic | 21003662006 | 2 |
| Klenk | Camphor, racemic | 444A180815 | 5 |
| Klenk | Camphor, racemic | 444A200110-01 | 1 |
| Noveda | Camphor, racemic | 192762009 | 1 |
| Noweda | Camphor, racemic | 21002072014 | 1 |
| Noweda | Camphor, racemic | 22001161005 | 1 |
| Noweda | Camphor, racemic | 22003278004 | 1 |
| Noweda | Camphor, racemic | 22003278007 | 1 |
| Noweda | Camphor, racemic | 24000108001 | 1 |
| Noweda | Camphor, racemic | 24000108004 | 1 |
| Oriental/Noweda | Camphor, racemic | 102/1819 | 1 |
| Orientel Aromatics | Camphor, racemic | 192762009 | 1 |
| Phoenix | Camphor, racemic | 192762002 | 1 |
| Phönix | Camphor, racemic | 183279002 | 1 |
| Phönix | Camphor, racemic | 21002072002 | 1 |
| Sanacorp | Camphor, racemic | 18327903 | 1 |
| Sanacorp | Camphor, racemic | 21000070026 | 1 |

- 256 451 spectra from 1666 *Apo-Ident* customers from a total of 52 085 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Camphor, racemic/D-Camphor* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Camphor, racemic/D-Camphor* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 540 | 0 | 212 400 |
| **Type C** | 0 | 434 | 1 | 255 722 |

The substance/substance group *Camphor, racemic/D-Camphor* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8889 %) |
| **Type C** | 100.0000 % (> 99.9025 %) | 99.7701 % (> 99.0805 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24680 | 24680 | 0.00 | 171.36 |
| 25048 | 24680 | 11.29 | 171.94 |
| 25049 | 24680 | 11.02 | 171.54 |
| 25050 | 27262 | 9.11 | 171.16 |
| 25051 | 25051 | 0.00 | 169.32 |
| 25053 | 24680 | 10.10 | 170.67 |
| 25562 | 25562 | 0.00 | 169.89 |
| 25977 | 24680 | 35.86 | 163.90 |
| 27091 | 25562 | 19.46 | 170.50 |
| 27262 | 27262 | 0.00 | 168.55 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,

thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cannabidiol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22416-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cannabidiol; Cannabidiolum

### Special notes

When selecting the *Cannabidiol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cannabidiol | 7 | 6 | 298 |

### Second-stage model

For differentiation of the substance/substance group *Cannabidiol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cannabidiol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 78.24 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cannabidiol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cannabidiol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Cannabidiol | 21000530 | 25612 | 40 | 20210218* |
| Caelo | Cannabidiol | 21000530 | 25612SI | 40 | 20210218* |
| Caelo | Cannabidiol | 21003190 | 25995 | 40 | 20211022* |
| Caelo | Cannabidiol | 21003190 | 25995SI | 40 | 20211022* |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22412 | 60 | 1316Q-07806 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22412SI | 60 | 1316Q-07806 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22413 | 60 | 1316Q-07806 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22414 | 60 | 1316Q-07806 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22415 | 60 | 1316Q-07806 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22416 | 60 | 1316Q-07806 |
| THC-Pharma GmbH | Cannabidiol | CBD-API17-003 | 23398 | 40 | 20170609 |
| THC-Pharma GmbH | Cannabidiol | CBD-API17-003 | 23399 | 40 | 20170609 |
| THC-Pharma GmbH | Cannabidiol | CBD-API16-003 | 23464 | 40 | 2017B-03911 |
| THC-Pharma GmbH | Cannabidiol | CBD-API16-004 | 23465 | 40 | 2017A-03911 |
| THC-Pharma GmbH | Cannabidiol | H230.320-1 | 25504 | 40 | 20200806 |
| THC-Pharma GmbH | Cannabidiol | H230.320-1 | 25504SI | 40 | 20200806 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 760 spectra of 16 reference samples from the substance/substance group *Cannabidiol*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 566 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 871 spectra of 20 reference samples from the substance/substance group *Cannabidiol*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| ADREXpharma GmbH | Cannabidiol | 19Y21746 | 26024 | 40 |
| Caelo | Cannabidiol | 21002319 | 25998 | 40 |
| Caelo | Cannabidiol | 22001216 | 26110 | 40 |
| Caelo | Cannabidiol | 23002758005 | 27193 | 40 |
| THC-Pharma GmbH | Cannabidiol | CBDAPI1801 | 23929 | 40 |
| THC-Pharma GmbH | Cannabidiol | H150.920-1 | 25730 | 40 |
| ADREXpharma GmbH | Cannabidiol | 19Y21746 | 26024SI | 40 |
| Caelo | Cannabidiol | 21002319 | 25998SI | 40 |
| Caelo | Cannabidiol | 22001216 | 26110SI | 40 |
| Caelo | Cannabidiol | 23002758005 | 27193SI | 40 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22413SI† | 60 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22414SI† | 60 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22415SI† | 60 |
| THC-Pharma GmbH | Cannabidiol | 15-7221-80338 | 22416SI† | 60 |
| THC-Pharma GmbH | Cannabidiol | CBD-API17-003 | 23398SI† | 40 |
| THC-Pharma GmbH | Cannabidiol | CBD-API17-003 | 23399SI† | 31 |
| THC-Pharma GmbH | Cannabidiol | CBD-API16-003 | 23464SI† | 40 |
| THC-Pharma GmbH | Cannabidiol | CBD-API16-004 | 23465SI† | 40 |
| THC-Pharma GmbH | Cannabidiol | CBDAPI1801 | 23929SI | 40 |
| THC-Pharma GmbH | Cannabidiol | H150.920-1 | 25730SI | 40 |

- 212 069 spectra from a total of 4277 batches from further 872 substances. These spectra were

recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1777 spectra from 193 *Apo-Ident* customers from 328 batches from the substance/substance group *Cannabidiol*.
- Among them are spectra of independent samples from 250 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cannabidiol | | 2 |
| | Cannabidiol | 10300024 | 3 |
| | Cannabidiol | 10C120722-0 | 1 |
| | Cannabidiol | 22001216008 | 3 |
| | Cannabidiol | 23002758009 | 1 |
| | Cannabidiol | 23167A | 1 |
| | Cannabidiol | 23230C | 1 |
| | Cannabidiol | 23231B | 1 |
| | Cannabidiol | 23274B | 1 |
| | Cannabidiol | 23N29251/00210300024 | 1 |
| | Cannabidiol | 23N29251/002-10300024 | 1 |
| | Cannabidiol | 23N29251/003-10300024 | 1 |
| | Cannabidiol | 23N29251/005-10300024 | 1 |
| | Cannabidiol | 23N29251/006-10300024 | 2 |
| | Cannabidiol | 23N29251/10300024 | 2 |
| | Cannabidiol | 23N9251 | 1 |
| | Cannabidiol | 24032A | 1 |
| | Cannabidiol | ACPN920903 | 1 |
| | Cannabidiol | ACPP308901 | 3 |
| | Cannabidiol | ACPT212902 | 1 |
| | Cannabidiol | CA215062024 | 2 |
| | Cannabidiol | CA216062024 | 1 |
| | Cannabidiol | CBD2102A01 | 1 |
| | Cannabidiol | CBD2105A02 | 1 |
| | Cannabidiol | CBDAPI2009 | 3 |
| | Cannabidiol | CBDAPI2102 | 4 |
| | Cannabidiol | CBDAPI2105 | 1 |
| | Cannabidiol | CBO2105A02 | 2 |
| | Cannabidiol | G23ACV-ICS1 | 3 |
| | Cannabidiol | G23ACV-ICS2 | 1 |
| | Cannabidiol | KI0001 | 1 |
| | Cannabidiol | KI0002 | 2 |
| | Cannabidiol | KI0003 | 2 |
| | Cannabidiol | KI0006 | 1 |
| | Cannabidiol | KI0007 | 2 |
| | Cannabidiol | KI0011 | 1 |
| | Cannabidiol | KI0018 | 2 |
| | Cannabidiol | KI0021 | 2 |
| | Cannabidiol | LL130122022 | 2 |
| | Cannabidiol | LL148032023 | 6 |
| | Cannabidiol | LL159052023 | 1 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cannabidiol | LL164062023 | 1 |
| | Cannabidiol | LL165062023 | 1 |
| | Cannabidiol | LL166062023 | 2 |
| | Cannabidiol | LL167062023 | 1 |
| | Cannabidiol | LL172072023 | 1 |
| | Cannabidiol | LL181092023 | 3 |
| | Cannabidiol | LL186102023 | 3 |
| | Cannabidiol | LL198012024 | 1 |
| | Cannabidiol | l174122021 | 1 |
| | Cannabidiol | LL86022022 | 1 |
| Adex Pharma | Cannabidiol | 100493 | 1 |
| Adrex / AH | Cannabidiol | 100492 | 1 |
| Adrex / Alli. HC | Cannabidiol | 100505 | 1 |
| Adrex / Anzag | Cannabidiol | 100493 | 1 |
| Adrex / Gehe | Cannabidiol | 100492 | 1 |
| Adrex / Gehe | Cannabidiol | 100493 | 2 |
| Adrex / Gehe | Cannabidiol | 100505 | 2 |
| Adrex / Gehe | Cannabidiol | 100506 | 1 |
| Adrex / Gehe | Cannabidiol | 19Y21748 | 1 |
| Adrex / Jenne | Cannabidiol | 100504 | 1 |
| Adrex / Jenne | Cannabidiol | 100505 | 1 |
| Adrex / Jenne | Cannabidiol | 19Y21746 | 7 |
| Adrex / Jenne | Cannabidiol | LL118092022 | 1 |
| Adrex / Jenne | Cannabidiol | LL35072021 | 2 |
| Adrex / Jenne | Cannabidiol | LL61102021 | 4 |
| Adrex / Jenne | Cannabidiol | LL75122021 | 1 |
| ADREX / Sana | Cannabidiol | 100441 | 1 |
| ADREX / Sana | Cannabidiol | 100462 | 1 |
| Adrex / Sanacorp | Cannabidiol | 100462 | 1 |
| Adrex /Gehe 07.03.22... | Cannabidiol | LL50092021 | 1 |
| Adrex /Gehe 17.09.21 | Cannabidiol | LL31072021 | 1 |
| Adrex /Phönix 14.03.... | Cannabidiol | LL137022023 | 1 |
| Adrex gEHE | Cannabidiol | 100461 | 1 |
| adrex Gehe | Cannabidiol | 100462 | 1 |
| Adrex pharm | Cannabidiol | 100461 | 2 |
| Adrex pharm | Cannabidiol | 100462 | 2 |
| Adrex pharm | Cannabidiol | 100506 | 1 |
| Adrex Pharm | Cannabidiol | 100506 | 1 |
| Adrex pharm | Cannabidiol | 100578 | 1 |
| adrex pharm | Cannabidiol | 13956-29-1 | 1 |
| Adrex Pharma / AHD 2... | Cannabidiol | 100505 | 1 |
| Adrex Pharma / AHD | Cannabidiol | LL35072021 | 1 |
| Adrex Pharma / Phoenix | Cannabidiol | LL115082022 | 1 |
| Adrex Pharma / Phoenix | Cannabidiol | LL62102021 | 1 |
| Adrex Pharma / Phoenix | Cannabidiol | LL63102021 | 1 |
| Adrex Pharma / Sanacorp | Cannabidiol | 19Y21748 | 2 |
| Adrex Pharma GmbH | Cannabidiol | 100462 | 1 |
| Adrex Pharma GmbH | Cannabidiol | l133072021 | 1 |
| Adrex Pharma GmbH | Cannabidiol | LL33072021 | 1 |
| Adrex Pharma/ Gehe | Cannabidiol | LL50092021 | 1 |
| Adrex Pharma/ Noweda | Cannabidiol | 100506 | 1 |
| Adrex Pharma/ Noweda | Cannabidiol | 19Y21748 | 1 |
| Adrex Pharma/ Phönix | Cannabidiol | 100506 | 1 |
| Adrex Pharma/ Phönix | Cannabidiol | LL63102021 | 1 |
| Adrex Pharma/ Sanacorp | Cannabidiol | 100441 | 2 |
| Adrex Pharma/ Sanacorp | Cannabidiol | 100492 | 2 |
| Adrex Pharma/4 | Cannabidiol | 100442 | 1 |
| Adrex Pharma/AEP | Cannabidiol | 100440 | 1 |
| Adrex Pharma/Jenne | Cannabidiol | LL62102021 | 1 |
| Adrex Pharma/Jenne | Cannabidiol | LL74122021 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Adrex Pharma/Noweda | Cannabidiol | 100442 | 1 |
| Adrex Pharma/Noweda | Cannabidiol | 100462 | 1 |
| Adrex pharma/Sanacorp | Cannabidiol | LL32072021 | 1 |
| adrex Pharma | Cannabidiol | 100442 | 2 |
| ADREX pharma | Cannabidiol | 100460 | 2 |
| Adrex Pharma | Cannabidiol | 100461 | 1 |
| Adrex Pharma | Cannabidiol | 100492 | 2 |
| Adrex Pharma | Cannabidiol | 100505 | 3 |
| adrex pharma | Cannabidiol | 100506 | 1 |
| Adrex pharma | Cannabidiol | 19Y21746 | 4 |
| Adrex Pharma | Cannabidiol | 19Y21746 | 1 |
| Adrex Pharma | Cannabidiol | 19Y21748 | 2 |
| Adrex Pharma | Cannabidiol | LL50092021 | 1 |
| Adrex pharma | Cannabidiol | LL61102021 | 2 |
| Adrex Pharma | Cannabidiol | LL75122021 | 1 |
| ADREX/ Jenne | Cannabidiol | 100504 | 1 |
| Adrex/AEP | Cannabidiol | 100493 | 3 |
| Adrex/AHD | Cannabidiol | LL115082022 | 1 |
| Adrex/AHD | Cannabidiol | LL117092022 | 1 |
| Adrex/AHD | Cannabidiol | LL120102022 | 1 |
| Adrex/AHD | Cannabidiol | LL97042022 | 1 |
| Adrex/Anzag | Cannabidiol | | 1 |
| Adrex/Anzag | Cannabidiol | 10(100492) | 1 |
| Adrex/Anzag | Cannabidiol | 100440 | 1 |
| Adrex/Anzag | Cannabidiol | 11(100492) | 1 |
| Adrex/Anzag | Cannabidiol | 12(100492) | 1 |
| Adrex/Anzag | Cannabidiol | 13(100505) | 1 |
| Adrex/Anzag | Cannabidiol | 14(100492) | 1 |
| Adrex/Anzag | Cannabidiol | 220504(LL61102021) | 1 |
| Adrex/Anzag | Cannabidiol | 230309(LL137022023) | 1 |
| Adrex/Anzag | Cannabidiol | 5(100460) | 1 |
| Adrex/Anzag | Cannabidiol | 6(100441) | 1 |
| Adrex/Anzag | Cannabidiol | 7(100461) | 1 |
| Adrex/Anzag | Cannabidiol | 8(100461) | 1 |
| Adrex/Anzag | Cannabidiol | 9(100461) | 1 |
| Adrex/Gehe | Cannabidiol | 100460 | 4 |
| Adrex/Gehe | Cannabidiol | 100461 | 1 |
| Adrex/Gehe | Cannabidiol | LL110072022 | 2 |
| Adrex/Gehe | Cannabidiol | LL62102021 | 1 |
| Adrex/Gehe | Cannabidiol | LL75122021 | 5 |
| Adrex/Jenne | Cannabidiol | 211020(LL35072021) | 1 |
| Adrex/Jenne | Cannabidiol | 220110(19Y21746) | 1 |
| Adrex/Jenne | Cannabidiol | 220307(LL61102021) | 1 |
| Adrex/Jenne | Cannabidiol | 220428(LL61102021) | 1 |
| Adrex/Jenne | Cannabidiol | 220715(LL97042022) | 1 |
| Adrex/Jenne | Cannabidiol | LL35072021 | 1 |
| Adrex/Noweda 20.10.2021 | Cannabidiol | LL35072021 | 1 |
| Adrex/Noweda | Cannabidiol | 100441 | 2 |
| Adrex/Noweda | Cannabidiol | 100460 | 3 |
| Adrex/Noweda | Cannabidiol | 100461 | 2 |
| Adrex/Noweda | Cannabidiol | 100493 | 1 |
| Adrex/Noweda | Cannabidiol | 100504 | 1 |
| Adrex/Phoenix | Cannabidiol | 100462 | 1 |
| Adrex/Phön 07.11.22 ... | Cannabidiol | LL115082022 | 1 |
| Adrex/Phön 6.01.23 E... | Cannabidiol | LL120102022 | 1 |
| Adrex/Phönix 02.09.2... | Cannabidiol | LL110072022 | 1 |
| Adrex/Phönix 12.07.2... | Cannabidiol | LL97042022 | 1 |
| Adrex/Phönix 17.05.2... | Cannabidiol | LL75122021 | 1 |
| Adrex/Phönix | Cannabidiol | 100493 | 1 |
| Adrex/Phönix | Cannabidiol | 100505 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Adrex/Phönix | Cannabidiol | LL35072021 | 2 |
| Adrex/Phönix | Cannabidiol | LL61102021 | 2 |
| Adrex/Sanacorp | Cannabidiol | 100441 | 1 |
| Adrex | Cannabidiol | 100491 | 1 |
| Adrex | Cannabidiol | 100505 | 1 |
| ADREX | Cannabidiol | 100505 | 1 |
| Adrex | Cannabidiol | 19Y21746 | 2 |
| Adrex | Cannabidiol | LL117092022 | 1 |
| Adrex | Cannabidiol | LL130122022 | 1 |
| Adrex | Cannabidiol | LL35072021 | 1 |
| adrex | Cannabidiol | LL48092021 | 1 |
| adrex | Cannabidiol | LL49092021 | 1 |
| Adrex | Cannabidiol | LL49092021 | 1 |
| Adrex | Cannabidiol | LL61102021 | 2 |
| adrex | Cannabidiol | LL62102021 | 1 |
| Adrex | Cannabidiol | LL63102021 | 1 |
| Adrex | Cannabidiol | LL75122021 | 2 |
| Adrex | Cannabidiol | LL82012022 | 1 |
| adrex | Cannabidiol | l184022022 | 1 |
| Adrexa/Jenne | Cannabidiol | 19Y21746 | 1 |
| Adrexa/Jenne | Cannabidiol | 21000530001 | 4 |
| Adrexa | Cannabidiol | LL48092021 | 6 |
| Adrex-Noweda | Cannabidiol | 100505 | 2 |
| ADREXpharma - Sanacorp | Cannabidiol | 100441 | 1 |
| Adrexpharma / Sanacorp | Cannabidiol | 100461 | 1 |
| ADREXpharma GmbH | Cannabidiol | 100400 | 1 |
| ADREXpharma GmbH | Cannabidiol | 100442 | 1 |
| ADREXpharma GmbH | Cannabidiol | 100462 | 1 |
| ADREXpharma GmbH | Cannabidiol | 100491 | 1 |
| ADREXpharma GmbH | Cannabidiol | 100493 | 2 |
| ADREXpharma GmbH | Cannabidiol | 19Y21746 | 4 |
| adrexpharma GmbH | Cannabidiol | LL114082022 | 1 |
| adrexpharma GmbH | Cannabidiol | LL117092022 | 2 |
| adrexpharma GmbH | Cannabidiol | LL120102022 | 3 |
| adrexpharma GmbH | Cannabidiol | LL129112022 | 2 |
| ADREXpharma GmbH | Cannabidiol | LL32072021 | 1 |
| adrexpharma GmbH | Cannabidiol | LL62102021 | 1 |
| Adrexpharma GmbH | Cannabidiol | LL82012022 | 1 |
| ADREXpharma, Gehe | Cannabidiol | 100491 | 1 |
| ADREXpharma, Gehe | Cannabidiol | LL48092021 | 1 |
| Adrexpharma/ Phoenix | Cannabidiol | LL110072022 | 1 |
| Adrexpharma/ Phoenix | Cannabidiol | LL115082022 | 2 |
| Adrexpharma/ Phoenix | Cannabidiol | LL117092022 | 1 |
| Adrexpharma/ Phoenix | Cannabidiol | LL48092021 | 2 |
| Adrexpharma/ Phoenix | Cannabidiol | LL49092021 | 2 |
| Adrexpharma/ Phoenix | Cannabidiol | LL97042022 | 3 |
| ADREXpharma/ Sanacorp | Cannabidiol | LL32072021 | 1 |
| Adrexpharma/AHD | Cannabidiol | LL97042022 | 6 |
| ADREXpharma/Gehe | Cannabidiol | 100442 | 2 |
| Adrexpharma/Gehe | Cannabidiol | LL97042022 | 2 |
| Adrexpharma/Noweda | Cannabidiol | LL114082022 | 3 |
| Adrexpharma/Noweda | Cannabidiol | LL115082022 | 1 |
| Adrexpharma/Noweda | Cannabidiol | LL118092022 | 1 |
| Adrexpharma/Noweda | Cannabidiol | LL14082022 | 1 |
| Adrexpharma/Noweda | Cannabidiol | LL50092021 | 1 |
| Adrexpharma/Noweda | Cannabidiol | LL62102021 | 3 |
| Adrexpharma/Noweda | Cannabidiol | LL63102021 | 1 |
| Adrexpharma/Noweda | Cannabidiol | LL7092022 | 1 |
| Adrexpharma/Noweda | Cannabidiol | LL75122021 | 2 |
| Adrexpharma | Cannabidiol | 100441 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AdrexPharma | Cannabidiol | 100442 | 7 |
| ADREXpharma | Cannabidiol | 100442 | 5 |
| Adrexpharma | Cannabidiol | 100460 | 1 |
| ADREXPharma | Cannabidiol | 100460 | 1 |
| Adrexpharma | Cannabidiol | 100461 | 1 |
| AdrexPharma | Cannabidiol | 100462 | 1 |
| AdrexPharma | Cannabidiol | 100493 | 1 |
| AdrexPharma | Cannabidiol | 100506 | 10 |
| AdrexPharma | Cannabidiol | 19Y21746 | 12 |
| ADREXpharma | Cannabidiol | 19Y21746 | 2 |
| AdrexPharma | Cannabidiol | 19Y21748 | 13 |
| ADREXpharma | Cannabidiol | 19Y21748 | 2 |
| ADREXpharma | Cannabidiol | 19Y217848 | 1 |
| AdrexPharma | Cannabidiol | LL31072021 | 2 |
| AdrexPharma | Cannabidiol | LL32072021 | 1 |
| AdrexPharma | Cannabidiol | LL33072021 | 1 |
| AdrexPharma | Cannabidiol | LL49092021 | 3 |
| AdrexPharma | Cannabidiol | LL50092021 | 6 |
| Adrexpharma | Cannabidiol | LL62102021 | 1 |
| AEP/Adrexpharma Gmbh | Cannabidiol | 100492 | 1 |
| Alliance Healthcare | Cannabidiol | 100441 | 1 |
| Alliance Healthcare | Cannabidiol | 19Y21748 | 1 |
| Alliance Healthcare | Cannabidiol | 22263A | 1 |
| Alliance Healthcare | Cannabidiol | 22398B | 1 |
| Alliance Healthcare | Cannabidiol | KI0007 | 1 |
| Alliance Healthcare | Cannabidiol | KI0018 | 1 |
| Alliance Healthcare | Cannabidiol | KI0021 | 1 |
| Alliance Healthcare | Cannabidiol | KI0036 | 1 |
| Alliance Healthcare | Cannabidiol | LL32072021 | 1 |
| Alliance Healthcare | Cannabidiol | LL62102021 | 1 |
| Alliance Healthcare | Cannabidiol | LL75122021 | 1 |
| alpha -Cannabis Phar... | Cannabidiol | ACPL418001 | 1 |
| Alpha Cannabis pharm... | Cannabidiol | ACPL418001 | 1 |
| alpha Cannabis/ApoCa... | Cannabidiol | ACPLO09001 | 11 |
| alpha Cannabis/ApoCa... | Cannabidiol | ACPM810901 | 6 |
| Alpha Cannabis/Apoca... | Cannabidiol | ACPL418001 | 1 |
| alpha cannabis | Cannabidiol | ACPL416001 | 1 |
| alpha-cannabis 09.07.20 | Cannabidiol | ACPLO09001P-200709-4 | 1 |
| alpha-cannabis 10.08.20 | Cannabidiol | ACPLO0900P-200810-1 | 1 |
| alpha-cannabis 31.03.20 | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPM810901 | 4 |
| alpha-cannabis Pharm... | Cannabidiol | ACPLO | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPLO09001 | 5 |
| alpha-cannabis Pharm... | Cannabidiol | ACLP416001 | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPK012405 | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPK911004 | 3 |
| alpha-cannabis Pharm... | Cannabidiol | ACPL416001 | 3 |
| alpha-cannabis Pharm... | Cannabidiol | ACPLO09001 | 2 |
| alpha-cannabis Pharm... | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPL418001P190711-1 | 1 |
| alpha-cannabis Pharm... | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPK012405P190430-2 | 1 |
| alpha-cannabis Pharm... | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPK012405P190405-1 | 1 |
| alpha-cannabis Pharm... | Cannabidiol | | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPL418001P-190613-2 | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPK312001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| alpha-cannabis Pharm... | Cannabidiol | ACPK91100P-181220-1 | 1 |
| alpha-cannabis Pharm... | Cannabidiol | ACPL41800P-190527-2 | 1 |
| alpha-cannabis Pharma | Cannabidiol | ACPL416001 | 2 |
| Alpha-Cannabis Pharma | Cannabidiol | ACPN920903 | 2 |
| Alpha-Cannabis Pharma | Cannabidiol | ACPP310901 | 3 |
| Andrex | Cannabidiol | 19y21748 | 1 |
| Anzag/Adrex Pharma | Cannabidiol | 100441 | 5 |
| Anzag/Adrex Pharma | Cannabidiol | 100461 | 8 |
| Anzag/trigal | Cannabidiol | F190205 | 1 |
| Anzag | Cannabidiol | 230517(LL152032023) | 2 |
| Anzag | Cannabidiol | 231109(LL186102023) | 1 |
| Anzag | Cannabidiol | 240704(KI0013) | 1 |
| Apocare Pharma 11.05.20 | Cannabidiol | | 1 |
| Apocare Pharma 15.06.2020 | Cannabidiol | | 1 |
| Apocare Pharma 16.12.19 | Cannabidiol | ACPL009001P-191216-1 | 1 |
| APOCARE Pharma GmbH | Cannabidiol | ACPL416001 | 3 |
| APOCARE Pharma GmbH | Cannabidiol | ACPL418001 | 1 |
| Apocare Pharma | Cannabidiol | | 1 |
| Apocare Pharma | Cannabidiol | ACPK312001 | 2 |
| Apocare Pharma | Cannabidiol | ACPL416001 | 1 |
| Apocare Pharma | Cannabidiol | ACPL418001 | 2 |
| Apocare | Cannabidiol | ACPK312001 | 1 |
| Apocare | Cannabidiol | ACPK911004 | 9 |
| Apocare | Cannabidiol | ACPL418001 | 3 |
| Apocare | Cannabidiol | ACPLO09001 | 1 |
| Ardex / Noweda | Cannabidiol | LL75122021 | 3 |
| Ardex / Noweda | Cannabidiol | LL97042022 | 8 |
| Ardex/Noweda | Cannabidiol | 19Y21746 | 1 |
| Ardrex / Sanacorp | Cannabidiol | 100462 | 2 |
| Arevipharma GmbH/ Phoenix | Cannabidiol | | 3 |
| Arevipharma GmbH/ Phoenix | Cannabidiol | 100505 | 5 |
| Arevipharma GmbH/ Phoenix | Cannabidiol | 19Y21746 | 1 |
| BAFA GmbH | Cannabidiol | | 1 |
| Bombastus | Cannabidiol | | 1 |
| BSPG Lab. Ltd UK/Can... | Cannabidiol | CKB20ICB4TB | 1 |
| BSPG/Pharma line | Cannabidiol | F181001 | 10 |
| BSPG/Trigal Pharm GmbH | Cannabidiol | FB181001 | 10 |
| BSPG | Cannabidiol | F200205 | 1 |
| Caelo | Cannabidiol | | 4 |
| Caelo | Cannabidiol | 110216-02 | 3 |
| Caelo | Cannabidiol | 16992311 | 1 |
| Caelo | Cannabidiol | 21000530001 | 1 |
| Caelo | Cannabidiol | 21001526003 | 3 |
| Caelo | Cannabidiol | 21002318002 | 1 |
| Caelo | Cannabidiol | 21002319002 | 13 |
| Caelo | Cannabidiol | 2100239002 | 1 |
| Caelo | Cannabidiol | 21003190004 | 1 |
| Caelo | Cannabidiol | 22001216003 | 3 |
| Caelo | Cannabidiol | ACPK911004P181203-1 | 1 |
| Caelo | Cannabidiol | CBD-API17-003 | 1 |
| Caelo | Cannabidiol | CBD-API17-006 | 2 |
| Caelo | Cannabidiol | CBDAPI1801 | 2 |
| Caelo | Cannabidiol | CBDAPI1803 | 1 |
| Caelo | Cannabidiol | F190205 | 1 |
| Caesar & Loretz GmbH... | Cannabidiol | LL97042022 | 1 |
| Caesar & Loretz GmbH | Cannabidiol | 21000530001 | 4 |
| Caesar & Loretz GmbH | Cannabidiol | 21000530003 | 1 |
| Caesar & Loretz GmbH | Cannabidiol | 21001526004 | 7 |
| Caesar & Loretz GmbH | Cannabidiol | 21003190001 | 5 |
| Caesar & Loretz GmbH | Cannabidiol | 22001216007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Cannamedical / Phönix | Cannabidiol | CKB20ICB4TB | 2 |
| Cannamedical GmbH | Cannabidiol | CKB20ICB35 | 1 |
| Cannamedical Pharma GmbH | Cannabidiol | ckb20icb35 | 1 |
| Cannamedical Pharma GmbH | Cannabidiol | CKB20ICB35 | 1 |
| Cannamedical Pharma GmbH | Cannabidiol | CKB20ICB4TB | 1 |
| Cannamedical Pharma GmbH | Cannabidiol | CKB20ICCB4TB | 1 |
| Cannamedical Pharma GmbH | Cannabidiol | ckb9icbanc | 1 |
| Cannamedical Pharma | Cannabidiol | CKB9ICBANC | 5 |
| Cannamedical/ Cannam... | Cannabidiol | CKB9ICBANB | 2 |
| Cannamedical | Cannabidiol | CKB20ICB4TB | 2 |
| CannaMedical | Cannabidiol | CMB21ICB08417 | 1 |
| CannAMEDICAL | Cannabidiol | CMB21ICB091432 | 1 |
| Cantourage/Gehe | Cannabidiol | 22020A | 1 |
| Cantourage/Phönix | Cannabidiol | 2021A | 1 |
| Cantourage/Phönix | Cannabidiol | 22012B | 5 |
| Cantourage/Phönix | Cannabidiol | 22020A | 1 |
| Cantourage/Phönix | Cannabidiol | 22021A | 5 |
| Cantourage | Cannabidiol | 22012B | 1 |
| CB21 Pharma /Jenne | Cannabidiol | LL97042022 | 3 |
| CB21 Pharma,s.r.o. | Cannabidiol | LL25032021 | 1 |
| CB21 Pharma | Cannabidiol | LL117092022 | 1 |
| Direkt Apocare Pharma | Cannabidiol | | 1 |
| Euro OTC | Cannabidiol | | 3 |
| Fagron | Cannabidiol | 20C12-F51-381419 | 2 |
| farmako GmbH | Cannabidiol | LL01022020 | 1 |
| Farmako GmbH | Cannabidiol | LL01022020 | 1 |
| farmako Gmbh | Cannabidiol | LL02022020 | 2 |
| Farmbios S.p.A. | Cannabidiol | 100461 | 1 |
| Gehe Rostock | Cannabidiol | 100492 | 2 |
| Gehe, Adrex | Cannabidiol | LL32072021 | 1 |
| Gehe/Adrex 21.1.22 E... | Cannabidiol | LL63102021 | 1 |
| Gehe/Adrex Pharma | Cannabidiol | 19Y21746 | 2 |
| Gehe/Adrex | Cannabidiol | 100440 | 1 |
| Gehe/Arevipharma Gmbh | Cannabidiol | 100505 | 1 |
| Gehe | Cannabidiol | 23230C | 1 |
| Gehe | Cannabidiol | LL148032023 | 1 |
| Gehe | Cannabidiol | LL159052023 | 1 |
| Gehe | Cannabidiol | LL181092023 | 2 |
| Gehe | Cannabidiol | LL48092021 | 1 |
| Gehe | Cannabidiol | LL49092021 | 1 |
| Hempartis | Cannabidiol | AL18120401 | 2 |
| Ichtyolgesellschaft ... | Cannabidiol | CA20190508 | 1 |
| Ilios Sante 01.04.21 | Cannabidiol | LL020222020 | 2 |
| Ilios Sante 2.2.21 | Cannabidiol | LL02022020 | 2 |
| Jenne / Adrex | Cannabidiol | 100505 | 4 |
| Jenne / Adrex | Cannabidiol | 19Y21748 | 4 |
| Jenne / Adrex | Cannabidiol | LL120102022 | 1 |
| Jenne / Adrex | Cannabidiol | LL32072021 | 1 |
| Jenne / Adrex | Cannabidiol | LL50092021 | 1 |
| Jenne / Adrex | Cannabidiol | LL74122021 | 5 |
| Jenne / Trigal Pharma | Cannabidiol | F190205 | 1 |
| Jenne / Trigal Pharma | Cannabidiol | F190703E | 1 |
| Jenne / Trigal Pharma | Cannabidiol | F190704 | 1 |
| Jenne | Cannabidiol | 240514(KI0006) | 1 |
| Jenne | Cannabidiol | ACPN920901 | 1 |
| Krieger am 5.3.und7.... | Cannabidiol | 19Y21746 | 3 |
| Laborchemie APOLDA GmbH | Cannabidiol | APCK312001 | 1 |
| Noweda/Adrex | Cannabidiol | LL82012022 | 2 |
| Noweda/THC Pharm | Cannabidiol | | 2 |
| Noweda | Cannabidiol | 100440 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Cannabidiol | 100505 | 2 |
| Noweda | Cannabidiol | 16013039 | 1 |
| Noweda | Cannabidiol | 23002758006 | 1 |
| Noweda | Cannabidiol | 23002758013 | 2 |
| Noweda | Cannabidiol | LL120102022 | 1 |
| Noweda | Cannabidiol | LL164062023 | 1 |
| Noweda | Cannabidiol | LL181092023 | 1 |
| NOWEDA | Cannabidiol | LL181092023 | 1 |
| Noweda | Cannabidiol | LL62102021 | 1 |
| Noweda | Cannabidiol | LL72112021 | 1 |
| Pharmachem GmbH & Co. KG | Cannabidiol | | 4 |
| Pharmachem GmbH & Co. KG | Cannabidiol | CBDAPI1801 | 2 |
| Phoenix / Adrexpharma | Cannabidiol | LL62102021 | 4 |
| Phoenix / Adrexpharma | Cannabidiol | LL63102021 | 1 |
| Phoenix | Cannabidiol | 10000024 | 1 |
| Phoenix | Cannabidiol | 100300024 | 1 |
| Phoenix | Cannabidiol | 10300024 | 4 |
| Phoenix | Cannabidiol | 10300025 | 1 |
| Phoenix | Cannabidiol | 10300026 | 1 |
| Phoenix | Cannabidiol | 23N29251 | 1 |
| Phoenix | Cannabidiol | 23N29252 | 1 |
| Phoenix | Cannabidiol | LL77122021 | 1 |
| Phönix/THC | Cannabidiol | 1C240220-2 | 1 |
| Phönix | Cannabidiol | | 1 |
| Phönix | Cannabidiol | 19Y21747 | 1 |
| Phönix | Cannabidiol | LL148032023 | 1 |
| Sanacorp Stralsund | Cannabidiol | LL63102021 | 1 |
| Sanacorp/Adrex | Cannabidiol | 100461 | 1 |
| Sanacorp | Cannabidiol | | 16 |
| Sanacorp | Cannabidiol | CBDAPI1804 | 3 |
| Sanum Kehlbeck GmbH | Cannabidiol | 22020A | 3 |
| SANUM-Kehlbeck GmbH&Co.KG | Cannabidiol | 22397A | 1 |
| SANUM-Kehlbeck/AHD | Cannabidiol | 22263A | 3 |
| SANUM-Kehlbeck/AHD | Cannabidiol | 22398B | 4 |
| SANUM-Kehlbeck/Phönix | Cannabidiol | 22262B | 1 |
| Sanum-Kehlbeck | Cannabidiol | 22020A | 1 |
| SolMic / Anzag | Cannabidiol | 3(100440) | 1 |
| SolMic / Anzag | Cannabidiol | 4(100441) | 1 |
| SolMic BioTechGmbH | Cannabidiol | 100492 | 3 |
| Spectrum T / Phönix | Cannabidiol | | 6 |
| Spectrum Therapeutics | Cannabidiol | 10C060421-0 | 3 |
| Spectrum Therapeutics | Cannabidiol | CBD2105A02 | 2 |
| Spectrum Therapeutis... | Cannabidiol | CBD2105A02 | 1 |
| Spectrum Therapeutis... | Cannabidiol | VC2002-007 | 1 |
| Spectrum | Cannabidiol | | 1 |
| Sterling Pharma/ Phoenix | Cannabidiol | LL32072021 | 7 |
| Sterling Pharma | Cannabidiol | LL35072021 | 1 |
| THC Pharm / THC Pharm | Cannabidiol | | 1 |
| THC Pharm GmbH / THC... | Cannabidiol | CBD-API17-005 | 1 |
| THC Pharm GmbH The ... | Cannabidiol | | 4 |
| THC Pharm GmbH/Noweda | Cannabidiol | | 4 |
| THC Pharm GmbH/Noweda | Cannabidiol | 10C080421-3 | 4 |
| THC Pharm GmbH/Noweda | Cannabidiol | 10C090421-2 | 1 |
| THC Pharm GmbH/Noweda | Cannabidiol | 10C150121-1 | 3 |
| THC Pharm GmbH/Noweda | Cannabidiol | 10C150321-1 | 2 |
| THC Pharm GmbH/Noweda | Cannabidiol | 10C150321-2 | 2 |
| THC Pharm GmbH/Noweda | Cannabidiol | 10C150321-3 | 3 |
| THC Pharm GmbH/Phönix | Cannabidiol | | 2 |
| THC Pharm GmbH/Phönix | Cannabidiol | 10C080421-1 | 1 |
| THC Pharm GmbH/Phönix | Cannabidiol | 10C150321-1 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| THC Pharm GmbH/Phönix | Cannabidiol | 10C160321-2 | 1 |
| thc pharm gmbh | Cannabidiol | | 3 |
| THC Pharm GmbH | Cannabidiol | | 89 |
| THC Pharm GmbH | Cannabidiol | 100493 | 1 |
| THC Pharm GmbH | Cannabidiol | 10C041219-0 | 1 |
| THC Pharm GmbH | Cannabidiol | 10C121119-2 | 1 |
| THC Pharm GmbH | Cannabidiol | 10C180520 | 1 |
| THC Pharm GmbH | Cannabidiol | 10C180520-0 | 3 |
| THC Pharm GmbH | Cannabidiol | 1C031219-0 | 5 |
| THC Pharm GmbH | Cannabidiol | CBD-API17-005 | 3 |
| THC Pharm GmbH | Cannabidiol | CBD-API17-006 | 2 |
| THC Pharm GmbH | Cannabidiol | CBDAPI1707 | 2 |
| THC Pharm GmbH | Cannabidiol | CBDAPI1801 | 3 |
| THC Pharm GmbH | Cannabidiol | CBDAPI1802 | 1 |
| THC Pharm GmbH | Cannabidiol | CBDAPI1804 | 2 |
| THC Pharm GmbH | Cannabidiol | CBDAPI1805 | 5 |
| THC Pharm GmbH | Cannabidiol | S20-017 | 1 |
| THC Pharm/ direkt | Cannabidiol | | 8 |
| THC Pharm/ Noweda | Cannabidiol | | 2 |
| THC Pharm/ THC Pharm GmbH | Cannabidiol | | 1 |
| THC Pharm/ THC Pharm | Cannabidiol | | 2 |
| THC Pharm/AHD | Cannabidiol | | 1 |
| THC PHARM/GEHE | Cannabidiol | | 2 |
| THC Pharm/Phönix | Cannabidiol | | 2 |
| THC Pharm/THC Pharma | Cannabidiol | | 1 |
| Thc Pharm | Cannabidiol | | 1 |
| THC Pharm | Cannabidiol | | 111 |
| THC PHARM | Cannabidiol | | 1 |
| THC Pharm | Cannabidiol | 10C140819-1 | 1 |
| THC Pharm | Cannabidiol | 10C170619-1 | 1 |
| THC Pharm | Cannabidiol | CA20190507_01 | 1 |
| THC Pharm | Cannabidiol | CA20190508_01 | 1 |
| THC Pharm | Cannabidiol | CA20190508_02 | 1 |
| THC PHARM | Cannabidiol | CBD2006A01 | 1 |
| THC PHARM | Cannabidiol | CBD2007A03 | 1 |
| THC PHARM | Cannabidiol | CBD2107A02 | 1 |
| THC Pharm | Cannabidiol | CBD-API16-004 | 6 |
| THC Pharm | Cannabidiol | CBD-API17-004 | 1 |
| THC Pharm | Cannabidiol | CBD-API17-006 | 2 |
| THC Pharm | Cannabidiol | CBDAPI1707 | 1 |
| THC Pharm | Cannabidiol | CBDAPI1708 | 2 |
| THC Pharm | Cannabidiol | CBDAPI1802 | 2 |
| THC Pharm | Cannabidiol | CBDAPI1804 | 5 |
| THC Pharm | Cannabidiol | CBDAPI1901 | 1 |
| THC Pharm | Cannabidiol | CBDAPL1802 | 1 |
| THC Pharm | Cannabidiol | H150218-1 | 1 |
| THC Pharma (direkt) | Cannabidiol | | 2 |
| THC Pharma (direkt) | Cannabidiol | CBD-API17-006 | 1 |
| THC Pharma (direkt) | Cannabidiol | CBDAPI1707 | 1 |
| THC Pharma (direkt) | Cannabidiol | CBDAPI1708 | 1 |
| THC Pharma (direkt) | Cannabidiol | CBDAPI1801 | 1 |
| THC Pharma / Cansati... | Cannabidiol | | 5 |
| THC PHARMA GMBH | Cannabidiol | 1C010420-2 | 1 |
| THC Pharma/ Phönix | Cannabidiol | | 13 |
| THC Pharma/ THC Pharma | Cannabidiol | | 1 |
| Thc Pharma/Gehe | Cannabidiol | | 6 |
| THC Pharma/Gehe | Cannabidiol | | 1 |
| THC Pharma/Noweda | Cannabidiol | | 1 |
| THC Pharma/Noweda | Cannabidiol | 10C250220-1 | 1 |
| THC Pharma/Phönix | Cannabidiol | | 26 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| THC Pharma/Phönix | Cannabidiol | 10C010420-2 | 4 |
| THC Pharma/Phönix | Cannabidiol | 10C180520-0 | 1 |
| THC Pharma/Phönix | Cannabidiol | 10C300320-3 | 4 |
| THC Pharma/THC Pharma | Cannabidiol | | 2 |
| THC pharma | Cannabidiol | | 3 |
| THC Pharma | Cannabidiol | | 226 |
| THC Pharma | Cannabidiol | 10C180520-0 | 2 |
| THC Pharma | Cannabidiol | 1C210619-1 | 6 |
| THC Pharma | Cannabidiol | CBD2108A02 | 1 |
| THC Pharma | Cannabidiol | CBDAP/1801 | 1 |
| THC Pharma | Cannabidiol | CBD-API16-004 | 3 |
| THC Pharma | Cannabidiol | CBD-API17-002 | 5 |
| THC Pharma | Cannabidiol | CBD-API17-004 | 9 |
| THC Pharma | Cannabidiol | CBD-API17-005 | 6 |
| THC Pharma | Cannabidiol | CBDAPI1706 | 4 |
| THC Pharma | Cannabidiol | CBDAPI1707 | 2 |
| THC Pharma | Cannabidiol | CBDAPI1802 | 4 |
| THC Pharma | Cannabidiol | CBDAPI1803 | 1 |
| THC Pharma | Cannabidiol | CBDAPI1804 | 6 |
| THC Pharma | Cannabidiol | CBDAPI1901 | 3 |
| THC Pharma | Cannabidiol | CBDAPI2003 | 1 |
| THC Pharma | Cannabidiol | CBDAPI2008 | 1 |
| THC PHRMA | Cannabidiol | | 24 |
| THC PHRMA | Cannabidiol | 1C090519-1 | 1 |
| THC Spectrum | Cannabidiol | | 4 |
| THC/ Direkt | Cannabidiol | CBDAPI1706 | 1 |
| THC/ Phönix | Cannabidiol | | 10 |
| THC/ THC | Cannabidiol | | 2 |
| THC/Gehe | Cannabidiol | CBD-API17-005 | 1 |
| THC/Phönix | Cannabidiol | | 10 |
| THC/THC | Cannabidiol | | 2 |
| THC | Cannabidiol | | 52 |
| THC | Cannabidiol | 10C150321-1 | 1 |
| THC | Cannabidiol | 14295559 | 1 |
| THC | Cannabidiol | CBD-API17-002 | 2 |
| THC | Cannabidiol | CBD-API17-003 | 1 |
| THC | Cannabidiol | CBD-API17-004 | 4 |
| THC | Cannabidiol | CBD-API17-006 | 2 |
| Thcph | Cannabidiol | | 1 |
| THC-Pharm/Phoenix | Cannabidiol | | 1 |
| THC-Pharm | Cannabidiol | | 13 |
| THC-Pharm | Cannabidiol | cbd-adi17-002 | 1 |
| THC-Pharm | Cannabidiol | CBDAP/17-003 | 3 |
| THC-Pharm | Cannabidiol | CBD-API17-004 | 1 |
| THC-Pharm | Cannabidiol | CBD-API17-005 | 1 |
| THC-Pharma GmbH | Cannabidiol | | 10 |
| THC-Pharma | Cannabidiol | | 21 |
| THC-PHARMA | Cannabidiol | | 8 |
| THC-PHARMA | Cannabidiol | 1C140819-0 | 5 |
| THC-Pharma | Cannabidiol | CBDAP/1708 | 1 |
| THC-Pharma | Cannabidiol | CBD-API17-003 | 1 |
| THC-Pharma | Cannabidiol | CBDAPI1708 | 1 |
| THC-Pharma | Cannabidiol | CBDAPI1802 | 1 |
| THC-Pharma | Cannabidiol | CBDAPI1804 | 1 |
| THC-Pharma | Cannabidiol | CBDAPI1904 | 1 |
| TRIGAL Pharma GmbH | Cannabidiol | F200205 | 1 |
| Trigal Pharma | Cannabidiol | F200205 | 1 |
| Trigal/Gehe | Cannabidiol | F190205K | 11 |
| Trigal/Gehe | Cannabidiol | F200205 | 10 |
| Trigal/Gehe | Cannabidiol | F200208 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Trigal/Gehe | Cannabidiol | F200701 | 31 |
| Trigal/Phoenix | Cannabidiol | F190205 | 11 |
| Trigal/Phoenix | Cannabidiol | F190704 | 8 |

- 255 109 spectra from 1666 *Apo-Ident* customers from a total of 51 826 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cannabidiol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cannabidiol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 760 | 0 | 157 566 |
| **Type B** | 0 | 871 | 0 | 212 069 |
| **Type C** | 0 | 1775 | 2 | 255 109 |

The substance/substance group *Cannabidiol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.2105 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3111 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8875 % (> 99.7186 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22412 | 22412 | 0.00 | 99.69 |
| 22413 | 22413 | 0.00 | 99.99 |
| 22414 | 22414 | 0.00 | 100.09 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22415 | 22415 | 0.00 | 100.05 |
| 22416 | 22416 | 0.00 | 99.52 |
| 23398 | 22412 | 6.44 | 100.01 |
| 23399 | 23465 | 7.38 | 100.48 |
| 23464 | 23464 | 0.00 | 101.54 |
| 23465 | 23465 | 0.00 | 98.78 |
| 25504 | 22415 | 8.10 | 100.57 |
| 25612 | 25612 | 0.00 | 102.37 |
| 25995 | 25995 | 0.00 | 102.27 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Capsaicin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20854-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Capsaicin; Capsacinum

### Special notes

When selecting the *Capsaicin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Capsaicin | 6 | 5 | 14 |

### Second-stage model

For differentiation of the substance/substance group *Capsaicin* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Capsaicin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 55.38 | – |
| ⋮ | ⋮ | ⋮ |
| Alfatradiol | >50 | 55.50 |
| Sodium citrate | >50 | 115.77 |
| Levocarnitine | >50 | 229.67 |
| Prednicarbate | >50 | 244.37 |
| Oxybutynin hydrochloride | >50 | 264.21 |
| Tetracaine | >50 | 278.70 |
| Norethisterone acetate | >50 | 361.79 |
| Heparin sodium | >50 | 376.80 |
| Quinine hydrochloride dihydrate | >50 | 388.77 |
| Cyproterone acetate | >50 | 453.51 |
| Pyridoxal-5-phosphate hydrate | >50 | 515.48 |
| Methoxsalen | >50 | 722.21 |
| Ciprofloxacin hydrochloride | >50 | 824.11 |
| Amifampridine | >50 | 904.30 |
| Amitriptyline hydrochloride | >50 | 1014.69 |
| Sucrose | >50 | 1264.61 |
| Triclosan | >50 | 1378.62 |
| Valine | >50 | 1529.72 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Capsaicin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Capsaicin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Capsaicin | 118066-04 | 21638 | 60 | 20140227 |
| Euro OTC | Capsaicin | 1703023 | 23145 | 40 | 20170407* |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Capsaicin | 1811009 | 24331 | 40 | 20181207* |
| Euro OTC | Capsaicin | 2003046 | 25258 | 40 | 20200701* |
| Fagron | Capsaicin | 13D12-N01 | 20854 | 40 | 1411392 |
| Fagron | Capsaicin | 13J07-N07 | 21340 | 40 | AR-15-FG-007151-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 6 reference samples from the substance/substance group *Capsaicin*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.
- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 260 spectra of 7 reference samples from the substance/substance group *Capsaicin*.
- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Capsaicin | 1603005-01 | 22930 | 40 |
| Euro OTC | Capsaicin | 1806013-01 | 24186 | 40 |
| Euro OTC | Capsaicin | 1812015 | 24457 | 40 |
| Euro OTC | Capsaicin | 1903032 | 24638 | 40 |
| Euro OTC | Capsaicin | 2312006 | 27296 | 40 |
| Euro OTC | Capsaicin | 1603005-01 | 22931 | 40 |
| Euro OTC | Capsaicin | 2312006 | 27296SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 680 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 52 spectra from 34 *Apo-Ident* customers from 15 batches from the substance/substance group *Capsaicin*.
- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Capsaicin | 2003046 | 1 |
| | Capsaicin | 2003046-03 | 3 |
| Caelo | Capsaicin | 1603005-01 | 1 |
| Caelo | Capsaicin | 180601301 | 1 |
| EuRho/Alliance Healthcare | Capsaicin | 2003046-02 | 1 |
| EuRho | Capsaicin | 1703023-02 | 1 |
| Euro OTC | Capsaicin | 1401043-02 | 2 |
| Euro OTC | Capsaicin | 1603005-01 | 14 |
| Euro OTC | Capsaicin | 1703023-02 | 1 |
| Euro OTC | Capsaicin | 1703023-025346 | 1 |
| Euro OTC | Capsaicin | 1806013-01 | 2 |
| Euro OTC | Capsaicin | 1812015-01 | 2 |
| Euro OTC | Capsaicin | 1903032-02 | 5 |
| Euro OTC | Capsaicin | 19H029 | 1 |
| Euro OTC | Capsaicin | 2003046-02 | 9 |
| Euro OTC | Capsaicin | I1812015-01 | 1 |
| Euro OTC | Capsaicin | II1812015-01 | 1 |
| Extraktion | Capsaicin | 2003046-02 | 1 |
| Fagron | Capsaicin | CP-12003 | 1 |
| Noweda | Capsaicin | 2003046-02 | 3 |

- 256 834 spectra from 1666 *Apo-Ident* customers from a total of 52 138 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Capsaicin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Capsaicin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 260 | 0 | 212 680 |
| **Type C** | 0 | 51 | 1 | 256 834 |


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The substance/substance group *Capsaicin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6923 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.0769 % (> 92.3077 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20854 | 20854 | 0.00 | 108.28 |
| 21340 | 21340 | 0.00 | 120.37 |
| 21638 | 21340 | 13.97 | 135.46 |
| 23145 | 23145 | 0.00 | 108.67 |
| 24331 | 24331 | 0.00 | 132.17 |
| 25258 | 25258 | 0.00 | 104.79 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Captopril** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20890-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Captopril; Captoprilum

### Special notes

When selecting the *Captopril* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Captopril | 6 | 8 | 194 |

### Second-stage model

For differentiation of the substance/substance group *Captopril* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Captopril* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 69.56 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Captopril* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Captopril*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Captopril | 12339610 | 21064 | 40 | 1403227 |
| Caelo | Captopril | 15189502 | 21874 | 60 | AR-15-FG-014855-01 |
| Caelo | Captopril | 190118 | 24546 | 40 | 20190312* |
| Fagron | Captopril | 12G25-N08 | 20890 | 40 | 20120814 |
| Fagron | Captopril | 14B26-B01-312221 | 21921 | 60 | 20140317 |
| Fagron | Captopril | 19I24-F01-369346 | 25370 | 40 | 20191031 |
| Fagron | Captopril | 19I24-F01-369346 | 25370SI | 40 | 20191031 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 7 reference samples from the substance/substance group *Captopril*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 700 spectra of 17 reference samples from the substance/substance group *Captopril*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Captopril | 170772 | 23366 | 40 |
| Caelo | Captopril | 172102 | 23676 | 40 |
| Caelo | Captopril | 21001156009 | 25932 | 40 |
| Caelo | Captopril | 23002616 | 27225 | 40 |
| Caelo | Captopril | 22004035 | 27229 | 30 |
| Fagron | Captopril | 17G21-B02-337989 | 23588 | 30 |
| Fagron | Captopril | 22C03-B01-220899 | 26380 | 40 |
| Fagron | Captopril | 24A05-B05-010217 | 27641 | 40 |
| Caelo | Captopril | 15189502 | 21874SI† | 60 |
| Caelo | Captopril | 170772 | 23366SI | 40 |
| Caelo | Captopril | 190118 | 24546SI† | 40 |
| Caelo | Captopril | 21001156009 | 25932SI | 40 |
| Caelo | Captopril | 23002616 | 27225SI | 40 |
| Caelo | Captopril | 22004035 | 27229SI | 40 |
| Fagron | Captopril | 14B26-B01-312221 | 21921SI† | 60 |
| Fagron | Captopril | 22C03-B01-220899 | 26380SI | 40 |
| Fagron | Captopril | 24A05-B05-010217 | 27641SI | 40 |

- 212 240 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 758 spectra from 265 *Apo-Ident* customers from 204 batches from the substance/substance group *Captopril*.
- Among them are spectra of independent samples from 193 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Captopril | | 1 |
| | Captopril | 21001156002 | 1 |
| | Captopril | 21003880001 | 2 |
| | Captopril | 21003880005 | 1 |
| | Captopril | 21003880009 | 1 |
| | Captopril | 2100388001 | 1 |
| | Captopril | 21003880010 | 1 |
| | Captopril | 22004035001 | 2 |
| | Captopril | 22004035002 | 22 |
| | Captopril | 22004035003 | 1 |
| | Captopril | 22004035006 | 6 |
| | Captopril | 2204035002 | 1 |
| | Captopril | 22C03-B01 | 1 |
| | Captopril | 22C03-B01-220899 | 1 |
| | Captopril | 22C03-B01-225379 | 1 |
| | Captopril | 22C03-B01-230379 | 1 |
| | Captopril | 23002616001 | 4 |
| | Captopril | 23002616002 | 6 |
| | Captopril | 23002616003 | 2 |
| | Captopril | 23002616005 | 1 |
| | Captopril | 24A05-B05-000792 | 4 |
| | Captopril | EC220112 | 1 |
| AHC | Captopril | 23002616001 | 1 |
| AHD | Captopril | 22004035001 | 1 |
| AHD | Captopril | 22004035003 | 1 |
| AHD | Captopril | 23002616002 | 1 |
| Bombastus | Captopril | 17210202 | 1 |
| Caelo | Captopril | 12339602 | 1 |
| Caelo | Captopril | 12339604 | 2 |
| Caelo | Captopril | 12339605 | 4 |
| Caelo | Captopril | 12339610 | 2 |
| Caelo | Captopril | 12339616 | 2 |
| Caelo | Captopril | 12339617 | 1 |
| Caelo | Captopril | 12339619 | 1 |
| Caelo | Captopril | 12F29-N04 | 1 |
| Caelo | Captopril | 14196901 | 1 |
| Caelo | Captopril | 14196903 | 2 |
| Caelo | Captopril | 14196904 | 8 |
| Caelo | Captopril | 14196905 | 3 |
| Caelo | Captopril | 14B26-B01 | 2 |
| Caelo | Captopril | 14B26-B01-291555 | 1 |
| Caelo | Captopril | 14B26-B01-291557 | 1 |
| Caelo | Captopril | 14B26-B01-310127 | 2 |
| Caelo | Captopril | 14B26-B40 | 1 |
| Caelo | Captopril | 14B26-B40-318894 | 1 |
| Caelo | Captopril | 14B26-B40-320183 | 1 |
| Caelo | Captopril | 14B26-B40-323267 | 2 |
| Caelo | Captopril | 14B26-B40-325275 | 2 |
| Caelo | Captopril | 14B26-B01-310127 | 1 |
| Caelo | Captopril | 15189501 | 6 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Captopril | 15189502 | 1 |
| Caelo | Captopril | 15189503 | 1 |
| Caelo | Captopril | 15189504 | 1 |
| Caelo | Captopril | 15189509 | 3 |
| Caelo | Captopril | 15189510 | 2 |
| Caelo | Captopril | 15189511 | 5 |
| Caelo | Captopril | 15189512 | 12 |
| Caelo | Captopril | 15189514 | 6 |
| Caelo | Captopril | 15189514I-041016 | 1 |
| Caelo | Captopril | 15189514I-041016-2 | 1 |
| Caelo | Captopril | 15189515 | 3 |
| Caelo | Captopril | 15189517 | 5 |
| Caelo | Captopril | 15189519 | 2 |
| Caelo | Captopril | 15189521 | 5 |
| Caelo | Captopril | 15189524 | 2 |
| Caelo | Captopril | 15189525 | 2 |
| Caelo | Captopril | 15189526 | 2 |
| Caelo | Captopril | 1519521 | 1 |
| Caelo | Captopril | 16B26-B01310127 | 1 |
| Caelo | Captopril | 17077201 | 5 |
| Caelo | Captopril | 17077202 | 4 |
| Caelo | Captopril | 17077203 | 1 |
| Caelo | Captopril | 17077205 | 1 |
| Caelo | Captopril | 17077206 | 1 |
| Caelo | Captopril | 17077208 | 8 |
| Caelo | Captopril | 17077209 | 18 |
| Caelo | Captopril | 1718A-03358 | 1 |
| Caelo | Captopril | 17210201 | 6 |
| Caelo | Captopril | 17210202 | 16 |
| Caelo | Captopril | 17210203 | 1 |
| Caelo | Captopril | 17210204 | 5 |
| Caelo | Captopril | 17210205 | 10 |
| Caelo | Captopril | 17G27-B02 | 3 |
| Caelo | Captopril | 17G27-B02-340798 | 1 |
| Caelo | Captopril | 17G27-B02-342412 | 1 |
| Caelo | Captopril | 17G27-B02-354613 | 1 |
| Caelo | Captopril | 1805005 | 1 |
| Caelo | Captopril | 18058001 | 1 |
| Caelo | Captopril | 18058002 | 8 |
| Caelo | Captopril | 18058003 | 1 |
| Caelo | Captopril | 18058004 | 6 |
| Caelo | Captopril | 18058005 | 10 |
| Caelo | Captopril | 18058006 | 3 |
| Caelo | Captopril | 18058007 | 2 |
| Caelo | Captopril | 18058009 | 1 |
| Caelo | Captopril | 18058010 | 2 |
| Caelo | Captopril | 19000652002 | 6 |
| Caelo | Captopril | 190006520020 | 1 |
| Caelo | Captopril | 19000652004 | 9 |
| Caelo | Captopril | 19000652005 | 23 |
| Caelo | Captopril | 190115001 | 1 |
| Caelo | Captopril | 190118001 | 5 |
| Caelo | Captopril | 19011801 | 7 |
| Caelo | Captopril | 19011802 | 4 |
| Caelo | Captopril | 19011803 | 2 |
| Caelo | Captopril | 19011805 | 3 |
| Caelo | Captopril | 19011806 | 4 |
| Caelo | Captopril | 19011807 | 10 |
| Caelo | Captopril | 21000272002 | 4 |
| Caelo | Captopril | 210003880001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Captopril | 21001156001 | 4 |
| Caelo | Captopril | 21001156002 | 15 |
| Caelo | Captopril | 21001156003 | 1 |
| Caelo | Captopril | 21001156005 | 4 |
| Caelo | Captopril | 21001156006 | 1 |
| Caelo | Captopril | 21001156007 | 5 |
| Caelo | Captopril | 21001156009 | 10 |
| Caelo | Captopril | 21001156010 | 3 |
| Caelo | Captopril | 21003880001 | 12 |
| Caelo | Captopril | 21003880002 | 2 |
| Caelo | Captopril | 21003880005 | 2 |
| Caelo | Captopril | 21003880006 | 10 |
| Caelo | Captopril | 21003880007 | 2 |
| Caelo | Captopril | 21003880009 | 3 |
| Caelo | Captopril | 21003880010 | 2 |
| Caelo | Captopril | 21003880011 | 2 |
| Caelo | Captopril | 2100388006 | 1 |
| Caelo | Captopril | 2100388009 | 1 |
| Caelo | Captopril | 210038807 | 1 |
| Caelo | Captopril | 22004035001 | 1 |
| Caelo | Captopril | 23002616002 | 1 |
| Caelo | Captopril | 3425007 | 1 |
| Caelo | Captopril | 5102-14-042 | 1 |
| Caelo | Captopril | 901180021 | 1 |
| Caeol/ Noweda | Captopril | 15189519 | 1 |
| Caeol/ Noweda | Captopril | 17077202 | 1 |
| Caesar & Loretz GmbH... | Captopril | 19000652002 | 1 |
| Caesar & Loretz GmbH... | Captopril | 19011802 | 1 |
| Caesar & Loretz GmbH/AHD | Captopril | 21001156002 | 1 |
| Caesar & Loretz GmbH/Gehe | Captopril | 19011805 | 1 |
| Caesar & Loretz GmbH/Gehe | Captopril | 21001156003 | 1 |
| Caesar & Loretz GmbH... | Captopril | 19000652002 | 1 |
| Caesar & Loretz GmbH... | Captopril | 21000272002 | 2 |
| Caesar & Loretz GmbH... | Captopril | 190118002 | 1 |
| Caesar & Loretz GmbH/Kehr | Captopril | 21003880007 | 1 |
| Caesar & Loretz GmbH/L10 | Captopril | 21003880002 | 3 |
| Caesar & Loretz GmbH... | Captopril | 21001156002 | 1 |
| Caesar & Loretz GmbH... | Captopril | 19000652002 | 1 |
| Caesar & Loretz GmbH... | Captopril | 190118001 | 3 |
| Caesar & Loretz GmbH... | Captopril | 21001156006 | 1 |
| Caesar & Loretz GmbH | Captopril | 18058002 | 1 |
| Caesar & Loretz GmbH | Captopril | 18058006 | 1 |
| Caesar & Loretz GmbH | Captopril | 19000652004 | 1 |
| Caesar & Loretz GmbH | Captopril | 19000652005 | 5 |
| Caesar & Loretz GmbH | Captopril | 19011801 | 1 |
| Caesar & Loretz GmbH | Captopril | 19011802 | 1 |
| Caesar & Loretz GmbH | Captopril | 19011805 | 2 |
| Caesar & Loretz GmbH | Captopril | 19011807 | 1 |
| Caesar & Loretz GmbH | Captopril | 21000272002 | 1 |
| Caesar & Loretz GmbH | Captopril | 21001156002 | 2 |
| Caesar & Loretz GmbH | Captopril | 21001156003 | 4 |
| Caesar & Loretz GmbH | Captopril | 21001156005 | 1 |
| Caesar & Loretz GmbH | Captopril | 21001156007 | 3 |
| Caesar & Loretz GmbH | Captopril | 21001156009 | 3 |
| Caesar & Loretz GmbH | Captopril | 21001156010 | 2 |
| Caesar & Loretz GmbH | Captopril | 21003880001 | 4 |
| Caesar & Loretz GmbH | Captopril | 21003880005 | 2 |
| Caesar & Loretz GmbH | Captopril | 21003880006 | 6 |
| Caesar & Loretz GmbH | Captopril | 21003880007 | 2 |
| Caesar & Loretz GmbH... | Captopril | 19000652005 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz | Captopril | 21001156002 | 1 |
| Caesar&Loretz | Captopril | 17210201 | 1 |
| Cealo/Sanacorp | Captopril | 12339617 | 1 |
| Cealo | Captopril | 19000652005 | 2 |
| Changzhou Pharmaceutical | Captopril | 14B26-B40-321319 | 1 |
| Euro OTC | Captopril | 14B26-B40-320183 | 1 |
| Euro OTC | Captopril | 15189507 | 3 |
| Euro OTC | Captopril | 17210204 | 1 |
| Euro OTC | Captopril | 18058003 | 1 |
| Euroct/Gehe | Captopril | 14B26-B40-320183 | 1 |
| Fagron | Captopril | | 1 |
| Fagron | Captopril | 12G25-N08 | 4 |
| Fagron | Captopril | 12K16-N04 | 1 |
| Fagron | Captopril | 12K-16N04 | 1 |
| Fagron | Captopril | 1369240 | 1 |
| Fagron | Captopril | 14196902 | 1 |
| Fagron | Captopril | 14B26B01 | 1 |
| Fagron | Captopril | 14B26-B01 | 4 |
| Fagron | Captopril | 14B26-B01_2911557 | 1 |
| Fagron | Captopril | 14B26-B01_302338 | 1 |
| Fagron | Captopril | 14B26-B01-291555 | 3 |
| Fagron | Captopril | 14B26-B01-291556 | 3 |
| Fagron | Captopril | 14B26-B01-291557 | 7 |
| Fagron | Captopril | 14B26-B01-302337 | 1 |
| Fagron | Captopril | 14B26-B01-302338 | 4 |
| Fagron | Captopril | 14B26-B01-310127 | 6 |
| Fagron | Captopril | 14B26-B01-312221 | 1 |
| Fagron | Captopril | 14B26-B01-314460 | 1 |
| Fagron | Captopril | 14B26-B01-316257 | 2 |
| Fagron | Captopril | 14B26-B40-318894 | 5 |
| Fagron | Captopril | 14B26-B40-320183 | 6 |
| Fagron | Captopril | 14B26-B40-321319 | 5 |
| Fagron | Captopril | 14B26B40323267 | 1 |
| Fagron | Captopril | 14B26-B40-323267 | 3 |
| Fagron | Captopril | 14B26-B40-325275 | 3 |
| Fagron | Captopril | 14B26-W0129-1557 | 1 |
| Fagron | Captopril | 17g27-b02-337989 | 1 |
| Fagron | Captopril | 17G27-B02-337989 | 5 |
| Fagron | Captopril | 17G27-B02-340789 | 1 |
| Fagron | Captopril | 17G27-B02-340798 | 2 |
| Fagron | Captopril | 17G27-B02-346203 | 2 |
| Fagron | Captopril | 17G27-B02-350227 | 1 |
| Fagron | Captopril | 17G27-B02-350997 | 1 |
| Fagron | Captopril | 17G27-B02-352730 | 2 |
| Fagron | Captopril | 17G27-B02-356147 | 6 |
| Fagron | Captopril | 17G-B02-352730 | 1 |
| Fagron | Captopril | 19/24-F01 | 1 |
| Fagron | Captopril | 19/24-F01-365391 | 1 |
| Fagron | Captopril | 19/24-F01-367084 | 1 |
| Fagron | Captopril | 19/24-F01-369346 | 1 |
| Fagron | Captopril | 19/24-FO1-367389 | 1 |
| Fagron | Captopril | 19124-F01-3692400 | 1 |
| Fagron | Captopril | 1924-f01-365391 | 1 |
| Fagron | Captopril | 1924-F01-367389 | 1 |
| Fagron | Captopril | 1924FO1365391 | 1 |
| Fagron | Captopril | 19I24-F01-365390 | 2 |
| Fagron | Captopril | 19I24-F01-365391 | 5 |
| Fagron | Captopril | 19I24-F01-367084 | 1 |
| Fagron | Captopril | 19I24-F01-367389 | 1 |
| Fagron | Captopril | 19I24-F01-369240 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Captopril | 19I24-F01-369345 | 1 |
| Fagron | Captopril | 19I24-F01-369346 | 3 |
| Fagron | Captopril | 19I24-F01-365391 | 2 |
| Fagron | Captopril | 19l24-F01365391 | 1 |
| Fagron | Captopril | 21/15-B05-2136403 | 1 |
| Fagron | Captopril | 21/15-B05-213643 | 6 |
| Fagron | Captopril | 2115_b05_213643 | 1 |
| Fagron | Captopril | 21I15-B05-213643 | 4 |
| Fagron | Captopril | 21l15-B05-213643 | 1 |
| Fagron | Captopril | 22003-B01-220899 | 1 |
| Fagron | Captopril | 22C03-B01 | 2 |
| Fagron | Captopril | 22C03-B01-220899 | 1 |
| Fagron | Captopril | 22C03-B01-230379 | 1 |
| Fagron | Captopril | 22C03-B01-234634 | 2 |
| Fagron | Captopril | 22c03-B01-225379 | 1 |
| Fagron | Captopril | 700766 | 1 |
| Fagron | Captopril | 80616-6 | 1 |
| Fagron | Captopril | EC140101 | 1 |
| Fagron | Captopril | EC170110 | 4 |
| Fagron | Captopril | EC18019 | 1 |
| Fagron | Captopril | EC181019 | 1 |
| Fagron | Captopril | EC220112 | 1 |
| Fagron | Captopril | F01-3653901 | 1 |
| Fagron | Captopril | F01-3673809 | 2 |
| Fagron | Captopril | F01-3692400 | 1 |
| Fagron | Captopril | F01-3693406 | 1 |
| Fagrron | Captopril | 14B26-B01-310127 | 2 |
| GEHE | Captopril | 17077209 | 1 |
| GEHE | Captopril | 17210203 | 1 |
| Gehe | Captopril | 18058002 | 1 |
| GEHE | Captopril | 18058003 | 1 |
| Gehe | Captopril | 18058004 | 2 |
| Gehe | Captopril | 18058010 | 1 |
| Gehe | Captopril | 19011805 | 2 |
| Gehe | Captopril | 21003880009 | 1 |
| Gehe | Captopril | 22C03-B01-234634 | 1 |
| Gehe | Captopril | 23002616003 | 1 |
| gepepharm GmbH | Captopril | 21003880007 | 1 |
| Hedinger | Captopril | 14B26-B40 | 2 |
| Herstellung | Captopril | 12339607 | 1 |
| Holdermann | Captopril | 22004035002 | 1 |
| Kehr | Captopril | 21003880010 | 1 |
| Kehr | Captopril | 22004035002 | 3 |
| Klosterring | Captopril | 17G27-B02-340471 | 1 |
| L12 | Captopril | 17077202 | 2 |
| Noweda | Captopril | 17210202 | 1 |
| Noweda | Captopril | 19011806 | 1 |
| Noweda | Captopril | 21001156009 | 1 |
| Noweda | Captopril | 210388010 | 1 |
| Noweda | Captopril | 22004035001 | 1 |
| Noweda | Captopril | 22004035003 | 1 |
| Noweda | Captopril | 220040358001 | 1 |
| Noweda | Captopril | 22C03-B01-230279 | 1 |
| Phoenix | Captopril | 22004035002 | 1 |
| Phonix | Captopril | 14B26-B01 | 1 |
| PHÖNIX | Captopril | 17g27-b02 | 1 |
| PHÖNIX | Captopril | 17G27-B02-354613 | 1 |
| PHÖNIX | Captopril | 17g27b02356147 | 1 |
| Phönix | Captopril | 18058002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Captopril | 190118001 | 2 |
| PHÖNIX | Captopril | 19124-f01-367389 | 1 |
| PHÖNIX | Captopril | 19124-f01-369346 | 2 |
| PHÖNIX | Captopril | 19124-f01-63946 | 1 |
| Phönix | Captopril | 2100156002 | 1 |
| Phönix | Captopril | 21003880009 | 3 |
| Phönix | Captopril | 22004035002 | 1 |
| Sanacorp | Captopril | 17077202 | 1 |
| Sanacorp | Captopril | 17077205 | 1 |
| Sanacorp | Captopril | 17210202 | 1 |
| Sanacorp | Captopril | 17G27B02 | 1 |
| Sanacorp | Captopril | 17G27B02356147 | 1 |
| Sanacorp | Captopril | 17G27-B02-356147 | 2 |
| Sanacorp | Captopril | 18058004 | 2 |
| Sanacorp | Captopril | 19/24-F01 | 1 |
| Sanacorp | Captopril | 19011805 | 1 |
| Sanacorp | Captopril | 19011806 | 1 |
| Sanacorp | Captopril | 191124-F01-0001 | 1 |
| Sanacorp | Captopril | 19124-F01-365391 | 1 |
| Sanacorp | Captopril | 19124-F01-367389 | 3 |
| Sanacorp | Captopril | EC181019 | 1 |
| THC Pharma | Captopril | 18058002 | 1 |

- 256 128 spectra from 1666 *Apo-Ident* customers from a total of 51 953 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Captopril* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Captopril* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 700 | 0 | 212 240 |
| **Type C** | 0 | 749 | 9 | 256 128 |

The substance/substance group *Captopril* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.1429 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8127 % (> 98.4169 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to

exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20890 | 21064 | 6.43 | 148.81 |
| 21064 | 21064 | 0.00 | 148.57 |
| 21874 | 21874 | 0.00 | 147.36 |
| 21921 | 21874 | 10.51 | 150.43 |
| 24546 | 24546 | 0.00 | 146.17 |
| 25370 | 24546 | 5.39 | 147.45 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Carbomers** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20548-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Carbomers; Carbomera

### Special notes

When selecting the *Carbomers* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Carbomers | 12 | 24 | 214 |

### Second-stage model

For differentiation of the substance/substance group *Carbomers* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Carbomers* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 43.57 | – |
| Riboflavin sodium phosphate hydrate | 46.64 | 42.34 |
| Cannabis flower, CBD-dominant type | 48.97 | – |
| Silver protein | 69.81 | – |
| ⋮ | ⋮ | ⋮ |
| Mg-Ca-K colamine phosphate | >50 | 91.26 |
| Magnesium citrate | >50 | 114.51 |
| Gentamicin sulfate | >50 | 409.06 |
| Tobramycin sulfate | >50 | 494.34 |
| Finasteride | >50 | 510.80 |
| Neomycin sulfate | >50 | 596.82 |
| Zinc gluconate | >50 | 936.46 |
| Sodium tetraborate | >50 | 1044.31 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Carbomers* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Carbomers*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Carbomers | 13135601 | 20978 | 40 | 1403767 |
| Caelo | Carbomers | 13186207 | 20979 | 40 | 1403768 |
| Caelo | Carbomers | 14057902 | 21354 | 40 | 20140228 |
| Caelo | Carbomers | 14057903 | 21557 | 60 | 20140228 |
| Caelo | Carbomers | 162530 | 22759 | 40 | 20161011* |
| Caelo | Carbomers | 21001724 | 25809 | 50 | 20210831* |
| Caelo | Carbomers | 24000748 | 27218 | 40 | 20240419* |
| Euro OTC | Carbomers | 1311027-02 | 21561 | 60 | 20131205 |
| Euro OTC | Carbomers | 1512010 | 22250 | 60 | 20151216* |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Carbomers | 1604032 | 22548 | 40 | 20160428* |
| Euro OTC | Carbomers | 1607028 | 22686 | 40 | 20160804* |
| Euro OTC | Carbomers | 1610024 | 22852 | 40 | 20161102* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 550 spectra of 12 reference samples from the substance/substance group *Carbomers*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.
- 157 776 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1080 spectra of 29 reference samples from the substance/substance group *Carbomers*.
- Among them are spectra of independent samples from 24 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Carbomers | 172520 | 23621 | 40 |
| Caelo | Carbomers | 173614 | 23783 | 40 |
| Caelo | Carbomers | 180924 | 24250 | 40 |
| Caelo | Carbomers | 183074 | 24543 | 40 |
| Caelo | Carbomers | 190245 | 24565 | 40 |
| Caelo | Carbomers | 20001190 | 25227 | 40 |
| Caelo | Carbomers | 21002358 | 25808 | 50 |
| Caelo | Carbomers | 22002190 | 26506 | 40 |
| Caelo | Carbomers | 24000213 | 27227 | 40 |
| Caelo | Carbomers | 25001010 | 27658 | 40 |
| Euro OTC | Carbomers | 1702012 | 23139 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Carbomers | 1706015 | 23534 | 40 |
| Euro OTC | Carbomers | 1801044 | 23959 | 40 |
| Euro OTC | Carbomers | 1810019 | 24315 | 40 |
| Euro OTC | Carbomers | 1903007 | 24468 | 40 |
| Euro OTC | Carbomers | 1908029 | 24858 | 40 |
| Euro OTC | Carbomers | 2003049 | 25124 | 40 |
| Euro OTC | Carbomers | 2104007 | 25669 | 40 |
| Euro OTC | Carbomers | 2112003 | 25915 | 40 |
| Euro OTC | Carbomers | 2203009 | 26092 | 40 |
| Euro OTC | Carbomers | 2206008 | 26195 | 40 |
| Euro OTC | Carbomers | 2302002 | 26579 | 40 |
| Euro OTC | Carbomers | 2310006 | 27010 | 40 |
| Euro OTC | Carbomers | 2403011 | 27200 | 40 |
| Caelo | Carbomers | 24000748 | 27243 | 40 |
| Euro OTC | Carbomers | 2112003 | 25915SI | 10 |
| Euro OTC | Carbomers | 2203009 | 26092SI | 20 |
| Euro OTC | Carbomers | 2206008 | 26195SI | 20 |
| Euro OTC | Carbomers | 2302002 | 26579SI | 20 |

- 211 860 spectra from a total of 4262 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1073 spectra from 620 *Apo-Ident* customers from 220 batches from the substance/substance group *Carbomers*.

- Among them are spectra of independent samples from 213 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Carbomers | 22002190002 | 3 |
| | Carbomers | 22002190003 | 11 |
| | Carbomers | 2202190003 | 1 |
| | Carbomers | 2206008-01 | 1 |
| | Carbomers | 23000179002 | 1 |
| | Carbomers | 23000625003 | 9 |
| | Carbomers | 23000625005 | 1 |
| | Carbomers | 23002015002 | 8 |
| | Carbomers | 23002015003 | 1 |
| | Carbomers | 23002015004 | 12 |
| | Carbomers | 2302002-01 | 4 |
| | Carbomers | 24000213002 | 1 |
| | Carbomers | 24000748001 | 7 |
| | Carbomers | 24000748006 | 2 |
| | Carbomers | 24000748009 | 1 |
| | Carbomers | 24002320003 | 2 |
| | Carbomers | 2403011-11 | 1 |
| Alliance H. | Carbomers | 1512010-01 | 1 |
| Alliance Healthcare | Carbomers | 21001724008 | 1 |
| Alliance | Carbomers | 22002190003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag | Carbomers | 23000625003 | 1 |
| Anzag | Carbomers | 240206(23002015002) | 1 |
| apo ident | Carbomers | 2003049-01 | 1 |
| Bombastus | Carbomers | 18092401 | 1 |
| Bombastus | Carbomers | 22002190003 | 1 |
| Caeli/sana | Carbomers | 21003605001 | 1 |
| Caelo | Carbomers | 10003550042 | 1 |
| Caelo | Carbomers | 1081702 | 1 |
| Caelo | Carbomers | 11013605 | 2 |
| Caelo | Carbomers | 1117I-01232 | 1 |
| Caelo | Carbomers | 11307511 | 1 |
| Caelo | Carbomers | 11351604 | 1 |
| Caelo | Carbomers | 11351605 | 3 |
| Caelo | Carbomers | 11351618 | 3 |
| Caelo | Carbomers | 11351623 | 1 |
| Caelo | Carbomers | 11676321 | 1 |
| Caelo | Carbomers | 12274907 | 7 |
| Caelo | Carbomers | 12274908 | 4 |
| Caelo | Carbomers | 12274910 | 1 |
| Caelo | Carbomers | 12274912 | 5 |
| Caelo | Carbomers | 12274914 | 3 |
| Caelo | Carbomers | 12274916 | 8 |
| Caelo | Carbomers | 12274922 | 1 |
| Caelo | Carbomers | 1311027-02 | 1 |
| Caelo | Carbomers | 13186201 | 2 |
| Caelo | Carbomers | 13186203 | 3 |
| Caelo | Carbomers | 13186205 | 6 |
| Caelo | Carbomers | 13186207 | 1 |
| Caelo | Carbomers | 13194501 | 5 |
| Caelo | Carbomers | 13194503 | 7 |
| Caelo | Carbomers | 13194505 | 2 |
| Caelo | Carbomers | 13194507 | 4 |
| Caelo | Carbomers | 13194511 | 1 |
| Caelo | Carbomers | 13194512 | 1 |
| Caelo | Carbomers | 14016208 | 7 |
| Caelo | Carbomers | 14016209 | 1 |
| Caelo | Carbomers | 14057902 | 2 |
| Caelo | Carbomers | 14057903 | 2 |
| Caelo | Carbomers | 1410001-02 | 1 |
| Caelo | Carbomers | 14149904 | 2 |
| Caelo | Carbomers | 14149905 | 1 |
| Caelo | Carbomers | 14149906 | 4 |
| Caelo | Carbomers | 14149910 | 2 |
| Caelo | Carbomers | 14149911 | 2 |
| Caelo | Carbomers | 15015702 | 1 |
| Caelo | Carbomers | 15015703 | 1 |
| Caelo | Carbomers | 15015709 | 2 |
| Caelo | Carbomers | 15101801 | 5 |
| Caelo | Carbomers | 15101802 | 6 |
| Caelo | Carbomers | 15101807 | 3 |
| Caelo | Carbomers | 15101809 | 4 |
| Caelo | Carbomers | 15101810 | 5 |
| Caelo | Carbomers | 1510801 | 1 |
| Caelo | Carbomers | 15257401 | 1 |
| Caelo | Carbomers | 15257403 | 1 |
| Caelo | Carbomers | 154390002 | 1 |
| Caelo | Carbomers | 15439002 | 12 |
| Caelo | Carbomers | 15439003 | 11 |
| Caelo | Carbomers | 15439004 | 1 |
| Caelo | Carbomers | 1604032-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Carbomers | 1607028-01 | 1 |
| Caelo | Carbomers | 1610024-01 | 1 |
| Caelo | Carbomers | 162375 | 1 |
| Caelo | Carbomers | 16237501 | 1 |
| Caelo | Carbomers | 162530 | 1 |
| Caelo | Carbomers | 16253001 | 2 |
| Caelo | Carbomers | 16253002 | 1 |
| Caelo | Carbomers | 16253003 | 1 |
| Caelo | Carbomers | 16253004 | 10 |
| Caelo | Carbomers | 16253005 | 6 |
| Caelo | Carbomers | 16253007 | 10 |
| Caelo | Carbomers | 16253009 | 13 |
| Caelo | Carbomers | 16253011 | 1 |
| Caelo | Carbomers | 16253012 | 7 |
| Caelo | Carbomers | 16253014 | 5 |
| Caelo | Carbomers | 17053182 | 1 |
| Caelo | Carbomers | 1706015-01 | 1 |
| Caelo | Carbomers | 17146501 | 2 |
| Caelo | Carbomers | 17361402 | 11 |
| Caelo | Carbomers | 17361403 | 5 |
| Caelo | Carbomers | 1801044-01 | 2 |
| Caelo | Carbomers | 18049301 | 1 |
| Caelo | Carbomers | 18049304 | 1 |
| Caelo | Carbomers | 180924006 | 1 |
| Caelo | Carbomers | 18092401 | 37 |
| Caelo | Carbomers | 18092402 | 4 |
| Caelo | Carbomers | 18092403 | 1 |
| Caelo | Carbomers | 18092405 | 21 |
| Caelo | Carbomers | 18092406 | 2 |
| Caelo | Carbomers | 18092408 | 12 |
| Caelo | Carbomers | 18092411 | 2 |
| Caelo | Carbomers | 18092412 | 2 |
| Caelo | Carbomers | 1810024-01 | 1 |
| Caelo | Carbomers | 181016184 | 1 |
| Caelo | Carbomers | 18307401 | 18 |
| Caelo | Carbomers | 18307402 | 2 |
| Caelo | Carbomers | 18307403 | 7 |
| Caelo | Carbomers | 18307406 | 3 |
| Caelo | Carbomers | 18307407 | 1 |
| Caelo | Carbomers | 18307408 | 14 |
| Caelo | Carbomers | 18307410 | 4 |
| Caelo | Carbomers | 18307411 | 4 |
| Caelo | Carbomers | 18307413 | 2 |
| Caelo | Carbomers | 19000614002 | 2 |
| Caelo | Carbomers | 19000614003 | 1 |
| Caelo | Carbomers | 19024505 | 3 |
| Caelo | Carbomers | 19145601 | 1 |
| Caelo | Carbomers | 192276003 | 5 |
| Caelo | Carbomers | 192276004 | 18 |
| Caelo | Carbomers | 19227601 | 5 |
| Caelo | Carbomers | 19227602 | 12 |
| Caelo | Carbomers | 19236601 | 2 |
| Caelo | Carbomers | 2000034003 | 1 |
| Caelo | Carbomers | 20000343 | 1 |
| Caelo | Carbomers | 20000343001 | 3 |
| Caelo | Carbomers | 20000343003 | 23 |
| Caelo | Carbomers | 20001190002 | 2 |
| Caelo | Carbomers | 20001190003 | 11 |
| Caelo | Carbomers | 200011910003 | 1 |
| Caelo | Carbomers | 2000190003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Carbomers | 2000190008 | 1 |
| Caelo | Carbomers | 20003095003 | 2 |
| Caelo | Carbomers | 20003238001 | 2 |
| Caelo | Carbomers | 20003924001 | 14 |
| Caelo | Carbomers | 20003924003 | 1 |
| Caelo | Carbomers | 20003924004 | 11 |
| Caelo | Carbomers | 20003929003 | 2 |
| Caelo | Carbomers | 210000355001 | 1 |
| Caelo | Carbomers | 2100035001 | 1 |
| Caelo | Carbomers | 21000355001 | 13 |
| Caelo | Carbomers | 21000355004 | 8 |
| Caelo | Carbomers | 21000355006 | 1 |
| Caelo | Carbomers | 210003605008 | 1 |
| Caelo | Carbomers | 21001724001 | 6 |
| Caelo | Carbomers | 21001724002 | 13 |
| Caelo | Carbomers | 21001724004 | 3 |
| Caelo | Carbomers | 21001724008 | 3 |
| Caelo | Carbomers | 21001724009 | 2 |
| Caelo | Carbomers | 21002358002 | 1 |
| Caelo | Carbomers | 21002358004 | 2 |
| Caelo | Carbomers | 21003605001 | 2 |
| Caelo | Carbomers | 21003605003 | 13 |
| Caelo | Carbomers | 21003605008 | 12 |
| Caelo | Carbomers | 2100605008 | 1 |
| Caelo | Carbomers | 22002190003 | 10 |
| Caelo | Carbomers | 2215M-01232 | 1 |
| Caelo | Carbomers | 23000823005 | 1 |
| Caelo | Carbomers | 23002015004 | 2 |
| Caelo | Carbomers | 28111310 | 1 |
| Caelo | Carbomers | 2913M1232 | 1 |
| Caelo | Carbomers | 3000034003 | 1 |
| Caelo | Carbomers | 31631293 | 1 |
| Caelo | Carbomers | 3441 | 1 |
| Caelo | Carbomers | 42(20003924001) | 1 |
| Caelo | Carbomers | 9011903 | 1 |
| Caeol | Carbomers | 16253004 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21001724008 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 23000179002 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 19227601 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21003605003 | 3 |
| Caesar & Loretz GmbH... | Carbomers | 19236601 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 20000343003 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 20003924004 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21001724002 | 1 |
| Caesar & Loretz GmbH/Gehe | Carbomers | 21001724001 | 1 |
| Caesar & Loretz GmbH/Gehe | Carbomers | 24000748009 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21001724001 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 22002190003 | 1 |
| Caesar & Loretz GmbH/Kehr | Carbomers | 18307411 | 1 |
| Caesar & Loretz GmbH/Kehr | Carbomers | 20001190003 | 1 |
| Caesar & Loretz GmbH/Kehr | Carbomers | 21001724001 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 19227601 | 1 |
| Caesar & Loretz GmbH/L10 | Carbomers | 20001190003 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 20003095003 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21001724008 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21002358004 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 20003924004 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 20003924004 | 2 |
| Caesar & Loretz GmbH... | Carbomers | 21000355001 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21000355004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Carbomers | 18307406 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 18307410 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 20003095003 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21000355001 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21003605008 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 19227601 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 21001724001 | 1 |
| Caesar & Loretz GmbH... | Carbomers | 19227602 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18092401 | 2 |
| Caesar & Loretz GmbH | Carbomers | 18092405 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18092406 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18092408 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18092412 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18307401 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18307402 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18307406 | 2 |
| Caesar & Loretz GmbH | Carbomers | 18307407 | 3 |
| Caesar & Loretz GmbH | Carbomers | 18307408 | 1 |
| Caesar & Loretz GmbH | Carbomers | 18307410 | 3 |
| Caesar & Loretz GmbH | Carbomers | 18307411 | 2 |
| Caesar & Loretz GmbH | Carbomers | 19024501 | 1 |
| Caesar & Loretz GmbH | Carbomers | 19024505 | 1 |
| Caesar & Loretz GmbH | Carbomers | 1903007-01 | 1 |
| Caesar & Loretz GmbH | Carbomers | 192276004 | 4 |
| Caesar & Loretz GmbH | Carbomers | 192276005 | 1 |
| Caesar & Loretz GmbH | Carbomers | 19227602 | 2 |
| Caesar & Loretz GmbH | Carbomers | 19227603 | 1 |
| Caesar & Loretz GmbH | Carbomers | 20000343001 | 2 |
| Caesar & Loretz GmbH | Carbomers | 20000343003 | 4 |
| Caesar & Loretz GmbH | Carbomers | 20001190003 | 7 |
| Caesar & Loretz GmbH | Carbomers | 20001190007 | 1 |
| Caesar & Loretz GmbH | Carbomers | 20001190008 | 2 |
| Caesar & Loretz GmbH | Carbomers | 20003095003 | 1 |
| Caesar & Loretz GmbH | Carbomers | 20003924001 | 7 |
| Caesar & Loretz GmbH | Carbomers | 20003924004 | 7 |
| Caesar & Loretz GmbH | Carbomers | 21000355001 | 1 |
| Caesar & Loretz GmbH | Carbomers | 21000355002 | 1 |
| Caesar & Loretz GmbH | Carbomers | 21000355004 | 6 |
| Caesar & Loretz GmbH | Carbomers | 21001724001 | 2 |
| Caesar & Loretz GmbH | Carbomers | 21001724002 | 2 |
| Caesar & Loretz GmbH | Carbomers | 21001724008 | 8 |
| Caesar & Loretz GmbH | Carbomers | 21003605001 | 2 |
| Caesar & Loretz GmbH | Carbomers | 21003605003 | 6 |
| Caesar & Loretz GmbH | Carbomers | 21003605008 | 5 |
| Caesar & Loretz GmbH | Carbomers | 22002070002 | 1 |
| Caesar & Loretz GmbH | Carbomers | 22002190003 | 4 |
| Caesar & Loretz Hild... | Carbomers | 18307403 | 1 |
| Caesar & Loretz/Geil... | Carbomers | 20000343003 | 1 |
| Caesar & Loretz | Carbomers | 18092408 | 1 |
| Caesar & Loretz | Carbomers | 18307408 | 1 |
| Caesar&Loretz,Phönix... | Carbomers | 15439003 | 1 |
| Caesar/Phönix | Carbomers | 21001724008 | 1 |
| Cealo | Carbomers | 18307408 | 1 |
| Cordes/Phönix | Carbomers | 192276004 | 1 |
| Eu Rho | Carbomers | 2203009-01 | 1 |
| EuRho/ Noweda | Carbomers | 1908029-01 | 1 |
| EuRho/ Phönix | Carbomers | 2003049-01 | 1 |
| EuRho | Carbomers | 1210037-01 | 1 |
| EuRho | Carbomers | 1311027-02 | 1 |
| EuRho | Carbomers | 1410001-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Carbomers | | 1 |
| Euro OTC | Carbomers | 101217279 | 1 |
| Euro OTC | Carbomers | 101616773 | 2 |
| Euro OTC | Carbomers | 102026590 | 1 |
| Euro OTC | Carbomers | 102540805 | 1 |
| Euro OTC | Carbomers | 120202001 | 2 |
| Euro OTC | Carbomers | 1202020-01 | 2 |
| Euro OTC | Carbomers | 12052014A | 1 |
| Euro OTC | Carbomers | 1210037-01 | 6 |
| Euro OTC | Carbomers | 1305007-01 | 2 |
| Euro OTC | Carbomers | 130800601 | 1 |
| Euro OTC | Carbomers | 1311027-01 | 3 |
| Euro OTC | Carbomers | 1311027-02 | 7 |
| Euro OTC | Carbomers | 141000-01 | 1 |
| Euro OTC | Carbomers | 141000101 | 1 |
| Euro OTC | Carbomers | 1410001-01 | 13 |
| Euro OTC | Carbomers | 1512010-01 | 8 |
| Euro OTC | Carbomers | 1512010-02 | 5 |
| Euro OTC | Carbomers | 151210-02 | 1 |
| Euro OTC | Carbomers | 1518E2 | 1 |
| Euro OTC | Carbomers | 1604032-01 | 8 |
| Euro OTC | Carbomers | 1607028-01 | 10 |
| Euro OTC | Carbomers | 1610024-01 | 21 |
| Euro OTC | Carbomers | 16253002 | 1 |
| Euro OTC | Carbomers | 16253014 | 1 |
| Euro OTC | Carbomers | 1702012-01 | 1 |
| Euro OTC | Carbomers | 1706015-01 | 4 |
| Euro OTC | Carbomers | 17361402 | 1 |
| Euro OTC | Carbomers | 18010019-01 | 1 |
| Euro OTC | Carbomers | 1801044-01 | 6 |
| Euro OTC | Carbomers | 1810019-01 | 11 |
| Euro OTC | Carbomers | 18307401 | 1 |
| Euro OTC | Carbomers | 190300-01 | 1 |
| Euro OTC | Carbomers | 1903007-01 | 5 |
| Euro OTC | Carbomers | 1908029-01 | 3 |
| Euro OTC | Carbomers | 2003049-01 | 8 |
| Euro OTC | Carbomers | 210400701 | 1 |
| Euro OTC | Carbomers | 2104007-01 | 6 |
| Euro OTC | Carbomers | 2112003-01 | 2 |
| Euro OTC | Carbomers | 2203009-01 | 1 |
| Euro OTC | Carbomers | 2206008-01 | 4 |
| Euro OTC | Carbomers | 41(1810019-01) | 1 |
| Euro OTC | Carbomers | 4311027-01 | 1 |
| Euro/Gehe | Carbomers | 1604032-01 | 1 |
| Euro/Phönix | Carbomers | 161002401 | 1 |
| Euro/Sanacorp | Carbomers | 1305007-01 | 1 |
| Euro | Carbomers | 1410001-01 | 2 |
| Fagron | Carbomers | 13194503 | 1 |
| Fagron | Carbomers | 1607028-01 | 1 |
| Fiebig | Carbomers | 2003049-01 | 1 |
| Fischer/Gehe | Carbomers | 1410001-02 | 1 |
| Gatt-Koller | Carbomers | 1800201 | 1 |
| Gehe 04.11.21 EK:7,78EUR | Carbomers | 211105CM | 1 |
| Gehe | Carbomers | 102669851 | 1 |
| Gehe | Carbomers | 13194505 | 1 |
| Gehe | Carbomers | 16237501 | 1 |
| GEHE | Carbomers | 18092405 | 1 |
| Gehe | Carbomers | 18307408 | 1 |
| Gehe | Carbomers | 22002190003 | 1 |
| Gehe | Carbomers | 2302002-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Hepart AG | Carbomers | 12274916 | 1 |
| Ichthyol/Phönix | Carbomers | 14149905 | 1 |
| Jenne | Carbomers | 18049301 | 2 |
| Kehr | Carbomers | 23000685003 | 1 |
| L10/apo-ident | Carbomers | 1512010-01 | 1 |
| L30 | Carbomers | 1610024-01 | 1 |
| Nachtestung | Carbomers | | 1 |
| Noweda Taucha | Carbomers | 21001724008 | 1 |
| Noweda/ Caesar&Loren… | Carbomers | 192276004 | 1 |
| Noweda | Carbomers | 16253012 | 1 |
| Noweda | Carbomers | 20000343003 | 1 |
| Noweda | Carbomers | 21000355004 | 1 |
| Noweda | Carbomers | 22002190003 | 1 |
| Noweda | Carbomers | 2206008-01 | 1 |
| Noweda | Carbomers | 23000625003 | 1 |
| Noweda | Carbomers | 23000823003 | 1 |
| Noweda | Carbomers | 240311-01 | 1 |
| Pharbil Waltrop GmbH | Carbomers | 102237289 | 4 |
| Pharbil Waltrop GmbH | Carbomers | 102246780 | 1 |
| Phoenix 16.04.2014 | Carbomers | 13194503 | 1 |
| Phoenix | Carbomers | 18307402 | 1 |
| Phoenix | Carbomers | 19227602 | 1 |
| Phoenix | Carbomers | 20003924003 | 1 |
| Phoenix | Carbomers | 23000625003 | 1 |
| Phoenix | Carbomers | 23002015002 | 2 |
| Phoenix | Carbomers | 23002015004 | 1 |
| Phoenix | Carbomers | 2400748001 | 1 |
| Phönix Gotha | Carbomers | 19227601 | 1 |
| Phönix | Carbomers | 18092405 | 1 |
| Phönix | Carbomers | 18092411 | 1 |
| Phönix | Carbomers | 200011980008 | 1 |
| Phönix | Carbomers | 22002190003 | 1 |
| Phönix | Carbomers | 23000625003 | 1 |
| Phönix | Carbomers | 23002015002 | 1 |
| Phönix | Carbomers | 24000748004 | 1 |
| Rezepturlager - Verl… | Carbomers | 115/14 | 1 |
| Sanacaorp | Carbomers | 14149905 | 1 |
| Sanacorp | Carbomers | 12274922 | 1 |
| Sanacorp | Carbomers | 1311027-01 | 1 |
| Sanacorp | Carbomers | 14149911 | 1 |
| Sanacorp | Carbomers | 1604032-01 | 1 |
| Sanacorp | Carbomers | 160702801 | 1 |
| Sanacorp | Carbomers | 18092406 | 4 |
| Sanacorp | Carbomers | 18307411 | 1 |
| Sanacorp | Carbomers | 19227601 | 1 |
| Sanacorp | Carbomers | 20003924004 | 1 |
| Sanacorp | Carbomers | 20003929003 | 2 |
| sanacorp | Carbomers | 22002190002 | 1 |
| Sanacorp | Carbomers | 23002015002 | 1 |
| Sanacorp | Carbomers | 2302002-01 | 1 |
| Sanacorp | Carbomers | 6/AKD13 | 1 |

- 255 813 spectra from 1666 *Apo-Ident* customers from a total of 51 936 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Carbomers* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Carbomers* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 550 | 0 | 157 776 |
| **Type B** | 0 | 1080 | 0 | 211 860 |
| **Type C** | 0 | 1070 | 3 | 255 813 |

The substance/substance group *Carbomers* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9091 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4444 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7204 % (> 99.4408 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20978 | 20978 | 0.00 | 120.28 |
| 20979 | 20979 | 0.00 | 109.46 |
| 21354 | 22852 | 12.57 | 118.34 |
| 21557 | 22686 | 12.57 | 119.96 |
| 21561 | 22548 | 6.91 | 111.15 |
| 22250 | 22250 | 0.00 | 113.60 |
| 22548 | 22548 | 0.00 | 110.70 |
| 22686 | 22686 | 0.00 | 113.16 |
| 22759 | 22759 | 0.00 | 185.41 |
| 22852 | 22852 | 0.00 | 109.33 |
| 25809 | 25809 | 0.00 | 196.98 |
| 27218 | 27218 | 0.00 | 122.09 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all

substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Carmellose sodium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20866-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Carmellose sodium; Carmellosum natricum

### Special notes

When selecting the *Carmellose sodium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Carmellose sodium | 10 | 7 | 70 |

### Second-stage model

For differentiation of the substance/substance group *Carmellose sodium* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Carmellose sodium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 31.95 | – |
| Cannabis flower, THC/CBD-intermedia… | 42.49 | – |
| Sodium cromoglicate | 53.55 | – |
| ⋮ | ⋮ | ⋮ |
| SyrSpend® SF Alka | >50 | 20.41 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 25.79 |
| Colistin sulfate | >50 | 33.68 |
| Corn starch | >50 | 37.36 |
| Rice starch | >50 | 38.56 |
| Calcium glycerophosphate | 58.21 | 39.12 |
| Acacia, dried dispersion | >50 | 39.33 |
| Polymyxin B sulfate | >50 | 39.94 |
| Cyanocobalamin | >50 | 45.46 |
| Bacitracin | >50 | 47.15 |
| Wheat starch | >50 | 47.42 |
| SyrSpend® SF pH4 | >50 | 50.74 |
| Amphotericin B | >50 | 64.82 |
| Riboflavin | >50 | 67.92 |
| Maltodextrin | >50 | 69.24 |
| Potato starch | >50 | 72.67 |
| Nystatin | >50 | 81.36 |
| Oxalic acid | >50 | 91.27 |
| Tosylchloramide sodium | >50 | 92.80 |
| Calcium pantothenate | >50 | 103.26 |
| alpha-tocopheryl acetate dry concentrate | >50 | 112.52 |
| Estradiol hemihydrate | >50 | 114.37 |
| Gelatine, white | >50 | 117.11 |
| Hyoscine hydrobromide | >50 | 123.43 |
| Estriol | >50 | 128.15 |
| Triamcinolone | >50 | 150.27 |
| Fructose | >50 | 177.45 |
| Methylcobalamin | >50 | 196.13 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Carmellose sodium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Carmellose sodium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Carmellose sodium | 12354404 | 20866 | 40 | 1401185 |
| Caelo | Carmellose sodium | 13104807 | 20872 | 40 | 1401186 |
| Caelo | Carmellose sodium | 14029211 | 21382 | 40 | 20140127 |
| Caelo | Carmellose sodium | 13299310 | 21432 | 60 | 20131002 |
| Caelo | Carmellose sodium | 161714 | 22645 | 40 | 20160713* |
| Caelo | Carmellose sodium | 16171406 | 23187 | 40 | AR-17-FG-015964-01 |
| Caelo | Carmellose sodium | 180486 | 24039 | 40 | 20180228* |
| Caelo | Carmellose sodium | 22002555 | 26352 | 40 | 20220922* |
| Caelo | Carmellose sodium | 22002555 | 26352SI | 20 | 20220922* |
| Fagron | Carmellose sodium | 13D22-N02 | 20892 | 40 | 1401187 |
| Fagron | Carmellose sodium | 18E15-B04-354617 | 24868 | 40 | 20180620 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 440 spectra of 11 reference samples from the substance/substance group *Carmellose sodium*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.
- 157 886 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 310 spectra of 9 reference samples from the substance/substance group *Carmellose sodium*.
- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Carmellose sodium | 17062304 | 23519 | 40 |
| Caelo | Carmellose sodium | 172446 | 23623 | 40 |
| Caelo | Carmellose sodium | 20000171001 | 25500 | 40 |
| Caelo | Carmellose sodium | 22000132008 | 26311 | 30 |
| Caelo | Carmellose sodium | 23000402 | 26712 | 40 |
| Caelo | Carmellose sodium | 23001501 | 26844 | 40 |
| Fagron | Carmellose sodium | 24H14-B05-003728 | 27486 | 40 |
| Caelo | Carmellose sodium | 22000132008 | 26311SI | 20 |
| Caelo | Carmellose sodium | 23000402 | 26712SI | 20 |

- 212 630 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 241 spectra from 153 *Apo-Ident* customers from 73 batches from the substance/substance group *Carmellose sodium*.
- Among them are spectra of independent samples from 70 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Carmellose sodium | 22000132001 | 2 |
| | Carmellose sodium | 23000402001 | 3 |
| | Carmellose sodium | 23000402002 | 10 |
| | Carmellose sodium | 23000402005 | 7 |
| | Carmellose sodium | 23001501001 | 4 |
| Alliance | Carmellose sodium | 23000402002 | 1 |
| Bombastus | Carmellose sodium | 13104813 | 1 |
| Caelo | Carmellose sodium | 10000620042 | 1 |
| Caelo | Carmellose sodium | 11124211 | 1 |
| Caelo | Carmellose sodium | 12255708 | 1 |
| Caelo | Carmellose sodium | 12354408 | 1 |
| Caelo | Carmellose sodium | 12354414 | 1 |
| Caelo | Carmellose sodium | 12354416 | 3 |
| Caelo | Carmellose sodium | 13104802 | 3 |
| Caelo | Carmellose sodium | 13104807 | 2 |
| Caelo | Carmellose sodium | 13104810 | 3 |
| Caelo | Carmellose sodium | 13104813 | 2 |
| Caelo | Carmellose sodium | 1315Q-03302 | 1 |
| Caelo | Carmellose sodium | 13299302 | 2 |
| Caelo | Carmellose sodium | 13G19-N02 | 1 |
| Caelo | Carmellose sodium | 14029201 | 1 |
| Caelo | Carmellose sodium | 14029211 | 1 |
| Caelo | Carmellose sodium | 14149806 | 2 |
| Caelo | Carmellose sodium | 15123901 | 5 |
| Caelo | Carmellose sodium | 15123908 | 5 |
| Caelo | Carmellose sodium | 15123909 | 1 |
| Caelo | Carmellose sodium | 15123912 | 1 |
| Caelo | Carmellose sodium | 16171402 | 3 |
| Caelo | Carmellose sodium | 17052304 | 1 |
| Caelo | Carmellose sodium | 17062303 | 2 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Carmellose sodium | 17062304 | 4 |
| Caelo | Carmellose sodium | 17062307 | 5 |
| Caelo | Carmellose sodium | 17062308 | 2 |
| Caelo | Carmellose sodium | 17062309 | 3 |
| Caelo | Carmellose sodium | 17244601 | 2 |
| Caelo | Carmellose sodium | 17348601 | 8 |
| Caelo | Carmellose sodium | 17348604 | 1 |
| Caelo | Carmellose sodium | 17348605 | 7 |
| Caelo | Carmellose sodium | 17348606 | 1 |
| Caelo | Carmellose sodium | 180486003 | 8 |
| Caelo | Carmellose sodium | 18048602 | 2 |
| Caelo | Carmellose sodium | 18048604 | 13 |
| Caelo | Carmellose sodium | 18048607 | 1 |
| Caelo | Carmellose sodium | 2000132001 | 1 |
| Caelo | Carmellose sodium | 20001837002 | 5 |
| Caelo | Carmellose sodium | 21000062003 | 1 |
| Caelo | Carmellose sodium | 21000062004 | 6 |
| Caelo | Carmellose sodium | 21000062007 | 2 |
| Caelo | Carmellose sodium | 2119M-04170 | 1 |
| Caelo | Carmellose sodium | 218U-03302 | 1 |
| Caelo | Carmellose sodium | 22000132001 | 4 |
| Caelo | Carmellose sodium | 22000132002 | 2 |
| Caelo | Carmellose sodium | 22000132009 | 2 |
| Caelo | Carmellose sodium | 22002555003 | 3 |
| Caelo | Carmellose sodium | 22002555005 | 1 |
| Caelo | Carmellose sodium | 22002555006 | 3 |
| Caelo | Carmellose sodium | 22002555007 | 2 |
| Caelo | Carmellose sodium | 23000402002 | 7 |
| Caelo | Carmellose sodium | 23000402005 | 1 |
| Caelo | Carmellose sodium | 23001501001 | 1 |
| Caelo | Carmellose sodium | 25041805 | 1 |
| Caelo | Carmellose sodium | 28051402 | 1 |
| Caelo | Carmellose sodium | 36/17 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 17244601 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 18048604 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 22002555007 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 23000402005 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 18048604 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 20001837002 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 22002555006 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 18048604 | 1 |
| Caesar & Loretz GmbH… | Carmellose sodium | 20001837002 | 3 |
| Caesar & Loretz GmbH… | Carmellose sodium | 23000402001 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 17062307 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 17348605 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 18048604 | 4 |
| Caesar & Loretz GmbH | Carmellose sodium | 20001837002 | 2 |
| Caesar & Loretz GmbH | Carmellose sodium | 21000062004 | 3 |
| Caesar & Loretz GmbH | Carmellose sodium | 21000062007 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 22000132001 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 22000132002 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 22000132009 | 2 |
| Caesar & Loretz GmbH | Carmellose sodium | 22002555003 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 22002555006 | 2 |
| Caesar & Loretz GmbH | Carmellose sodium | 22002555007 | 1 |
| Caesar & Loretz GmbH | Carmellose sodium | 23000402002 | 3 |
| Caesar & Loretz/AHD | Carmellose sodium | 20001837002 | 1 |
| Caesar&Loretz GmbH | Carmellose sodium | 21000062007 | 1 |
| Fagro | Carmellose sodium | 15G03-B02-321790 | 1 |
| Fagro | Carmellose sodium | 16G05-B05-329314 | 1 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagro | Carmellose sodium | 17C20-B07-337104 | 1 |
| Fagro | Carmellose sodium | 17K06-B03-345975 | 1 |
| Fagron | Carmellose sodium | 13D22-N02 | 1 |
| Fagron | Carmellose sodium | 15G03-B02-312862 | 1 |
| Fagron | Carmellose sodium | 15G03-Bo2-312862 | 1 |
| Fagron | Carmellose sodium | 15G03-B02-321790 | 1 |
| Fagron | Carmellose sodium | 7006400006 | 1 |
| Gehe 06.10.14 | Carmellose sodium | 13299312 | 1 |
| Gehe | Carmellose sodium | 17062307 | 1 |
| GEHE | Carmellose sodium | 17062307 | 1 |
| Gehe | Carmellose sodium | 22000132001 | 1 |
| Gehe | Carmellose sodium | 23000402002 | 1 |
| Gehe | Carmellose sodium | 23001501001 | 1 |
| Gutenberg-Apotheke | Carmellose sodium | 4811E-03302 | 1 |
| Kehr | Carmellose sodium | 22000132001 | 1 |
| Kehr | Carmellose sodium | 22002555003 | 1 |
| Kehr | Carmellose sodium | 2300402005 | 1 |
| Noweda | Carmellose sodium | 12354401 | 1 |
| Noweda | Carmellose sodium | 20001837002 | 1 |
| Noweda | Carmellose sodium | 22002555004 | 1 |
| Noweda | Carmellose sodium | 23000402002 | 2 |
| Phoenix | Carmellose sodium | 17348601 | 2 |
| Phönix | Carmellose sodium | 23001501005 | 1 |
| Sanacorp | Carmellose sodium | 180486003 | 1 |
| Sanacorp | Carmellose sodium | AKD6 | 1 |

- 256 645 spectra from 1666 *Apo-Ident* customers from a total of 52 083 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Carmellose sodium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Carmellose sodium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 310 | 0 | 212 630 |
| **Type C** | 0 | 239 | 2 | 256 645 |

The substance/substance group *Carmellose sodium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0645 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.1701 % (> 97.9253 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20866 | 20866 | 0.00 | 77.47 |
| 20872 | 20872 | 0.00 | 75.79 |
| 20892 | 20892 | 0.00 | 71.89 |
| 21382 | 20872 | 14.61 | 81.16 |
| 21432 | 20866 | 34.15 | 73.38 |
| 22645 | 22645 | 0.00 | 73.37 |
| 23187 | 23187 | 0.00 | 75.56 |
| 24039 | 24039 | 0.00 | 101.44 |
| 24868 | 20892 | 17.97 | 79.62 |
| 26352 | 26352 | 0.00 | 73.47 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cellulose, microcrystalline** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20708-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cellulose, microcrystalline; Cellulosum microcristallinum

### Special notes

When selecting the *Cellulose, microcrystalline* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cellulose, microcrystalline | 8 | 12 | 76 |

### Second-stage model

For differentiation of the substance/substance group *Cellulose, microcrystalline* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cellulose, microcrystalline* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 50.95 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cellulose, microcrystalline* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cellulose, microcrystalline*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Cellulose, microcrystalline | 1201004-01 | 20728 | 40 | 20120201 |
| Euro OTC | Cellulose, microcrystalline | 1211037-01 | 21080 | 30 | 20121207 |
| Euro OTC | Cellulose, microcrystalline | 1211037-01 | 21085 | 40 | 20121207 |
| Euro OTC | Cellulose, microcrystalline | 1507022 | 21857 | 60 | 20150805* |
| Euro OTC | Cellulose, microcrystalline | 1604029 | 22559 | 40 | 20160512* |
| Euro OTC | Cellulose, microcrystalline | 2010026 | 25464 | 40 | 20201209* |
| Euro OTC | Cellulose, microcrystalline | 2212016 | 26527 | 40 | 20230112* |
| Euro OTC | Cellulose, microcrystalline | 2212016 | 26527SI | 20 | 20230112* |
| Fagron | Cellulose, microcrystalline | 12C23-N06 | 20708 | 70 | 1403080 |
| Fagron | Cellulose, microcrystalline | 16B24-B11-323324 | 22896 | 40 | 20160311 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 10 reference samples from the substance/substance group *Cellulose, microcrystalline*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 906 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 540 spectra of 15 reference samples from the substance/substance group *Cellulose, microcrystalline*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Cellulose, microcrystalline | 1607042 | 22794 | 40 |
| Euro OTC | Cellulose, microcrystalline | 1604029-01 | 22815 | 40 |
| Euro OTC | Cellulose, microcrystalline | 1610030 | 22876 | 40 |
| Euro OTC | Cellulose, microcrystalline | 1712009 | 23909 | 40 |
| Euro OTC | Cellulose, microcrystalline | 1811011 | 24346 | 40 |
| Euro OTC | Cellulose, microcrystalline | 1911018 | 25076 | 40 |
| Euro OTC | Cellulose, microcrystalline | 2005004 | 25248 | 40 |
| Euro OTC | Cellulose, microcrystalline | 2109026 | 25880 | 50 |
| Euro OTC | Cellulose, microcrystalline | 2309002 | 26938 | 40 |
| Euro OTC | Cellulose, microcrystalline | 2410009 | 27464 | 40 |
| Fagron | Cellulose, microcrystalline | 22A15-B01-217413 | 26293 | 40 |
| Fagron | Cellulose, microcrystalline | 24A09-B01-237270 | 27174 | 40 |
| Euro OTC | Cellulose, microcrystalline | 2109026 | 25880SI | 10 |
| Euro OTC | Cellulose, microcrystalline | 2309002 | 26938SI | 20 |
| Fagron | Cellulose, microcrystalline | 22A15-B01-217413 | 26293SI | 20 |

- 212 400 spectra from a total of 4275 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 258 spectra from 166 *Apo-Ident* customers from 79 batches from the substance/substance group *Cellulose, microcrystalline*.

- Among them are spectra of independent samples from 76 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cellulose, microcrystalline | 2010026-01 | 2 |
| | Cellulose, microcrystalline | 2109026-01 | 3 |
| | Cellulose, microcrystalline | 2212016-01 | 5 |
| | Cellulose, microcrystalline | 22K19-B10-224131 | 1 |
| | Cellulose, microcrystalline | 2309002-01 | 4 |
| | Cellulose, microcrystalline | 2309002-02 | 3 |
| | Cellulose, microcrystalline | 23L11-B04-235326 | 1 |
| | Cellulose, microcrystalline | 23L11-B04-235327 | 2 |
| | Cellulose, microcrystalline | 2410009-01 | 1 |
| | Cellulose, microcrystalline | 24A09-B01-237270 | 1 |
| AHD | Cellulose, microcrystalline | 2109026-1 | 1 |
| ahd | Cellulose, microcrystalline | 2309002-01 | 1 |
| Anzag | Cellulose, microcrystalline | 2005004-01 | 1 |
| Anzag | Cellulose, microcrystalline | 24A09-B01-237270 | 5 |
| apo-ident. | Cellulose, microcrystalline | 1604029-01 | 1 |
| apo-ident | Cellulose, microcrystalline | 1610030-01 | 1 |
| Caelo | Cellulose, microcrystalline | 160402901 | 1 |
| Caelo | Cellulose, microcrystalline | 1604029-01 | 2 |
| Caelo | Cellulose, microcrystalline | 1610030-01 | 4 |
| Caelo | Cellulose, microcrystalline | 8722 | 1 |
| DuPont | Cellulose, microcrystalline | R0025 | 1 |
| EuRho | Cellulose, microcrystalline | 1201004-02 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1201004-02 | 2 |
| Euro OTC | Cellulose, microcrystalline | 121103701 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1211037-01 | 2 |
| Euro OTC | Cellulose, microcrystalline | 1309001-01 | 3 |
| Euro OTC | Cellulose, microcrystalline | 1309001-02 | 3 |
| Euro OTC | Cellulose, microcrystalline | 135010001 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1410002-01 | 5 |
| Euro OTC | Cellulose, microcrystalline | 1507022 | 1 |
| Euro OTC | Cellulose, microcrystalline | 150702201 | 1 |
| Euro OTC | Cellulose, microcrystalline | 150722-01 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1604029-01 | 8 |
| Euro OTC | Cellulose, microcrystalline | 160704201 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1607042-01 | 3 |
| Euro OTC | Cellulose, microcrystalline | 1610030-01 | 11 |
| Euro OTC | Cellulose, microcrystalline | 1704b50351755 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1712009-01 | 2 |
| Euro OTC | Cellulose, microcrystalline | 1712009-02 | 7 |
| Euro OTC | Cellulose, microcrystalline | 1811011 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1811011-01 | 18 |
| Euro OTC | Cellulose, microcrystalline | 181101103 | 1 |
| Euro OTC | Cellulose, microcrystalline | 1811011-03 | 6 |
| Euro OTC | Cellulose, microcrystalline | 1911018-01 | 6 |
| Euro OTC | Cellulose, microcrystalline | 195010861 | 2 |
| Euro OTC | Cellulose, microcrystalline | 2005004-01 | 12 |
| Euro OTC | Cellulose, microcrystalline | 201002601 | 2 |
| Euro OTC | Cellulose, microcrystalline | 2010026-01 | 31 |
| Euro OTC | Cellulose, microcrystalline | 205010638 | 3 |
| Euro OTC | Cellulose, microcrystalline | 2109026-01 | 8 |
| Euro OTC | Cellulose, microcrystalline | 2109026-02 | 3 |
| Euro OTC | Cellulose, microcrystalline | 2763 | 1 |
| Euro OTC | Cellulose, microcrystalline | 2780 | 1 |
| Euro OTC | Cellulose, microcrystalline | 7/21 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Cellulose, microcrystalline | 700204 | 2 |
| Euro OTC | Cellulose, microcrystalline | 8710 | 1 |
| Euro OTC | Cellulose, microcrystalline | SD17070102 | 2 |
| Euro/Noweda | Cellulose, microcrystalline | 1410002-02 | 1 |
| Euro/Sanacorp | Cellulose, microcrystalline | 1911018-01 | 1 |
| Fagron | Cellulose, microcrystalline | 13A03-N01 | 1 |
| Fagron | Cellulose, microcrystalline | 15C03-B06-305242 | 1 |
| Fagron | Cellulose, microcrystalline | 17/04-B50 | 1 |
| Fagron | Cellulose, microcrystalline | 17/04-B50-351755 | 1 |
| Fagron | Cellulose, microcrystalline | 17A11-B04-331463 | 1 |
| Fagron | Cellulose, microcrystalline | 17A11-B04-340541 | 1 |
| Fagron | Cellulose, microcrystalline | 17I04-B50-351755 | 1 |
| Fagron | Cellulose, microcrystalline | 18/19-B50-360110 | 2 |
| Fagron | Cellulose, microcrystalline | 18B16-B50-355434 | 1 |
| Fagron | Cellulose, microcrystalline | 18K16-B50 | 1 |
| Fagron | Cellulose, microcrystalline | 18k16-b50-360224 | 1 |
| Fagron | Cellulose, microcrystalline | 18K16-B50-360224 | 1 |
| Fagron | Cellulose, microcrystalline | 18K16-B50-364001 | 1 |
| Fagron | Cellulose, microcrystalline | 18K16-B50-364002 | 1 |
| Fagron | Cellulose, microcrystalline | 18l19-B05-360110 | 1 |
| Fagron | Cellulose, microcrystalline | 2005004-41 | 1 |
| Fagron | Cellulose, microcrystalline | 2013M-01350 | 1 |
| Fagron | Cellulose, microcrystalline | 205001122 | 2 |
| Fagron | Cellulose, microcrystalline | 20E15-F03-371624 | 1 |
| Fagron | Cellulose, microcrystalline | 20E15-F03-371625 | 1 |
| Fagron | Cellulose, microcrystalline | 20L01-F02 | 1 |
| Fagron | Cellulose, microcrystalline | 20L01-F02-376412 | 2 |
| Fagron | Cellulose, microcrystalline | 20L01F02376414 | 2 |
| Fagron | Cellulose, microcrystalline | 20L01-F02-376414 | 7 |
| Fagron | Cellulose, microcrystalline | 23C02-B11-226149 | 1 |
| Fagron | Cellulose, microcrystalline | 9K10-N10 | 1 |
| Gehe | Cellulose, microcrystalline | 2212016-01 | 1 |
| Kehr | Cellulose, microcrystalline | 2212016-01 | 1 |
| Koisser | Cellulose, microcrystalline | E0790 | 1 |
| Noweda | Cellulose, microcrystalline | 1811011-03 | 1 |
| Noweda | Cellulose, microcrystalline | 1911018-01 | 1 |
| Noweda | Cellulose, microcrystalline | 2109026-01 | 1 |
| Noweda | Cellulose, microcrystalline | 2212016-01 | 1 |
| Noweda | Cellulose, microcrystalline | 2215016-01 | 1 |
| Noweda | Cellulose, microcrystalline | 23L11-B04-235326 | 3 |
| Phnoix | Cellulose, microcrystalline | 1211037-01 | 1 |
| Phoenix | Cellulose, microcrystalline | 1309001-02 | 1 |
| Phoenix | Cellulose, microcrystalline | 1712009-02 | 1 |
| Phoenix | Cellulose, microcrystalline | 3235 | 1 |
| ROHA | Cellulose, microcrystalline | 140010 | 1 |
| Sanacorp/EuRho | Cellulose, microcrystalline | 2109026-01 | 1 |
| Sanacorp | Cellulose, microcrystalline | 2005004-01 | 1 |
| Sanacorp | Cellulose, microcrystalline | 2010026-01 | 1 |
| Sanacorp | Cellulose, microcrystalline | 2212016-01 | 1 |
| Sanacorp | Cellulose, microcrystalline | 2309002-01 | 1 |
| Sanacorp | Cellulose, microcrystalline | 2309002-03 | 2 |

- 256 628 spectra from 1666 *Apo-Ident* customers from a total of 52 074 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cellulose, microcrystalline* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cellulose, microcrystalline* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 540 | 0 | 212 400 |
| **Type C** | 0 | 258 | 0 | 256 628 |

The substance/substance group *Cellulose, microcrystalline* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8889 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.6744 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20708 | 20708 | 0.00 | 118.91 |
| 20728 | 20708 | 9.55 | 120.65 |
| 21080 | 20708 | 8.66 | 118.01 |
| 21085 | 20708 | 8.31 | 118.90 |
| 21857 | 21857 | 0.00 | 114.55 |
| 22559 | 22559 | 0.00 | 116.92 |
| 22896 | 21857 | 7.58 | 115.34 |
| 25464 | 25464 | 0.00 | 117.75 |
| 26527 | 26527 | 0.00 | 112.30 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cetirizine dihydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006116-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cetirizine dihydrochloride; Cetirizini dihydrochloridum

### Special notes

When selecting the *Cetirizine dihydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cetirizine dihydrochloride | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Cetirizine dihydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cetirizine dihydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Doxylamine hydrogen succinate | 105.62 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cetirizine dihydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cetirizine dihydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Cetirizine dihydrochloride | 2210014 | 26509 | 40 | 20230112* |
| FSA Chemicals | Cetirizine dihydrochloride | 23A02-APR23228 | 27654 | 40 | 20221019 |
| FSA Chemicals | Cetirizine dihydrochloride | 23A02-APR23228 | 27654SI | 20 | 20221019 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 100 spectra of 3 reference samples from the substance/substance group *Cetirizine dihydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 226 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Cetirizine dihydrochloride*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Cetirizine dihydrochloride | 23C08-B01-227628 | 26686 | 40 |
| Euro OTC | Cetirizine dihydrochloride | 2210014 | 26509SI† | 20 |
| Fagron | Cetirizine dihydrochloride | 23C08-B01-227628 | 26686SI | 20 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Cetirizine dihydrochloride*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

### Validation results

The validation runs checked whether the substance/substance group *Cetirizine dihydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cetirizine dihydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 100 | 0 | 158 226 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Cetirizine dihydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 94.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26509 | 26509 | 0.00 | 147.07 |
| 27654 | 26509 | 11.69 | 142.56 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cetostearyl alcohol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20738-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cetostearyl alcohol; Alcohol cetylicus; Alcohol cetylicus et stearylicus; Alcohol cetylicus et stearylicus emulsificans A; Cetomacrogol emulsifying wax 1000 NI; Cetyl alcohol; Emulsifying cetostearyl alcohol (type A)

### Special notes

When selecting the *Cetostearyl alcohol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cetostearyl alcohol | 33 | 28 | 498 |

### Second-stage model

For differentiation of the substance/substance group *Cetostearyl alcohol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cetostearyl alcohol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Non-ionic emulsifying alcohol | 20.40 | – |
| Glycerol monostearate, emulsifying | 42.61 | – |
| Glycerol monostearate 60 | 69.79 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cetostearyl alcohol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cetostearyl alcohol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Cetomacrogol emulsifying … | 160804 | 22396 | 40 | 20160323* |
| Caelo | Cetomacrogol emulsifying … | 21002092004 | 25978 | 35 | 2208569 |
| Caelo | Cetomacrogol emulsifying … | 21002092004 | 25978SI | 30 | 2208569 |
| Caelo | Cetomacrogol emulsifying … | 22002953003 | 26744 | 40 | 20221012 |
| Caelo | Cetomacrogol emulsifying … | 24002878002 | 27573 | 40 | 20250107 |
| Fagron | Cetomacrogol emulsifying … | 12H07-N06 | 20738 | 40 | 20120905 |
| Fagron | Cetomacrogol emulsifying … | 13C05-B40-289262 | 21054 | 40 | 1408003 |
| Caelo | Cetostearyl alcohol | 14054504 | 21314 | 40 | 20140226 |
| Caelo | Cetostearyl alcohol | 14054504 | 21442 | 60 | 20140226 |
| Caelo | Cetostearyl alcohol | 17049205 | 23725 | 40 | 20170302 |
| Caelo | Cetostearyl alcohol | 20002898002 | 25499 | 40 | 20200916 |
| Caelo | Cetostearyl alcohol | 21003928003 | 26231 | 40 | 20211208 |
| Caelo | Cetostearyl alcohol | 23000403 | 26698 | 40 | 20230228* |
| Caelo | Cetostearyl alcohol | 23002042 | 26941 | 40 | 20230922* |
| Caelo | Cetostearyl alcohol | 23002042 | 26941SI | 20 | 20230922* |
| Fagron | Cetostearyl alcohol | 13C13-N13 | 20968 | 40 | 1402265 |
| Caelo | Cetyl alcohol | 13096901 | 20896 | 40 | 1405179 |
| Caelo | Cetyl alcohol | 13286502 | 21318 | 40 | 20130925 |
| Caelo | Cetyl alcohol | 13286502 | 21435 | 60 | 20130925 |
| Caelo | Cetyl alcohol | 15323301 | 22266 | 60 | AR-16-FG-008835-01 |

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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Cetyl alcohol | 161063 | 22398 | 40 | 20160420* |
| Caelo | Cetyl alcohol | 161063 | 22399 | 40 | 20160420* |
| Caelo | Cetyl alcohol | 161063 | 22400 | 40 | 20160420* |
| Caelo | Cetyl alcohol | 161063 | 22401 | 40 | 20160420* |
| Caelo | Cetyl alcohol | 161063 | 22402 | 40 | 20160420* |
| Caelo | Cetyl alcohol | 161063 | 22403 | 40 | 20160420* |
| Caelo | Cetyl alcohol | 20002637001 | 25498 | 40 | 20201009 |
| Caelo | Cetyl alcohol | 22000377002 | 26586 | 40 | 20220308 |
| Caelo | Cetyl alcohol | 22000377002 | 26586SI | 20 | 20220308 |
| Caelo | Cetyl alcohol | 23000249 | 26695 | 40 | 20230224* |
| Caelo | Cetyl alcohol | 23000249 | 26695SI | 20 | 20230224* |
| Caelo | Cetyl alcohol | 23000130 | 26697 | 40 | 20230224* |
| Caelo | Cetyl alcohol | 23000130 | 26697SI | 20 | 20230224* |
| Euro OTC | Cetyl alcohol | 1508014-01 | 22611 | 40 | 20150821 |
| Bombastus | Emulsifying cetostearyl a… | 21004319 | 26025 | 40 | 20211011 |
| Caelo | Emulsifying cetostearyl a… | 13233005 | 21319 | 30 | 1506057 |
| Caelo | Emulsifying cetostearyl a… | 13233005 | 21434 | 60 | 20130816 |
| Caelo | Emulsifying cetostearyl a… | 14322505 | 21830 | 60 | 20141031 |
| Caelo | Emulsifying cetostearyl a… | 153857 | 22331 | 60 | 20151202* |
| Caelo | Emulsifying cetostearyl a… | 153857 | 22332 | 60 | 20151202* |
| Caelo | Emulsifying cetostearyl a… | 153856 | 22333 | 60 | 20160210* |
| Caelo | Emulsifying cetostearyl a… | 153856 | 22334 | 60 | 20160210* |
| Euro OTC | Emulsifying cetostearyl a… | 1510043 | 21998 | 60 | 20151124* |
| Euro OTC | Emulsifying cetostearyl a… | 1504010-01 | 22264 | 60 | 20150423 |
| Euro OTC | Emulsifying cetostearyl a… | 2002033 | 25253 | 40 | 20200617* |
| Euro OTC | Emulsifying cetostearyl a… | 2012002 | 25528 | 40 | 20210104* |
| Fagron | Emulsifying cetostearyl a… | 13L17-B05 | 21279 | 40 | 1505070 |
| Fagron | Emulsifying cetostearyl a… | 16I13-B01-326511 | 23022 | 40 | 20161024 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 2035 spectra of 48 reference samples from the substance/substance group *Cetostearyl alcohol*. These samples are listed above in the *calibration samples* section. The reference samples come from 33 different batches.
- 156 291 spectra from a total of 2924 batches from further 493 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1390 spectra of 38 reference samples from the substance/substance group *Cetostearyl alcohol*.
- Among them are spectra of independent samples from 28 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Cetomacrogol emulsifying … | 14055001 | 21381 | 40 |
| Caelo | Cetomacrogol emulsifying … | 15277504 | 22390 | 40 |
| Caelo | Cetomacrogol emulsifying … | 20000858003 | 25519 | 40 |
| Caelo | Cetostearyl alcohol | 170492 | 23097 | 40 |
| Caelo | Cetostearyl alcohol | 172979 | 23819 | 40 |
| Caelo | Cetostearyl alcohol | 190552 | 24721 | 40 |
| Caelo | Cetostearyl alcohol | 21000059005 | 25935 | 40 |
| Caelo | Cetostearyl alcohol | 24001586 | 27328 | 40 |
| Caelo | Cetostearyl alcohol | 24002892 | 27534 | 40 |
| Caelo | Cetyl alcohol | 170473 | 23068 | 40 |
| Caelo | Cetyl alcohol | 173155 | 23973 | 40 |
| Caelo | Cetyl alcohol | 21001593 | 25697 | 50 |
| Caelo | Cetyl alcohol | 23003036 | 27420 | 40 |
| Caelo | Cetyl alcohol | 24002178 | 27421 | 40 |
| Bombastus | Emulsifying cetostearyl a… | 23004942 | 27060 | 40 |
| Caelo | Emulsifying cetostearyl a… | 171980 | 23575 | 40 |
| Caelo | Emulsifying cetostearyl a… | 180180 | 24033 | 40 |
| Caelo | Emulsifying cetostearyl a… | 191857 | 25068 | 40 |
| Caelo | Emulsifying cetostearyl a… | 20002023 | 25377 | 40 |
| Caelo | Emulsifying cetostearyl a… | 21000566 | 25663 | 40 |
| Caelo | Emulsifying cetostearyl a… | 22004149 | 26699 | 40 |
| Caelo | Emulsifying cetostearyl a… | 24002417 | 27417 | 40 |
| Euro OTC | Emulsifying cetostearyl a… | 1604013 | 22540 | 40 |
| Euro OTC | Emulsifying cetostearyl a… | 1701031 | 22999 | 40 |
| Euro OTC | Emulsifying cetostearyl a… | 1705001 | 23381 | 40 |
| Euro OTC | Emulsifying cetostearyl a… | 1711001 | 23737 | 40 |
| Fagron | Emulsifying cetostearyl a… | 23A11-B07-224497 | 26611 | 40 |
| Fagron | Emulsifying cetostearyl a… | 24G09-B04-003936 | 27470 | 40 |
| Caelo | Cetomacrogol emulsifying … | 160804 | 22395 | 40 |
| Caelo | Cetomacrogol emulsifying … | 160804 | 22397 | 40 |
| Caelo | Cetomacrogol emulsifying … | 22002953003 | 26744SI† | 20 |
| Caelo | Cetomacrogol emulsifying … | 24002878002 | 27573SI† | 20 |
| Caelo | Cetostearyl alcohol | 21003928003 | 26231SI† | 20 |
| Caelo | Cetostearyl alcohol | 23000403 | 26698SI† | 20 |
| Bombastus | Emulsifying cetostearyl a… | 23004942 | 27060SI | 20 |
| Caelo | Emulsifying cetostearyl a… | 22004149 | 26699SI | 20 |
| Euro OTC | Emulsifying cetostearyl a… | 1711001 | 25093 | 40 |
| Fagron | Emulsifying cetostearyl a… | 23A11-B07-224497 | 26611SI | 20 |

- 211 550 spectra from a total of 4254 batches from further 869 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1681 spectra from 652 *Apo-Ident* customers from 425 batches from the substance/substance group *Cetostearyl alcohol*.
- Among them are spectra of independent samples from 405 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cetostearyl alcohol | 1711001-02 | 1 |
| | Emulsifying cetostearyl a... | 2012002-02 | 1 |
| | Cetostearyl alcohol | 21000086001 | 2 |
| | Emulsifying cetostearyl a... | 21003223007 | 1 |
| | Emulsifying cetostearyl a... | 21003223008 | 3 |
| | Emulsifying cetostearyl a... | 21003223010 | 1 |
| | Emulsifying cetostearyl a... | 21003223011 | 3 |
| | Cetyl alcohol | 22000377002 | 1 |
| | Cetomacrogol emulsifying ... | 22001170001 | 3 |
| | Emulsifying cetostearyl a... | 22001324007 | 2 |
| | Emulsifying cetostearyl a... | 22001329004 | 8 |
| | Emulsifying cetostearyl a... | 22001329006 | 1 |
| | Emulsifying cetostearyl a... | 22001329007 | 1 |
| | Emulsifying cetostearyl a... | 22001329008 | 15 |
| | Cetostearyl alcohol | 22003074003 | 2 |
| | Emulsifying cetostearyl a... | 22004149003 | 1 |
| | Emulsifying cetostearyl a... | 22004149004 | 5 |
| | Emulsifying cetostearyl a... | 22004149005 | 3 |
| | Emulsifying cetostearyl a... | 22004149006 | 2 |
| | Emulsifying cetostearyl a... | 22004189 | 2 |
| | Emulsifying cetostearyl a... | 2201329008 | 1 |
| | Emulsifying cetostearyl a... | 2204149004 | 1 |
| | Emulsifying cetostearyl a... | 22C11-B02-222108 | 1 |
| | Cetyl alcohol | 23000130003 | 1 |
| | Cetyl alcohol | 23000130004 | 9 |
| | Cetyl alcohol | 23000130007 | 1 |
| | Cetyl alcohol | 2300013004 | 1 |
| | Cetostearyl alcohol | 23000403003 | 2 |
| | Cetyl alcohol | 23003036004 | 1 |
| | Cetyl alcohol | 23003036008 | 2 |
| | Cetostearyl alcohol | 23003382008 | 2 |
| | Cetostearyl alcohol | 23003569001 | 1 |
| | Emulsifying cetostearyl a... | 23004942 | 2 |
| | Emulsifying cetostearyl a... | 23A11-B07-224497 | 2 |
| | Cetyl alcohol | 23E25-B05_230388 | 1 |
| | Emulsifying cetostearyl a... | 23E25-B05229965 | 1 |
| | Emulsifying cetostearyl a... | 2400011008 | 1 |
| | Emulsifying cetostearyl a... | 24000111005 | 2 |
| | Emulsifying cetostearyl a... | 24000111008 | 4 |
| | Cetostearyl alcohol | 2400011108 | 1 |
| | Emulsifying cetostearyl a... | 24002417006 | 1 |
| | Emulsifying cetostearyl a... | 280060037 | 1 |
| | Cetomacrogol emulsifying ... | 2953003 | 1 |
| | Cetyl alcohol | 522202021 | 1 |
| A.H.D. | Emulsifying cetostearyl a... | 12L19-N03 | 2 |
| ahd/lamotte | Cetostearyl alcohol | 13210504 | 1 |
| AHD | Cetyl alcohol | 17321603 | 1 |
| AHD | Cetyl alcohol | 20002637001 | 1 |
| AHD | Cetomacrogol emulsifying ... | 8073743 | 1 |
| ALH | Emulsifying cetostearyl a... | 15271405 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Health 24.0... | Emulsifying cetostearyl a... | 13L17-B05-289805 | 1 |
| alliance health. 05.... | Emulsifying cetostearyl a... | 14G31-B03-297610 | 1 |
| Anzag | Cetostearyl alcohol | 12G02-N04 | 4 |
| Audor Pharma | Emulsifying cetostearyl a... | 16238602 | 1 |
| BASF / Sanacorp | Emulsifying cetostearyl a... | B04-1953003 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 18000081P-180824-1 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 18000081P181203-4 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 18000081P-190312-9 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 18002312 | 3 |
| Bombastus | Emulsifying cetostearyl a... | 18003404 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 18003437 | 4 |
| Bombastus | Emulsifying cetostearyl a... | 18006205P-190312-10 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 19002555 | 5 |
| Bombastus | Emulsifying cetostearyl a... | 19005207P-200116-3 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 19005208 | 2 |
| Bombastus | Emulsifying cetostearyl a... | 20001742 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 20005694 | 2 |
| Bombastus | Emulsifying cetostearyl a... | 265360 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 278418 | 1 |
| Bombastus | Emulsifying cetostearyl a... | 288691 | 3 |
| Bombastus | Emulsifying cetostearyl a... | 295148 | 2 |
| Bombastus | Emulsifying cetostearyl a... | 300132 | 5 |
| Bombastus | Emulsifying cetostearyl a... | 303935 | 3 |
| Bombastus | Emulsifying cetostearyl a... | 308514 | 5 |
| Bombastus | Emulsifying cetostearyl a... | 60083112P-200326-4 | 1 |
| Caelo | Emulsifying cetostearyl a... |  | 3 |
| Caelo | Emulsifying cetostearyl a... | 11009204 | 1 |
| Caelo | Cetyl alcohol | 1112013B | 1 |
| Caelo | Cetyl alcohol | 11153405 | 1 |
| Caelo | Cetostearyl alcohol | 11162305 | 1 |
| Caelo | Emulsifying cetostearyl a... | 11291101 | 1 |
| Caelo | Emulsifying cetostearyl a... | 11291103 | 1 |
| Caelo | Cetostearyl alcohol | 11302101 | 1 |
| Caelo | Cetyl alcohol | 11320702 | 2 |
| Caelo | Cetyl alcohol | 12018605 | 2 |
| Caelo | Cetostearyl alcohol | 12021304 | 1 |
| Caelo | Cetostearyl alcohol | 12025301 | 2 |
| Caelo | Cetostearyl alcohol | 12065709 | 7 |
| Caelo | Cetyl alcohol | 1212E-01076 | 1 |
| Caelo | Emulsifying cetostearyl a... | 12134203 | 1 |
| Caelo | Emulsifying cetostearyl a... | 12229402 | 2 |
| Caelo | Emulsifying cetostearyl a... | 12231402 | 1 |
| Caelo | Cetyl alcohol | 12271103 | 5 |
| Caelo | Emulsifying cetostearyl a... | 12331402 | 7 |
| Caelo | Emulsifying cetostearyl a... | 12331407 | 3 |
| Caelo | Cetyl alcohol | 12338604 | 6 |
| Caelo | Emulsifying cetostearyl a... | 12C30-N01 | 1 |
| Caelo | Cetostearyl alcohol | 13018305 | 4 |
| Caelo | Cetostearyl alcohol | 13018306 | 1 |
| Caelo | Cetyl alcohol | 13096901 | 5 |
| Caelo | Cetyl alcohol | 13096904 | 2 |
| Caelo | Cetostearyl alcohol | 1314405 | 1 |
| Caelo | Emulsifying cetostearyl a... | 13144103 | 1 |
| Caelo | Emulsifying cetostearyl a... | 13144104 | 2 |
| Caelo | Emulsifying cetostearyl a... | 13144105 | 12 |
| Caelo | Emulsifying cetostearyl a... | 13144107 | 2 |
| Caelo | Cetostearyl alcohol | 13206206 | 3 |
| Caelo | Cetyl alcohol | 13210504 | 9 |
| Caelo | Emulsifying cetostearyl a... | 13233001 | 1 |
| Caelo | Cetostearyl alcohol | 13233002 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Emulsifying cetostearyl a… | 13233005 | 12 |
| Caelo | Emulsifying cetostearyl a… | 13233006 | 1 |
| Caelo | Emulsifying cetostearyl a… | 13233008 | 2 |
| Caelo | Cetyl alcohol | 13286502 | 3 |
| Caelo | Emulsifying cetostearyl a… | 13352102 | 1 |
| Caelo | Cetostearyl alcohol | 13-B01-327355 | 1 |
| Caelo | Emulsifying cetostearyl a… | 13L17-B05-289806 | 1 |
| Caelo | Cetostearyl alcohol | 14054504 | 4 |
| Caelo | Cetostearyl alcohol | 14054508 | 3 |
| Caelo | Cetomacrogol emulsifying … | 14055002 | 1 |
| Caelo | Cetostearyl alcohol | 14061317 | 1 |
| Caelo | Emulsifying cetostearyl a… | 14156201 | 1 |
| Caelo | Emulsifying cetostearyl a… | 14158201 | 13 |
| Caelo | Emulsifying cetostearyl a… | 14158202 | 1 |
| Caelo | Cetostearyl alcohol | 14215007 | 6 |
| Caelo | Cetyl alcohol | 14262204 | 5 |
| Caelo | Emulsifying cetostearyl a… | 14322502 | 2 |
| Caelo | Cetostearyl alcohol | 14322505 | 12 |
| Caelo | Emulsifying cetostearyl a… | 14322506 | 2 |
| Caelo | Emulsifying cetostearyl a… | 14322512 | 1 |
| Caelo | Cetostearyl alcohol | 14346201 | 3 |
| Caelo | Cetostearyl alcohol | 14346202 | 1 |
| Caelo | Cetyl alcohol | 14349101 | 14 |
| Caelo | Emulsifying cetostearyl a… | 15071704 | 1 |
| Caelo | Emulsifying cetostearyl a… | 15090701 | 10 |
| Caelo | Emulsifying cetostearyl a… | 15090703 | 2 |
| Caelo | Emulsifying cetostearyl a… | 15090706 | 3 |
| Caelo | Emulsifying cetostearyl a… | 1510043-01 | 1 |
| Caelo | Cetomacrogol emulsifying … | 15113703 | 1 |
| Caelo | Cetyl alcohol | 1523316 | 1 |
| Caelo | Emulsifying cetostearyl a… | 15271402 | 9 |
| Caelo | Emulsifying cetostearyl a… | 15271403 | 3 |
| Caelo | Cetostearyl alcohol | 15271405 | 12 |
| Caelo | Emulsifying cetostearyl a… | 15271407 | 9 |
| Caelo | Emulsifying cetostearyl a… | 15271408 | 3 |
| Caelo | Emulsifying cetostearyl a… | 15271410 | 1 |
| Caelo | Cetostearyl alcohol | 15272702 | 2 |
| Caelo | Cetostearyl alcohol | 15272709 | 7 |
| Caelo | Cetostearyl alcohol | 15272717 | 6 |
| Caelo | Cetomacrogol emulsifying … | 15277501 | 1 |
| Caelo | Cetomacrogol emulsifying … | 15277505 | 1 |
| Caelo | Cetyl alcohol | 15323301 | 8 |
| Caelo | Cetyl alcohol | 15323308 | 1 |
| Caelo | Cetyl alcohol | 15323311 | 11 |
| Caelo | Cetyl alcohol | 15323316 | 4 |
| Caelo | Emulsifying cetostearyl a… | 15385602 | 3 |
| Caelo | Emulsifying cetostearyl a… | 15385606 | 1 |
| Caelo | Emulsifying cetostearyl a… | 15789271 | 1 |
| Caelo | Emulsifying cetostearyl a… | 15C31-B99-307062 | 1 |
| Caelo | Cetostearyl alcohol | 16048812 | 3 |
| Caelo | Cetomacrogol emulsifying … | 16080403 | 1 |
| Caelo | Cetomacrogol emulsifying … | 16080407 | 2 |
| Caelo | Cetostearyl alcohol | 160914 | 1 |
| Caelo | Cetyl alcohol | 16106307 | 4 |
| Caelo | Emulsifying cetostearyl a… | 16119604 | 14 |
| Caelo | Emulsifying cetostearyl a… | 16119607 | 2 |
| Caelo | Cetostearyl alcohol | 16230603 | 2 |
| Caelo | Cetostearyl alcohol | 16238604 | 3 |
| Caelo | Emulsifying cetostearyl a… | 16238607 | 11 |
| Caelo | Cetyl alcohol | 16335802 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Cetyl alcohol | 16335805 | 1 |
| Caelo | Cetyl alcohol | 16335807 | 7 |
| Caelo | Cetomacrogol emulsifying … | 16348101 | 2 |
| Caelo | Emulsifying cetostearyl a… | 16I13-B01-327355 | 1 |
| Caelo | Emulsifying cetostearyl a… | 16I13-B01-327864 | 1 |
| Caelo | Cetyl alcohol | 17047303 | 1 |
| Caelo | Cetyl alcohol | 17047306 | 3 |
| Caelo | Cetyl alcohol | 17047307 | 13 |
| Caelo | Cetostearyl alcohol | 17049209 | 2 |
| Caelo | Cetostearyl alcohol | 1705001-01 | 1 |
| Caelo | Emulsifying cetostearyl a… | 17056802 | 1 |
| Caelo | Emulsifying cetostearyl a… | 17056806 | 6 |
| Caelo | Cetyl alcohol | 1711001-02 | 2 |
| Caelo | Cetostearyl alcohol | 171215CSA/15272717 | 1 |
| Caelo | Emulsifying cetostearyl a… | 17132001 | 11 |
| Caelo | Emulsifying cetostearyl a… | 17139201 | 5 |
| Caelo | Emulsifying cetostearyl a… | 17198002 | 5 |
| Caelo | Emulsifying cetostearyl a… | 17198003 | 24 |
| Caelo | Cetomacrogol emulsifying … | 17210402 | 1 |
| Caelo | Cetyl alcohol | 17234902 | 1 |
| Caelo | Cetyl alcohol | 17234903 | 1 |
| Caelo | Cetyl alcohol | 17234904 | 5 |
| Caelo | Emulsifying cetostearyl a… | 17261701 | 2 |
| Caelo | Emulsifying cetostearyl a… | 17261702 | 4 |
| Caelo | Cetostearyl alcohol | 17321303 | 10 |
| Caelo | Cetostearyl alcohol | 17321305 | 1 |
| Caelo | Cetostearyl alcohol | 17321319 | 1 |
| Caelo | Cetyl alcohol | 17321603 | 16 |
| Caelo | Cetyl alcohol | 17321612 | 6 |
| Caelo | Cetostearyl alcohol | 17D28-B06-334609 | 1 |
| Caelo | Emulsifying cetostearyl a… | 17D28-B06-338141 | 2 |
| Caelo | Emulsifying cetostearyl a… | 17F21-B01-341021 | 1 |
| Caelo | Emulsifying cetostearyl a… | 18003401 | 1 |
| Caelo | Emulsifying cetostearyl a… | 18003404 | 13 |
| Caelo | Emulsifying cetostearyl a… | 18006205P-190719-1 | 1 |
| Caelo | Cetostearyl alcohol | 18018001 | 4 |
| Caelo | Emulsifying cetostearyl a… | 18018002 | 1 |
| Caelo | Emulsifying cetostearyl a… | 18018003P-190308-2 | 1 |
| Caelo | Emulsifying cetostearyl a… | 18018005 | 9 |
| Caelo | Emulsifying cetostearyl a… | 18018006 | 2 |
| Caelo | Emulsifying cetostearyl a… | 18081201 | 1 |
| Caelo | Cetyl alcohol | 18153102 | 18 |
| Caelo | Cetyl alcohol | 18237701 | 19 |
| Caelo | Cetostearyl alcohol | 18248502 | 12 |
| Caelo | Cetostearyl alcohol | 18248510 | 3 |
| Caelo | Emulsifying cetostearyl a… | 18291403 | 2 |
| Caelo | Emulsifying cetostearyl a… | 18291404 | 16 |
| Caelo | Emulsifying cetostearyl a… | 18291406 | 4 |
| Caelo | Emulsifying cetostearyl a… | 18291407 | 11 |
| Caelo | Emulsifying cetostearyl a… | 18291408 | 1 |
| Caelo | Cetostearyl alcohol | 18A23-B04 | 1 |
| Caelo | Emulsifying cetostearyl a… | 18A23-B04-349155 | 1 |
| Caelo | Cetostearyl alcohol | 18A23-B04-352987 | 2 |
| Caelo | Emulsifying cetostearyl a… | 19005207P-191101-2 | 1 |
| Caelo | Cetyl alcohol | 19012504 | 6 |
| Caelo | Cetyl alcohol | 19012509 | 11 |
| Caelo | Emulsifying cetostearyl a… | 19032014B | 1 |
| Caelo | Emulsifying cetostearyl a… | 19055206 | 5 |
| Caelo | Cetostearyl alcohol | 191857002 | 23 |
| Caelo | Emulsifying cetostearyl a… | 19185702 | 24 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Emulsifying cetostearyl a… | 19185703 | 3 |
| Caelo | Cetostearyl alcohol | 192139002 | 3 |
| Caelo | Cetostearyl alcohol | 192139007 | 3 |
| Caelo | Cetomacrogol emulsifying … | 192199001 | 2 |
| Caelo | Cetyl alcohol | 192219005 | 16 |
| Caelo | Emulsifying cetostearyl a… | 192747003 | 9 |
| Caelo | Emulsifying cetostearyl a… | 192747007 | 27 |
| Caelo | Cetyl alcohol | 192921001 | 9 |
| Caelo | Cetyl alcohol | 200002637001 | 1 |
| Caelo | Cetomacrogol emulsifying … | 20000858003 | 3 |
| Caelo | Cetomacrogol emulsifying … | 20002050001 | 1 |
| Caelo | Cetyl alcohol | 20002637001 | 18 |
| Caelo | Cetostearyl alcohol | 20002898002 | 5 |
| Caelo | Cetyl alcohol | 20004011001 | 1 |
| Caelo | Cetyl alcohol | 2002637001 | 1 |
| Caelo | Emulsifying cetostearyl a… | 2011404 | 1 |
| Caelo | Cetyl alcohol | 20250112-1 | 1 |
| Caelo | Emulsifying cetostearyl a… | 20F30B01200749 | 1 |
| Caelo | Emulsifying cetostearyl a… | 210000566007 | 1 |
| Caelo | Cetostearyl alcohol | 21000059001 | 9 |
| Caelo | Cetostearyl alcohol | 21000059005 | 8 |
| Caelo | Emulsifying cetostearyl a… | 21000086001 | 24 |
| Caelo | Emulsifying cetostearyl a… | 21000086002 | 5 |
| Caelo | Emulsifying cetostearyl a… | 21000086003 | 1 |
| Caelo | Cetyl alcohol | 210001593001 | 1 |
| Caelo | Emulsifying cetostearyl a… | 21000566 | 1 |
| Caelo | Emulsifying cetostearyl a… | 21000566005 | 1 |
| Caelo | Emulsifying cetostearyl a… | 21000566006 | 1 |
| Caelo | Emulsifying cetostearyl a… | 21000566007 | 14 |
| Caelo | Cetostearyl alcohol | 2100059001 | 1 |
| Caelo | Cetostearyl alcohol | 2100086001 | 2 |
| Caelo | Cetostearyl alcohol | 21001071005 | 1 |
| Caelo | Cetostearyl alcohol | 21001071007 | 5 |
| Caelo | Cetyl alcohol | 21001593001 | 11 |
| Caelo | Cetomacrogol emulsifying … | 21002092002 | 2 |
| Caelo | Cetomacrogol emulsifying … | 21002092004 | 2 |
| Caelo | Cetyl alcohol | 21002870003 | 5 |
| Caelo | Emulsifying cetostearyl a… | 21003223003 | 10 |
| Caelo | Emulsifying cetostearyl a… | 21003223004 | 1 |
| Caelo | Emulsifying cetostearyl a… | 21003223008 | 4 |
| Caelo | Emulsifying cetostearyl a… | 21003223010 | 2 |
| Caelo | Cetostearyl alcohol | 21003928003 | 3 |
| Caelo | Cetostearyl alcohol | 22001324007 | 4 |
| Caelo | Emulsifying cetostearyl a… | 22001329004 | 2 |
| Caelo | Emulsifying cetostearyl a… | 22001329007 | 1 |
| Caelo | Cetostearyl alcohol | 2201324007 | 1 |
| Caelo | Emulsifying cetostearyl a… | 23051503 | 1 |
| Caelo | Emulsifying cetostearyl a… | 23091402 | 1 |
| Caelo | Emulsifying cetostearyl a… | 24101305 | 1 |
| Caelo | Emulsifying cetostearyl a… | 25/AKD1 | 1 |
| Caelo | Emulsifying cetostearyl a… | 25051201 | 1 |
| Caelo | Cetyl alcohol | 28101701 | 1 |
| Caelo | Emulsifying cetostearyl a… | 29091803 | 1 |
| Caelo | Emulsifying cetostearyl a… | 303935 | 1 |
| Caelo | Emulsifying cetostearyl a… | 31032015B | 1 |
| Caelo | Emulsifying cetostearyl a… | 3256 | 1 |
| Caelo | Emulsifying cetostearyl a… | 5011505 | 1 |
| Caelo | Emulsifying cetostearyl a… | 608/10072017 | 1 |
| Caelo | Cetyl alcohol | 7071807 | 1 |
| Caelo | Cetostearyl alcohol | 8041708 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Emulsifying cetostearyl a… | 9170717 | 1 |
| Caelo | Emulsifying cetostearyl a… | Unbekannt | 1 |
| Caeolo/Phönix | Emulsifying cetostearyl a… | 15271403 | 6 |
| Caeolo | Emulsifying cetostearyl a… | 17056807 | 1 |
| Caesar & Lorenz GmbH | Emulsifying cetostearyl a… | 18291404 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21003223003 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 18018005 | 1 |
| Caesar & Loretz GmbH… | Cetyl alcohol | 22000377002 | 1 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 11302101 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 192747005 | 1 |
| Caesar & Loretz GmbH… | Cetyl alcohol | 21001593001 | 2 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 191857002 | 4 |
| Caesar & Loretz GmbH… | Cetyl alcohol | 20002637001 | 1 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 21000059001 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21000086001 | 2 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 192747007 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21000566007 | 1 |
| Caesar & Loretz GmbH/Gehe | Emulsifying cetostearyl a… | 18291401 | 1 |
| Caesar & Loretz GmbH/Gehe | Cetyl alcohol | 192219005 | 2 |
| Caesar & Loretz GmbH/Gehe | Cetyl alcohol | 20002637001 | 1 |
| Caesar & Loretz GmbH/Gehe | Emulsifying cetostearyl a… | 21000566006 | 1 |
| Caesar & Loretz GmbH/GEHE | Cetostearyl alcohol | 22001324007 | 1 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 21001071007 | 1 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 22001324007 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 18291404 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 191857002 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21000086001 | 3 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 19055206 | 1 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 19185702 | 1 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 21001071007 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21003223003 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21003223008 | 1 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 21003928003 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21003223010 | 1 |
| Caesar & Loretz GmbH… | Cetyl alcohol | 19012509 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 19185702 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21000566007 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21001071007 | 1 |
| Caesar & Loretz GmbH/Sana | Cetyl alcohol | 192219005 | 2 |
| Caesar & Loretz GmbH… | Cetostearyl alcohol | 18291404 | 2 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 18291406 | 1 |
| Caesar & Loretz GmbH… | Emulsifying cetostearyl a… | 21000566007 | 1 |
| Caesar & Loretz GmbH… | Cetyl alcohol | 21001593001 | 1 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 13233008 | 1 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 16119604 | 3 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 17056806 | 1 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 17132001 | 1 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 18018005 | 1 |
| Caesar & Loretz GmbH | Cetomacrogol emulsifying … | 18143802 | 1 |
| Caesar & Loretz GmbH | Cetyl alcohol | 18153102 | 3 |
| Caesar & Loretz GmbH | Cetyl alcohol | 18237701 | 3 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 18248502 | 5 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 18291403 | 2 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 18291404 | 2 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 18291407 | 1 |
| Caesar & Loretz GmbH | Cetyl alcohol | 19012504 | 2 |
| Caesar & Loretz GmbH | Cetyl alcohol | 19012509 | 2 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 19055206 | 3 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 191857002 | 5 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a… | 19185702 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 19185704 | 1 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 192139002 | 3 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 192139007 | 3 |
| Caesar & Loretz GmbH | Cetomacrogol emulsifying ... | 192199001 | 1 |
| Caesar & Loretz GmbH | Cetyl alcohol | 192219005 | 2 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 192747005 | 1 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 192747007 | 9 |
| Caesar & Loretz GmbH | Cetyl alcohol | 192921001 | 3 |
| Caesar & Loretz GmbH | Cetomacrogol emulsifying ... | 20000858003 | 1 |
| Caesar & Loretz GmbH | Cetyl alcohol | 20001279002 | 1 |
| Caesar & Loretz GmbH | Cetomacrogol emulsifying ... | 20002050001 | 2 |
| Caesar & Loretz GmbH | Cetyl alcohol | 20002637001 | 7 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 20002898002 | 2 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 21000059001 | 3 |
| Caesar & Loretz GmbH | Cetyl alcohol | 21000059005 | 1 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 21000086001 | 7 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 21000086003 | 2 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 21000566007 | 4 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 21001071007 | 1 |
| Caesar & Loretz GmbH | Cetyl alcohol | 21001593001 | 2 |
| Caesar & Loretz GmbH | Cetyl alcohol | 21002870003 | 2 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 21003223002 | 2 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 21003223003 | 1 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 21003223010 | 1 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 21003928003 | 1 |
| Caesar & Loretz GmbH | Cetyl alcohol | 22000377001 | 1 |
| Caesar & Loretz GmbH | Cetyl alcohol | 22000377002 | 1 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 22001324007 | 2 |
| Caesar & Loretz GmbH | Emulsifying cetostearyl a... | 22001329004 | 3 |
| Caesar & Loretz GmbH | Cetostearyl alcohol | 22003074003 | 1 |
| Caesar & Loretz/Gehe | Cetyl alcohol | 19012504 | 1 |
| Caesar & Loretz/Geil... | Emulsifying cetostearyl a... | 192747007 | 1 |
| Caesar & Loretz | Emulsifying cetostearyl a... | 18291407 | 1 |
| Caesar & Noweda | Emulsifying cetostearyl a... | 19185703 | 1 |
| Caesar &Loretz GmbH | Emulsifying cetostearyl a... | 12065703 | 1 |
| Caesar&loretz,Phoenix | Emulsifying cetostearyl a... | 14158201 | 1 |
| Caesar&Loretz/Noweda | Emulsifying cetostearyl a... | 15271405 | 1 |
| Caesar/Lorenz | Emulsifying cetostearyl a... | 13233005 | 1 |
| Caesar/Noweda | Emulsifying cetostearyl a... | 11343405 | 1 |
| Caesar/Noweda | Emulsifying cetostearyl a... | 12065707 | 1 |
| Caesar/Noweda | Cetostearyl alcohol | 15272705 | 1 |
| Caesar/Noweda | Cetostearyl alcohol | 2911E-01077 | 2 |
| Calo/AHD | Cetyl alcohol | 192921001 | 1 |
| Cealo/AHD | Cetostearyl alcohol | 16106307 | 1 |
| Cealo/Alliance Healthcare | Cetostearyl alcohol | 18291403 | 1 |
| Cealo/Gehe | Emulsifying cetostearyl a... | 21003223008 | 1 |
| Cealo/Sanacorp | Cetostearyl alcohol | 21003223003 | 1 |
| Cealo | Cetostearyl alcohol | 15385602 | 2 |
| Cealo | Cetostearyl alcohol | 19012504 | 1 |
| Celo/Jenne | Emulsifying cetostearyl a... | 21000086001 | 1 |
| Ebert-Jacobi | Cetostearyl alcohol | 16230603 | 1 |
| EuRho Anzag ek:3,47EUR | Cetyl alcohol | 110505501 | 1 |
| EuRho | Cetyl alcohol | 1206020-01 | 1 |
| Euro OTC | Emulsifying cetostearyl a... | 10836573 | 1 |
| Euro OTC | Cetyl alcohol | 1105055-01 | 1 |
| Euro OTC | Cetostearyl alcohol | 1107035-01 | 1 |
| Euro OTC | Cetostearyl alcohol | 1204015-01 | 1 |
| Euro OTC | Cetyl alcohol | 1206020-01 | 1 |
| Euro OTC | Cetyl alcohol | 1211002-01 | 2 |
| Euro OTC | Emulsifying cetostearyl a... | 1212019-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Emulsifying cetostearyl a… | 1305035-01 | 2 |
| Euro OTC | Emulsifying cetostearyl a… | 1404019-01 | 2 |
| Euro OTC | Cetostearyl alcohol | 1404019-02 | 2 |
| Euro OTC | Emulsifying cetostearyl a… | 1404019-03 | 1 |
| Euro OTC | Emulsifying cetostearyl a… | 14G31-B03-297610 | 1 |
| Euro OTC | Cetostearyl alcohol | 150401001 | 1 |
| Euro OTC | Emulsifying cetostearyl a… | 1504010-01 | 3 |
| Euro OTC | Emulsifying cetostearyl a… | 150410-01 | 1 |
| Euro OTC | Cetyl alcohol | 1508014-01 | 1 |
| Euro OTC | Cetyl alcohol | 150818C | 1 |
| Euro OTC | Cetostearyl alcohol | 1510043-01 | 4 |
| Euro OTC | Cetostearyl alcohol | 15271403 | 2 |
| Euro OTC | Emulsifying cetostearyl a… | 1604013-02 | 5 |
| Euro OTC | Emulsifying cetostearyl a… | 1701031-01 | 5 |
| Euro OTC | Cetostearyl alcohol | 17050001-01 | 1 |
| Euro OTC | Cetostearyl alcohol | 1705001-01 | 11 |
| Euro OTC | Emulsifying cetostearyl a… | 171001-02 | 1 |
| Euro OTC | Cetostearyl alcohol | 1711001-02 | 5 |
| Euro OTC | Emulsifying cetostearyl a… | 17110011-01 | 1 |
| Euro OTC | Cetyl alcohol | 18153102 | 1 |
| Euro OTC | Emulsifying cetostearyl a… | 2002033-01 | 3 |
| Euro OTC | Emulsifying cetostearyl a… | 2012002-01 | 1 |
| Euro OTC | Cetostearyl alcohol | 2012002-02 | 1 |
| Euro OTC | Cetostearyl alcohol | 20270912-2 | 1 |
| Euro OTC | Emulsifying cetostearyl a… | 21897043 | 1 |
| Euro OTC | Cetostearyl alcohol | 2806 | 1 |
| Euro/Gehe | Emulsifying cetostearyl a… | 150401-01 | 1 |
| Euroh/Noweda | Emulsifying cetostearyl a… | 1504010-01 | 1 |
| Fagro | Emulsifying cetostearyl a… | 5211Q-01078 | 1 |
| Fagron | Cetostearyl alcohol | 10F17-N02 | 1 |
| Fagron | Emulsifying cetostearyl a… | 11499002 | 1 |
| Fagron | Cetostearyl alcohol | 11E17-N13 | 1 |
| Fagron | Cetostearyl alcohol | 11f30-n11 | 1 |
| Fagron | Emulsifying cetostearyl a… | 11L22-N09 | 1 |
| Fagron | Cetostearyl alcohol | 12/17-N05 | 1 |
| Fagron | Emulsifying cetostearyl a… | 12602-N04 | 1 |
| Fagron | Cetyl alcohol | 12A-02N12 | 1 |
| Fagron | Emulsifying cetostearyl a… | 12C30-N01 | 2 |
| Fagron | Cetostearyl alcohol | 12E30-N13 | 1 |
| Fagron | Cetostearyl alcohol | 12g02-n04 | 1 |
| Fagron | Emulsifying cetostearyl a… | 12G02N04 | 1 |
| Fagron | Cetostearyl alcohol | 12G02-N04 | 9 |
| Fagron | Cetostearyl alcohol | 12J17-N05 | 2 |
| Fagron | Cetostearyl alcohol | 12J17-NO5 | 1 |
| Fagron | Cetostearyl alcohol | 12J29-N04 | 4 |
| Fagron | Cetostearyl alcohol | 12K22-N03 | 3 |
| Fagron | Cetostearyl alcohol | 12L19-N03 | 8 |
| Fagron | Cetostearyl alcohol | 13C13-N13 | 1 |
| Fagron | Emulsifying cetostearyl a… | 13F07-N05 | 12 |
| Fagron | Emulsifying cetostearyl a… | 13I06-N04 | 1 |
| Fagron | Cetostearyl alcohol | 13L17-B05 | 2 |
| Fagron | Emulsifying cetostearyl a… | 13L17B05289805 | 1 |
| Fagron | Cetostearyl alcohol | 13L17-B05-289805 | 7 |
| Fagron | Cetostearyl alcohol | 13L17-B05-289806 | 5 |
| Fagron | Emulsifying cetostearyl a… | 13L17-B05-289807 | 1 |
| Fagron | Emulsifying cetostearyl a… | 13L17-B05-294999 | 4 |
| Fagron | Cetostearyl alcohol | 14346201 | 1 |
| Fagron | Emulsifying cetostearyl a… | 14G31-B03 | 1 |
| Fagron | Emulsifying cetostearyl a… | 14G31-B03-297610 | 2 |
| Fagron | Cetostearyl alcohol | 14G31-B03-297611 | 1 |

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|---|---|---|---|
| Fagron | Emulsifying cetostearyl a… | 14G31-B03-305612 | 7 |
| Fagron | Cetostearyl alcohol | 15789271 | 2 |
| Fagron | Emulsifying cetostearyl a… | 15C31-B00-307062 | 1 |
| Fagron | Emulsifying cetostearyl a… | 15C31-B99-307062 | 5 |
| Fagron | Emulsifying cetostearyl a… | 15D24-B02 | 2 |
| Fagron | Emulsifying cetostearyl a… | 15D24-B02-308261 | 5 |
| Fagron | Emulsifying cetostearyl a… | 15D24-B02-311993 | 9 |
| Fagron | Emulsifying cetostearyl a… | 16/13-B01-327355 | 2 |
| Fagron | Emulsifying cetostearyl a… | 16/13-B01-331290 | 1 |
| Fagron | Emulsifying cetostearyl a… | 16/13-Bo1-327864 | 1 |
| Fagron | Emulsifying cetostearyl a… | 161006CSA | 1 |
| Fagron | Emulsifying cetostearyl a… | 16990201 | 1 |
| Fagron | Emulsifying cetostearyl a… | 16B23-B07 | 1 |
| Fagron | Cetostearyl alcohol | 16B23-B07-318218 | 4 |
| Fagron | Emulsifying cetostearyl a… | 16B23-B07-320384 | 7 |
| Fagron | Emulsifying cetostearyl a… | 16B23-B07-323025 | 3 |
| Fagron | Emulsifying cetostearyl a… | 16I13-B01 | 2 |
| Fagron | Emulsifying cetostearyl a… | 16I13-B01_326511 | 1 |
| Fagron | Emulsifying cetostearyl a… | 17028-B06-334609 | 1 |
| Fagron | Emulsifying cetostearyl a… | 171216CAE/0016830715 | 1 |
| Fagron | Cetyl alcohol | 17321612 | 1 |
| Fagron | Emulsifying cetostearyl a… | 17894959 | 1 |
| Fagron | Emulsifying cetostearyl a… | 17D21-B01-341021 | 1 |
| Fagron | Emulsifying cetostearyl a… | 17D28-B06 | 2 |
| Fagron | Emulsifying cetostearyl a… | 17D28-B06-334609 | 6 |
| Fagron | Emulsifying cetostearyl a… | 17D28-B06-338141 | 8 |
| Fagron | Cetostearyl alcohol | 17F21-B01 | 1 |
| Fagron | Emulsifying cetostearyl a… | 17F21-B01-341021 | 10 |
| Fagron | Emulsifying cetostearyl a… | 17F21-B01-344775 | 3 |
| Fagron | Emulsifying cetostearyl a… | 18003401 | 1 |
| Fagron | Emulsifying cetostearyl a… | 18A12-B04-355659 | 1 |
| Fagron | Cetostearyl alcohol | 18A23-B04 | 1 |
| Fagron | Emulsifying cetostearyl a… | 18A23-B04-349155 | 8 |
| Fagron | Emulsifying cetostearyl a… | 18A23-B04-352987 | 6 |
| Fagron | Emulsifying cetostearyl a… | 18A23-B04-355659 | 2 |
| Fagron | Cetostearyl alcohol | 18A23-B64 | 1 |
| Fagron | Emulsifying cetostearyl a… | 19/04-B04-195303 | 1 |
| Fagron | Cetostearyl alcohol | 19104-B04-195303 | 2 |
| Fagron | Emulsifying cetostearyl a… | 19I04-B04 | 1 |
| Fagron | Cetostearyl alcohol | 19I04-B04-195303 | 5 |
| Fagron | Cetostearyl alcohol | 19I04-BO4-195303 | 1 |
| Fagron | Emulsifying cetostearyl a… | 19IO4-BO4-195303 | 2 |
| Fagron | Cetostearyl alcohol | 19l04-B04-195303 | 1 |
| Fagron | Emulsifying cetostearyl a… | 20260712-2 | 1 |
| Fagron | Emulsifying cetostearyl a… | 20F30B01200749 | 1 |
| Fagron | Emulsifying cetostearyl a… | 20F30-B01-200749 | 8 |
| Fagron | Emulsifying cetostearyl a… | 21139741 | 1 |
| Fagron | Emulsifying cetostearyl a… | 21J20-B05-213671 | 4 |
| Fagron | Emulsifying cetostearyl a… | 2215I-01078 | 1 |
| Fagron | Emulsifying cetostearyl a… | 22803390 | 1 |
| Fagron | Emulsifying cetostearyl a… | 22C11-B02-222108 | 2 |
| Fagron | Emulsifying cetostearyl a… | 23A11-B07-224497 | 1 |
| Fagron | Emulsifying cetostearyl a… | 2717M-01078 | 1 |
| Fagron | Emulsifying cetostearyl a… | 2797 | 1 |
| Fagron | Emulsifying cetostearyl a… | 2918E-01078 | 1 |
| Fagron | Emulsifying cetostearyl a… | 297611 | 1 |
| Fagron | Emulsifying cetostearyl a… | 3013M-01078 | 1 |
| Fagron | Cetostearyl alcohol | 3414E-01078 | 1 |
| Fagron | Emulsifying cetostearyl a… | 68955-20-4 | 1 |
| Fagron | Cetostearyl alcohol | 7886542 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Cetostearyl alcohol | 8256792 | 4 |
| Fagron | Emulsifying cetostearyl a… | 9652865 | 2 |
| Fagron | Emulsifying cetostearyl a… | B04-1953003 | 1 |
| fargon | Emulsifying cetostearyl a… | 18A23-B04-352987 | 1 |
| Fiebig | Cetostearyl alcohol | 21000059001 | 1 |
| Finze | Cetyl alcohol | 10321703 | 1 |
| fragron | Emulsifying cetostearyl a… | 16113-b01-326511 | 1 |
| Gatt-Koller | Cetyl alcohol | 1690/06162416 | 1 |
| Gatt-Koller | Cetostearyl alcohol | 1803965 | 1 |
| Gehe | Emulsifying cetostearyl a… | 12L19-N03 | 1 |
| Gehe | Cetostearyl alcohol | 15272713 | 1 |
| Gehe | Cetostearyl alcohol | 15272717 | 1 |
| Gehe | Emulsifying cetostearyl a… | 1701031-01 | 1 |
| Gehe | Cetyl alcohol | 18237701 | 1 |
| Gehe | Emulsifying cetostearyl a… | 18291406 | 1 |
| Gehe | Cetyl alcohol | 19012504 | 1 |
| Gehe | Emulsifying cetostearyl a… | 22001329004 | 1 |
| GEHE | Emulsifying cetostearyl a… | 22001329908 | 1 |
| Gehe | Emulsifying cetostearyl a… | 22004149004 | 1 |
| Gehe | Emulsifying cetostearyl a… | 22004189 | 1 |
| Gepepharm/Gehe | Cetyl alcohol | 181531102 | 1 |
| Henry Lamotte / Noweda | Emulsifying cetostearyl a… | 300132 | 1 |
| Herba | Cetostearyl alcohol | KNC1133J18 | 1 |
| Jenne | Emulsifying cetostearyl a… | 24000111005 | 1 |
| Kehr | Cetyl alcohol | 17047303 | 1 |
| Kehr | Emulsifying cetostearyl a… | 18003404 | 1 |
| kehr | Emulsifying cetostearyl a… | 22001329004 | 1 |
| Klenk | Emulsifying cetostearyl a… | 16238607 | 1 |
| Krieger | Emulsifying cetostearyl a… | 1711001-01 | 1 |
| Krieger | Cetyl alcohol | 19012509 | 1 |
| L12 | Emulsifying cetostearyl a… | 17056806 | 1 |
| Nachprüfung | Cetyl alcohol | 123456 | 2 |
| Nachprüfung | Cetyl alcohol | 13286502 | 2 |
| Noweda/ Caesar&Loren… | Cetyl alcohol | 192921001 | 1 |
| Noweda | Cetostearyl alcohol | 12065709 | 1 |
| Noweda | Emulsifying cetostearyl a… | 13065576 | 1 |
| Noweda | Emulsifying cetostearyl a… | 13144104 | 1 |
| Noweda | Emulsifying cetostearyl a… | 13CA9 | 1 |
| Noweda | Cetostearyl alcohol | 17321303 | 1 |
| Noweda | Emulsifying cetostearyl a… | 18003404 | 1 |
| Noweda | Emulsifying cetostearyl a… | 18018005 | 1 |
| Noweda | Cetostearyl alcohol | 18248510 | 1 |
| Noweda | Emulsifying cetostearyl a… | 192747007 | 1 |
| Noweda | Emulsifying cetostearyl a… | 22001329008 | 2 |
| Noweda | Cetomacrogol emulsifying … | 22002953003 | 2 |
| Noweda | Emulsifying cetostearyl a… | 22004149006 | 1 |
| Noweda | Cetostearyl alcohol | 23000403003 | 1 |
| Noweda | Emulsifying cetostearyl a… | 23002494 | 1 |
| Noweda | Emulsifying cetostearyl a… | 24000111005 | 1 |
| Pala | Emulsifying cetostearyl a… | 19185702 | 1 |
| Ph.Eur/AHD | Cetostearyl alcohol | 18291407 | 1 |
| Phoenix 10.01.2020 | Cetyl alcohol | 19012509 | 1 |
| Phoenix 26.11.12 | Emulsifying cetostearyl a… | 13144105 | 1 |
| PHOENIX am07.04.2014 | Emulsifying cetostearyl a… | 13F07-N05 | 1 |
| Phoenix | Cetostearyl alcohol | 14322505 | 1 |
| Phoenix | Emulsifying cetostearyl a… | 15789271 | 1 |
| Phoenix | Emulsifying cetostearyl a… | 17198003 | 1 |
| Phoenix | Emulsifying cetostearyl a… | 17D28-B06-338141 | 1 |
| Phoenix | Cetomacrogol emulsifying … | 18335402 | 1 |
| Phoenix | Cetostearyl alcohol | 18A23-B04-352987 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Cetostearyl alcohol | 192139007 | 1 |
| Phoenix | Emulsifying cetostearyl a… | 21003223010 | 1 |
| Phoenix | Cetostearyl alcohol | 3071 | 1 |
| Phönix, Caesar&Loret… | Emulsifying cetostearyl a… | 192747007 | 1 |
| Phönix | Cetyl alcohol | 13096901 | 1 |
| Phonix | Cetyl alcohol | 13210504 | 1 |
| Phönix | Emulsifying cetostearyl a… | 1323305 | 1 |
| Phönix | Emulsifying cetostearyl a… | 15C31-B99-307062 | 1 |
| Phönix | Cetostearyl alcohol | 17D28-B06-338141 | 1 |
| Phönix | Emulsifying cetostearyl a… | 18A23-B04-355659 | 1 |
| Phönix | Emulsifying cetostearyl a… | 191857002 | 1 |
| Phönix | Emulsifying cetostearyl a… | 19185702 | 1 |
| Phönix | Emulsifying cetostearyl a… | 20005694 | 1 |
| Phönix | Cetostearyl alcohol | 21000566007 | 3 |
| Phönix | Emulsifying cetostearyl a… | 22001329008 | 1 |
| Phönix | Cetomacrogol emulsifying … | 22002953003 | 2 |
| Phönx | Emulsifying cetostearyl a… | 210086001 | 1 |
| Sanacorp/Bombstus | Emulsifying cetostearyl a… | 18003437 | 2 |
| Sanacorp | Emulsifying cetostearyl a… | 12J29-N04 | 1 |
| Sanacorp | Cetostearyl alcohol | 13206206 | 1 |
| Sanacorp | Emulsifying cetostearyl a… | 13F07-N05 | 1 |
| Sanacorp | Emulsifying cetostearyl a… | 13I06-N04 | 1 |
| Sanacorp | Emulsifying cetostearyl a… | 15090701 | 1 |
| Sanacorp | Emulsifying cetostearyl a… | 17198003 | 1 |
| Sanacorp | Cetyl alcohol | 17321603 | 1 |
| Sanacorp | Emulsifying cetostearyl a… | 191857002 | 1 |
| Sanacorp | Emulsifying cetostearyl a… | 210032230058 | 1 |
| Sanacorp | Emulsifying cetostearyl a… | 21003223011 | 2 |
| Sanacorp | Cetostearyl alcohol | 22003074003 | 1 |
| Sanacorp | Cetostearyl alcohol | 575778 | 1 |
| Sanacorpaelo /Sanacorp | Cetyl alcohol | 1AKS11 | 1 |
| Spinn | Cetyl alcohol | 1119202023 | 1 |
| Spinnrad/ Noweda/ 19… | Cetyl alcohol | 219302021 | 1 |
| Spinnrad/Sanacorp | Cetyl alcohol | 1018202022 | 1 |
| Spinnrad | Cetyl alcohol | 115202022 | 1 |
| Spinnrad | Cetyl alcohol | 416202023 | 1 |
| Spinnrad | Cetyl alcohol | 418302021 | 1 |
| spinrad/pHÖNIX | Cetyl alcohol | 418202021 | 1 |

- 255 205 spectra from 1666 *Apo-Ident* customers from a total of 51 734 batches from a further 721 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cetostearyl alcohol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cetostearyl alcohol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 2035 | 0 | 156 291 |
| **Type B** | 0 | 1390 | 0 | 211 550 |
| **Type C** | 0 | 1675 | 6 | 255 205 |

The substance/substance group *Cetostearyl alcohol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.7052 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.5683 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6431 % (> 99.4646 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20738 | 21054 | 7.49 | 79.66 |
| 20896 | 20896 | 0.00 | 128.44 |
| 20968 | 20968 | 0.00 | 132.47 |
| 21054 | 21054 | 0.00 | 74.97 |
| 21279 | 21279 | 0.00 | 134.34 |
| 21314 | 26698 | 22.06 | 128.66 |
| 21318 | 20896 | 50.39 | 127.64 |
| 21319 | 21319 | 0.00 | 125.48 |
| 21434 | 22334 | 3.89 | 134.28 |
| 21435 | 20896 | 50.10 | 126.84 |
| 21442 | 26698 | 14.77 | 129.96 |
| 21830 | 21998 | 3.35 | 101.56 |
| 21998 | 21998 | 0.00 | 113.91 |
| 22264 | 22334 | 3.52 | 134.86 |
| 22266 | 22266 | 0.00 | 129.44 |
| 22331 | 22331 | 0.00 | 128.68 |
| 22332 | 22332 | 0.00 | 143.41 |
| 22333 | 22333 | 0.00 | 121.94 |
| 22334 | 22334 | 0.00 | 134.44 |
| 22396 | 22396 | 0.00 | 80.38 |
| 22398 | 22398 | 0.00 | 129.65 |
| 22399 | 22399 | 0.00 | 129.36 |
| 22400 | 22400 | 0.00 | 128.83 |
| 22401 | 22401 | 0.00 | 128.64 |
| 22402 | 22402 | 0.00 | 128.17 |
| 22403 | 22403 | 0.00 | 132.23 |
| 22611 | 22401 | 27.04 | 123.89 |
| 23022 | 22334 | 3.56 | 136.16 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23725 | 26698 | 15.04 | 131.85 |
| 25253 | 25253 | 0.00 | 92.20 |
| 25498 | 26695 | 11.77 | 133.65 |
| 25499 | 21998 | 27.02 | 130.14 |
| 25528 | 25528 | 0.00 | 131.52 |
| 25978 | 25978 | 0.00 | 35.40 |
| 26025 | 22333 | 8.98 | 108.67 |
| 26231 | 26698 | 11.89 | 132.09 |
| 26586 | 26695 | 6.61 | 132.46 |
| 26695 | 26695 | 0.00 | 132.08 |
| 26697 | 26697 | 0.00 | 129.37 |
| 26698 | 26698 | 0.00 | 133.11 |
| 26744 | 21054 | 10.71 | 88.68 |
| 26941 | 26941 | 0.00 | 132.40 |
| 27573 | 21279 | 16.79 | 107.68 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Chloral hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20322-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Chloral hydrate; Chlorali hydras

### Special notes

When selecting the *Chloral hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Chloral hydrate | 6 | 11 | 203 |

### Second-stage model

For differentiation of the substance/substance group *Chloral hydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Chloral hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 79.92 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Chloral hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Chloral hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Chloral hydrate | 13213311 | 21309 | 40 | 20130712 |
| Caelo | Chloral hydrate | 15448318 | 22963 | 40 | 1704462 |
| Caelo | Chloral hydrate | 16355802 | 23094 | 40 | 20170112 |
| Fagron | Chloral hydrate | 13F06-N07 | 21231 | 40 | 20130626 |
| Fagron | Chloral hydrate | 17E05-B05-335580 | 23572 | 40 | 20170623 |
| Fagron | Chloral hydrate | 19K04-B01-201434 | 25488 | 40 | 20191128 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 240 spectra of 6 reference samples from the substance/substance group *Chloral hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.
- 158 086 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 530 spectra of 14 reference samples from the substance/substance group *Chloral hydrate*.
- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Chloral hydrate | 154483 | 23355 | 40 |
| Caelo | Chloral hydrate | 172506 | 23646 | 40 |
| Caelo | Chloral hydrate | 172477 | 23678 | 40 |
| Caelo | Chloral hydrate | 190914 | 24556 | 40 |
| Caelo | Chloral hydrate | 192361 | 24882 | 40 |
| Caelo | Chloral hydrate | 192872 | 24891 | 40 |
| Caelo | Chloral hydrate | 21001025 | 25668 | 50 |
| Caelo | Chloral hydrate | 22004038 | 26689 | 40 |
| Caelo | Chloral hydrate | 24001050 | 27304 | 40 |
| Fagron | Chloral hydrate | 22D25-B01-220429 | 26180 | 40 |
| Fagron | Chloral hydrate | 24A24-B10-238074 | 27185 | 40 |
| Caelo | Chloral hydrate | 172477 | 23815 | 40 |
| Caelo | Chloral hydrate | 22004038 | 26689SI | 20 |
| Fagron | Chloral hydrate | 22D25-B01-220429 | 26180SI | 20 |

- 212 410 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1228 spectra from 469 *Apo-Ident* customers from 210 batches from the substance/substance group *Chloral hydrate*.
- Among them are spectra of independent samples from 203 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Chloral hydrate | 10224/2311B066 | 1 |
| | Chloral hydrate | 21001025007 | 1 |
| | Chloral hydrate | 21001025014 | 1 |
| | Chloral hydrate | 21001025016 | 1 |
| | Chloral hydrate | 21001025019 | 1 |
| | Chloral hydrate | 21001025020 | 7 |
| | Chloral hydrate | 21001025023 | 2 |
| | Chloral hydrate | 21001025024 | 3 |
| | Chloral hydrate | 21001025026 | 1 |
| | Chloral hydrate | 22004038001 | 22 |
| | Chloral hydrate | 22004038003 | 4 |
| | Chloral hydrate | 22004038004 | 5 |
| | Chloral hydrate | 22004038007 | 4 |
| | Chloral hydrate | 2204038001 | 1 |
| | Chloral hydrate | 2400026006 | 1 |
| | Chloral hydrate | 24002447003 | 1 |
| | Chloral hydrate | 24002447004 | 3 |
| | Chloral hydrate | 24002447005 | 3 |
| | Chloral hydrate | 24002447006 | 11 |
| | Chloral hydrate | 24002447007 | 1 |
| | Chloral hydrate | 2400247005 | 1 |
| | Chloral hydrate | 24A24-B10-001840 | 2 |
| | Chloral hydrate | 24A24-B10-229467 | 7 |
| | Chloral hydrate | 24A24-B10-238074 | 2 |
| | Chloral hydrate | 24C11-B08-001839 | 1 |
| | Chloral hydrate | 24K06-b13-005063 | 1 |
| | Chloral hydrate | 24K06-B13-005063 | 1 |
| | Chloral hydrate | B08-0018309 | 2 |
| AHD | Chloral hydrate | 22004038001 | 1 |
| Alli | Chloral hydrate | 22004038001 | 2 |
| Alliance | Chloral hydrate | 21001025010 | 1 |
| Anzag | Chloral hydrate | 20003841003 | 1 |
| Anzag | Chloral hydrate | 230504(22004038001) | 1 |
| Anzag | Chloral hydrate | 250320(24002447006) | 1 |
| Apotheke Tellingstedt | Chloral hydrate | 19091404 | 1 |
| Bombastus | Chloral hydrate | 17346301 | 1 |
| Caelo | Chloral hydrate | | 1 |
| Caelo | Chloral hydrate | 1(2002323002) | 1 |
| Caelo | Chloral hydrate | 12017503 | 1 |
| Caelo | Chloral hydrate | 12017512 | 1 |
| Caelo | Chloral hydrate | 12017518 | 1 |
| Caelo | Chloral hydrate | 13002425 | 2 |
| Caelo | Chloral hydrate | 13213311 | 1 |
| Caelo | Chloral hydrate | 13d22-n11 | 1 |
| Caelo | Chloral hydrate | 1403815 | 1 |
| Caelo | Chloral hydrate | 14038301 | 2 |
| Caelo | Chloral hydrate | 14038306 | 1 |
| Caelo | Chloral hydrate | 14038311 | 5 |
| Caelo | Chloral hydrate | 14101307 | 1 |
| Caelo | Chloral hydrate | 14218701 | 1 |
| Caelo | Chloral hydrate | 14218704 | 3 |
| Caelo | Chloral hydrate | 14218705 | 3 |
| Caelo | Chloral hydrate | 14218709 | 5 |
| Caelo | Chloral hydrate | 14218710 | 1 |
| Caelo | Chloral hydrate | 14218711 | 1 |
| Caelo | Chloral hydrate | 14218712 | 1 |
| Caelo | Chloral hydrate | 14218713 | 2 |
| Caelo | Chloral hydrate | 14218714 | 4 |
| Caelo | Chloral hydrate | 14218719 | 4 |
| Caelo | Chloral hydrate | 14218720 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chloral hydrate | 15083701 | 2 |
| Caelo | Chloral hydrate | 15083703 | 9 |
| Caelo | Chloral hydrate | 15083704 | 1 |
| Caelo | Chloral hydrate | 15083705 | 2 |
| Caelo | Chloral hydrate | 15163901 | 1 |
| Caelo | Chloral hydrate | 15166501 | 4 |
| Caelo | Chloral hydrate | 15166502 | 4 |
| Caelo | Chloral hydrate | 15166503 | 4 |
| Caelo | Chloral hydrate | 15166505 | 11 |
| Caelo | Chloral hydrate | 15166506 | 7 |
| Caelo | Chloral hydrate | 15166507 | 13 |
| Caelo | Chloral hydrate | 15166508 | 6 |
| Caelo | Chloral hydrate | 15166513 | 3 |
| Caelo | Chloral hydrate | 15448303 | 3 |
| Caelo | Chloral hydrate | 15448304 | 2 |
| Caelo | Chloral hydrate | 15448306 | 7 |
| Caelo | Chloral hydrate | 15448307 | 5 |
| Caelo | Chloral hydrate | 15448310 | 1 |
| Caelo | Chloral hydrate | 15448312 | 11 |
| Caelo | Chloral hydrate | 15448313 | 8 |
| Caelo | Chloral hydrate | 15448314 | 8 |
| Caelo | Chloral hydrate | 15448315 | 6 |
| Caelo | Chloral hydrate | 15448318 | 11 |
| Caelo | Chloral hydrate | 15448320 | 6 |
| Caelo | Chloral hydrate | 15448321 | 7 |
| Caelo | Chloral hydrate | 15448322 | 7 |
| Caelo | Chloral hydrate | 15448324 | 10 |
| Caelo | Chloral hydrate | 15448325 | 2 |
| Caelo | Chloral hydrate | 15448326 | 10 |
| Caelo | Chloral hydrate | 15448327 | 1 |
| Caelo | Chloral hydrate | 15458322 | 1 |
| Caelo | Chloral hydrate | 160906C | 1 |
| Caelo | Chloral hydrate | 16248703 | 1 |
| Caelo | Chloral hydrate | 16355803 | 1 |
| Caelo | Chloral hydrate | 16355804 | 2 |
| Caelo | Chloral hydrate | 16355810 | 1 |
| Caelo | Chloral hydrate | 16355811 | 2 |
| Caelo | Chloral hydrate | 17121402 | 1 |
| Caelo | Chloral hydrate | 17247702 | 20 |
| Caelo | Chloral hydrate | 17247704 | 16 |
| Caelo | Chloral hydrate | 17250601 | 14 |
| Caelo | Chloral hydrate | 17314301 | 3 |
| Caelo | Chloral hydrate | 17314303 | 1 |
| Caelo | Chloral hydrate | 17314309 | 1 |
| Caelo | Chloral hydrate | 17314312 | 1 |
| Caelo | Chloral hydrate | 17314318 | 2 |
| Caelo | Chloral hydrate | 17314319 | 1 |
| Caelo | Chloral hydrate | 17314320 | 1 |
| Caelo | Chloral hydrate | 17314322 | 5 |
| Caelo | Chloral hydrate | 173406306 | 1 |
| Caelo | Chloral hydrate | 1734602 | 1 |
| Caelo | Chloral hydrate | 17346301 | 29 |
| Caelo | Chloral hydrate | 17346302 | 16 |
| Caelo | Chloral hydrate | 173463021 | 1 |
| Caelo | Chloral hydrate | 17346303 | 5 |
| Caelo | Chloral hydrate | 17346306 | 46 |
| Caelo | Chloral hydrate | 17346307 | 21 |
| Caelo | Chloral hydrate | 17346308 | 14 |
| Caelo | Chloral hydrate | 17346309 | 11 |
| Caelo | Chloral hydrate | 17346310 | 12 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chloral hydrate | 17346311 | 10 |
| Caelo | Chloral hydrate | 1746302 | 1 |
| Caelo | Chloral hydrate | 17520601 | 1 |
| Caelo | Chloral hydrate | 17550601 | 1 |
| Caelo | Chloral hydrate | 18054001 | 1 |
| Caelo | Chloral hydrate | 18327909 | 1 |
| Caelo | Chloral hydrate | 19000511001 | 12 |
| Caelo | Chloral hydrate | 19000511003 | 5 |
| Caelo | Chloral hydrate | 19091401 | 6 |
| Caelo | Chloral hydrate | 19091402 | 1 |
| Caelo | Chloral hydrate | 19091404 | 5 |
| Caelo | Chloral hydrate | 19091405 | 4 |
| Caelo | Chloral hydrate | 19091408 | 4 |
| Caelo | Chloral hydrate | 19091409 | 3 |
| Caelo | Chloral hydrate | 19091410 | 3 |
| Caelo | Chloral hydrate | 19236101 | 12 |
| Caelo | Chloral hydrate | 19236102 | 4 |
| Caelo | Chloral hydrate | 19236103 | 2 |
| Caelo | Chloral hydrate | 19236104 | 3 |
| Caelo | Chloral hydrate | 192872001 | 38 |
| Caelo | Chloral hydrate | 192872002 | 3 |
| Caelo | Chloral hydrate | 192872003 | 4 |
| Caelo | Chloral hydrate | 192872004 | 3 |
| Caelo | Chloral hydrate | 19287201 | 8 |
| Caelo | Chloral hydrate | 19287206 | 5 |
| Caelo | Chloral hydrate | 20000232002 | 1 |
| Caelo | Chloral hydrate | 200002323002 | 1 |
| Caelo | Chloral hydrate | 20002323002 | 35 |
| Caelo | Chloral hydrate | 20002323004 | 6 |
| Caelo | Chloral hydrate | 2000233002 | 1 |
| Caelo | Chloral hydrate | 20003841002 | 11 |
| Caelo | Chloral hydrate | 20003841003 | 51 |
| Caelo | Chloral hydrate | 20003841005 | 2 |
| Caelo | Chloral hydrate | 2003841003 | 1 |
| Caelo | Chloral hydrate | 2019Q-01257 | 1 |
| Caelo | Chloral hydrate | 21001025002 | 7 |
| Caelo | Chloral hydrate | 21001025003 | 4 |
| Caelo | Chloral hydrate | 21001025004 | 33 |
| Caelo | Chloral hydrate | 21001025005 | 21 |
| Caelo | Chloral hydrate | 21001025007 | 4 |
| Caelo | Chloral hydrate | 21001025009 | 1 |
| Caelo | Chloral hydrate | 21001025010 | 25 |
| Caelo | Chloral hydrate | 21001025014 | 1 |
| Caelo | Chloral hydrate | 21001025015 | 5 |
| Caelo | Chloral hydrate | 21001025016 | 2 |
| Caelo | Chloral hydrate | 21001025017 | 5 |
| Caelo | Chloral hydrate | 21001025019 | 1 |
| Caelo | Chloral hydrate | 21001025020 | 1 |
| Caelo | Chloral hydrate | 21001025023 | 1 |
| Caelo | Chloral hydrate | 210010250236 | 2 |
| Caelo | Chloral hydrate | 21001025024 | 8 |
| Caelo | Chloral hydrate | 2100105004 | 1 |
| Caelo | Chloral hydrate | 22004038001 | 5 |
| Caelo | Chloral hydrate | 24002447007 | 1 |
| Caelo | Chloral hydrate | 25021401 | 1 |
| Caelo | Chloral hydrate | 2818A-01257 | 1 |
| Caelo | Chloral hydrate | 2826 | 1 |
| Caelo | Chloral hydrate | 30081807 | 1 |
| Caelo | Chloral hydrate | 3121403 | 1 |
| Caelo | Chloral hydrate | 3299 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chloral hydrate | 3333 | 1 |
| Caelo | Chloral hydrate | 3449 | 1 |
| Caelo | Chloral hydrate | 4616Q-01257 | 1 |
| Caelo | Chloral hydrate | 6051703 | 1 |
| Caelo | Chloral hydrate | 928720011 | 1 |
| Caeol/Noweda | Chloral hydrate | 15448313 | 1 |
| Caesar & Lorenz GmbH | Chloral hydrate | 19000511001 | 1 |
| Caesar & Lorenz GmbH | Chloral hydrate | 192872001 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 20003841003 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025004 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025004 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025005 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025024 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 20003841003 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 20003841003 | 2 |
| Caesar & Loretz GmbH... | Chloral hydrate | 119236101 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 20002323002 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloral hydrate | 19000511001 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloral hydrate | 19236101 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloral hydrate | 20002323002 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloral hydrate | 20003841003 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloral hydrate | 21001025005 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloral hydrate | 21001025024 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloral hydrate | 22004038001 | 2 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025020 | 3 |
| Caesar & Loretz GmbH... | Chloral hydrate | 19287206 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 20003841003 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025010 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025016 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025024 | 2 |
| Caesar & Loretz GmbH... | Chloral hydrate | 22004038001 | 2 |
| Caesar & Loretz GmbH... | Chloral hydrate | 192872001 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025010 | 1 |
| Caesar & Loretz GmbH... | Chloral hydrate | 21001025024 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 17314317 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 17314319 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 17314320 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 17346301 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 17346310 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 19000511001 | 3 |
| Caesar & Loretz GmbH | Chloral hydrate | 19091401 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 19091409 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 19236101 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 19236104 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 192872001 | 6 |
| Caesar & Loretz GmbH | Chloral hydrate | 192872002 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 192872004 | 3 |
| Caesar & Loretz GmbH | Chloral hydrate | 19287201 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 19287206 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 20002323002 | 11 |
| Caesar & Loretz GmbH | Chloral hydrate | 20002323003 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 20002323004 | 6 |
| Caesar & Loretz GmbH | Chloral hydrate | 20002323022 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 20003841002 | 6 |
| Caesar & Loretz GmbH | Chloral hydrate | 20003841003 | 12 |
| Caesar & Loretz GmbH | Chloral hydrate | 20003841004 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 20003841005 | 3 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025002 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025003 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025004 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Chloral hydrate | 21001025005 | 4 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025007 | 3 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025009 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025010 | 11 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025012 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025016 | 3 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025017 | 3 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025023 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025024 | 4 |
| Caesar & Loretz GmbH | Chloral hydrate | 21001025026 | 1 |
| Caesar & Loretz GmbH | Chloral hydrate | 2100102517 | 2 |
| Caesar & Loretz GmbH | Chloral hydrate | 22004038004 | 3 |
| Caesar & Loretz Hild... | Chloral hydrate | 192872001 | 1 |
| Caesar & Loretz/AHD | Chloral hydrate | 20002323002 | 1 |
| Caesar & Loretz/Noweda | Chloral hydrate | 20002323002 | 2 |
| Caesar & Loretz/Noweda | Chloral hydrate | 20003841003 | 1 |
| Caesar/Phoenix | Chloral hydrate | 17250601 | 1 |
| Caesar | Chloral hydrate | 15166501 | 1 |
| Cealo/ Alliance | Chloral hydrate | 17247702 | 1 |
| Chemische Fabrik Ber... | Chloral hydrate | 192872001 | 2 |
| Ebert & Jacobi | Chloral hydrate | 16D14-B02-322991 | 1 |
| Ebert KKH 10.10.16 | Chloral hydrate | 15448308 | 1 |
| Eder Apotheke | Chloral hydrate | 19236101 | 1 |
| Euro OTC | Chloral hydrate | 15448318 | 1 |
| Euro OTC | Chloral hydrate | 16122001 | 1 |
| Fagron | Chloral hydrate | 11D13-N07 | 1 |
| Fagron | Chloral hydrate | 11J05-N01 | 1 |
| Fagron | Chloral hydrate | 12C26-M04 | 1 |
| Fagron | Chloral hydrate | 12C26-M05 | 1 |
| Fagron | Chloral hydrate | 12H06_N08 | 1 |
| Fagron | Chloral hydrate | 12H06N08 | 2 |
| Fagron | Chloral hydrate | 12H06-N08 | 8 |
| Fagron | Chloral hydrate | 12H06-N080101/1612 | 1 |
| Fagron | Chloral hydrate | 12H06-N080160/161 | 1 |
| Fagron | Chloral hydrate | 12H06N8 | 1 |
| Fagron | Chloral hydrate | 13D22-N11 | 1 |
| Fagron | Chloral hydrate | 13F06-N07 | 2 |
| Fagron | Chloral hydrate | 13F06-N070631/786 | 1 |
| Fagron | Chloral hydrate | 13K05-B13 | 1 |
| Fagron | Chloral hydrate | 14218710 | 1 |
| Fagron | Chloral hydrate | 14218712 | 1 |
| Fagron | Chloral hydrate | 15166505 | 1 |
| Fagron | Chloral hydrate | 160609/1 | 1 |
| Fagron | Chloral hydrate | 17346301 | 1 |
| Fagron | Chloral hydrate | 17J31-B02-342155 | 2 |
| Fagron | Chloral hydrate | 18F15-B01-355393 | 2 |
| Fagron | Chloral hydrate | 18F15-B01-355394 | 2 |
| Fagron | Chloral hydrate | 18L18-B01-193679 | 1 |
| Fagron | Chloral hydrate | 192872002 | 1 |
| Fagron | Chloral hydrate | 19K04-B01 | 1 |
| Fagron | Chloral hydrate | 19K04-B01-1955569 | 1 |
| Fagron | Chloral hydrate | 19K04-B01-195569 | 1 |
| Fagron | Chloral hydrate | 19K04-B01-201434 | 3 |
| Fagron | Chloral hydrate | 21001025016 | 1 |
| Fagron | Chloral hydrate | 21B25-B03-203396 | 2 |
| Fagron | Chloral hydrate | 22D25-B01-2202B060 | 2 |
| Fagron | Chloral hydrate | 22D25-B01-220429 | 2 |
| Gehe amax | Chloral hydrate | 19000511001 | 1 |
| Gehe | Chloral hydrate | 15083703 | 1 |
| GEHE | Chloral hydrate | 15448312 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Chloral hydrate | 15448326 | 1 |
| Gehe | Chloral hydrate | 17346301 | 1 |
| Gehe | Chloral hydrate | 192872001 | 1 |
| Gehe | Chloral hydrate | 2000232302 | 1 |
| Gehe | Chloral hydrate | 21001025010 | 1 |
| Gehe | Chloral hydrate | 22004038001 | 2 |
| Gehe | Chloral hydrate | 24002447005 | 1 |
| Gehe | Chloral hydrate | 24002447006 | 1 |
| Ichthyol GmBH | Chloral hydrate | 13002425 | 2 |
| Ichthyol | Chloral hydrate | 15448314 | 1 |
| Jenne | Chloral hydrate | 21001025020 | 1 |
| Kehr | Chloral hydrate | 17346302 | 1 |
| L12 | Chloral hydrate | 17346301 | 1 |
| Noweda | Chloral hydrate | 17247704 | 2 |
| Noweda | Chloral hydrate | 17314319 | 1 |
| Noweda | Chloral hydrate | 17346306 | 1 |
| Noweda | Chloral hydrate | 17346310 | 1 |
| Noweda | Chloral hydrate | 19091404 | 1 |
| Noweda | Chloral hydrate | 19091408 | 1 |
| Noweda | Chloral hydrate | 19287201 | 1 |
| Noweda | Chloral hydrate | 21001025005 | 3 |
| Noweda | Chloral hydrate | 22004038001 | 1 |
| Noweda | Chloral hydrate | 22004038004 | 1 |
| Noweda | Chloral hydrate | 24A24-B10-238074 | 1 |
| Noweda29.04.2015 | Chloral hydrate | 15083701 | 2 |
| Phoenix | Chloral hydrate | 15448318 | 1 |
| Phoenix | Chloral hydrate | 21001025020 | 1 |
| Phoenix | Chloral hydrate | 3187 | 1 |
| Phönix Gotha | Chloral hydrate | 13F06-N07 | 2 |
| Phönix Gotha | Chloral hydrate | 14038302 | 1 |
| Phönix/Noweda | Chloral hydrate | 21001025004 | 1 |
| Phönix | Chloral hydrate | 17346301 | 1 |
| Phönix | Chloral hydrate | 17346303 | 3 |
| Phönix | Chloral hydrate | 17346311 | 5 |
| Phönix | Chloral hydrate | 192872001 | 1 |
| phönix | Chloral hydrate | 20003841003 | 2 |
| Phönix | Chloral hydrate | 22004038001 | 2 |
| Phönix | Chloral hydrate | 2202204038007 | 1 |
| Sanacorp | Chloral hydrate | 12H06-N08 | 1 |
| Sanacorp | Chloral hydrate | 14218705 | 1 |
| Sanacorp | Chloral hydrate | 15448326 | 1 |
| Sanacorp | Chloral hydrate | 17346301 | 1 |
| Sanacorp | Chloral hydrate | 17346306 | 1 |
| Sanacorp | Chloral hydrate | 192872001 | 1 |
| Sanacorp | Chloral hydrate | 21001025002 | 2 |
| Sanacorp | Chloral hydrate | 21001025007 | 1 |
| Sanacorp | Chloral hydrate | 21001025023 | 3 |
| Sanacorp | Chloral hydrate | 22004038001 | 3 |
| Sanacorp | Chloral hydrate | 22004038007 | 1 |

- 255 658 spectra from 1666 *Apo-Ident* customers from a total of 51 944 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Chloral hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Chloral hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 240 | 0 | 158 086 |
| **Type B** | 0 | 530 | 0 | 212 410 |
| **Type C** | 0 | 1201 | 27 | 255 658 |

The substance/substance group *Chloral hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8679 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.8013 % (> 97.5570 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21231 | 22963 | 13.15 | 152.76 |
| 21309 | 22963 | 6.66 | 153.53 |
| 22963 | 22963 | 0.00 | 147.73 |
| 23094 | 22963 | 7.58 | 152.43 |
| 23572 | 22963 | 5.57 | 150.53 |
| 25488 | 22963 | 11.14 | 154.95 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Chloramphenicol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20097-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Chloramphenicol; Chloramphenicolum

### Special notes

When selecting the *Chloramphenicol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Chloramphenicol | 10 | 15 | 358 |

### Second-stage model

For differentiation of the substance/substance group *Chloramphenicol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Chloramphenicol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 85.55 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Chloramphenicol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Chloramphenicol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Chloramphenicol | 11370716 | 20787 | 40 | 20120202 |
| Caelo | Chloramphenicol | 12248507 | 20807 | 40 | 20120831 |
| Caelo | Chloramphenicol | 13080924 | 21701 | 60 | 1509287 |
| Caelo | Chloramphenicol | 14346908 | 21988 | 60 | 20150115 |
| Euro OTC | Chloramphenicol | 1209019-02 | 20813 | 80 | 20130408 |
| Euro OTC | Chloramphenicol | 1209019-02 | 20815 | 80 | 20130408 |
| Euro OTC | Chloramphenicol | 1407043-01 | 21752 | 60 | 20140903 |
| Euro OTC | Chloramphenicol | 1602002 | 22367 | 45 | 20160309* |
| Fagron | Chloramphenicol | 11F20-N05 | 20777 | 120 | 1412249 |
| Fagron | Chloramphenicol | 13A11-N02 | 20822 | 40 | 20130125 |
| Fagron | Chloramphenicol | 14E01-B02-308559 | 21910 | 60 | 20140513 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 685 spectra of 11 reference samples from the substance/substance group *Chloramphenicol*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 641 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 650 spectra of 18 reference samples from the substance/substance group *Chloramphenicol*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Chloramphenicol | 15358906 | 22961 | 40 |
| Caelo | Chloramphenicol | 162786 | 23353 | 40 |
| Caelo | Chloramphenicol | 180178 | 24049 | 40 |
| Caelo | Chloramphenicol | 192260 | 24892 | 40 |
| Caelo | Chloramphenicol | 20000261 | 25211 | 40 |
| Caelo | Chloramphenicol | 22002986 | 26495 | 40 |
| Caelo | Chloramphenicol | 24001644 | 27439 | 40 |
| Euro OTC | Chloramphenicol | 1704021 | 23392 | 40 |
| Euro OTC | Chloramphenicol | 1903028 | 24625 | 40 |
| Euro OTC | Chloramphenicol | 2002043 | 25264 | 40 |
| Euro OTC | Chloramphenicol | 2201014 | 25958 | 40 |
| Euro OTC | Chloramphenicol | 2306004 | 26924 | 40 |
| Euro OTC | Chloramphenicol | 2403008 | 27362 | 40 |
| Fagron | Chloramphenicol | 22B02-B09-219706 | 26158 | 40 |
| Fagron | Chloramphenicol | 24D11-B05-003078 | 27482 | 40 |
| Caelo | Chloramphenicol | 22002986 | 26495SI | 20 |
| Euro OTC | Chloramphenicol | 2201014 | 25958SI | 10 |
| Fagron | Chloramphenicol | 22B02-B09-219706 | 26158SI | 20 |

- 212 290 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information

provided by the customer regarding manufacturer and batch number.

- 3555 spectra from 1058 *Apo-Ident* customers from 372 batches from the substance/substance group *Chloramphenicol*.
- Among them are spectra of independent samples from 355 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Chloramphenicol | 1302024-02 | 2 |
| | Chloramphenicol | 181023/5 | 2 |
| | Chloramphenicol | 2002043-03 | 1 |
| | Chloramphenicol | 21001144006 | 1 |
| | Chloramphenicol | 21001144007 | 2 |
| | Chloramphenicol | 21001144009 | 1 |
| | Chloramphenicol | 21001144014 | 2 |
| | Chloramphenicol | 2100114404 | 1 |
| | Chloramphenicol | 2100114408 | 1 |
| | Chloramphenicol | 220002986002 | 1 |
| | Chloramphenicol | 22002986001 | 13 |
| | Chloramphenicol | 22002986002 | 4 |
| | Chloramphenicol | 22002986003 | 23 |
| | Chloramphenicol | 22002986006 | 10 |
| | Chloramphenicol | 22002986007 | 19 |
| | Chloramphenicol | 22002986008 | 1 |
| | Chloramphenicol | 2200986003 | 2 |
| | Chloramphenicol | 2201014-01 | 7 |
| | Chloramphenicol | 2201014-02 | 22 |
| | Chloramphenicol | 2201014-03 | 9 |
| | Chloramphenicol | 220101404 | 1 |
| | Chloramphenicol | 2201014-04 | 6 |
| | Chloramphenicol | 220104-02 | 1 |
| | Chloramphenicol | 22098607 | 1 |
| | Chloramphenicol | 221014-01 | 1 |
| | Chloramphenicol | 2303004-03 | 1 |
| | Chloramphenicol | 230600401 | 1 |
| | Chloramphenicol | 2306004-01 | 25 |
| | Chloramphenicol | 2306004-02 | 6 |
| | Chloramphenicol | 2306004-03 | 4 |
| | Chloramphenicol | 24001644004 | 1 |
| | Chloramphenicol | 24001644005 | 8 |
| | Chloramphenicol | 2403008 | 1 |
| | Chloramphenicol | 240300801 | 1 |
| | Chloramphenicol | 2403008-01 | 20 |
| | Chloramphenicol | 2403008-02 | 2 |
| | Chloramphenicol | 24D11-B05-001343 | 3 |
| | Chloramphenicol | BO3-2309707 | 1 |
| | Chloramphenicol | CHL001E23 | 1 |
| | Chloramphenicol | DY0092000082 | 1 |
| 4,64 | Chloramphenicol | 1903028-03 | 1 |
| AHD | Chloramphenicol | 12248507 | 1 |
| AHD | Chloramphenicol | 12248509 | 1 |
| AHD | Chloramphenicol | 13080904 | 1 |
| AHD | Chloramphenicol | 14346912 | 1 |
| AHD | Chloramphenicol | 18017807 | 1 |
| AHD | Chloramphenicol | 22002986007 | 1 |
| AHD | Chloramphenicol | 2201014-02 | 1 |
| AHD | Chloramphenicol | 2306004-01 | 1 |
| AHD | Chloramphenicol | 2306004-02 | 2 |
| AHDE 20.08.15 | Chloramphenicol | DY00912128 | 1 |
| Alli | Chloramphenicol | 2306004-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alli | Chloramphenicol | 2403008-01 | 1 |
| Alliance 15.04.2015 ... | Chloramphenicol | 1407043-01 | 1 |
| Alliance Health | Chloramphenicol | 1209019-02 | 1 |
| Alliance Healthcare | Chloramphenicol | 20E14-B19-202352 | 1 |
| Alliance Healthcare | Chloramphenicol | 21001144009 | 1 |
| Alliance Healthcare | Chloramphenicol | 2306004-01 | 1 |
| Alliance | Chloramphenicol | 20E14-B19202352 | 1 |
| ANZ | Chloramphenicol | 22002986003 | 1 |
| Anzag 03.04.13 ek: 3,18EUR | Chloramphenicol | 12248501 | 1 |
| Anzag ek:2.98EUR 25.08.12 | Chloramphenicol | 11370711 | 1 |
| Anzag | Chloramphenicol | 1302024-01 | 1 |
| Anzag | Chloramphenicol | 1308017-02 | 1 |
| ANZAG | Chloramphenicol | 1308017-02 | 1 |
| Anzag | Chloramphenicol | 14346924 | 2 |
| anzag | Chloramphenicol | 15358907 | 1 |
| Anzag | Chloramphenicol | 1602002-03 | 1 |
| apo-ident | Chloramphenicol | 1602002-03 | 1 |
| Audor Pharma | Chloramphenicol | 2002043/01 | 1 |
| Audor Pharma | Chloramphenicol | 2201014-01 | 1 |
| Beiersdorf | Chloramphenicol | 1704021-03 | 1 |
| Bombastus | Chloramphenicol | 1308017-01 | 1 |
| Bombastus | Chloramphenicol | 1602002-03 | 1 |
| Bombastus | Chloramphenicol | 1704021-01 | 1 |
| Caelo | Chloramphenicol | | 1 |
| Caelo | Chloramphenicol | 10341703 | 1 |
| Caelo | Chloramphenicol | 10341707 | 1 |
| Caelo | Chloramphenicol | 10341711 | 2 |
| Caelo | Chloramphenicol | 10341717 | 1 |
| Caelo | Chloramphenicol | 1062002-04 | 1 |
| Caelo | Chloramphenicol | 11031402 | 1 |
| Caelo | Chloramphenicol | 1137004 | 1 |
| Caelo | Chloramphenicol | 1137070 | 1 |
| Caelo | Chloramphenicol | 11370702 | 3 |
| Caelo | Chloramphenicol | 11370703 | 2 |
| Caelo | Chloramphenicol | 11370705 | 3 |
| Caelo | Chloramphenicol | 11370706 | 3 |
| Caelo | Chloramphenicol | 11370707 | 2 |
| Caelo | Chloramphenicol | 11370711 | 12 |
| Caelo | Chloramphenicol | 11370712 | 4 |
| Caelo | Chloramphenicol | 11370713 | 3 |
| Caelo | Chloramphenicol | 11370714 | 2 |
| Caelo | Chloramphenicol | 11370715 | 1 |
| Caelo | Chloramphenicol | 11370716 | 4 |
| Caelo | Chloramphenicol | 11370717 | 2 |
| Caelo | Chloramphenicol | 1137714 | 1 |
| Caelo | Chloramphenicol | 1203012-02 | 1 |
| Caelo | Chloramphenicol | 12072606 | 1 |
| Caelo | Chloramphenicol | 12248501 | 12 |
| Caelo | Chloramphenicol | 12248505 | 2 |
| Caelo | Chloramphenicol | 12248506 | 8 |
| Caelo | Chloramphenicol | 12248507 | 9 |
| Caelo | Chloramphenicol | 12248509 | 12 |
| Caelo | Chloramphenicol | 12248520 | 7 |
| Caelo | Chloramphenicol | 12248524 | 7 |
| Caelo | Chloramphenicol | 12248525 | 7 |
| Caelo | Chloramphenicol | 12g02n01 | 1 |
| Caelo | Chloramphenicol | 1302024-01 | 1 |
| Caelo | Chloramphenicol | 130416-1 | 1 |
| Caelo | Chloramphenicol | 130416-2 | 1 |
| Caelo | Chloramphenicol | 1308017-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chloramphenicol | 13080303 | 1 |
| Caelo | Chloramphenicol | 130809 | 1 |
| Caelo | Chloramphenicol | 13080902 | 1 |
| Caelo | Chloramphenicol | 13080903 | 8 |
| Caelo | Chloramphenicol | 13080904 | 5 |
| Caelo | Chloramphenicol | 13080907 | 11 |
| Caelo | Chloramphenicol | 13080908 | 6 |
| Caelo | Chloramphenicol | 13080915 | 1 |
| Caelo | Chloramphenicol | 13080917 | 4 |
| Caelo | Chloramphenicol | 13080918 | 2 |
| Caelo | Chloramphenicol | 13080921 | 4 |
| Caelo | Chloramphenicol | 13080923 | 13 |
| Caelo | Chloramphenicol | 13080924 | 15 |
| Caelo | Chloramphenicol | 13080925 | 11 |
| Caelo | Chloramphenicol | 13A31-B02 | 1 |
| Caelo | Chloramphenicol | 13A31-B02-286708 | 3 |
| Caelo | Chloramphenicol | 13A31-B02-286709 | 1 |
| Caelo | Chloramphenicol | 140704301 | 2 |
| Caelo | Chloramphenicol | 1407043-01 | 1 |
| Caelo | Chloramphenicol | 14246917 | 1 |
| Caelo | Chloramphenicol | 1434608 | 1 |
| Caelo | Chloramphenicol | 14346901 | 2 |
| Caelo | Chloramphenicol | 14346903 | 1 |
| Caelo | Chloramphenicol | 14346904 | 4 |
| Caelo | Chloramphenicol | 14346906 | 4 |
| Caelo | Chloramphenicol | 14346907 | 9 |
| Caelo | Chloramphenicol | 14346908 | 10 |
| Caelo | Chloramphenicol | 14346910 | 15 |
| Caelo | Chloramphenicol | 14346911 | 20 |
| Caelo | Chloramphenicol | 14346912 | 3 |
| Caelo | Chloramphenicol | 14346913 | 8 |
| Caelo | Chloramphenicol | 14346914 | 4 |
| Caelo | Chloramphenicol | 14346917 | 8 |
| Caelo | Chloramphenicol | 14346918 | 18 |
| Caelo | Chloramphenicol | 14346918I-080816-1 | 1 |
| Caelo | Chloramphenicol | 14346922 | 1 |
| Caelo | Chloramphenicol | 14346924 | 5 |
| Caelo | Chloramphenicol | 14356910 | 1 |
| Caelo | Chloramphenicol | 1436908 | 1 |
| Caelo | Chloramphenicol | 1436918 | 1 |
| Caelo | Chloramphenicol | 14E01-B02-296623 | 1 |
| Caelo | Chloramphenicol | 14E01B02296624 | 1 |
| Caelo | Chloramphenicol | 14E01-B02-308559 | 2 |
| Caelo | Chloramphenicol | 14EO01-B02 | 1 |
| Caelo | Chloramphenicol | 1502036-01 | 3 |
| Caelo | Chloramphenicol | 1502036-02 | 2 |
| Caelo | Chloramphenicol | 150203603 | 1 |
| Caelo | Chloramphenicol | 1502036-03 | 4 |
| Caelo | Chloramphenicol | 150528C | 1 |
| Caelo | Chloramphenicol | 153589 | 1 |
| Caelo | Chloramphenicol | 15358903 | 3 |
| Caelo | Chloramphenicol | 15358905 | 25 |
| Caelo | Chloramphenicol | 15358906 | 13 |
| Caelo | Chloramphenicol | 15358907 | 3 |
| Caelo | Chloramphenicol | 15358908 | 10 |
| Caelo | Chloramphenicol | 15358909 | 6 |
| Caelo | Chloramphenicol | 15358911 | 1 |
| Caelo | Chloramphenicol | 15358912 | 14 |
| Caelo | Chloramphenicol | 15358913 | 29 |
| Caelo | Chloramphenicol | 15358914 | 21 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chloramphenicol | 1535896 | 1 |
| Caelo | Chloramphenicol | 160200201 | 1 |
| Caelo | Chloramphenicol | 1602002-01 | 5 |
| Caelo | Chloramphenicol | 1602002-02 | 2 |
| Caelo | Chloramphenicol | 1602002-03 | 4 |
| Caelo | Chloramphenicol | 16258612 | 1 |
| Caelo | Chloramphenicol | 16278009 | 1 |
| Caelo | Chloramphenicol | 16278601 | 1 |
| Caelo | Chloramphenicol | 16278602 | 9 |
| Caelo | Chloramphenicol | 16278605 | 1 |
| Caelo | Chloramphenicol | 16278606 | 12 |
| Caelo | Chloramphenicol | 16278608 | 18 |
| Caelo | Chloramphenicol | 16278609 | 29 |
| Caelo | Chloramphenicol | 16278609/180420CA | 1 |
| Caelo | Chloramphenicol | 16278610 | 1 |
| Caelo | Chloramphenicol | 16278611 | 2 |
| Caelo | Chloramphenicol | 16278612 | 31 |
| Caelo | Chloramphenicol | 1627862 | 1 |
| Caelo | Chloramphenicol | 1627898 | 1 |
| Caelo | Chloramphenicol | 16358909 | 1 |
| Caelo | Chloramphenicol | 170402101 | 1 |
| Caelo | Chloramphenicol | 1704021-01 | 18 |
| Caelo | Chloramphenicol | 1704021-02 | 7 |
| Caelo | Chloramphenicol | 1704021-03 | 3 |
| Caelo | Chloramphenicol | 1704021-04 | 6 |
| Caelo | Chloramphenicol | 17343802 | 13 |
| Caelo | Chloramphenicol | 17343803 | 32 |
| Caelo | Chloramphenicol | 174021-02 | 2 |
| Caelo | Chloramphenicol | 180178 | 1 |
| Caelo | Chloramphenicol | 18017802 | 6 |
| Caelo | Chloramphenicol | 18017804 | 5 |
| Caelo | Chloramphenicol | 18017806 | 40 |
| Caelo | Chloramphenicol | 18017807 | 14 |
| Caelo | Chloramphenicol | 18017809 | 38 |
| Caelo | Chloramphenicol | 18017810 | 9 |
| Caelo | Chloramphenicol | 18017811 | 21 |
| Caelo | Chloramphenicol | 18017813 | 4 |
| Caelo | Chloramphenicol | 18017814 | 9 |
| Caelo | Chloramphenicol | 18025702 | 2 |
| Caelo | Chloramphenicol | 181017809 | 1 |
| Caelo | Chloramphenicol | 1903028-01 | 5 |
| Caelo | Chloramphenicol | 1903028-02 | 6 |
| Caelo | Chloramphenicol | 1903028-041 | 1 |
| Caelo | Chloramphenicol | 19222226003 | 1 |
| Caelo | Chloramphenicol | 19225003 | 1 |
| Caelo | Chloramphenicol | 192260001 | 3 |
| Caelo | Chloramphenicol | 19226001 | 1 |
| Caelo | Chloramphenicol | 19226002 | 25 |
| Caelo | Chloramphenicol | 19226003 | 106 |
| Caelo | Chloramphenicol | 19226003P-200323-1 | 1 |
| Caelo | Chloramphenicol | 19226004 | 1 |
| Caelo | Chloramphenicol | 1922603 | 1 |
| Caelo | Chloramphenicol | 20000261003 | 8 |
| Caelo | Chloramphenicol | 20000261004 | 38 |
| Caelo | Chloramphenicol | 20003760002 | 10 |
| Caelo | Chloramphenicol | 20003760003 | 58 |
| Caelo | Chloramphenicol | 20003760006 | 5 |
| Caelo | Chloramphenicol | 2000376003 | 1 |
| Caelo | Chloramphenicol | 2000376006 | 1 |
| Caelo | Chloramphenicol | 2002043-01 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chloramphenicol | 2002043-02 | 6 |
| Caelo | Chloramphenicol | 200204303 | 1 |
| Caelo | Chloramphenicol | 2003760003 | 2 |
| Caelo | Chloramphenicol | 20102012J1 | 1 |
| Caelo | Chloramphenicol | 21001144003 | 3 |
| Caelo | Chloramphenicol | 21001144004 | 23 |
| Caelo | Chloramphenicol | 21001144006 | 6 |
| Caelo | Chloramphenicol | 21001144007 | 18 |
| Caelo | Chloramphenicol | 21001144009 | 1 |
| Caelo | Chloramphenicol | 21001144010 | 1 |
| Caelo | Chloramphenicol | 21001144014 | 6 |
| Caelo | Chloramphenicol | 2100114404 | 4 |
| Caelo | Chloramphenicol | 2100144004 | 2 |
| Caelo | Chloramphenicol | 21002415002 | 1 |
| Caelo | Chloramphenicol | 2181116 | 1 |
| Caelo | Chloramphenicol | 22002986001 | 6 |
| Caelo | Chloramphenicol | 22002986003 | 1 |
| Caelo | Chloramphenicol | 2201014-01 | 4 |
| Caelo | Chloramphenicol | 28011401 | 1 |
| Caelo | Chloramphenicol | 3081602 | 1 |
| Caelo | Chloramphenicol | 310311 | 1 |
| Caelo | Chloramphenicol | 3125204 | 1 |
| Caelo | Chloramphenicol | 3217A-01259 | 1 |
| Caelo | Chloramphenicol | 4412Q-01259 | 1 |
| Caelo | Chloramphenicol | 4654572 | 1 |
| Caelo | Chloramphenicol | 4712Q-01259 | 1 |
| Caelo | Chloramphenicol | 8017811 | 1 |
| Caelo | Chloramphenicol | 82853399 | 1 |
| Caelo | Chloramphenicol | 8701 | 1 |
| Caelo | Chloramphenicol | 93323801 | 1 |
| Caelo | Chloramphenicol | DY00911233 | 1 |
| Caelo | Chloramphenicol | DY00916161 | 1 |
| Caelo | Chloramphenicol | DY130525 | 2 |
| Caeolo / Anzag | Chloramphenicol | 15358914 | 1 |
| Caeolo | Chloramphenicol | 20003760003 | 4 |
| Caesar & Loretz Gmb | Chloramphenicol | 18017814 | 2 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760003 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 19226003 | 2 |
| Caesar & Loretz GmbH... | Chloramphenicol | 18017809 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 18017811 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20000261004 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760002 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 21001144007 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 21001144004 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 22002986001 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 19226003 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20000261003 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760002 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 19226003 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 21001144007 | 2 |
| Caesar & Loretz GmbH... | Chloramphenicol | 21001144004 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 18017809 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760003 | 3 |
| Caesar & Loretz GmbH/Gehe | Chloramphenicol | 18017811 | 2 |
| Caesar & Loretz GmbH/Gehe | Chloramphenicol | 20003760002 | 1 |
| Caesar & Loretz GmbH/Gehe | Chloramphenicol | 21001144007 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760003 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 19226002 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20000261004 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Chloramphenicol | 192260001 | 1 |
| Caesar & Loretz GmbH/Otto | Chloramphenicol | 19226003 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 18017814 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20000261004 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760003 | 3 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20000261004 | 2 |
| Caesar & Loretz GmbH... | Chloramphenicol | 20003760003 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 21001144004 | 1 |
| Caesar & Loretz GmbH... | Chloramphenicol | 18017811 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 11370711 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 18017806 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 18017809 | 8 |
| Caesar & Loretz GmbH | Chloramphenicol | 18017810 | 2 |
| Caesar & Loretz GmbH | Chloramphenicol | 18017811 | 10 |
| Caesar & Loretz GmbH | Chloramphenicol | 18017813 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 18017814 | 3 |
| Caesar & Loretz GmbH | Chloramphenicol | 1903028-01 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 1903028-02 | 3 |
| Caesar & Loretz GmbH | Chloramphenicol | 192260001 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 19226001 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 19226002 | 12 |
| Caesar & Loretz GmbH | Chloramphenicol | 19226003 | 59 |
| Caesar & Loretz GmbH | Chloramphenicol | 19226004 | 2 |
| Caesar & Loretz GmbH | Chloramphenicol | 20000261003 | 3 |
| Caesar & Loretz GmbH | Chloramphenicol | 20000261004 | 9 |
| Caesar & Loretz GmbH | Chloramphenicol | 20003343004 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 20003760002 | 5 |
| Caesar & Loretz GmbH | Chloramphenicol | 20003760003 | 29 |
| Caesar & Loretz GmbH | Chloramphenicol | 20003760006 | 8 |
| Caesar & Loretz GmbH | Chloramphenicol | 2000376003 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 21001144004 | 22 |
| Caesar & Loretz GmbH | Chloramphenicol | 21001144006 | 2 |
| Caesar & Loretz GmbH | Chloramphenicol | 21001144007 | 13 |
| Caesar & Loretz GmbH | Chloramphenicol | 21001144009 | 1 |
| Caesar & Loretz GmbH | Chloramphenicol | 21001144014 | 2 |
| Caesar & Loretz GmbH | Chloramphenicol | 22002986001 | 3 |
| Caesar & Loretz GmbH | Chloramphenicol | 22002986003 | 2 |
| Caesar & Loretz | Chloramphenicol | 15358908 | 1 |
| Caesar & Loretz | Chloramphenicol | 16278609 | 2 |
| Caesar & Loretz | Chloramphenicol | 18017809 | 1 |
| Caesar & Loretz | Chloramphenicol | 21001144004 | 1 |
| Caesar & Loretz | Chloramphenicol | 21001144014 | 1 |
| Caesar Loretz | Chloramphenicol | 16278609 | 1 |
| Caesar Loretz | Chloramphenicol | 21001144007 | 1 |
| Caesar&Lorenz | Chloramphenicol | 20003760003 | 1 |
| Caesar&Loretz | Chloramphenicol | 16278612 | 1 |
| Caeser und Loretz GmbH | Chloramphenicol | 19226002 | 1 |
| Caleo/ Noweda | Chloramphenicol | 173436803 | 1 |
| Caolo- Noweda | Chloramphenicol | 14346908 | 1 |
| Cealo/Gehe | Chloramphenicol | 20003760002 | 2 |
| Cealo/Gehe | Chloramphenicol | 2100114406 | 3 |
| Cealo | Chloramphenicol | 1602002-03 | 1 |
| Chloramphenicol | Chloramphenicol | 2002043-01 | 1 |
| Eu Rho Pharm/E | Chloramphenicol | 1903028-02 | 1 |
| Eu Rho Pharm/K | Chloramphenicol | 1704021-04 | 1 |
| Eu Rho | Chloramphenicol | 2002043-02 | 2 |
| Eur Rho Phönix | Chloramphenicol | 2002043-02 | 1 |
| EuRho / 20 | Chloramphenicol | 1502036-01 | 1 |
| EuRho / Noweda | Chloramphenicol | 1903028-02 | 1 |
| Eurho No | Chloramphenicol | 1903028-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho Noweda | Chloramphenicol | 2002043-01 | 1 |
| Eurho ph | Chloramphenicol | 1903028-02 | 1 |
| Eurho Phönix | Chloramphenicol | 1704021-02 | 1 |
| EuRho/ Phönix | Chloramphenicol | 1903028-01 | 2 |
| EuRho/ Phönix | Chloramphenicol | 20002043-01 | 1 |
| EuRho/ Sanacorp | Chloramphenicol | 2002043-02 | 1 |
| Eurho/AHD | Chloramphenicol | 2002043-02 | 1 |
| EuRho/Alliance | Chloramphenicol | 2002043-01 | 1 |
| EuRho/Gehe | Chloramphenicol | 1704021-04 | 1 |
| EuRho/Gehe | Chloramphenicol | 1903028-02 | 1 |
| EuRho/Gehe | Chloramphenicol | 2002043-01 | 1 |
| EuRho/Gehe | Chloramphenicol | 919110016 | 1 |
| EuRho/Noweda | Chloramphenicol | 1704021-02 | 1 |
| EuRho/Noweda | Chloramphenicol | 2002043-02 | 1 |
| EuRho/Phoenix | Chloramphenicol | 2201014-03 | 1 |
| EuRho/Phönix | Chloramphenicol | 123012-01 | 1 |
| EuRho/Phönix | Chloramphenicol | 1308017-01 | 1 |
| EuRho/Phönix | Chloramphenicol | 1903028-02 | 1 |
| Eurho/Phönix | Chloramphenicol | 2002043-01 | 1 |
| EuRho/Phönix | Chloramphenicol | 2002043-01 | 1 |
| Eurho/Phönix | Chloramphenicol | 2002043-02 | 4 |
| EuRho/Sanacorp | Chloramphenicol | 1704021-01 | 1 |
| EuRho | Chloramphenicol | 1308017-02 | 1 |
| EuRho | Chloramphenicol | 15358913 | 1 |
| EuRho | Chloramphenicol | 1704021-01 | 2 |
| EuRho | Chloramphenicol | 1704021-02 | 2 |
| EuRho | Chloramphenicol | 1704021-03 | 2 |
| EuRho | Chloramphenicol | 1704021-04 | 1 |
| Eurho | Chloramphenicol | 1704087-03 | 1 |
| EuRho | Chloramphenicol | 1903028-01 | 2 |
| Eurho | Chloramphenicol | 1903028-02 | 1 |
| EuRho | Chloramphenicol | 1903028-02 | 1 |
| EuRho | Chloramphenicol | 2002043-01 | 7 |
| EuRho | Chloramphenicol | 2002043-02 | 3 |
| euRho | Chloramphenicol | 2002043-03 | 2 |
| Eurho | Chloramphenicol | 2002043-03 | 1 |
| EuRho | Chloramphenicol | 2002043-03 | 2 |
| EuRho | Chloramphenicol | 2002043-1 | 1 |
| EuRho | Chloramphenicol | 216A-01259 | 1 |
| Euro OCT / Krieger | Chloramphenicol | 2002043-01 | 1 |
| Euro OCT | Chloramphenicol | 1203012-02 | 1 |
| Euro OTC | Chloramphenicol | | 5 |
| Euro OTC | Chloramphenicol | 1(1903028-01) | 1 |
| Euro OTC | Chloramphenicol | 10061707 | 1 |
| Euro OTC | Chloramphenicol | 1012013-01 | 2 |
| Euro OTC | Chloramphenicol | 1107002-01 | 2 |
| Euro OTC | Chloramphenicol | 110700202 | 1 |
| Euro OTC | Chloramphenicol | 1107002-02 | 1 |
| Euro OTC | Chloramphenicol | 120250 | 1 |
| Euro OTC | Chloramphenicol | 1203012-01 | 7 |
| Euro OTC | Chloramphenicol | 1203012-02 | 12 |
| Euro OTC | Chloramphenicol | 1203012-12 | 1 |
| Euro OTC | Chloramphenicol | 1209010-02 | 3 |
| Euro OTC | Chloramphenicol | 1209019-01 | 6 |
| Euro OTC | Chloramphenicol | 120901902 | 3 |
| Euro OTC | Chloramphenicol | 1209019-02 | 11 |
| Euro OTC | Chloramphenicol | 1302024-01 | 12 |
| Euro OTC | Chloramphenicol | 1302024-02 | 7 |
| Euro OTC | Chloramphenicol | 130801701 | 1 |
| Euro OTC | Chloramphenicol | 1308017-01 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Chloramphenicol | 130801702 | 2 |
| Euro OTC | Chloramphenicol | 1308017-02 | 12 |
| Euro OTC | Chloramphenicol | 13080907 | 2 |
| Euro OTC | Chloramphenicol | 13111410 | 1 |
| Euro OTC | Chloramphenicol | 1317M-01259 | 1 |
| Euro OTC | Chloramphenicol | 1407043 | 1 |
| Euro OTC | Chloramphenicol | 140704301 | 5 |
| Euro OTC | Chloramphenicol | 1407043-01 | 24 |
| Euro OTC | Chloramphenicol | 14101717 | 1 |
| Euro OTC | Chloramphenicol | 14346910 | 1 |
| Euro OTC | Chloramphenicol | 1502036 | 1 |
| Euro OTC | Chloramphenicol | 150203601 | 5 |
| Euro OTC | Chloramphenicol | 1502036-01 | 36 |
| Euro OTC | Chloramphenicol | 150203602 | 2 |
| Euro OTC | Chloramphenicol | 1502036-02 | 21 |
| Euro OTC | Chloramphenicol | 1502036022016030911 | 1 |
| Euro OTC | Chloramphenicol | 150203603 | 1 |
| Euro OTC | Chloramphenicol | 1502036-03 | 23 |
| Euro OTC | Chloramphenicol | 1502063-02 | 1 |
| Euro OTC | Chloramphenicol | 1509211259 | 1 |
| Euro OTC | Chloramphenicol | 15358906 | 1 |
| Euro OTC | Chloramphenicol | 15358914 | 4 |
| Euro OTC | Chloramphenicol | 16020002-02 | 1 |
| Euro OTC | Chloramphenicol | 16020002-03 | 1 |
| Euro OTC | Chloramphenicol | 1602002-01 | 44 |
| Euro OTC | Chloramphenicol | 1602002-02 | 28 |
| Euro OTC | Chloramphenicol | 160200203 | 2 |
| Euro OTC | Chloramphenicol | 1602002-03 | 39 |
| Euro OTC | Chloramphenicol | 1602002-04 | 2 |
| Euro OTC | Chloramphenicol | 1602002-07 | 1 |
| Euro OTC | Chloramphenicol | 1701021-04 | 1 |
| Euro OTC | Chloramphenicol | 1704021 | 4 |
| Euro OTC | Chloramphenicol | 1704021_02 | 1 |
| Euro OTC | Chloramphenicol | 170402101 | 2 |
| Euro OTC | Chloramphenicol | 1704021-01 | 104 |
| Euro OTC | Chloramphenicol | 1704021-015505 | 1 |
| Euro OTC | Chloramphenicol | 1704021-01A | 1 |
| Euro OTC | Chloramphenicol | 170402102 | 1 |
| Euro OTC | Chloramphenicol | 1704021-02 | 60 |
| Euro OTC | Chloramphenicol | 170402103 | 3 |
| Euro OTC | Chloramphenicol | 1704021-03 | 50 |
| Euro OTC | Chloramphenicol | 170402104 | 2 |
| Euro OTC | Chloramphenicol | 1704021-04 | 75 |
| Euro OTC | Chloramphenicol | 17040212-04 | 1 |
| Euro OTC | Chloramphenicol | 170421-01 | 1 |
| Euro OTC | Chloramphenicol | 17044021-01 | 1 |
| Euro OTC | Chloramphenicol | 1707021-02 | 1 |
| Euro OTC | Chloramphenicol | 17704021-01 | 1 |
| Euro OTC | Chloramphenicol | 18017802 | 1 |
| Euro OTC | Chloramphenicol | 180178091903028-01 | 1 |
| Euro OTC | Chloramphenicol | 1903028 | 8 |
| Euro OTC | Chloramphenicol | 1903028_01 | 1 |
| Euro OTC | Chloramphenicol | 190302801 | 6 |
| Euro OTC | Chloramphenicol | 1903028-01 | 134 |
| Euro OTC | Chloramphenicol | 1903028-010 | 1 |
| Euro OTC | Chloramphenicol | 190302802 | 1 |
| Euro OTC | Chloramphenicol | 1903028-02 | 112 |
| Euro OTC | Chloramphenicol | 190302803 | 1 |
| Euro OTC | Chloramphenicol | 1903028-03 | 31 |
| Euro OTC | Chloramphenicol | 1903028-42 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Chloramphenicol | 191210111 | 1 |
| Euro OTC | Chloramphenicol | 193028-03 | 1 |
| Euro OTC | Chloramphenicol | 20012043-02 | 1 |
| Euro OTC | Chloramphenicol | 2002043 | 3 |
| Euro OTC | Chloramphenicol | 200204301 | 2 |
| Euro OTC | Chloramphenicol | 2002043-01 | 112 |
| Euro OTC | Chloramphenicol | 2002043-01/4420 | 1 |
| Euro OTC | Chloramphenicol | 200204302 | 5 |
| Euro OTC | Chloramphenicol | 2002043-02 | 145 |
| Euro OTC | Chloramphenicol | 200204303 | 4 |
| Euro OTC | Chloramphenicol | 2002043-03 | 52 |
| Euro OTC | Chloramphenicol | 2002043-1 | 1 |
| Euro OTC | Chloramphenicol | 20022043-01 | 1 |
| Euro OTC | Chloramphenicol | 200243-02 | 2 |
| Euro OTC | Chloramphenicol | 2004030-01 | 1 |
| Euro OTC | Chloramphenicol | 211217(2002043-01) | 1 |
| Euro OTC | Chloramphenicol | 2121211203012-0 | 1 |
| Euro OTC | Chloramphenicol | 220101401 | 1 |
| Euro OTC | Chloramphenicol | 2201014-01 | 40 |
| Euro OTC | Chloramphenicol | 2201014-02 | 11 |
| Euro OTC | Chloramphenicol | 2201014-04 | 2 |
| Euro OTC | Chloramphenicol | 22010144-01 | 1 |
| Euro OTC | Chloramphenicol | 22101402 | 1 |
| Euro OTC | Chloramphenicol | 221014-02 | 1 |
| Euro OTC | Chloramphenicol | 2306004-01 | 1 |
| Euro OTC | Chloramphenicol | 314Q1259 | 1 |
| Euro OTC | Chloramphenicol | 90302801 | 1 |
| Euro OTC | Chloramphenicol | 916161 | 1 |
| Euro OTC | Chloramphenicol | 919110016 | 7 |
| Euro OTC | Chloramphenicol | DY00912128 | 6 |
| Euro OTC | Chloramphenicol | DY00914151 | 1 |
| Euro OTC | Chloramphenicol | DY00918024 | 1 |
| Euro OTC | Chloramphenicol | DY00918024/1903028-02 | 1 |
| Euro OTC | Chloramphenicol | DY0092000082 | 2 |
| Euro OTC | Chloramphenicol | DY130525 | 1 |
| Euro OTC | Chloramphenicol | T02-55/1407043-01 | 1 |
| Euro OTG | Chloramphenicol | 1502036-01 | 1 |
| euro pharm | Chloramphenicol | 1602002-01 | 1 |
| Euro/ Sanacorp | Chloramphenicol | 1308017-02 | 1 |
| Euro//Sanacorp | Chloramphenicol | 2002043-01 | 1 |
| EUro/AHD | Chloramphenicol | 1209019-01 | 1 |
| EUro/AHD | Chloramphenicol | 1209019-02 | 1 |
| Euro/Alliance Healthcare | Chloramphenicol | 1502036-01 | 1 |
| Euro/Krieger | Chloramphenicol | 1602002-02 | 1 |
| Euro/Krieger | Chloramphenicol | 1602002-03 | 1 |
| Euro/Noweda | Chloramphenicol | 1602002-02 | 1 |
| Euro/Phönix | Chloramphenicol | 1502036-03 | 1 |
| Euro/Phönix | Chloramphenicol | 1704021-02 | 1 |
| Euro/Phönix | Chloramphenicol | 1704021-04 | 1 |
| Euro/Phönix | Chloramphenicol | 1903028-01 | 1 |
| euro | Chloramphenicol | 2002043-01 | 1 |
| Fa.Phönix | Chloramphenicol | 18017809 | 1 |
| fafron | Chloramphenicol | 12G02-N01 | 2 |
| Fagron | Chloramphenicol | | 2 |
| Fagron | Chloramphenicol | 11/14-N03 | 2 |
| Fagron | Chloramphenicol | 11J14-N03 | 1 |
| Fagron | Chloramphenicol | 120250-0002 | 1 |
| Fagron | Chloramphenicol | 1202500003 | 1 |
| Fagron | Chloramphenicol | 12A11-N02 | 1 |
| Fagron | Chloramphenicol | 12B13-N06 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Chloramphenicol | 12F01-N23 | 1 |
| Fagron | Chloramphenicol | 12G02-N01 | 9 |
| Fagron | Chloramphenicol | 12L11-N06 | 9 |
| Fagron | Chloramphenicol | 13A11N02 | 1 |
| Fagron | Chloramphenicol | 13A11-N02 | 6 |
| Fagron | Chloramphenicol | 13A1-802 | 3 |
| Fagron | Chloramphenicol | 13A31-B02 | 8 |
| Fagron | Chloramphenicol | 13A31-B02_286708 | 1 |
| Fagron | Chloramphenicol | 13A31-B02-286708 | 1 |
| Fagron | Chloramphenicol | 13A31-B02-286709 | 2 |
| Fagron | Chloramphenicol | 13A31-B02-290263 | 1 |
| Fagron | Chloramphenicol | 13A31-B02-290300 | 4 |
| Fagron | Chloramphenicol | 14346911 | 2 |
| Fagron | Chloramphenicol | 14E01-B02 | 5 |
| Fagron | Chloramphenicol | 14E01-B02_296624 | 1 |
| Fagron | Chloramphenicol | 14E01-B02-296623 | 1 |
| Fagron | Chloramphenicol | 14e01-b02-296624 | 1 |
| Fagron | Chloramphenicol | 14E01B02296624 | 2 |
| Fagron | Chloramphenicol | 14E01-B02-296624 | 7 |
| Fagron | Chloramphenicol | 14E01-B02-296625 | 1 |
| Fagron | Chloramphenicol | 14E01-B02-306146 | 7 |
| Fagron | Chloramphenicol | 14E01-B02-308559 | 7 |
| Fagron | Chloramphenicol | 1502036-01 | 1 |
| Fagron | Chloramphenicol | 15358914 | 1 |
| Fagron | Chloramphenicol | 1602002-01 | 2 |
| Fagron | Chloramphenicol | 1602002-02 | 1 |
| Fagron | Chloramphenicol | 1602002-03 | 1 |
| Fagron | Chloramphenicol | 1612-B07-329313 | 1 |
| Fagron | Chloramphenicol | 1704021-01 | 3 |
| Fagron | Chloramphenicol | 1903028-01 | 1 |
| Fagron | Chloramphenicol | 1903028-02 | 1 |
| Fagron | Chloramphenicol | 20E14-B19-202352 | 2 |
| Fagron | Chloramphenicol | 2111I-01259 | 1 |
| Fagron | Chloramphenicol | DY00911233 | 4 |
| Fagron | Chloramphenicol | DY00912129 | 1 |
| Fagron | Chloramphenicol | LTOCHL/049/16-17M | 1 |
| Fiebig | Chloramphenicol | 1502036-01 | 1 |
| Fiebig | Chloramphenicol | 15358913 | 1 |
| Fiebig | Chloramphenicol | 1602002-01 | 1 |
| Fiebig | Chloramphenicol | 16278608 | 1 |
| Fiebig | Chloramphenicol | 16278609 | 1 |
| Fiebig | Chloramphenicol | 16278612 | 1 |
| Fiebig | Chloramphenicol | 1704021-01 | 1 |
| Fiebig | Chloramphenicol | 1734803 | 1 |
| Fiebig | Chloramphenicol | 18017809 | 1 |
| Fiebig | Chloramphenicol | 18017810 | 1 |
| Fiebig | Chloramphenicol | 19226002 | 1 |
| fiebig | Chloramphenicol | 2201014-03 | 1 |
| Finteler Apotheke | Chloramphenicol | 15358913 | 1 |
| Fischar/Sanacorp | Chloramphenicol | 1704021-04 | 1 |
| Fischer/ Noweda | Chloramphenicol | 1502036-03 | 1 |
| Fragon | Chloramphenicol | 12G02-N01 | 1 |
| Gatt-Koller / Phoenix | Chloramphenicol | 5615/12115211 | 1 |
| Gehe - Hedinger | Chloramphenicol | 1704021-01 | 1 |
| Gehe 013.09.2014 | Chloramphenicol | 1308017-02 | 2 |
| Gehe 27.06.15/euro | Chloramphenicol | 1502036-01 | 2 |
| Gehe amax | Chloramphenicol | 1602002-03 | 1 |
| gehe/ Northeast Pharma | Chloramphenicol | 2002043-01 | 1 |
| Gehe | Chloramphenicol | 1107002-02 | 1 |
| Gehe | Chloramphenicol | 1203012-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Chloramphenicol | 1209019-02 | 1 |
| Gehe | Chloramphenicol | 1308017-02 | 1 |
| Gehe | Chloramphenicol | 14346910 | 1 |
| Gehe | Chloramphenicol | 15358906 | 1 |
| Gehe | Chloramphenicol | 15358909 | 1 |
| Gehe | Chloramphenicol | 15358913 | 2 |
| GEHE | Chloramphenicol | 15358914 | 1 |
| GEHE | Chloramphenicol | 160200202 | 1 |
| GEHE | Chloramphenicol | 16278608 | 1 |
| Gehe | Chloramphenicol | 16278612 | 1 |
| Gehe | Chloramphenicol | 17021-04 | 1 |
| Gehe | Chloramphenicol | 1704021 | 1 |
| Gehe | Chloramphenicol | 1704021-01 | 3 |
| Gehe | Chloramphenicol | 1704021-02 | 3 |
| Gehe | Chloramphenicol | 1704021-03 | 2 |
| Gehe | Chloramphenicol | 1704021-04 | 1 |
| GEHE | Chloramphenicol | 17343803 | 1 |
| GEHE | Chloramphenicol | 18017806 | 1 |
| Gehe | Chloramphenicol | 18017811 | 1 |
| GEHE | Chloramphenicol | 18017811 | 1 |
| Gehe | Chloramphenicol | 1903028_02 | 1 |
| Gehe | Chloramphenicol | 1903028-01 | 6 |
| Gehe | Chloramphenicol | 1903028-02 | 1 |
| Gehe | Chloramphenicol | 1903028-03 | 1 |
| GEHE | Chloramphenicol | 19226002 | 1 |
| Gehe | Chloramphenicol | 19226003 | 1 |
| Gehe | Chloramphenicol | 2002043-01 | 1 |
| Gehe | Chloramphenicol | 2002043-02 | 1 |
| Gehe | Chloramphenicol | 22002986007 | 2 |
| Gehe | Chloramphenicol | 2201014-01 | 1 |
| GEHE | Chloramphenicol | 2201014-02 | 1 |
| Gehe | Chloramphenicol | 220-1014-03 | 1 |
| GEHE | Chloramphenicol | 2201014-03 | 1 |
| Gehe | Chloramphenicol | 2306004-01 | 3 |
| Gehe | Chloramphenicol | 24001644005 | 1 |
| Gutenberg-Apotheke | Chloramphenicol | 13A31-B02-286710 | 1 |
| Jenne | Chloramphenicol | 1903028 | 1 |
| Jenne | Chloramphenicol | 200204301 | 1 |
| Jenne | Chloramphenicol | 2002043-02 | 1 |
| Jenne | Chloramphenicol | 2201014-01 | 2 |
| Jenne | Chloramphenicol | 2201014-02 | 2 |
| Kehr | Chloramphenicol | 1704021-01 | 1 |
| Kehr | Chloramphenicol | 22002986001 | 1 |
| Kehr | Chloramphenicol | 22005298 | 1 |
| Kehr | Chloramphenicol | 2200986001 | 1 |
| Kehr | Chloramphenicol | 2403008-01 | 1 |
| Mehta API | Chloramphenicol | 181113082 | 1 |
| Nanjing / Gehe | Chloramphenicol | 14346910 | 1 |
| Nanjing Baijingyu Ph... | Chloramphenicol | 14346917 | 1 |
| NanjingBajingyu | Chloramphenicol | 1538914 | 1 |
| Northeast Gen | Chloramphenicol | DY122127 | 1 |
| Northeast General / Gehe | Chloramphenicol | 1602002-02 | 1 |
| Northeast General/Noweda | Chloramphenicol | 1502036-02 | 1 |
| Northeast General | Chloramphenicol | 1407043-01 | 1 |
| Northeast General | Chloramphenicol | 1602002-02 | 1 |
| Northeast General | Chloramphenicol | DY00914151 | 2 |
| Northeast/Noweda | Chloramphenicol | DY00918024 | 1 |
| Noweda/EuRho | Chloramphenicol | 2002043-01 | 1 |
| Noweda | Chloramphenicol | 1137014 | 1 |
| Noweda | Chloramphenicol | 11370712 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Chloramphenicol | 12248509 | 1 |
| noweda | Chloramphenicol | 13080908 | 2 |
| Noweda | Chloramphenicol | 14346901 | 2 |
| Noweda | Chloramphenicol | 14346910 | 1 |
| Noweda | Chloramphenicol | 1502036-03 | 1 |
| Noweda | Chloramphenicol | 15358906 | 1 |
| Noweda | Chloramphenicol | 15358914 | 1 |
| Noweda | Chloramphenicol | 1602002-02 | 1 |
| Noweda | Chloramphenicol | 16278609 | 1 |
| Noweda | Chloramphenicol | 1704021-01 | 3 |
| Noweda | Chloramphenicol | 1704021-02 | 2 |
| Noweda | Chloramphenicol | 1903028 | 2 |
| Noweda | Chloramphenicol | 1903028-01 | 1 |
| Noweda | Chloramphenicol | 1903028-02 | 1 |
| Noweda | Chloramphenicol | 192260001 | 1 |
| Noweda | Chloramphenicol | 19226002 | 1 |
| Noweda | Chloramphenicol | 2002043-02 | 1 |
| Noweda | Chloramphenicol | 2002043-03 | 1 |
| noweda | Chloramphenicol | 22002986002 | 1 |
| Noweda | Chloramphenicol | 22002986002 | 1 |
| Noweda | Chloramphenicol | 22002986003 | 2 |
| NOWEDA | Chloramphenicol | 22002986003 | 1 |
| Noweda | Chloramphenicol | 2201014-02 | 3 |
| Noweda | Chloramphenicol | 2201014-04 | 1 |
| Noweda | Chloramphenicol | 220104-01 | 1 |
| Noweda | Chloramphenicol | 2202986003 | 1 |
| Noweda | Chloramphenicol | 2306004-01 | 2 |
| Noweda | Chloramphenicol | 24000255001 | 1 |
| Noweda | Chloramphenicol | 24001644005 | 1 |
| Noweda | Chloramphenicol | CHL014B24P | 1 |
| Parthe Apotheke | Chloramphenicol | 67/20 | 1 |
| Ph/Euro | Chloramphenicol | 1704021-02 | 1 |
| Ph/Euro | Chloramphenicol | 2002043-03 | 1 |
| Phoe | Chloramphenicol | 15358905 | 1 |
| Phoenix | Chloramphenicol | 13080903 | 1 |
| Phoenix | Chloramphenicol | 16278609 | 1 |
| Phoenix | Chloramphenicol | 1704021-01 | 1 |
| phoenix | Chloramphenicol | 1704021-02 | 1 |
| Phoenix | Chloramphenicol | 1704021-02 | 1 |
| Phoenix | Chloramphenicol | 18017814 | 1 |
| phoenix | Chloramphenicol | 1903028 | 1 |
| Phoenix | Chloramphenicol | 1903028-01 | 2 |
| Phoenix | Chloramphenicol | 2002043 | 1 |
| Phoenix | Chloramphenicol | 2002043-01 | 1 |
| Phoenix | Chloramphenicol | 200204302 | 1 |
| Phoenix | Chloramphenicol | 2002043-02 | 1 |
| Phoenix | Chloramphenicol | 22002986007 | 1 |
| Phoenix | Chloramphenicol | 2201014-01 | 1 |
| Phoenix | Chloramphenicol | 2201014-02 | 2 |
| Phoenix | Chloramphenicol | 2306004-01 | 3 |
| Phoenix | Chloramphenicol | 3087 | 1 |
| phoenix-06.11.18 | Chloramphenicol | 17343803 | 1 |
| Phönix /EURO | Chloramphenicol | 2002043-01 | 1 |
| Phönix 11.11.2019 | Chloramphenicol | 19226003 | 1 |
| Phönix 12.10.2019 | Chloramphenicol | 1903028-01 | 1 |
| Phönix Gotha | Chloramphenicol | 13080907 | 1 |
| Phönix/Fagon | Chloramphenicol | 14346922 | 1 |
| Phönix/Noweda | Chloramphenicol | 2002043-03 | 1 |
| Phönix | Chloramphenicol | 10341710 | 1 |
| Phönix | Chloramphenicol | 10341716 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Chloramphenicol | 13080921 | 1 |
| Phönix | Chloramphenicol | 13A11-N02 | 3 |
| phönix | Chloramphenicol | 15358912 | 1 |
| PHÖNIX | Chloramphenicol | 16278608 | 1 |
| Phönix | Chloramphenicol | 170402103 | 1 |
| Phönix | Chloramphenicol | 18017806 | 1 |
| Phönix | Chloramphenicol | 1903028 | 1 |
| Phönix | Chloramphenicol | 1903028-02 | 1 |
| Phönix | Chloramphenicol | 190328-03 | 1 |
| Phönix | Chloramphenicol | 20003760003 | 1 |
| Phönix | Chloramphenicol | 2002043-01 | 1 |
| Phönix | Chloramphenicol | 2002043-02 | 2 |
| Phönix | Chloramphenicol | 20E14-B19-202352 | 3 |
| Phönix | Chloramphenicol | 22002986007 | 3 |
| Phönix | Chloramphenicol | 2306004 | 1 |
| Phönix | Chloramphenicol | 2306004-01 | 3 |
| Phönix | Chloramphenicol | 3157 | 1 |
| Sana 22.11.2017 5.90 | Chloramphenicol | 16278608 | 1 |
| Sanacorp/EuRho | Chloramphenicol | 1704021-02 | 1 |
| Sanacorp | Chloramphenicol | | 1 |
| Sanacorp | Chloramphenicol | 11370711 | 1 |
| Sanacorp | Chloramphenicol | 120901902 | 1 |
| Sanacorp | Chloramphenicol | 12248501 | 1 |
| Sanacorp | Chloramphenicol | 1308017-02 | 1 |
| Sanacorp | Chloramphenicol | 140704301 | 1 |
| Sanacorp | Chloramphenicol | 1407043-01 | 2 |
| Sanacorp | Chloramphenicol | 1502036-01 | 1 |
| Sanacorp | Chloramphenicol | 15358913 | 1 |
| Sanacorp | Chloramphenicol | 16278612 | 1 |
| Sanacorp | Chloramphenicol | 1704021-01 | 1 |
| Sanacorp | Chloramphenicol | 17343803 | 1 |
| Sanacorp | Chloramphenicol | 18017806 | 2 |
| Sanacorp | Chloramphenicol | 18017809 | 1 |
| Sanacorp | Chloramphenicol | 18017814 | 2 |
| Sanacorp | Chloramphenicol | 1903028-02 | 2 |
| Sanacorp | Chloramphenicol | 19226003 | 1 |
| Sanacorp | Chloramphenicol | 20E14-B19-202352 | 1 |
| Sanacorp | Chloramphenicol | 21001144004 | 1 |
| Sanacorp | Chloramphenicol | 21001144009 | 1 |
| Sanacorp | Chloramphenicol | 22002986001 | 2 |
| Sanacorp | Chloramphenicol | 220101-04 | 1 |
| Sanacorp | Chloramphenicol | 2201014-01 | 1 |
| sanacorp | Chloramphenicol | 2201014-04 | 1 |
| Sanacorp | Chloramphenicol | 2306004-01 | 2 |
| Sanacorp | Chloramphenicol | 2306004-03 | 4 |
| Sanacorp | Chloramphenicol | 24D11-B05-001343 | 1 |
| Sanacorp | Chloramphenicol | 41/AKD23 | 1 |
| Sanacorp | Chloramphenicol | 41/AKD24 | 1 |
| Sannacorp | Chloramphenicol | 2201014 | 1 |
| Spangro 12.05.2014 | Chloramphenicol | 1308017-01 | 1 |
| Spangro 14.03.2014 | Chloramphenicol | 12248524 | 1 |
| Spangro_22.11.2018 | Chloramphenicol | 17343803 | 1 |
| vdl | Chloramphenicol | 12248501 | 1 |
| VDL | Chloramphenicol | 1308017-01 | 1 |
| VDL | Chloramphenicol | 140743-01 | 1 |

- 253 331 spectra from 1666 *Apo-Ident* customers from a total of 51 789 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,


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the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Chloramphenicol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Chloramphenicol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 685 | 0 | 157 641 |
| **Type B** | 0 | 650 | 0 | 212 290 |
| **Type C** | 0 | 3549 | 6 | 253 331 |

The substance/substance group *Chloramphenicol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1241 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0769 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8312 % (> 99.7468 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20777 | 20777 | 0.00 | 178.74 |
| 20787 | 20777 | 7.29 | 180.11 |
| 20807 | 20777 | 4.71 | 179.69 |
| 20813 | 20777 | 3.65 | 179.17 |
| 20815 | 20777 | 3.63 | 179.24 |
| 20822 | 20777 | 3.67 | 179.00 |
| 21701 | 21701 | 0.00 | 184.99 |
| 21752 | 22367 | 13.22 | 189.21 |
| 21910 | 22367 | 3.31 | 184.46 |
| 21988 | 20777 | 7.26 | 182.04 |
| 22367 | 22367 | 0.00 | 182.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at

least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Chlorhexidine diacetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20989-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Chlorhexidine diacetate; Chlorhexidini acetas

### Special notes

When selecting the *Chlorhexidine diacetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Chlorhexidine diacetate | 11 | 6 | 142 |

### Second-stage model

For differentiation of the substance/substance group *Chlorhexidine diacetate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Chlorhexidine diacetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 73.29 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Chlorhexidine diacetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Chlorhexidine diacetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Chlorhexidine diacetate | 12142726 | 20989 | 40 | 1402685 |
| Caelo | Chlorhexidine diacetate | 12142727 | 21041 | 40 | 20120711 |
| Caelo | Chlorhexidine diacetate | 154389 | 22456 | 60 | 20160309* |
| Caelo | Chlorhexidine diacetate | 15438914 | 22900 | 40 | 1704392 |
| Caelo | Chlorhexidine diacetate | 15438914 | 22951 | 40 | 20160309 |
| Caelo | Chlorhexidine diacetate | 15438913 | 23041 | 40 | 20160309* |
| Caelo | Chlorhexidine diacetate | 154389 | 23042 | 40 | 20160309* |
| Caelo | Chlorhexidine diacetate | 154389 | 23043 | 40 | 20160309* |
| Caelo | Chlorhexidine diacetate | 15438909 | 23044 | 40 | 20160309* |
| Caelo | Chlorhexidine diacetate | 154389 | 23048 | 40 | 20160309* |
| Caelo | Chlorhexidine diacetate | 22003198 | 26483 | 40 | 20221123* |
| Caelo | Chlorhexidine diacetate | 22003198 | 26483SI | 40 | 20221123* |
| Fagron | Chlorhexidine diacetate | 14I08-B02-306223 | 22280 | 60 | 20140922 |
| Fagron | Chlorhexidine diacetate | 14I08-B02-306223 | 22280SI | 40 | 20140922 |
| Fagron | Chlorhexidine diacetate | 15J02-B08-322916 | 22946 | 40 | 20151104 |
| Fagron | Chlorhexidine diacetate | 15J02-B08-322916 | 22947 | 40 | 20151104 |
| Fagron | Chlorhexidine diacetate | 22C12-B01-223585 | 26456 | 40 | 20220610 |
| Fagron | Chlorhexidine diacetate | 22C12-B01-223585 | 26456SI | 40 | 20220610 |
| Fagron | Chlorhexidine diacetate | 23A26-B06-230994 | 26816 | 40 | 20230313 |
| Fagron | Chlorhexidine diacetate | 23A26-B06-230994 | 26816SI | 40 | 20230313 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 840 spectra of 20 reference samples from the substance/substance group *Chlorhexidine diacetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 486 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 475 spectra of 12 reference samples from the substance/substance group *Chlorhexidine diacetate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Chlorhexidine diacetate | 152610 | 23045 | 40 |
| Caelo | Chlorhexidine diacetate | 171858 | 23640 | 40 |
| Caelo | Chlorhexidine diacetate | 21001181 | 25696 | 50 |
| Caelo | Chlorhexidine diacetate | 22000764 | 26116 | 35 |
| Caelo | Chlorhexidine diacetate | 23001289 | 26832 | 30 |
| Fagron | Chlorhexidine diacetate | 18A17-B02-354548 | 25486 | 40 |
| Caelo | Chlorhexidine diacetate | 15438914 | 22951SI† | 40 |
| Caelo | Chlorhexidine diacetate | 21001181 | 25696SI | 50 |
| Caelo | Chlorhexidine diacetate | 22000764 | 26116SI | 40 |
| Caelo | Chlorhexidine diacetate | 23001289 | 26832SI | 30 |
| Fagron | Chlorhexidine diacetate | 15J02-B08-322916 | 22947SI† | 40 |
| Fagron | Chlorhexidine diacetate | 18A17-B02-354548 | 25486SI | 40 |

- 212 465 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1222 spectra from 668 *Apo-Ident* customers from 150 batches from the substance/substance group *Chlorhexidine diacetate*.
- Among them are spectra of independent samples from 140 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Chlorhexidine diacetate | 19122104 | 1 |
| | Chlorhexidine diacetate | 2200312010 | 1 |
| | Chlorhexidine diacetate | 22003123004 | 3 |
| | Chlorhexidine diacetate | 22003123005 | 2 |
| | Chlorhexidine diacetate | 22003123009 | 16 |
| | Chlorhexidine diacetate | 22003123010 | 7 |
| | Chlorhexidine diacetate | 22003123017 | 20 |
| | Chlorhexidine diacetate | 2203123017 | 1 |
| | Chlorhexidine diacetate | 22C12-B01-223585 | 3 |
| | Chlorhexidine diacetate | 23001289005 | 2 |
| | Chlorhexidine diacetate | 23001289006 | 15 |
| | Chlorhexidine diacetate | 23001289008 | 7 |
| | Chlorhexidine diacetate | 2300129800 | 1 |
| | Chlorhexidine diacetate | 23003317002 | 5 |
| | Chlorhexidine diacetate | 24001730003 | 2 |
| AEP | Chlorhexidine diacetate | 200004515004 | 1 |
| AEP | Chlorhexidine diacetate | 20004515004 | 1 |
| AHD | Chlorhexidine diacetate | 17185812 | 1 |
| AHD | Chlorhexidine diacetate | 22003123017 | 1 |
| AHD | Chlorhexidine diacetate | 23001289006 | 2 |
| AHL | Chlorhexidine diacetate | 15438903 | 1 |
| Alliance Healthcare | Chlorhexidine diacetate | 12177510 | 1 |
| Alliance | Chlorhexidine diacetate | 22003123005 | 1 |
| Anzag | Chlorhexidine diacetate | 12177505 | 1 |
| Anzag | Chlorhexidine diacetate | 18072404 | 1 |
| Anzag | Chlorhexidine diacetate | 230601(22003123017) | 1 |
| Anzag | Chlorhexidine diacetate | 70558377 | 1 |
| Bomastus / Alliance ... | Chlorhexidine diacetate | 17185804 | 1 |
| Caelo | Chlorhexidine diacetate | 10154407 | 1 |
| Caelo | Chlorhexidine diacetate | 10154417 | 1 |
| Caelo | Chlorhexidine diacetate | 10154421 | 1 |
| Caelo | Chlorhexidine diacetate | 10154424 | 1 |
| Caelo | Chlorhexidine diacetate | 10154429 | 1 |
| Caelo | Chlorhexidine diacetate | 10154430 | 2 |
| Caelo | Chlorhexidine diacetate | 1072015C | 1 |
| Caelo | Chlorhexidine diacetate | 11204401 | 3 |
| Caelo | Chlorhexidine diacetate | 11204402 | 1 |
| Caelo | Chlorhexidine diacetate | 11204405 | 1 |
| Caelo | Chlorhexidine diacetate | 11204406 | 2 |
| Caelo | Chlorhexidine diacetate | 11204407 | 1 |
| Caelo | Chlorhexidine diacetate | 11204408 | 2 |
| Caelo | Chlorhexidine diacetate | 12142702 | 2 |
| Caelo | Chlorhexidine diacetate | 12142704 | 6 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chlorhexidine diacetate | 12142704ok | 1 |
| Caelo | Chlorhexidine diacetate | 12142705 | 3 |
| Caelo | Chlorhexidine diacetate | 12142709 | 1 |
| Caelo | Chlorhexidine diacetate | 12142715 | 4 |
| Caelo | Chlorhexidine diacetate | 12142720 | 10 |
| Caelo | Chlorhexidine diacetate | 12142725 | 6 |
| Caelo | Chlorhexidine diacetate | 12142726 | 9 |
| Caelo | Chlorhexidine diacetate | 12142727 | 10 |
| Caelo | Chlorhexidine diacetate | 12142734 | 13 |
| Caelo | Chlorhexidine diacetate | 12177502 | 1 |
| Caelo | Chlorhexidine diacetate | 12177503 | 2 |
| Caelo | Chlorhexidine diacetate | 12177504 | 1 |
| Caelo | Chlorhexidine diacetate | 12177505 | 3 |
| Caelo | Chlorhexidine diacetate | 12177510 | 8 |
| Caelo | Chlorhexidine diacetate | 123456 | 1 |
| Caelo | Chlorhexidine diacetate | 1242720 | 1 |
| Caelo | Chlorhexidine diacetate | 1317021 | 1 |
| Caelo | Chlorhexidine diacetate | 13177001 | 6 |
| Caelo | Chlorhexidine diacetate | 13177002 | 12 |
| Caelo | Chlorhexidine diacetate | 13177007 | 20 |
| Caelo | Chlorhexidine diacetate | 13177008 | 4 |
| Caelo | Chlorhexidine diacetate | 13177009 | 1 |
| Caelo | Chlorhexidine diacetate | 13177021 | 15 |
| Caelo | Chlorhexidine diacetate | 13177022 | 1 |
| Caelo | Chlorhexidine diacetate | 13177024 | 7 |
| Caelo | Chlorhexidine diacetate | 15261003 | 7 |
| Caelo | Chlorhexidine diacetate | 15261004 | 2 |
| Caelo | Chlorhexidine diacetate | 15261005 | 7 |
| Caelo | Chlorhexidine diacetate | 15261007 | 19 |
| Caelo | Chlorhexidine diacetate | 15261009 | 15 |
| Caelo | Chlorhexidine diacetate | 15261011 | 1 |
| Caelo | Chlorhexidine diacetate | 15261012 | 10 |
| Caelo | Chlorhexidine diacetate | 15261014 | 27 |
| Caelo | Chlorhexidine diacetate | 15438902 | 9 |
| Caelo | Chlorhexidine diacetate | 15438903 | 11 |
| Caelo | Chlorhexidine diacetate | 15438909 | 5 |
| Caelo | Chlorhexidine diacetate | 15438911 | 20 |
| Caelo | Chlorhexidine diacetate | 15438913 | 1 |
| Caelo | Chlorhexidine diacetate | 15438914 | 7 |
| Caelo | Chlorhexidine diacetate | 15438917 | 12 |
| Caelo | Chlorhexidine diacetate | 1543909 | 1 |
| Caelo | Chlorhexidine diacetate | 15J02-B08-322916 | 1 |
| Caelo | Chlorhexidine diacetate | 160912CH | 1 |
| Caelo | Chlorhexidine diacetate | 17185802 | 3 |
| Caelo | Chlorhexidine diacetate | 17185803 | 6 |
| Caelo | Chlorhexidine diacetate | 17185804 | 29 |
| Caelo | Chlorhexidine diacetate | 17185805 | 6 |
| Caelo | Chlorhexidine diacetate | 17185807 | 22 |
| Caelo | Chlorhexidine diacetate | 17185808 | 20 |
| Caelo | Chlorhexidine diacetate | 17185810 | 27 |
| Caelo | Chlorhexidine diacetate | 17185811 | 24 |
| Caelo | Chlorhexidine diacetate | 17185812 | 24 |
| Caelo | Chlorhexidine diacetate | 17188504 | 1 |
| Caelo | Chlorhexidine diacetate | 17325801 | 8 |
| Caelo | Chlorhexidine diacetate | 17325803 | 29 |
| Caelo | Chlorhexidine diacetate | 17325808 | 16 |
| Caelo | Chlorhexidine diacetate | 17325809 | 35 |
| Caelo | Chlorhexidine diacetate | 17326809 | 1 |
| Caelo | Chlorhexidine diacetate | 1735801 | 1 |
| Caelo | Chlorhexidine diacetate | 1735803 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chlorhexidine diacetate | 1735809 | 1 |
| Caelo | Chlorhexidine diacetate | 1785808 | 1 |
| Caelo | Chlorhexidine diacetate | 180130CA/17185804 | 1 |
| Caelo | Chlorhexidine diacetate | 18072403 | 2 |
| Caelo | Chlorhexidine diacetate | 18072404 | 21 |
| Caelo | Chlorhexidine diacetate | 1907502 | 1 |
| Caelo | Chlorhexidine diacetate | 190975001 | 22 |
| Caelo | Chlorhexidine diacetate | 19097501 | 17 |
| Caelo | Chlorhexidine diacetate | 19097502 | 34 |
| Caelo | Chlorhexidine diacetate | 19121804 | 1 |
| Caelo | Chlorhexidine diacetate | 191221001 | 11 |
| Caelo | Chlorhexidine diacetate | 191221004 | 6 |
| Caelo | Chlorhexidine diacetate | 19122103 | 4 |
| Caelo | Chlorhexidine diacetate | 19122104 | 38 |
| Caelo | Chlorhexidine diacetate | 200004515003 | 1 |
| Caelo | Chlorhexidine diacetate | 20004515003 | 11 |
| Caelo | Chlorhexidine diacetate | 20004515004 | 34 |
| Caelo | Chlorhexidine diacetate | 20004515005 | 1 |
| Caelo | Chlorhexidine diacetate | 20004515006 | 15 |
| Caelo | Chlorhexidine diacetate | 20004515007 | 8 |
| Caelo | Chlorhexidine diacetate | 2004515006 | 1 |
| Caelo | Chlorhexidine diacetate | 2195172 | 1 |
| Caelo | Chlorhexidine diacetate | 2195195 | 1 |
| Caelo | Chlorhexidine diacetate | 22003123004 | 11 |
| Caelo | Chlorhexidine diacetate | 22003123005 | 12 |
| Caelo | Chlorhexidine diacetate | 22003123006 | 1 |
| Caelo | Chlorhexidine diacetate | 22003123009 | 9 |
| Caelo | Chlorhexidine diacetate | 22003123010 | 3 |
| Caelo | Chlorhexidine diacetate | 22003123017 | 2 |
| Caelo | Chlorhexidine diacetate | 22C12-B01-223585 | 1 |
| Caelo | Chlorhexidine diacetate | 23001289006 | 1 |
| Caelo | Chlorhexidine diacetate | 23001289008 | 1 |
| Caelo | Chlorhexidine diacetate | 23012015D | 1 |
| Caelo | Chlorhexidine diacetate | 31032014B | 1 |
| Caelo | Chlorhexidine diacetate | 433218072404 | 1 |
| Caelo | Chlorhexidine diacetate | 70558377 | 1 |
| Caelo | Chlorhexidine diacetate | 9(191221004) | 1 |
| Caelo | Chlorhexidine diacetate | 9113903 | 1 |
| Caelo | Chlorhexidine diacetate | 9113904 | 2 |
| Caelo | Chlorhexidine diacetate | 91139389 | 1 |
| Caelo | Chlorhexidine diacetate | AK31122020 | 1 |
| Caeol/ Noweda | Chlorhexidine diacetate | 15438911 | 1 |
| Caeol/Noweda | Chlorhexidine diacetate | 19097502 | 2 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 18072404 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 19122104 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 15261012 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 18072403 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 220031263004 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 12142720 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 17185812 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 22003123005 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 20004515003 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 17185810 | 2 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 19097501 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 19122103 | 2 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 19122104 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 22003123008 | 1 |
| Caesar & Loretz GmbH/AHD | Chlorhexidine diacetate | 22003123004 | 1 |
| Caesar & Loretz GmbH/Alli | Chlorhexidine diacetate | 22003123004 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 22003123009 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 190975001 | 2 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 19122104 | 3 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 20004515004 | 1 |
| Caesar & Loretz GmbH/Gehe | Chlorhexidine diacetate | 17185810 | 1 |
| Caesar & Loretz GmbH/Gehe | Chlorhexidine diacetate | 18072404 | 1 |
| Caesar & Loretz GmbH/Gehe | Chlorhexidine diacetate | 23001289006 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 20004515003 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 22003123010 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 19122104 | 1 |
| Caesar & Loretz GmbH/Otto | Chlorhexidine diacetate | 19097502 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 20004515004 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 190975001 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 191221001 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 20004515004 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 22003123004 | 1 |
| Caesar & Loretz GmbH... | Chlorhexidine diacetate | 19122104 | 1 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 17185802 | 1 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 17185812 | 2 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 17325808 | 2 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 17325809 | 2 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 18072403 | 1 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 18072404 | 7 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 190975001 | 2 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 19097501 | 3 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 19097502 | 8 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 191221001 | 12 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 191221004 | 2 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 19122103 | 1 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 19122104 | 8 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 20004515003 | 6 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 20004515004 | 13 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 20004515006 | 1 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 20004515007 | 1 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 22003123004 | 4 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 22003123005 | 9 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 22003123009 | 8 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 22003123010 | 2 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 22003123017 | 2 |
| Caesar & Loretz GmbH | Chlorhexidine diacetate | 2203123004 | 1 |
| Caesar & Loretz/Geil... | Chlorhexidine diacetate | 19097502 | 1 |
| Caesar&loretz,Anzag | Chlorhexidine diacetate | 12142704 | 1 |
| caesar | Chlorhexidine diacetate | 15261014 | 1 |
| Cealo/Phoenix | Chlorhexidine diacetate | 22003123005 | 1 |
| Cealo | Chlorhexidine diacetate | 13177002 | 2 |
| cealo | Chlorhexidine diacetate | 17185804 | 1 |
| Cealo | Chlorhexidine diacetate | 17325803 | 1 |
| Ceasar & Loretz GmbH | Chlorhexidine diacetate | 80104278 | 1 |
| Cordes/Noweda | Chlorhexidine diacetate | 15438914 | 1 |
| Euro OTC | Chlorhexidine diacetate | 10154430 | 1 |
| Euro OTC | Chlorhexidine diacetate | 15261004 | 1 |
| Euro OTC | Chlorhexidine diacetate | 17185810 | 3 |
| Euro OTC | Chlorhexidine diacetate | 17325809 | 1 |
| Euro OTC | Chlorhexidine diacetate | 1785805 | 1 |
| Fagron | Chlorhexidine diacetate | 12E14-N11 | 1 |
| Fagron | Chlorhexidine diacetate | 13177008 | 1 |
| Fagron | Chlorhexidine diacetate | 13E03-B06 | 1 |
| Fagron | Chlorhexidine diacetate | 13E03-B06-287926 | 2 |
| Fagron | Chlorhexidine diacetate | 13E03-B06-287929 | 1 |
| Fagron | Chlorhexidine diacetate | 15261009 | 1 |
| Fagron | Chlorhexidine diacetate | 15438901 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Chlorhexidine diacetate | 15J02-B08 | 2 |
| Fagron | Chlorhexidine diacetate | 15J02-B08-322916 | 2 |
| Fagron | Chlorhexidine diacetate | 17185811 | 1 |
| Fagron | Chlorhexidine diacetate | 17325801 | 1 |
| Fagron | Chlorhexidine diacetate | 17D25-B04-339937 | 3 |
| Fagron | Chlorhexidine diacetate | 1-8991-1-01-01 | 1 |
| Fagron | Chlorhexidine diacetate | 19F27-B03-364809 | 1 |
| Fagron | Chlorhexidine diacetate | 22C12-B01-223585 | 1 |
| Fagron | Chlorhexidine diacetate | A-130037 | 1 |
| Fagron | Chlorhexidine diacetate | A-170073 | 1 |
| Fiebig | Chlorhexidine diacetate | 15261014 | 1 |
| Fiebig | Chlorhexidine diacetate | 17185807 | 1 |
| Fiebig | Chlorhexidine diacetate | 17325803 | 1 |
| Fiebig | Chlorhexidine diacetate | 23003317002 | 1 |
| GEHE | Chlorhexidine diacetate | 12142734 | 1 |
| Gehe | Chlorhexidine diacetate | 15261007 | 1 |
| Gehe | Chlorhexidine diacetate | 15438909 | 1 |
| Gehe | Chlorhexidine diacetate | 17185804 | 1 |
| Gehe | Chlorhexidine diacetate | 17185805 | 1 |
| Gehe | Chlorhexidine diacetate | 17325803 | 1 |
| Gehe | Chlorhexidine diacetate | 22003123009 | 2 |
| Gehe | Chlorhexidine diacetate | 22003123017 | 1 |
| Jenne | Chlorhexidine diacetate | 17185808 | 1 |
| Jenne | Chlorhexidine diacetate | 17185810 | 1 |
| Jenne | Chlorhexidine diacetate | 22003123010 | 1 |
| Kehr | Chlorhexidine diacetate | 22003123017 | 1 |
| keine Angabe | Chlorhexidine diacetate | 11204402 | 2 |
| Medichem S.A. ES/Noweda | Chlorhexidine diacetate | 13177007 | 1 |
| Nachprüfung | Chlorhexidine diacetate | 2082019-9 | 1 |
| Neweda | Chlorhexidine diacetate | 23001289006 | 1 |
| Noweda | Chlorhexidine diacetate | 12142720 | 1 |
| Noweda | Chlorhexidine diacetate | 12142727 | 1 |
| Noweda | Chlorhexidine diacetate | 15438911 | 2 |
| Noweda | Chlorhexidine diacetate | 17185804 | 1 |
| Noweda | Chlorhexidine diacetate | 17185805 | 1 |
| Noweda | Chlorhexidine diacetate | 17185808 | 1 |
| Noweda | Chlorhexidine diacetate | 17185811 | 1 |
| Noweda | Chlorhexidine diacetate | 17325803 | 3 |
| Noweda | Chlorhexidine diacetate | 17325808 | 2 |
| Noweda | Chlorhexidine diacetate | 1785803 | 1 |
| Noweda | Chlorhexidine diacetate | 19097501 | 2 |
| Noweda | Chlorhexidine diacetate | 22003123009 | 2 |
| Noweda | Chlorhexidine diacetate | 22003123010 | 1 |
| Noweda | Chlorhexidine diacetate | 22003123017 | 1 |
| Noweda | Chlorhexidine diacetate | 23001289006 | 1 |
| noweda | Chlorhexidine diacetate | 23001289008 | 1 |
| Noweda | Chlorhexidine diacetate | 23001289008 | 1 |
| Phoenix | Chlorhexidine diacetate | 11204408 | 1 |
| Phoenix | Chlorhexidine diacetate | 12142726 | 1 |
| Phoenix | Chlorhexidine diacetate | 12142734 | 1 |
| Phoenix | Chlorhexidine diacetate | 13177002 | 1 |
| Phoenix | Chlorhexidine diacetate | 15438917 | 1 |
| Phoenix | Chlorhexidine diacetate | 191221000 | 1 |
| Phoenix | Chlorhexidine diacetate | 23003317002 | 1 |
| phönix | Chlorhexidine diacetate | | 1 |
| Phönix | Chlorhexidine diacetate | | 1 |
| phönix | Chlorhexidine diacetate | 15438911 | 1 |
| Phönix | Chlorhexidine diacetate | 15438917 | 1 |
| Phönix | Chlorhexidine diacetate | 15J02-B08-322916 | 1 |
| Phönix | Chlorhexidine diacetate | 17185803 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Chlorhexidine diacetate | 17185804 | 1 |
| PHÖNIX | Chlorhexidine diacetate | 17185811 | 1 |
| Phönix | Chlorhexidine diacetate | 17325803 | 1 |
| phönix | Chlorhexidine diacetate | 19122104 | 1 |
| Phönix | Chlorhexidine diacetate | 22003123004 | 1 |
| Phönix | Chlorhexidine diacetate | 22003123009 | 1 |
| Phönix | Chlorhexidine diacetate | 22003123017 | 1 |
| Phönix | Chlorhexidine diacetate | 9113916 | 2 |
| Phönix | Chlorhexidine diacetate | Retest09113916 | 1 |
| Sanacorp 107 | Chlorhexidine diacetate | 190975001 | 1 |
| Sanacorp | Chlorhexidine diacetate | | 1 |
| Sanacorp | Chlorhexidine diacetate | 12142734 | 1 |
| Sanacorp | Chlorhexidine diacetate | 17185804 | 1 |
| Sanacorp | Chlorhexidine diacetate | 18072403 | 1 |
| SANACORP | Chlorhexidine diacetate | 19097502 | 1 |
| Sanacorp | Chlorhexidine diacetate | 191221004 | 1 |
| Sanacorp | Chlorhexidine diacetate | 22003123009 | 1 |
| Sanacorp | Chlorhexidine diacetate | 22003123017 | 1 |
| Sanacorp | Chlorhexidine diacetate | 7/AKD6 | 1 |
| Shaanxi / Gehe | Chlorhexidine diacetate | 15261009 | 2 |
| Shaanxi dasehng Phar… | Chlorhexidine diacetate | 19122104 | 1 |
| Shaanxi Dasheng Phar… | Chlorhexidine diacetate | 17185807 | 1 |
| Shaanxi/Phoenix | Chlorhexidine diacetate | CAB-180103 | 1 |
| Wepa/Wepa | Chlorhexidine diacetate | 15438902 | 1 |

- 255 664 spectra from 1666 *Apo-Ident* customers from a total of 52 005 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Chlorhexidine diacetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Chlorhexidine diacetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 840 | 0 | 157 486 |
| **Type B** | 0 | 475 | 0 | 212 465 |
| **Type C** | 0 | 1208 | 14 | 255 664 |

The substance/substance group *Chlorhexidine diacetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.2857 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7368 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8543 % (> 98.6088 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20989 | 20989 | 0.00 | 180.56 |
| 21041 | 20989 | 18.29 | 180.57 |
| 22280 | 20989 | 5.53 | 184.71 |
| 22456 | 22456 | 0.00 | 182.01 |
| 22900 | 22900 | 0.00 | 184.09 |
| 22946 | 23044 | 5.95 | 182.81 |
| 22947 | 22456 | 5.81 | 181.90 |
| 22951 | 22900 | 6.06 | 184.18 |
| 23041 | 23041 | 0.00 | 183.95 |
| 23042 | 23042 | 0.00 | 184.32 |
| 23043 | 23043 | 0.00 | 184.73 |
| 23044 | 23044 | 0.00 | 183.97 |
| 23048 | 23048 | 0.00 | 183.12 |
| 26456 | 22456 | 5.27 | 184.25 |
| 26483 | 26483 | 0.00 | 181.65 |
| 26816 | 20989 | 51.22 | 178.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Chlorocresol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20185-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Chlorocresol; Chlorocresolum

### Special notes

When selecting the *Chlorocresol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Chlorocresol | 5 | 2 | 17 |

### Second-stage model

For differentiation of the substance/substance group *Chlorocresol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Chlorocresol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 89.60 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Chlorocresol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Chlorocresol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Chlorocresol | 13275106 | 21512 | 60 | 20130828 |
| Caelo | Chlorocresol | 13275106 | 21513 | 60 | 20130828 |
| Caelo | Chlorocresol | 163378 | 23357 | 40 | 20170124* |
| Caelo | Chlorocresol | 182523 | 24406 | 40 | 20180919* |
| Caelo | Chlorocresol | 190837 | 24717 | 40 | 20190508* |
| Caelo | Chlorocresol | 21004157 | 27127 | 40 | 20220303* |
| Caelo | Chlorocresol | 21004157 | 27127SI | 20 | 20220303* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 7 reference samples from the substance/substance group *Chlorocresol*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

- 158 026 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 2 reference samples from the substance/substance group *Chlorocresol*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Chlorocresol | 15114107 | 23411 | 40 |
| Caelo | Chlorocresol | 181360 | 24050 | 40 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 37 spectra from 28 *Apo-Ident* customers from 17 batches from the substance/substance group *Chlorocresol*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Chlorocresol | 22002861005 | 1 |
| | Chlorocresol | 22002861013 | 1 |
| Caelo | Chlorocresol | 10145239 | 3 |
| Caelo | Chlorocresol | 12111013 | 2 |
| Caelo | Chlorocresol | 12111017 | 2 |
| Caelo | Chlorocresol | 13275117 | 1 |
| Caelo | Chlorocresol | 15114107 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Chlorocresol | 18027101 | 4 |
| Caelo | Chlorocresol | 18027110 | 2 |
| Caelo | Chlorocresol | 18136006 | 6 |
| Caelo | Chlorocresol | 20004363020 | 1 |
| Caelo | Chlorocresol | 20101808 | 1 |
| Caelo | Chlorocresol | 2041513 | 1 |
| Caelo | Chlorocresol | 23415422 | 1 |
| Caelo | Chlorocresol | 4613M-01260 | 1 |
| Caelo | Chlorocresol | 7061304 | 1 |
| Caesar & Loretz GmbH/Gehe | Chlorocresol | 18136006 | 1 |
| Caesar & Loretz GmbH… | Chlorocresol | 18027101 | 1 |
| Caesar & Loretz GmbH | Chlorocresol | 12111017 | 1 |
| Caesar & Loretz GmbH | Chlorocresol | 18136006 | 2 |
| Noweda | Chlorocresol | 12111017 | 1 |
| Noweda | Chlorocresol | 22002861005 | 1 |
| Spangropharm | Chlorocresol | | 1 |

- 256 849 spectra from 1666 *Apo-Ident* customers from a total of 52 136 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Chlorocresol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Chlorocresol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 37 | 0 | 256 849 |

The substance/substance group *Chlorocresol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 83.7838 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21512 | 24406 | 15.91 | 162.41 |
| 21513 | 27127 | 12.69 | 165.60 |
| 23357 | 23357 | 0.00 | 151.87 |
| 24406 | 24406 | 0.00 | 167.97 |
| 24717 | 24717 | 0.00 | 154.51 |
| 27127 | 27127 | 0.00 | 166.03 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Chlorprothixene hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24105-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Chlorprothixene hydrochloride; Chlorprothixeni hydrochloridum

### Special notes

When selecting the *Chlorprothixene hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Chlorprothixene hydrochloride | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Chlorprothixene hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Chlorprothixene hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Doxepin hydrochloride | 36.94 | – |
| Benzydamine hydrochloride | 131.46 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Chlorprothixene hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Chlorprothixene hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Chlorprothixene hydrochloride | AP05061117C | 24105 | 40 | 1810394 |
| Euro OTC | Chlorprothixene hydrochloride | 2003005 | 25290 | 40 | 20200728* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 80 spectra of 2 reference samples from the substance/substance group *Chlorprothixene hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 246 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *Chlorprothixene hydrochloride*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Audor Pharma | Chlorprothixene hydrochloride | AP04120418C | 24434 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Chlorprothixene hydrochloride*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Chlorprothixene hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Chlorprothixene hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or

incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 80 | 0 | 158 246 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Chlorprothixene hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 92.5000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24105 | 24105 | 0.00 | 61.83 |
| 25290 | 25290 | 0.00 | 62.70 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Chlortetracycline hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20845-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Chlortetracycline hydrochloride; Chlortetracyclini hydrochloridum

### Special notes

When selecting the *Chlortetracycline hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Chlortetracycline hydrochloride | 7 | 4 | 91 |

### Second-stage model

For differentiation of the substance/substance group *Chlortetracycline hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Chlortetracycline hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Tetracycline hydrochloride | 54.66 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Chlortetracycline hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Chlortetracycline hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Chlortetracycline hydroch… | 1108051-02 | 21241 | 40 | 20111013 |
| Euro OTC | Chlortetracycline hydroch… | 1604015 | 22541 | 40 | 20160510* |
| Euro OTC | Chlortetracycline hydroch… | 1910002 | 24959 | 40 | 20191107* |
| Euro OTC | Chlortetracycline hydroch… | 2009026 | 25573 | 40 | 20210104* |
| Euro OTC | Chlortetracycline hydroch… | 2205011 | 26229 | 40 | 20220704* |
| Fagron | Chlortetracycline hydroch… | 12K30-N07 | 20845 | 40 | 1405318 |
| Fagron | Chlortetracycline hydroch… | 12K30-N07 | 21222 | 40 | 20121210 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07-307742 | 21877 | 60 | 20141029 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 340 spectra of 8 reference samples from the substance/substance group *Chlortetracycline - hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 986 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 190 spectra of 6 reference samples from the substance/substance group *Chlortetracycline - hydrochloride*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Chlortetracycline hydroch… | 1604015-01 | 22975 | 40 |
| Euro OTC | Chlortetracycline hydroch… | 1803037 | 24092 | 40 |
| Euro OTC | Chlortetracycline hydroch… | 2402024 | 27365 | 40 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-329778 | 23571 | 30 |
| Euro OTC | Chlortetracycline hydroch… | 2205011 | 26229SI† | 20 |
| Euro OTC | Chlortetracycline hydroch… | 2402024 | 27365SI | 20 |

- 212 750 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 691 spectra from 313 *Apo-Ident* customers from 104 batches from the substance/substance group *Chlortetracycline hydrochloride*.

- Among them are spectra of independent samples from 90 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Chlortetracycline hydroch… | 1604015-01 | 2 |
| | Chlortetracycline hydroch… | 2009026-01 | 8 |
| | Chlortetracycline hydroch… | 2205011-01 | 11 |
| | Chlortetracycline hydroch… | 225011-01 | 1 |
| | Chlortetracycline hydroch… | 2411011-01 | 2 |
| AHD/Euro | Chlortetracycline hydroch… | 1803037 | 2 |
| ALH | Chlortetracycline hydroch… | 16B10-B09-320304 | 1 |
| Alliance Healthcare | Chlortetracycline hydroch… | 12K30-N07 | 1 |
| Alliance/EuRho | Chlortetracycline hydroch… | 1910002-02 | 2 |
| Anzag/ Euro OT | Chlortetracycline hydroch… | 1803037-02 | 1 |
| Anzag: 07.09.12 ek:4.01 | Chlortetracycline hydroch… | 12C16-N01 | 1 |
| Anzag | Chlortetracycline hydroch… | 1604015-01 | 1 |
| apo-ident | Chlortetracycline hydroch… | 1803037-01 | 2 |
| apomix | Chlortetracycline hydroch… | 2009026-01 | 1 |
| Caelo | Chlortetracycline hydroch… | | 1 |
| Caelo | Chlortetracycline hydroch… | 1412008-01 | 1 |
| Caelo | Chlortetracycline hydroch… | 141200802 | 1 |
| Caelo | Chlortetracycline hydroch… | 1412008-02 | 1 |
| Caelo | Chlortetracycline hydroch… | 141200803 | 1 |
| Caelo | Chlortetracycline hydroch… | 142008-03 | 1 |
| Caelo | Chlortetracycline hydroch… | 14J08-B07-300249 | 1 |
| Caelo | Chlortetracycline hydroch… | 14J08-B07-303352 | 1 |
| Caelo | Chlortetracycline hydroch… | 14j08-b07-307100 | 1 |
| Caelo | Chlortetracycline hydroch… | 1604015-01 | 4 |
| Caelo | Chlortetracycline hydroch… | 1604015-61 | 1 |
| Caelo | Chlortetracycline hydroch… | 16B10-B09-318088 | 1 |
| Caelo | Chlortetracycline hydroch… | 16B10-B09-322716 | 1 |
| Caelo | Chlortetracycline hydroch… | 16B10B09329778 | 1 |
| Caelo | Chlortetracycline hydroch… | 16B10-B09-336332 | 1 |
| Caelo | Chlortetracycline hydroch… | 16B10-B09-347439 | 3 |
| Caelo | Chlortetracycline hydroch… | 1803037-01 | 3 |
| Caelo | Chlortetracycline hydroch… | 1803037-03 | 1 |
| Caelo | Chlortetracycline hydroch… | 1803038-01 | 1 |
| Caelo | Chlortetracycline hydroch… | 1910002-01 | 3 |
| Caelo | Chlortetracycline hydroch… | 191002-02 | 1 |
| Caelo | Chlortetracycline hydroch… | FC13030134 | 1 |
| Caelo | Chlortetracycline hydroch… | FC15100204 | 1 |
| Caesar & Loretz GmbH | Chlortetracycline hydroch… | 12C16-N01 | 1 |
| EuRho/ NOWEDA | Chlortetracycline hydroch… | 1803037-02 | 1 |
| Eurho/Fiebig | Chlortetracycline hydroch… | 1910002-01 | 1 |
| EuRho/Gehe | Chlortetracycline hydroch… | 1803037 | 1 |
| EuRho/Gehe | Chlortetracycline hydroch… | 2009026-01 | 1 |
| Eurho/Phönix | Chlortetracycline hydroch… | 220501101 | 1 |
| EuRho | Chlortetracycline hydroch… | 1412008-02 | 1 |
| EuRho | Chlortetracycline hydroch… | 1803037-01 | 1 |
| Euro OTC | Chlortetracycline hydroch… | | 1 |
| Euro OTC | Chlortetracycline hydroch… | 10I29-N04 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1108051-01 | 8 |
| Euro OTC | Chlortetracycline hydroch… | 110805102 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1108051-02 | 7 |
| Euro OTC | Chlortetracycline hydroch… | 1412008/03 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1412008-01 | 9 |
| Euro OTC | Chlortetracycline hydroch… | 141200802 | 2 |
| Euro OTC | Chlortetracycline hydroch… | 1412008-02 | 15 |
| Euro OTC | Chlortetracycline hydroch… | 141200803 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1412008-03 | 5 |
| Euro OTC | Chlortetracycline hydroch… | 16004015-15 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 160401501 | 2 |
| Euro OTC | Chlortetracycline hydroch… | 1604015-01 | 59 |
| Euro OTC | Chlortetracycline hydroch… | 160401502 | 1 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Chlortetracycline hydroch… | 1604015-02 | 3 |
| Euro OTC | Chlortetracycline hydroch… | 16b10-b09-326865 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 16B10-B09-348359 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 16B10-B09-352970 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1803037 | 2 |
| Euro OTC | Chlortetracycline hydroch… | 1803037_01 | 4 |
| Euro OTC | Chlortetracycline hydroch… | 180303701 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1803037-01 | 66 |
| Euro OTC | Chlortetracycline hydroch… | 1803037-02 | 3 |
| Euro OTC | Chlortetracycline hydroch… | 1803037-03 | 22 |
| Euro OTC | Chlortetracycline hydroch… | 190002-02 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 19100002-02 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1910002 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 191000201 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 1910002-01 | 87 |
| Euro OTC | Chlortetracycline hydroch… | 1910002-02 | 24 |
| Euro OTC | Chlortetracycline hydroch… | 191002-01 | 2 |
| Euro OTC | Chlortetracycline hydroch… | 200902601 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 2009026-01 | 60 |
| Euro OTC | Chlortetracycline hydroch… | 2009026-02 | 2 |
| Euro OTC | Chlortetracycline hydroch… | 2205011-01 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 2901009V-03 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 4612Q-01155 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 4931439 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 5113I01155 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 700156 | 1 |
| Euro OTC | Chlortetracycline hydroch… | 80218-A | 1 |
| Euro OTC | Chlortetracycline hydroch… | FC15110253 | 1 |
| Euro OTC | Chlortetracycline hydroch… | FC21020106 | 1 |
| EURO Pharma | Chlortetracycline hydroch… | 1108051-01 | 1 |
| EUro/AHD | Chlortetracycline hydroch… | 1108051-02 | 1 |
| euro/gehe | Chlortetracycline hydroch… | 1604015-01 | 1 |
| Euro/Noweda | Chlortetracycline hydroch… | 1604015-01 | 1 |
| EuRo/Phönix | Chlortetracycline hydroch… | 160401501 | 1 |
| Euro | Chlortetracycline hydroch… | 1108051-02 | 1 |
| Fagron | Chlortetracycline hydroch… | | 1 |
| Fagron | Chlortetracycline hydroch… | 12C16-N01 | 1 |
| Fagron | Chlortetracycline hydroch… | 12H28N09 | 1 |
| Fagron | Chlortetracycline hydroch… | 12H28-N09 | 4 |
| Fagron | Chlortetracycline hydroch… | 12k30-N07 | 1 |
| Fagron | Chlortetracycline hydroch… | 12K30-N07 | 9 |
| Fagron | Chlortetracycline hydroch… | 13/11-N07 | 4 |
| Fagron | Chlortetracycline hydroch… | 13K26-N06 | 2 |
| Fagron | Chlortetracycline hydroch… | 13l11-N07 | 1 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07 | 4 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07-300247 | 2 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07-300250 | 8 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07-303350 | 1 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07-303352 | 7 |
| Fagron | Chlortetracycline hydroch… | 14J08B07307100 | 3 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07-307100 | 7 |
| Fagron | Chlortetracycline hydroch… | 14J08-B07-307742 | 4 |
| Fagron | Chlortetracycline hydroch… | 1604015-01 | 2 |
| Fagron | Chlortetracycline hydroch… | 16b10-b09 | 1 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09 | 9 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-318088 | 5 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-320304 | 6 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-322715 | 5 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-322716 | 2 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-326865 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Chlortetracycline hydroch… | 16B10-B09-329778 | 2 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-331443 | 1 |
| Fagron | Chlortetracycline hydroch… | 16b10-b09-336332 | 1 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-336332 | 10 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-342410 | 2 |
| Fagron | Chlortetracycline hydroch… | 16b10b09347439 | 1 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-348359 | 1 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-351565 | 5 |
| Fagron | Chlortetracycline hydroch… | 16B10-B09-352970 | 6 |
| Fagron | Chlortetracycline hydroch… | 16b10b09355611 | 1 |
| Fagron | Chlortetracycline hydroch… | 1803037-01 | 2 |
| Fagron | Chlortetracycline hydroch… | 1803037-03 | 2 |
| Fagron | Chlortetracycline hydroch… | 191002-01 | 1 |
| Fagron | Chlortetracycline hydroch… | 27121306 | 1 |
| Fagron | Chlortetracycline hydroch… | 3918Q-01155 | 1 |
| Fagron | Chlortetracycline hydroch… | 5014M-01155T | 1 |
| Fagron | Chlortetracycline hydroch… | 700156-B09-347439 | 1 |
| Fagron | Chlortetracycline hydroch… | FC11051038 | 1 |
| Fagron | Chlortetracycline hydroch… | FC13030134 | 1 |
| Fagron | Chlortetracycline hydroch… | FC15100204 | 5 |
| Fiebig/EuRho | Chlortetracycline hydroch… | 1803037-01 | 2 |
| Fiebig/EuRho | Chlortetracycline hydroch… | 1910002-01 | 1 |
| Fiebig | Chlortetracycline hydroch… | 1412008-01 | 1 |
| Fiebig | Chlortetracycline hydroch… | 1604015-01 | 1 |
| Fiebig | Chlortetracycline hydroch… | 1910002-02 | 2 |
| Fiebig | Chlortetracycline hydroch… | FC15100204 | 1 |
| Fragon/Sanacorp | Chlortetracycline hydroch… | 16B10-B09-352970 | 1 |
| Fuijan/Noweda | Chlortetracycline hydroch… | FC17090368 | 1 |
| Fuijan/Phoenix | Chlortetracycline hydroch… | FC19040113 | 2 |
| Fujan Pharmaceutic | Chlortetracycline hydroch… | 2009026-01 | 3 |
| Fujang Fukang China | Chlortetracycline hydroch… | 200902601 | 1 |
| Fujian Fukang Phamaceutic | Chlortetracycline hydroch… | 2205011-01 | 1 |
| Gehe/Fagro | Chlortetracycline hydroch… | 16B10-B09-338800 | 1 |
| GEHE | Chlortetracycline hydroch… | 1604015-01 | 1 |
| Gehe | Chlortetracycline hydroch… | 16B10-B09-322715 | 1 |
| Gehe | Chlortetracycline hydroch… | 16B10-B09-322716 | 1 |
| Gehe | Chlortetracycline hydroch… | 1910002-02 | 1 |
| Gehe | Chlortetracycline hydroch… | 2205011-01 | 2 |
| Geibo/Euro11.06.19 | Chlortetracycline hydroch… | 1803037-01 | 1 |
| Krieger | Chlortetracycline hydroch… | 12C16-No1 | 1 |
| Nachprüfung 2574 | Chlortetracycline hydroch… | 1108051-01 | 1 |
| Nachprüfung | Chlortetracycline hydroch… | 1108051-01 | 1 |
| Noweda | Chlortetracycline hydroch… | 12c16-n01 | 1 |
| Noweda | Chlortetracycline hydroch… | 1412008-01 | 1 |
| Noweda | Chlortetracycline hydroch… | 160401501 | 1 |
| Noweda | Chlortetracycline hydroch… | 1803037 | 1 |
| Noweda | Chlortetracycline hydroch… | 1803037-01 | 1 |
| Noweda | Chlortetracycline hydroch… | 1910002-02 | 2 |
| Noweda | Chlortetracycline hydroch… | 2205011-01 | 2 |
| Noweda | Chlortetracycline hydroch… | EurootcPharama | 1 |
| Noweda | Chlortetracycline hydroch… | EuroOTCPharma | 1 |
| Phoenix | Chlortetracycline hydroch… | 110805102 | 1 |
| Phoenix | Chlortetracycline hydroch… | 16B10-B09-322716 | 1 |
| Phoenix | Chlortetracycline hydroch… | 1803037-01 | 1 |
| Phoenix | Chlortetracycline hydroch… | 3407 | 1 |
| Phönix/apo ident | Chlortetracycline hydroch… | 1604015-01 | 1 |
| Phönix/EurHo | Chlortetracycline hydroch… | 1803037-01 | 1 |
| Phönix/EurHo | Chlortetracycline hydroch… | 191000201 | 1 |
| Phönix/Euro | Chlortetracycline hydroch… | 180303701 | 2 |
| Phönix/EuRo | Chlortetracycline hydroch… | 1910002-02 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Chlortetracycline hydroch… | 1108051-02 | 2 |
| Phönix | Chlortetracycline hydroch… | 1412008-01 | 1 |
| phönix | Chlortetracycline hydroch… | 16B10-B09-336332 | 1 |
| Phönix | Chlortetracycline hydroch… | 1803037 | 1 |
| Phönix | Chlortetracycline hydroch… | 1803037-03 | 1 |
| Phönix | Chlortetracycline hydroch… | 2009026-01 | 2 |
| Phönix | Chlortetracycline hydroch… | FC17090368 | 1 |
| Sanacop | Chlortetracycline hydroch… | 1412008-02 | 1 |
| Sanacorp | Chlortetracycline hydroch… | 1108051-01 | 1 |
| Sanacorp | Chlortetracycline hydroch… | 14J08-B07 | 1 |
| Sanacorp | Chlortetracycline hydroch… | 1604015-01 | 1 |
| Sanacorp | Chlortetracycline hydroch… | 16B10-B09 | 1 |
| Sanacorp | Chlortetracycline hydroch… | 180303701 | 1 |
| Sanacorp | Chlortetracycline hydroch… | FC15100204 | 1 |

- 256 195 spectra from 1666 *Apo-Ident* customers from a total of 52 051 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Chlortetracycline hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Chlortetracycline hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 340 | 0 | 157 986 |
| **Type B** | 0 | 190 | 0 | 212 750 |
| **Type C** | 0 | 679 | 12 | 256 195 |

The substance/substance group *Chlortetracycline hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2353 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.8421 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.2634 % (> 97.8292 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20845 | 20845 | 0.00 | 58.29 |
| 21222 | 20845 | 7.53 | 60.76 |
| 21241 | 20845 | 10.14 | 58.22 |
| 21877 | 22541 | 10.21 | 65.96 |
| 22541 | 22541 | 0.00 | 61.97 |
| 24959 | 24959 | 0.00 | 87.68 |
| 25573 | 25573 | 0.00 | 76.99 |
| 26229 | 26229 | 0.00 | 59.65 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cholesterol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20446-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cholesterol; Cholesterolum

### Special notes

When selecting the *Cholesterol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cholesterol | 8 | 5 | 196 |

### Second-stage model

For differentiation of the substance/substance group *Cholesterol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cholesterol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Testosterone | 60.79 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cholesterol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cholesterol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Cholesterol | 160444 | 22461 | 60 | 20160222* |
| Caelo | Cholesterol | 16044415 | 23760 | 40 | 1804387 |
| Caelo | Cholesterol | 21000039004 | 25517 | 40 | 20210127 |
| Caelo | Cholesterol | 23002121 | 26963 | 40 | 20230922* |
| Caelo | Cholesterol | 23002121 | 26963SI | 20 | 20230922* |
| Fagron | Cholesterol | 13F10-B40 | 21219 | 40 | 20131223 |
| Fagron | Cholesterol | 15J23-B03-325106 | 22971 | 40 | 20151103 |
| Fagron | Cholesterol | 17E17-B05-339074 | 23937 | 40 | 20170620 |
| Fagron | Cholesterol | 22D05-B03-220575 | 26160 | 40 | 20220519 |
| Fagron | Cholesterol | 22D05-B03-220575 | 26160SI | 20 | 20220519 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 380 spectra of 10 reference samples from the substance/substance group *Cholesterol*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 946 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 220 spectra of 6 reference samples from the substance/substance group *Cholesterol*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Cholesterol | 13148703 | 21310 | 40 |
| Caelo | Cholesterol | 190549 | 24712 | 40 |
| Caelo | Cholesterol | 22001179 | 26111 | 40 |
| Fagron | Cholesterol | 16G05-B03-331396 | 23522 | 40 |
| Fagron | Cholesterol | 24D26-B01-240098 | 27424 | 40 |
| Caelo | Cholesterol | 22001179 | 26111SI | 20 |

- 212 720 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 487 spectra from 192 *Apo-Ident* customers from 204 batches from the substance/substance group *Cholesterol*.

- Among them are spectra of independent samples from 195 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cholesterol | 1238675 | 2 |
| | Cholesterol | 21C18-B01-213585 | 2 |
| | Cholesterol | 22001179008 | 1 |
| | Cholesterol | 22001179013 | 1 |
| | Cholesterol | 2203-B01-229435 | 1 |
| | Cholesterol | 22D05-B03-220341 | 1 |
| | Cholesterol | 22J03-B01 | 1 |
| | Cholesterol | 22j03b01224448 | 1 |
| | Cholesterol | 22J03-B01-224448 | 2 |
| | Cholesterol | 22j03-b01-224452 | 1 |
| | Cholesterol | 22J03-B01-229435 | 6 |
| | Cholesterol | 23002121001 | 1 |
| | Cholesterol | 23003286002 | 1 |
| | Cholesterol | 23D21-B03-229928 | 2 |
| | Cholesterol | 23D21-B03-22992815/24P | 1 |
| | Cholesterol | 23J11-B01-2386705 | 1 |
| | Cholesterol | 23J11-B01-238675 | 4 |
| | Cholesterol | 23J11-B01-238678 | 1 |
| | Cholesterol | 23J11-B01-238678 | 1 |
| | Cholesterol | 23J-B01-238675 | 1 |
| | Cholesterol | 2400152001 | 1 |
| | Cholesterol | 24001525004 | 1 |
| | Cholesterol | 24D26-B01-004353 | 4 |
| | Cholesterol | 24D26-B01-00435329/25P | 1 |
| | Cholesterol | 41172 | 2 |
| | Cholesterol | 41259 | 1 |
| | Cholesterol | 42492 | 1 |
| | Cholesterol | B01-2244502 | 1 |
| | Cholesterol | B01-2386705 | 5 |
| AHD | Cholesterol | 17K16-B11-352718 | 1 |
| Alliance Healthcare | Cholesterol | 23J11-B01-238675 | 1 |
| Anzag/Fargon | Cholesterol | 19J18-B02 | 1 |
| Anzag | Cholesterol | 23J11-B01-238675 | 1 |
| Anzag | Cholesterol | 250507(045580) | 1 |
| Caelo | Cholesterol | 11242103 | 1 |
| Caelo | Cholesterol | 12155605 | 1 |
| Caelo | Cholesterol | 12248403 | 1 |
| Caelo | Cholesterol | 13056903 | 1 |
| Caelo | Cholesterol | 13148704 | 1 |
| Caelo | Cholesterol | 14027201 | 1 |
| Caelo | Cholesterol | 14122501 | 2 |
| Caelo | Cholesterol | 14208602 | 1 |
| Caelo | Cholesterol | 15028303 | 1 |
| Caelo | Cholesterol | 15301803 | 3 |
| Caelo | Cholesterol | 15358801 | 5 |
| Caelo | Cholesterol | 15407101 | 2 |
| Caelo | Cholesterol | 15407102 | 2 |
| Caelo | Cholesterol | 15B09-B02-308259 | 1 |
| Caelo | Cholesterol | 15G31-B05-312376 | 1 |
| Caelo | Cholesterol | 15J23-B03 | 1 |
| Caelo | Cholesterol | 15J23-B03_329505 | 1 |
| Caelo | Cholesterol | 16044402 | 1 |
| Caelo | Cholesterol | 16044407 | 4 |
| Caelo | Cholesterol | 16044408 | 3 |
| Caelo | Cholesterol | 16044409 | 2 |
| Caelo | Cholesterol | 16044413 | 4 |
| Caelo | Cholesterol | 16044415 | 4 |
| Caelo | Cholesterol | 16044416 | 6 |
| Caelo | Cholesterol | 16G05-B03 | 1 |
| Caelo | Cholesterol | 17K16-B11-343922 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Cholesterol | 17K16-B11-345814 | 1 |
| Caelo | Cholesterol | 17K16-B11-348760 | 1 |
| Caelo | Cholesterol | 17K16-B11-350557 | 2 |
| Caelo | Cholesterol | 18097102 | 2 |
| Caelo | Cholesterol | 18097202 | 2 |
| Caelo | Cholesterol | 19054901 | 7 |
| Caelo | Cholesterol | 19054903 | 6 |
| Caelo | Cholesterol | 191949001 | 2 |
| Caelo | Cholesterol | 191949003 | 2 |
| Caelo | Cholesterol | 19194902 | 4 |
| Caelo | Cholesterol | 19194903 | 2 |
| Caelo | Cholesterol | 19194904 | 12 |
| Caelo | Cholesterol | 19I18-B02 | 1 |
| Caelo | Cholesterol | 19I20-B08 | 1 |
| Caelo | Cholesterol | 19J18-B02-201592 | 1 |
| Caelo | Cholesterol | 19J18-BO1-201136 | 1 |
| Caelo | Cholesterol | 20G08-B02 | 1 |
| Caelo | Cholesterol | 20G08-B02-202266 | 3 |
| Caelo | Cholesterol | 21000039004 | 2 |
| Caelo | Cholesterol | 21000039006 | 4 |
| Caelo | Cholesterol | 21000039009 | 1 |
| Caelo | Cholesterol | 2100039009 | 1 |
| Caelo | Cholesterol | 21F08-B20-215610 | 1 |
| Caelo | Cholesterol | 22001179004 | 1 |
| Caelo | Cholesterol | 27212 | 1 |
| Caelo | Cholesterol | 32124 | 1 |
| Caelo | Cholesterol | B02-2015901 | 1 |
| Caesar & Loretz GmbH | Cholesterol | 18097202 | 1 |
| Caesar & Loretz GmbH | Cholesterol | 19194903 | 2 |
| Carbogen Amcis B.V. | Cholesterol | 21F08-B20-215324 | 1 |
| Ebert-Jacobi | Cholesterol | 16044408 | 1 |
| Ensbona /Alliance He... | Cholesterol | 17E17-B05-339074 | 3 |
| Euro OTC | Cholesterol | 13F10-B40-289016 | 1 |
| Fagon/Gehe | Cholesterol | 23J11-B01-238675 | 1 |
| Fagro/EJ | Cholesterol | 17K16-B11_348760 | 1 |
| Fagron | Cholesterol | | 1 |
| Fagron | Cholesterol | 10B15-NO7 | 1 |
| Fagron | Cholesterol | 10H24-N06 | 1 |
| Fagron | Cholesterol | 11A17-N07 | 1 |
| Fagron | Cholesterol | 1213585 | 1 |
| Fagron | Cholesterol | 12D02-N10 | 1 |
| Fagron | Cholesterol | 12I13-N02 | 2 |
| Fagron | Cholesterol | 13C25-N12 | 2 |
| Fagron | Cholesterol | 13F10-B40 | 1 |
| Fagron | Cholesterol | 13F10-B40-289016 | 2 |
| Fagron | Cholesterol | 13G10-N11 | 3 |
| Fagron | Cholesterol | 14B27-B05 | 2 |
| Fagron | Cholesterol | 14B27-B05-293548 | 3 |
| Fagron | Cholesterol | 14B27-B05-293550 | 1 |
| Fagron | Cholesterol | 14G04-B02 | 1 |
| Fagron | Cholesterol | 14G04-B02-300830 | 2 |
| Fagron | Cholesterol | 14G04-B02-300831 | 1 |
| Fagron | Cholesterol | 15B09 | 1 |
| Fagron | Cholesterol | 15B09-B02 | 1 |
| Fagron | Cholesterol | 15B09-B02-308259 | 4 |
| Fagron | Cholesterol | 15B09-B02-308847 | 2 |
| Fagron | Cholesterol | 15G31-B05 | 2 |
| Fagron | Cholesterol | 15G31-B05_316721 | 1 |
| Fagron | Cholesterol | 15G31-B05-312377 | 1 |
| Fagron | Cholesterol | 15G31-B05-312378 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Cholesterol | 15G31-B05-314182 | 2 |
| Fagron | Cholesterol | 15G31-B05-316721 | 3 |
| Fagron | Cholesterol | 15J23-B03 | 1 |
| Fagron | Cholesterol | 15J23B03320483 | 1 |
| Fagron | Cholesterol | 15J23-B03-320483 | 5 |
| Fagron | Cholesterol | 15J23B03322902 | 1 |
| Fagron | Cholesterol | 15J23-B03-322902 | 1 |
| Fagron | Cholesterol | 15j23-B03-325106 | 1 |
| Fagron | Cholesterol | 15J23B03325106 | 1 |
| Fagron | Cholesterol | 15J23-B03-325106 | 5 |
| Fagron | Cholesterol | 15J23B03328249 | 1 |
| Fagron | Cholesterol | 15J23-B03-328249 | 2 |
| Fagron | Cholesterol | 16G05-B03 | 1 |
| Fagron | Cholesterol | 16G05-B03-331396 | 2 |
| Fagron | Cholesterol | 16G05-B03-331397 | 1 |
| Fagron | Cholesterol | 16G05-B03-333996 | 3 |
| Fagron | Cholesterol | 16G05-B03-334366 | 1 |
| Fagron | Cholesterol | 16GB05-B03 | 1 |
| Fagron | Cholesterol | 17E17-B05 | 2 |
| Fagron | Cholesterol | 17E17-B05-337588 | 5 |
| Fagron | Cholesterol | 17E17-B05-339074 | 5 |
| Fagron | Cholesterol | 17E17-B05-339075 | 2 |
| Fagron | Cholesterol | 17K16-B11-343922 | 3 |
| Fagron | Cholesterol | 17K16-B11-343923 | 1 |
| Fagron | Cholesterol | 17K16-B11-345814 | 2 |
| Fagron | Cholesterol | 17K16-B11-348760 | 4 |
| Fagron | Cholesterol | 17K16-B11-348761 | 3 |
| Fagron | Cholesterol | 17K16-B11-348762 | 1 |
| Fagron | Cholesterol | 17K16-B11-349922 | 1 |
| Fagron | Cholesterol | 17K16B11350557 | 1 |
| Fagron | Cholesterol | 17K16-B11-350557 | 6 |
| Fagron | Cholesterol | 17K16-B11-352718 | 13 |
| Fagron | Cholesterol | 17K16-B11-355385 | 7 |
| Fagron | Cholesterol | 17k16-B11-43922 | 1 |
| Fagron | Cholesterol | 18I03-B06 | 1 |
| Fagron | Cholesterol | 18I03-B06-353374 | 2 |
| Fagron | Cholesterol | 18I03-B06-355386 | 1 |
| Fagron | Cholesterol | 18I03-B06-356700 | 1 |
| Fagron | Cholesterol | 18J18-B02-201591 | 1 |
| Fagron | Cholesterol | 19120B08200506 | 1 |
| Fagron | Cholesterol | 19120-B08-200506 | 2 |
| Fagron | Cholesterol | 19120-BO8-200506 | 1 |
| Fagron | Cholesterol | 1920B0B-200561 | 1 |
| Fagron | Cholesterol | 19E20-B02-191413 | 1 |
| Fagron | Cholesterol | 19E20-B02-192819 | 2 |
| Fagron | Cholesterol | 19G12-B0313-194214 | 1 |
| Fagron | Cholesterol | 19g12-b13-194214 | 1 |
| Fagron | Cholesterol | 19G12-B13-194214 | 8 |
| Fagron | Cholesterol | 19G12-B13-194216 | 1 |
| Fagron | Cholesterol | 19I20-B08 | 2 |
| Fagron | Cholesterol | 19I20-B08-196479 | 4 |
| Fagron | Cholesterol | 19I20-B08-196480 | 1 |
| Fagron | Cholesterol | 19I20-B08-200506 | 6 |
| Fagron | Cholesterol | 19I20-B08-200559 | 2 |
| Fagron | Cholesterol | 19I20-B08-200561 | 4 |
| Fagron | Cholesterol | 19J18-B01-201136 | 5 |
| Fagron | Cholesterol | 19J18-B02 | 1 |
| Fagron | Cholesterol | 19J18B02196477 | 1 |
| Fagron | Cholesterol | 19J18-B02-196477 | 8 |
| Fagron | Cholesterol | 19J18-B02-201591 | 5 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Cholesterol | 19J18-B02-201592 | 1 |
| Fagron | Cholesterol | 19j18-B02 | 1 |
| Fagron | Cholesterol | 19j18-bo2-201595 | 1 |
| Fagron | Cholesterol | 19J19-B02-201592 | 1 |
| Fagron | Cholesterol | 19l20-B08-196480 | 1 |
| Fagron | Cholesterol | 2013U-01270 | 1 |
| Fagron | Cholesterol | 20F25-B99-201594 | 3 |
| Fagron | Cholesterol | 20G08-0B02-202266 | 1 |
| Fagron | Cholesterol | 20G08-B02 | 4 |
| Fagron | Cholesterol | 20G08-B02-201946 | 6 |
| Fagron | Cholesterol | 20G08-B02-202265 | 5 |
| Fagron | Cholesterol | 20G08-B02-202266 | 9 |
| Fagron | Cholesterol | 20G08-B02-202266 | 1 |
| Fagron | Cholesterol | 20G08-BO2-201946 | 1 |
| Fagron | Cholesterol | 20G08-N02-202265 | 1 |
| Fagron | Cholesterol | 21c18B01213585 | 1 |
| Fagron | Cholesterol | 21C18B01213585 | 2 |
| Fagron | Cholesterol | 21C18-B01-213585 | 18 |
| Fagron | Cholesterol | 21C18-B01-2135858 | 1 |
| Fagron | Cholesterol | 21C18-B01-213586 | 1 |
| Fagron | Cholesterol | 21C18-BO1 | 1 |
| Fagron | Cholesterol | 21C18-BO1-213588 | 1 |
| Fagron | Cholesterol | 21F08-b20-213589 | 1 |
| Fagron | Cholesterol | 21F08-B20 | 1 |
| Fagron | Cholesterol | 21F08-B20-215324 | 1 |
| Fagron | Cholesterol | 22d05-b03-220495 | 1 |
| Fagron | Cholesterol | 22J03-B01-224448 | 2 |
| Fagron | Cholesterol | 27212 | 1 |
| Fagron | Cholesterol | 2OG08-B02-202266 | 1 |
| Fagron | Cholesterol | 30197 | 1 |
| Fagron | Cholesterol | 30969 | 2 |
| Fagron | Cholesterol | 31941 | 2 |
| Fagron | Cholesterol | 322124 | 1 |
| Fagron | Cholesterol | 34342 | 4 |
| Fagron | Cholesterol | 36062 | 2 |
| Fagron | Cholesterol | 8J28-N10 | 1 |
| Fagron | Cholesterol | B01-2011306 | 1 |
| Fagron | Cholesterol | B02_2022606 | 1 |
| Fagron | Cholesterol | B02-1964707 | 1 |
| Fagron | Cholesterol | B02-2015901 | 1 |
| Fagron | Cholesterol | B02-2015905 | 1 |
| Fagron | Cholesterol | B02-2022606 | 6 |
| Fagron | Cholesterol | B20-2135809 | 1 |
| Fargon / AHD | Cholesterol | 16G05-B03-334366 | 1 |
| Fargon/AllianceH. | Cholesterol | 16G05-B03-328689 | 1 |
| Fargon | Cholesterol | 19G12-B13-194214 | 1 |
| Fargron/Noweda | Cholesterol | 21C18-B01-213585 | 2 |
| Gehe | Cholesterol | 24D26-B01-004353 | 1 |
| Gehe | Cholesterol | B02-2019406 | 1 |
| Noweda | Cholesterol | 15358802 | 1 |
| Noweda | Cholesterol | 15J23-B03-320483 | 1 |
| Noweda | Cholesterol | 17K16-B11-343922 | 2 |
| Noweda | Cholesterol | 22001179013 | 1 |
| Phönix/Fargon | Cholesterol | 17K16-B11-355385 | 1 |
| Phönix | Cholesterol | 19G-12-B13-194214 | 1 |
| Phönix | Cholesterol | 1K16-B11-343922 | 1 |
| Sanacorp | Cholesterol | 21000039010 | 1 |
| Sanacorp | Cholesterol | 22J03-B01-229435 | 1 |
| Sanacorp | Cholesterol | 23003286002 | 1 |

- 256 399 spectra from 1666 *Apo-Ident* customers from a total of 51 950 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cholesterol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cholesterol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 220 | 0 | 212 720 |
| **Type C** | 0 | 483 | 4 | 256 399 |

The substance/substance group *Cholesterol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.2727 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.1786 % (> 98.5626 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21219 | 23760 | 6.76 | 124.58 |
| 22461 | 22461 | 0.00 | 125.46 |
| 22971 | 22461 | 22.24 | 126.49 |
| 23760 | 23760 | 0.00 | 122.83 |
| 23937 | 23760 | 22.61 | 126.99 |
| 25517 | 22461 | 8.61 | 123.49 |
| 26160 | 22461 | 15.32 | 126.62 |
| 26963 | 26963 | 0.00 | 121.89 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at


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least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Choline chloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22639-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Choline chloride; Cholinii chloridum

### Special notes

When selecting the *Choline chloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Choline chloride | 6 | 4 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Choline chloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Choline chloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 111.01 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Choline chloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Choline chloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Choline chloride | 162092 | 22639 | 40 | 20160801* |
| Caelo | Choline chloride | 14273819 | 22663 | 40 | 20141002 |
| Caelo | Choline chloride | 14273819 | 22734 | 40 | 20141002 |
| Caelo | Choline chloride | 16209209 | 23582 | 40 | 20160801 |
| Caelo | Choline chloride | 20001839 | 25557 | 40 | 20200721* |
| Caelo | Choline chloride | 21002730 | 25853 | 50 | 20210908* |
| Fagron | Choline chloride | 23C20-B09-230712 | 26918 | 40 | 20230424 |
| Fagron | Choline chloride | 23C20-B09-230712 | 26918SI | 20 | 20230424 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 310 spectra of 8 reference samples from the substance/substance group *Choline chloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 016 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 170 spectra of 5 reference samples from the substance/substance group *Choline chloride*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Choline chloride | 172053 | 23618 | 40 |
| Caelo | Choline chloride | 181082 | 24264 | 40 |
| Caelo | Choline chloride | 20003488 | 25662 | 40 |
| Caelo | Choline chloride | 22000199 | 25990 | 40 |
| Caelo | Choline chloride | 22000199 | 25990SI | 10 |

- 212 770 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Choline chloride*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Choline chloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Choline chloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 310 | 0 | 158 016 |
| **Type B** | 0 | 170 | 0 | 212 770 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Choline chloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0645 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.4706 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22639 | 22639 | 0.00 | 142.12 |
| 22663 | 25853 | 18.05 | 140.84 |
| 22734 | 25853 | 17.41 | 140.09 |
| 23582 | 22639 | 10.84 | 140.04 |
| 25557 | 25557 | 0.00 | 151.48 |
| 25853 | 25853 | 0.00 | 143.36 |
| 26918 | 25853 | 10.80 | 141.95 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Choline hydrogen tartrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20719-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Choline hydrogen tartrate; Cholinium bitartaricum

### Special notes

When selecting the *Choline hydrogen tartrate* substance/substance group, the following information is displayed to the user:

- Advice: Currently no longer available from major pharmaceutical manufacturers. Therefore, batch maintenance is currently not possible.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Choline hydrogen tartrate | 7 | 6 | 5 |

### Second-stage model

For differentiation of the substance/substance group *Choline hydrogen tartrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Choline hydrogen tartrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 150.29 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Choline hydrogen tartrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Choline hydrogen tartrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Choline hydrogen tartrate | 1603044 | 22549 | 40 | 20160429* |
| Euro OTC | Choline hydrogen tartrate | 1607020 | 22689 | 40 | 20160808* |
| Euro OTC | Choline hydrogen tartrate | 1603044-01 | 23010 | 40 | 20160429 |
| Euro OTC | Choline hydrogen tartrate | 1603044-01 | 23101 | 40 | 20160429 |
| Euro OTC | Choline hydrogen tartrate | 1702005 | 23130 | 40 | 20170307* |
| Euro OTC | Choline hydrogen tartrate | 1901053 | 24484 | 40 | 20190228* |
| Euro OTC | Choline hydrogen tartrate | 1910013 | 24922 | 40 | 20191107* |
| Euro OTC | Choline hydrogen tartrate | 2009020 | 25419 | 40 | 20200925* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 8 reference samples from the substance/substance group *Choline hydrogen tartrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 006 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 260 spectra of 7 reference samples from the substance/substance group *Choline hydrogen tartrate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Choline hydrogen tartrate | 1707023 | 23610 | 40 |
| Euro OTC | Choline hydrogen tartrate | 1711022 | 23903 | 40 |
| Euro OTC | Choline hydrogen tartrate | 1802008 | 23958 | 40 |
| Euro OTC | Choline hydrogen tartrate | 2006031 | 25303 | 40 |
| Euro OTC | Choline hydrogen tartrate | 2101036 | 25567 | 40 |
| Euro OTC | Choline hydrogen tartrate | 2110006 | 25872 | 50 |
| Euro OTC | Choline hydrogen tartrate | 2110006 | 25872SI | 10 |

- 212 680 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 8 spectra from 4 *Apo-Ident* customers from 6 batches from the substance/substance group *Choline hydrogen tartrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag/ Euro OT | Choline hydrogen tartrate | 1910013-01 | 1 |
| Euro OTC | Choline hydrogen tartrate | 1309023-01 | 2 |
| Euro OTC | Choline hydrogen tartrate | 1603044-01 | 1 |
| Euro OTC | Choline hydrogen tartrate | 1607020-01 | 2 |
| Euro OTC | Choline hydrogen tartrate | 1707023-01 | 1 |
| Euro OTC | Choline hydrogen tartrate | 1711022-01 | 1 |

- 256 878 spectra from 1666 *Apo-Ident* customers from a total of 52 147 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Choline hydrogen tartrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Choline hydrogen tartrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 260 | 0 | 212 680 |
| **Type C** | 0 | 8 | 0 | 256 878 |

The substance/substance group *Choline hydrogen tartrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6923 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22549 | 22549 | 0.00 | 270.43 |
| 22689 | 22689 | 0.00 | 272.99 |
| 23010 | 22549 | 5.20 | 273.24 |
| 23101 | 22549 | 5.23 | 272.01 |
| 23130 | 23130 | 0.00 | 289.45 |
| 24484 | 24484 | 0.00 | 278.78 |
| 24922 | 24922 | 0.00 | 281.78 |
| 25419 | 25419 | 0.00 | 284.30 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ciclopirox olamine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20601-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ciclopirox olamine; Ciclopirox olaminum

### Special notes

When selecting the *Ciclopirox olamine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ciclopirox olamine | 12 | 4 | 101 |

### Second-stage model

For differentiation of the substance/substance group *Ciclopirox olamine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ciclopirox olamine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 78.41 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ciclopirox olamine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ciclopirox olamine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ciclopirox olamine | 13343209 | 21298 | 40 | AR-15-FG-016214-01 |
| Caelo | Ciclopirox olamine | 14147406 | 21655 | 60 | AR-15-FG-014857-01 |
| Caelo | Ciclopirox olamine | 14147406 | 21655SI | 60 | AR-15-FG-014857-01 |
| Caelo | Ciclopirox olamine | 14378809 | 21991 | 60 | 20150227 |
| Caelo | Ciclopirox olamine | 14378809 | 21991SI | 60 | 20150227 |
| Caelo | Ciclopirox olamine | 15364408 | 23011 | 40 | 20151201 |
| Caelo | Ciclopirox olamine | 15364408 | 23011SI | 40 | 20151201 |
| Caelo | Ciclopirox olamine | 22001499003 | 26233 | 40 | 20220627 |
| Caelo | Ciclopirox olamine | 22001499003 | 26233SI | 40 | 20220627 |
| Caelo | Ciclopirox olamine | 24000678 | 27327 | 40 | 20240506* |
| Caelo | Ciclopirox olamine | 24000678 | 27327SI | 40 | 20240506* |
| Fagron | Ciclopirox olamine | 13A16-N04 | 21218 | 40 | 20130117 |
| Fagron | Ciclopirox olamine | 14F13-B03-302340 | 21964 | 60 | 1608170 |
| Fagron | Ciclopirox olamine | 14F13-B03-302340 | 21964SI | 60 | 1608170 |
| Fagron | Ciclopirox olamine | 16G26-B02-324884 | 22969 | 40 | 20160907 |
| Fagron | Ciclopirox olamine | 16G26-B02-324884 | 23108 | 40 | 20160907 |
| Fagron | Ciclopirox olamine | 20B24-F02-370988 | 25481 | 40 | 2102412 |
| Fagron | Ciclopirox olamine | 20B24-F02-370988 | 25481SI | 40 | 2102412 |
| Fagron | Ciclopirox olamine | 21B03-B08-210563 | 25839 | 50 | 20210331 |
| Fagron | Ciclopirox olamine | 21B03-B08-210563 | 25839SI | 70 | 20210331 |
| Fagron | Ciclopirox olamine | 24A17-B07-237541 | 27475 | 40 | 20240313 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 1000 spectra of 21 reference samples from the substance/substance group *Ciclopirox olamine*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.

- 157 326 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 440 spectra of 10 reference samples from the substance/substance group *Ciclopirox olamine*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ciclopirox olamine | 182102 | 24280 | 40 |
| Caelo | Ciclopirox olamine | 22003201 | 26507 | 40 |
| Fagron | Ciclopirox olamine | 14E21-M04 | 21594 | 60 |
| Fagron | Ciclopirox olamine | 22A11-B03-215669 | 26176 | 40 |
| Caelo | Ciclopirox olamine | 22003201 | 26507SI | 40 |
| Fagron | Ciclopirox olamine | 14E21-M04 | 21594SI | 60 |
| Fagron | Ciclopirox olamine | 16G26-B02-324884 | 22969SI† | 40 |
| Fagron | Ciclopirox olamine | 16G26-B02-324884 | 23108SI† | 40 |
| Fagron | Ciclopirox olamine | 22A11-B03-215669 | 26176SI | 40 |
| Fagron | Ciclopirox olamine | 24A17-B07-237541 | 27475SI† | 40 |

- 212 500 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 428 spectra from 187 *Apo-Ident* customers from 107 batches from the substance/substance group *Ciclopirox olamine*.
- Among them are spectra of independent samples from 101 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ciclopirox olamine | 22001499004 | 4 |
| | Ciclopirox olamine | 22003201002 | 2 |
| | Ciclopirox olamine | 22003201004 | 6 |
| | Ciclopirox olamine | 22003201009 | 4 |
| | Ciclopirox olamine | 23000858003 | 2 |
| | Ciclopirox olamine | 24000678004 | 1 |
| | Ciclopirox olamine | 24000678005 | 5 |
| Caelo | Ciclopirox olamine | 12040906 | 1 |
| Caelo | Ciclopirox olamine | 12040911 | 3 |
| Caelo | Ciclopirox olamine | 12B22-N03 | 1 |
| Caelo | Ciclopirox olamine | 13343 | 1 |
| Caelo | Ciclopirox olamine | 13343201 | 1 |
| Caelo | Ciclopirox olamine | 13343203 | 1 |
| Caelo | Ciclopirox olamine | 13343208 | 2 |
| Caelo | Ciclopirox olamine | 13343209 | 3 |
| Caelo | Ciclopirox olamine | 14147402 | 4 |
| Caelo | Ciclopirox olamine | 14147405 | 1 |
| Caelo | Ciclopirox olamine | 14275801 | 2 |
| Caelo | Ciclopirox olamine | 14275802 | 2 |
| Caelo | Ciclopirox olamine | 14378801 | 2 |
| Caelo | Ciclopirox olamine | 14378802 | 1 |
| Caelo | Ciclopirox olamine | 14378803 | 1 |
| Caelo | Ciclopirox olamine | 14378804 | 2 |
| Caelo | Ciclopirox olamine | 14378805 | 2 |
| Caelo | Ciclopirox olamine | 14378806 | 5 |
| Caelo | Ciclopirox olamine | 14378809 | 1 |
| Caelo | Ciclopirox olamine | 14378810 | 9 |
| Caelo | Ciclopirox olamine | 15018802 | 3 |
| Caelo | Ciclopirox olamine | 15018803 | 2 |
| Caelo | Ciclopirox olamine | 15304407 | 1 |
| Caelo | Ciclopirox olamine | 15364402 | 6 |
| Caelo | Ciclopirox olamine | 15364404 | 2 |
| Caelo | Ciclopirox olamine | 15364405 | 5 |
| Caelo | Ciclopirox olamine | 15364407 | 6 |
| Caelo | Ciclopirox olamine | 15364408 | 4 |
| Caelo | Ciclopirox olamine | 15364409 | 2 |
| Caelo | Ciclopirox olamine | 15364412 | 5 |
| Caelo | Ciclopirox olamine | 15364414 | 1 |
| Caelo | Ciclopirox olamine | 15364416 | 2 |
| Caelo | Ciclopirox olamine | 16G26-B02-330862 | 1 |
| Caelo | Ciclopirox olamine | 16G26-B02-337355 | 3 |
| Caelo | Ciclopirox olamine | 17118801 | 5 |
| Caelo | Ciclopirox olamine | 17118802 | 3 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ciclopirox olamine | 17118806 | 11 |
| Caelo | Ciclopirox olamine | 17118807 | 4 |
| Caelo | Ciclopirox olamine | 17118808 | 7 |
| Caelo | Ciclopirox olamine | 17118811 | 4 |
| Caelo | Ciclopirox olamine | 17307402 | 10 |
| Caelo | Ciclopirox olamine | 17307403 | 4 |
| Caelo | Ciclopirox olamine | 17307405 | 6 |
| Caelo | Ciclopirox olamine | 173074055727 | 1 |
| Caelo | Ciclopirox olamine | 17307408 | 2 |
| Caelo | Ciclopirox olamine | 17307410 | 8 |
| Caelo | Ciclopirox olamine | 1810201 | 1 |
| Caelo | Ciclopirox olamine | 182102002 | 30 |
| Caelo | Ciclopirox olamine | 182102003 | 6 |
| Caelo | Ciclopirox olamine | 182102004 | 3 |
| Caelo | Ciclopirox olamine | 182102007 | 1 |
| Caelo | Ciclopirox olamine | 18210201 | 17 |
| Caelo | Ciclopirox olamine | 18210202 | 4 |
| Caelo | Ciclopirox olamine | 18210203 | 1 |
| Caelo | Ciclopirox olamine | 18210204 | 1 |
| Caelo | Ciclopirox olamine | 18210205 | 3 |
| Caelo | Ciclopirox olamine | 18210209 | 5 |
| Caelo | Ciclopirox olamine | 18210210 | 14 |
| Caelo | Ciclopirox olamine | 18212003 | 1 |
| Caelo | Ciclopirox olamine | 1850000758 | 1 |
| Caelo | Ciclopirox olamine | 21000032002 | 3 |
| Caelo | Ciclopirox olamine | 21000032003 | 3 |
| Caelo | Ciclopirox olamine | 21000032007 | 2 |
| Caelo | Ciclopirox olamine | 21000032008 | 2 |
| Caelo | Ciclopirox olamine | 21000032010 | 6 |
| Caelo | Ciclopirox olamine | 21000032012 | 3 |
| Caelo | Ciclopirox olamine | 21000032015 | 2 |
| Caelo | Ciclopirox olamine | 21000032016 | 1 |
| Caelo | Ciclopirox olamine | 2100032010 | 1 |
| Caelo | Ciclopirox olamine | 21B03-B08-210563 | 1 |
| Caelo | Ciclopirox olamine | 22001499003 | 6 |
| Caelo | Ciclopirox olamine | 22001499004 | 6 |
| Caelo | Ciclopirox olamine | 22001499009 | 2 |
| Caelo | Ciclopirox olamine | 22001499011 | 2 |
| Caelo | Ciclopirox olamine | 22003201002 | 2 |
| Caelo | Ciclopirox olamine | 22003201004 | 2 |
| Caelo | Ciclopirox olamine | 23000858005 | 1 |
| Caelo | Ciclopirox olamine | 3200003 | 1 |
| Caeol/ Noweda | Ciclopirox olamine | 14378809 | 2 |
| Caesar & Lorenz GmbH | Ciclopirox olamine | 171188007 | 1 |
| Caesar & Loretz GmbH... | Ciclopirox olamine | 18210205 | 1 |
| Caesar & Loretz GmbH... | Ciclopirox olamine | 21000032007 | 1 |
| Caesar & Loretz GmbH/GEHE | Ciclopirox olamine | 182102002 | 1 |
| Caesar & Loretz GmbH/GEHE | Ciclopirox olamine | 21000032007 | 4 |
| Caesar & Loretz GmbH... | Ciclopirox olamine | 21000032008 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 17307405 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 17307407 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 17307410 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 182102002 | 6 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 182102003 | 4 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 18210201 | 4 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 18210205 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 18210210 | 5 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 21000032002 | 4 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 21000032003 | 2 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 21000032007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Ciclopirox olamine | 21000032008 | 2 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 21000032010 | 7 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 21000032012 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 21000032016 | 2 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 22001499004 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 22001499011 | 2 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 22003201002 | 1 |
| Caesar & Loretz GmbH | Ciclopirox olamine | 22003201004 | 1 |
| Caesar & Loretz Hild… | Ciclopirox olamine | 18210205 | 1 |
| Caesar & Loretz Hilden | Ciclopirox olamine | 17307408 | 1 |
| Caesar & Loretz Hilden | Ciclopirox olamine | 182102002 | 1 |
| Caesar & Loretz Hilden | Ciclopirox olamine | 182102003 | 1 |
| Caesar & Loretz | Ciclopirox olamine | 14378805 | 2 |
| Cealo | Ciclopirox olamine | 14147403 | 2 |
| Euro OTC | Ciclopirox olamine | 14378811 | 2 |
| Euro OTC | Ciclopirox olamine | 17118806 | 1 |
| Euro OTC | Ciclopirox olamine | 1718806 | 1 |
| Fagron | Ciclopirox olamine | 10L09-N03 | 1 |
| Fagron | Ciclopirox olamine | 11h03-n02 | 1 |
| Fagron | Ciclopirox olamine | 12G12-N09 | 2 |
| Fagron | Ciclopirox olamine | 13A16-N04 | 1 |
| Fagron | Ciclopirox olamine | 14378806 | 1 |
| Fagron | Ciclopirox olamine | 14E21-M05 | 1 |
| Fagron | Ciclopirox olamine | 14F13-B03 | 1 |
| Fagron | Ciclopirox olamine | 14F13-B03-302339 | 1 |
| Fagron | Ciclopirox olamine | 16G26-B02 | 1 |
| Fagron | Ciclopirox olamine | 16G26-B02-335198 | 1 |
| Fagron | Ciclopirox olamine | 16G26-B02-348603 | 1 |
| Fagron | Ciclopirox olamine | 19A21-B02-362290 | 2 |
| Fagron | Ciclopirox olamine | 20B24_F02_368880 | 1 |
| Fagron | Ciclopirox olamine | 20B24-F02-372655 | 1 |
| Fagron | Ciclopirox olamine | 21B03B08210563 | 1 |
| Fagron | Ciclopirox olamine | A160013 | 1 |
| Fargon/Phönix | Ciclopirox olamine | 21B03B08210563 | 1 |
| fiebig | Ciclopirox olamine | 22003201009 | 1 |
| Gehe | Ciclopirox olamine | 14E21-M04 | 1 |
| Gehe | Ciclopirox olamine | 14F13-B03-302339 | 1 |
| GEHE | Ciclopirox olamine | 15364405 | 1 |
| Gehe | Ciclopirox olamine | 17118808 | 1 |
| Gehe | Ciclopirox olamine | 2300858003 | 1 |
| Noweda | Ciclopirox olamine | 12040911 | 1 |
| Noweda | Ciclopirox olamine | 12B22-N03 | 1 |
| Noweda | Ciclopirox olamine | 17307404 | 1 |
| Noweda | Ciclopirox olamine | 182102003 | 1 |
| Noweda | Ciclopirox olamine | 18210204 | 1 |
| Noweda | Ciclopirox olamine | 18210210 | 2 |
| Noweda | Ciclopirox olamine | 22001499011 | 1 |
| Pharmachem | Ciclopirox olamine | 17118808 | 1 |
| Phoenix | Ciclopirox olamine | 15364412 | 1 |
| Phönix | Ciclopirox olamine | 13A16-N04 | 1 |
| Phönix | Ciclopirox olamine | 17307410 | 1 |
| Phönix | Ciclopirox olamine | 18210209 | 1 |
| phönix | Ciclopirox olamine | 21000032016 | 1 |
| Phönix | Ciclopirox olamine | 22003201004 | 1 |
| phönix | Ciclopirox olamine | 22003201009 | 1 |
| Phönix | Ciclopirox olamine | 22003201099 | 1 |
| Phönix | Ciclopirox olamine | 23000858003 | 2 |
| Sanacorp | Ciclopirox olamine | 17118806 | 1 |
| Sanacorp | Ciclopirox olamine | 19A21-B02-362290 | 1 |
| Sanacorp | Ciclopirox olamine | 24000678005 | 1 |



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- 256 458 spectra from 1666 *Apo-Ident* customers from a total of 52 046 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ciclopirox olamine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ciclopirox olamine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 1000 | 0 | 157 326 |
| **Type B** | 0 | 440 | 0 | 212 500 |
| **Type C** | 0 | 421 | 7 | 256 458 |

The substance/substance group *Ciclopirox olamine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.4000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6364 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.3645 % (> 97.6636 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21218 | 21964 | 6.86 | 186.16 |
| 21298 | 21298 | 0.00 | 162.68 |
| 21655 | 21655 | 0.00 | 170.49 |
| 21964 | 21964 | 0.00 | 189.37 |
| 21991 | 21298 | 7.94 | 163.34 |
| 22969 | 21964 | 7.37 | 183.93 |
| 23011 | 21298 | 6.82 | 155.85 |
| 23108 | 21964 | 6.68 | 185.20 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25481 | 25481 | 0.00 | 144.64 |
| 25839 | 27327 | 45.04 | 166.42 |
| 26233 | 21964 | 22.42 | 180.44 |
| 27327 | 27327 | 0.00 | 165.07 |
| 27475 | 21964 | 12.72 | 181.42 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ciclosporin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20941-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ciclosporin; Ciclosporinum

### Special notes

When selecting the *Ciclosporin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ciclosporin | 7 | 8 | 130 |

### Second-stage model

For differentiation of the substance/substance group *Ciclosporin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ciclosporin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 98.60 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ciclosporin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ciclosporin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ciclosporin | 13148604 | 21474 | 60 | 1412541 |
| Caelo | Ciclosporin | 13148604 | 21475 | 60 | 20130613 |
| Caelo | Ciclosporin | 173327 | 24401 | 35 | 20180111* |
| Caelo | Ciclosporin | 192538 | 25200 | 40 | 20191107* |
| Euro OTC | Ciclosporin | 2002031 | 25356 | 40 | 20200825* |
| Fagron | Ciclosporin | 13D26-N07 | 20941 | 40 | 1402057 |
| Fagron | Ciclosporin | 13D26-N07 | 21671 | 42 | 1508429 |
| Fagron | Ciclosporin | 18G30_B04-354759 | 24441 | 40 | 20181115 |
| Fagron | Ciclosporin | 20B13-F03-368652 | 25182 | 40 | 20200313 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 397 spectra of 9 reference samples from the substance/substance group *Ciclosporin*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 929 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 383 spectra of 13 reference samples from the substance/substance group *Ciclosporin*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ciclosporin | 12317707 | 21082 | 30 |
| Caelo | Ciclosporin | 15278907 | 22966 | 40 |
| Caelo | Ciclosporin | 171583 | 23669 | 40 |
| Euro OTC | Ciclosporin | 2209015 | 26342 | 40 |
| Euro OTC | Ciclosporin | 2304018 | 26772 | 40 |
| Euro OTC | Ciclosporin | 2405004 | 27363 | 40 |
| Fagron | Ciclosporin | 16C09-B02-325955 | 23521 | 30 |
| Fagron | Ciclosporin | 23C01-B04-228703 | 26667 | 40 |
| Caelo | Ciclosporin | 173327 | 24401† | 5 |
| Euro OTC | Ciclosporin | 2209015 | 26342SI | 20 |
| Euro OTC | Ciclosporin | 2304018 | 26772SI | 20 |
| Fagron | Ciclosporin | 13D26-N07 | 21671† | 18 |
| Fagron | Ciclosporin | 23C01-B04-228703 | 26667SI | 20 |

- 212 557 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 501 spectra from 185 *Apo-Ident* customers from 138 batches from the substance/substance group *Ciclosporin*.

- Among them are spectra of independent samples from 130 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ciclosporin | 1213A422106 | 2 |
| | Ciclosporin | 1213A423045 | 1 |
| | Ciclosporin | 19055805 | 1 |
| | Ciclosporin | 20E08-F06-371273 | 2 |
| | Ciclosporin | 22003878002 | 15 |
| | Ciclosporin | 2203878002 | 1 |
| | Ciclosporin | 2209015-01 | 1 |
| | Ciclosporin | 23001155004 | 1 |
| | Ciclosporin | 23001155005 | 4 |
| | Ciclosporin | 2304018-01 | 8 |
| | Ciclosporin | 23C01-B04-224118 | 4 |
| | Ciclosporin | 23C01-B04-226120 | 4 |
| | Ciclosporin | 23C01-B04-228702 | 3 |
| | Ciclosporin | 23c01-b04-228703 | 1 |
| | Ciclosporin | 23C01-B04-228703 | 1 |
| | Ciclosporin | 23C01-B04-231019 | 4 |
| Alliance healfcare | Ciclosporin | 18136104 | 1 |
| Alliance healfcare | Ciclosporin | 19055804 | 1 |
| Audor Pharma | Ciclosporin | AP170802HBC | 2 |
| Caelo | Ciclosporin | 1(192538002) | 2 |
| Caelo | Ciclosporin | 12165602 | 3 |
| Caelo | Ciclosporin | 12165603 | 2 |
| Caelo | Ciclosporin | 12317702 | 2 |
| Caelo | Ciclosporin | 12317703 | 1 |
| Caelo | Ciclosporin | 12317707 | 4 |
| Caelo | Ciclosporin | 13031303 | 1 |
| Caelo | Ciclosporin | 13031801 | 1 |
| Caelo | Ciclosporin | 13148604 | 2 |
| Caelo | Ciclosporin | 13148606 | 6 |
| Caelo | Ciclosporin | 13346803 | 3 |
| Caelo | Ciclosporin | 13346808 | 1 |
| Caelo | Ciclosporin | 13A28-N04 | 4 |
| Caelo | Ciclosporin | 13D26-N07 | 4 |
| Caelo | Ciclosporin | 14199104 | 3 |
| Caelo | Ciclosporin | 14A15-No1 | 1 |
| Caelo | Ciclosporin | 15049703 | 4 |
| Caelo | Ciclosporin | 15278901 | 4 |
| Caelo | Ciclosporin | 15278902 | 2 |
| Caelo | Ciclosporin | 15278903 | 3 |
| Caelo | Ciclosporin | 15278904 | 7 |
| Caelo | Ciclosporin | 15278910 | 1 |
| Caelo | Ciclosporin | 15278913 | 1 |
| Caelo | Ciclosporin | 15278916 | 1 |
| Caelo | Ciclosporin | 15D23-B05-308853 | 1 |
| Caelo | Ciclosporin | 17158303 | 7 |
| Caelo | Ciclosporin | 17158306 | 4 |
| Caelo | Ciclosporin | 17158309 | 5 |
| Caelo | Ciclosporin | 17332702 | 6 |
| Caelo | Ciclosporin | 17332703 | 3 |
| Caelo | Ciclosporin | 1733702 | 1 |
| Caelo | Ciclosporin | 18041817 | 1 |
| Caelo | Ciclosporin | 18136101 | 8 |
| Caelo | Ciclosporin | 18136104 | 14 |
| Caelo | Ciclosporin | 18136108 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ciclosporin | 19011301 | 1 |
| Caelo | Ciclosporin | 19055803 | 1 |
| Caelo | Ciclosporin | 19055804 | 18 |
| Caelo | Ciclosporin | 19055805 | 14 |
| Caelo | Ciclosporin | 19055807 | 1 |
| Caelo | Ciclosporin | 19055808 | 2 |
| Caelo | Ciclosporin | 19055809 | 1 |
| Caelo | Ciclosporin | 19055810 | 1 |
| Caelo | Ciclosporin | 192538002 | 9 |
| Caelo | Ciclosporin | 192538004 | 1 |
| Caelo | Ciclosporin | 192538005 | 4 |
| Caelo | Ciclosporin | 192538007 | 6 |
| Caelo | Ciclosporin | 20E08-F06-371274 | 1 |
| Caelo | Ciclosporin | 21000144001 | 1 |
| Caelo | Ciclosporin | 21000144002 | 16 |
| Caelo | Ciclosporin | 21000144010 | 9 |
| Caelo | Ciclosporin | 21000144012 | 5 |
| Caelo | Ciclosporin | 21000144013 | 1 |
| Caelo | Ciclosporin | 2100144012 | 1 |
| Caelo | Ciclosporin | 21A25-F02-376839 | 1 |
| Caelo | Ciclosporin | 29689114C22B02 | 1 |
| Caesar & Loretz GmbH... | Ciclosporin | 19055805 | 1 |
| Caesar & Loretz GmbH... | Ciclosporin | 21000144010 | 2 |
| Caesar & Loretz GmbH... | Ciclosporin | 192538002 | 1 |
| Caesar & Loretz GmbH... | Ciclosporin | 192538002 | 1 |
| Caesar & Loretz GmbH... | Ciclosporin | 21000144002 | 1 |
| Caesar & Loretz GmbH | Ciclosporin | 17332702 | 1 |
| Caesar & Loretz GmbH | Ciclosporin | 18136104 | 6 |
| Caesar & Loretz GmbH | Ciclosporin | 19055804 | 1 |
| Caesar & Loretz GmbH | Ciclosporin | 19055805 | 8 |
| Caesar & Loretz GmbH | Ciclosporin | 192538002 | 10 |
| Caesar & Loretz GmbH | Ciclosporin | 192538007 | 6 |
| Caesar & Loretz GmbH | Ciclosporin | 21000144002 | 7 |
| Caesar & Loretz GmbH | Ciclosporin | 21000144004 | 1 |
| Caesar & Loretz GmbH | Ciclosporin | 21000144010 | 5 |
| Caesar & Loretz GmbH | Ciclosporin | 21000144011 | 1 |
| Caesar & Loretz GmbH | Ciclosporin | 21000144012 | 5 |
| Caesar & Loretz GmbH | Ciclosporin | 21000941001 | 1 |
| Caesar & Loretz GmbH | Ciclosporin | F06-3712702 | 1 |
| Caesar & Loretz | Ciclosporin | 17158306 | 1 |
| Concord Biotech Ltd.... | Ciclosporin | 14G22-B02-296891 | 1 |
| Concord Biotech Ltd | Ciclosporin | 21K15-B05-217761 | 1 |
| Euro OTC | Ciclosporin | 256866 | 1 |
| Fa.Phönix | Ciclosporin | 18136108 | 1 |
| Fa.Phönix | Ciclosporin | 192538002 | 1 |
| Fa.Phönix | Ciclosporin | 192538007 | 2 |
| Fa.Phönix | Ciclosporin | 21000144002 | 1 |
| Fagron | Ciclosporin | 10J18-N06 | 1 |
| Fagron | Ciclosporin | 1103531 | 1 |
| Fagron | Ciclosporin | 11K17-N13 | 1 |
| Fagron | Ciclosporin | 12E31-N02 | 7 |
| Fagron | Ciclosporin | 13414038 | 1 |
| Fagron | Ciclosporin | 13417083 | 2 |
| Fagron | Ciclosporin | 13420003 | 1 |
| Fagron | Ciclosporin | 13420023 | 5 |
| Fagron | Ciclosporin | 13420107 | 2 |
| Fagron | Ciclosporin | 13421135 | 1 |
| Fagron | Ciclosporin | 13A28-n04 | 1 |
| Fagron | Ciclosporin | 13A28-N04 | 4 |
| Fagron | Ciclosporin | 13B19N02 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Ciclosporin | 13B19-N02 | 4 |
| Fagron | Ciclosporin | 13d026N07 | 1 |
| Fagron | Ciclosporin | 13D26-N07 | 10 |
| Fagron | Ciclosporin | 13H19_N09 | 1 |
| Fagron | Ciclosporin | 13H19-N09 | 4 |
| Fagron | Ciclosporin | 14/18-B02-300180 | 1 |
| Fagron | Ciclosporin | 14718-b02-300180 | 1 |
| Fagron | Ciclosporin | 14a15-n01 | 1 |
| Fagron | Ciclosporin | 14A15-N01 | 3 |
| Fagron | Ciclosporin | 14g22-b02-296891 | 1 |
| Fagron | Ciclosporin | 14G22-B02-296891 | 5 |
| Fagron | Ciclosporin | 15D23-B05 | 2 |
| Fagron | Ciclosporin | 15D23-B05-307217 | 1 |
| Fagron | Ciclosporin | 15D23-B05-308853 | 7 |
| Fagron | Ciclosporin | 15F29-B14 | 1 |
| Fagron | Ciclosporin | 15f29-b14-316270 | 2 |
| Fagron | Ciclosporin | 15F29B14316270 | 1 |
| Fagron | Ciclosporin | 15F29-B14-316270 | 1 |
| Fagron | Ciclosporin | 15F29-B14-321791 | 1 |
| Fagron | Ciclosporin | 15f29-b14-325654 | 1 |
| Fagron | Ciclosporin | 16121401 | 1 |
| Fagron | Ciclosporin | 18136104 | 1 |
| Fagron | Ciclosporin | 18A18-B07-344620 | 3 |
| Fagron | Ciclosporin | 18A18-B07-344621 | 1 |
| Fagron | Ciclosporin | 18A18-B07-344622 | 1 |
| Fagron | Ciclosporin | 18A18-B07-349163 | 2 |
| Fagron | Ciclosporin | 18G30-B04 | 3 |
| Fagron | Ciclosporin | 18G30-B04-0001 | 1 |
| Fagron | Ciclosporin | 18G30-B04-354758 | 1 |
| Fagron | Ciclosporin | 18G30-B04-354759 | 4 |
| Fagron | Ciclosporin | 18G30-B04-3568304 | 1 |
| Fagron | Ciclosporin | 18G30-B04-358809 | 3 |
| Fagron | Ciclosporin | 20B13-F03 | 2 |
| Fagron | Ciclosporin | 20B13-F03-368653 | 1 |
| Fagron | Ciclosporin | 20E08-F06-3124 | 1 |
| Fagron | Ciclosporin | 20E08-F06-371272 | 2 |
| Fagron | Ciclosporin | 20E08-F06-371273 | 7 |
| Fagron | Ciclosporin | 20E08-F06-371275 | 2 |
| Fagron | Ciclosporin | 21A25-F02-376839 | 2 |
| Fagron | Ciclosporin | 21J12-B19-216847 | 1 |
| Fagron | Ciclosporin | 21J12-B19-217253 | 2 |
| Fagron | Ciclosporin | 21K15-B05-215789 | 3 |
| Fagron | Ciclosporin | 21K15-B05-216970 | 2 |
| Fagron | Ciclosporin | 21K15-B05-217761 | 2 |
| Fagron | Ciclosporin | 21L14-B02-219484 | 2 |
| Fagron | Ciclosporin | 21L14-B02-221862 | 2 |
| Fagron | Ciclosporin | 23C01-B04-223807 | 1 |
| Fagron | Ciclosporin | 23C01-B04-226120 | 2 |
| Fagron | Ciclosporin | 25051302 | 1 |
| Fagron | Ciclosporin | 59865-13-3 | 1 |
| Fargon/Gehe | Ciclosporin | 18A18-B07-344620 | 1 |
| Fargon | Ciclosporin | 13D26-No7 | 1 |
| Gehe | Ciclosporin | 17158303 | 1 |
| Gehe | Ciclosporin | 17158306 | 1 |
| Gehe | Ciclosporin | 17332702 | 1 |
| Gehe | Ciclosporin | 17332703 | 1 |
| Gehe | Ciclosporin | 18136101 | 1 |
| Gehe | Ciclosporin | 18136104 | 1 |
| Gehe | Ciclosporin | 22003878002 | 2 |
| Gehe | Ciclosporin | 23001155005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| L20 | Ciclosporin | 23C01-B04-228703 | 2 |
| Medisca/Ortscheidt | Ciclosporin | | 1 |
| Noweda | Ciclosporin | 14G22-B02-296891 | 1 |
| Noweda | Ciclosporin | 22003878002 | 2 |
| Noweda | Ciclosporin | 23C01-B04-231019 | 2 |
| Ortscheid 21.10.2021 | Ciclosporin | | 1 |
| Phoenix | Ciclosporin | 17158303 | 1 |
| Phoenix | Ciclosporin | 20B13-F03-368653 | 1 |
| Phönix | Ciclosporin | 13D26-N07 | 1 |
| Sanacorp | Ciclosporin | 23C01-B04-226120 | 1 |
| Sanarcorp | Ciclosporin | 17332702 | 1 |
| Sanarcorp | Ciclosporin | 19055805 | 1 |
| VDL | Ciclosporin | 13D26-N07 | 1 |

- 256 385 spectra from 1666 *Apo-Ident* customers from a total of 52 018 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ciclosporin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ciclosporin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 397 | 0 | 157 929 |
| **Type B** | 0 | 383 | 0 | 212 557 |
| **Type C** | 0 | 499 | 2 | 256 385 |

The substance/substance group *Ciclosporin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4887 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4334 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6008 % (> 99.0020 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested

reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20941 | 20941 | 0.00 | 118.90 |
| 21474 | 21474 | 0.00 | 128.20 |
| 21475 | 21474 | 2.91 | 128.07 |
| 21671 | 21671 | 0.00 | 120.55 |
| 24401 | 24401 | 0.00 | 127.63 |
| 24441 | 21474 | 16.00 | 127.05 |
| 25182 | 20941 | 13.30 | 121.34 |
| 25200 | 25200 | 0.00 | 126.32 |
| 25356 | 25356 | 0.00 | 113.79 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ciprofloxacin hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20945-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ciprofloxacin hydrochloride; Ciprofloxacini hydrochloridum

### Special notes

When selecting the *Ciprofloxacin hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ciprofloxacin hydrochloride | 6 | 3 | 14 |

### Second-stage model

For differentiation of the substance/substance group *Ciprofloxacin hydrochloride* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ciprofloxacin hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 121.53 | – |
| ⋮ | ⋮ | ⋮ |
| Quinine hydrochloride dihydrate | >50 | 143.68 |
| Sodium citrate | >50 | 218.07 |
| Methoxsalen | >50 | 239.08 |
| Capsaicin | >50 | 308.02 |
| Pyridoxal-5-phosphate hydrate | >50 | 338.66 |
| Oxybutynin hydrochloride | >50 | 346.72 |
| Prednicarbate | >50 | 362.12 |
| Levocarnitine | >50 | 389.18 |
| Heparin sodium | >50 | 423.83 |
| Cyproterone acetate | >50 | 472.05 |
| Tetracaine | >50 | 670.28 |
| Triclosan | >50 | 744.32 |
| Amitriptyline hydrochloride | >50 | 956.54 |
| Alfatradiol | >50 | 1056.77 |
| Norethisterone acetate | >50 | 1179.38 |
| Valine | >50 | 1273.00 |
| Sucrose | >50 | 1411.76 |
| Amifampridine | >50 | 1855.13 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ciprofloxacin hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ciprofloxacin hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ciprofloxacin hydrochloride | 12B08-N03 | 20945 | 40 | 1401421 |
| Fagron | Ciprofloxacin hydrochloride | 14B25-B02 | 21254 | 40 | 20140324 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ciprofloxacin hydrochloride | 16B17-B05-341882 | 23938 | 40 | 20160302 |
| Fagron | Ciprofloxacin hydrochloride | 18F27-B01-353346 | 24581 | 40 | 20180814 |
| Fagron | Ciprofloxacin hydrochloride | 20G01-F04-373719 | 25719 | 50 | 20200924 |
| Fagron | Ciprofloxacin hydrochloride | 21J08-B07-215636 | 26330 | 40 | 20220315 |
| Fagron | Ciprofloxacin hydrochloride | 21J08-B07-215636 | 26330SI | 20 | 20220315 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 270 spectra of 7 reference samples from the substance/substance group *Ciprofloxacin hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 056 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 5 reference samples from the substance/substance group *Ciprofloxacin hydrochloride*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Ciprofloxacin hydrochloride | 15D07-B01-312864 | 22755 | 40 |
| Fagron | Ciprofloxacin hydrochloride | 17K09-B02-345976 | 23991 | 40 |
| Fagron | Ciprofloxacin hydrochloride | 23F23-B08-228691 | 26898 | 40 |
| Fagron | Ciprofloxacin hydrochloride | 15D07-B01-312864 | 23568 | 40 |
| Fagron | Ciprofloxacin hydrochloride | 23F23-B08-228691 | 26898SI | 20 |

- 212 760 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by

this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 15 spectra from 12 *Apo-Ident* customers from 14 batches from the substance/substance group *Ciprofloxacin hydrochloride*.
- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ciprofloxacin hydrochloride | 21J08-B07-223799 | 1 |
| Caelo | Ciprofloxacin hydrochloride | 16B17-B05-324218 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 14/15-B08-303363 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 14B25-B02-291783 | 2 |
| Fagron | Ciprofloxacin hydrochloride | 14B25-B02-291-783 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 14F13-B01-303362 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 14I15-B08 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 14I15-B08-303363 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 14115-B08 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 15D07-B01-312864 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 17K09-B02-345976 | 1 |
| Fagron | Ciprofloxacin hydrochloride | 18F27-B01-363555 | 1 |
| Fagron | Ciprofloxacin hydrochloride | CI0A003 | 1 |
| Fargon/Anzag | Ciprofloxacin hydrochloride | F04-3737109 | 1 |

- 256 871 spectra from 1666 *Apo-Ident* customers from a total of 52 139 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ciprofloxacin hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ciprofloxacin hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 270 | 0 | 158 056 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 15 | 0 | 256 871 |

The substance/substance group *Ciprofloxacin hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7778 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20945 | 20945 | 0.00 | 207.53 |
| 21254 | 20945 | 13.45 | 203.34 |
| 23938 | 20945 | 36.62 | 195.19 |
| 24581 | 20945 | 21.34 | 199.94 |
| 25719 | 20945 | 32.51 | 197.58 |
| 26330 | 20945 | 25.78 | 200.26 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Citric acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20019-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Citric acid; Acidum citricum

### Special notes

When selecting the *Citric acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Citric acid | 8 | 25 | 678 |

### Second-stage model

For differentiation of the substance/substance group *Citric acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Citric acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Magnesium hydrogen citrate | 93.19 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Citric acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Citric acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Citric acid | 11380204 | 20682 | 40 | 20120127 |
| Caelo | Citric acid | 12043112 | 20683 | 40 | 20120229 |
| Caelo | Citric acid | 13396502 | 21455 | 60 | 20140110 |
| Caelo | Citric acid | 13243213 | 21487 | 40 | 20130821 |
| Caelo | Citric acid | 160386 | 22463 | 60 | 20160315* |
| Caelo | Citric acid | 22002250 | 26350 | 40 | 20220912* |
| Caelo | Citric acid | 22002250 | 26350SI | 20 | 20220912* |
| Fagron | Citric acid | 12F18-N03 | 20706 | 40 | 20120628 |
| Fagron | Citric acid | 13G24-N13 | 20913 | 40 | 20130827 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 380 spectra of 9 reference samples from the substance/substance group *Citric acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 946 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1170 spectra of 31 reference samples from the substance/substance group *Citric acid*.

- Among them are spectra of independent samples from 25 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Citric acid | 160387 | 22478 | 60 |
| Caelo | Citric acid | 162086 | 22620 | 40 |
| Caelo | Citric acid | 162154 | 22622 | 40 |
| Caelo | Citric acid | 171627 | 23303 | 40 |
| Caelo | Citric acid | 171626 | 23421 | 40 |
| Caelo | Citric acid | 180976 | 24034 | 40 |
| Caelo | Citric acid | 181292 | 24232 | 40 |
| Caelo | Citric acid | 183121 | 24366 | 40 |
| Caelo | Citric acid | 183071 | 24367 | 40 |
| Caelo | Citric acid | 192036 | 24740 | 40 |
| Caelo | Citric acid | 192073 | 24744 | 40 |
| Caelo | Citric acid | 21000543 | 25631 | 40 |
| Caelo | Citric acid | 21000544 | 25635 | 40 |
| Caelo | Citric acid | 21002657 | 25855 | 50 |
| Caelo | Citric acid | 22000645 | 26122 | 40 |
| Caelo | Citric acid | 22002309 | 26358 | 40 |
| Caelo | Citric acid | 23002104 | 26946 | 40 |
| Caelo | Citric acid | 23002107 | 26955 | 40 |
| Caelo | Citric acid | 24001159 | 27253 | 40 |
| Euro OTC | Citric acid | 2112002 | 25947 | 40 |
| Euro OTC | Citric acid | 2301021 | 26510 | 40 |
| Euro OTC | Citric acid | 2310005 | 27007 | 40 |
| Euro OTC | Citric acid | 2407008 | 27457 | 40 |
| Fagron | Citric acid | 21F11-B04-213849 | 26146 | 40 |
| Fagron | Citric acid | 23C01-B01-228324 | 26828 | 30 |
| Caelo | Citric acid | 171626 | 23648 | 40 |
| Caelo | Citric acid | 171627 | 23677 | 40 |
| Caelo | Citric acid | 22000645 | 26122SI | 20 |
| Caelo | Citric acid | 22002309 | 26358SI | 20 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Citric acid | 2112002 | 25947SI | 10 |
| Fagron | Citric acid | 21F11-B04-213849 | 26146SI | 20 |

- 211 770 spectra from a total of 4262 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4673 spectra from 1341 *Apo-Ident* customers from 698 batches from the substance/substance group *Citric acid*.
- Among them are spectra of independent samples from 673 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Citric acid | 12345 | 1 |
| | Citric acid | 1287460 | 1 |
| | Citric acid | 1293187 | 1 |
| | Citric acid | 13K18-B34-291523 | 1 |
| | Citric acid | 16038606 | 1 |
| | Citric acid | 2000645001 | 1 |
| | Citric acid | 21000543002 | 1 |
| | Citric acid | 21000543008 | 1 |
| | Citric acid | 21000543010 | 1 |
| | Citric acid | 21000544002 | 3 |
| | Citric acid | 21002657002 | 2 |
| | Citric acid | 21002657003 | 3 |
| | Citric acid | 21002657006 | 4 |
| | Citric acid | 21002657007 | 1 |
| | Citric acid | 21002657012 | 6 |
| | Citric acid | 21002657015 | 16 |
| | Citric acid | 21002657016 | 2 |
| | Citric acid | 21002657017 | 14 |
| | Citric acid | 2112002-03 | 2 |
| | Citric acid | 21F11-B04-213768 | 1 |
| | Citric acid | 220000645004 | 1 |
| | Citric acid | 22000645001 | 2 |
| | Citric acid | 22000645004 | 3 |
| | Citric acid | 22000645005 | 5 |
| | Citric acid | 22000645008 | 1 |
| | Citric acid | 22000645009 | 8 |
| | Citric acid | 22000645011 | 8 |
| | Citric acid | 220021564 | 1 |
| | Citric acid | 22002250001 | 10 |
| | Citric acid | 22002250004 | 2 |
| | Citric acid | 22002309001 | 11 |
| | Citric acid | 22002309002 | 1 |
| | Citric acid | 22002309004 | 39 |
| | Citric acid | 22002309008 | 11 |
| | Citric acid | 2200239004 | 1 |
| | Citric acid | 22H11-B02-227794 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Citric acid | 22I05-B07-222923 | 1 |
| | Citric acid | 22I05-B07-225242 | 1 |
| | Citric acid | 23003592004 | 1 |
| | Citric acid | 23003597001 | 3 |
| | Citric acid | 23003598003 | 4 |
| | Citric acid | 23003598004 | 31 |
| | Citric acid | 23003598007 | 4 |
| | Citric acid | 23003598009 | 5 |
| | Citric acid | 23003715 | 2 |
| | Citric acid | 2301021-01 | 4 |
| | Citric acid | 2301021-03 | 1 |
| | Citric acid | 2310005-01 | 2 |
| | Citric acid | 23568 | 1 |
| | Citric acid | 24001159001 | 1 |
| | Citric acid | 24001159002 | 10 |
| | Citric acid | 24001159003 | 7 |
| | Citric acid | 2407008-01 | 3 |
| | Citric acid | 6491041 | 2 |
| | Citric acid | c144 | 1 |
| 092522438 | Citric acid | 22000645001 | 2 |
| 12.12.2016 Phoenix 4,59EUR | Citric acid | 15088008 | 1 |
| A.H. 08.06.13 ek: 6,92EUR | Citric acid | 13050604 | 1 |
| AEP | Citric acid | 22002309001 | 1 |
| AEP | Citric acid | 22002309004 | 2 |
| AHD | Citric acid | 13050607 | 1 |
| AHD | Citric acid | 13396502 | 1 |
| AHD | Citric acid | 15063218 | 1 |
| AHD | Citric acid | 16208614 | 1 |
| AHD | Citric acid | 20000886003 | 1 |
| AHD | Citric acid | 21000543008 | 1 |
| AHD | Citric acid | 21002657003 | 1 |
| AHD | Citric acid | 21002657015 | 2 |
| AHD | Citric acid | 22000645001 | 1 |
| AHD | Citric acid | 23003598004 | 1 |
| ALH | Citric acid | L1508013-01 | 1 |
| Alliance healfcare | Citric acid | 11805017-02 | 1 |
| Alliance Health 03.0... | Citric acid | 13K18-B34 | 1 |
| Alliance Healthcare | Citric acid | 12043123 | 1 |
| ALLIANCE HEALTHCARE | Citric acid | 19003185 | 1 |
| Alliance Healthcare | Citric acid | 21000543008 | 1 |
| Alliance Healthcare | Citric acid | 22002309004 | 1 |
| Alliance | Citric acid | 22002309004 | 1 |
| Anzag | Citric acid | 10049712 | 1 |
| Anzag | Citric acid | 10049713 | 1 |
| anzag | Citric acid | 13175409 | 1 |
| Anzag | Citric acid | 192073009 | 2 |
| Anzag | Citric acid | 21002657017 | 1 |
| Anzag | Citric acid | 250502(23003598004) | 1 |
| Anzag | Citric acid | 250612(23003598009) | 1 |
| Anzag | Citric acid | 6494061 | 1 |
| apomix | Citric acid | 11380204 | 1 |
| apomix | Citric acid | 16208612 | 2 |
| Apotheke | Citric acid | 21000543005 | 1 |
| Audor Pharma | Citric acid | PA201 | 1 |
| Beyvers | Citric acid | 16038606 | 1 |
| Bombastus | Citric acid | 122500004 | 1 |
| Bombastus | Citric acid | 12250004-3-0 | 1 |
| Bombastus | Citric acid | 13396502 | 1 |
| Bombastus | Citric acid | 17162601 | 2 |
| Bombastus | Citric acid | 17162602 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Citric acid | 18097060 | 1 |
| Bombastus | Citric acid | 20002872 | 1 |
| Bombastus | Citric acid | 21004820 | 1 |
| Bombastus | Citric acid | 272757 | 2 |
| Caelo | Citric acid | | 10 |
| Caelo | Citric acid | 10049716 | 1 |
| Caelo | Citric acid | 1015U-01024 | 1 |
| Caelo | Citric acid | 10182420 | 1 |
| Caelo | Citric acid | 1044905 | 1 |
| Caelo | Citric acid | 1072015B | 1 |
| Caelo | Citric acid | 11066806 | 1 |
| Caelo | Citric acid | 11159801 | 2 |
| Caelo | Citric acid | 11159817 | 1 |
| Caelo | Citric acid | 11159821 | 1 |
| Caelo | Citric acid | 11159824 | 1 |
| Caelo | Citric acid | 11178303 | 5 |
| Caelo | Citric acid | 11189817 | 1 |
| Caelo | Citric acid | 11380204 | 5 |
| Caelo | Citric acid | 11380208 | 1 |
| Caelo | Citric acid | 11380213 | 1 |
| Caelo | Citric acid | 11380215 | 3 |
| Caelo | Citric acid | 11380217 | 2 |
| Caelo | Citric acid | 1150817/16208614 | 1 |
| Caelo | Citric acid | 1155609 | 2 |
| Caelo | Citric acid | 1172673 | 1 |
| Caelo | Citric acid | 1175409 | 2 |
| Caelo | Citric acid | 1181765 | 2 |
| Caelo | Citric acid | 11C24-N02 | 1 |
| Caelo | Citric acid | 11C24-N03 | 1 |
| Caelo | Citric acid | 11K07-N01 | 1 |
| Caelo | Citric acid | 11K11-N02 | 1 |
| Caelo | Citric acid | 12043105 | 2 |
| Caelo | Citric acid | 12043110 | 4 |
| Caelo | Citric acid | 12043112 | 3 |
| Caelo | Citric acid | 12043113 | 3 |
| Caelo | Citric acid | 12043118 | 3 |
| Caelo | Citric acid | 12043119 | 1 |
| Caelo | Citric acid | 12043120 | 5 |
| Caelo | Citric acid | 12043123 | 6 |
| Caelo | Citric acid | 12043124 | 3 |
| Caelo | Citric acid | 12156801 | 2 |
| Caelo | Citric acid | 12156803 | 8 |
| Caelo | Citric acid | 12156804 | 3 |
| Caelo | Citric acid | 12156811 | 11 |
| Caelo | Citric acid | 12156812 | 4 |
| Caelo | Citric acid | 12156818 | 1 |
| Caelo | Citric acid | 12156822 | 2 |
| Caelo | Citric acid | 12156823 | 4 |
| Caelo | Citric acid | 12156824 | 5 |
| Caelo | Citric acid | 12156827 | 1 |
| Caelo | Citric acid | 12156830 | 1 |
| Caelo | Citric acid | 12156832 | 7 |
| Caelo | Citric acid | 121568704 | 1 |
| Caelo | Citric acid | 12175708 | 3 |
| Caelo | Citric acid | 12175711 | 1 |
| Caelo | Citric acid | 12175716 | 2 |
| Caelo | Citric acid | 12175717 | 1 |
| Caelo | Citric acid | 12175718 | 1 |
| Caelo | Citric acid | 1218A-01024 | 2 |
| Caelo | Citric acid | 1230616 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid | 12345 | 1 |
| Caelo | Citric acid | 12353613 | 1 |
| Caelo | Citric acid | 125356 | 1 |
| Caelo | Citric acid | 12B01-N01 | 3 |
| Caelo | Citric acid | 13011801 | 1 |
| Caelo | Citric acid | 13031502 | 1 |
| Caelo | Citric acid | 13050601 | 9 |
| Caelo | Citric acid | 13050604 | 13 |
| Caelo | Citric acid | 13050606 | 2 |
| Caelo | Citric acid | 13050607 | 9 |
| Caelo | Citric acid | 13050610 | 6 |
| Caelo | Citric acid | 13050611 | 6 |
| Caelo | Citric acid | 13050613 | 18 |
| Caelo | Citric acid | 13050614 | 7 |
| Caelo | Citric acid | 13050617 | 12 |
| Caelo | Citric acid | 13050618 | 3 |
| Caelo | Citric acid | 13050621 | 2 |
| Caelo | Citric acid | 13050622 | 7 |
| Caelo | Citric acid | 13050623 | 2 |
| Caelo | Citric acid | 13050623-3376319052 | 1 |
| Caelo | Citric acid | 13050624 | 1 |
| Caelo | Citric acid | 1305601 | 1 |
| Caelo | Citric acid | 13061502 | 1 |
| Caelo | Citric acid | 1306911 | 1 |
| Caelo | Citric acid | 130-7612 | 1 |
| Caelo | Citric acid | 13157404 | 1 |
| Caelo | Citric acid | 13175402 | 3 |
| Caelo | Citric acid | 13175403 | 14 |
| Caelo | Citric acid | 13175404 | 4 |
| Caelo | Citric acid | 13175405 | 5 |
| Caelo | Citric acid | 13175406 | 3 |
| Caelo | Citric acid | 13175409 | 20 |
| Caelo | Citric acid | 13175410 | 4 |
| Caelo | Citric acid | 13175411 | 10 |
| Caelo | Citric acid | 13175414 | 2 |
| Caelo | Citric acid | 13175426 | 4 |
| Caelo | Citric acid | 13243005 | 1 |
| Caelo | Citric acid | 13243201 | 17 |
| Caelo | Citric acid | 13243202 | 10 |
| Caelo | Citric acid | 13243208 | 2 |
| Caelo | Citric acid | 13243210 | 10 |
| Caelo | Citric acid | 13243213 | 21 |
| Caelo | Citric acid | 13243214 | 15 |
| Caelo | Citric acid | 13243216 | 11 |
| Caelo | Citric acid | 13243217 | 6 |
| Caelo | Citric acid | 13243218 | 9 |
| Caelo | Citric acid | 13243219 | 4 |
| Caelo | Citric acid | 13243220 | 2 |
| Caelo | Citric acid | 13243221 | 8 |
| Caelo | Citric acid | 13243222 | 1 |
| Caelo | Citric acid | 13243224 | 2 |
| Caelo | Citric acid | 13243225 | 4 |
| Caelo | Citric acid | 13243229 | 2 |
| Caelo | Citric acid | 133243218 | 1 |
| Caelo | Citric acid | 13396502 | 3 |
| Caelo | Citric acid | 13396504 | 3 |
| Caelo | Citric acid | 13396505 | 3 |
| Caelo | Citric acid | 13396506 | 1 |
| Caelo | Citric acid | 13396515 | 2 |
| Caelo | Citric acid | 1380208 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid | 1396505 | 1 |
| Caelo | Citric acid | 13A04-N04 | 1 |
| Caelo | Citric acid | 13D29-N02 | 1 |
| Caelo | Citric acid | 13K18-B34 | 1 |
| Caelo | Citric acid | 13K18-B34-288371TEST | 1 |
| Caelo | Citric acid | 13K18-B34-288372 | 1 |
| Caelo | Citric acid | 13K18-B34-291520 | 1 |
| Caelo | Citric acid | 13K18-B34-291522 | 1 |
| Caelo | Citric acid | 13K18-B34-291523 | 2 |
| Caelo | Citric acid | 14041506 | 1 |
| Caelo | Citric acid | 14071501 | 1 |
| Caelo | Citric acid | 14162701 | 1 |
| Caelo | Citric acid | 14186301 | 26 |
| Caelo | Citric acid | 14186302 | 14 |
| Caelo | Citric acid | 14186312 | 20 |
| Caelo | Citric acid | 14186313 | 11 |
| Caelo | Citric acid | 14186314 | 4 |
| Caelo | Citric acid | 1418E-01024 | 1 |
| Caelo | Citric acid | 14E06-B07 | 1 |
| Caelo | Citric acid | 14G04-B09 | 1 |
| Caelo | Citric acid | 14G04-B09-293874 | 2 |
| Caelo | Citric acid | 14G04-B09-293876 | 1 |
| Caelo | Citric acid | 14G04B09293877 | 1 |
| Caelo | Citric acid | 14G04-B09-293877 | 2 |
| Caelo | Citric acid | 14K05-B04-302815 | 1 |
| Caelo | Citric acid | 1501-B06-324348 | 1 |
| Caelo | Citric acid | 15044901 | 9 |
| Caelo | Citric acid | 15044902 | 4 |
| Caelo | Citric acid | 15044903 | 8 |
| Caelo | Citric acid | 15044904 | 10 |
| Caelo | Citric acid | 15044905 | 10 |
| Caelo | Citric acid | 15063003 | 26 |
| Caelo | Citric acid | 15063003-20160615Ma1 | 1 |
| Caelo | Citric acid | 15063006 | 5 |
| Caelo | Citric acid | 150632 | 1 |
| Caelo | Citric acid | 15063202 | 1 |
| Caelo | Citric acid | 15063203 | 15 |
| Caelo | Citric acid | 15063204 | 14 |
| Caelo | Citric acid | 15063205 | 3 |
| Caelo | Citric acid | 15063206 | 25 |
| Caelo | Citric acid | 15063211 | 5 |
| Caelo | Citric acid | 15063213 | 28 |
| Caelo | Citric acid | 15063214 | 9 |
| Caelo | Citric acid | 15063217 | 12 |
| Caelo | Citric acid | 15063218 | 11 |
| Caelo | Citric acid | 15087510 | 1 |
| Caelo | Citric acid | 15087902 | 5 |
| Caelo | Citric acid | 15087903 | 19 |
| Caelo | Citric acid | 15087904 | 1 |
| Caelo | Citric acid | 15088008 | 2 |
| Caelo | Citric acid | 15088016 | 4 |
| Caelo | Citric acid | 15088017 | 2 |
| Caelo | Citric acid | 15091401 | 1 |
| Caelo | Citric acid | 15124202 | 1 |
| Caelo | Citric acid | 15124301 | 10 |
| Caelo | Citric acid | 15124303 | 1 |
| Caelo | Citric acid | 1516Q-01024 | 1 |
| Caelo | Citric acid | 15185320 | 1 |
| Caelo | Citric acid | 15214301 | 1 |
| Caelo | Citric acid | 15G16-B01-330449 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid | 15G16-B01-330450 | 3 |
| Caelo | Citric acid | 16004701 | 21 |
| Caelo | Citric acid | 16004702 | 28 |
| Caelo | Citric acid | 16004705 | 4 |
| Caelo | Citric acid | 16004706 | 23 |
| Caelo | Citric acid | 16038602 | 3 |
| Caelo | Citric acid | 16038603 | 5 |
| Caelo | Citric acid | 16038604 | 9 |
| Caelo | Citric acid | 16038606 | 22 |
| Caelo | Citric acid | 16038607 | 7 |
| Caelo | Citric acid | 16038608 | 14 |
| Caelo | Citric acid | 16038613 | 11 |
| Caelo | Citric acid | 16038614 | 5 |
| Caelo | Citric acid | 16038617 | 2 |
| Caelo | Citric acid | 16038621 | 20 |
| Caelo | Citric acid | 16038622 | 9 |
| Caelo | Citric acid | 16038701 | 5 |
| Caelo | Citric acid | 16038704 | 12 |
| Caelo | Citric acid | 16038707 | 11 |
| Caelo | Citric acid | 16038708 | 11 |
| Caelo | Citric acid | 16038709 | 6 |
| Caelo | Citric acid | 16038710 | 3 |
| Caelo | Citric acid | 16038712 | 7 |
| Caelo | Citric acid | 16038713 | 1 |
| Caelo | Citric acid | 160607AC | 1 |
| Caelo | Citric acid | 160614 | 1 |
| Caelo | Citric acid | 1606141 | 1 |
| Caelo | Citric acid | 160808/3 | 1 |
| Caelo | Citric acid | 16088607 | 1 |
| Caelo | Citric acid | 1620610 | 1 |
| Caelo | Citric acid | 16206813 | 1 |
| Caelo | Citric acid | 16208605 | 17 |
| Caelo | Citric acid | 162086055525 | 1 |
| Caelo | Citric acid | 16208606 | 31 |
| Caelo | Citric acid | 16208607 | 33 |
| Caelo | Citric acid | 16208608 | 6 |
| Caelo | Citric acid | 16208610 | 14 |
| Caelo | Citric acid | 16208612 | 25 |
| Caelo | Citric acid | 16208613 | 14 |
| Caelo | Citric acid | 16208614 | 55 |
| Caelo | Citric acid | 16208615 | 3 |
| Caelo | Citric acid | 162088606 | 1 |
| Caelo | Citric acid | 162154 | 1 |
| Caelo | Citric acid | 16215403 | 3 |
| Caelo | Citric acid | 16215405 | 6 |
| Caelo | Citric acid | 16215408 | 6 |
| Caelo | Citric acid | 16215409 | 10 |
| Caelo | Citric acid | 170607C/16208605 | 1 |
| Caelo | Citric acid | 17071301 | 1 |
| Caelo | Citric acid | 17161601 | 1 |
| Caelo | Citric acid | 17162601 | 34 |
| Caelo | Citric acid | 17162602 | 29 |
| Caelo | Citric acid | 17162603 | 9 |
| Caelo | Citric acid | 17162604 | 3 |
| Caelo | Citric acid | 1716262601 | 1 |
| Caelo | Citric acid | 17162701 | 32 |
| Caelo | Citric acid | 17162702 | 12 |
| Caelo | Citric acid | 17162706 | 1 |
| Caelo | Citric acid | 1716271 | 1 |
| Caelo | Citric acid | 171652601 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid | 173295002 | 1 |
| Caelo | Citric acid | 17329502 | 20 |
| Caelo | Citric acid | 17329503 | 8 |
| Caelo | Citric acid | 17329504 | 2 |
| Caelo | Citric acid | 17329511 | 10 |
| Caelo | Citric acid | 17329512 | 3 |
| Caelo | Citric acid | 17329513 | 3 |
| Caelo | Citric acid | 177162601 | 1 |
| Caelo | Citric acid | 17E15-B04-335435 | 1 |
| Caelo | Citric acid | 17E15-B04-339371 | 1 |
| Caelo | Citric acid | 180257004 | 1 |
| Caelo | Citric acid | 18025701 | 46 |
| Caelo | Citric acid | 18025702 | 55 |
| Caelo | Citric acid | 18025704 | 21 |
| Caelo | Citric acid | 180257045617 | 1 |
| Caelo | Citric acid | 18025801 | 31 |
| Caelo | Citric acid | 18025802 | 6 |
| Caelo | Citric acid | 180297609 | 1 |
| Caelo | Citric acid | 18091409 | 1 |
| Caelo | Citric acid | 18097202 | 1 |
| Caelo | Citric acid | 18097601 | 48 |
| Caelo | Citric acid | 18097602 | 15 |
| Caelo | Citric acid | 18097603 | 25 |
| Caelo | Citric acid | 18097604 | 1 |
| Caelo | Citric acid | 18097606 | 19 |
| Caelo | Citric acid | 18097607 | 21 |
| Caelo | Citric acid | 18097609 | 31 |
| Caelo | Citric acid | 18097610 | 1 |
| Caelo | Citric acid | 18097611 | 25 |
| Caelo | Citric acid | 18097615 | 1 |
| Caelo | Citric acid | 18111704 | 1 |
| Caelo | Citric acid | 1812104 | 1 |
| Caelo | Citric acid | 1812905 | 2 |
| Caelo | Citric acid | 18129204 | 3 |
| Caelo | Citric acid | 18129205 | 38 |
| Caelo | Citric acid | 18129206 | 4 |
| Caelo | Citric acid | 18129207 | 5 |
| Caelo | Citric acid | 183006905 | 1 |
| Caelo | Citric acid | 18304909 | 1 |
| Caelo | Citric acid | 18306902 | 34 |
| Caelo | Citric acid | 18306903 | 29 |
| Caelo | Citric acid | 18306905 | 49 |
| Caelo | Citric acid | 18306905P-190531-4 | 1 |
| Caelo | Citric acid | 18306906 | 50 |
| Caelo | Citric acid | 18306908 | 9 |
| Caelo | Citric acid | 18306909 | 40 |
| Caelo | Citric acid | 18306911 | 67 |
| Caelo | Citric acid | 18306913 | 2 |
| Caelo | Citric acid | 183069606 | 1 |
| Caelo | Citric acid | 18306999 | 1 |
| Caelo | Citric acid | 18307101 | 2 |
| Caelo | Citric acid | 18307102 | 12 |
| Caelo | Citric acid | 18307104 | 16 |
| Caelo | Citric acid | 1831209 | 1 |
| Caelo | Citric acid | 18312102 | 3 |
| Caelo | Citric acid | 18312103 | 3 |
| Caelo | Citric acid | 18312104 | 18 |
| Caelo | Citric acid | 18312107 | 1 |
| Caelo | Citric acid | 18312109 | 10 |
| Caelo | Citric acid | 1836911 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid | 18F25-B02 | 1 |
| Caelo | Citric acid | 18F25-B02-351453 | 1 |
| Caelo | Citric acid | 18F25-B02-351454 | 1 |
| Caelo | Citric acid | 19041304 | 1 |
| Caelo | Citric acid | 19041305 | 1 |
| Caelo | Citric acid | 1917A-01024 | 1 |
| Caelo | Citric acid | 19203003 | 1 |
| Caelo | Citric acid | 192036002 | 5 |
| Caelo | Citric acid | 192036003 | 32 |
| Caelo | Citric acid | 1920366003 | 1 |
| Caelo | Citric acid | 192037005 | 1 |
| Caelo | Citric acid | 192073002 | 32 |
| Caelo | Citric acid | 192073003 | 20 |
| Caelo | Citric acid | 192073003P-200602-1 | 1 |
| Caelo | Citric acid | 192073004 | 44 |
| Caelo | Citric acid | 192073005 | 34 |
| Caelo | Citric acid | 192073005P-200507-3 | 1 |
| Caelo | Citric acid | 192073005P-200609-5 | 1 |
| Caelo | Citric acid | 192073009 | 27 |
| Caelo | Citric acid | 192073010 | 2 |
| Caelo | Citric acid | 19H23-B07-194438 | 1 |
| Caelo | Citric acid | 200000886003 | 1 |
| Caelo | Citric acid | 200003515014 | 1 |
| Caelo | Citric acid | 200008860003 | 1 |
| Caelo | Citric acid | 20000886001 | 2 |
| Caelo | Citric acid | 20000886002 | 46 |
| Caelo | Citric acid | 20000886003 | 67 |
| Caelo | Citric acid | 20000886006 | 1 |
| Caelo | Citric acid | 20000886007 | 30 |
| Caelo | Citric acid | 20000886009 | 40 |
| Caelo | Citric acid | 20000886012 | 1 |
| Caelo | Citric acid | 20000889002 | 1 |
| Caelo | Citric acid | 20003515003 | 17 |
| Caelo | Citric acid | 20003515007 | 1 |
| Caelo | Citric acid | 20003515008 | 4 |
| Caelo | Citric acid | 20003515009 | 1 |
| Caelo | Citric acid | 20003515010 | 8 |
| Caelo | Citric acid | 20003515013 | 1 |
| Caelo | Citric acid | 20003515014 | 12 |
| Caelo | Citric acid | 2000886007 | 2 |
| Caelo | Citric acid | 20060912-3 | 1 |
| Caelo | Citric acid | 20151112-1 | 1 |
| Caelo | Citric acid | 2017-04-18AVLu | 1 |
| Caelo | Citric acid | 20170728/Ma1 | 1 |
| Caelo | Citric acid | 2019Q-01024 | 1 |
| Caelo | Citric acid | 2051703 | 1 |
| Caelo | Citric acid | 2071303 | 1 |
| Caelo | Citric acid | 20F19-B01-201169 | 1 |
| Caelo | Citric acid | 210000200004 | 1 |
| Caelo | Citric acid | 21000020004 | 2 |
| Caelo | Citric acid | 210000543005 | 1 |
| Caelo | Citric acid | 210000543011 | 1 |
| Caelo | Citric acid | 21000211004 | 1 |
| Caelo | Citric acid | 210002657003 | 1 |
| Caelo | Citric acid | 2100054002 | 1 |
| Caelo | Citric acid | 21000542008 | 1 |
| Caelo | Citric acid | 21000543001 | 1 |
| Caelo | Citric acid | 21000543002 | 9 |
| Caelo | Citric acid | 21000543003 | 23 |
| Caelo | Citric acid | 21000543004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid | 21000543005 | 13 |
| Caelo | Citric acid | 21000543006 | 3 |
| Caelo | Citric acid | 21000543008 | 27 |
| Caelo | Citric acid | 21000543010 | 10 |
| Caelo | Citric acid | 21000543011 | 9 |
| Caelo | Citric acid | 21000544001 | 11 |
| Caelo | Citric acid | 21000544002 | 66 |
| Caelo | Citric acid | 21000544003 | 2 |
| Caelo | Citric acid | 21000544004 | 8 |
| Caelo | Citric acid | 21000544006 | 10 |
| Caelo | Citric acid | 2100054401 | 1 |
| Caelo | Citric acid | 2100054402 | 2 |
| Caelo | Citric acid | 2100054404 | 1 |
| Caelo | Citric acid | 210005543003 | 1 |
| Caelo | Citric acid | 210026570 | 1 |
| Caelo | Citric acid | 21002657001 | 9 |
| Caelo | Citric acid | 21002657002 | 11 |
| Caelo | Citric acid | 21002657003 | 35 |
| Caelo | Citric acid | 21002657004 | 1 |
| Caelo | Citric acid | 21002657006 | 7 |
| Caelo | Citric acid | 21002657012 | 6 |
| Caelo | Citric acid | 21002657015 | 15 |
| Caelo | Citric acid | 21002657016 | 4 |
| Caelo | Citric acid | 2100543006 | 1 |
| Caelo | Citric acid | 2100544002 | 1 |
| Caelo | Citric acid | 2100544004 | 1 |
| Caelo | Citric acid | 21531 | 1 |
| Caelo | Citric acid | 22000645001 | 8 |
| Caelo | Citric acid | 22000645004 | 3 |
| Caelo | Citric acid | 22000645005 | 2 |
| Caelo | Citric acid | 22000645008 | 1 |
| Caelo | Citric acid | 22002309004 | 1 |
| Caelo | Citric acid | 23003598004 | 1 |
| Caelo | Citric acid | 230313(21002657003) | 2 |
| Caelo | Citric acid | 2317M-01024 | 1 |
| Caelo | Citric acid | 2317Q-01024 | 1 |
| Caelo | Citric acid | 24021502 | 1 |
| Caelo | Citric acid | 26051803 | 1 |
| Caelo | Citric acid | 26071701 | 1 |
| Caelo | Citric acid | 26111301 | 1 |
| Caelo | Citric acid | 2617Q-01024 | 1 |
| Caelo | Citric acid | 27091303 | 1 |
| Caelo | Citric acid | 2716A-01024 | 1 |
| Caelo | Citric acid | 2789 | 1 |
| Caelo | Citric acid | 28021405 | 1 |
| Caelo | Citric acid | 28051401 | 1 |
| Caelo | Citric acid | 3091701 | 1 |
| Caelo | Citric acid | 3275 | 1 |
| Caelo | Citric acid | 4918Q-01024 | 1 |
| Caelo | Citric acid | 501170606 | 1 |
| Caelo | Citric acid | 5041802 | 1 |
| Caelo | Citric acid | 5315I-01024 | 1 |
| Caelo | Citric acid | 59(20000886009) | 1 |
| Caelo | Citric acid | 6071713 | 1 |
| Caelo | Citric acid | 6498011 | 2 |
| Caelo | Citric acid | 713I-01024 | 1 |
| Caelo | Citric acid | 7808 | 2 |
| Caelo | Citric acid | 8031702 | 1 |
| Caelo | Citric acid | 8306911 | 1 |
| Caelo | Citric acid | 886007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid | 9158408 | 1 |
| Caelo | Citric acid | 9199105 | 1 |
| Caelo | Citric acid | 9494185 | 1 |
| Caelo | Citric acid | A-040513-1 | 1 |
| Caelo | Citric acid | AP220721-01 | 1 |
| Caelo | Citric acid | jjjjjj | 1 |
| Caelo | Citric acid | L130404202 | 1 |
| Caelo | Citric acid | L1508013-01 | 1 |
| Caelo | Citric acid | L1609021-01 | 1 |
| Caelo | Citric acid | L1805017-03 | 2 |
| Caelo | Citric acid | nnnnn | 1 |
| Caelo | Citric acid | P-12061921/18097611 | 1 |
| Caelo | Citric acid | P-12081922/18312102 | 1 |
| Caelo | Citric acid | P170612AC06/19 | 1 |
| Caelo | Citric acid | xxxx | 1 |
| Caelo | Citric acid | xxxxxx | 1 |
| Caesar & Lorenz GmbH | Citric acid | 16004706 | 1 |
| Caesar & Lorenz | Citric acid | 21002657003 | 1 |
| Caesar & Loretz /Sanacorp | Citric acid | 20000886002 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 22002309004 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 16208614 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 15063203 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 192073002 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000543003 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 18306906 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 20000886009 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 18025702 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 18097611 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 192073003 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 192073005 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 192073009 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000543008 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000544006 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 22000645001 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000544001 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21002657006 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 18306905 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000544002 | 1 |
| Caesar & Loretz GmbH /G | Citric acid | 18306911 | 1 |
| Caesar & Loretz GmbH/ AEP | Citric acid | 192073003 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 17162712 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 18306909 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 192073009 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000543002 | 3 |
| Caesar & Loretz GmbH… | Citric acid | 21000543005 | 2 |
| Caesar & Loretz GmbH… | Citric acid | 20000886003 | 1 |
| Caesar & Loretz GmbH/AEP | Citric acid | 192073005 | 3 |
| Caesar & Loretz GmbH/AEP | Citric acid | 21002657001 | 1 |
| Caesar & Loretz GmbH/AHD | Citric acid | 18306906 | 1 |
| Caesar & Loretz GmbH/AHD | Citric acid | 20000886003 | 1 |
| Caesar & Loretz GmbH/AHD | Citric acid | 21000544002 | 2 |
| Caesar & Loretz GmbH… | Citric acid | 21000543011 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000544001 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000544002 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 20000886003 | 1 |
| Caesar & Loretz GmbH/E | Citric acid | 21000543003 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 18306902 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 192073009 | 1 |
| Caesar & Loretz GmbH… | Citric acid | 21000543010 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 18129211 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Citric acid | 18306905 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 18306911 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 18307104 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 18312107 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 192073005 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 192073009 | 2 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 20000886007 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 20000886009 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 20003515003 | 1 |
| Caesar & Loretz GmbH/GEHE | Citric acid | 20003515004 | 1 |
| Caesar & Loretz GmbH/GEHE | Citric acid | 21000544001 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid | 23003598004 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21002657006 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 19073004 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 192073009 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 20000886003 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21000544002 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 22002309004 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18306906 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 18306909 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 18306911 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 20003515003 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 20000886002 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 18306906 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 18306908 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 192073003 | 4 |
| Caesar & Loretz GmbH... | Citric acid | 21000543006 | 4 |
| Caesar & Loretz GmbH... | Citric acid | 21000543008 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 21000544002 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 21002657002 | 1 |
| Caesar & Loretz GmbH/P | Citric acid | 192073002 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18097611 | 3 |
| Caesar & Loretz GmbH... | Citric acid | 18306905 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18306909 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 2000886003 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21000544002 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21000544004 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 21002657002 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21000543006 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18097606 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18306906 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18306908 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18307104 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 192073002 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 20000886007 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 20000886009 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21000543008 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21000544002 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21002657002 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21002657015 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 192073002 | 1 |
| Caesar & Loretz GmbH/Sa | Citric acid | 192073003 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 192036004 | 1 |
| Caesar & Loretz GmbH/Sana | Citric acid | 20000886009 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 192036009 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18306909 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 18312104 | 2 |
| Caesar & Loretz GmbH... | Citric acid | 192073003 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 20003515003 | 1 |
| Caesar & Loretz GmbH... | Citric acid | 21000544002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Citric acid | 21002657001 | 1 |
| Caesar & Loretz GmbH/Sani | Citric acid | 20003515003 | 1 |
| Caesar & Loretz GmbH | Citric acid | 13243201 | 1 |
| Caesar & Loretz GmbH | Citric acid | 13243214 | 1 |
| Caesar & Loretz GmbH | Citric acid | 15063003 | 2 |
| Caesar & Loretz GmbH | Citric acid | 15063203 | 1 |
| Caesar & Loretz GmbH | Citric acid | 16208607 | 1 |
| Caesar & Loretz GmbH | Citric acid | 16208614 | 1 |
| Caesar & Loretz GmbH | Citric acid | 162154403 | 1 |
| Caesar & Loretz GmbH | Citric acid | 17162602 | 1 |
| Caesar & Loretz GmbH | Citric acid | 17162701 | 1 |
| Caesar & Loretz GmbH | Citric acid | 17329502 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18025701 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18097606 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18097611 | 2 |
| Caesar & Loretz GmbH | Citric acid | 18129204 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18129205 | 2 |
| Caesar & Loretz GmbH | Citric acid | 18129207 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18306902 | 5 |
| Caesar & Loretz GmbH | Citric acid | 18306903 | 5 |
| Caesar & Loretz GmbH | Citric acid | 18306904 | 2 |
| Caesar & Loretz GmbH | Citric acid | 18306905 | 19 |
| Caesar & Loretz GmbH | Citric acid | 18306906 | 11 |
| Caesar & Loretz GmbH | Citric acid | 18306908 | 3 |
| Caesar & Loretz GmbH | Citric acid | 18306909 | 11 |
| Caesar & Loretz GmbH | Citric acid | 18306911 | 15 |
| Caesar & Loretz GmbH | Citric acid | 18307102 | 2 |
| Caesar & Loretz GmbH | Citric acid | 18307104 | 6 |
| Caesar & Loretz GmbH | Citric acid | 18312103 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18312104 | 9 |
| Caesar & Loretz GmbH | Citric acid | 18312107 | 2 |
| Caesar & Loretz GmbH | Citric acid | 18312109 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18F25-B02 | 1 |
| Caesar & Loretz GmbH | Citric acid | 18F25-B02_351454 | 1 |
| Caesar & Loretz GmbH | Citric acid | 192036002 | 2 |
| Caesar & Loretz GmbH | Citric acid | 192036003 | 14 |
| Caesar & Loretz GmbH | Citric acid | 192036004 | 2 |
| Caesar & Loretz GmbH | Citric acid | 192036009 | 1 |
| Caesar & Loretz GmbH | Citric acid | 192073002 | 10 |
| Caesar & Loretz GmbH | Citric acid | 192073003 | 4 |
| Caesar & Loretz GmbH | Citric acid | 192073004 | 8 |
| Caesar & Loretz GmbH | Citric acid | 192073005 | 10 |
| Caesar & Loretz GmbH | Citric acid | 192073009 | 9 |
| Caesar & Loretz GmbH | Citric acid | 192073010 | 4 |
| Caesar & Loretz GmbH | Citric acid | 19H23-B07 | 1 |
| Caesar & Loretz GmbH | Citric acid | 200000886003 | 1 |
| Caesar & Loretz GmbH | Citric acid | 20000886002 | 16 |
| Caesar & Loretz GmbH | Citric acid | 20000886003 | 7 |
| Caesar & Loretz GmbH | Citric acid | 20000886007 | 7 |
| Caesar & Loretz GmbH | Citric acid | 20000886008 | 3 |
| Caesar & Loretz GmbH | Citric acid | 20000886009 | 13 |
| Caesar & Loretz GmbH | Citric acid | 20003515002 | 2 |
| Caesar & Loretz GmbH | Citric acid | 20003515003 | 4 |
| Caesar & Loretz GmbH | Citric acid | 20003515004 | 1 |
| Caesar & Loretz GmbH | Citric acid | 20003515008 | 1 |
| Caesar & Loretz GmbH | Citric acid | 20003515010 | 2 |
| Caesar & Loretz GmbH | Citric acid | 20003515014 | 2 |
| Caesar & Loretz GmbH | Citric acid | 21000020004 | 1 |
| Caesar & Loretz GmbH | Citric acid | 210000544002 | 1 |
| Caesar & Loretz GmbH | Citric acid | 21000543002 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Citric acid | 21000543003 | 3 |
| Caesar & Loretz GmbH | Citric acid | 21000543005 | 4 |
| Caesar & Loretz GmbH | Citric acid | 21000543008 | 6 |
| Caesar & Loretz GmbH | Citric acid | 21000543010 | 7 |
| Caesar & Loretz GmbH | Citric acid | 21000543011 | 1 |
| Caesar & Loretz GmbH | Citric acid | 21000544001 | 8 |
| Caesar & Loretz GmbH | Citric acid | 21000544002 | 20 |
| Caesar & Loretz GmbH | Citric acid | 21000544004 | 11 |
| Caesar & Loretz GmbH | Citric acid | 21000544006 | 4 |
| Caesar & Loretz GmbH | Citric acid | 21002657001 | 7 |
| Caesar & Loretz GmbH | Citric acid | 21002657002 | 6 |
| Caesar & Loretz GmbH | Citric acid | 21002657003 | 12 |
| Caesar & Loretz GmbH | Citric acid | 21002657006 | 4 |
| Caesar & Loretz GmbH | Citric acid | 21002657015 | 4 |
| Caesar & Loretz GmbH | Citric acid | 21002657016 | 1 |
| Caesar & Loretz GmbH | Citric acid | 2100543003 | 1 |
| Caesar & Loretz GmbH | Citric acid | 22000645001 | 4 |
| Caesar & Loretz Hilden | Citric acid | 18312104 | 1 |
| Caesar & Loretz Hilden | Citric acid | 18312109 | 1 |
| Caesar & Loretz/ Noweda | Citric acid | 12156812 | 1 |
| Caesar & Loretz/Geil... | Citric acid | 20003515003 | 1 |
| Caesar & Loretz/Noweda | Citric acid | 20003515003 | 1 |
| Caesar & Loretz | Citric acid | 15087904 | 2 |
| Caesar & Loretz | Citric acid | 16038613 | 1 |
| Caesar & Loretz | Citric acid | 18097603 | 1 |
| Caesar & Loretz | Citric acid | 18307102 | 1 |
| Caesar / Gehe | Citric acid | 15087904 | 1 |
| Caesar u. Loretz GmbH | Citric acid | 18307104 | 1 |
| Caesar u. Loretz GmbH | Citric acid | 192073005 | 1 |
| Caesar u. Loretz GmbH | Citric acid | 21000544001 | 1 |
| Caesar und Loretz | Citric acid | 18306911 | 1 |
| Caesar&Lorenz | Citric acid | 21000544002 | 1 |
| Caesar&Loretz GmbH,1... | Citric acid | 16004706 | 1 |
| Caesar&Loretz GmbH | Citric acid | 15063213 | 1 |
| Caesar&Loretz GmbH | Citric acid | 16038604 | 1 |
| Caesar&Loretz GmbH | Citric acid | 22000645001 | 1 |
| Caesar&loretz,Phoenix | Citric acid | 13243201 | 1 |
| Caesar&Loretz/Geilen... | Citric acid | 18312104 | 1 |
| Caesar/Lorenz | Citric acid | 13050610 | 1 |
| Caesar/Noweda | Citric acid | 12B01-N01 | 2 |
| Caleo/ Noweda | Citric acid | 18097607 | 1 |
| Caleo/Fiebig | Citric acid | 18025704 | 1 |
| Caleo | Citric acid | 16038613 | 1 |
| Caolo- Noweda | Citric acid | 15063213 | 1 |
| Cealo / Otto Geilenk... | Citric acid | 18306909 | 1 |
| Cealo/AHD | Citric acid | 16038704 | 1 |
| Cealo/Anzag | Citric acid | 16208607 | 1 |
| Cealo/Sanacorp | Citric acid | 17329502 | 1 |
| Cealo | Citric acid | 14186301 | 3 |
| Cealo | Citric acid | 16004701 | 1 |
| Cealo | Citric acid | 18025701 | 2 |
| Cordes/Noweda | Citric acid | 16208607 | 1 |
| E Plus | Citric acid | 16208613 | 1 |
| Ebert & Jacobi 12... | Citric acid | 1506214 | 1 |
| Ebert & Jacobi | Citric acid | 16215403 | 1 |
| Ebert & Jacobi | Citric acid | 6493071 | 1 |
| Ebert-Jacobi | Citric acid | 16208607 | 1 |
| Eu Rho | Citric acid | L1202001-01 | 1 |
| EuRho/Alliance Healthcare | Citric acid | L1609021-02 | 1 |
| EuRho/Phönix | Citric acid | L1408011-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Citric acid | 2112002-01 | 1 |
| euro / Phoenix 19.02.2018 | Citric acid | 11609021 | 1 |
| Euro OTC | Citric acid | | 4 |
| Euro OTC | Citric acid | 1011047-03 | 2 |
| Euro OTC | Citric acid | 1018M-01024 | 1 |
| Euro OTC | Citric acid | 1018M-0124 | 1 |
| Euro OTC | Citric acid | 1275983 | 2 |
| Euro OTC | Citric acid | 13175410 | 1 |
| Euro OTC | Citric acid | 13396515 | 1 |
| Euro OTC | Citric acid | 13K18-B34 | 1 |
| Euro OTC | Citric acid | 1406014-02 | 1 |
| Euro OTC | Citric acid | 150317-965 | 1 |
| Euro OTC | Citric acid | 1505029B | 1 |
| Euro OTC | Citric acid | 15G16-B01-330449 | 3 |
| Euro OTC | Citric acid | 16004702 | 1 |
| Euro OTC | Citric acid | 16038713 | 1 |
| Euro OTC | Citric acid | 17162601 | 2 |
| Euro OTC | Citric acid | 17329502 | 1 |
| Euro OTC | Citric acid | 2112002-01 | 2 |
| Euro OTC | Citric acid | 2112002-02 | 1 |
| Euro OTC | Citric acid | 2301021-01 | 2 |
| Euro OTC | Citric acid | 2310005-01 | 1 |
| Euro OTC | Citric acid | 702260 | 5 |
| Euro OTC | Citric acid | Intern-Ch1018M-01024 | 1 |
| Euro OTC | Citric acid | L1202001-01 | 5 |
| Euro OTC | Citric acid | L1202001-02 | 1 |
| Euro OTC | Citric acid | L130404201 | 2 |
| Euro OTC | Citric acid | L1304042-01 | 2 |
| Euro OTC | Citric acid | L1304042-02 | 1 |
| Euro OTC | Citric acid | L1408011-01 | 2 |
| Euro OTC | Citric acid | L1408011-02 | 2 |
| Euro OTC | Citric acid | L1503027-01 | 1 |
| Euro OTC | Citric acid | L1503027-02 | 7 |
| Euro OTC | Citric acid | L1508013-01 | 4 |
| Euro OTC | Citric acid | L1508013-02 | 1 |
| Euro OTC | Citric acid | L1604061-02 | 5 |
| Euro OTC | Citric acid | L1604062-01 | 1 |
| Euro OTC | Citric acid | L160461-02 | 1 |
| Euro OTC | Citric acid | L1609021-01 | 8 |
| Euro OTC | Citric acid | L1609021-02 | 4 |
| Euro OTC | Citric acid | L1805017-01 | 2 |
| Euro OTC | Citric acid | L1812017-01 | 5 |
| Euro OTC | Citric acid | L1812017-02 | 1 |
| Euro OTC | Citric acid | L2002036-01 | 2 |
| Euro OTC | Citric acid | L2002036-02 | 1 |
| Euro OTC | Citric acid | L2010013-01 | 2 |
| Fa.Phönix | Citric acid | 20000886009 | 1 |
| Fagron | Citric acid | | 1 |
| Fagron | Citric acid | 100614d | 1 |
| Fagron | Citric acid | 10G21-N05 | 2 |
| Fagron | Citric acid | 1151608 | 2 |
| Fagron | Citric acid | 1155609 | 9 |
| Fagron | Citric acid | 1156158 | 1 |
| Fagron | Citric acid | 1172673 | 10 |
| Fagron | Citric acid | 1181765 | 3 |
| Fagron | Citric acid | 11C24-N02 | 3 |
| Fagron | Citric acid | 11C24N022869/4250 | 1 |
| Fagron | Citric acid | 11C24-N03 | 6 |
| Fagron | Citric acid | 11H30-N05 | 1 |
| Fagron | Citric acid | 11K07N01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Citric acid | 11K07-N01 | 7 |
| Fagron | Citric acid | 11K11-N02 | 2 |
| Fagron | Citric acid | 11K11-N020444/1975 | 1 |
| Fagron | Citric acid | 12175711 | 1 |
| Fagron | Citric acid | 12801-N01 | 1 |
| Fagron | Citric acid | 12b01-N01 | 1 |
| Fagron | Citric acid | 12B01N01 | 1 |
| Fagron | Citric acid | 12B01-N01 | 20 |
| Fagron | Citric acid | 12B01-No1 | 1 |
| Fagron | Citric acid | 12B01-NO1 | 1 |
| Fagron | Citric acid | 12BO1-N01 | 1 |
| Fagron | Citric acid | 12F06-M06 | 3 |
| Fagron | Citric acid | 13804-N02 | 1 |
| Fagron | Citric acid | 13A04N04 | 1 |
| Fagron | Citric acid | 13A04-N04 | 16 |
| Fagron | Citric acid | 13A-04-N04 | 2 |
| Fagron | Citric acid | 13A04-N040019/4900 | 1 |
| Fagron | Citric acid | 13A04-NO4 | 1 |
| Fagron | Citric acid | 13B04-N01 | 1 |
| Fagron | Citric acid | 13F12-N01 | 3 |
| Fagron | Citric acid | 13F12-N08 | 1 |
| Fagron | Citric acid | 13G04-N05 | 5 |
| Fagron | Citric acid | 13G24N13 | 2 |
| Fagron | Citric acid | 13G24-N13 | 10 |
| Fagron | Citric acid | 13G24-N24 | 13 |
| Fagron | Citric acid | 13G24-N240029/900 | 1 |
| Fagron | Citric acid | 13G24-N240739/900 | 1 |
| Fagron | Citric acid | 13H22-N09 | 2 |
| Fagron | Citric acid | 13K18-B34 | 5 |
| Fagron | Citric acid | 13K18-B34_291522 | 1 |
| Fagron | Citric acid | 13K18-B34-288371 | 4 |
| Fagron | Citric acid | 13k18-B34-288372 | 1 |
| Fagron | Citric acid | 13K18-B34-288372 | 7 |
| Fagron | Citric acid | 13K18-B34-288373 | 1 |
| Fagron | Citric acid | 13K18-B34-291071 | 4 |
| Fagron | Citric acid | 13K18-B34-291072 | 2 |
| Fagron | Citric acid | 13K18-B34-291519 | 5 |
| Fagron | Citric acid | 13K18-B34-291520 | 4 |
| Fagron | Citric acid | 13K18-B34-291521 | 4 |
| Fagron | Citric acid | 13k18-b34-291522 | 1 |
| Fagron | Citric acid | 13K18-B34-291522 | 6 |
| Fagron | Citric acid | 13K18-B34-291523 | 2 |
| Fagron | Citric acid | 13K18-B34-293871 | 2 |
| Fagron | Citric acid | 13L05-B02-296246 | 3 |
| Fagron | Citric acid | 13L05B02296247 | 1 |
| Fagron | Citric acid | 13L05-B02-309050 | 1 |
| Fagron | Citric acid | 13L18-B39-289347 | 4 |
| Fagron | Citric acid | 14b06-b07-293872 | 1 |
| Fagron | Citric acid | 14E06-B07293872 | 1 |
| Fagron | Citric acid | 14E06-B07-293872 | 4 |
| Fagron | Citric acid | 14E06-B07293873 | 1 |
| Fagron | Citric acid | 14E06-B07-293873 | 1 |
| Fagron | Citric acid | 14E06-B07-293875 | 3 |
| Fagron | Citric acid | 14E06-B07-293890 | 4 |
| Fagron | Citric acid | 14E-06-B07-293890 | 1 |
| Fagron | Citric acid | 14G04-B09-293874 | 11 |
| Fagron | Citric acid | 14G04-b09-293876 | 1 |
| Fagron | Citric acid | 14G04B09293876 | 1 |
| Fagron | Citric acid | 14G04-B09-293876 | 4 |
| Fagron | Citric acid | 14g04-b09293877 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Citric acid | 14G04-B09-293877 | 10 |
| Fagron | Citric acid | 14G04-B09-296361 | 1 |
| Fagron | Citric acid | 14G04-B09-309707 | 1 |
| Fagron | Citric acid | 14G04-B09-309836 | 3 |
| Fagron | Citric acid | 14K05_B04_302815 | 1 |
| Fagron | Citric acid | 14K05-B04-302815 | 6 |
| Fagron | Citric acid | 14k05-b04-302816 | 1 |
| Fagron | Citric acid | 14K05-B04-302816 | 6 |
| Fagron | Citric acid | 14K05-B04-302817 | 2 |
| Fagron | Citric acid | 14K05-B04-302826 | 1 |
| Fagron | Citric acid | 15044902 | 1 |
| Fagron | Citric acid | 15G16b01 | 1 |
| Fagron | Citric acid | 15G16B01 | 1 |
| Fagron | Citric acid | 15G16-B01 | 2 |
| Fagron | Citric acid | 15G16-B01330449 | 2 |
| Fagron | Citric acid | 15G16-B01-330449 | 9 |
| Fagron | Citric acid | 15g16-b01-330450 | 2 |
| Fagron | Citric acid | 15G16B01330450 | 1 |
| Fagron | Citric acid | 15G16-B01330450 | 1 |
| Fagron | Citric acid | 15G16-B01-330450 | 6 |
| Fagron | Citric acid | 15G16-B01-330450 | 1 |
| Fagron | Citric acid | 15l01-B06-324348 | 1 |
| Fagron | Citric acid | 16072014B | 1 |
| Fagron | Citric acid | 16208607 | 1 |
| Fagron | Citric acid | 1714Q1024 | 1 |
| Fagron | Citric acid | 17E15-B04 | 2 |
| Fagron | Citric acid | 17E15-B04-335435 | 3 |
| Fagron | Citric acid | 17E15-B04-341741 | 1 |
| Fagron | Citric acid | 17E15-B04-345678 | 6 |
| Fagron | Citric acid | 17E15-B04-345679 | 3 |
| Fagron | Citric acid | 17E15-B04-347168 | 3 |
| Fagron | Citric acid | 17E15-B04-347169 | 3 |
| Fagron | Citric acid | 18129205 | 1 |
| Fagron | Citric acid | 18F25-B02 | 1 |
| Fagron | Citric acid | 18F25-B02-351448 | 1 |
| Fagron | Citric acid | 18F25-B02-351454 | 1 |
| Fagron | Citric acid | 18F25-B02-355281 | 3 |
| Fagron | Citric acid | 18F25-B02-355298 | 2 |
| Fagron | Citric acid | 1913A-01024 | 1 |
| Fagron | Citric acid | 19B06-B02-191458 | 1 |
| Fagron | Citric acid | 19h23-B07-194438 | 1 |
| Fagron | Citric acid | 19H23-B07-194438 | 4 |
| Fagron | Citric acid | 19H23B07194441 | 1 |
| Fagron | Citric acid | 19H23-B07-200458 | 1 |
| Fagron | Citric acid | 19H23-Bo7-200458 | 1 |
| Fagron | Citric acid | 20071203 | 1 |
| Fagron | Citric acid | 20F16-B02-201199 | 2 |
| Fagron | Citric acid | 20G31-B01-201878 | 3 |
| Fagron | Citric acid | 20L01-B10-202958 | 2 |
| Fagron | Citric acid | 214U-01024 | 1 |
| Fagron | Citric acid | 21F00-B04-218885 | 1 |
| Fagron | Citric acid | 21F11-804-218885 | 1 |
| Fagron | Citric acid | 21F11-B03-216679 | 1 |
| Fagron | Citric acid | 21F11-B04-213768 | 2 |
| Fagron | Citric acid | 21F11-B04-218885 | 2 |
| Fagron | Citric acid | 21F11-B04-221484 | 1 |
| Fagron | Citric acid | 2203140l | 1 |
| Fagron | Citric acid | 22G15-B05-220815 | 1 |
| Fagron | Citric acid | 26082013B | 1 |
| Fagron | Citric acid | 28021404 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Citric acid | 20F16-B02_201199 | 1 |
| Fagron | Citric acid | 330449 | 1 |
| Fagron | Citric acid | 351453 | 1 |
| Fagron | Citric acid | 4111A | 1 |
| Fagron | Citric acid | 4810E-01024 | 1 |
| Fagron | Citric acid | 6496091 | 1 |
| Fagron | Citric acid | 700309-0001 | 1 |
| Fagron | Citric acid | 700309-0003 | 2 |
| Fagron | Citric acid | 700309-0006 | 1 |
| Fagron | Citric acid | 700309-001 | 1 |
| Fagron | Citric acid | 7200458 | 1 |
| Fagron | Citric acid | L1604061-02 | 1 |
| Fagron | Citric acid | L1812017-01 | 2 |
| Fagron | Citric acid | probe | 1 |
| Fagron | Citric acid | UJ051 | 1 |
| Fagron | Citric acid | UJ501 | 2 |
| Fargon/Sanacorp | Citric acid | | 1 |
| Fargon | Citric acid | 12B01-N01 | 1 |
| Fargon | Citric acid | 12B01-NN01 | 1 |
| fargon | Citric acid | 13A04-N04 | 1 |
| Faron | Citric acid | UJ45 | 1 |
| Fiebig | Citric acid | 13243201 | 1 |
| Fiebig | Citric acid | 14K05-B04-302815 | 1 |
| Fiebig | Citric acid | 15063204 | 1 |
| Fiebig | Citric acid | 17162702 | 1 |
| Finze | Citric acid | 12156812 | 2 |
| Fischar/Noweda | Citric acid | 6494061 | 1 |
| Fischar | Citric acid | 649061 | 2 |
| fischar | Citric acid | 6491041 | 1 |
| Fischar | Citric acid | 6491041 | 2 |
| Fischar | Citric acid | 6493071 | 2 |
| fischar | Citric acid | 6494061 | 6 |
| Fischar | Citric acid | 6494061 | 2 |
| Fischar | Citric acid | 6496091 | 2 |
| Fischar | Citric acid | 6498011 | 2 |
| Fischar | Citric acid | 6499061 | 1 |
| Fischer/Noweda | Citric acid | 6496091 | 1 |
| fishar | Citric acid | 6494061 | 1 |
| Fragon/Phoenix | Citric acid | 14G04-B09-293976 | 1 |
| Fragon/Phönix | Citric acid | 18F25-B02-351463 | 1 |
| Fragron/Noweda | Citric acid | 15G16-B01-330449 | 1 |
| GEHE 02.07.2014 | Citric acid | 13243217 | 1 |
| Gehe 21-01-2019 | Citric acid | 18097609 | 1 |
| Gehe amax | Citric acid | 18129205 | 1 |
| Gehe amax | Citric acid | 192036003 | 1 |
| Gehe Kassel, 22.05.2015 | Citric acid | 14E06-B07-293872 | 1 |
| Gehe Rostock | Citric acid | 21000543006 | 1 |
| Gehe/Euro | Citric acid | 160406-02 | 1 |
| Gehe/Fragon | Citric acid | 14G04B09293876 | 1 |
| Gehe | Citric acid | 11C24-N02 | 1 |
| Gehe | Citric acid | 11C24-N03 | 2 |
| Gehe | Citric acid | 11K07-N01 | 2 |
| Gehe | Citric acid | 12043111 | 1 |
| Gehe | Citric acid | 13175403 | 1 |
| Gehe | Citric acid | 13175404 | 1 |
| Gehe | Citric acid | 15044902 | 1 |
| Gehe | Citric acid | 15063003 | 1 |
| Gehe | Citric acid | 15063203 | 1 |
| Gehe | Citric acid | 15063217 | 1 |
| Gehe | Citric acid | 15087902 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Citric acid | 15G16-B01-330450 | 1 |
| Gehe | Citric acid | 16004706 | 1 |
| Gehe | Citric acid | 16038614 | 1 |
| GEHE | Citric acid | 16208606 | 1 |
| Gehe | Citric acid | 16208612 | 1 |
| Gehe | Citric acid | 17162601 | 2 |
| Gehe | Citric acid | 17162602 | 1 |
| Gehe | Citric acid | 17162603 | 1 |
| GEHE | Citric acid | 17329511 | 2 |
| Gehe | Citric acid | 18097607 | 1 |
| GEHE | Citric acid | 18097607 | 1 |
| GEHE | Citric acid | 18097611 | 1 |
| Gehe | Citric acid | 18306906 | 1 |
| Gehe | Citric acid | 18307102 | 1 |
| Gehe | Citric acid | 192073009 | 1 |
| Gehe | Citric acid | 20000886003 | 1 |
| Gehe | Citric acid | 21000544001 | 1 |
| Gehe | Citric acid | 21000544004 | 2 |
| Gehe | Citric acid | 21002657003 | 1 |
| GEHE | Citric acid | 21002657003 | 1 |
| Gehe | Citric acid | 22000645004 | 1 |
| Gehe | Citric acid | 22000645009 | 1 |
| Gehe | Citric acid | 22000645011 | 1 |
| GEHE | Citric acid | 22000645011 | 1 |
| Gehe | Citric acid | 22002309001 | 1 |
| Gehe | Citric acid | 23003598004 | 2 |
| GEHE | Citric acid | 24001159002 | 1 |
| Geilenkirchen | Citric acid | 16208606 | 1 |
| Geilenkirchen | Citric acid | 18306906 | 1 |
| Geilenkirchen | Citric acid | 21000544002 | 1 |
| Hedinger | Citric acid | 18306906 | 1 |
| Henry Lamotte Oils GmbH | Citric acid | | 1 |
| Hepart | Citric acid | 16208614 | 1 |
| Ichthyol | Citric acid | 16038608 | 1 |
| Ichtyhol Gesellschaf... | Citric acid | 16038618 | 1 |
| Jenne 05.11.21 EK:6,97EUR | Citric acid | 211108C | 1 |
| Jenne | Citric acid | 15063002 | 1 |
| Jenne | Citric acid | 200000886007 | 1 |
| Jenne | Citric acid | 21002657015 | 1 |
| Jenne | Citric acid | 22002309008 | 1 |
| Jungbunzlauer Ladenb... | Citric acid | 1156158 | 1 |
| Jungbunzlauer Ladenb... | Citric acid | 1155609 | 1 |
| Jungbunzlauer Ladenb... | Citric acid | 12B01-N01 | 3 |
| Kehr Holdermann | Citric acid | 22002309008 | 1 |
| Kehr.21.07.2020 | Citric acid | 192073004 | 1 |
| Kehr.28.04.2020 | Citric acid | 192073005 | 2 |
| Kehr | Citric acid | 17162602 | 1 |
| Kehr | Citric acid | 22000645011 | 1 |
| Kehr | Citric acid | 22002250001 | 1 |
| Kehr | Citric acid | 22002309004 | 1 |
| Kehr | Citric acid | 23003598004 | 1 |
| Kehr | Citric acid | 24001159002 | 1 |
| Kehr | Citric acid | 6494111 | 1 |
| Klenk | Citric acid | 13243201 | 1 |
| Klosterring | Citric acid | 16208614 | 2 |
| Krieger | Citric acid | 16038606 | 2 |
| Krieger | Citric acid | 21002657015 | 1 |
| Krömpke | Citric acid | 12B01-N01 | 2 |
| L10 | Citric acid | 18025704 | 2 |
| L10 | Citric acid | 9494185 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Lamotte | Citric acid | 15063213 | 1 |
| Max Jenne | Citric acid | 22002309004 | 1 |
| Merck | Citric acid | | 1 |
| Merck | Citric acid | K53604941 | 1 |
| Nachtestung-Verlängerung | Citric acid | 278/18 | 1 |
| Noweda 13.6.2019 | Citric acid | 18306905 | 2 |
| Noweda EG Essen | Citric acid | 24001159002 | 1 |
| Noweda | Citric acid | 12043110 | 1 |
| Noweda | Citric acid | 13050601 | 1 |
| Noweda | Citric acid | 13050621 | 1 |
| Noweda | Citric acid | 13243216 | 1 |
| Noweda | Citric acid | 15063203 | 1 |
| Noweda | Citric acid | 16004701 | 1 |
| Noweda | Citric acid | 16208606 | 3 |
| Noweda | Citric acid | 16208607 | 1 |
| Noweda | Citric acid | 16208614 | 1 |
| Noweda | Citric acid | 18025701 | 1 |
| Noweda | Citric acid | 18025704 | 1 |
| Noweda | Citric acid | 18097606 | 1 |
| Noweda | Citric acid | 18306903 | 1 |
| Noweda | Citric acid | 18306906 | 2 |
| Noweda | Citric acid | 18306911 | 1 |
| Noweda | Citric acid | 18307102 | 1 |
| Noweda | Citric acid | 18312104 | 1 |
| Noweda | Citric acid | 20000886002 | 1 |
| Noweda | Citric acid | 20000886009 | 1 |
| Noweda | Citric acid | 21000543008 | 1 |
| Noweda | Citric acid | 21000543010 | 1 |
| Noweda | Citric acid | 21002657003 | 2 |
| Noweda | Citric acid | 21002657015 | 2 |
| Noweda | Citric acid | 21002657016 | 1 |
| Noweda | Citric acid | 21002657017 | 1 |
| Noweda | Citric acid | 2100657003 | 1 |
| Noweda | Citric acid | 220002309004 | 1 |
| Noweda | Citric acid | 22000645001 | 1 |
| Noweda | Citric acid | 22000645005 | 1 |
| Noweda | Citric acid | 22000645008 | 2 |
| Noweda | Citric acid | 22000645009 | 1 |
| Noweda | Citric acid | 22002309001 | 1 |
| Noweda | Citric acid | 22002309004 | 3 |
| Noweda | Citric acid | 23003598004 | 6 |
| Noweda | Citric acid | 23003598009 | 2 |
| Noweda | Citric acid | 2301021-01 | 1 |
| Noweda | Citric acid | 6491041 | 2 |
| Noweda | Citric acid | L1202001-02 | 1 |
| O.Fischer GmbH/Anzag... | Citric acid | 6498011 | 1 |
| Otto Fischar GmbH&Co KG | Citric acid | 6496091 | 1 |
| Otto Fischar GmbH&Co. KG | Citric acid | 6496051 | 1 |
| Otto Fischar GmbH/ N... | Citric acid | 6494061 | 1 |
| Otto Fischar GmbH | Citric acid | 6498011 | 1 |
| Otto Fischar/Kehr | Citric acid | 6498011 | 1 |
| Otto Fischar | Citric acid | 6494061 | 1 |
| Otto Fischar | Citric acid | 6498011 | 1 |
| Otto Fischer / Sana | Citric acid | 6493071 | 1 |
| Otto Fischer GmbH & ... | Citric acid | 6496091 | 1 |
| Otto Fischer GmbH/Sana | Citric acid | 6497051 | 1 |
| Otto Fischer GmbH | Citric acid | 6492061 | 1 |
| Otto Fishar | Citric acid | 6496091 | 2 |
| Phoenix 07.04.2014 | Citric acid | 13A04-N04 | 1 |
| Phoenix 12.12.2016 4,59EUR | Citric acid | 1508808 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix 14.08.2017 | Citric acid | 16038712 | 1 |
| Phoenix 29.05.2019 2,48EUR | Citric acid | 18306902 | 1 |
| Phoenix 31.01.2019 | Citric acid | 18097607 | 1 |
| phoenix 5.6.14 | Citric acid | 1172673 | 1 |
| Phoenix | Citric acid | 1172673 | 1 |
| Phoenix | Citric acid | 12b01-N01 | 1 |
| Phoenix | Citric acid | 13243202 | 1 |
| Phoenix | Citric acid | 13K18-B34-288372 | 1 |
| Phoenix | Citric acid | 16208606 | 1 |
| Phoenix | Citric acid | 16208614 | 1 |
| Phoenix | Citric acid | 18025701 | 1 |
| Phoenix | Citric acid | 18097603 | 1 |
| Phoenix | Citric acid | 18097607 | 1 |
| Phoenix | Citric acid | 18306911 | 1 |
| Phoenix | Citric acid | 19B06-B02-191458 | 1 |
| Phoenix | Citric acid | 20000886009 | 1 |
| Phoenix | Citric acid | 21000544002 | 2 |
| Phoenix | Citric acid | 21002657015 | 1 |
| Phoenix | Citric acid | 22000645011 | 1 |
| Phoenix | Citric acid | 22002309004 | 1 |
| Phoenix | Citric acid | 2202309004 | 1 |
| Phoenix | Citric acid | 23003598004 | 1 |
| Phoenix | Citric acid | 2310005-01 | 1 |
| Phönix Gotha | Citric acid | 12B01-N011973/6000 | 1 |
| Phönix Gotha | Citric acid | 12B01-N012028/6000 | 1 |
| Phönix Gotha | Citric acid | 12B01-N012125/6000 | 1 |
| Phönix Gotha | Citric acid | 13050609 | 1 |
| Phönix Gotha | Citric acid | 13050618 | 1 |
| Phönix Gotha | Citric acid | 13A04-N040049-100 | 1 |
| Phönix/Fagon | Citric acid | 14604-B09-293876 | 1 |
| Phönix/Fischar | Citric acid | 6497051 | 2 |
| Phönix/Gehe | Citric acid | 16208614 | 1 |
| Phönix | Citric acid | 10005440022 | 1 |
| Phönix | Citric acid | 1155609 | 1 |
| Phönix | Citric acid | 123456 | 1 |
| Phönix | Citric acid | 13A04-N04 | 1 |
| Phönix | Citric acid | 14G04-B09-293876 | 3 |
| Phönix | Citric acid | 15063213 | 1 |
| phönix | Citric acid | 16038604 | 3 |
| phönix | Citric acid | 16208608 | 1 |
| Phönix | Citric acid | 16208613 | 1 |
| Phönix | Citric acid | 16215406 | 1 |
| Phönix | Citric acid | 18025702 | 2 |
| Phönix | Citric acid | 18025704 | 1 |
| Phönix | Citric acid | 18097601 | 1 |
| Phönix | Citric acid | 18097603 | 3 |
| Phönix | Citric acid | 18097607 | 1 |
| Phönix | Citric acid | 18097609 | 2 |
| Phönix | Citric acid | 192073003 | 1 |
| Phönix | Citric acid | 192073005 | 1 |
| Phönix | Citric acid | 20000886002 | 1 |
| Phönix | Citric acid | 20000886003 | 1 |
| Phönix | Citric acid | 20000886009 | 1 |
| Phönix | Citric acid | 21000543002 | 1 |
| Phönix | Citric acid | 21000543011 | 1 |
| Phönix | Citric acid | 21000544004 | 1 |
| Phönix | Citric acid | 21002657003 | 1 |
| Phönix | Citric acid | 21002657015 | 1 |
| Phönix | Citric acid | 22002309004 | 1 |
| Phönix | Citric acid | 22002309008 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Citric acid | 23003598004 | 2 |
| Reichelt | Citric acid | 15G16-B01-330449 | 4 |
| Röntgen | Citric acid | 18097609 | 2 |
| Sanacorb;20.04.15; 7,45EUR | Citric acid | 1375410 | 1 |
| Sanacorp/Bionorica Ethics | Citric acid | 16038622 | 1 |
| Sanacorp | Citric acid | 12156811 | 1 |
| Sanacorp | Citric acid | 12156823 | 1 |
| Sanacorp | Citric acid | 12156824 | 1 |
| Sanacorp | Citric acid | 12156832 | 1 |
| Sanacorp | Citric acid | 1216832 | 1 |
| Sanacorp | Citric acid | 13050604 | 1 |
| Sanacorp | Citric acid | 13243214 | 1 |
| sanacorp | Citric acid | 13396505 | 1 |
| Sanacorp | Citric acid | 13K18-B34-291072 | 1 |
| Sanacorp | Citric acid | 15i01-b06-324348 | 1 |
| Sanacorp | Citric acid | 16208608 | 1 |
| Sanacorp | Citric acid | 16208614 | 1 |
| Sanacorp | Citric acid | 17162601 | 5 |
| Sanacorp | Citric acid | 18025702 | 1 |
| Sanacorp | Citric acid | 18025704 | 1 |
| Sanacorp | Citric acid | 18097603 | 1 |
| Sanacorp | Citric acid | 183066905 | 1 |
| Sanacorp | Citric acid | 18306909 | 1 |
| Sanacorp | Citric acid | 192073004 | 1 |
| Sanacorp | Citric acid | 192073005 | 1 |
| Sanacorp | Citric acid | 20000886002 | 1 |
| Sanacorp | Citric acid | 20003515003 | 1 |
| Sanacorp | Citric acid | 21000544001 | 1 |
| Sanacorp | Citric acid | 21002657012 | 2 |
| Sanacorp | Citric acid | 21002657015 | 3 |
| Sanacorp | Citric acid | 22000645004 | 1 |
| Sanacorp | Citric acid | 22002309001 | 2 |
| Sanacorp | Citric acid | 22002309004 | 2 |
| Sanacorp | Citric acid | 23003598004 | 1 |
| Sanacorp | Citric acid | 24001159002 | 1 |
| Sanacorp | Citric acid | 40/AKD2 | 1 |
| Sanacorp | Citric acid | 41/AKD4 | 1 |
| SanacorpWE:15.02.201… | Citric acid | 15063203 | 1 |
| SanacorpWE:30.01.201… | Citric acid | 16038707 | 1 |
| Sanarcorp | Citric acid | 11609021-01 | 1 |
| Spangropharm | Citric acid | 13050611 | 3 |
| VDL 16.03.15; 2,54EUR | Citric acid | 13243201 | 1 |
| VDL;23.6.14; 2.49EUR | Citric acid | 13243213 | 1 |
| Wolf Apotheke | Citric acid | 58(18097609) | 1 |

- 252 213 spectra from 1664 *Apo-Ident* customers from a total of 51 471 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Citric acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Citric acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table


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breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 1170 | 0 | 211 770 |
| **Type C** | 0 | 4650 | 23 | 252 213 |

The substance/substance group *Citric acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4872 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.5078 % (> 99.4436 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20682 | 22463 | 20.42 | 98.87 |
| 20683 | 22463 | 5.49 | 111.47 |
| 20706 | 22463 | 19.53 | 99.33 |
| 20913 | 22463 | 5.54 | 124.06 |
| 21455 | 22463 | 23.46 | 98.26 |
| 21487 | 22463 | 14.89 | 104.21 |
| 22463 | 22463 | 0.00 | 118.76 |
| 26350 | 26350 | 0.00 | 114.04 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Citric acid monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20012-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Citric acid monohydrate; Acidum citricum monohydricum

### Special notes

When selecting the *Citric acid monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Citric acid monohydrate | 8 | 4 | 111 |

### Second-stage model

For differentiation of the substance/substance group *Citric acid monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Citric acid monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 83.53 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Citric acid monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Citric acid monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Citric acid monohydrate | 15185301 | 22340 | 60 | 20150708 |
| Caelo | Citric acid monohydrate | 17085602 | 23409 | 40 | 20170410 |
| Caelo | Citric acid monohydrate | 181305 | 24222 | 40 | 20180606* |
| Caelo | Citric acid monohydrate | 19000762 | 25563 | 40 | 20200204* |
| Caelo | Citric acid monohydrate | 23001973 | 26954 | 40 | 20231108* |
| Caelo | Citric acid monohydrate | 23001973 | 26954SI | 20 | 20231108* |
| Fagron | Citric acid monohydrate | 12D26-N02 | 20926 | 40 | 20120515 |
| Hedinger | Citric acid monohydrate | 202029 | 23457 | 40 | 20161110 |
| Hedinger | Citric acid monohydrate | 202029 | 23458 | 40 | 1908675 |
| Hedinger | Citric acid monohydrate | 202030 | 24874 | 40 | 20180727 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 10 reference samples from the substance/substance group *Citric acid monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 926 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 250 spectra of 7 reference samples from the substance/substance group *Citric acid monohydrate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Citric acid monohydrate | 161865 | 22617 | 40 |
| Caelo | Citric acid monohydrate | 21001368 | 25796 | 50 |
| Caelo | Citric acid monohydrate | 22001438 | 26121 | 40 |
| Caelo | Citric acid monohydrate | 23001974 | 26948 | 40 |
| Caelo | Citric acid monohydrate | 161865 | 23298 | 40 |
| Caelo | Citric acid monohydrate | 22001438 | 26121SI | 20 |
| Caelo | Citric acid monohydrate | 23001974 | 26948SI | 20 |

- 212 690 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 426 spectra from 195 *Apo-Ident* customers from 115 batches from the substance/substance group *Citric acid monohydrate*.

- Among them are spectra of independent samples from 107 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Citric acid monohydrate | 21001368006 | 1 |
| | Citric acid monohydrate | 21001368013 | 2 |
| | Citric acid monohydrate | 22001438003 | 1 |
| | Citric acid monohydrate | 22001438007 | 7 |
| | Citric acid monohydrate | 23003302002 | 3 |
| | Citric acid monohydrate | 23003305003 | 1 |
| AEP | Citric acid monohydrate | 190884005 | 1 |
| AHD | Citric acid monohydrate | 22001438007 | 2 |
| AHD | Citric acid monohydrate | 23003303002 | 1 |
| Alliance Healthcare | Citric acid monohydrate | 18130503 | 1 |
| Bombastus | Citric acid monohydrate | | 1 |
| Bombastus | Citric acid monohydrate | 18000110 | 1 |
| Bombastus | Citric acid monohydrate | 18003283 | 1 |
| Bombastus | Citric acid monohydrate | 18003407 | 1 |
| Bombastus | Citric acid monohydrate | 201-069-1 | 2 |
| Bombastus | Citric acid monohydrate | 259437 | 1 |
| Bombastus | Citric acid monohydrate | 294630 | 1 |
| Bombastus | Citric acid monohydrate | 309343 | 1 |
| Bombastus | Citric acid monohydrate | 309344 | 2 |
| Bombastus | Citric acid monohydrate | 309650 | 1 |
| Bombastus | Citric acid monohydrate | 310803 | 2 |
| Bombastus | Citric acid monohydrate | 70620101 | 1 |
| Caelo | Citric acid monohydrate | 11208132 | 3 |
| Caelo | Citric acid monohydrate | 11208133 | 4 |
| Caelo | Citric acid monohydrate | 12125904 | 2 |
| Caelo | Citric acid monohydrate | 12125907 | 6 |
| Caelo | Citric acid monohydrate | 12125937 | 3 |
| Caelo | Citric acid monohydrate | 12125938 | 1 |
| Caelo | Citric acid monohydrate | 1212937 | 1 |
| Caelo | Citric acid monohydrate | 1215907 | 1 |
| Caelo | Citric acid monohydrate | 1215911 | 1 |
| Caelo | Citric acid monohydrate | 13069103 | 1 |
| Caelo | Citric acid monohydrate | 13069104 | 6 |
| Caelo | Citric acid monohydrate | 13069105 | 2 |
| Caelo | Citric acid monohydrate | 13069106 | 3 |
| Caelo | Citric acid monohydrate | 13069110 | 4 |
| Caelo | Citric acid monohydrate | 13069111 | 3 |
| Caelo | Citric acid monohydrate | 13069113 | 2 |
| Caelo | Citric acid monohydrate | 13069124 | 4 |
| Caelo | Citric acid monohydrate | 13069125 | 2 |
| Caelo | Citric acid monohydrate | 13069128 | 3 |
| Caelo | Citric acid monohydrate | 13069129 | 4 |
| Caelo | Citric acid monohydrate | 13069130 | 1 |
| Caelo | Citric acid monohydrate | 13069133 | 5 |
| Caelo | Citric acid monohydrate | 14038401 | 4 |
| Caelo | Citric acid monohydrate | 14038403 | 8 |
| Caelo | Citric acid monohydrate | 14071701 | 1 |
| Caelo | Citric acid monohydrate | 14311807 | 2 |
| Caelo | Citric acid monohydrate | 14311808 | 4 |
| Caelo | Citric acid monohydrate | 14311812 | 4 |
| Caelo | Citric acid monohydrate | 14311813 | 1 |
| Caelo | Citric acid monohydrate | 15087502 | 2 |
| Caelo | Citric acid monohydrate | 15087503 | 2 |
| Caelo | Citric acid monohydrate | 15087509 | 9 |
| Caelo | Citric acid monohydrate | 15087510 | 2 |
| Caelo | Citric acid monohydrate | 15087512 | 1 |
| Caelo | Citric acid monohydrate | 15185301 | 2 |
| Caelo | Citric acid monohydrate | 15185302 | 15 |
| Caelo | Citric acid monohydrate | 15185304 | 12 |
| Caelo | Citric acid monohydrate | 15185309 | 5 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Citric acid monohydrate | 15185314 | 5 |
| Caelo | Citric acid monohydrate | 15185316 | 6 |
| Caelo | Citric acid monohydrate | 15185317 | 2 |
| Caelo | Citric acid monohydrate | 15185320 | 3 |
| Caelo | Citric acid monohydrate | 15185321 | 6 |
| Caelo | Citric acid monohydrate | 161865001 | 1 |
| Caelo | Citric acid monohydrate | 16186501 | 5 |
| Caelo | Citric acid monohydrate | 16186502 | 6 |
| Caelo | Citric acid monohydrate | 16186508 | 6 |
| Caelo | Citric acid monohydrate | 17085602 | 9 |
| Caelo | Citric acid monohydrate | 17085603 | 8 |
| Caelo | Citric acid monohydrate | 17085607 | 5 |
| Caelo | Citric acid monohydrate | 17329801 | 1 |
| Caelo | Citric acid monohydrate | 17329804 | 17 |
| Caelo | Citric acid monohydrate | 17329807 | 1 |
| Caelo | Citric acid monohydrate | 17329808 | 4 |
| Caelo | Citric acid monohydrate | 18130503 | 3 |
| Caelo | Citric acid monohydrate | 18130506 | 1 |
| Caelo | Citric acid monohydrate | 18130509 | 1 |
| Caelo | Citric acid monohydrate | 18130510 | 2 |
| Caelo | Citric acid monohydrate | 19000762002 | 4 |
| Caelo | Citric acid monohydrate | 1900762002 | 1 |
| Caelo | Citric acid monohydrate | 190884001 | 4 |
| Caelo | Citric acid monohydrate | 190884002 | 1 |
| Caelo | Citric acid monohydrate | 190884005 | 11 |
| Caelo | Citric acid monohydrate | 190884006 | 1 |
| Caelo | Citric acid monohydrate | 190884008 | 4 |
| Caelo | Citric acid monohydrate | 19088401 | 10 |
| Caelo | Citric acid monohydrate | 19088402 | 3 |
| Caelo | Citric acid monohydrate | 19088405 | 1 |
| Caelo | Citric acid monohydrate | 19088407 | 6 |
| Caelo | Citric acid monohydrate | 19088408 | 1 |
| Caelo | Citric acid monohydrate | 20003892007 | 2 |
| Caelo | Citric acid monohydrate | 20003892008 | 11 |
| Caelo | Citric acid monohydrate | 20003892012 | 1 |
| Caelo | Citric acid monohydrate | 21001368003 | 1 |
| Caelo | Citric acid monohydrate | 21001368006 | 13 |
| Caelo | Citric acid monohydrate | 21001368009 | 1 |
| Caelo | Citric acid monohydrate | 21001368010 | 2 |
| Caelo | Citric acid monohydrate | 21001368013 | 1 |
| Caelo | Citric acid monohydrate | 22001438003 | 5 |
| Caelo | Citric acid monohydrate | 22001438006 | 1 |
| Caelo | Citric acid monohydrate | 22001438007 | 1 |
| Caelo | Citric acid monohydrate | 2515Q-02959 | 1 |
| Caelo | Citric acid monohydrate | 2x19088400 | 1 |
| Caelo | Citric acid monohydrate | 9522496 | 1 |
| Caelo | Citric acid monohydrate | sjdfksjfdkl | 1 |
| Caesar & Loretz GmbH… | Citric acid monohydrate | 22001438003 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid monohydrate | 19088401 | 1 |
| Caesar & Loretz GmbH/Gehe | Citric acid monohydrate | 22001438003 | 1 |
| Caesar & Loretz GmbH… | Citric acid monohydrate | 21001368006 | 1 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 14038401 | 2 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 18130506 | 1 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 19000762002 | 2 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 190884001 | 2 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 190884005 | 4 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 190884008 | 1 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 19088405 | 2 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 19088407 | 3 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 19088408 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Citric acid monohydrate | 20003892002 | 4 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 20003892007 | 1 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 20003892008 | 4 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 2000392002 | 1 |
| Caesar & Loretz GmbH | Citric acid monohydrate | 21001368006 | 6 |
| Caesar &Loretz GmbH | Citric acid monohydrate | 12125937 | 1 |
| Cealo | Citric acid monohydrate | 15185320 | 1 |
| E Plus | Citric acid monohydrate | 16186508 | 1 |
| Ebert 17.08.16 | Citric acid monohydrate | 15185314 | 1 |
| Euro OTC | Citric acid monohydrate | 17085607 | 1 |
| Europharm / Gehe | Citric acid monohydrate | 17329804 | 1 |
| Fiebig28.08.13 EK6,60 | Citric acid monohydrate | 13069111 | 1 |
| Gehe | Citric acid monohydrate | 17085602 | 1 |
| Gehe | Citric acid monohydrate | 17329804 | 1 |
| Gehe | Citric acid monohydrate | 22001438003 | 1 |
| Gehe | Citric acid monohydrate | 22001438007 | 1 |
| Geilenkirchen | Citric acid monohydrate | 16186502 | 1 |
| Hänseler | Citric acid monohydrate | | 4 |
| Hedinger / Phönix | Citric acid monohydrate | 202029 | 1 |
| Hedinger/Phönix | Citric acid monohydrate | 202029 | 1 |
| Hedinger | Citric acid monohydrate | 202028 | 2 |
| Hedinger | Citric acid monohydrate | 202029 | 3 |
| Henry Lamotte/AHD | Citric acid monohydrate | 17329804 | 1 |
| Herba Gatt Koller | Citric acid monohydrate | 201103153211 | 1 |
| Krieger | Citric acid monohydrate | 613001-1-P | 1 |
| Nachprüfung | Citric acid monohydrate | AP201218-07 | 1 |
| Phönix | Citric acid monohydrate | 10111503 | 1 |
| Phönix | Citric acid monohydrate | 1403/3 | 1 |
| Sanacaorp | Citric acid monohydrate | 14038401 | 2 |
| Sanacorp | Citric acid monohydrate | 1215937 | 1 |
| Sanacorp | Citric acid monohydrate | 21001368006 | 1 |
| Sanacorp | Citric acid monohydrate | 22001438007 | 1 |
| VDL | Citric acid monohydrate | 263669 | 1 |

- 256 460 spectra from 1666 *Apo-Ident* customers from a total of 52 042 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Citric acid monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Citric acid monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 250 | 0 | 212 690 |
| **Type C** | 0 | 423 | 3 | 256 460 |

The substance/substance group *Citric acid monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.2958 % (> 98.5915 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20926 | 23458 | 7.00 | 229.02 |
| 22340 | 26954 | 13.77 | 227.98 |
| 23409 | 23458 | 11.53 | 230.37 |
| 23457 | 26954 | 9.15 | 229.04 |
| 23458 | 23458 | 0.00 | 229.26 |
| 24222 | 24222 | 0.00 | 231.59 |
| 24874 | 26954 | 5.02 | 228.31 |
| 25563 | 25563 | 0.00 | 229.13 |
| 26954 | 26954 | 0.00 | 225.98 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Citrulline** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21095-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Citrulline; Citrullinum; L-citrulline

### Special notes

When selecting the *Citrulline* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Citrulline | 9 | 12 | 28 |

### Second-stage model

For differentiation of the substance/substance group *Citrulline* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Citrulline* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 93.69 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Citrulline* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Citrulline*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Citrulline | 1310015-01 | 21095 | 40 | 20131120 |
| Euro OTC | Citrulline | 1403021-01 | 21565 | 59 | 1411031 |
| Euro OTC | Citrulline | 1604038 | 22560 | 40 | 20160523* |
| Euro OTC | Citrulline | 1703036 | 23175 | 40 | 20170418* |
| Euro OTC | Citrulline | 1811028 | 24348 | 40 | 20181127* |
| Euro OTC | Citrulline | 2003033 | 25415 | 40 | 20200914* |
| Euro OTC | Citrulline | 2011009 | 25462 | 40 | 20201126* |
| Fagron | Citrulline | 16D11-B02-326797 | 23567 | 40 | 20160421 |
| Fagron | Citrulline | 18K15-B01-356962 | 24643 | 40 | 20190123 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 379 spectra of 9 reference samples from the substance/substance group *Citrulline*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 947 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 550 spectra of 15 reference samples from the substance/substance group *Citrulline*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Citrulline | 1609013 | 22866 | 40 |
| Euro OTC | Citrulline | 1707003 | 23538 | 40 |
| Euro OTC | Citrulline | 1710039 | 23913 | 40 |
| Euro OTC | Citrulline | 1805028 | 24117 | 40 |
| Euro OTC | Citrulline | 1904013 | 24627 | 40 |
| Euro OTC | Citrulline | 2001002 | 25070 | 40 |
| Euro OTC | Citrulline | 2109012 | 25827 | 50 |
| Euro OTC | Citrulline | 2301010 | 26517 | 40 |
| Euro OTC | Citrulline | 2401009 | 27163 | 40 |
| Fagron | Citrulline | 19E03-B01-362002 | 24819 | 40 |
| Fagron | Citrulline | 22G22-B05-222418 | 26375 | 40 |
| Fagron | Citrulline | 24J17-B07-005432 | 27562 | 40 |
| Euro OTC | Citrulline | 2301010 | 26517SI | 20 |
| Euro OTC | Citrulline | 2401009 | 27163SI | 20 |
| Fagron | Citrulline | 22G22-B05-222418 | 26375SI | 20 |

- 212 390 spectra from a total of 4275 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 107 spectra from 10 *Apo-Ident* customers from 29 batches from the substance/substance group *Citrulline*.

- Among them are spectra of independent samples from 26 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Citrulline | 23B02-B06-228296 | 11 |
| | Citrulline | 23B02-B06-2282906 | 2 |
| | Citrulline | 23G24-B01-231732 | 37 |
| | Citrulline | 23G24-B01-236137 | 21 |
| | Citrulline | 2401009-01 | 2 |
| | Citrulline | CIT-PL-22031 | 2 |
| Caelo | Citrulline | 17C14-B01-339452 | 2 |
| Dr. Schär | Citrulline | R1216-022A | 1 |
| Dr.Schär GmbH (Direkt) | Citrulline | 20190700 | 1 |
| Dr.Schär GmbH (Direkt) | Citrulline | 20200027 | 1 |
| Euro OTC | Citrulline | 16040038-01 | 1 |
| Euro OTC | Citrulline | 1811028-01 | 1 |
| Euro OTC | Citrulline | 1904013-01 | 2 |
| Euro OTC | Citrulline | 2001002-01 | 3 |
| Euro OTC | Citrulline | 20011002-01 | 1 |
| Euro OTC | Citrulline | 2003033-01 | 3 |
| Euro OTC | Citrulline | 2011009-01 | 2 |
| Euro OTC | Citrulline | 2109012-01 | 1 |
| Euro OTC | Citrulline | CIT-PL-19102 | 1 |
| Fagron | Citrulline | 18B12-B02 | 1 |
| Fagron | Citrulline | 18K15-B01 | 1 |
| Fagron | Citrulline | 19M17F01366482 | 1 |
| Fagron | Citrulline | 20A28-F02-368558 | 1 |
| Fagron | Citrulline | 21C08-F05-377311 | 2 |
| Gall-Pharma GmbH/Noweda | Citrulline | | 1 |
| Gall-Pharma GmbH | Citrulline | | 1 |
| Hecht-Pharma/ Noweda | Citrulline | | 1 |
| Nutricia | Citrulline | 100803609 | 1 |
| Nutricia | Citrulline | 100915050 | 2 |

- 256 779 spectra from 1666 *Apo-Ident* customers from a total of 52 125 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Citrulline* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Citrulline* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 379 | 0 | 157 947 |
| **Type B** | 0 | 550 | 0 | 212 390 |
| **Type C** | 0 | 107 | 0 | 256 779 |

The substance/substance group *Citrulline* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4169 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.9091 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 94.3925 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21095 | 21565 | 10.20 | 130.12 |
| 21565 | 21565 | 0.00 | 126.75 |
| 22560 | 22560 | 0.00 | 137.55 |
| 23175 | 23175 | 0.00 | 141.60 |
| 23567 | 22560 | 4.80 | 139.95 |
| 24348 | 24348 | 0.00 | 125.98 |
| 24643 | 25462 | 5.53 | 136.17 |
| 25415 | 25415 | 0.00 | 143.21 |
| 25462 | 25462 | 0.00 | 135.50 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Clindamycin hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20214-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Clindamycin hydrochloride; Clindamycini hydrochloridum

### Special notes

When selecting the *Clindamycin hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Clindamycin hydrochloride | 11 | 13 | 360 |

### Second-stage model

For differentiation of the substance/substance group *Clindamycin hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Clindamycin hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 46.43 | – |
| Colistin sulfate | 63.45 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Clindamycin hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Clindamycin hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Clindamycin hydrochloride | 15392809 | 22958 | 40 | 20151204 |
| Caelo | Clindamycin hydrochloride | 15392817 | 23245 | 40 | 20151204 |
| Caelo | Clindamycin hydrochloride | 21000113013 | 25927 | 40 | 20210212 |
| Caelo | Clindamycin hydrochloride | 21000113013 | 25927SI | 40 | 20210212 |
| Euro OTC | Clindamycin hydrochloride | 1111058-01 | 20757 | 80 | 20120516 |
| Euro OTC | Clindamycin hydrochloride | 1511004 | 21996 | 60 | 20151123* |
| Euro OTC | Clindamycin hydrochloride | 1510038 | 22224 | 60 | 20151120* |
| Euro OTC | Clindamycin hydrochloride | 2001044 | 25074 | 40 | 20200303* |
| Euro OTC | Clindamycin hydrochloride | 2004001 | 25307 | 40 | 20200804* |
| Euro OTC | Clindamycin hydrochloride | 2004001 | 25307SI | 40 | 20200804* |
| Fagron | Clindamycin hydrochloride | 13G24-N09 | 21224 | 40 | 1412075 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-332106 | 23264 | 40 | 20160504 |
| Fagron | Clindamycin hydrochloride | 24A23-B01-003404 | 27423 | 40 | 20240304 |
| Fagron | Clindamycin hydrochloride | 24A23-B01-003404 | 27423SI | 40 | 20240304 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 640 spectra of 14 reference samples from the substance/substance group *Clindamycin hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 686 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 790 spectra of 20 reference samples from the substance/substance group *Clindamycin hydrochloride*.

- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Clindamycin hydrochloride | 153928 | 23365 | 40 |
| Caelo | Clindamycin hydrochloride | 172093 | 23681 | 40 |
| Caelo | Clindamycin hydrochloride | 22001232 | 26128 | 30 |
| Caelo | Clindamycin hydrochloride | 23003574 | 27135 | 40 |
| Euro OTC | Clindamycin hydrochloride | 1401041-01 | 21239 | 40 |
| Euro OTC | Clindamycin hydrochloride | 1710013 | 23769 | 40 |
| Euro OTC | Clindamycin hydrochloride | 1811003 | 24336 | 40 |
| Euro OTC | Clindamycin hydrochloride | 1903009 | 24637 | 40 |
| Euro OTC | Clindamycin hydrochloride | 2201043 | 25949 | 40 |
| Euro OTC | Clindamycin hydrochloride | 2208011 | 26341 | 40 |
| Euro OTC | Clindamycin hydrochloride | 2307031 | 26875 | 40 |
| Euro OTC | Clindamycin hydrochloride | 2410002 | 27452 | 40 |
| Fagron | Clindamycin hydrochloride | 23B24-B05-231501 | 26825 | 40 |
| Caelo | Clindamycin hydrochloride | 22001232 | 26128SI | 40 |
| Caelo | Clindamycin hydrochloride | 23003574 | 27135SI | 40 |
| Euro OTC | Clindamycin hydrochloride | 2201043 | 25949SI | 40 |
| Euro OTC | Clindamycin hydrochloride | 2208011 | 26341SI | 40 |
| Euro OTC | Clindamycin hydrochloride | 2307031 | 26875SI | 40 |
| Euro OTC | Clindamycin hydrochloride | 2410002 | 27452SI | 40 |
| Fagron | Clindamycin hydrochloride | 23B24-B05-231501 | 26825SI | 40 |

- 212 150 spectra from a total of 4274 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1243 spectra from 426 *Apo-Ident* customers from 373 batches from the substance/substance group *Clindamycin hydrochloride*.

- Among them are spectra of independent samples from 360 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clindamycin hydrochloride | 22001232003 | 5 |
| | Clindamycin hydrochloride | 22001232004 | 5 |
| | Clindamycin hydrochloride | 22001232007 | 3 |
| | Clindamycin hydrochloride | 22001232008 | 8 |
| | Clindamycin hydrochloride | 22001232009 | 7 |
| | Clindamycin hydrochloride | 2201232007 | 1 |
| | Clindamycin hydrochloride | 2208011-01 | 5 |
| | Clindamycin hydrochloride | 220811-01 | 1 |
| | Clindamycin hydrochloride | 22A31-F04-382350 | 1 |
| | Clindamycin hydrochloride | 22A31-F04-383139 | 4 |
| | Clindamycin hydrochloride | 22A31-F04-383864 | 1 |
| | Clindamycin hydrochloride | 22A31-FO4-382350 | 1 |
| | Clindamycin hydrochloride | 22G06-F011-384362 | 1 |
| | Clindamycin hydrochloride | 22G06-F01-383254 | 2 |
| | Clindamycin hydrochloride | 22G06-F01-383866 | 5 |
| | Clindamycin hydrochloride | 22G06-F01-383867 | 3 |
| | Clindamycin hydrochloride | 22G06-F01-384360 | 1 |
| | Clindamycin hydrochloride | 22G06-F01-384362 | 2 |
| | Clindamycin hydrochloride | 22GO6-FO1-383254 | 1 |
| | Clindamycin hydrochloride | 23003574001 | 8 |
| | Clindamycin hydrochloride | 23003574002 | 5 |
| | Clindamycin hydrochloride | 23003574003 | 9 |
| | Clindamycin hydrochloride | 23003574004 | 1 |
| | Clindamycin hydrochloride | 23003574005 | 1 |
| | Clindamycin hydrochloride | 2307031-01 | 19 |
| | Clindamycin hydrochloride | 23128-B02-236392 | 3 |
| | Clindamycin hydrochloride | 23B24-B05-233771 | 2 |
| | Clindamycin hydrochloride | 23B24-B05-235823 | 3 |
| | Clindamycin hydrochloride | 23I28-B02-236133 | 2 |
| | Clindamycin hydrochloride | 23I28-B02-236391 | 1 |
| | Clindamycin hydrochloride | 24/19-B04-005149 | 1 |
| | Clindamycin hydrochloride | 24/19-B04-005150 | 1 |
| | Clindamycin hydrochloride | 24002217001 | 2 |
| | Clindamycin hydrochloride | 2410002-01 | 2 |
| | Clindamycin hydrochloride | 24A23-B01-003394 | 3 |
| | Clindamycin hydrochloride | 24A23-B01-003401 | 2 |
| | Clindamycin hydrochloride | 24A23-B01-003404 | 1 |
| | Clindamycin hydrochloride | 24I19-B04-005150 | 3 |
| | Clindamycin hydrochloride | 700168-0001 | 1 |
| | Clindamycin hydrochloride | B05-2315001 | 2 |
| | Clindamycin hydrochloride | C-202307302 | 1 |
| | Clindamycin hydrochloride | F0138325004 | 1 |
| | Clindamycin hydrochloride | F01-3843600 | 3 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clindamycin hydrochloride | F01-3843601 | 2 |
| | Clindamycin hydrochloride | F01-3843602 | 1 |
| | Clindamycin hydrochloride | K-211147B | 2 |
| | Clindamycin hydrochloride | K-220417B | 1 |
| 34543453 | Clindamycin hydrochloride | 5345435345 | 1 |
| adfgafda | Clindamycin hydrochloride | dsgadgadfg | 1 |
| AHD | Clindamycin hydrochloride | 130402X5 | 1 |
| AHD | Clindamycin hydrochloride | 16H03-B02-343063 | 1 |
| AHD | Clindamycin hydrochloride | 1710013-01 | 1 |
| AHD | Clindamycin hydrochloride | 23003574002 | 1 |
| Alliance Healthcare | Clindamycin hydrochloride | 22A31-F04-381645 | 1 |
| Anzag | Clindamycin hydrochloride | 15392815 | 1 |
| Anzag | Clindamycin hydrochloride | 22G06-F01-384360 | 2 |
| apo-ident | Clindamycin hydrochloride | 1510038-01 | 5 |
| Bombastus | Clindamycin hydrochloride | 1710013-01 | 1 |
| Caelo | Clindamycin hydrochloride | | 1 |
| Caelo | Clindamycin hydrochloride | 10809406 | 1 |
| Caelo | Clindamycin hydrochloride | 1111058-03 | 1 |
| Caelo | Clindamycin hydrochloride | 11K04-N12 | 1 |
| Caelo | Clindamycin hydrochloride | 13G24-N09 | 1 |
| Caelo | Clindamycin hydrochloride | 1401041-01 | 2 |
| Caelo | Clindamycin hydrochloride | 140104102 | 1 |
| Caelo | Clindamycin hydrochloride | 14K04B05309851 | 1 |
| Caelo | Clindamycin hydrochloride | 151003801 | 2 |
| Caelo | Clindamycin hydrochloride | 1511004-01 | 3 |
| Caelo | Clindamycin hydrochloride | 1511004-02 | 1 |
| Caelo | Clindamycin hydrochloride | 1511004-03 | 2 |
| Caelo | Clindamycin hydrochloride | 15189512 | 1 |
| Caelo | Clindamycin hydrochloride | 15392802 | 1 |
| Caelo | Clindamycin hydrochloride | 15392804 | 4 |
| Caelo | Clindamycin hydrochloride | 15392805 | 1 |
| Caelo | Clindamycin hydrochloride | 15392807 | 1 |
| Caelo | Clindamycin hydrochloride | 15392811 | 2 |
| Caelo | Clindamycin hydrochloride | 15392814 | 1 |
| Caelo | Clindamycin hydrochloride | 15392815 | 4 |
| Caelo | Clindamycin hydrochloride | 15392816 | 1 |
| Caelo | Clindamycin hydrochloride | 15392817 | 3 |
| Caelo | Clindamycin hydrochloride | 15392818 | 2 |
| Caelo | Clindamycin hydrochloride | 15392819 | 1 |
| Caelo | Clindamycin hydrochloride | 15392822 | 2 |
| Caelo | Clindamycin hydrochloride | 15E06-B12-310472 | 1 |
| Caelo | Clindamycin hydrochloride | 15L22-B03-318788 | 1 |
| Caelo | Clindamycin hydrochloride | 160712C | 2 |
| Caelo | Clindamycin hydrochloride | 16d05-b08-332106 | 1 |
| Caelo | Clindamycin hydrochloride | 16H03-B02 | 1 |
| Caelo | Clindamycin hydrochloride | 16H03-B02-336706 | 1 |
| Caelo | Clindamycin hydrochloride | 16H03-B02-339275 | 1 |
| Caelo | Clindamycin hydrochloride | 16H03-B03-334345 | 1 |
| Caelo | Clindamycin hydrochloride | 17001301 | 1 |
| Caelo | Clindamycin hydrochloride | 17209301 | 2 |
| Caelo | Clindamycin hydrochloride | 17209302 | 3 |
| Caelo | Clindamycin hydrochloride | 17209303 | 3 |
| Caelo | Clindamycin hydrochloride | 180009408 | 1 |
| Caelo | Clindamycin hydrochloride | 18009401 | 3 |
| Caelo | Clindamycin hydrochloride | 18009402 | 2 |
| Caelo | Clindamycin hydrochloride | 18009403 | 5 |
| Caelo | Clindamycin hydrochloride | 18009405 | 4 |
| Caelo | Clindamycin hydrochloride | 18009406 | 3 |
| Caelo | Clindamycin hydrochloride | 18009408 | 1 |
| Caelo | Clindamycin hydrochloride | 18009409 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clindamycin hydrochloride | 18009410 | 1 |
| Caelo | Clindamycin hydrochloride | 18009412 | 6 |
| Caelo | Clindamycin hydrochloride | 18009413 | 2 |
| Caelo | Clindamycin hydrochloride | 18009414 | 3 |
| Caelo | Clindamycin hydrochloride | 18009416 | 4 |
| Caelo | Clindamycin hydrochloride | 1811003-01 | 3 |
| Caelo | Clindamycin hydrochloride | 18A18-B08-346106 | 2 |
| Caelo | Clindamycin hydrochloride | 18A18-B08-346107 | 1 |
| Caelo | Clindamycin hydrochloride | 18D11-B01-349677 | 1 |
| Caelo | Clindamycin hydrochloride | 18J15-B04-355581 | 2 |
| Caelo | Clindamycin hydrochloride | 18J15-B04-358084 | 1 |
| Caelo | Clindamycin hydrochloride | 1903009-01 | 2 |
| Caelo | Clindamycin hydrochloride | 191332001 | 1 |
| Caelo | Clindamycin hydrochloride | 191392001 | 3 |
| Caelo | Clindamycin hydrochloride | 191392003 | 1 |
| Caelo | Clindamycin hydrochloride | 19139201 | 4 |
| Caelo | Clindamycin hydrochloride | 19139202 | 14 |
| Caelo | Clindamycin hydrochloride | 19139203 | 8 |
| Caelo | Clindamycin hydrochloride | 193087001 | 4 |
| Caelo | Clindamycin hydrochloride | 193087003 | 7 |
| Caelo | Clindamycin hydrochloride | 193087005 | 2 |
| Caelo | Clindamycin hydrochloride | 20001357001 | 3 |
| Caelo | Clindamycin hydrochloride | 20001357002 | 6 |
| Caelo | Clindamycin hydrochloride | 20001357003 | 3 |
| Caelo | Clindamycin hydrochloride | 20001357004 | 2 |
| Caelo | Clindamycin hydrochloride | 20001357005 | 7 |
| Caelo | Clindamycin hydrochloride | 20001357006 | 1 |
| Caelo | Clindamycin hydrochloride | 200035705 | 1 |
| Caelo | Clindamycin hydrochloride | 20004499001 | 3 |
| Caelo | Clindamycin hydrochloride | 20004499002 | 3 |
| Caelo | Clindamycin hydrochloride | 2072002 | 1 |
| Caelo | Clindamycin hydrochloride | 2100011300 | 1 |
| Caelo | Clindamycin hydrochloride | 21000113002 | 10 |
| Caelo | Clindamycin hydrochloride | 21000113003 | 6 |
| Caelo | Clindamycin hydrochloride | 21000113004 | 1 |
| Caelo | Clindamycin hydrochloride | 21000113005 | 1 |
| Caelo | Clindamycin hydrochloride | 21000113006 | 3 |
| Caelo | Clindamycin hydrochloride | 21000113007 | 8 |
| Caelo | Clindamycin hydrochloride | 21000113008 | 3 |
| Caelo | Clindamycin hydrochloride | 21000113009 | 1 |
| Caelo | Clindamycin hydrochloride | 21000113010 | 3 |
| Caelo | Clindamycin hydrochloride | 21000113011 | 2 |
| Caelo | Clindamycin hydrochloride | 21000113012 | 1 |
| Caelo | Clindamycin hydrochloride | 21000113013 | 9 |
| Caelo | Clindamycin hydrochloride | 21000113014 | 2 |
| Caelo | Clindamycin hydrochloride | 21000113015 | 1 |
| Caelo | Clindamycin hydrochloride | 21000113017 | 2 |
| Caelo | Clindamycin hydrochloride | 2100113002 | 1 |
| Caelo | Clindamycin hydrochloride | 22001232002 | 1 |
| Caelo | Clindamycin hydrochloride | 22001232003 | 6 |
| Caelo | Clindamycin hydrochloride | 22001232004 | 2 |
| Caelo | Clindamycin hydrochloride | 22001232008 | 1 |
| Caelo | Clindamycin hydrochloride | 3304 | 1 |
| Caelo | Clindamycin hydrochloride | 379/19AI | 1 |
| Caelo | Clindamycin hydrochloride | P-003-WS10100301 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 21000113005 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 193087005 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 20001357002 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 19139202 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 19139203 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 21000113003 | 1 |
| Caesar & Loretz GmbH/ E | Clindamycin hydrochloride | 20004499002 | 1 |
| Caesar & Loretz GmbH/Gehe | Clindamycin hydrochloride | 193087003 | 1 |
| Caesar & Loretz GmbH/Gehe | Clindamycin hydrochloride | 22001232008 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 22001232004 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 20001357004 | 2 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 21000113004 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | F06-3643002 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 21000113004 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | 21000113013 | 1 |
| Caesar & Loretz GmbH... | Clindamycin hydrochloride | CN201810404 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 191392001 | 2 |
| CAESAR & LORETZ GMBH | Clindamycin hydrochloride | 191392001 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 19139201 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 19139202 | 4 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 19139203 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 19190703 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 193087001 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 193087002 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 193087003 | 5 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 193087004 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 19H28-F06-3643002 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 20001357001 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 20001357002 | 3 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 20001357003 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 20001357004 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 20001357005 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 20004499001 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 20004499003 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113002 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113003 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113004 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113005 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113006 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113007 | 2 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113010 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113011 | 3 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113012 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 21000113015 | 3 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 2100013015 | 1 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 22001232002 | 6 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 22001232003 | 3 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | 22001232004 | 3 |
| Caesar & Loretz GmbH | Clindamycin hydrochloride | F06-3661407 | 1 |
| Caesar & Loretz Hilden | Clindamycin hydrochloride | 18009401 | 1 |
| Cealo/AHD | Clindamycin hydrochloride | 16D05-B08-325088 | 1 |
| Cealo | Clindamycin hydrochloride | 1111058-01 | 1 |
| EuRho/Noweda | Clindamycin hydrochloride | 2201043-01 | 1 |
| EuRho | Clindamycin hydrochloride | 1401041-01 | 1 |
| EuRho | Clindamycin hydrochloride | 1710013-01 | 1 |
| Euro OTC | Clindamycin hydrochloride | 1111058-01 | 6 |
| Euro OTC | Clindamycin hydrochloride | 1111058-02 | 2 |
| Euro OTC | Clindamycin hydrochloride | 1111058-03 | 3 |
| Euro OTC | Clindamycin hydrochloride | 111158-01 | 1 |
| Euro OTC | Clindamycin hydrochloride | 130709X8 | 2 |
| Euro OTC | Clindamycin hydrochloride | 140104101 | 1 |
| Euro OTC | Clindamycin hydrochloride | 1401041-01 | 11 |
| Euro OTC | Clindamycin hydrochloride | 140104102 | 3 |
| Euro OTC | Clindamycin hydrochloride | 1401041-02 | 6 |
| Euro OTC | Clindamycin hydrochloride | 1401401-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clindamycin hydrochloride | 150714B | 1 |
| Euro OTC | Clindamycin hydrochloride | 150901B | 1 |
| Euro OTC | Clindamycin hydrochloride | 1510030-01 | 1 |
| Euro OTC | Clindamycin hydrochloride | 151003502 | 1 |
| Euro OTC | Clindamycin hydrochloride | 1510038-01 | 15 |
| Euro OTC | Clindamycin hydrochloride | 1510038-02 | 4 |
| Euro OTC | Clindamycin hydrochloride | 1511004-002 | 1 |
| Euro OTC | Clindamycin hydrochloride | 151100401 | 2 |
| Euro OTC | Clindamycin hydrochloride | 1511004-01 | 15 |
| Euro OTC | Clindamycin hydrochloride | 1511004-02 | 4 |
| Euro OTC | Clindamycin hydrochloride | 1511004-03 | 2 |
| Euro OTC | Clindamycin hydrochloride | 16D05-B08-328259 | 1 |
| Euro OTC | Clindamycin hydrochloride | 16H03-B02-334974 | 1 |
| Euro OTC | Clindamycin hydrochloride | 16H03-B02-339275 | 1 |
| Euro OTC | Clindamycin hydrochloride | 171001301 | 2 |
| Euro OTC | Clindamycin hydrochloride | 1710013-01 | 29 |
| Euro OTC | Clindamycin hydrochloride | 1710019-01 | 1 |
| Euro OTC | Clindamycin hydrochloride | 1811003-01 | 13 |
| Euro OTC | Clindamycin hydrochloride | 1903009 | 1 |
| Euro OTC | Clindamycin hydrochloride | 1903009-01 | 35 |
| Euro OTC | Clindamycin hydrochloride | 200104401 | 1 |
| Euro OTC | Clindamycin hydrochloride | 2001044-01 | 22 |
| Euro OTC | Clindamycin hydrochloride | 200400101 | 2 |
| Euro OTC | Clindamycin hydrochloride | 2004001-01 | 18 |
| Euro OTC | Clindamycin hydrochloride | 2004001-02 | 1 |
| Euro OTC | Clindamycin hydrochloride | 2004001-03 | 1 |
| Euro OTC | Clindamycin hydrochloride | 20H18-F02-374182 | 2 |
| Euro OTC | Clindamycin hydrochloride | 2201043-01 | 13 |
| Euro OTC | Clindamycin hydrochloride | 220801-01 | 2 |
| Euro OTC | Clindamycin hydrochloride | 2208011-01 | 4 |
| Euro OTC | Clindamycin hydrochloride | 230703101 | 1 |
| Euro OTC | Clindamycin hydrochloride | 2307031-01 | 1 |
| Euro OTC | Clindamycin hydrochloride | 25071401 | 1 |
| Euro OTC | Clindamycin hydrochloride | 2908019-01 | 1 |
| Euro OTC | Clindamycin hydrochloride | 2908019V-03 | 4 |
| Euro OTC | Clindamycin hydrochloride | 4988149 | 1 |
| Euro OTC | Clindamycin hydrochloride | 700168 | 1 |
| Euro OTC | Clindamycin hydrochloride | 8061801 | 1 |
| Euro OTC | Clindamycin hydrochloride | 813M-03534 | 1 |
| Euro OTC | Clindamycin hydrochloride | P-301-CN20181044 | 1 |
| Euro OTC | Clindamycin hydrochloride | P-301-CN20210601 | 1 |
| Euro OTC | Clindamycin hydrochloride | SCHE1107035 | 1 |
| Euro OTC | Clindamycin hydrochloride | T03-05/1401041-01 | 1 |
| Euro/Gehe16.03.16 | Clindamycin hydrochloride | 1510038-01 | 1 |
| Europharm/Otto | Clindamycin hydrochloride | 1111058-01 | 1 |
| Fagron | Clindamycin hydrochloride | 1010616 | 1 |
| Fagron | Clindamycin hydrochloride | 111105803 | 1 |
| Fagron | Clindamycin hydrochloride | 12C19-N06 | 1 |
| Fagron | Clindamycin hydrochloride | 12F19-N07 | 3 |
| Fagron | Clindamycin hydrochloride | 1370983 | 1 |
| Fagron | Clindamycin hydrochloride | 13A22/N01 | 1 |
| Fagron | Clindamycin hydrochloride | 13A22-N01 | 6 |
| Fagron | Clindamycin hydrochloride | 13C15-N06 | 1 |
| Fagron | Clindamycin hydrochloride | 13G24N09 | 1 |
| Fagron | Clindamycin hydrochloride | 13G24-N09 | 7 |
| Fagron | Clindamycin hydrochloride | 13J03-B02 | 1 |
| Fagron | Clindamycin hydrochloride | 13J03-B02_288654 | 1 |
| Fagron | Clindamycin hydrochloride | 13j03-B02-288653 | 1 |
| Fagron | Clindamycin hydrochloride | 13J03B02288654 | 1 |
| Fagron | Clindamycin hydrochloride | 13J03-B02-288654 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clindamycin hydrochloride | 13J03-B02-288655 | 1 |
| Fagron | Clindamycin hydrochloride | 14D23-B03 | 1 |
| Fagron | Clindamycin hydrochloride | 14K04-B05-304995 | 1 |
| Fagron | Clindamycin hydrochloride | 14K04-B05-304996 | 1 |
| Fagron | Clindamycin hydrochloride | 14K04-B05-309851 | 1 |
| Fagron | Clindamycin hydrochloride | 14K04-B05-313090 | 2 |
| Fagron | Clindamycin hydrochloride | 15E06-B12-310472 | 1 |
| Fagron | Clindamycin hydrochloride | 15E06-B12-311886 | 4 |
| Fagron | Clindamycin hydrochloride | 15E06-B12-313089 | 2 |
| Fagron | Clindamycin hydrochloride | 15E06-B12-314064 | 2 |
| Fagron | Clindamycin hydrochloride | 15E06-B12-314065 | 2 |
| Fagron | Clindamycin hydrochloride | 15E06-B12-314066 | 1 |
| Fagron | Clindamycin hydrochloride | 15L22-B03-316670 | 1 |
| Fagron | Clindamycin hydrochloride | 15L22-B03-318787 | 2 |
| Fagron | Clindamycin hydrochloride | 1600324C | 1 |
| Fagron | Clindamycin hydrochloride | 160324C | 2 |
| Fagron | Clindamycin hydrochloride | 16D05-B08 | 4 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-320327 | 5 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-321572 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-323320 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-323321 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-325087 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-325088 | 3 |
| Fagron | Clindamycin hydrochloride | 16d05-b08-325089 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05B08327127 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-327127 | 7 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-328259 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-328260 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-330624 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-332105 | 2 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-332106 | 5 |
| Fagron | Clindamycin hydrochloride | 16d05-b08-332107 | 1 |
| Fagron | Clindamycin hydrochloride | 16D05-B08-332107 | 1 |
| Fagron | Clindamycin hydrochloride | 16H03-B02 | 5 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-334344 | 3 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-334345 | 1 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-334974 | 1 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-336706 | 5 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-338802 | 2 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-338803 | 2 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-339275 | 1 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-341602 | 2 |
| Fagron | Clindamycin hydrochloride | 16-H03-B02-341602 | 1 |
| Fagron | Clindamycin hydrochloride | 16H03-B02-39275 | 1 |
| Fagron | Clindamycin hydrochloride | 16HO3-B02-341602 | 1 |
| Fagron | Clindamycin hydrochloride | 17F22-B07-341603 | 1 |
| Fagron | Clindamycin hydrochloride | 18/15-B04-358084 | 2 |
| Fagron | Clindamycin hydrochloride | 18/15-B04-360142 | 1 |
| Fagron | Clindamycin hydrochloride | 18041801 | 1 |
| Fagron | Clindamycin hydrochloride | 1815B04355580 | 1 |
| Fagron | Clindamycin hydrochloride | 18A18-B08 | 4 |
| Fagron | Clindamycin hydrochloride | 18A18-B08-346106 | 1 |
| Fagron | Clindamycin hydrochloride | 18A18-B08-346107 | 2 |
| Fagron | Clindamycin hydrochloride | 18A18-B08-347483 | 7 |
| Fagron | Clindamycin hydrochloride | 18D11B01 | 1 |
| Fagron | Clindamycin hydrochloride | 18D11-B01 | 6 |
| Fagron | Clindamycin hydrochloride | 18D11-B01-349677 | 3 |
| Fagron | Clindamycin hydrochloride | 18D11-B01-351175 | 4 |
| Fagron | Clindamycin hydrochloride | 18D11-B01-351176 | 4 |
| Fagron | Clindamycin hydrochloride | 18D11-B01-351866 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clindamycin hydrochloride | 18D11-B01-352131 | 2 |
| Fagron | Clindamycin hydrochloride | 18D11-B01-352732 | 2 |
| Fagron | Clindamycin hydrochloride | 18D11-B01-352733 | 2 |
| Fagron | Clindamycin hydrochloride | 18D11-B01-353162 | 1 |
| Fagron | Clindamycin hydrochloride | 18J15-B04 | 4 |
| Fagron | Clindamycin hydrochloride | 18J15-B04-355579 | 4 |
| Fagron | Clindamycin hydrochloride | 18J15-B04-355580 | 1 |
| Fagron | Clindamycin hydrochloride | 18J15-b04-358082 | 1 |
| Fagron | Clindamycin hydrochloride | 18J15-B04-358082 | 1 |
| Fagron | Clindamycin hydrochloride | 18J15-B04-358084 | 1 |
| Fagron | Clindamycin hydrochloride | 18j15-b04-360142 | 1 |
| Fagron | Clindamycin hydrochloride | 18J15-B04-360142 | 8 |
| Fagron | Clindamycin hydrochloride | 18j15b04360143 | 1 |
| Fagron | Clindamycin hydrochloride | 19E23-B02-362301 | 1 |
| Fagron | Clindamycin hydrochloride | 19H28-F06 | 5 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-364300 | 6 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-3643000 | 1 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-3643000855646 | 1 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-364301 | 10 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-364302 | 8 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-366145 | 6 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-366146 | 7 |
| Fagron | Clindamycin hydrochloride | 19h28f06366147 | 1 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-366147 | 5 |
| Fagron | Clindamycin hydrochloride | 19H28-F06-366854 | 1 |
| Fagron | Clindamycin hydrochloride | 19H8-F06364302 | 1 |
| Fagron | Clindamycin hydrochloride | 201210B | 1 |
| Fagron | Clindamycin hydrochloride | 20A27-F01 | 3 |
| Fagron | Clindamycin hydrochloride | 20A27-F01_369463 | 1 |
| Fagron | Clindamycin hydrochloride | 20A27-F01-3694602 | 1 |
| Fagron | Clindamycin hydrochloride | 20A27-F01-369462 | 2 |
| Fagron | Clindamycin hydrochloride | 20A27-F01-369463 | 7 |
| Fagron | Clindamycin hydrochloride | 20D07-F01 | 3 |
| Fagron | Clindamycin hydrochloride | 20D07-F01-370643 | 2 |
| Fagron | Clindamycin hydrochloride | 20D07-F01-370644 | 1 |
| Fagron | Clindamycin hydrochloride | 20D07-F01-370645 | 6 |
| Fagron | Clindamycin hydrochloride | 20D07-F01-370646 | 1 |
| Fagron | Clindamycin hydrochloride | 20D07F01-3709803 | 1 |
| Fagron | Clindamycin hydrochloride | 20D07-F01-370983 | 3 |
| Fagron | Clindamycin hydrochloride | 20H18-F02-374182 | 3 |
| Fagron | Clindamycin hydrochloride | 20J02F03376986 | 1 |
| Fagron | Clindamycin hydrochloride | 21D09-F01 | 2 |
| Fagron | Clindamycin hydrochloride | 21D09-F01-3784605 | 1 |
| Fagron | Clindamycin hydrochloride | 21D09-F01-378464 | 1 |
| Fagron | Clindamycin hydrochloride | 21D09-F01-378465 | 6 |
| Fagron | Clindamycin hydrochloride | 21D09-F01-378495 | 1 |
| Fagron | Clindamycin hydrochloride | 21G01-F01 | 2 |
| Fagron | Clindamycin hydrochloride | 21G01-F01-379129 | 6 |
| Fagron | Clindamycin hydrochloride | 21G01-F01-379598 | 6 |
| Fagron | Clindamycin hydrochloride | 21G01F01379599 | 1 |
| Fagron | Clindamycin hydrochloride | 21G01-F01379599 | 1 |
| Fagron | Clindamycin hydrochloride | 21G01-F01-379599 | 12 |
| Fagron | Clindamycin hydrochloride | 21G01-F01-379600 | 7 |
| Fagron | Clindamycin hydrochloride | 2208011-01 | 1 |
| Fagron | Clindamycin hydrochloride | 22A31-F04-381645 | 2 |
| Fagron | Clindamycin hydrochloride | 22A31-F04-381646 | 2 |
| Fagron | Clindamycin hydrochloride | 22A31-F04-382349 | 1 |
| Fagron | Clindamycin hydrochloride | 22A31-F04-382350 | 3 |
| Fagron | Clindamycin hydrochloride | 22A31-F04-382351 | 4 |
| Fagron | Clindamycin hydrochloride | 22G06-F01-383867 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clindamycin hydrochloride | 22G06-F01-384360 | 1 |
| Fagron | Clindamycin hydrochloride | 23I28-B02-236392 | 1 |
| Fagron | Clindamycin hydrochloride | 2714Q-03534 | 1 |
| Fagron | Clindamycin hydrochloride | 2816 | 1 |
| Fagron | Clindamycin hydrochloride | 700168-0001 | 1 |
| Fagron | Clindamycin hydrochloride | 700168-0004 | 1 |
| Fagron | Clindamycin hydrochloride | 700168-0009 | 1 |
| Fagron | Clindamycin hydrochloride | 700168-F01-379600 | 1 |
| Fagron | Clindamycin hydrochloride | B04-3580803 | 1 |
| Fagron | Clindamycin hydrochloride | F01-3706404 | 1 |
| Fagron | Clindamycin hydrochloride | F01-3706405 | 2 |
| Fagron | Clindamycin hydrochloride | F01-370645 | 1 |
| Fagron | Clindamycin hydrochloride | F01-3791209 | 1 |
| Fagron | Clindamycin hydrochloride | F02-3741802 | 2 |
| Fagron | Clindamycin hydrochloride | F03-3769806 | 1 |
| Fagron | Clindamycin hydrochloride | F06-3643000 | 1 |
| Fagron | Clindamycin hydrochloride | F06-3643002 | 1 |
| Fagron | Clindamycin hydrochloride | F06-3661405 | 1 |
| Fagron | Clindamycin hydrochloride | Fagron20H18-F02-374182 | 1 |
| Fagron | Clindamycin hydrochloride | K-171217B | 2 |
| Fagron | Clindamycin hydrochloride | K-171219B | 2 |
| Fagron | Clindamycin hydrochloride | K-180507B | 8 |
| Fagron | Clindamycin hydrochloride | K-190507B | 1 |
| Fagron | Clindamycin hydrochloride | K-190610B | 7 |
| Fagron | Clindamycin hydrochloride | K-190909B | 1 |
| Fagron | Clindamycin hydrochloride | K-191226B | 1 |
| Fagron | Clindamycin hydrochloride | K-200516B | 1 |
| Fagron | Clindamycin hydrochloride | k-210407B | 1 |
| Fagron | Clindamycin hydrochloride | K210407B | 1 |
| Fagron | Clindamycin hydrochloride | K-210407B | 4 |
| Fagron | Clindamycin hydrochloride | P-003-CN20150406 | 1 |
| Fagron | Clindamycin hydrochloride | P003-WS10100301 | 1 |
| Fagron | Clindamycin hydrochloride | P003WS13091401 | 1 |
| Fagrun | Clindamycin hydrochloride | 18A18-B08-346107 | 1 |
| Fargon /Phönix | Clindamycin hydrochloride | 18J15-B04-3555579 | 1 |
| Fargon/Noweda | Clindamycin hydrochloride | 18D11-B01 | 1 |
| Fargon/Sanacorp | Clindamycin hydrochloride | K-180507B | 1 |
| Fargon | Clindamycin hydrochloride | 11L20-No5 | 1 |
| Fargon | Clindamycin hydrochloride | 16D05-B08-320327 | 1 |
| Fargron/Noweda | Clindamycin hydrochloride | 18J15-B04-358084 | 1 |
| Fargron/Noweda | Clindamycin hydrochloride | 19H28-F06-364302 | 3 |
| Fiebig | Clindamycin hydrochloride | 11023741802 | 1 |
| Fiebig | Clindamycin hydrochloride | f01-3706405 | 1 |
| Fiebig | Clindamycin hydrochloride | F06-3643002 | 1 |
| Fiebig | Clindamycin hydrochloride | K-190909B | 1 |
| Gehe/EuRho | Clindamycin hydrochloride | 2004001-01 | 1 |
| Gehe/EuRho | Clindamycin hydrochloride | 2208011-01 | 1 |
| Gehe | Clindamycin hydrochloride | 11E12-N02 | 1 |
| Gehe | Clindamycin hydrochloride | 11K04-N12 | 1 |
| Gehe | Clindamycin hydrochloride | 13a22-n01 | 1 |
| Gehe | Clindamycin hydrochloride | 13A22-N01 | 1 |
| GEHE | Clindamycin hydrochloride | 1811003-01 | 1 |
| Gehe | Clindamycin hydrochloride | 19H28-F06 | 1 |
| Gehe | Clindamycin hydrochloride | 20A27-F01-369462 | 1 |
| Gehe | Clindamycin hydrochloride | 22A31-F04-381645 | 1 |
| Gehe | Clindamycin hydrochloride | 22A31-F04-382350 | 1 |
| Gehe | Clindamycin hydrochloride | 22G06-F01-383866 | 1 |
| Gehe | Clindamycin hydrochloride | 22G06-F01-383867 | 1 |
| Gehe | Clindamycin hydrochloride | 2307031 | 1 |
| Gehe | Clindamycin hydrochloride | 24A23-B003401 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Clindamycin hydrochloride | 24A23-B01-003401 | 1 |
| Gehe | Clindamycin hydrochloride | 700168-0002 | 1 |
| Gehe | Clindamycin hydrochloride | K-210407B | 1 |
| gfsdgs | Clindamycin hydrochloride | sgfsgf | 1 |
| GUMO | Clindamycin hydrochloride | 21000113010 | 1 |
| hfdhsdhsh | Clindamycin hydrochloride | dfhdhsd | 1 |
| Hoffmann&Sommer | Clindamycin hydrochloride | 21G01-F01-379600 | 4 |
| Jenne | Clindamycin hydrochloride | 18D11-B01-352732 | 2 |
| Jenne | Clindamycin hydrochloride | 18J15-B04-360142 | 1 |
| Jenne | Clindamycin hydrochloride | 23003574002 | 1 |
| Jenne | Clindamycin hydrochloride | K210407B | 1 |
| Jenne | Clindamycin hydrochloride | K-210407B | 1 |
| L12 | Clindamycin hydrochloride | 17209302 | 1 |
| L12 | Clindamycin hydrochloride | 18009402 | 2 |
| L12 | Clindamycin hydrochloride | 18009403 | 2 |
| L30 | Clindamycin hydrochloride | 17209301 | 1 |
| Noweda/EuRho | Clindamycin hydrochloride | 2201043-01 | 1 |
| Noweda/Schönbuch | Clindamycin hydrochloride | 23003574004 | 1 |
| noweda | Clindamycin hydrochloride | 1511004-03 | 1 |
| Noweda | Clindamycin hydrochloride | 1811003-01 | 1 |
| Noweda | Clindamycin hydrochloride | 18D11-B01-351176 | 1 |
| Noweda | Clindamycin hydrochloride | 22001232002 | 1 |
| Noweda | Clindamycin hydrochloride | 22001232003 | 2 |
| Noweda | Clindamycin hydrochloride | 22G06-F01 | 1 |
| Noweda | Clindamycin hydrochloride | 22G06-F01-383867 | 1 |
| Noweda | Clindamycin hydrochloride | 22G06-F01-384360 | 1 |
| Noweda | Clindamycin hydrochloride | 230031-01 | 1 |
| Noweda | Clindamycin hydrochloride | 23003574003 | 2 |
| Noweda | Clindamycin hydrochloride | 24I19-B04-007924 | 1 |
| Noweda | Clindamycin hydrochloride | 2908019V-03 | 1 |
| Otto Geilenkirchen | Clindamycin hydrochloride | 200400101 | 1 |
| Phoenix 5.12.2018 | Clindamycin hydrochloride | 18A18-B08-346106 | 1 |
| Phoenix | Clindamycin hydrochloride | 16D05-B08-327127 | 1 |
| Phoenix | Clindamycin hydrochloride | 1710013-010 | 1 |
| Phoenix | Clindamycin hydrochloride | 1811003-01 | 1 |
| Phoenix | Clindamycin hydrochloride | 2004001-01 | 1 |
| Phoenix | Clindamycin hydrochloride | 22A31-F04-382350 | 1 |
| Phoenix | Clindamycin hydrochloride | 3367 | 1 |
| Phoenix | Clindamycin hydrochloride | K-171217B | 1 |
| Phönix | Clindamycin hydrochloride | 12H30-N04 | 1 |
| Phönix | Clindamycin hydrochloride | 15392803 | 1 |
| phönix | Clindamycin hydrochloride | 15392820 | 1 |
| Phönix | Clindamycin hydrochloride | 193087005 | 1 |
| Phönix | Clindamycin hydrochloride | 2001044-01 | 1 |
| Phönix | Clindamycin hydrochloride | 20D07-F011 | 1 |
| Phönix | Clindamycin hydrochloride | 24A23-B01-003401 | 1 |
| Phönix | Clindamycin hydrochloride | P-301-CN20220414 | 2 |
| rfgrgrgr | Clindamycin hydrochloride | | 1 |
| Sanacorp | Clindamycin hydrochloride | 1511004-03 | 1 |
| Sanacorp | Clindamycin hydrochloride | 16D05-B08-332106 | 1 |
| Sanacorp | Clindamycin hydrochloride | 16H03-B02-339275 | 1 |
| Sanacorp | Clindamycin hydrochloride | 16H03-B02-341602 | 1 |
| Sanacorp | Clindamycin hydrochloride | 18A18-B08-347483 | 1 |
| Sanacorp | Clindamycin hydrochloride | 18D11-B01-352732 | 1 |
| Sanacorp | Clindamycin hydrochloride | 21462-39-S | 1 |
| Sanacorp | Clindamycin hydrochloride | 21G01-F01-379600 | 1 |
| Sanacorp | Clindamycin hydrochloride | 220801-01 | 1 |
| Sanacorp | Clindamycin hydrochloride | 2208011-01 | 1 |
| Sanacorp | Clindamycin hydrochloride | 22G06-F01-384360 | 2 |
| Sanacorp | Clindamycin hydrochloride | F01-3694602 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Clindamycin hydrochloride | K-171219B | 1 |
| Sanacorp | Clindamycin hydrochloride | K-180507B | 1 |
| Spangro 22.05.2014 | Clindamycin hydrochloride | 13G24-N09 | 1 |
| Spangro_04.04.2019 | Clindamycin hydrochloride | 18D11-B01-352131 | 1 |

- 255 643 spectra from 1666 *Apo-Ident* customers from a total of 51 783 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Clindamycin hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Clindamycin hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 640 | 0 | 157 686 |
| **Type B** | 0 | 790 | 0 | 212 150 |
| **Type C** | 0 | 1234 | 9 | 255 643 |

The substance/substance group *Clindamycin hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0625 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2405 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.2759 % (> 99.0346 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20757 | 21996 | 8.13 | 70.48 |
| 21224 | 21224 | 0.00 | 71.77 |

*continued on the next page*

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21996 | 21996 | 0.00 | 70.70 |
| 22224 | 22224 | 0.00 | 69.84 |
| 22958 | 22224 | 9.17 | 71.10 |
| 23245 | 22224 | 3.72 | 70.19 |
| 23264 | 21996 | 3.39 | 70.07 |
| 25074 | 25074 | 0.00 | 69.62 |
| 25307 | 25307 | 0.00 | 71.99 |
| 25927 | 21996 | 13.72 | 69.68 |
| 27423 | 21996 | 18.61 | 72.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Clindamycin-2-dihydrogen phosphate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10003687-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Clindamycin-2-dihydrogen phosphate; Clindamycini phosphas

### Special notes

When selecting the *Clindamycin-2-dihydrogen phosphate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Clindamycin-2-dihydrogen phosphate | 10 | 4 | 11 |

### Second-stage model

For differentiation of the substance/substance group *Clindamycin-2-dihydrogen phosphate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Clindamycin-2-dihydrogen phosphate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 66.81 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Clindamycin-2-dihydrogen phosphate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Clindamycin-2-dihydrogen phosphate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Clindamycin-2-dihydrogen … | 13166605 | 21063 | 40 | 1403485 |
| Caelo | Clindamycin-2-dihydrogen … | 13166605 | 21116 | 40 | 20130624 |
| Caelo | Clindamycin-2-dihydrogen … | 14257305 | 21798 | 60 | AR-15-FG-015412-01 |
| Caelo | Clindamycin-2-dihydrogen … | 15435801 | 22312 | 60 | AR-16-FG-009129-01 |
| Caelo | Clindamycin-2-dihydrogen … | 163265 | 23055 | 40 | 20161214* |
| Caelo | Clindamycin-2-dihydrogen … | 16326504 | 23586 | 40 | AR-17-FG-022557-01 |
| Caelo | Clindamycin-2-dihydrogen … | 20002497001 | 25389 | 40 | 20200922 |
| Caelo | Clindamycin-2-dihydrogen … | 21003094 | 25849 | 50 | 20211007* |
| Caelo | Clindamycin-2-dihydrogen … | 22000385 | 26022 | 40 | 20220317* |
| Caelo | Clindamycin-2-dihydrogen … | 22001647 | 26246 | 40 | 20220622* |
| Caelo | Clindamycin-2-dihydrogen … | 22001647 | 26246SI | 20 | 20220622* |
| Caelo | Clindamycin-2-dihydrogen … | 24000953 | 27242 | 40 | 20240529* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 510 spectra of 12 reference samples from the substance/substance group *Clindamycin-2-dihydrogen phosphate*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 816 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 210 spectra of 7 reference samples from the substance/substance group *Clindamycin-2-dihydrogen phosphate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Clindamycin-2-dihydrogen … | 172964 | 24047 | 40 |
| Caelo | Clindamycin-2-dihydrogen … | 191224 | 24729 | 40 |
| Caelo | Clindamycin-2-dihydrogen … | 23001027 | 26846 | 40 |
| Caelo | Clindamycin-2-dihydrogen … | 25000023 | 27551 | 40 |
| Caelo | Clindamycin-2-dihydrogen … | 22000385 | 26022SI† | 10 |
| Caelo | Clindamycin-2-dihydrogen … | 23001027 | 26846SI | 20 |
| Caelo | Clindamycin-2-dihydrogen … | 25000023 | 27551SI | 20 |

- 212 730 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 23 spectra from 14 *Apo-Ident* customers from 12 batches from the substance/substance group *Clindamycin-2-dihydrogen phosphate*.

- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clindamycin-2-dihydrogen … | 22002545004 | 1 |
| | Clindamycin-2-dihydrogen … | 23001027002 | 1 |
| | Clindamycin-2-dihydrogen … | 23001027005 | 1 |
| | Clindamycin-2-dihydrogen … | 24001355003 | 3 |
| Caelo | Clindamycin-2-dihydrogen … | 14257305 | 1 |
| Caelo | Clindamycin-2-dihydrogen … | 16326507 | 1 |
| Caelo | Clindamycin-2-dihydrogen … | 17344101 | 6 |
| Caelo | Clindamycin-2-dihydrogen … | 17344102 | 1 |
| Caelo | Clindamycin-2-dihydrogen … | 19122402 | 3 |
| Caelo | Clindamycin-2-dihydrogen … | 22000385002 | 1 |
| Caesar & Loretz GmbH | Clindamycin-2-dihydrogen … | 19122401 | 1 |
| Caesar & Loretz GmbH | Clindamycin-2-dihydrogen … | 19122402 | 2 |
| Noweda | Clindamycin-2-dihydrogen … | 23001027001 | 1 |

- 256 863 spectra from 1666 *Apo-Ident* customers from a total of 52 141 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Clindamycin-2-dihydrogen phosphate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Clindamycin-2-dihydrogen phosphate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 510 | 0 | 157 816 |
| **Type B** | 0 | 210 | 0 | 212 730 |
| **Type C** | 0 | 23 | 0 | 256 863 |

The substance/substance group *Clindamycin-2-dihydrogen phosphate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8235 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.1429 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 73.9130 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21063 | 21063 | 0.00 | 117.34 |
| 21116 | 21063 | 2.94 | 117.30 |
| 21798 | 21798 | 0.00 | 118.65 |
| 22312 | 22312 | 0.00 | 120.70 |
| 23055 | 23055 | 0.00 | 133.50 |
| 23586 | 23586 | 0.00 | 142.42 |
| 25389 | 23586 | 62.85 | 129.57 |
| 25849 | 25849 | 0.00 | 135.64 |
| 26022 | 26022 | 0.00 | 150.27 |
| 26246 | 26246 | 0.00 | 146.40 |
| 27242 | 27242 | 0.00 | 105.35 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Clioquinol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20095-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Clioquinol; Clioquinolum

### Special notes

When selecting the *Clioquinol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Clioquinol | 7 | 14 | 371 |

### Second-stage model

For differentiation of the substance/substance group *Clioquinol* the following second-stage model is used:

- Submodel 12

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Clioquinol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dithranol | 114.78 | – |
| ⋮ | ⋮ | ⋮ |
| Mesalazine | >50 | 25.56 |
| Miconazole nitrate | >50 | 41.94 |
| Theophylline-ethylenediamine hydrate | >50 | 60.48 |
| Nicotinic acid | >50 | 76.82 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Clioquinol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Clioquinol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Clioquinol | 11304120 | 20895 | 40 | 20111208 |
| Caelo | Clioquinol | 163072 | 23047 | 40 | 20161202* |
| Euro OTC | Clioquinol | 1309009-02 | 21246 | 40 | AR-15-FG-009542-01 |
| Euro OTC | Clioquinol | 1509038 | 21944 | 60 | 20151009* |
| Euro OTC | Clioquinol | 2309015 | 27002 | 40 | 20231120* |
| Fagron | Clioquinol | 13I26-N15 | 21236 | 40 | 20131028 |
| Fagron | Clioquinol | 14I11-B03-300049 | 21913 | 60 | 20140926 |
| Fagron | Clioquinol | 14I11-B03-300049 | 21972 | 60 | 20140926 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 380 spectra of 8 reference samples from the substance/substance group *Clioquinol*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 946 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 610 spectra of 17 reference samples from the substance/substance group *Clioquinol*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Clioquinol | 13114413 | 21308 | 40 |
| Caelo | Clioquinol | 16307206 | 22960 | 40 |
| Caelo | Clioquinol | 172046 | 23633 | 40 |
| Caelo | Clioquinol | 182782 | 24374 | 40 |
| Caelo | Clioquinol | 21000089 | 25923 | 40 |
| Caelo | Clioquinol | 22000908001 | 26413 | 40 |
| Caelo | Clioquinol | 23000424 | 26850 | 40 |
| Euro OTC | Clioquinol | 1612020 | 22985 | 40 |
| Euro OTC | Clioquinol | 1903010 | 24624 | 40 |
| Euro OTC | Clioquinol | 1910030 | 24968 | 40 |
| Euro OTC | Clioquinol | 2011013 | 25566 | 40 |
| Euro OTC | Clioquinol | 2208002 | 26268 | 40 |
| Fagron | Clioquinol | 21J01-B08-218979 | 26159 | 40 |
| Fagron | Clioquinol | 25A21-B07-007463 | 27592 | 40 |
| Caelo | Clioquinol | 21000089 | 25923SI | 10 |
| Euro OTC | Clioquinol | 2208002 | 26268SI | 20 |
| Fagron | Clioquinol | 21J01-B08-218979 | 26159SI | 20 |

- 212 330 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2222 spectra from 902 *Apo-Ident* customers from 383 batches from the substance/substance group *Clioquinol*.
- Among them are spectra of independent samples from 371 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clioquinol | 2000424003 | 1 |
| | Clioquinol | 22000908001 | 1 |
| | Clioquinol | 22000908003 | 3 |
| | Clioquinol | 22000908004 | 1 |
| | Clioquinol | 22000908007 | 3 |
| | Clioquinol | 22000908008 | 4 |
| | Clioquinol | 22000908011 | 6 |
| | Clioquinol | 22000908012 | 16 |
| | Clioquinol | 220009098008 | 1 |
| | Clioquinol | 22001088008 | 2 |
| | Clioquinol | 2208002 | 1 |
| | Clioquinol | 2208002-01 | 9 |
| | Clioquinol | 220800202 | 1 |
| | Clioquinol | 2208002-02 | 3 |
| | Clioquinol | 220802-01 | 1 |
| | Clioquinol | 22C15-B07-223056 | 2 |
| | Clioquinol | 22G25-B03-2277706 | 1 |
| | Clioquinol | 22G25B03227776 | 1 |
| | Clioquinol | 22G25-B03-227776 | 6 |
| | Clioquinol | 22G25-B03-2278803 | 1 |
| | Clioquinol | 22G25-B03-227776 | 2 |
| | Clioquinol | 2300042003 | 1 |
| | Clioquinol | 2300042007 | 1 |
| | Clioquinol | 23000424001 | 51 |
| | Clioquinol | 23000424003 | 10 |
| | Clioquinol | 23000424004 | 1 |
| | Clioquinol | 23000424007 | 18 |
| | Clioquinol | 23003409006 | 12 |
| | Clioquinol | 23003409010 | 2 |
| | Clioquinol | 23003409011 | 1 |
| | Clioquinol | 2300424001 | 1 |
| | Clioquinol | 2300424003 | 1 |
| | Clioquinol | 24001423003 | 2 |
| | Clioquinol | 24001423004 | 4 |
| | Clioquinol | 240014230047 | 1 |
| | Clioquinol | 24001423014 | 1 |
| | Clioquinol | 24A10-B04-004312 | 3 |
| | Clioquinol | 8069D22 | 6 |
| | Clioquinol | 8146J23 | 2 |
| | Clioquinol | 938545 | 1 |
| | Clioquinol | B03-2277706 | 7 |
| | Clioquinol | BO3-2277706 | 1 |
| aelo/Noweda | Clioquinol | 21000089001 | 1 |
| AHD | Clioquinol | 1612020-01 | 1 |
| AHD | Clioquinol | 18011502 | 1 |
| AHD | Clioquinol | 2011013-01 | 1 |
| AHD | Clioquinol | 2208002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AHD | Clioquinol | 23000424001 | 1 |
| allaince | Clioquinol | 23003409006 | 1 |
| Alliance Healthcare | Clioquinol | 19120-B01-196485 | 1 |
| Alliance Healthcare | Clioquinol | 22000908001 | 1 |
| Alliance | Clioquinol | 182782002 | 1 |
| Alliance | Clioquinol | 2011013-01 | 1 |
| Alliance | Clioquinol | 22000908001 | 1 |
| Alliance | Clioquinol | 22000908012 | 1 |
| Alliance | Clioquinol | 2205002-01 | 1 |
| Alliance | Clioquinol | 23000424001 | 2 |
| Anzag | Clioquinol | 12L04-N08 | 1 |
| anzag | Clioquinol | 13114418 | 1 |
| Anzag | Clioquinol | 18011517 | 3 |
| Anzag | Clioquinol | 18278210 | 1 |
| Anzag | Clioquinol | 22001088008 | 1 |
| Anzag | Clioquinol | 23000424003 | 1 |
| Anzag | Clioquinol | 23003409006 | 1 |
| Apo-ident | Clioquinol | 1509038-02 | 1 |
| apo-ident | Clioquinol | 1612020-02 | 1 |
| apomix | Clioquinol | 1509038-02 | 1 |
| Axyntis Group | Clioquinol | 1301014-02 | 1 |
| Axyntis Group | Clioquinol | 1301014-03 | 1 |
| Axyntis Group | Clioquinol | 1612020-02 | 1 |
| Axyntis Group | Clioquinol | F001461 | 1 |
| Bombastus | Clioquinol | 14359118 | 1 |
| Bombastus | Clioquinol | 1509038-03 | 1 |
| Bombastus | Clioquinol | 1903010-01 | 1 |
| Cael Sanacorp 05.02.2016 | Clioquinol | 14359103 | 1 |
| Caelo | Clioquinol | 103415 | 2 |
| Caelo | Clioquinol | 10341510 | 1 |
| Caelo | Clioquinol | 10341601 | 2 |
| Caelo | Clioquinol | 10341605 | 4 |
| Caelo | Clioquinol | 10341608 | 1 |
| Caelo | Clioquinol | 11(18011523) | 1 |
| Caelo | Clioquinol | 1130312 | 1 |
| Caelo | Clioquinol | 11304102 | 7 |
| Caelo | Clioquinol | 11304103 | 2 |
| Caelo | Clioquinol | 11304105 | 3 |
| Caelo | Clioquinol | 11304107 | 5 |
| Caelo | Clioquinol | 11304109 | 1 |
| Caelo | Clioquinol | 11304111 | 2 |
| Caelo | Clioquinol | 11304112 | 6 |
| Caelo | Clioquinol | 11304113 | 4 |
| Caelo | Clioquinol | 11304116 | 3 |
| Caelo | Clioquinol | 11304117 | 10 |
| Caelo | Clioquinol | 11304119 | 3 |
| Caelo | Clioquinol | 11304120 | 12 |
| Caelo | Clioquinol | 11304124 | 13 |
| Caelo | Clioquinol | 1201034-01 | 1 |
| Caelo | Clioquinol | 1201034-02 | 2 |
| Caelo | Clioquinol | 1214I02562 | 1 |
| Caelo | Clioquinol | 12F20-N05 | 1 |
| Caelo | Clioquinol | 130114-02 | 1 |
| Caelo | Clioquinol | 1309009-02 | 1 |
| Caelo | Clioquinol | 13114404 | 2 |
| Caelo | Clioquinol | 13114406 | 1 |
| Caelo | Clioquinol | 13114408 | 3 |
| Caelo | Clioquinol | 13114410 | 2 |
| Caelo | Clioquinol | 13114413 | 11 |
| Caelo | Clioquinol | 13114415 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clioquinol | 13114417 | 7 |
| Caelo | Clioquinol | 13114418 | 5 |
| Caelo | Clioquinol | 13114421 | 1 |
| Caelo | Clioquinol | 13114422 | 7 |
| Caelo | Clioquinol | 13114423 | 12 |
| Caelo | Clioquinol | 13114424 | 10 |
| Caelo | Clioquinol | 13114427 | 2 |
| Caelo | Clioquinol | 13A29-N07 | 1 |
| Caelo | Clioquinol | 14/11-B03-309181 | 1 |
| Caelo | Clioquinol | 14/11-BG03-309181 | 1 |
| Caelo | Clioquinol | 14/-B03-309181 | 1 |
| Caelo | Clioquinol | 1405080031 | 1 |
| Caelo | Clioquinol | 1405080036 | 1 |
| Caelo | Clioquinol | 1409031-01 | 1 |
| Caelo | Clioquinol | 14353120 | 1 |
| Caelo | Clioquinol | 14359102 | 12 |
| Caelo | Clioquinol | 14359103 | 11 |
| Caelo | Clioquinol | 14359111 | 14 |
| Caelo | Clioquinol | 14359112 | 14 |
| Caelo | Clioquinol | 14359113 | 2 |
| Caelo | Clioquinol | 14359116 | 1 |
| Caelo | Clioquinol | 14359117 | 4 |
| Caelo | Clioquinol | 14359118 | 10 |
| Caelo | Clioquinol | 14359119 | 4 |
| Caelo | Clioquinol | 14359120 | 8 |
| Caelo | Clioquinol | 1435918 | 1 |
| Caelo | Clioquinol | 144359111 | 1 |
| Caelo | Clioquinol | 14C21-B06-293104 | 1 |
| Caelo | Clioquinol | 14I11-B03 | 1 |
| Caelo | Clioquinol | 1509038-01 | 1 |
| Caelo | Clioquinol | 1509038-02 | 3 |
| Caelo | Clioquinol | 150903803 | 1 |
| Caelo | Clioquinol | 1509038-03 | 4 |
| Caelo | Clioquinol | 1509038-OTC-Pharma | 1 |
| Caelo | Clioquinol | 15L30-B05-314974 | 1 |
| Caelo | Clioquinol | 15L30-B05-321899 | 2 |
| Caelo | Clioquinol | 16021505 | 1 |
| Caelo | Clioquinol | 1605100084 | 1 |
| Caelo | Clioquinol | 160916CL | 1 |
| Caelo | Clioquinol | 1612020-01 | 4 |
| Caelo | Clioquinol | 1612020-02 | 1 |
| Caelo | Clioquinol | 1612020-03 | 1 |
| Caelo | Clioquinol | 16122020-01 | 1 |
| Caelo | Clioquinol | 163072 | 1 |
| Caelo | Clioquinol | 16307203 | 3 |
| Caelo | Clioquinol | 16307204 | 1 |
| Caelo | Clioquinol | 16307205 | 14 |
| Caelo | Clioquinol | 16307206 | 23 |
| Caelo | Clioquinol | 16307207 | 23 |
| Caelo | Clioquinol | 163072073 | 1 |
| Caelo | Clioquinol | 16307208 | 17 |
| Caelo | Clioquinol | 16307209 | 1 |
| Caelo | Clioquinol | 16307210 | 6 |
| Caelo | Clioquinol | 16307211 | 9 |
| Caelo | Clioquinol | 16307213 | 1 |
| Caelo | Clioquinol | 16307214 | 18 |
| Caelo | Clioquinol | 16307215 | 15 |
| Caelo | Clioquinol | 16307216 | 18 |
| Caelo | Clioquinol | 16I18-B04-332852 | 1 |
| Caelo | Clioquinol | 16J18-B04-328520 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clioquinol | 16118-B04-329141 | 1 |
| Caelo | Clioquinol | 170926CL/16307208 | 1 |
| Caelo | Clioquinol | 172041603 | 1 |
| Caelo | Clioquinol | 17204601 | 4 |
| Caelo | Clioquinol | 17204603 | 22 |
| Caelo | Clioquinol | 172046303 | 1 |
| Caelo | Clioquinol | 18011501 | 2 |
| Caelo | Clioquinol | 18011502 | 48 |
| Caelo | Clioquinol | 18011511 | 2 |
| Caelo | Clioquinol | 180115117 | 1 |
| Caelo | Clioquinol | 18011516 | 35 |
| Caelo | Clioquinol | 18011516P-190705-1 | 1 |
| Caelo | Clioquinol | 18011517 | 2 |
| Caelo | Clioquinol | 18011523 | 30 |
| Caelo | Clioquinol | 18011527 | 1 |
| Caelo | Clioquinol | 180127C/16307215 | 1 |
| Caelo | Clioquinol | 1801523 | 1 |
| Caelo | Clioquinol | 18121714 | 1 |
| Caelo | Clioquinol | 1827782008 | 1 |
| Caelo | Clioquinol | 18278002 | 1 |
| Caelo | Clioquinol | 182782002 | 43 |
| Caelo | Clioquinol | 182782003 | 1 |
| Caelo | Clioquinol | 182782007 | 1 |
| Caelo | Clioquinol | 182782008 | 16 |
| Caelo | Clioquinol | 182782009 | 15 |
| Caelo | Clioquinol | 18278202 | 4 |
| Caelo | Clioquinol | 18278205 | 2 |
| Caelo | Clioquinol | 18278206 | 22 |
| Caelo | Clioquinol | 18278210 | 10 |
| Caelo | Clioquinol | 18278214 | 30 |
| Caelo | Clioquinol | 18278215 | 26 |
| Caelo | Clioquinol | 182792008 | 1 |
| Caelo | Clioquinol | 18E08-B06-355575 | 2 |
| Caelo | Clioquinol | 19I20-B01-196485 | 1 |
| Caelo | Clioquinol | 20001561001 | 2 |
| Caelo | Clioquinol | 20001561003 | 7 |
| Caelo | Clioquinol | 20001561006 | 5 |
| Caelo | Clioquinol | 2001561001 | 2 |
| Caelo | Clioquinol | 2011013-01 | 2 |
| Caelo | Clioquinol | 21000089001 | 52 |
| Caelo | Clioquinol | 21000089004 | 5 |
| Caelo | Clioquinol | 21000089006 | 30 |
| Caelo | Clioquinol | 2100008901 | 2 |
| Caelo | Clioquinol | 21000089011 | 23 |
| Caelo | Clioquinol | 21000089015 | 3 |
| Caelo | Clioquinol | 210000899004 | 1 |
| Caelo | Clioquinol | 21000098006 | 1 |
| Caelo | Clioquinol | 2100089001 | 1 |
| Caelo | Clioquinol | 22000308003 | 1 |
| Caelo | Clioquinol | 220009080001 | 1 |
| Caelo | Clioquinol | 220009080003 | 1 |
| Caelo | Clioquinol | 22000908001 | 22 |
| Caelo | Clioquinol | 22000908003 | 4 |
| Caelo | Clioquinol | 22000908007 | 1 |
| Caelo | Clioquinol | 22000908008 | 9 |
| Caelo | Clioquinol | 22000908011 | 1 |
| Caelo | Clioquinol | 22000908012 | 2 |
| Caelo | Clioquinol | 22001088003 | 10 |
| Caelo | Clioquinol | 22001088004 | 2 |
| Caelo | Clioquinol | 22001088009 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clioquinol | 2200108804 | 1 |
| Caelo | Clioquinol | 23000424001 | 2 |
| Caelo | Clioquinol | 2773 | 1 |
| Caelo | Clioquinol | 3041409 | 1 |
| Caelo | Clioquinol | 3513I-02562 | 1 |
| Caelo | Clioquinol | 3713A2562 | 1 |
| Caelo | Clioquinol | 4111707 | 1 |
| Caelo | Clioquinol | 4214Q-02562 | 1 |
| Caelo | Clioquinol | 4613E2562 | 1 |
| Caelo | Clioquinol | 5031302 | 1 |
| Caelo | Clioquinol | 5089 | 1 |
| Caelo | Clioquinol | 5213A2562 | 1 |
| Caelo | Clioquinol | 8714 | 1 |
| Caelo | Clioquinol | B01-1964805 | 1 |
| Caesar & Lorenz GmbH | Clioquinol | 14359112 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089004 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 22000908008 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089015 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089006 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 22001088003 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 18278214 | 2 |
| Caesar & Loretz GmbH… | Clioquinol | 18278215 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 182782008 | 2 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH/AEP | Clioquinol | 21000089012 | 1 |
| Caesar & Loretz GmbH/AHD | Clioquinol | 18011523 | 1 |
| Caesar & Loretz GmbH/AHD | Clioquinol | 22000908008 | 1 |
| Caesar & Loretz GmbH/AHD | Clioquinol | 22001088003 | 1 |
| Caesar & Loretz GmbH/Alli | Clioquinol | 18278215 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 18011502 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH/Gehe | Clioquinol | 182782002 | 1 |
| Caesar & Loretz GmbH/Gehe | Clioquinol | 21000089006 | 1 |
| Caesar & Loretz GmbH/Gehe | Clioquinol | 22001088004 | 2 |
| Caesar & Loretz GmbH/Gehe | Clioquinol | 23000424001 | 2 |
| Caesar & Loretz GmbH… | Clioquinol | 22000908003 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089004 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 22001088008 | 1 |
| Caesar & Loretz GmbH/K | Clioquinol | 182782009 | 1 |
| Caesar & Loretz GmbH/Kehr | Clioquinol | 182782008 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 18278202 | 1 |
| Caesar & Loretz GmbH/Ph | Clioquinol | 18278214 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 20001561006 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089015 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 22000908001 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 182782008 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089001 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089015 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 22000908008 | 2 |
| Caesar & Loretz GmbH… | Clioquinol | 182782008 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 182782009 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 18278214 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 20001561006 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 21000089011 | 1 |
| Caesar & Loretz GmbH… | Clioquinol | 22001088004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Clioquinol | 1612020-02 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 16307207 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 16307216 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 18011516 | 7 |
| Caesar & Loretz GmbH | Clioquinol | 18011517 | 3 |
| Caesar & Loretz GmbH | Clioquinol | 18011523 | 3 |
| Caesar & Loretz GmbH | Clioquinol | 18273214 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 182778215 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 182782002 | 10 |
| Caesar & Loretz GmbH | Clioquinol | 182782003 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 182782006 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 182782008 | 5 |
| Caesar & Loretz GmbH | Clioquinol | 182782009 | 3 |
| Caesar & Loretz GmbH | Clioquinol | 18278202 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 18278206 | 2 |
| Caesar & Loretz GmbH | Clioquinol | 18278210 | 2 |
| Caesar & Loretz GmbH | Clioquinol | 18278214 | 11 |
| Caesar & Loretz GmbH | Clioquinol | 18278215 | 5 |
| Caesar & Loretz GmbH | Clioquinol | 20001561003 | 1 |
| Caesar & Loretz GmbH | Clioquinol | 20001561006 | 2 |
| Caesar & Loretz GmbH | Clioquinol | 21000089001 | 15 |
| Caesar & Loretz GmbH | Clioquinol | 21000089004 | 2 |
| Caesar & Loretz GmbH | Clioquinol | 21000089006 | 15 |
| Caesar & Loretz GmbH | Clioquinol | 21000089011 | 4 |
| Caesar & Loretz GmbH | Clioquinol | 21000089012 | 2 |
| Caesar & Loretz GmbH | Clioquinol | 21000089015 | 2 |
| Caesar & Loretz GmbH | Clioquinol | 22000908001 | 11 |
| Caesar & Loretz GmbH | Clioquinol | 22000908003 | 4 |
| Caesar & Loretz GmbH | Clioquinol | 22000908008 | 2 |
| Caesar & Loretz GmbH | Clioquinol | 22001088003 | 6 |
| Caesar & Loretz GmbH | Clioquinol | 22001088004 | 2 |
| Caesar & Loretz Hilden | Clioquinol | 18011516 | 1 |
| Caesar & Loretz Hilden | Clioquinol | 18011523 | 1 |
| Caesar & Loretz/Noweda | Clioquinol | 182782008 | 1 |
| Caesar & Loretz | Clioquinol | 18011502 | 1 |
| Caesar&Lorenz | Clioquinol | 2100089001 | 1 |
| caesar&loretz,Phönix | Clioquinol | 14359111 | 1 |
| Caolo- Noweda | Clioquinol | 14359118 | 1 |
| Cealo/ Anzag | Clioquinol | 16307215 | 1 |
| Cealo/Sanacorp | Clioquinol | 1309009-01 | 1 |
| Cealo/Sanacorp | Clioquinol | 18278206 | 1 |
| Cealo | Clioquinol | 182782009 | 1 |
| China Medica | Clioquinol | 1201034-02 | 2 |
| Ebert & Jacobi | Clioquinol | 14359103 | 1 |
| EuRho / AHD | Clioquinol | 2011013-01 | 2 |
| EuRho/Gehe | Clioquinol | 1910030-02 | 2 |
| EuRho/Noweda | Clioquinol | 2208002-01 | 1 |
| EuRho/Phönix | Clioquinol | 1903010-01 | 1 |
| Eurho/Phönix | Clioquinol | 1910030-01 | 1 |
| Eurho/Phönix | Clioquinol | 201101301 | 1 |
| EuRho | Clioquinol | 1201034-02 | 1 |
| EuRho | Clioquinol | 1309009-02 | 2 |
| EuRho | Clioquinol | 161202001 | 1 |
| EuRho | Clioquinol | 1612020-01 | 1 |
| EuRho | Clioquinol | 1612020-02 | 1 |
| EuRho | Clioquinol | 1910030-02 | 1 |
| Eurho | Clioquinol | 2011013-01 | 1 |
| EuRho | Clioquinol | 201101301 | 1 |
| EuRho | Clioquinol | 2011013-01 | 3 |
| EURO / Sanacorp | Clioquinol | 150903802 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clioquinol | | 1 |
| Euro OTC | Clioquinol | 1102022-01 | 2 |
| Euro OTC | Clioquinol | 1102022-02 | 3 |
| Euro OTC | Clioquinol | 1201004-01 | 1 |
| Euro OTC | Clioquinol | 1201034-01 | 5 |
| Euro OTC | Clioquinol | 120103402 | 1 |
| Euro OTC | Clioquinol | 1201034-02 | 7 |
| Euro OTC | Clioquinol | 1213A-02562 | 1 |
| Euro OTC | Clioquinol | 13010104-03 | 1 |
| Euro OTC | Clioquinol | 1301014 | 1 |
| Euro OTC | Clioquinol | 1301014-01 | 2 |
| Euro OTC | Clioquinol | 1301014-02 | 7 |
| Euro OTC | Clioquinol | 1301041-01 | 1 |
| Euro OTC | Clioquinol | 1303009-02 | 1 |
| Euro OTC | Clioquinol | 1305070109 | 1 |
| Euro OTC | Clioquinol | 1309009-01 | 7 |
| Euro OTC | Clioquinol | 130900902 | 1 |
| Euro OTC | Clioquinol | 1309009-02 | 15 |
| Euro OTC | Clioquinol | 1405080031 | 1 |
| Euro OTC | Clioquinol | 14090131-02 | 1 |
| Euro OTC | Clioquinol | 140903101 | 1 |
| Euro OTC | Clioquinol | 1409031-01 | 5 |
| Euro OTC | Clioquinol | 1409031-02 | 13 |
| Euro OTC | Clioquinol | 14359118 | 1 |
| Euro OTC | Clioquinol | 14359120 | 1 |
| Euro OTC | Clioquinol | 150903-01 | 1 |
| Euro OTC | Clioquinol | 1509038 | 2 |
| Euro OTC | Clioquinol | 1509038-0 | 1 |
| Euro OTC | Clioquinol | 1509038-01 | 15 |
| Euro OTC | Clioquinol | 150903802 | 2 |
| Euro OTC | Clioquinol | 1509038-02 | 40 |
| Euro OTC | Clioquinol | 1509038-03 | 29 |
| Euro OTC | Clioquinol | 150903804 | 1 |
| Euro OTC | Clioquinol | 1509038-04 | 5 |
| Euro OTC | Clioquinol | 1509038-31 | 1 |
| Euro OTC | Clioquinol | 1605100084 | 1 |
| Euro OTC | Clioquinol | 1612020 | 4 |
| Euro OTC | Clioquinol | 1612020_01 | 2 |
| Euro OTC | Clioquinol | 161202001 | 3 |
| Euro OTC | Clioquinol | 1612020-01 | 48 |
| Euro OTC | Clioquinol | 1612020-02 | 21 |
| Euro OTC | Clioquinol | 161202003 | 1 |
| Euro OTC | Clioquinol | 1612020-03 | 26 |
| Euro OTC | Clioquinol | 1612022001 | 1 |
| Euro OTC | Clioquinol | 16307208 | 1 |
| Euro OTC | Clioquinol | 16307216 | 1 |
| Euro OTC | Clioquinol | 16J18-B04 | 1 |
| Euro OTC | Clioquinol | 18011516 | 2 |
| Euro OTC | Clioquinol | 1903010 | 1 |
| Euro OTC | Clioquinol | 1903010-01 | 11 |
| Euro OTC | Clioquinol | 19100030-02 | 1 |
| Euro OTC | Clioquinol | 1910020-01 | 1 |
| Euro OTC | Clioquinol | 1910030 | 2 |
| Euro OTC | Clioquinol | 19100300-01 | 1 |
| Euro OTC | Clioquinol | 191003001 | 2 |
| Euro OTC | Clioquinol | 1910030-01 | 20 |
| Euro OTC | Clioquinol | 191003002 | 3 |
| Euro OTC | Clioquinol | 1910030-02 | 25 |
| Euro OTC | Clioquinol | 2011013-01 | 39 |
| Euro OTC | Clioquinol | 211013-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clioquinol | 2195137 | 1 |
| Euro OTC | Clioquinol | 22022021-1 | 1 |
| Euro OTC | Clioquinol | 2208002-01 | 7 |
| Euro OTC | Clioquinol | 2507212562 | 1 |
| Euro OTC | Clioquinol | 3719U-02562 | 1 |
| Euro OTC | Clioquinol | 5219E32562 | 1 |
| Euro OTC | Clioquinol | ghjiki | 1 |
| Euro OTC | Clioquinol | PC86 | 1 |
| Euro OTC | Clioquinol | RetestCharge24619/3 | 1 |
| Euro/Phoenix | Clioquinol | 1612020-02 | 3 |
| Euro/Phönix | Clioquinol | 1509038-02 | 1 |
| europharm | Clioquinol | 1509038 | 1 |
| Fa.Phönix | Clioquinol | 18011502 | 1 |
| Fagron | Clioquinol | | 1 |
| Fagron | Clioquinol | 1005090024 | 1 |
| Fagron | Clioquinol | 11304112 | 1 |
| Fagron | Clioquinol | 11304120 | 1 |
| Fagron | Clioquinol | 11G20/N09 | 1 |
| Fagron | Clioquinol | 11G20-N09 | 1 |
| Fagron | Clioquinol | 11K21-N18 | 4 |
| Fagron | Clioquinol | 1205110014 | 1 |
| Fagron | Clioquinol | 12F20-N05 | 3 |
| Fagron | Clioquinol | 12L04-N08 | 9 |
| Fagron | Clioquinol | 13/26-N15 | 2 |
| Fagron | Clioquinol | 1305120028 | 1 |
| Fagron | Clioquinol | 1309009-01 | 1 |
| Fagron | Clioquinol | 13114417 | 1 |
| Fagron | Clioquinol | 13114424 | 1 |
| Fagron | Clioquinol | 1326-N15 | 3 |
| Fagron | Clioquinol | 13A29-N07 | 7 |
| Fagron | Clioquinol | 13A29-N07-3398310111 | 1 |
| Fagron | Clioquinol | 13D15-N01 | 8 |
| Fagron | Clioquinol | 13DS15-NO1 | 1 |
| Fagron | Clioquinol | 13F12-N20 | 2 |
| Fagron | Clioquinol | 13F12-N200463480 | 1 |
| Fagron | Clioquinol | 13I26N15 | 1 |
| Fagron | Clioquinol | 13I26-N15 | 5 |
| Fagron | Clioquinol | 14/11-803-309181 | 1 |
| Fagron | Clioquinol | 14/11-B03-300049 | 4 |
| Fagron | Clioquinol | 14/11-B03-309181 | 4 |
| Fagron | Clioquinol | 14/11-Bo3 | 1 |
| Fagron | Clioquinol | 14052014C | 1 |
| Fagron | Clioquinol | 1411-813 | 1 |
| Fagron | Clioquinol | 1411B03300049 | 1 |
| Fagron | Clioquinol | 1411-B03-300049 | 4 |
| Fagron | Clioquinol | 1411-B03-309181 | 1 |
| Fagron | Clioquinol | 14359118 | 1 |
| Fagron | Clioquinol | 14C21806293104 | 1 |
| Fagron | Clioquinol | 14C21-B06 | 2 |
| Fagron | Clioquinol | 14c21B06293104 | 1 |
| Fagron | Clioquinol | 14C21B06293104 | 1 |
| Fagron | Clioquinol | 14C21-B06-293104 | 6 |
| Fagron | Clioquinol | 14C21-B06-293132 | 2 |
| Fagron | Clioquinol | 14-C21-B06-293132 | 1 |
| Fagron | Clioquinol | 14C21-B06-297159 | 3 |
| Fagron | Clioquinol | 14C21-B08 | 1 |
| Fagron | Clioquinol | 14I11-B03 | 2 |
| Fagron | Clioquinol | 14I11-B03-3000049 | 1 |
| Fagron | Clioquinol | 14I11B03300049 | 1 |
| Fagron | Clioquinol | 14I11-B03-300049 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clioquinol | 14I11-B03-309048 | 2 |
| Fagron | Clioquinol | 14I11-B03-309181 | 3 |
| Fagron | Clioquinol | 14L11-B03 | 1 |
| Fagron | Clioquinol | 14l11-B03-300049 | 1 |
| Fagron | Clioquinol | 1505120044 | 1 |
| Fagron | Clioquinol | 15L30-321899 | 1 |
| Fagron | Clioquinol | 15L30-B05 | 2 |
| Fagron | Clioquinol | 15L30-B05-314974 | 8 |
| Fagron | Clioquinol | 15L30-B05-319616 | 2 |
| Fagron | Clioquinol | 15L30-B05-321899 | 8 |
| Fagron | Clioquinol | 15L30-BO5-321899 | 1 |
| Fagron | Clioquinol | 16/18-b04-328511 | 1 |
| Fagron | Clioquinol | 16/18-B04-328511 | 1 |
| Fagron | Clioquinol | 16/18-B04-332852 | 2 |
| Fagron | Clioquinol | 1605100008 | 2 |
| Fagron | Clioquinol | 1612020-03 | 1 |
| Fagron | Clioquinol | 1618B04-329141 | 1 |
| Fagron | Clioquinol | 16J18B04 | 1 |
| Fagron | Clioquinol | 16J18-B04 | 3 |
| Fagron | Clioquinol | 16J18-B04-29141 | 1 |
| Fagron | Clioquinol | 16J18-B04-328511 | 8 |
| Fagron | Clioquinol | 16J18-B04-328520 | 2 |
| Fagron | Clioquinol | 16J18-B04-32914 | 1 |
| Fagron | Clioquinol | 16j18-b04-329141 | 1 |
| Fagron | Clioquinol | 16j18-B04-329141 | 1 |
| Fagron | Clioquinol | 16J18B04329141 | 1 |
| Fagron | Clioquinol | 16J18-B04-329141 | 5 |
| Fagron | Clioquinol | 16J18-B04-329704 | 1 |
| Fagron | Clioquinol | 16J18-B04-332852 | 6 |
| Fagron | Clioquinol | 16J18-B04-332861 | 1 |
| Fagron | Clioquinol | 17204603 | 1 |
| Fagron | Clioquinol | 18805B07345488 | 1 |
| Fagron | Clioquinol | 18805-B07-3475B6 | 1 |
| Fagron | Clioquinol | 188B05-B07345483 | 1 |
| Fagron | Clioquinol | 18B05-B07 | 3 |
| Fagron | Clioquinol | 18B05-B07-345483 | 4 |
| Fagron | Clioquinol | 18B05-B07-345488 | 2 |
| Fagron | Clioquinol | 18B05-B07-347586 | 3 |
| Fagron | Clioquinol | 18E08-B06 | 3 |
| Fagron | Clioquinol | 18E08-B06-350976 | 2 |
| Fagron | Clioquinol | 18E08-B06-352127 | 4 |
| Fagron | Clioquinol | 18E08-B06-355552 | 2 |
| Fagron | Clioquinol | 18E08-B06355575 | 1 |
| Fagron | Clioquinol | 18E08-B06-355575 | 2 |
| Fagron | Clioquinol | 19/20-B01-196485 | 1 |
| Fagron | Clioquinol | 19/20-B01-197294 | 1 |
| Fagron | Clioquinol | 19F17B07-191238 | 1 |
| Fagron | Clioquinol | 19F17-B07-191238 | 4 |
| Fagron | Clioquinol | 19F17-B07-191238/08122I18 | 1 |
| Fagron | Clioquinol | 19F17-B07-191239 | 3 |
| Fagron | Clioquinol | 19I20-B01-196485 | 4 |
| Fagron | Clioquinol | 19I20-B01-1972904 | 1 |
| Fagron | Clioquinol | 19I20-B01-197294 | 3 |
| Fagron | Clioquinol | 19I20-B01-197295 | 3 |
| Fagron | Clioquinol | 19I20-Bo1-196485 | 1 |
| Fagron | Clioquinol | 19l20-B01-196485 | 1 |
| Fagron | Clioquinol | 2011013-01 | 1 |
| Fagron | Clioquinol | 2014Q2562 | 1 |
| Fagron | Clioquinol | 21D01-B08-217230 | 1 |
| Fagron | Clioquinol | 21G22-B05-213512 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clioquinol | 21J01-B08-218979 | 1 |
| Fagron | Clioquinol | 21J01-B08-219069 | 1 |
| Fagron | Clioquinol | 22C15-B07-220931 | 6 |
| Fagron | Clioquinol | 22G25-B03-222915 | 2 |
| Fagron | Clioquinol | 22G25B03227776 | 1 |
| Fagron | Clioquinol | 22G25-B03-227776 | 2 |
| Fagron | Clioquinol | 22G25-B03-2229105 | 1 |
| Fagron | Clioquinol | 2514U2562 | 1 |
| Fagron | Clioquinol | 28031401 | 1 |
| Fagron | Clioquinol | 3916U-02562 | 1 |
| Fagron | Clioquinol | 7D20-N03 | 1 |
| Fagron | Clioquinol | 8069d22 | 1 |
| Fagron | Clioquinol | 812218 | 1 |
| Fagron | Clioquinol | 8122I18 | 1 |
| Fagron | Clioquinol | B01-1964805 | 1 |
| Fagron | Clioquinol | B01-1972904 | 1 |
| Fagron | Clioquinol | B10-1964805 | 1 |
| Fargon | Clioquinol | 16J18-B04-329704 | 1 |
| Fiebig | Clioquinol | 14/11-B03-300048 | 1 |
| Fiebig | Clioquinol | 19I20-B01-196485 | 1 |
| Fiebig | Clioquinol | 23003409010 | 1 |
| Gatt-Koller | Clioquinol | 1802295 | 2 |
| GEHE 04.08.2014 | Clioquinol | 13114418 | 1 |
| Gehe amax | Clioquinol | 13114418 | 1 |
| Gehe/EuRho | Clioquinol | 1910030-01 | 1 |
| Gehe | Clioquinol | 14/11-B03-300049 | 1 |
| Gehe | Clioquinol | 1409031-02 | 1 |
| GEHE | Clioquinol | 1509038-02 | 1 |
| Gehe | Clioquinol | 1509038-03 | 1 |
| GEHE | Clioquinol | 1509038-03 | 1 |
| Gehe | Clioquinol | 1612020-01 | 1 |
| Gehe | Clioquinol | 16307216 | 1 |
| Gehe | Clioquinol | 18011502 | 1 |
| GEHE | Clioquinol | 18B05-B07 | 1 |
| Gehe | Clioquinol | 2195137 | 1 |
| Gehe | Clioquinol | 22000908004 | 1 |
| Gehe | Clioquinol | 22000908008 | 1 |
| GEHE | Clioquinol | 22000908008 | 1 |
| Gehe | Clioquinol | 22000908012 | 1 |
| Gehe | Clioquinol | 22001088003 | 1 |
| Gehe | Clioquinol | 2208002-01 | 1 |
| GEHE | Clioquinol | 2208002-01 | 1 |
| Gehe | Clioquinol | 2300024003 | 1 |
| Gehe | Clioquinol | 23000424007 | 1 |
| Geibo/EuRho 16.09.2020 | Clioquinol | 1910030-01 | 1 |
| Hedinger / Noweda | Clioquinol | 1509038-03 | 4 |
| Henry Lamote Oils GmbH | Clioquinol | 28151-02562 | 1 |
| Ichthyol-Gesellschaft | Clioquinol | 1612020 | 1 |
| Jenne | Clioquinol | 2208002-01 | 1 |
| Jenne | Clioquinol | 22G25-B03-227776 | 1 |
| jenne | Clioquinol | 23000424007 | 1 |
| Kehr | Clioquinol | 22G25-B03-227776 | 1 |
| Klenk | Clioquinol | 11304120 | 1 |
| L10 | Clioquinol | 1612020-01 | 2 |
| M/s Eskayiodine Pvt.... | Clioquinol | 18278206 | 1 |
| Nachprüfung | Clioquinol | 13L26-N15 | 2 |
| Nachprüfung | Clioquinol | 3021U-02562 | 1 |
| Nachprüfung | Clioquinol | AP200615-12 | 1 |
| Noweda/Noweda | Clioquinol | 16L18-B04-328520 | 1 |
| Noweda/Noweda | Clioquinol | 16L18-B04-329704 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Clioquinol | 10057206 | 1 |
| Noweda | Clioquinol | 11304107 | 1 |
| Noweda | Clioquinol | 11304111 | 1 |
| Noweda | Clioquinol | 1201034-02 | 2 |
| Noweda | Clioquinol | 1309009-01 | 1 |
| Noweda | Clioquinol | 14359103 | 1 |
| Noweda | Clioquinol | 14359120 | 1 |
| Noweda | Clioquinol | 1612020-01 | 1 |
| Noweda | Clioquinol | 16307208 | 1 |
| Noweda | Clioquinol | 17204603 | 1 |
| Noweda | Clioquinol | 18278214 | 1 |
| Noweda | Clioquinol | 18278215 | 1 |
| Noweda | Clioquinol | 1903010-01 | 1 |
| Noweda | Clioquinol | 22000908003 | 2 |
| Noweda | Clioquinol | 22000908012 | 3 |
| Noweda | Clioquinol | 2208002-01 | 2 |
| Noweda | Clioquinol | 22G25-B03-222915 | 1 |
| Noweda | Clioquinol | 22G25-B03-227776 | 1 |
| Noweda | Clioquinol | 23000424007 | 1 |
| Noweda | Clioquinol | 23003409006 | 1 |
| Phö/Dr.Wolff | Clioquinol | 18011523 | 1 |
| Phoenix | Clioquinol | 11304119 | 1 |
| Phoenix | Clioquinol | 13114408 | 2 |
| Phoenix | Clioquinol | 13114417 | 1 |
| Phoenix | Clioquinol | 1612020-02 | 1 |
| Phoenix | Clioquinol | 16J18-B04-332852 | 2 |
| Phoenix | Clioquinol | 18011523 | 1 |
| Phoenix | Clioquinol | 18278206 | 1 |
| Phoenix | Clioquinol | 21000089006 | 2 |
| Phoenix | Clioquinol | 22000908008 | 1 |
| Phoenix | Clioquinol | 22001088003 | 1 |
| Phoenix | Clioquinol | 23000424001 | 1 |
| Phoenix | Clioquinol | 8178L17 | 1 |
| Phönix Gotha | Clioquinol | 11304124 | 1 |
| phönix | Clioquinol | | 1 |
| Phönix | Clioquinol | 1102022-02 | 3 |
| Phönix | Clioquinol | 1201034-02 | 1 |
| Phönix | Clioquinol | 1309009-02 | 1 |
| Phönix | Clioquinol | 13114417 | 1 |
| Phönix | Clioquinol | 14C21-B06 | 2 |
| Phönix | Clioquinol | 14C21-B08 | 1 |
| Phönix | Clioquinol | 15L30-B05-314974 | 1 |
| Phönix | Clioquinol | 1612020-01 | 1 |
| Phönix | Clioquinol | 16718b04332852 | 1 |
| Phönix | Clioquinol | 182782008 | 1 |
| Phönix | Clioquinol | 1903010-01 | 1 |
| Phönix | Clioquinol | 1910030-02 | 2 |
| Phönix | Clioquinol | 2011013-01 | 1 |
| Phönix | Clioquinol | 21000089001 | 1 |
| Phönix | Clioquinol | 21000089006 | 1 |
| Phönix | Clioquinol | 22000908012 | 1 |
| Phönix | Clioquinol | 2208002-01 | 1 |
| Phönix | Clioquinol | 22C15-B07 | 1 |
| Phönix | Clioquinol | 23000424001 | 1 |
| phönix | Clioquinol | 23003409006 | 1 |
| Phönix | Clioquinol | 2300340910 | 1 |
| Phönix | Clioquinol | 3165 | 1 |
| Sanacorp | Clioquinol | 11304111 | 1 |
| Sanacorp | Clioquinol | 11304124 | 1 |
| Sanacorp | Clioquinol | 1201034-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Clioquinol | 13114422 | 1 |
| Sanacorp | Clioquinol | 1612020-03 | 1 |
| Sanacorp | Clioquinol | 16J18-B04-328511 | 1 |
| Sanacorp | Clioquinol | 1910030-01 | 1 |
| Sanacorp | Clioquinol | 20001561006 | 1 |
| Sanacorp | Clioquinol | 21000089001 | 2 |
| Sanacorp | Clioquinol | 22000908004 | 2 |
| Sanacorp | Clioquinol | 22000908007 | 1 |
| Sanacorp | Clioquinol | 22G25-B03-227776 | 2 |
| Sanacorp | Clioquinol | 23000424001 | 1 |
| Sanacorp | Clioquinol | 23000424003 | 1 |
| Sanacorp | Clioquinol | 23000424007 | 1 |
| Sanacorp | Clioquinol | 8/AKD4 | 1 |
| Sanacorp | Clioquinol | 8075E19 | 1 |
| Sanacorp04 | Clioquinol | 1612020-02 | 1 |
| Synthexim / Gehe | Clioquinol | 14359118 | 1 |
| Synthexim | Clioquinol | 1405080036 | 1 |
| Unisan | Clioquinol | 14/11-B03 | 1 |
| VDL | Clioquinol | 131144131 | 1 |
| wepa/Sanaco | Clioquinol | 1439118 | 1 |

- 254 664 spectra from 1666 *Apo-Ident* customers from a total of 51 775 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Clioquinol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Clioquinol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 610 | 0 | 212 330 |
| **Type C** | 0 | 2217 | 5 | 254 664 |

The substance/substance group *Clioquinol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0164 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7750 % (> 99.6400 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20895 | 23047 | 6.72 | 202.87 |
| 21236 | 21246 | 6.56 | 201.94 |
| 21246 | 21246 | 0.00 | 200.34 |
| 21913 | 21944 | 6.48 | 198.00 |
| 21944 | 21944 | 0.00 | 197.51 |
| 21972 | 21246 | 9.61 | 196.46 |
| 23047 | 23047 | 0.00 | 201.57 |
| 27002 | 27002 | 0.00 | 178.05 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Clobetasol propionate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20030-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Clobetasol propionate; Clobetasoli propionas

### Special notes

When selecting the *Clobetasol propionate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Clobetasol propionate | 9 | 14 | 636 |

### Second-stage model

For differentiation of the substance/substance group *Clobetasol propionate* the following second-stage model is used:

- Submodel 15

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Clobetasol propionate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Betamethasone dipropionate | 52.95 | 61.97 |
| ⋮ | ⋮ | ⋮ |
| Beclometasone dipropionate | 56.05 | 64.36 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Clobetasol propionate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Clobetasol propionate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Clobetasol propionate | 13134705 | 21092 | 80 | AR-15-FG-005328-01 |
| Caelo | Clobetasol propionate | 13269505 | 21473 | 60 | AR-15-FG-000622-02 |
| Caelo | Clobetasol propionate | 14338001 | 21802 | 60 | AR-16-FG-008581-01 |
| Caelo | Clobetasol propionate | 14338001 | 21802SI | 59 | AR-16-FG-008581-01 |
| Caelo | Clobetasol propionate | 14338001 | 21896 | 59 | 1607072 |
| Caelo | Clobetasol propionate | 14338001 | 21896SI | 45 | 1607072 |
| Caelo | Clobetasol propionate | 15439504 | 22724 | 40 | 20160204 |
| Caelo | Clobetasol propionate | 15439504 | 22724SI | 37 | 20160204 |
| Caelo | Clobetasol propionate | 192245 | 24904 | 40 | 20200127* |
| Euro OTC | Clobetasol propionate | 1211021-04 | 21611 | 60 | 1605044 |
| Euro OTC | Clobetasol propionate | 1606022 | 22714 | 40 | 20160713* |
| Euro OTC | Clobetasol propionate | 1606022 | 22714SI | 40 | 20160713* |
| Euro OTC | Clobetasol propionate | 2005025 | 25349 | 40 | 20200917* |
| Euro OTC | Clobetasol propionate | 2005025 | 25349SI | 40 | 20200917* |
| Fagron | Clobetasol propionate | 18I12-B02-357669 | 24691 | 40 | 20181001 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 740 spectra of 15 reference samples from the substance/substance group *Clobetasol propionate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 586 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1184 spectra of 30 reference samples from the substance/substance group *Clobetasol propionate*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Clobetasol propionate | 161067 | 22470 | 60 |
| Caelo | Clobetasol propionate | 170967 | 23665 | 40 |
| Caelo | Clobetasol propionate | 21001700 | 25793 | 40 |
| Caelo | Clobetasol propionate | 24001314 | 27311 | 40 |
| Euro OTC | Clobetasol propionate | 1704020 | 23397 | 40 |
| Euro OTC | Clobetasol propionate | 1804002 | 24075 | 40 |
| Euro OTC | Clobetasol propionate | 1903014 | 24615 | 40 |
| Euro OTC | Clobetasol propionate | 2003026 | 25313 | 40 |
| Euro OTC | Clobetasol propionate | 2109003 | 25870 | 50 |
| Euro OTC | Clobetasol propionate | 2209014 | 26428 | 40 |
| Euro OTC | Clobetasol propionate | 2406006 | 27346 | 40 |
| Fagron | Clobetasol propionate | 19B06-B03-360421 | 24822 | 40 |
| Fagron | Clobetasol propionate | 22L20-B03-227672 | 26546 | 40 |
| Fagron | Clobetasol propionate | 23H24-B04-238756 | 27468 | 40 |
| Caelo | Clobetasol propionate | 161067 | 22470SI | 48 |
| Caelo | Clobetasol propionate | 170967 | 23665SI | 20 |
| Caelo | Clobetasol propionate | 192245 | 24904SI† | 40 |
| Caelo | Clobetasol propionate | 21001700 | 25793SI | 40 |
| Caelo | Clobetasol propionate | 24001314 | 27311SI | 34 |
| Euro OTC | Clobetasol propionate | 1704020 | 23397SI | 20 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Clobetasol propionate | 1804002 | 24075SI | 22 |
| Euro OTC | Clobetasol propionate | 1903014 | 24615SI | 40 |
| Euro OTC | Clobetasol propionate | 2003026 | 25313SI | 40 |
| Euro OTC | Clobetasol propionate | 2109003 | 25870SI | 50 |
| Euro OTC | Clobetasol propionate | 2209014 | 26428SI | 40 |
| Euro OTC | Clobetasol propionate | 2406006 | 27346SI | 40 |
| Fagron | Clobetasol propionate | 18I12-B02-357669 | 24691SI[†] | 40 |
| Fagron | Clobetasol propionate | 19B06-B03-360421 | 24822SI | 40 |
| Fagron | Clobetasol propionate | 22L20-B03-227672 | 26546SI | 40 |
| Fagron | Clobetasol propionate | 23H24-B04-238756 | 27468SI | 40 |

- 211 756 spectra from a total of 4271 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4886 spectra from 1290 *Apo-Ident* customers from 661 batches from the substance/substance group *Clobetasol propionate*.

- Among them are spectra of independent samples from 635 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clobetasol propionate | 11/29-N07 | 1 |
| | Clobetasol propionate | 18044002-01 | 1 |
| | Clobetasol propionate | 181023/12 | 1 |
| | Clobetasol propionate | 181023/15 | 1 |
| | Clobetasol propionate | 192245009 | 1 |
| | Clobetasol propionate | 21001700008 | 1 |
| | Clobetasol propionate | 21001700013 | 1 |
| | Clobetasol propionate | 21001700015 | 1 |
| | Clobetasol propionate | 21001700018 | 2 |
| | Clobetasol propionate | 21001700021 | 4 |
| | Clobetasol propionate | 21001700023 | 5 |
| | Clobetasol propionate | 21001700025 | 7 |
| | Clobetasol propionate | 21001700026 | 8 |
| | Clobetasol propionate | 21001700027 | 1 |
| | Clobetasol propionate | 2100170025 | 1 |
| | Clobetasol propionate | 2109003-001 | 1 |
| | Clobetasol propionate | 2109003-01 | 24 |
| | Clobetasol propionate | 21L16-B08-216879 | 1 |
| | Clobetasol propionate | 21L16-B08-216942 | 1 |
| | Clobetasol propionate | 21L16-B08-221088 | 1 |
| | Clobetasol propionate | 21L16-B08 | 1 |
| | Clobetasol propionate | 22009014-01 | 1 |
| | Clobetasol propionate | 22090-01 | 1 |
| | Clobetasol propionate | 2209014 | 1 |
| | Clobetasol propionate | 2209014_01 | 1 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clobetasol propionate | 2209014-01 | 49 |
| | Clobetasol propionate | 220901402 | 1 |
| | Clobetasol propionate | 2209014-02 | 9 |
| | Clobetasol propionate | 220914-04 | 1 |
| | Clobetasol propionate | 22H25-B08-223089 | 1 |
| | Clobetasol propionate | 22H-25-B08-223089 | 1 |
| | Clobetasol propionate | 22H25-B08-223090 | 2 |
| | Clobetasol propionate | 22H25-B08-223091 | 2 |
| | Clobetasol propionate | 22H25-B08-225386 | 1 |
| | Clobetasol propionate | 22L20-B03-226835 | 1 |
| | Clobetasol propionate | 22L20-B03-227671 | 2 |
| | Clobetasol propionate | 22L20-B03-227672 | 2 |
| | Clobetasol propionate | 23000426001 | 60 |
| | Clobetasol propionate | 23000426002 | 18 |
| | Clobetasol propionate | 23000426003 | 26 |
| | Clobetasol propionate | 23000426004 | 1 |
| | Clobetasol propionate | 23000426006 | 2 |
| | Clobetasol propionate | 23000426009 | 7 |
| | Clobetasol propionate | 230033150003 | 1 |
| | Clobetasol propionate | 23003315001 | 25 |
| | Clobetasol propionate | 23003315003 | 10 |
| | Clobetasol propionate | 2300426001 | 2 |
| | Clobetasol propionate | 23D01-B01-227673 | 1 |
| | Clobetasol propionate | 23D01-B01-228378 | 3 |
| | Clobetasol propionate | 23G04-B08-232382 | 3 |
| | Clobetasol propionate | 23G04-B08-234639 | 3 |
| | Clobetasol propionate | 23G04-B28-232382 | 1 |
| | Clobetasol propionate | 23H24-B04-238754 | 2 |
| | Clobetasol propionate | 24001314002 | 1 |
| | Clobetasol propionate | 24001314003 | 1 |
| | Clobetasol propionate | 2400131400340/25P | 1 |
| | Clobetasol propionate | 2406006-01 | 6 |
| | Clobetasol propionate | B08-2368209 | 1 |
| | Clobetasol propionate | CLO001/0722 | 1 |
| 170420-01 | Clobetasol propionate | 17A057 | 1 |
| 20.12.2016 Phoenix 17,49EUR | Clobetasol propionate | 15439504 | 1 |
| AEP | Clobetasol propionate | 23000426001 | 1 |
| AHC | Clobetasol propionate | 1903014-01 | 5 |
| AHC | Clobetasol propionate | 23D01-B01-227673 | 1 |
| AHD 14.06.19 Ek: 18,50 | Clobetasol propionate | 18082718 | 1 |
| AHD | Clobetasol propionate | 17E04-B02-338441 | 1 |
| AHD | Clobetasol propionate | 17L18-B02-347993 | 1 |
| AHD | Clobetasol propionate | 18/12-B02-35302 | 1 |
| AHD | Clobetasol propionate | 18/12-B02-355390 | 1 |
| AHD | Clobetasol propionate | 18/12-B02-357669 | 1 |
| AHD | Clobetasol propionate | 19j02-f02-3653202 | 1 |
| AHD | Clobetasol propionate | 20F24-F03-374147 | 1 |
| AHD | Clobetasol propionate | 21F11-B01 | 1 |
| AHD | Clobetasol propionate | 21L16-B08-221088 | 1 |
| AHD | Clobetasol propionate | 2209014-01 | 2 |
| AHD | Clobetasol propionate | 23000426003 | 1 |
| AHD | Clobetasol propionate | F02-3653202 | 1 |
| AHD | Clobetasol propionate | F03-3741407 | 1 |
| AHZ | Clobetasol propionate | 1606022 | 1 |
| Alliance H. | Clobetasol propionate | 15234002 | 2 |
| Alliance Health 17.0... | Clobetasol propionate | APBOO547/112010C | 1 |
| Alliance Health Care | Clobetasol propionate | 23003315001 | 1 |
| Alliance Healthcare | Clobetasol propionate | 12J25-N01 | 1 |
| Alliance Healthcare | Clobetasol propionate | 18082714 | 1 |
| Alliance Healthcare | Clobetasol propionate | 18I12-B02-357669 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Healthcare | Clobetasol propionate | 21001700003 | 1 |
| Alliance Healthcare | Clobetasol propionate | 21001700007 | 1 |
| Alliance Healthcare | Clobetasol propionate | 21L16-B08-221090 | 1 |
| Alliance Healthcare | Clobetasol propionate | 23003315001 | 3 |
| Alliance | Clobetasol propionate | 12342305 | 1 |
| Alliance | Clobetasol propionate | 21001700023 | 1 |
| Alliance | Clobetasol propionate | 21L16-B08-221088 | 1 |
| Allianz Healthcare 0… | Clobetasol propionate | 1408018-01 | 1 |
| Allianz Healthcare | Clobetasol propionate | 18082709 | 1 |
| allianz | Clobetasol propionate | 15234009 | 1 |
| Allianz | Clobetasol propionate | 17325606 | 1 |
| Anzag | Clobetasol propionate | 1211021-02 | 1 |
| Anzag | Clobetasol propionate | 12E08-N04 | 1 |
| Anzag | Clobetasol propionate | 15246001 | 1 |
| Anzag | Clobetasol propionate | 16106703 | 1 |
| Anzag | Clobetasol propionate | 192245012 | 1 |
| Anzag | Clobetasol propionate | 21001700003 | 1 |
| Anzag | Clobetasol propionate | 2109003-01 | 1 |
| Anzag | Clobetasol propionate | 2209014-01 | 1 |
| Anzag | Clobetasol propionate | 230503(2109003-01) | 1 |
| Anzag | Clobetasol propionate | 230725(2109003-01) | 1 |
| Anzag | Clobetasol propionate | 230906(2109003-01) | 1 |
| Anzag | Clobetasol propionate | CLO103/0220 | 1 |
| apomix | Clobetasol propionate | 1211021-03 | 1 |
| apomix | Clobetasol propionate | 16106703 | 1 |
| apomix | Clobetasol propionate | 16G18-B02-325571 | 1 |
| apomix | Clobetasol propionate | 200502501 | 2 |
| Audor Pharma | Clobetasol propionate | ABCLP/M/036/16C | 1 |
| Audor Pharma | Clobetasol propionate | APAPL/035/E-12C | 2 |
| Audor Pharma | Clobetasol propionate | APB0054/112010C | 1 |
| Audor Pharma | Clobetasol propionate | APCLO102/0518C | 8 |
| Audor Pharma | Clobetasol propionate | APCLP | 1 |
| Audor Pharma | Clobetasol propionate | APCLP/M/036/16C | 5 |
| Audor Pharma | Clobetasol propionate | APL/035/E-12C | 1 |
| Audor Pharma | Clobetasol propionate | APL035E12C | 1 |
| Audor Pharma | Clobetasol propionate | sieheBemerkung | 1 |
| Bombastus | Clobetasol propionate | 12342303 | 1 |
| Bombastus | Clobetasol propionate | 13G23-NO | 1 |
| Bombastus | Clobetasol propionate | 13G23-NO1 | 1 |
| Caelo | Clobetasol propionate | | 1 |
| Caelo | Clobetasol propionate | 1070317/16106704 | 1 |
| Caelo | Clobetasol propionate | 1105044-03 | 1 |
| Caelo | Clobetasol propionate | 1108044-02 | 1 |
| Caelo | Clobetasol propionate | 1108044-04 | 1 |
| Caelo | Clobetasol propionate | 1110116 | 1 |
| Caelo | Clobetasol propionate | 11101311 | 1 |
| Caelo | Clobetasol propionate | 11101315 | 1 |
| Caelo | Clobetasol propionate | 11300702 | 3 |
| Caelo | Clobetasol propionate | 11300703 | 5 |
| Caelo | Clobetasol propionate | 11300707 | 2 |
| Caelo | Clobetasol propionate | 12107601 | 3 |
| Caelo | Clobetasol propionate | 12107602 | 3 |
| Caelo | Clobetasol propionate | 12107604 | 1 |
| Caelo | Clobetasol propionate | 12107606 | 1 |
| Caelo | Clobetasol propionate | 12107607 | 6 |
| Caelo | Clobetasol propionate | 12107608 | 1 |
| Caelo | Clobetasol propionate | 12107609 | 6 |
| Caelo | Clobetasol propionate | 121102104 | 1 |
| Caelo | Clobetasol propionate | 12342303 | 1 |
| Caelo | Clobetasol propionate | 12342306 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clobetasol propionate | 12342307 | 3 |
| Caelo | Clobetasol propionate | 12342308 | 1 |
| Caelo | Clobetasol propionate | 12342309 | 14 |
| Caelo | Clobetasol propionate | 12342310 | 7 |
| Caelo | Clobetasol propionate | 12342312 | 1 |
| Caelo | Clobetasol propionate | 123645 | 1 |
| Caelo | Clobetasol propionate | 12E08-N04 | 1 |
| Caelo | Clobetasol propionate | 12J25-N01 | 1 |
| Caelo | Clobetasol propionate | 13134701 | 17 |
| Caelo | Clobetasol propionate | 13134702 | 7 |
| Caelo | Clobetasol propionate | 13134703 | 4 |
| Caelo | Clobetasol propionate | 13134704 | 4 |
| Caelo | Clobetasol propionate | 13134705 | 4 |
| Caelo | Clobetasol propionate | 13269501 | 1 |
| Caelo | Clobetasol propionate | 13269502 | 3 |
| Caelo | Clobetasol propionate | 13269503 | 3 |
| Caelo | Clobetasol propionate | 13269504 | 9 |
| Caelo | Clobetasol propionate | 13269505 | 2 |
| Caelo | Clobetasol propionate | 13269506 | 1 |
| Caelo | Clobetasol propionate | 13269507 | 1 |
| Caelo | Clobetasol propionate | 13269508 | 13 |
| Caelo | Clobetasol propionate | 13269509 | 1 |
| Caelo | Clobetasol propionate | 13269510 | 2 |
| Caelo | Clobetasol propionate | 1369504 | 1 |
| Caelo | Clobetasol propionate | 13A02-N04 | 1 |
| Caelo | Clobetasol propionate | 13G23-N01 | 1 |
| Caelo | Clobetasol propionate | 13K08-B30-287726 | 1 |
| Caelo | Clobetasol propionate | 13K08-B30-287728 | 1 |
| Caelo | Clobetasol propionate | 1408018-02 | 8 |
| Caelo | Clobetasol propionate | 1408018-03 | 6 |
| Caelo | Clobetasol propionate | 14102416 | 1 |
| Caelo | Clobetasol propionate | 14188501 | 4 |
| Caelo | Clobetasol propionate | 14188502 | 6 |
| Caelo | Clobetasol propionate | 14188503 | 17 |
| Caelo | Clobetasol propionate | 14188504 | 7 |
| Caelo | Clobetasol propionate | 14188506 | 3 |
| Caelo | Clobetasol propionate | 14338001 | 9 |
| Caelo | Clobetasol propionate | 14338002 | 3 |
| Caelo | Clobetasol propionate | 14338005 | 3 |
| Caelo | Clobetasol propionate | 14338006 | 12 |
| Caelo | Clobetasol propionate | 14338007 | 6 |
| Caelo | Clobetasol propionate | 14338008 | 5 |
| Caelo | Clobetasol propionate | 1438007 | 1 |
| Caelo | Clobetasol propionate | 14G30_B07_302114 | 1 |
| Caelo | Clobetasol propionate | 14G30-B07-302114 | 2 |
| Caelo | Clobetasol propionate | 14g30bo7302114 | 1 |
| Caelo | Clobetasol propionate | 15031401 | 1 |
| Caelo | Clobetasol propionate | 152340004 | 1 |
| Caelo | Clobetasol propionate | 15234001 | 11 |
| Caelo | Clobetasol propionate | 15234002 | 1 |
| Caelo | Clobetasol propionate | 15234003 | 19 |
| Caelo | Clobetasol propionate | 15234004 | 22 |
| Caelo | Clobetasol propionate | 15234008 | 1 |
| Caelo | Clobetasol propionate | 15234009 | 7 |
| Caelo | Clobetasol propionate | 1524003 | 1 |
| Caelo | Clobetasol propionate | 15246001 | 6 |
| Caelo | Clobetasol propionate | 15253032 | 1 |
| Caelo | Clobetasol propionate | 15412910 | 1 |
| Caelo | Clobetasol propionate | 154390504 | 1 |
| Caelo | Clobetasol propionate | 15439501 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clobetasol propionate | 15439502 | 8 |
| Caelo | Clobetasol propionate | 15439503 | 23 |
| Caelo | Clobetasol propionate | 15439504 | 27 |
| Caelo | Clobetasol propionate | 15439507 | 2 |
| Caelo | Clobetasol propionate | 1543953 | 1 |
| Caelo | Clobetasol propionate | 15A14-B02 | 1 |
| Caelo | Clobetasol propionate | 15C23-B02-310473 | 2 |
| Caelo | Clobetasol propionate | 15J-15-B04-316616 | 1 |
| Caelo | Clobetasol propionate | 15j15-b04-317698 | 1 |
| Caelo | Clobetasol propionate | 160115CP | 1 |
| Caelo | Clobetasol propionate | 1606022 | 1 |
| Caelo | Clobetasol propionate | 160602201 | 1 |
| Caelo | Clobetasol propionate | 1606022-01 | 2 |
| Caelo | Clobetasol propionate | 1606022-02 | 8 |
| Caelo | Clobetasol propionate | 1606022-025349 | 1 |
| Caelo | Clobetasol propionate | 160829CP | 1 |
| Caelo | Clobetasol propionate | 160919Di | 1 |
| Caelo | Clobetasol propionate | 1610670 | 1 |
| Caelo | Clobetasol propionate | 16106701 | 5 |
| Caelo | Clobetasol propionate | 16106702 | 17 |
| Caelo | Clobetasol propionate | 16106703 | 22 |
| Caelo | Clobetasol propionate | 16106704 | 28 |
| Caelo | Clobetasol propionate | 16106709 | 21 |
| Caelo | Clobetasol propionate | 16106710 | 12 |
| Caelo | Clobetasol propionate | 16106711 | 26 |
| Caelo | Clobetasol propionate | 16106712 | 5 |
| Caelo | Clobetasol propionate | 16106713 | 6 |
| Caelo | Clobetasol propionate | 16106715 | 9 |
| Caelo | Clobetasol propionate | 16106718 | 3 |
| Caelo | Clobetasol propionate | 16106719 | 6 |
| Caelo | Clobetasol propionate | 16106720 | 8 |
| Caelo | Clobetasol propionate | 16107704 | 1 |
| Caelo | Clobetasol propionate | 1616703 | 1 |
| Caelo | Clobetasol propionate | 1616715 | 1 |
| Caelo | Clobetasol propionate | 16348001 | 1 |
| Caelo | Clobetasol propionate | 16353208 | 1 |
| Caelo | Clobetasol propionate | 16C18-B02-325573 | 1 |
| Caelo | Clobetasol propionate | 16E04-B12 | 1 |
| Caelo | Clobetasol propionate | 16E04-B12-321034 | 4 |
| Caelo | Clobetasol propionate | 16E04-B12-321036 | 1 |
| Caelo | Clobetasol propionate | 16E04-B12-322020 | 2 |
| Caelo | Clobetasol propionate | 16G18-B02-324627 | 1 |
| Caelo | Clobetasol propionate | 16G18-B02-325572 | 1 |
| Caelo | Clobetasol propionate | 16H22-B07-328012 | 1 |
| Caelo | Clobetasol propionate | 1704020 | 1 |
| Caelo | Clobetasol propionate | 170402001 | 2 |
| Caelo | Clobetasol propionate | 1704020-01 | 12 |
| Caelo | Clobetasol propionate | 170404CP1606022-02 | 1 |
| Caelo | Clobetasol propionate | 17090708 | 1 |
| Caelo | Clobetasol propionate | 17096701 | 13 |
| Caelo | Clobetasol propionate | 17096702 | 9 |
| Caelo | Clobetasol propionate | 17096703 | 2 |
| Caelo | Clobetasol propionate | 17096704 | 5 |
| Caelo | Clobetasol propionate | 17096705 | 23 |
| Caelo | Clobetasol propionate | 17096706 | 24 |
| Caelo | Clobetasol propionate | 17096706/1180418 | 1 |
| Caelo | Clobetasol propionate | 17096707 | 16 |
| Caelo | Clobetasol propionate | 17096708 | 38 |
| Caelo | Clobetasol propionate | 17096709 | 12 |
| Caelo | Clobetasol propionate | 1709704 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clobetasol propionate | 17097608 | 1 |
| Caelo | Clobetasol propionate | 17325601 | 15 |
| Caelo | Clobetasol propionate | 17325602 | 39 |
| Caelo | Clobetasol propionate | 17325603 | 22 |
| Ĉaelo | Clobetasol propionate | 17325604 | 1 |
| Caelo | Clobetasol propionate | 17325605 | 20 |
| Caelo | Clobetasol propionate | 17325606 | 4 |
| Caelo | Clobetasol propionate | 17325607 | 1 |
| Caelo | Clobetasol propionate | 1735603 | 1 |
| Caelo | Clobetasol propionate | 17E04-B02-336882 | 1 |
| Caelo | Clobetasol propionate | 17g14 | 1 |
| Caelo | Clobetasol propionate | 17G14-B12-340176 | 1 |
| Caelo | Clobetasol propionate | 17G14-B12-341742 | 1 |
| Caelo | Clobetasol propionate | 17L18-B02-347993 | 1 |
| Caelo | Clobetasol propionate | 18/12-B02-353203 | 1 |
| Caelo | Clobetasol propionate | 18/12-B02-35480 | 1 |
| Caelo | Clobetasol propionate | 18/12-B02-355390 | 1 |
| Caelo | Clobetasol propionate | 18/12-b02-355657 | 1 |
| Caelo | Clobetasol propionate | 180400201 | 2 |
| Caelo | Clobetasol propionate | 1804002-01 | 6 |
| Caelo | Clobetasol propionate | 18040020108638392 | 1 |
| Caelo | Clobetasol propionate | 18082701 | 1 |
| Caelo | Clobetasol propionate | 18082702 | 14 |
| Caelo | Clobetasol propionate | 18082703 | 29 |
| Caelo | Clobetasol propionate | 18082708 | 27 |
| Caelo | Clobetasol propionate | 18082709 | 37 |
| Caelo | Clobetasol propionate | 18082710 | 21 |
| Caelo | Clobetasol propionate | 18082711 | 6 |
| Caelo | Clobetasol propionate | 18082714 | 15 |
| Caelo | Clobetasol propionate | 18082717 | 6 |
| Caelo | Clobetasol propionate | 18082718 | 15 |
| Caelo | Clobetasol propionate | 180827708 | 1 |
| Caelo | Clobetasol propionate | 181016709 | 1 |
| Caelo | Clobetasol propionate | 1812B02355390 | 1 |
| Caelo | Clobetasol propionate | 183000204 | 2 |
| Caelo | Clobetasol propionate | 183000209 | 1 |
| Caelo | Clobetasol propionate | 183002001 | 6 |
| Caelo | Clobetasol propionate | 18300202 | 6 |
| Caelo | Clobetasol propionate | 18300203 | 19 |
| Caelo | Clobetasol propionate | 18300204 | 18 |
| Caelo | Clobetasol propionate | 18300204P-191206-1 | 1 |
| Caelo | Clobetasol propionate | 18300207 | 2 |
| Caelo | Clobetasol propionate | 18300208 | 22 |
| Caelo | Clobetasol propionate | 18300209 | 24 |
| Caelo | Clobetasol propionate | 18300210 | 27 |
| Caelo | Clobetasol propionate | 18300212 | 11 |
| Caelo | Clobetasol propionate | 18300213 | 20 |
| Caelo | Clobetasol propionate | 1830024 | 1 |
| Caelo | Clobetasol propionate | 18H22-B017-328012 | 1 |
| Caelo | Clobetasol propionate | 190301401 | 1 |
| Caelo | Clobetasol propionate | 1922245002 | 1 |
| Caelo | Clobetasol propionate | 192245002 | 19 |
| Caelo | Clobetasol propionate | 192245003 | 24 |
| Caelo | Clobetasol propionate | 192245004 | 26 |
| Caelo | Clobetasol propionate | 192245007 | 13 |
| Caelo | Clobetasol propionate | 192245009 | 16 |
| Caelo | Clobetasol propionate | 192245011 | 46 |
| Caelo | Clobetasol propionate | 192245012 | 18 |
| Caelo | Clobetasol propionate | 192245012/5020 | 1 |
| Caelo | Clobetasol propionate | 192245014 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clobetasol propionate | 192245015 | 15 |
| Caelo | Clobetasol propionate | 19224507 | 1 |
| Caelo | Clobetasol propionate | 19224514 | 1 |
| Caelo | Clobetasol propionate | 1922455004 | 1 |
| Caelo | Clobetasol propionate | 19300213 | 1 |
| Caelo | Clobetasol propionate | 19G23-B05-363805 | 1 |
| Caelo | Clobetasol propionate | 20004302002 | 18 |
| Caelo | Clobetasol propionate | 20004302003 | 51 |
| Caelo | Clobetasol propionate | 20004302004 | 1 |
| Caelo | Clobetasol propionate | 20004302006 | 11 |
| Caelo | Clobetasol propionate | 20004302009 | 21 |
| Caelo | Clobetasol propionate | 200043202009 | 1 |
| Caelo | Clobetasol propionate | 2004302003 | 1 |
| Caelo | Clobetasol propionate | 20043202003 | 1 |
| Caelo | Clobetasol propionate | 2005025-01 | 3 |
| Caelo | Clobetasol propionate | 20111700001 | 1 |
| Caelo | Clobetasol propionate | 20121012-4 | 1 |
| Caelo | Clobetasol propionate | 2014E-02835 | 1 |
| Caelo | Clobetasol propionate | 20F24-F03-374147 | 2 |
| Caelo | Clobetasol propionate | 21001700001 | 23 |
| Caelo | Clobetasol propionate | 21001700003 | 35 |
| Caelo | Clobetasol propionate | 21001700004 | 2 |
| Caelo | Clobetasol propionate | 21001700007 | 38 |
| Caelo | Clobetasol propionate | 21001700008 | 27 |
| Caelo | Clobetasol propionate | 2100170001 | 2 |
| Caelo | Clobetasol propionate | 21001700011 | 4 |
| Caelo | Clobetasol propionate | 21001700013 | 46 |
| Caelo | Clobetasol propionate | 21001700015 | 15 |
| Caelo | Clobetasol propionate | 21001700018 | 4 |
| Caelo | Clobetasol propionate | 21001700019 | 1 |
| Caelo | Clobetasol propionate | 21001700021 | 16 |
| Caelo | Clobetasol propionate | 21001700023 | 1 |
| Caelo | Clobetasol propionate | 21001700025 | 8 |
| Caelo | Clobetasol propionate | 21001700026 | 4 |
| Caelo | Clobetasol propionate | 21001700027 | 2 |
| Caelo | Clobetasol propionate | 2100170003 | 3 |
| Caelo | Clobetasol propionate | 2100170013 | 1 |
| Caelo | Clobetasol propionate | 2100170015 | 1 |
| Caelo | Clobetasol propionate | 2100170026 | 1 |
| Caelo | Clobetasol propionate | 210170015 | 1 |
| Caelo | Clobetasol propionate | 2109003-01 | 2 |
| Caelo | Clobetasol propionate | 23000426001 | 1 |
| Caelo | Clobetasol propionate | 23000426002 | 1 |
| Caelo | Clobetasol propionate | 23003315001 | 1 |
| Caelo | Clobetasol propionate | 23111202 | 1 |
| Caelo | Clobetasol propionate | 2778 | 1 |
| Caelo | Clobetasol propionate | 2829 | 1 |
| Caelo | Clobetasol propionate | 2x17325602 | 1 |
| Caelo | Clobetasol propionate | 3012Q02835 | 1 |
| Caelo | Clobetasol propionate | 31071302 | 1 |
| Caelo | Clobetasol propionate | 3110350 | 1 |
| Caelo | Clobetasol propionate | 3440 | 1 |
| Caelo | Clobetasol propionate | 36/AKD2 | 1 |
| Caelo | Clobetasol propionate | 4/0216 | 1 |
| Caelo | Clobetasol propionate | 5119U02835 | 1 |
| Caelo | Clobetasol propionate | 8082703 | 1 |
| Caelo | Clobetasol propionate | apl/294/b-14 | 1 |
| Caelo | Clobetasol propionate | CLO/1191217 | 1 |
| Caelo | Clobetasol propionate | CLO004/0216 | 1 |
| Caelo | Clobetasol propionate | CLO024/0915 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caeolo /Sana | Clobetasol propionate | 18082711 | 1 |
| Caeolo/Krieger | Clobetasol propionate | 17096706 | 3 |
| Caeolo/Noweda | Clobetasol propionate | 15439503 | 1 |
| Caeolo | Clobetasol propionate | 17096709 | 1 |
| Caesar & Loretz /Phönix | Clobetasol propionate | 20004302003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300212 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300210 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245009 | 2 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300204 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300213 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18082718 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 2000430203 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700001 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700013 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700021 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245002 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700008 | 2 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245011 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245002 | 2 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 20004302003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 20004302009 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700007 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245002 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 20004302003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700021 | 1 |
| Caesar & Loretz GmbH/AEP | Clobetasol propionate | 18300203 | 1 |
| Caesar & Loretz GmbH/AHD | Clobetasol propionate | 20004302009 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18082714 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300204 | 1 |
| Caesar & Loretz GmbH/G | Clobetasol propionate | 20004302003 | 1 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 18082702 | 1 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 18082709 | 2 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 18082714 | 1 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 192245002 | 1 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 192245004 | 1 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 20004302002 | 2 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 20004302009 | 1 |
| Caesar & Loretz GmbH/Gehe | Clobetasol propionate | 21001700008 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 20004302004 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700013 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300213 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245002 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 20004302003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 23000426001 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | AP221112-02 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300212 | 2 |
| Caesar & Loretz GmbH/l10 | Clobetasol propionate | 21001700013 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245004 | 2 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245009 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 20004302009 | 2 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700001 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700008 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700015 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700021 | 2 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300213 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 20004302009 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300204 | 2 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300212 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245007 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700007 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700013 | 1 |
| Caesar & Loretz GmbH/Sana | Clobetasol propionate | 21001700003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18082709 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 18300212 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245003 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245007 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 192245011 | 1 |
| Caesar & Loretz GmbH... | Clobetasol propionate | 21001700013 | 2 |
| Caesar & Loretz GmbH | Clobetasol propionate | 16106702 | 3 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18082703 | 1 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18082708 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18082709 | 8 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18082710 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18082711 | 1 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18082714 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18082718 | 6 |
| Caesar & Loretz GmbH | Clobetasol propionate | 183002001 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300202 | 2 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300203 | 2 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300204 | 14 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300208 | 6 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300209 | 9 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300210 | 5 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300212 | 5 |
| Caesar & Loretz GmbH | Clobetasol propionate | 18300213 | 6 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245002 | 11 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245003 | 10 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245004 | 5 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245005 | 1 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245007 | 7 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245009 | 5 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245011 | 21 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245012 | 5 |
| Caesar & Loretz GmbH | Clobetasol propionate | 192245015 | 2 |
| Caesar & Loretz GmbH | Clobetasol propionate | 20004302002 | 8 |
| Caesar & Loretz GmbH | Clobetasol propionate | 20004302003 | 25 |
| Caesar & Loretz GmbH | Clobetasol propionate | 20004302006 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 20004302009 | 8 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700001 | 6 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700002 | 1 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700003 | 10 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700004 | 2 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700007 | 7 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700008 | 3 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700011 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700013 | 15 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700015 | 5 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700018 | 1 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700019 | 1 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700021 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700025 | 7 |
| Caesar & Loretz GmbH | Clobetasol propionate | 21001700026 | 4 |
| Caesar & Loretz GmbH | Clobetasol propionate | 23000426003 | 1 |
| Caesar & Loretz GmbH | Clobetasol propionate | F02-3669403 | 1 |
| Caesar & Loretz Hild... | Clobetasol propionate | 192245002 | 1 |
| Caesar & Loretz Hild... | Clobetasol propionate | 192245003 | 1 |
| Caesar & Loretz Hild... | Clobetasol propionate | 192245011 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz Hilden | Clobetasol propionate | 18300204 | 1 |
| Caesar & Loretz Hilden | Clobetasol propionate | 18300213 | 1 |
| Caesar & Loretz/ Noweda | Clobetasol propionate | 12342306 | 1 |
| Caesar & Loretz/AHD | Clobetasol propionate | 192245003 | 1 |
| Caesar & Loretz/Gehe | Clobetasol propionate | 192245011 | 1 |
| Caesar & Loretz/Geil... | Clobetasol propionate | 20004302003 | 1 |
| Caesar & Loretz/Noweda | Clobetasol propionate | 20004302009 | 1 |
| Caesar & Loretz | Clobetasol propionate | 17096705 | 2 |
| Caesar & Loretz | Clobetasol propionate | 192245015 | 1 |
| Caesar & Loretz | Clobetasol propionate | 20004302002 | 1 |
| Caesar Loretz | Clobetasol propionate | 17096705 | 1 |
| Caesar Loretz | Clobetasol propionate | 192245011 | 1 |
| Caesar u Loretz | Clobetasol propionate | 12107608 | 2 |
| Caesar und Loretz | Clobetasol propionate | 18300203 | 1 |
| Caesar und Loretz | Clobetasol propionate | 18300208 | 2 |
| Caesar&Lorenz | Clobetasol propionate | 1610370 | 1 |
| Caesar&Lorenz | Clobetasol propionate | 20004302002 | 1 |
| Caesar&Loretz GmbH | Clobetasol propionate | 15234001 | 1 |
| Caesar&Loretz GmbH | Clobetasol propionate | 15439501 | 1 |
| Caesar&Loretz GmbH | Clobetasol propionate | 192245015 | 1 |
| Caesar&Loretz | Clobetasol propionate | 21001700013 | 1 |
| Caesar/Lorenz | Clobetasol propionate | 12342305 | 3 |
| Caesar/Lorenz | Clobetasol propionate | 12342309 | 1 |
| Caesar/Loretz | Clobetasol propionate | 12342310 | 1 |
| Cealo /Gehe | Clobetasol propionate | 18082710 | 1 |
| Cealo | Clobetasol propionate | 1408018 | 1 |
| Cealo | Clobetasol propionate | 16106702 | 2 |
| cealo | Clobetasol propionate | 16106703 | 1 |
| Cealo | Clobetasol propionate | 192245003 | 1 |
| Cealo | Clobetasol propionate | 21001700003 | 1 |
| Crystal Pharma | Clobetasol propionate | C0054/1 | 1 |
| Delta | Clobetasol propionate | 17096701 | 1 |
| DR.WOLFF | Clobetasol propionate | 15J15-B04-317699 | 1 |
| E Plus | Clobetasol propionate | 16106702 | 1 |
| eur | Clobetasol propionate | 1704020-01 | 2 |
| EuRho / Noweda | Clobetasol propionate | 2109003-01 | 1 |
| EuRho 06.10.2011 Anzag | Clobetasol propionate | 1108044-01 | 1 |
| EuRho Anzag | Clobetasol propionate | 1108044-03 | 2 |
| EuRho- Phoenix | Clobetasol propionate | 2109003-01 | 1 |
| EuRho/ Anzag | Clobetasol propionate | 29(1903014-01) | 1 |
| EuRho/ NOWEDA | Clobetasol propionate | 1704020-01 | 1 |
| EuRho/ NOWEDA | Clobetasol propionate | 1804002-01 | 1 |
| EuRho/ Phönix | Clobetasol propionate | 1408018-02 | 2 |
| EuRho/ Phönix | Clobetasol propionate | 1704020-01 | 1 |
| EuRho/Fiebig | Clobetasol propionate | 2005025-01 | 1 |
| EuRho/Gehe | Clobetasol propionate | 1704020-01 | 2 |
| EuRho/Noveda | Clobetasol propionate | 1804002-01 | 1 |
| EuRho/Noweda | Clobetasol propionate | 2005025-01 | 2 |
| EuRho/Phoenix | Clobetasol propionate | 160602202 | 1 |
| EuRho/Phoenix | Clobetasol propionate | 1903014 | 1 |
| EuRho/Sanacorp | Clobetasol propionate | 1704020-01 | 1 |
| EuRho/Sanacorp | Clobetasol propionate | 1804002-01 | 1 |
| EuRho/Sanacorp | Clobetasol propionate | 1903014-01 | 1 |
| EuRho/Sanacorp | Clobetasol propionate | 2005025-01 | 1 |
| EuRho | Clobetasol propionate | 1108044-04 | 2 |
| EuRho | Clobetasol propionate | 1408018-01 | 1 |
| EuRho | Clobetasol propionate | 1408018-02 | 2 |
| EuRho | Clobetasol propionate | 1704020-01 | 1 |
| EuRho | Clobetasol propionate | 1804002-01 | 2 |
| EuRho | Clobetasol propionate | 1903014-01 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| euRho | Clobetasol propionate | 2109003-01 | 1 |
| EuRho | Clobetasol propionate | 2109003-01 | 5 |
| euro AHD | Clobetasol propionate | 1704020-015592 | 1 |
| euro AHD | Clobetasol propionate | 1804002-015788 | 1 |
| Euro OCT / Krieger | Clobetasol propionate | 1903014-01 | 1 |
| Euro OT | Clobetasol propionate | 14081018-02 | 1 |
| Euro OTC | Clobetasol propionate | 100402-01 | 1 |
| Euro OTC | Clobetasol propionate | 1072015D | 1 |
| Euro OTC | Clobetasol propionate | 1105044-04 | 1 |
| Euro OTC | Clobetasol propionate | 1108044 | 1 |
| Euro OTC | Clobetasol propionate | 1108044-01 | 4 |
| Euro OTC | Clobetasol propionate | 1108044-02 | 8 |
| Euro OTC | Clobetasol propionate | 1108044-03 | 12 |
| Euro OTC | Clobetasol propionate | 1108044-037-16 | 1 |
| Euro OTC | Clobetasol propionate | 110804404 | 2 |
| Euro OTC | Clobetasol propionate | 1108044-04 | 15 |
| Euro OTC | Clobetasol propionate | 112/1018 | 1 |
| Euro OTC | Clobetasol propionate | 1204037-01 | 1 |
| Euro OTC | Clobetasol propionate | 12082013B | 1 |
| Euro OTC | Clobetasol propionate | 12110-01 | 1 |
| Euro OTC | Clobetasol propionate | 1211021/02 | 1 |
| Euro OTC | Clobetasol propionate | 121102101 | 2 |
| Euro OTC | Clobetasol propionate | 1211021-01 | 19 |
| Euro OTC | Clobetasol propionate | 1211021-02 | 33 |
| Euro OTC | Clobetasol propionate | 1211021-03 | 30 |
| Euro OTC | Clobetasol propionate | 1211021-04 | 21 |
| Euro OTC | Clobetasol propionate | 121K021-01 | 1 |
| Euro OTC | Clobetasol propionate | 13042015A | 1 |
| Euro OTC | Clobetasol propionate | 130604002 | 1 |
| Euro OTC | Clobetasol propionate | 13269507 | 2 |
| Euro OTC | Clobetasol propionate | 13G23-N01 | 1 |
| Euro OTC | Clobetasol propionate | 1402018-03 | 1 |
| Euro OTC | Clobetasol propionate | 14080-02 | 1 |
| Euro OTC | Clobetasol propionate | 1408015-01 | 1 |
| Euro OTC | Clobetasol propionate | 1408018 | 1 |
| Euro OTC | Clobetasol propionate | 140801801 | 1 |
| Euro OTC | Clobetasol propionate | 1408018-01 | 17 |
| Euro OTC | Clobetasol propionate | 140801802 | 1 |
| Euro OTC | Clobetasol propionate | 1408018-02 | 76 |
| Euro OTC | Clobetasol propionate | 140801803 | 2 |
| Euro OTC | Clobetasol propionate | 1408018-03 | 33 |
| Euro OTC | Clobetasol propionate | 140808-02 | 1 |
| Euro OTC | Clobetasol propionate | 14080818-02 | 1 |
| Euro OTC | Clobetasol propionate | 15234003 | 1 |
| Euro OTC | Clobetasol propionate | 1601046-01 | 1 |
| Euro OTC | Clobetasol propionate | 16042014C | 1 |
| Euro OTC | Clobetasol propionate | 1606022 | 3 |
| Euro OTC | Clobetasol propionate | 160602201 | 6 |
| Euro OTC | Clobetasol propionate | 1606022-01 | 36 |
| Euro OTC | Clobetasol propionate | 160602202 | 6 |
| Euro OTC | Clobetasol propionate | 1606022-02 | 61 |
| Euro OTC | Clobetasol propionate | 160622-02 | 1 |
| Euro OTC | Clobetasol propionate | 16106720 | 1 |
| Euro OTC | Clobetasol propionate | 1704020 | 2 |
| Euro OTC | Clobetasol propionate | 170402001 | 9 |
| Euro OTC | Clobetasol propionate | 1704020-01 | 146 |
| Euro OTC | Clobetasol propionate | 1704020-015498 | 1 |
| Euro OTC | Clobetasol propionate | 17044020-01 | 2 |
| Euro OTC | Clobetasol propionate | 17096705 | 1 |
| Euro OTC | Clobetasol propionate | 17096709 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clobetasol propionate | 171107CP/1704020-01 | 1 |
| Euro OTC | Clobetasol propionate | 17E04-B02-338441 | 1 |
| Euro OTC | Clobetasol propionate | 17L18-B02-347993 | 1 |
| Euro OTC | Clobetasol propionate | 18004002-01 | 1 |
| Euro OTC | Clobetasol propionate | 1801002-01 | 1 |
| Euro OTC | Clobetasol propionate | 180400002 | 1 |
| Euro OTC | Clobetasol propionate | 180400-01 | 1 |
| Euro OTC | Clobetasol propionate | 18040002-01 | 1 |
| Euro OTC | Clobetasol propionate | 1804001-01 | 1 |
| Euro OTC | Clobetasol propionate | 1804002 | 1 |
| Euro OTC | Clobetasol propionate | 180400201 | 5 |
| Euro OTC | Clobetasol propionate | 1804002-01 | 203 |
| Euro OTC | Clobetasol propionate | 1804002201 | 1 |
| Euro OTC | Clobetasol propionate | 1804002-41 | 1 |
| Euro OTC | Clobetasol propionate | 18041808 | 1 |
| Euro OTC | Clobetasol propionate | 18082703 | 2 |
| Euro OTC | Clobetasol propionate | 18082708 | 1 |
| Euro OTC | Clobetasol propionate | 18082709 | 1 |
| Euro OTC | Clobetasol propionate | 18082717 | 1 |
| Euro OTC | Clobetasol propionate | 18111403 | 1 |
| Euro OTC | Clobetasol propionate | 1903014 | 1 |
| Euro OTC | Clobetasol propionate | 190301401 | 5 |
| Euro OTC | Clobetasol propionate | 1903014-01 | 186 |
| Euro OTC | Clobetasol propionate | 19030414-01 | 1 |
| Euro OTC | Clobetasol propionate | 19031401 | 1 |
| Euro OTC | Clobetasol propionate | 191142210 | 1 |
| Euro OTC | Clobetasol propionate | 200025-01 | 1 |
| Euro OTC | Clobetasol propionate | 2003023-01 | 1 |
| Euro OTC | Clobetasol propionate | 2003026/01 | 2 |
| Euro OTC | Clobetasol propionate | 200302601 | 1 |
| Euro OTC | Clobetasol propionate | 2003026-01 | 10 |
| Euro OTC | Clobetasol propionate | 2005025 | 1 |
| Euro OTC | Clobetasol propionate | 200502501 | 11 |
| Euro OTC | Clobetasol propionate | 2005025-01 | 124 |
| Euro OTC | Clobetasol propionate | 200505-01 | 1 |
| Euro OTC | Clobetasol propionate | 21001700008 | 2 |
| Euro OTC | Clobetasol propionate | 21090003-01 | 1 |
| Euro OTC | Clobetasol propionate | 210900301 | 5 |
| Euro OTC | Clobetasol propionate | 2109003-01 | 86 |
| Euro OTC | Clobetasol propionate | 2111I-02835 | 1 |
| Euro OTC | Clobetasol propionate | 219003-01 | 1 |
| Euro OTC | Clobetasol propionate | 22019014-01 | 1 |
| Euro OTC | Clobetasol propionate | 220826(2005025-01) | 1 |
| Euro OTC | Clobetasol propionate | 2209014-01 | 1 |
| Euro OTC | Clobetasol propionate | 28(1903014-01) | 1 |
| Euro OTC | Clobetasol propionate | 2835 | 1 |
| Euro OTC | Clobetasol propionate | 30092014A | 1 |
| Euro OTC | Clobetasol propionate | 31606022-02 | 1 |
| Euro OTC | Clobetasol propionate | 4091512 | 1 |
| Euro OTC | Clobetasol propionate | 4113Q-02835 | 1 |
| Euro OTC | Clobetasol propionate | 700225 | 2 |
| Euro OTC | Clobetasol propionate | 80616-1 | 1 |
| Euro OTC | Clobetasol propionate | 819081-39 | 1 |
| Euro OTC | Clobetasol propionate | CLO105-0519 | 1 |
| Euro OTC | Clobetasol propionate | CLO112/1018 | 2 |
| Euro OTC | Clobetasol propionate | CLO119/1217 | 2 |
| Euro OTC | Clobetasol propionate | Clob100123 | 1 |
| Euro OTC | Clobetasol propionate | CLO-BL2153/0711 | 1 |
| Euro OTC | Clobetasol propionate | CLO-BL2322/1012 | 2 |
| Euro OTC | Clobetasol propionate | CLO-BLT223/1216 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clobetasol propionate | clo-blt223/126 | 1 |
| Euro OTC | Clobetasol propionate | EuroOTC | 4 |
| Euro OTC | Clobetasol propionate | P14091725/1606022-01 | 1 |
| Euro Pharma / Noweda | Clobetasol propionate | 2109003-01 | 4 |
| Euro/ Alliance Healthcare | Clobetasol propionate | 1408018-03 | 2 |
| Euro/ANZAG | Clobetasol propionate | 1606022-02 | 1 |
| Euro/ANZAG | Clobetasol propionate | 1804002-01 | 1 |
| Euro/ANZAG | Clobetasol propionate | 1903014-01 | 1 |
| Euro/Noweda | Clobetasol propionate | 1408018-02 | 2 |
| Euro/Phönix | Clobetasol propionate | 210900301 | 1 |
| Euro/Sanacorp | Clobetasol propionate | 1408018-03 | 1 |
| EuRo/Sanacorp | Clobetasol propionate | 1804002-01 | 3 |
| euro/Symbiotica/Alli | Clobetasol propionate | 1903014-01 | 1 |
| Euroct/Gehe | Clobetasol propionate | 1408018-03 | 2 |
| EuRoh/ Sanacorp | Clobetasol propionate | 2109003-01 | 2 |
| euroho/gehe | Clobetasol propionate | 1211021-01 | 1 |
| Euro-OT/Noweda 14.11... | Clobetasol propionate | 2109003-01 | 2 |
| EurRho/Noweda | Clobetasol propionate | 2005025-01 | 1 |
| Eurro/Phoenix | Clobetasol propionate | 1804002-01 | 1 |
| Fa.Phönix | Clobetasol propionate | 18082708 | 1 |
| Fa.Phönix | Clobetasol propionate | 192245004 | 1 |
| Fa.Phönix | Clobetasol propionate | 21001700007 | 1 |
| Fagon / Gehe | Clobetasol propionate | 18/12-B02-354809 | 1 |
| Fagron | Clobetasol propionate | | 1 |
| Fagron | Clobetasol propionate | 11/29-N07 | 1 |
| Fagron | Clobetasol propionate | 11-05-N06 | 1 |
| Fagron | Clobetasol propionate | 1108044-03 | 2 |
| Fagron | Clobetasol propionate | 11300703 | 1 |
| Fagron | Clobetasol propionate | 11C16-N01 | 1 |
| Fagron | Clobetasol propionate | 11D26-N04 | 1 |
| Fagron | Clobetasol propionate | 11H10-N02 | 1 |
| Fagron | Clobetasol propionate | 11L12-N05 | 2 |
| Fagron | Clobetasol propionate | 11129-N07 | 1 |
| Fagron | Clobetasol propionate | 1211021 | 1 |
| Fagron | Clobetasol propionate | 1211021-02 | 1 |
| Fagron | Clobetasol propionate | 12A02-N04 | 1 |
| Fagron | Clobetasol propionate | 12E08N04 | 1 |
| Fagron | Clobetasol propionate | 12E08-N04 | 11 |
| Fagron | Clobetasol propionate | 12J25-N01 | 5 |
| Fagron | Clobetasol propionate | 1314705 | 1 |
| Fagron | Clobetasol propionate | 13A02-N04 | 18 |
| Fagron | Clobetasol propionate | 13Ao2-N04 | 1 |
| Fagron | Clobetasol propionate | 13G23N01 | 1 |
| Fagron | Clobetasol propionate | 13G23-N01 | 18 |
| Fagron | Clobetasol propionate | 13G23-N01NT0421M | 1 |
| Fagron | Clobetasol propionate | 13G23-NO1 | 1 |
| Fagron | Clobetasol propionate | 13K08-B03-287728 | 1 |
| Fagron | Clobetasol propionate | 13K08-B30 | 2 |
| Fagron | Clobetasol propionate | 13K08-B30-287726 | 2 |
| Fagron | Clobetasol propionate | 13K08B30287727 | 1 |
| Fagron | Clobetasol propionate | 13K08-B30-287727 | 2 |
| Fagron | Clobetasol propionate | 13-K08-B30-287727 | 1 |
| Fagron | Clobetasol propionate | 13k08b30287728 | 1 |
| Fagron | Clobetasol propionate | 13K08-B30-287728 | 6 |
| Fagron | Clobetasol propionate | 13K08-B30-287729 | 2 |
| Fagron | Clobetasol propionate | 13K08B30287730 | 1 |
| Fagron | Clobetasol propionate | 13K08-B30-287730 | 2 |
| Fagron | Clobetasol propionate | 1405018-02 | 1 |
| Fagron | Clobetasol propionate | 14188502 | 2 |
| Fagron | Clobetasol propionate | 14C03-B07 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clobetasol propionate | 14C03-B07-293560 | 3 |
| Fagron | Clobetasol propionate | 14C03-B07-293561 | 2 |
| Fagron | Clobetasol propionate | 14C03-B07-293562 | 10 |
| Fagron | Clobetasol propionate | 14C03-B07-293563 | 2 |
| Fagron | Clobetasol propionate | 14C03-B07-305985 | 1 |
| Fagron | Clobetasol propionate | 14C03-B07-305986 | 2 |
| Fagron | Clobetasol propionate | 14C03-B07-305987 | 2 |
| Fagron | Clobetasol propionate | 14G30_B07_302112 | 1 |
| Fagron | Clobetasol propionate | 14G30-B07 | 1 |
| Fagron | Clobetasol propionate | 14G30-B07-302112 | 2 |
| Fagron | Clobetasol propionate | 14G30-B07-302113 | 2 |
| Fagron | Clobetasol propionate | 14G30-B07-302114 | 11 |
| Fagron | Clobetasol propionate | 14G30-B07-302115 | 2 |
| Fagron | Clobetasol propionate | 14G30B07-302116 | 1 |
| Fagron | Clobetasol propionate | 14G30-B07-302116 | 4 |
| Fagron | Clobetasol propionate | 14G30-B07-303114 | 1 |
| Fagron | Clobetasol propionate | 15/15-B04-317699 | 1 |
| Fagron | Clobetasol propionate | 15a14-b02-303125 | 2 |
| Fagron | Clobetasol propionate | 15A14-B02-303125 | 12 |
| Fagron | Clobetasol propionate | 15C23-B02_310473 | 2 |
| Fagron | Clobetasol propionate | 15c23-b02-310473 | 2 |
| Fagron | Clobetasol propionate | 15C23-B02-310473 | 14 |
| Fagron | Clobetasol propionate | 15C23-B02-310522 | 3 |
| Fagron | Clobetasol propionate | 15G01-B02-311578 | 1 |
| Fagron | Clobetasol propionate | 15H26-B03-312355 | 4 |
| Fagron | Clobetasol propionate | 15H26-B03-312860 | 1 |
| Fagron | Clobetasol propionate | 15J15-B04 | 1 |
| Fagron | Clobetasol propionate | 15J15-B04-316615 | 1 |
| Fagron | Clobetasol propionate | 15j15-B04-317698 | 1 |
| Fagron | Clobetasol propionate | 15J15-B04-317698 | 6 |
| Fagron | Clobetasol propionate | 15J15-B04-317699 | 1 |
| Fagron | Clobetasol propionate | 1606022-02 | 1 |
| Fagron | Clobetasol propionate | 16106704 | 1 |
| Fagron | Clobetasol propionate | 16E04-B12 | 1 |
| Fagron | Clobetasol propionate | 16E04-B12-321032 | 1 |
| Fagron | Clobetasol propionate | 16E04-B12-321033 | 3 |
| Fagron | Clobetasol propionate | 16E04-B12-321034 | 4 |
| Fagron | Clobetasol propionate | 16E04-B12-321035 | 1 |
| Fagron | Clobetasol propionate | 16E04-B12-321036 | 2 |
| Fagron | Clobetasol propionate | 16E04-B12-322020 | 4 |
| Fagron | Clobetasol propionate | 16G18-B02-324627 | 6 |
| Fagron | Clobetasol propionate | 16G18B02325571 | 1 |
| Fagron | Clobetasol propionate | 16G18-B02-325571 | 2 |
| Fagron | Clobetasol propionate | 16G18-B02-325572 | 1 |
| Fagron | Clobetasol propionate | 16G18-B02-325573 | 8 |
| Fagron | Clobetasol propionate | 16G18-B02-32571 | 1 |
| Fagron | Clobetasol propionate | 16H22-B07 | 1 |
| Fagron | Clobetasol propionate | 16H22-B07-328012 | 14 |
| Fagron | Clobetasol propionate | 16H22-B07-330169 | 3 |
| Fagron | Clobetasol propionate | 16K24-B04 | 2 |
| Fagron | Clobetasol propionate | 16K24-B04-331220 | 1 |
| Fagron | Clobetasol propionate | 16k24-b04-332086 | 1 |
| Fagron | Clobetasol propionate | 16K24-B04-332086 | 6 |
| Fagron | Clobetasol propionate | 16K24-B04-333120 | 6 |
| Fagron | Clobetasol propionate | 16K24B04333121 | 1 |
| Fagron | Clobetasol propionate | 16K24-B04-333121 | 3 |
| Fagron | Clobetasol propionate | 16K24-B04-333143 | 5 |
| Fagron | Clobetasol propionate | 16K24-BO4-333120 | 1 |
| Fagron | Clobetasol propionate | 170402001 | 1 |
| Fagron | Clobetasol propionate | 1704020-01 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clobetasol propionate | 17096708 | 1 |
| Fagron | Clobetasol propionate | 17E04B02335335 | 1 |
| Fagron | Clobetasol propionate | 17E04-B02-335335 | 5 |
| Fagron | Clobetasol propionate | 17E04B02336882 | 1 |
| Fagron | Clobetasol propionate | 17E04-B02-336882 | 2 |
| Fagron | Clobetasol propionate | 17e04-b02-338441 | 1 |
| Fagron | Clobetasol propionate | 17E04-B02-338441 | 6 |
| Fagron | Clobetasol propionate | 17G14-B12 | 1 |
| Fagron | Clobetasol propionate | 17G14-B12-340175 | 6 |
| Fagron | Clobetasol propionate | 17G14-B12-340176 | 3 |
| Fagron | Clobetasol propionate | 17G14-B12-341742 | 1 |
| Fagron | Clobetasol propionate | 17g14-b12-341743 | 1 |
| Fagron | Clobetasol propionate | 17G14-B12-341743 | 3 |
| Fagron | Clobetasol propionate | 17L18-B02 | 3 |
| Fagron | Clobetasol propionate | 17L18B02-344841 | 1 |
| Fagron | Clobetasol propionate | 17L18-B02-344841 | 3 |
| Fagron | Clobetasol propionate | 17L18-B02-344842 | 3 |
| Fagron | Clobetasol propionate | 17L18-B02-345403 | 7 |
| Fagron | Clobetasol propionate | 17L18-B02-345404 | 4 |
| Fagron | Clobetasol propionate | 17L18B02347991 | 1 |
| Fagron | Clobetasol propionate | 17L18-B02347991 | 1 |
| Fagron | Clobetasol propionate | 17L18-B02-347991 | 1 |
| Fagron | Clobetasol propionate | 17L18-B02-347992 | 4 |
| Fagron | Clobetasol propionate | 17l18-b02-347993 | 1 |
| Fagron | Clobetasol propionate | 17L18-B02-347993 | 7 |
| Fagron | Clobetasol propionate | 17L18-B02-351867 | 3 |
| Fagron | Clobetasol propionate | 17LK18-B02-344841 | 1 |
| Fagron | Clobetasol propionate | 18/12-B02_357669 | 1 |
| Fagron | Clobetasol propionate | 18/12-b02-0002 | 1 |
| Fagron | Clobetasol propionate | 18/12-B02-353201 | 6 |
| Fagron | Clobetasol propionate | 18/12-B02-353202 | 8 |
| Fagron | Clobetasol propionate | 18/12-B02-353203 | 1 |
| Fagron | Clobetasol propionate | 18/12-B02-354809 | 2 |
| Fagron | Clobetasol propionate | 18/12-B02-355065 | 1 |
| Fagron | Clobetasol propionate | 18/12-B02-355390 | 3 |
| Fagron | Clobetasol propionate | 18/12-B02-355657 | 3 |
| Fagron | Clobetasol propionate | 18/12-B02-357670 | 1 |
| Fagron | Clobetasol propionate | 18/12-BO2-353202 | 2 |
| Fagron | Clobetasol propionate | 18/12-BO2-354809 | 1 |
| Fagron | Clobetasol propionate | 1804002-01 | 1 |
| Fagron | Clobetasol propionate | 18112-B02-357669 | 1 |
| Fagron | Clobetasol propionate | 1812-B02-353202 | 1 |
| Fagron | Clobetasol propionate | 1812-B02-353203 | 1 |
| Fagron | Clobetasol propionate | 18I12-02 | 1 |
| Fagron | Clobetasol propionate | 18I12-B02 | 5 |
| Fagron | Clobetasol propionate | 18I12-B02_357670 | 1 |
| Fagron | Clobetasol propionate | 18I12-B02-353202 | 4 |
| Fagron | Clobetasol propionate | 18I12-B02-353203 | 3 |
| Fagron | Clobetasol propionate | 18I12-B02-355065 | 1 |
| Fagron | Clobetasol propionate | 18I12-B02-355390 | 4 |
| Fagron | Clobetasol propionate | 18I12-B02-355391 | 4 |
| Fagron | Clobetasol propionate | 18I12-B02-357669 | 3 |
| Fagron | Clobetasol propionate | 18I12-B02-357670 | 1 |
| Fagron | Clobetasol propionate | 18I12-BO2-355391 | 1 |
| Fagron | Clobetasol propionate | 18l12-B02-353202 | 1 |
| Fagron | Clobetasol propionate | 18l12-B02-353203 | 1 |
| Fagron | Clobetasol propionate | 18l12-B02-354809 | 1 |
| Fagron | Clobetasol propionate | 18l12-B02-355065 | 1 |
| Fagron | Clobetasol propionate | 18l12-B02-355657 | 2 |
| Fagron | Clobetasol propionate | 18l12-B02-357669 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clobetasol propionate | 18112-Bo2-353201 | 1 |
| Fagron | Clobetasol propionate | 19/L10F02-366943 | 1 |
| Fagron | Clobetasol propionate | 1903014-01 | 1 |
| Fagron | Clobetasol propionate | 19B06-B03 | 2 |
| Fagron | Clobetasol propionate | 19B06-B03-360420 | 1 |
| Fagron | Clobetasol propionate | 19B06-B03-360421 | 4 |
| Fagron | Clobetasol propionate | 19B06-B03-360426 | 1 |
| Fagron | Clobetasol propionate | 19b06-b03-360603 | 1 |
| Fagron | Clobetasol propionate | 19B06-B03-360603 | 1 |
| Fagron | Clobetasol propionate | 19B06-B03-60603 | 1 |
| Fagron | Clobetasol propionate | 19G23_B05_363805 | 1 |
| Fagron | Clobetasol propionate | 19G23-B05 | 3 |
| Fagron | Clobetasol propionate | 19G23-B05-363804 | 3 |
| Fagron | Clobetasol propionate | 19G23-B05-363805 | 7 |
| Fagron | Clobetasol propionate | 19G23-B05-363806 | 11 |
| Fagron | Clobetasol propionate | 19G23-B05-363808 | 2 |
| Fagron | Clobetasol propionate | 19G23-BO5-363806 | 1 |
| Fagron | Clobetasol propionate | 19J02-F02 | 3 |
| Fagron | Clobetasol propionate | 19J02-F02-365320 | 4 |
| Fagron | Clobetasol propionate | 19J02-F02-365321 | 6 |
| Fagron | Clobetasol propionate | 19J02F02-365322 | 1 |
| Fagron | Clobetasol propionate | 19J02-F02365322 | 1 |
| Fagron | Clobetasol propionate | 19J02-F02-365322 | 12 |
| Fagron | Clobetasol propionate | 19J02-F02-365324 | 4 |
| Fagron | Clobetasol propionate | 19JO2-F02-365322 | 1 |
| Fagron | Clobetasol propionate | 19L10-F02 | 1 |
| Fagron | Clobetasol propionate | 19L10-F02-3669402 | 1 |
| Fagron | Clobetasol propionate | 19L10-F02-366941 | 6 |
| Fagron | Clobetasol propionate | 19L10F02366942 | 1 |
| Fagron | Clobetasol propionate | 19L10-F02-366942 | 9 |
| Fagron | Clobetasol propionate | 19L10-F02-366942CLO113/0619 | 1 |
| Fagron | Clobetasol propionate | 19L10F02366943 | 2 |
| Fagron | Clobetasol propionate | 19L10-F02-366943 | 10 |
| Fagron | Clobetasol propionate | 19L10-FO2-366945 | 1 |
| Fagron | Clobetasol propionate | 20F24-F03-374147 | 8 |
| Fagron | Clobetasol propionate | 20F24-F03-374148 | 3 |
| Fagron | Clobetasol propionate | 20F-24-F03-374148 | 1 |
| Fagron | Clobetasol propionate | 21F11-B01-213854 | 5 |
| Fagron | Clobetasol propionate | 21f11-b01-217282 | 1 |
| Fagron | Clobetasol propionate | 21F11-B01-217282 | 4 |
| Fagron | Clobetasol propionate | 21L16-B08-216942 | 1 |
| Fagron | Clobetasol propionate | 21L16-B08-218980 | 2 |
| Fagron | Clobetasol propionate | 21L16-B08-219012 | 1 |
| Fagron | Clobetasol propionate | 21L16-B08-221087 | 1 |
| Fagron | Clobetasol propionate | 21L16-B08-221088 | 4 |
| Fagron | Clobetasol propionate | 21L16-BO8-216879 | 1 |
| Fagron | Clobetasol propionate | 21L16-BO8-221088 | 1 |
| Fagron | Clobetasol propionate | 21L6BO8 | 1 |
| Fagron | Clobetasol propionate | 22H25BO8 | 1 |
| Fagron | Clobetasol propionate | 22H25-B08-223090 | 1 |
| Fagron | Clobetasol propionate | 22L20-B03-227672 | 1 |
| Fagron | Clobetasol propionate | 22L2O-B03-227672 | 1 |
| Fagron | Clobetasol propionate | 341743 | 1 |
| Fagron | Clobetasol propionate | 3713M-02835 | 1 |
| Fagron | Clobetasol propionate | B05-3638004 | 1 |
| Fagron | Clobetasol propionate | B05-3638006 | 1 |
| Fagron | Clobetasol propionate | B05-3680006 | 1 |
| Fagron | Clobetasol propionate | CLO001/0421 | 1 |
| Fagron | Clobetasol propionate | CLO002/0621 | 2 |
| Fagron | Clobetasol propionate | CLO101/0417 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clobetasol propionate | Clo103/0220 | 1 |
| Fagron | Clobetasol propionate | CLO103/0220 | 2 |
| Fagron | Clobetasol propionate | CLO103/0518 | 3 |
| Fagron | Clobetasol propionate | CLO105/0519 | 1 |
| Fagron | Clobetasol propionate | CLO111/1018 | 2 |
| Fagron | Clobetasol propionate | CLO113/0619 | 6 |
| Fagron | Clobetasol propionate | CLO4645878 | 1 |
| Fagron | Clobetasol propionate | F02-3653202 | 2 |
| Fagron | Clobetasol propionate | F02-3669401 | 1 |
| Fagron | Clobetasol propionate | F02-3669403 | 2 |
| Fagron | Clobetasol propionate | NS0292-M | 1 |
| Fagron | Clobetasol propionate | NS0486M | 1 |
| Fagron | Clobetasol propionate | NT0421M | 3 |
| Fargon/Phoenix 23.01.2018 | Clobetasol propionate | 17E04-B02-338441 | 1 |
| Fargon | Clobetasol propionate | 14C03-B07 | 1 |
| Fargon | Clobetasol propionate | 18/12-B02-355657 | 1 |
| Farmabios / Gehe | Clobetasol propionate | 15234003 | 1 |
| Farmabios / Gehe | Clobetasol propionate | 18082703 | 1 |
| Farmabios S.p.A./Cae... | Clobetasol propionate | 14338006 | 1 |
| Farmabios S.p.A. | Clobetasol propionate | 18300204 | 1 |
| Farmabios S.p.A/AHD | Clobetasol propionate | 18082708 | 1 |
| Farmabios S.p.A/AHD | Clobetasol propionate | 18082718 | 1 |
| Fgaron | Clobetasol propionate | 15H26-B03 | 1 |
| fgron Services B.V./ Gehe | Clobetasol propionate | F02-3669401 | 1 |
| Fiebig | Clobetasol propionate | 1804002-01 | 1 |
| Fiebig | Clobetasol propionate | 23000426003 | 2 |
| Fiebig | Clobetasol propionate | 24001314003 | 1 |
| Fischar | Clobetasol propionate | 14188506 | 1 |
| GEHE 21.03.2014 | Clobetasol propionate | 1211021-02 | 1 |
| Gehe amax | Clobetasol propionate | 15439501 | 1 |
| Gehe amax | Clobetasol propionate | 18300204 | 1 |
| Gehe/Euroh | Clobetasol propionate | 190301401 | 1 |
| Gehe | Clobetasol propionate | 10D21-N04 | 1 |
| Gehe | Clobetasol propionate | 12107606 | 1 |
| Gehe | Clobetasol propionate | 12342306 | 2 |
| Gehe | Clobetasol propionate | 12342310 | 1 |
| Gehe | Clobetasol propionate | 12J25-N01 | 1 |
| Gehe | Clobetasol propionate | 1408018-02 | 1 |
| Gehe | Clobetasol propionate | 1408018-03 | 1 |
| Gehe | Clobetasol propionate | 14188504 | 1 |
| Gehe | Clobetasol propionate | 15234003 | 1 |
| Gehe | Clobetasol propionate | 1606022-01 | 2 |
| Gehe | Clobetasol propionate | 16106701 | 1 |
| Gehe | Clobetasol propionate | 16106704 | 1 |
| Gehe | Clobetasol propionate | 16106711 | 1 |
| GEHE | Clobetasol propionate | 16G18-B02-324627 | 1 |
| Gehe | Clobetasol propionate | 170402001 | 1 |
| Gehe | Clobetasol propionate | 1704020-01 | 3 |
| Gehe | Clobetasol propionate | 17096705 | 1 |
| GEHE | Clobetasol propionate | 17096707 | 1 |
| Gehe | Clobetasol propionate | 17096708 | 1 |
| Gehe | Clobetasol propionate | 17325601 | 2 |
| Gehe | Clobetasol propionate | 1804002-01 | 1 |
| GEHE | Clobetasol propionate | 18082702 | 1 |
| Gehe | Clobetasol propionate | 18082703 | 1 |
| Gehe | Clobetasol propionate | 18I12-B02-353203 | 1 |
| Gehe | Clobetasol propionate | 18I12-B02-355391 | 1 |
| Gehe | Clobetasol propionate | 1903014-01 | 2 |
| Gehe | Clobetasol propionate | 20004302009 | 1 |
| Gehe | Clobetasol propionate | 209014-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| GEHE | Clobetasol propionate | 210017000003 | 1 |
| Gehe | Clobetasol propionate | 21001700013 | 1 |
| Gehe | Clobetasol propionate | 21001700018 | 1 |
| Gehe | Clobetasol propionate | 21001700025 | 2 |
| gehe | Clobetasol propionate | 21001700026 | 4 |
| Gehe | Clobetasol propionate | 21001700026 | 3 |
| Gehe | Clobetasol propionate | 2100700026 | 1 |
| Gehe | Clobetasol propionate | 2109003-01 | 1 |
| GEHE | Clobetasol propionate | 2209014_01 | 1 |
| Gehe | Clobetasol propionate | 2209014-01 | 2 |
| GEHE | Clobetasol propionate | 2209014-01 | 1 |
| GEHE | Clobetasol propionate | 22H25-B08-223090 | 1 |
| Gehe | Clobetasol propionate | 23000426001 | 1 |
| GEHE | Clobetasol propionate | 23000426001 | 1 |
| Gehe | Clobetasol propionate | 23000426002 | 2 |
| Gehe | Clobetasol propionate | 23000426003 | 8 |
| gehe | Clobetasol propionate | 23000426006 | 6 |
| Gehe | Clobetasol propionate | 23003315001 | 3 |
| Gehe | Clobetasol propionate | 23003315003 | 2 |
| Gehe | Clobetasol propionate | 2406006-01 | 1 |
| gehe | Clobetasol propionate | APCLPM03616C | 1 |
| gehe | Clobetasol propionate | Fagron23D-01B01-227673 | 1 |
| Geilenkirchen | Clobetasol propionate | 18082703 | 1 |
| Geilenkirchen | Clobetasol propionate | 192245011 | 1 |
| Geilenkirchen | Clobetasol propionate | 210017000003 | 1 |
| HCK | Clobetasol propionate | 11/05-N06 | 1 |
| Hedinger/ Sanacorp | Clobetasol propionate | APAPL/035/E-12C | 1 |
| Hedinger | Clobetasol propionate | 1704020-01 | 1 |
| henry lamotte/gehe | Clobetasol propionate | 16K24-B04-333121 | 2 |
| Henry Lamotte | Clobetasol propionate | 16106704 | 1 |
| Heyl/Noweda | Clobetasol propionate | 15234001 | 2 |
| Ichtyol / Noweda | Clobetasol propionate | 17325605 | 1 |
| Jenapharm/Noweda | Clobetasol propionate | 15234004 | 1 |
| Jenne | Clobetasol propionate | 21001700001 | 1 |
| Jenne | Clobetasol propionate | 21001700013 | 5 |
| Jenne | Clobetasol propionate | 22H25-B0B-225386 | 1 |
| Kehr Holdermann | Clobetasol propionate | 23000426001 | 1 |
| Kehr | Clobetasol propionate | 22000315001 | 1 |
| Kehr | Clobetasol propionate | 23000426001 | 1 |
| Kehr | Clobetasol propionate | 2300042600214 | 1 |
| Kehr | Clobetasol propionate | 23003315003 | 1 |
| Krieger | Clobetasol propionate | 2209014-01 | 1 |
| L10 | Clobetasol propionate | 16106703 | 2 |
| L10 | Clobetasol propionate | 18082708 | 1 |
| L12 | Clobetasol propionate | 16106711 | 1 |
| L12 | Clobetasol propionate | 17325602 | 1 |
| Midas | Clobetasol propionate | 16106704 | 2 |
| Midas | Clobetasol propionate | 17096705 | 1 |
| Nachprüfung vom 19.06.17 | Clobetasol propionate | 9302004 | 2 |
| Nachprüfung | Clobetasol propionate | 2082019-11 | 1 |
| Newchem / Gehe | Clobetasol propionate | 17096708 | 1 |
| Newchem S.p.A./Link | Clobetasol propionate | NZ0263M/X2835 | 1 |
| Newchem S.p.A. | Clobetasol propionate | 192245008 | 1 |
| Newchem/Phoenix | Clobetasol propionate | NZ0263M | 2 |
| Newchem | Clobetasol propionate | 15439504 | 2 |
| Noweda /Cealo | Clobetasol propionate | 18300209 | 1 |
| Noweda 6.4.17 | Clobetasol propionate | 1606022-01 | 1 |
| Noweda/ Ichthyol | Clobetasol propionate | 15439503 | 1 |
| Noweda/EuRo | Clobetasol propionate | 1606022-01 | 1 |
| Noweda | Clobetasol propionate | 11300702 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Clobetasol propionate | 12342305 | 1 |
| Noweda | Clobetasol propionate | 12342310 | 1 |
| Noweda | Clobetasol propionate | 13134701 | 1 |
| Noweda | Clobetasol propionate | 13134705 | 1 |
| Noweda | Clobetasol propionate | 13269504 | 1 |
| Noweda | Clobetasol propionate | 14338007 | 1 |
| Noweda | Clobetasol propionate | 15234004 | 1 |
| Noweda | Clobetasol propionate | 1606022-02 | 1 |
| Noweda | Clobetasol propionate | 16106720 | 1 |
| Noweda | Clobetasol propionate | 17096706 | 1 |
| Noweda | Clobetasol propionate | 17325605 | 1 |
| Noweda | Clobetasol propionate | 17G14-B12-340175 | 1 |
| Noweda | Clobetasol propionate | 1804002-01 | 5 |
| Noweda | Clobetasol propionate | 18300202 | 2 |
| Noweda | Clobetasol propionate | 18300204 | 1 |
| Noweda | Clobetasol propionate | 18300208 | 1 |
| Noweda | Clobetasol propionate | 18300213 | 1 |
| Noweda | Clobetasol propionate | 1903014-01 | 2 |
| Noweda | Clobetasol propionate | 192245003 | 1 |
| Noweda | Clobetasol propionate | 20004302006 | 1 |
| Noweda | Clobetasol propionate | 21001700003 | 1 |
| Noweda | Clobetasol propionate | 21001700023 | 2 |
| Noweda | Clobetasol propionate | 21001700025 | 1 |
| Noweda | Clobetasol propionate | 2100700023 | 1 |
| noweda | Clobetasol propionate | 2109003 | 1 |
| Noweda | Clobetasol propionate | 2109003-01 | 6 |
| Noweda | Clobetasol propionate | 2209014-01 | 2 |
| Noweda | Clobetasol propionate | 220914-02 | 1 |
| Noweda | Clobetasol propionate | 22H25-B08-223090 | 1 |
| noweda | Clobetasol propionate | 22L20-B03-225387 | 1 |
| Noweda | Clobetasol propionate | 23000426001 | 6 |
| NOWEDA | Clobetasol propionate | 23000426001 | 1 |
| Noweda | Clobetasol propionate | 23000426002 | 2 |
| Noweda | Clobetasol propionate | 23000426003 | 3 |
| Noweda | Clobetasol propionate | 2300315003 | 1 |
| Noweda | Clobetasol propionate | 23003315001 | 3 |
| Noweda | Clobetasol propionate | 23003315003 | 2 |
| Noweda | Clobetasol propionate | 24001314003 | 1 |
| Noweda | Clobetasol propionate | B03-3606003 | 1 |
| Oberlinden Apotheke | Clobetasol propionate | B0054/116010Mg60g | 1 |
| Parthe Apotheke | Clobetasol propionate | 96/21 | 1 |
| Ph.Eur 8.0 | Clobetasol propionate | 16106709 | 1 |
| Phoenix 02.04.2014 | Clobetasol propionate | 1211021-03 | 3 |
| Phoenix 24.11.2017 | Clobetasol propionate | 17096706 | 1 |
| Phoenix 29.11.12 | Clobetasol propionate | 700225 | 2 |
| Phoenix WE 29.04.17 … | Clobetasol propionate | 1606022-02 | 1 |
| Phoenix/Cealo | Clobetasol propionate | 17096701 | 1 |
| phoenix/fargon | Clobetasol propionate | 17L18-B02-345403 | 1 |
| Phoenix | Clobetasol propionate | 13K08B30287728 | 1 |
| Phoenix | Clobetasol propionate | 15439502 | 1 |
| Phoenix | Clobetasol propionate | 16h22-b07-328012 | 1 |
| Phoenix | Clobetasol propionate | 16H-B07-330169 | 1 |
| Phoenix | Clobetasol propionate | 1704020-01 | 1 |
| Phoenix | Clobetasol propionate | 1804002-01 | 1 |
| Phoenix | Clobetasol propionate | 18082703 | 2 |
| Phoenix | Clobetasol propionate | 18082709 | 1 |
| Phoenix | Clobetasol propionate | 183002001 | 1 |
| Phoenix | Clobetasol propionate | 192245002 | 1 |
| Phoenix | Clobetasol propionate | 192245011 | 1 |
| Phoenix | Clobetasol propionate | 20004302002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Clobetasol propionate | 20004302003 | 2 |
| Phoenix | Clobetasol propionate | 200451305 | 1 |
| Phoenix | Clobetasol propionate | 21001700007 | 1 |
| Phoenix | Clobetasol propionate | 2100170003 | 1 |
| Phoenix | Clobetasol propionate | 210900301 | 1 |
| Phoenix | Clobetasol propionate | 2109003-01 | 1 |
| Phoenix | Clobetasol propionate | 2209014-01 | 1 |
| Phoenix | Clobetasol propionate | 22H25-B08-223090 | 1 |
| Phoenix | Clobetasol propionate | 23000426001 | 4 |
| Phoenix | Clobetasol propionate | 23000426003 | 1 |
| Phoenix | Clobetasol propionate | 23003315001 | 1 |
| Phoenix | Clobetasol propionate | 2406006-01 | 2 |
| Phoenix | Clobetasol propionate | 3063 | 1 |
| Phoenix | Clobetasol propionate | 3365 | 1 |
| Phoenix | Clobetasol propionate | 3366 | 1 |
| Phönix Caesar u. Loretz | Clobetasol propionate | 13269508 | 1 |
| Phönix Gotha | Clobetasol propionate | 1108044-04 | 1 |
| Phönix Gotha | Clobetasol propionate | 1211021-02 | 3 |
| Phönix Gotha | Clobetasol propionate | 18082708 | 1 |
| phönix herne | Clobetasol propionate | 180400201 | 1 |
| Phönix, Caesar&Loret… | Clobetasol propionate | 18300213 | 1 |
| Phönix/Apo-Ident | Clobetasol propionate | 1606022-02 | 1 |
| Phönix/Euro | Clobetasol propionate | 1804002-01 | 1 |
| Phönix | Clobetasol propionate | | 1 |
| Phönix | Clobetasol propionate | 1211021-04 | 1 |
| Phönix | Clobetasol propionate | 13134701 | 1 |
| phönix | Clobetasol propionate | 15439503 | 1 |
| phönix | Clobetasol propionate | 15439504 | 1 |
| Phönix | Clobetasol propionate | 15H26-B03-312860 | 1 |
| Phönix | Clobetasol propionate | 16106703 | 1 |
| phönix | Clobetasol propionate | 16106704 | 1 |
| Phönix | Clobetasol propionate | 17096706 | 2 |
| Phönix | Clobetasol propionate | 1804002-01 | 1 |
| phönix | Clobetasol propionate | 18082703 | 1 |
| Phönix | Clobetasol propionate | 18300204 | 1 |
| Phönix | Clobetasol propionate | 192245004 | 1 |
| Phönix | Clobetasol propionate | 20004302002 | 1 |
| Phönix | Clobetasol propionate | 2002025-01 | 1 |
| Phönix | Clobetasol propionate | 2005025-01 | 4 |
| Phönix | Clobetasol propionate | 200990910 | 1 |
| Phönix | Clobetasol propionate | 21001700026 | 1 |
| phönix | Clobetasol propionate | 2109003-01 | 1 |
| Phönix | Clobetasol propionate | 2109003-01 | 1 |
| Phönix | Clobetasol propionate | 23000426001 | 2 |
| Phönix | Clobetasol propionate | 23003315001 | 2 |
| Phönix | Clobetasol propionate | 23003315003 | 1 |
| Phonix | Clobetasol propionate | 23003315007 | 1 |
| Phönix | Clobetasol propionate | 3161 | 1 |
| Phönix | Clobetasol propionate | 3182 | 1 |
| Phönix | Clobetasol propionate | F02-3653202 | 1 |
| PhönixWE24.10.2014 … | Clobetasol propionate | 1211021-04 | 1 |
| Raben-Apotheke Mildenau | Clobetasol propionate | 13k08-b30-287727 | 1 |
| Röntgen | Clobetasol propionate | 1804002-01 | 1 |
| Sanacorp | Clobetasol propionate | 1108044-03 | 1 |
| Sanacorp | Clobetasol propionate | 12107608 | 1 |
| Sanacorp | Clobetasol propionate | 12107609 | 2 |
| Sanacorp | Clobetasol propionate | 1211021-01 | 1 |
| Sanacorp | Clobetasol propionate | 12342310 | 1 |
| Sanacorp | Clobetasol propionate | 13269507 | 1 |
| sanacorp | Clobetasol propionate | 13269508 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Clobetasol propionate | 13g23n01 | 1 |
| Sanacorp | Clobetasol propionate | 1408018-01 | 2 |
| sanacorp | Clobetasol propionate | 14188506 | 1 |
| Sanacorp | Clobetasol propionate | 15234003 | 1 |
| Sanacorp | Clobetasol propionate | 1606022-02 | 2 |
| Sanacorp | Clobetasol propionate | 18082708 | 1 |
| Sanacorp | Clobetasol propionate | 183002001 | 2 |
| Sanacorp | Clobetasol propionate | 18300204 | 1 |
| Sanacorp | Clobetasol propionate | 18I12-B02_357669 | 1 |
| Sanacorp | Clobetasol propionate | 192245004 | 1 |
| Sanacorp | Clobetasol propionate | 20004302009 | 1 |
| Sanacorp | Clobetasol propionate | 2005025-01 | 1 |
| Sanacorp | Clobetasol propionate | 21001700003 | 2 |
| Sanacorp | Clobetasol propionate | 21001700023 | 1 |
| Sanacorp | Clobetasol propionate | 21L16-B08-221088 | 1 |
| Sanacorp | Clobetasol propionate | 2209014-01 | 1 |
| Sanacorp | Clobetasol propionate | 230003315003 | 1 |
| Sanacorp | Clobetasol propionate | 23000426001 | 2 |
| sanacorp | Clobetasol propionate | 23000426002 | 1 |
| Sanacorp | Clobetasol propionate | 23003315001 | 1 |
| Sanacorp | Clobetasol propionate | 23G-B08-236828 | 1 |
| Sanacorp;19.03.15;87,60EUR | Clobetasol propionate | 14C03-B07-293563 | 1 |
| Symbiotica / Gehe | Clobetasol propionate | 1408018-02 | 1 |
| Symbiotica / Gehe | Clobetasol propionate | 1408018-03 | 2 |
| Symbiotica / Noweda | Clobetasol propionate | 1704020-01 | 1 |
| Symbiotica Spec. Ing. . . | Clobetasol propionate | 19J02-F02-365322 | 1 |
| Symbiotica Spec./Phönix | Clobetasol propionate | 1108044-04 | 1 |
| Symbiotica Spec./Phönix | Clobetasol propionate | 1211021-01 | 2 |
| Symbiotica Spec./Phönix | Clobetasol propionate | CLO-B12153/0711 | 1 |
| Symbiotica Spec. | Clobetasol propionate | 1211021-03 | 1 |
| Symbiotica/ | Clobetasol propionate | CLO111/0521 | 1 |
| symbiotica/gehe | Clobetasol propionate | 1211021-03 | 1 |
| Symbiotica/Noweda | Clobetasol propionate | CLO119/1217 | 1 |
| Symbiotica/Phönix | Clobetasol propionate | 1408018-02 | 1 |
| Symbiotica/Sanacorp | Clobetasol propionate | 1408018-03 | 1 |
| Symbiotica | Clobetasol propionate | 2005025-01 | 2 |
| symbiotica | Clobetasol propionate | 2109003 | 1 |
| Symbiotica | Clobetasol propionate | 2109003-01 | 1 |
| Symbiotitica/Noweda | Clobetasol propionate | 1606022-01 | 1 |
| VDL | Clobetasol propionate | 2109003-01 | 1 |
| WE: 20.01.16 | Clobetasol propionate | 15234004 | 1 |

- 252 000 spectra from 1665 *Apo-Ident* customers from a total of 51 507 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Clobetasol propionate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Clobetasol propionate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 740 | 0 | 157 586 |
| **Type B** | 0 | 1184 | 0 | 211 756 |
| **Type C** | 0 | 4780 | 106 | 252 000 |

The substance/substance group *Clobetasol propionate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1892 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4932 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.8305 % (> 97.7691 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21092 | 21092 | 0.00 | 75.61 |
| 21473 | 21473 | 0.00 | 56.05 |
| 21611 | 21611 | 0.00 | 53.75 |
| 21802 | 21802 | 0.00 | 113.92 |
| 21896 | 21896 | 0.00 | 79.12 |
| 22714 | 22714 | 0.00 | 53.90 |
| 22724 | 21092 | 5.95 | 74.79 |
| 24691 | 25349 | 8.12 | 52.95 |
| 24904 | 24904 | 0.00 | 80.12 |
| 25349 | 25349 | 0.00 | 53.03 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Clonidine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20637-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Clonidine hydrochloride; Clonidini hydrochloridum

### Special notes

When selecting the *Clonidine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Clonidine hydrochloride | 6 | 4 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Clonidine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Clonidine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 123.32 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Clonidine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Clonidine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Clonidine hydrochloride | 13I25-B07 | 21220 | 40 | 20131009 |
| Fagron | Clonidine hydrochloride | 14H11-B04-311163 | 21966 | 60 | AR-18-FG-006797-02 |
| Fagron | Clonidine hydrochloride | 14H11-B04-311163 | 22967 | 40 | 20140929 |
| Fagron | Clonidine hydrochloride | 14H11-B04-311163 | 22967SI | 40 | 20140929 |
| Fagron | Clonidine hydrochloride | 19B27-B02-361777 | 24687 | 40 | 20190607 |
| Fagron | Clonidine hydrochloride | 22A26-B04-216708 | 26141 | 40 | 20220316 |
| Fagron | Clonidine hydrochloride | 22A26-B04-216708 | 26141SI | 40 | 20220316 |
| Fagron | Clonidine hydrochloride | 22B22-B03-216999 | 26142 | 40 | 20220505 |
| Fagron | Clonidine hydrochloride | 22B22-B03-216999 | 26142SI | 40 | 20220505 |
| Fagron | Clonidine hydrochloride | 24A29-B05-234630 | 27186 | 40 | 20240227 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 420 spectra of 10 reference samples from the substance/substance group *Clonidine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference


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samples come from 6 different batches.

- 157 906 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 540 spectra of 13 reference samples from the substance/substance group *Clonidine hydrochloride*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Clonidine hydrochloride | 15L11-B01-332270 | 23228 | 40 |
| Fagron | Clonidine hydrochloride | 18B12-B04-353341 | 24443 | 40 |
| Fagron | Clonidine hydrochloride | 20D29-F02-374142 | 25785 | 40 |
| Fagron | Clonidine hydrochloride | 21F07-B03-213617 | 25907 | 40 |
| Fagron | Clonidine hydrochloride | 14H11-B04-311163 | 21966SI† | 60 |
| Fagron | Clonidine hydrochloride | 15L11-B01-332270 | 23228SI | 40 |
| Fagron | Clonidine hydrochloride | 15L11-B01-332270 | 23410 | 40 |
| Fagron | Clonidine hydrochloride | 15L11-B01-332270 | 23410SI | 40 |
| Fagron | Clonidine hydrochloride | 18B12-B04-353341 | 24443SI | 40 |
| Fagron | Clonidine hydrochloride | 19B27-B02-361777 | 24687SI† | 40 |
| Fagron | Clonidine hydrochloride | 20D29-F02-374142 | 25785SI | 40 |
| Fagron | Clonidine hydrochloride | 21F07-B03-213617 | 25907SI | 40 |
| Fagron | Clonidine hydrochloride | 24A29-B05-234630 | 27186SI† | 40 |

- 212 400 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 57 spectra from 18 *Apo-Ident* customers from 13 batches from the substance/substance group *Clonidine hydrochloride*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clonidine hydrochloride | 22B22-B03-225373 | 1 |
| | Clonidine hydrochloride | 24A29-B05-230375 | 1 |
| Fagron | Clonidine hydrochloride | 14H11-B04-298642 | 1 |
| Fagron | Clonidine hydrochloride | 14H11-B04-311163 | 42 |
| Fagron | Clonidine hydrochloride | 15L11-B01 | 1 |
| Fagron | Clonidine hydrochloride | 18B12-B04-353341 | 1 |
| Fagron | Clonidine hydrochloride | 20D29-F02-3705608 | 1 |
| Fagron | Clonidine hydrochloride | 20D29-F02-370567 | 1 |
| Fagron | Clonidine hydrochloride | 21F07-B03-213617 | 1 |
| Fagron | Clonidine hydrochloride | 22B22-B03-217792 | 1 |
| Fagron | Clonidine hydrochloride | 22B22-B03-221078 | 2 |
| Fagron | Clonidine hydrochloride | 22B22-B03-225373 | 1 |
| Fagron | Clonidine hydrochloride | 77543E004 | 1 |
| Fagron | Clonidine hydrochloride | F02-370567 | 1 |
| Regenbogen Apotheke | Clonidine hydrochloride | 18B12-B04-353341 | 1 |

- 256 829 spectra from 1666 *Apo-Ident* customers from a total of 52 140 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Clonidine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Clonidine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 540 | 0 | 212 400 |
| **Type C** | 0 | 57 | 0 | 256 829 |

The substance/substance group *Clonidine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8889 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 89.4737 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21220 | 21966 | 21.05 | 214.46 |
| 21966 | 21966 | 0.00 | 236.46 |
| 22967 | 21966 | 28.63 | 212.08 |
| 24687 | 21966 | 33.78 | 212.56 |
| 26141 | 21966 | 31.91 | 212.43 |
| 26142 | 21966 | 38.88 | 214.23 |
| 27186 | 21966 | 45.55 | 214.65 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Clotrimazole** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20000-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Clotrimazole; Clotrimazolum

### Special notes

When selecting the *Clotrimazole* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Clotrimazole | 12 | 16 | 954 |

### Second-stage model

For differentiation of the substance/substance group *Clotrimazole* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Clotrimazole* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Bifonazole | 42.31 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Clotrimazole* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Clotrimazole*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Clotrimazole | 13184113 | 21087 | 40 | 20130614 |
| Caelo | Clotrimazole | 13224204 | 21114 | 40 | 20130815 |
| Caelo | Clotrimazole | 13224220 | 21352 | 40 | 20130815 |
| Caelo | Clotrimazole | 13224220 | 21353 | 40 | 20130815 |
| Caelo | Clotrimazole | 153956 | 23791 | 40 | 20151215* |
| Caelo | Clotrimazole | 21000121 | 25649 | 40 | 20210330* |
| Caelo | Clotrimazole | 21000123 | 25656 | 40 | 20210330* |
| Euro OTC | Clotrimazole | 1306036-01 | 21207 | 40 | 20130823 |
| Euro OTC | Clotrimazole | 1510003 | 22229 | 60 | 20151111* |
| Fagron | Clotrimazole | 12I21-N01 | 20794 | 40 | 20120322 |
| Fagron | Clotrimazole | 14B05-B36 | 21259 | 40 | 20140225 |
| Fagron | Clotrimazole | 14C04-B31 | 21264 | 40 | 20140319 |
| Fagron | Clotrimazole | 22A21-B02-217361 | 26137 | 40 | 20220411 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 540 spectra of 13 reference samples from the substance/substance group *Clotrimazole*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.

- 157 786 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 680 spectra of 19 reference samples from the substance/substance group *Clotrimazole*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Clotrimazole | 12320815 | 20861 | 30 |
| Caelo | Clotrimazole | 171116 | 23322 | 40 |
| Caelo | Clotrimazole | 17111616 | 23781 | 40 |
| Caelo | Clotrimazole | 190161 | 24512 | 40 |
| Caelo | Clotrimazole | 190162 | 24517 | 40 |
| Caelo | Clotrimazole | 21004117 | 26001 | 40 |
| Caelo | Clotrimazole | 23001597 | 26834 | 40 |
| Euro OTC | Clotrimazole | 1607046 | 22793 | 40 |
| Euro OTC | Clotrimazole | 1703028 | 23129 | 40 |
| Euro OTC | Clotrimazole | 1808028 | 24298 | 40 |
| Euro OTC | Clotrimazole | 1902004 | 24461 | 40 |
| Euro OTC | Clotrimazole | 2007033 | 25300 | 40 |
| Euro OTC | Clotrimazole | 2103024 | 25672 | 40 |
| Euro OTC | Clotrimazole | 2301055 | 26582 | 40 |
| Euro OTC | Clotrimazole | 2406013 | 27400 | 40 |
| Fagron | Clotrimazole | 24K18-B02-005751 | 27646 | 40 |
| Caelo | Clotrimazole | 21004117 | 26001SI | 10 |
| Euro OTC | Clotrimazole | 2301055 | 26582SI | 20 |
| Fagron | Clotrimazole | 22A21-B02-217361 | 26137SI† | 20 |

- 212 260 spectra from a total of 4270 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this

entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 7685 spectra from 1452 *Apo-Ident* customers from 1009 batches from the substance/substance group *Clotrimazole*.
- Among them are spectra of independent samples from 951 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clotrimazole | 1306036-01 | 1 |
| | Clotrimazole | 14C04-B30-291661 | 1 |
| | Clotrimazole | 181023/14 | 1 |
| | Clotrimazole | 181023/16 | 1 |
| | Clotrimazole | 181023/7 | 1 |
| | Clotrimazole | 20H26-F05 | 1 |
| | Clotrimazole | 20H26-F05-373735 | 1 |
| | Clotrimazole | 20H26-F05-373736 | 1 |
| | Clotrimazole | 20H26-F05-373737 | 1 |
| | Clotrimazole | 20H26-F05-373738 | 1 |
| | Clotrimazole | 21/24-B11-213292 | 1 |
| | Clotrimazole | 21000123010 | 1 |
| | Clotrimazole | 2100116005 | 1 |
| | Clotrimazole | 2100411016 | 1 |
| | Clotrimazole | 210041160007 | 1 |
| | Clotrimazole | 21004116005 | 7 |
| | Clotrimazole | 21004116007 | 18 |
| | Clotrimazole | 21004116008 | 9 |
| | Clotrimazole | 21004116012 | 3 |
| | Clotrimazole | 21004116013 | 9 |
| | Clotrimazole | 21004116014 | 38 |
| | Clotrimazole | 21004116016 | 6 |
| | Clotrimazole | 21004116017 | 1 |
| | Clotrimazole | 2100411614 | 1 |
| | Clotrimazole | 21004117004 | 2 |
| | Clotrimazole | 21004117005 | 2 |
| | Clotrimazole | 21004117007 | 1 |
| | Clotrimazole | 2100411701 | 1 |
| | Clotrimazole | 21004117011 | 3 |
| | Clotrimazole | 21004117012 | 1 |
| | Clotrimazole | 21004117013 | 1 |
| | Clotrimazole | 21004117016 | 3 |
| | Clotrimazole | 21004117017 | 9 |
| | Clotrimazole | 21004117018 | 18 |
| | Clotrimazole | 21004117019 | 10 |
| | Clotrimazole | 21004117022 | 16 |
| | Clotrimazole | 21004117023 | 8 |
| | Clotrimazole | 2100416016 | 1 |
| | Clotrimazole | 2103024-01 | 5 |
| | Clotrimazole | 2103024-02 | 15 |
| | Clotrimazole | 2103024-03 | 4 |
| | Clotrimazole | 21124-B11-213292 | 1 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clotrimazole | 214116014 | 1 |
| | Clotrimazole | 21D22-B03 | 1 |
| | Clotrimazole | 21D22-B03-0003 | 1 |
| | Clotrimazole | 21D22-B03-217092 | 3 |
| | Clotrimazole | 21H13-B14-213291 | 2 |
| | Clotrimazole | 21i24_b11_213292 | 1 |
| | Clotrimazole | 21I24-B11 | 1 |
| | Clotrimazole | 21I24-B11-213292 | 6 |
| | Clotrimazole | 21I24-B11-218638 | 2 |
| | Clotrimazole | 22A21-B02_217361 | 1 |
| | Clotrimazole | 22A21-B02-217361 | 2 |
| | Clotrimazole | 22A21-B02-217510 | 2 |
| | Clotrimazole | 22A21-B02-221671 | 1 |
| | Clotrimazole | 22A21-B02-221730 | 3 |
| | Clotrimazole | 22A21-B02-221731 | 7 |
| | Clotrimazole | 22A21-B02-221737 | 1 |
| | Clotrimazole | 22G29-B05-223684 | 2 |
| | Clotrimazole | 22G29-B05-228695 | 1 |
| | Clotrimazole | 23001596002 | 49 |
| | Clotrimazole | 23001596003 | 16 |
| | Clotrimazole | 23001596004 | 1 |
| | Clotrimazole | 23001596008 | 11 |
| | Clotrimazole | 23001596009 | 20 |
| | Clotrimazole | 23001596010 | 9 |
| | Clotrimazole | 23003390001 | 20 |
| | Clotrimazole | 23003390003 | 4 |
| | Clotrimazole | 23003390004 | 15 |
| | Clotrimazole | 23003390005 | 18 |
| | Clotrimazole | 23003390006 | 7 |
| | Clotrimazole | 23003390007 | 2 |
| | Clotrimazole | 2300339005 | 1 |
| | Clotrimazole | 2301055_01 | 1 |
| | Clotrimazole | 23010550-01 | 1 |
| | Clotrimazole | 23010550-03 | 2 |
| | Clotrimazole | 230105501 | 2 |
| | Clotrimazole | 2301055-01 | 30 |
| | Clotrimazole | 2301055-02 | 22 |
| | Clotrimazole | 2301055-03 | 10 |
| | Clotrimazole | 2301055-04 | 8 |
| | Clotrimazole | 2301055-05 | 2 |
| | Clotrimazole | 231055-01 | 2 |
| | Clotrimazole | 23D11-B01-228541 | 1 |
| | Clotrimazole | 23D11-b01-228693 | 1 |
| | Clotrimazole | 23D11-B01-228693 | 2 |
| | Clotrimazole | 23H09-B07-230826 | 5 |
| | Clotrimazole | 23H09-B07-230827 | 6 |
| | Clotrimazole | 23H09-B07-235131 | 2 |
| | Clotrimazole | 23H09-B07-235132 | 2 |
| | Clotrimazole | 23H09-B07-235133 | 1 |
| | Clotrimazole | 24001098001 | 4 |
| | Clotrimazole | 24001099005 | 2 |
| | Clotrimazole | 240601301 | 1 |
| | Clotrimazole | 2406013-01 | 2 |
| | Clotrimazole | 24E08-B10-002511 | 2 |
| | Clotrimazole | 250409(23003390006) | 1 |
| | Clotrimazole | 4933131 | 1 |
| | Clotrimazole | 7-23082007 | 1 |
| | Clotrimazole | A21130J001 | 4 |
| | Clotrimazole | A22130J037 | 1 |
| | Clotrimazole | A2213OJ037 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Clotrimazole | AP230225-02 | 1 |
| | Clotrimazole | B11-2132902 | 1 |
| | Clotrimazole | B11-2132903 | 1 |
| | Clotrimazole | B11-2186308 | 1 |
| | Clotrimazole | caelo | 2 |
| | Clotrimazole | HCZ00923 | 1 |
| | Clotrimazole | HCZ20120 | 1 |
| A.H.D. | Clotrimazole | 14337801 | 1 |
| AEP | Clotrimazole | 23001596002 | 1 |
| AEP | Clotrimazole | 23003390005 | 1 |
| AHC | Clotrimazole | 23001596009 | 1 |
| AHD 27.10 Ek.7,07 | Clotrimazole | 1607046 | 1 |
| AHD/EuRho 04.03.2021... | Clotrimazole | 2007033-01 | 2 |
| AHD/EuRho | Clotrimazole | 1902004-01 | 1 |
| AHD/Euro | Clotrimazole | 1808028-02 | 1 |
| AHD/Hedinger | Clotrimazole | 14337807 | 1 |
| AHD | Clotrimazole | 13184105 | 1 |
| AHD | Clotrimazole | 14144914 | 1 |
| AHD | Clotrimazole | 16J07-B02-335773 | 1 |
| AHD | Clotrimazole | 16J07-B02-344817 | 1 |
| AHD | Clotrimazole | 1703028-03 | 1 |
| AHD | Clotrimazole | 1808028-01 | 1 |
| AHD | Clotrimazole | 18A18-B05-352114 | 1 |
| AHD | Clotrimazole | 190200-02 | 2 |
| AHD | Clotrimazole | 1902004-01 | 3 |
| AHD | Clotrimazole | 19B14-B01-359538 | 1 |
| AHD | Clotrimazole | 21004116008 | 1 |
| ahd | Clotrimazole | 21004116014 | 1 |
| ahd | Clotrimazole | 21004116016 | 1 |
| AHD | Clotrimazole | 21004116016 | 1 |
| AHD | Clotrimazole | 21004117023 | 1 |
| AHD | Clotrimazole | 2103024-02 | 1 |
| AHD | Clotrimazole | 2103024-03 | 1 |
| AHD | Clotrimazole | 22A21-B02-221730 | 1 |
| AHD | Clotrimazole | 23001596008 | 1 |
| AHD | Clotrimazole | 23003390005 | 1 |
| AHD | Clotrimazole | 23H09-B07-235135 | 1 |
| Alli | Clotrimazole | 21004116007 | 1 |
| Alliance healfcare | Clotrimazole | 17j25-b06-349161 | 1 |
| Alliance healfcare | Clotrimazole | 18g10-b06-358825 | 1 |
| Alliance Health care | Clotrimazole | 21004117018 | 1 |
| Alliance Healthcare | Clotrimazole | 1309034-01 | 1 |
| Alliance Healthcare | Clotrimazole | 18147216 | 1 |
| Alliance Healthcare | Clotrimazole | 21004117001 | 1 |
| Alliance Healthcare | Clotrimazole | 23001596009 | 1 |
| Alliance Healthcare | Clotrimazole | 23H09-B07-235131 | 1 |
| Alliance Healthcare | Clotrimazole | AP1510003-01C | 1 |
| Alliance/Euro | Clotrimazole | 1703028-01 | 1 |
| Alliance | Clotrimazole | 21004117011 | 1 |
| Alliance | Clotrimazole | 21004117018 | 1 |
| Alliance | Clotrimazole | 23001596002 | 1 |
| Allianz Healthcare | Clotrimazole | 18g10-b06-355382 | 1 |
| Amoli / Ebert | Clotrimazole | CLT/1505/0016B | 2 |
| Amoli Organics Plot ... | Clotrimazole | 17J25-Bo6-349161 | 1 |
| Anzag | Clotrimazole | 14C04-B30-2916618 | 1 |
| Anzag | Clotrimazole | 15395610 | 1 |
| Anzag | Clotrimazole | 15G14-B06 | 1 |
| Anzag | Clotrimazole | 1703028-01 | 1 |
| Anzag | Clotrimazole | 2007033-02 | 1 |
| Anzag | Clotrimazole | 22A21-B02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag | Clotrimazole | 23001596009 | 1 |
| Anzag | Clotrimazole | 2301055-04 | 1 |
| Anzag | Clotrimazole | 230417(2103024-01) | 1 |
| Anzag | Clotrimazole | 231128(21004116016) | 1 |
| Anzag | Clotrimazole | 240320(21004116008) | 1 |
| Anzag | Clotrimazole | 250709(24001098003) | 1 |
| apo ident | Clotrimazole | 1607046-02 | 1 |
| apo-ident | Clotrimazole | 1902004-03 | 1 |
| apo-ident | Clotrimazole | 2103024-02 | 1 |
| ApoIdent | Clotrimazole | 2103024-1 | 1 |
| Apo-klent | Clotrimazole | 2103024-02 | 1 |
| apomix | Clotrimazole | 14B05-B36 | 1 |
| apomix | Clotrimazole | 15G14-B05-311100 | 1 |
| Audor Pharma | Clotrimazole | 1703/0016CC | 1 |
| Audor Pharma | Clotrimazole | 1703028-02 | 1 |
| Audor Pharma | Clotrimazole | 2007033-01 | 1 |
| Audor Pharma | Clotrimazole | 2007033-02 | 1 |
| Audor Pharma | Clotrimazole | 213024-02 | 2 |
| Audor Pharma | Clotrimazole | AP1306036-01C | 1 |
| Audor Pharma | Clotrimazole | APCL/1703/0016C | 1 |
| Audor Pharma | Clotrimazole | APCLT/1703/0016C | 2 |
| Audor Pharma | Clotrimazole | APCLT/1703/0016CC | 4 |
| Beiersdorf | Clotrimazole | 15395611 | 1 |
| Bombastus | Clotrimazole | 1210039/02 | 1 |
| Bombastus | Clotrimazole | 12320815 | 1 |
| Bombastus | Clotrimazole | 14337817 | 1 |
| Bombastus | Clotrimazole | 1607046-01 | 2 |
| Bombastus | Clotrimazole | 17360203 | 1 |
| Bombastus | Clotrimazole | 18147211 | 1 |
| Bombastus | Clotrimazole | Validierungsmessung | 1 |
| Caeelo / Gehe | Clotrimazole | 18147211 | 1 |
| cael | Clotrimazole | 19016208 | 2 |
| Caello/Anzag | Clotrimazole | 14337815 | 1 |
| Caelo | Clotrimazole | | 10 |
| Caelo | Clotrimazole | 10147203 | 1 |
| Caelo | Clotrimazole | 10247328 | 3 |
| Caelo | Clotrimazole | 1070716 | 1 |
| Caelo | Clotrimazole | 108/AKD1 | 1 |
| Caelo | Clotrimazole | 11/22-N10 | 1 |
| Caelo | Clotrimazole | 1105014-02 | 1 |
| Caelo | Clotrimazole | 1108120I | 1 |
| Caelo | Clotrimazole | 11305505 | 1 |
| Caelo | Clotrimazole | 11305506 | 2 |
| Caelo | Clotrimazole | 11305507 | 1 |
| Caelo | Clotrimazole | 11305511 | 1 |
| Caelo | Clotrimazole | 11305513 | 8 |
| Caelo | Clotrimazole | 1150817/16234512 | 1 |
| Caelo | Clotrimazole | 1170717 | 1 |
| Caelo | Clotrimazole | 11-K21-N19 | 1 |
| Caelo | Clotrimazole | 12000123011 | 1 |
| Caelo | Clotrimazole | 1210030-02 | 1 |
| Caelo | Clotrimazole | 1210039-01 | 1 |
| Caelo | Clotrimazole | 12159902 | 11 |
| Caelo | Clotrimazole | 12159904 | 2 |
| Caelo | Clotrimazole | 12159911 | 2 |
| Caelo | Clotrimazole | 12159913 | 9 |
| Caelo | Clotrimazole | 12159916 | 6 |
| Caelo | Clotrimazole | 123011 | 1 |
| Caelo | Clotrimazole | 12320805 | 4 |
| Caelo | Clotrimazole | 12320806 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clotrimazole | 12320807 | 4 |
| Caelo | Clotrimazole | 12320808 | 11 |
| Caelo | Clotrimazole | 12320809 | 4 |
| Caelo | Clotrimazole | 12320813 | 3 |
| Caelo | Clotrimazole | 12320814 | 9 |
| Caelo | Clotrimazole | 12320815 | 1 |
| Caelo | Clotrimazole | 1234567 | 1 |
| Caelo | Clotrimazole | 1259913 | 1 |
| Caelo | Clotrimazole | 12B27-N05 | 2 |
| Caelo | Clotrimazole | 12E02-N12 | 2 |
| Caelo | Clotrimazole | 12E30-N07 | 1 |
| Caelo | Clotrimazole | 12I21-N04 | 1 |
| Caelo | Clotrimazole | 1306036 | 1 |
| Caelo | Clotrimazole | 130603601 | 1 |
| Caelo | Clotrimazole | 1306036-01 | 4 |
| Caelo | Clotrimazole | 1309034-01 | 2 |
| Caelo | Clotrimazole | 1309034-02 | 3 |
| Caelo | Clotrimazole | 1309034-C1 | 1 |
| Caelo | Clotrimazole | 13148007 | 1 |
| Caelo | Clotrimazole | 13184103 | 10 |
| Caelo | Clotrimazole | 13184105 | 13 |
| Caelo | Clotrimazole | 13184111 | 7 |
| Caelo | Clotrimazole | 131841111 | 1 |
| Caelo | Clotrimazole | 13184113 | 2 |
| Caelo | Clotrimazole | 132234216 | 1 |
| Caelo | Clotrimazole | 1322401 | 1 |
| Caelo | Clotrimazole | 13224201 | 21 |
| Caelo | Clotrimazole | 13224204 | 2 |
| Caelo | Clotrimazole | 13224210 | 11 |
| Caelo | Clotrimazole | 13224211 | 5 |
| Caelo | Clotrimazole | 13224212 | 8 |
| Caelo | Clotrimazole | 13224214 | 9 |
| Caelo | Clotrimazole | 13224215 | 3 |
| Caelo | Clotrimazole | 13224216 | 9 |
| Caelo | Clotrimazole | 13224217 | 9 |
| Caelo | Clotrimazole | 13224218 | 12 |
| Caelo | Clotrimazole | 13224219 | 7 |
| Caelo | Clotrimazole | 13224220 | 6 |
| Caelo | Clotrimazole | 13224221 | 2 |
| Caelo | Clotrimazole | 13224225 | 2 |
| Caelo | Clotrimazole | 132243218 | 1 |
| Caelo | Clotrimazole | 13324204 | 1 |
| Caelo | Clotrimazole | 1409027-03 | 1 |
| Caelo | Clotrimazole | 1409027-04 | 1 |
| Caelo | Clotrimazole | 14101716 | 1 |
| Caelo | Clotrimazole | 141104C | 1 |
| Caelo | Clotrimazole | 14144905 | 17 |
| Caelo | Clotrimazole | 14144911 | 13 |
| Caelo | Clotrimazole | 14144912 | 2 |
| Caelo | Clotrimazole | 14144913 | 2 |
| Caelo | Clotrimazole | 14144914 | 8 |
| Caelo | Clotrimazole | 14144917 | 5 |
| Caelo | Clotrimazole | 14144918 | 12 |
| Caelo | Clotrimazole | 143337811 | 1 |
| Caelo | Clotrimazole | 14337801 | 14 |
| Caelo | Clotrimazole | 14337802 | 8 |
| Caelo | Clotrimazole | 14337807 | 12 |
| Caelo | Clotrimazole | 14337809 | 14 |
| Caelo | Clotrimazole | 14337811 | 4 |
| Caelo | Clotrimazole | 14337812 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clotrimazole | 14337813 | 8 |
| Caelo | Clotrimazole | 14337814 | 9 |
| Caelo | Clotrimazole | 14337815 | 8 |
| Caelo | Clotrimazole | 14337816 | 17 |
| Caelo | Clotrimazole | 14337817 | 18 |
| Caelo | Clotrimazole | 14337818 | 14 |
| Caelo | Clotrimazole | 14337819 | 8 |
| Caelo | Clotrimazole | 14337824 | 3 |
| Caelo | Clotrimazole | 14337824NP | 1 |
| Caelo | Clotrimazole | 14337827 | 10 |
| Caelo | Clotrimazole | 14337828 | 13 |
| Caelo | Clotrimazole | 14337829 | 18 |
| Caelo | Clotrimazole | 14337830 | 3 |
| Caelo | Clotrimazole | 14337832 | 1 |
| Caelo | Clotrimazole | 14338712 | 1 |
| Caelo | Clotrimazole | 1437816 | 1 |
| Caelo | Clotrimazole | 14B05-B35 | 1 |
| Caelo | Clotrimazole | 14B05-B35-293544 | 2 |
| Caelo | Clotrimazole | 14B05-B36-291167 | 1 |
| Caelo | Clotrimazole | 14B05-B36-291168 | 1 |
| Caelo | Clotrimazole | 14c04-b30-291656 | 1 |
| Caelo | Clotrimazole | 14C04-B30-291656 | 4 |
| Caelo | Clotrimazole | 14c04-B31 | 1 |
| Caelo | Clotrimazole | 14C04-B31-294939 | 1 |
| Caelo | Clotrimazole | 14c04-b31-299954 | 2 |
| Caelo | Clotrimazole | 14C04B31-299954 | 1 |
| Caelo | Clotrimazole | 14C04-B31-299955 | 1 |
| Caelo | Clotrimazole | 14C04-B32-291657 | 1 |
| Caelo | Clotrimazole | 1510003-01 | 6 |
| Caelo | Clotrimazole | 15295603 | 1 |
| Caelo | Clotrimazole | 15395602 | 20 |
| Caelo | Clotrimazole | 15395603 | 10 |
| Caelo | Clotrimazole | 15395604 | 15 |
| Caelo | Clotrimazole | 15395605 | 15 |
| Caelo | Clotrimazole | 1539561 | 1 |
| Caelo | Clotrimazole | 15395610 | 7 |
| Caelo | Clotrimazole | 15395611 | 13 |
| Caelo | Clotrimazole | 15395613 | 8 |
| Caelo | Clotrimazole | 15395614 | 8 |
| Caelo | Clotrimazole | 15395615 | 8 |
| Caelo | Clotrimazole | 15395617 | 14 |
| Caelo | Clotrimazole | 15395618 | 20 |
| Caelo | Clotrimazole | 15395618I-81216/1 | 1 |
| Caelo | Clotrimazole | 15395623 | 2 |
| Caelo | Clotrimazole | 1539613 | 1 |
| Caelo | Clotrimazole | 153965604 | 1 |
| Caelo | Clotrimazole | 156546 | 1 |
| Caelo | Clotrimazole | 15G14-B05-311101 | 1 |
| Caelo | Clotrimazole | 15G14-B05-311103 | 2 |
| Caelo | Clotrimazole | 15G14-B05-316483 | 2 |
| Caelo | Clotrimazole | 15G14-B06-311054 | 1 |
| Caelo | Clotrimazole | 15G14-B06-311055 | 2 |
| Caelo | Clotrimazole | 15G14-B06-311057 | 1 |
| Caelo | Clotrimazole | 16051913 | 1 |
| Caelo | Clotrimazole | 160614 | 1 |
| Caelo | Clotrimazole | 160704601 | 1 |
| Caelo | Clotrimazole | 1607046-01 | 7 |
| Caelo | Clotrimazole | 1607046-02 | 5 |
| Caelo | Clotrimazole | 16131901 | 1 |
| Caelo | Clotrimazole | 1623417 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clotrimazole | 16234501 | 8 |
| Caelo | Clotrimazole | 16234502 | 6 |
| Caelo | Clotrimazole | 16234503 | 19 |
| Caelo | Clotrimazole | 16234504 | 11 |
| Caelo | Clotrimazole | 16234505 | 30 |
| Caelo | Clotrimazole | 16234506 | 1 |
| Caelo | Clotrimazole | 16234509 | 11 |
| Caelo | Clotrimazole | 16234511 | 24 |
| Caelo | Clotrimazole | 16234512 | 19 |
| Caelo | Clotrimazole | 16234513 | 26 |
| Caelo | Clotrimazole | 162345135319 | 1 |
| Caelo | Clotrimazole | 16234515 | 1 |
| Caelo | Clotrimazole | 16234517 | 10 |
| Caelo | Clotrimazole | 16234520 | 25 |
| Caelo | Clotrimazole | 16234521 | 11 |
| Caelo | Clotrimazole | 16234522 | 23 |
| Caelo | Clotrimazole | 162345225555 | 1 |
| Caelo | Clotrimazole | 16234523 | 1 |
| Caelo | Clotrimazole | 16234525 | 7 |
| Caelo | Clotrimazole | 1623455 | 1 |
| Caelo | Clotrimazole | 16B09-B06-3115007 | 1 |
| Caelo | Clotrimazole | 16B09B06311506 | 1 |
| Caelo | Clotrimazole | 16B09-B06-311785 | 1 |
| Caelo | Clotrimazole | 16B11-B04-320088 | 3 |
| Caelo | Clotrimazole | 16B11-B04-322393 | 1 |
| Caelo | Clotrimazole | 16B11-B04-325221 | 1 |
| Caelo | Clotrimazole | 16B11-B04-327611 | 1 |
| Caelo | Clotrimazole | 16E20-B10 | 2 |
| Caelo | Clotrimazole | 16E20-B10-324555 | 1 |
| Caelo | Clotrimazole | 16J07-B02 | 1 |
| Caelo | Clotrimazole | 16J07-B02_330236 | 1 |
| Caelo | Clotrimazole | 16J07-B02-329385 | 4 |
| Caelo | Clotrimazole | 16J07-B02-329386 | 1 |
| Caelo | Clotrimazole | 16J07-B02-330216 | 2 |
| Caelo | Clotrimazole | 16J07-B02-335773 | 1 |
| Caelo | Clotrimazole | 16J07-B02-344817 | 1 |
| Caelo | Clotrimazole | 16J07-B02-344818 | 2 |
| Caelo | Clotrimazole | 17/25-B06-345048 | 1 |
| Caelo | Clotrimazole | 17011601 | 1 |
| Caelo | Clotrimazole | 1703028 | 1 |
| Caelo | Clotrimazole | 170302801 | 7 |
| Caelo | Clotrimazole | 1703028-01 | 18 |
| Caelo | Clotrimazole | 1703028-02 | 6 |
| Caelo | Clotrimazole | 170302803 | 1 |
| Caelo | Clotrimazole | 1703028-03 | 4 |
| Caelo | Clotrimazole | 1703028-0318147206 | 1 |
| Caelo | Clotrimazole | 17053186 | 1 |
| Caelo | Clotrimazole | 171113608 | 1 |
| Caelo | Clotrimazole | 17111601 | 15 |
| Caelo | Clotrimazole | 17111603 | 4 |
| Caelo | Clotrimazole | 17111604 | 8 |
| Caelo | Clotrimazole | 17111605 | 19 |
| Caelo | Clotrimazole | 17111606 | 30 |
| Caelo | Clotrimazole | 17111608 | 12 |
| Caelo | Clotrimazole | 1711161 | 1 |
| Caelo | Clotrimazole | 17111612 | 1 |
| Caelo | Clotrimazole | 17111613 | 27 |
| Caelo | Clotrimazole | 17111615 | 27 |
| Caelo | Clotrimazole | 17111616 | 37 |
| Caelo | Clotrimazole | 17111617 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clotrimazole | 1711603 | 2 |
| Caelo | Clotrimazole | 1711604 | 2 |
| Caelo | Clotrimazole | 1711605 | 1 |
| Caelo | Clotrimazole | 1711606 | 2 |
| Caelo | Clotrimazole | 1711613 | 2 |
| Caelo | Clotrimazole | 1711816 | 1 |
| Caelo | Clotrimazole | 17260204 | 1 |
| Caelo | Clotrimazole | 1736002001 | 1 |
| Caelo | Clotrimazole | 173600201 | 2 |
| Caelo | Clotrimazole | 17360023 | 1 |
| Caelo | Clotrimazole | 17360201 | 30 |
| Caelo | Clotrimazole | 17360202 | 36 |
| Caelo | Clotrimazole | 17360203 | 16 |
| Caelo | Clotrimazole | 17360204 | 29 |
| Caelo | Clotrimazole | 17A19-B04 | 1 |
| Caelo | Clotrimazole | 17A19-B04-332097 | 1 |
| Caelo | Clotrimazole | 17A19-B04-340476 | 1 |
| Caelo | Clotrimazole | 17J25-B06-345045 | 1 |
| Caelo | Clotrimazole | 17J25-B06-345048 | 1 |
| Caelo | Clotrimazole | 17J25-B06-347476 | 1 |
| Caelo | Clotrimazole | 18016104 | 1 |
| Caelo | Clotrimazole | 1808028-01 | 5 |
| Caelo | Clotrimazole | 1808028-02 | 2 |
| Caelo | Clotrimazole | 18081408 | 1 |
| Caelo | Clotrimazole | 1814211 | 1 |
| Caelo | Clotrimazole | 18147101 | 49 |
| Caelo | Clotrimazole | 18147102 | 41 |
| Caelo | Clotrimazole | 18147103 | 24 |
| Caelo | Clotrimazole | 181471035763 | 1 |
| Caelo | Clotrimazole | 18147201 | 2 |
| Caelo | Clotrimazole | 18147202 | 2 |
| Caelo | Clotrimazole | 18147203 | 35 |
| Caelo | Clotrimazole | 18147206 | 1 |
| Caelo | Clotrimazole | 18147208 | 2 |
| Caelo | Clotrimazole | 18147210 | 54 |
| Caelo | Clotrimazole | 18147211 | 45 |
| Caelo | Clotrimazole | 18147212 | 14 |
| Caelo | Clotrimazole | 18147215 | 3 |
| Caelo | Clotrimazole | 18147216 | 7 |
| Caelo | Clotrimazole | 18147217 | 8 |
| Caelo | Clotrimazole | 1847103 | 1 |
| Caelo | Clotrimazole | 1882321 | 2 |
| Caelo | Clotrimazole | 1882404 | 1 |
| Caelo | Clotrimazole | 18A18-B05-347865 | 2 |
| Caelo | Clotrimazole | 18A18-B05-348429 | 1 |
| Caelo | Clotrimazole | 18A18-B05-349662 | 1 |
| Caelo | Clotrimazole | 18A18B05350778 | 1 |
| Caelo | Clotrimazole | 18A18-B05-350780 | 1 |
| Caelo | Clotrimazole | 18A18-B05-350781 | 1 |
| Caelo | Clotrimazole | 18A18-b05-352115 | 1 |
| Caelo | Clotrimazole | 18A18-B05-352115 | 1 |
| Caelo | Clotrimazole | 18A18-B05-353892 | 1 |
| Caelo | Clotrimazole | 18A18-B056-352115 | 1 |
| Caelo | Clotrimazole | 18G10-B06-352425 | 1 |
| Caelo | Clotrimazole | 18G10-B06-352427 | 2 |
| Caelo | Clotrimazole | 18g10-b06-358825 | 1 |
| Caelo | Clotrimazole | 190016207 | 1 |
| Caelo | Clotrimazole | 19015107 | 1 |
| Caelo | Clotrimazole | 190160106 | 1 |
| Caelo | Clotrimazole | 1901606 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clotrimazole | 19016103 | 19 |
| Caelo | Clotrimazole | 19016104 | 17 |
| Caelo | Clotrimazole | 19016105 | 31 |
| Caelo | Clotrimazole | 19016106 | 27 |
| Caelo | Clotrimazole | 19016107 | 27 |
| Caelo | Clotrimazole | 19016108 | 18 |
| Caelo | Clotrimazole | 19016115 | 1 |
| Caelo | Clotrimazole | 19016115P-191111-1 | 1 |
| Caelo | Clotrimazole | 19016116 | 30 |
| Caelo | Clotrimazole | 19016119 | 24 |
| Caelo | Clotrimazole | 190162001 | 2 |
| Caelo | Clotrimazole | 19016202 | 22 |
| Caelo | Clotrimazole | 19016203 | 25 |
| Caelo | Clotrimazole | 19016204 | 22 |
| Caelo | Clotrimazole | 19016205 | 12 |
| Caelo | Clotrimazole | 19016206 | 16 |
| Caelo | Clotrimazole | 19016207 | 1 |
| Caelo | Clotrimazole | 19016208 | 25 |
| Caelo | Clotrimazole | 19016210 | 2 |
| Caelo | Clotrimazole | 19016212 | 1 |
| Caelo | Clotrimazole | 190200401 | 1 |
| Caelo | Clotrimazole | 1902004-01 | 4 |
| Caelo | Clotrimazole | 1902004-02 | 3 |
| Caelo | Clotrimazole | 1902004-3 | 1 |
| Caelo | Clotrimazole | 19052401 | 1 |
| Caelo | Clotrimazole | 1906106 | 1 |
| Caelo | Clotrimazole | 190652002 | 1 |
| Caelo | Clotrimazole | 1916202 | 1 |
| Caelo | Clotrimazole | 192004-03 | 1 |
| Caelo | Clotrimazole | 19B14-B01 | 1 |
| Caelo | Clotrimazole | 19B14-B01-359537 | 1 |
| Caelo | Clotrimazole | 19B14-B01-359539 | 2 |
| Caelo | Clotrimazole | 19J23-F06-367382 | 1 |
| Caelo | Clotrimazole | 200000 | 1 |
| Caelo | Clotrimazole | 200000000094008 | 1 |
| Caelo | Clotrimazole | 200000092005 | 1 |
| Caelo | Clotrimazole | 200000094003 | 1 |
| Caelo | Clotrimazole | 200000094004 | 2 |
| Caelo | Clotrimazole | 2000002005 | 1 |
| Caelo | Clotrimazole | 2000004002 | 1 |
| Caelo | Clotrimazole | 200000892006 | 1 |
| Caelo | Clotrimazole | 2000009 | 1 |
| Caelo | Clotrimazole | 20000092002 | 17 |
| Caelo | Clotrimazole | 20000092005 | 11 |
| Caelo | Clotrimazole | 20000092006 | 24 |
| Caelo | Clotrimazole | 20000092007 | 27 |
| Caelo | Clotrimazole | 2000009202 | 1 |
| Caelo | Clotrimazole | 2000009207 | 1 |
| Caelo | Clotrimazole | 20000094001 | 1 |
| Caelo | Clotrimazole | 20000094002 | 24 |
| Caelo | Clotrimazole | 20000094003 | 26 |
| Caelo | Clotrimazole | 200000940033 | 1 |
| Caelo | Clotrimazole | 20000094004 | 34 |
| Caelo | Clotrimazole | 20000094005 | 34 |
| Caelo | Clotrimazole | 20000094006 | 26 |
| Caelo | Clotrimazole | 2000009400601882404 | 1 |
| Caelo | Clotrimazole | 20000094007 | 1 |
| Caelo | Clotrimazole | 20000094008 | 17 |
| Caelo | Clotrimazole | 20000094009 | 1 |
| Caelo | Clotrimazole | 20000094012 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clotrimazole | 2000009404 | 2 |
| Caelo | Clotrimazole | 2000009405 | 1 |
| Caelo | Clotrimazole | 2000009408 | 1 |
| Caelo | Clotrimazole | 200003904005 | 1 |
| Caelo | Clotrimazole | 2000092002 | 1 |
| Caelo | Clotrimazole | 2000092006 | 1 |
| Caelo | Clotrimazole | 2000092007 | 1 |
| Caelo | Clotrimazole | 2000094003 | 1 |
| Caelo | Clotrimazole | 2000094004 | 1 |
| Caelo | Clotrimazole | 2000094005 | 1 |
| Caelo | Clotrimazole | 2000094008 | 3 |
| Caelo | Clotrimazole | 200009402 | 1 |
| Caelo | Clotrimazole | 20003904003 | 16 |
| Caelo | Clotrimazole | 20003904004 | 37 |
| Caelo | Clotrimazole | 20003904005 | 9 |
| Caelo | Clotrimazole | 20003904008 | 7 |
| Caelo | Clotrimazole | 2007033-01 | 7 |
| Caelo | Clotrimazole | 2007033-02 | 1 |
| Caelo | Clotrimazole | 2007033-03 | 1 |
| Caelo | Clotrimazole | 20111018 | 1 |
| Caelo | Clotrimazole | 20111115 | 1 |
| Caelo | Clotrimazole | 20160801 | 5 |
| Caelo | Clotrimazole | 2092 | 1 |
| Caelo | Clotrimazole | 20B27-F02-370980 | 1 |
| Caelo | Clotrimazole | 20H26F05373737 | 1 |
| Caelo | Clotrimazole | 21/24-B11-218638 | 1 |
| Caelo | Clotrimazole | 210000121002 | 1 |
| Caelo | Clotrimazole | 21000121002 | 44 |
| Caelo | Clotrimazole | 21000121003 | 27 |
| Caelo | Clotrimazole | 21000121004 | 49 |
| Caelo | Clotrimazole | 21000121005 | 2 |
| Caelo | Clotrimazole | 21000121006 | 27 |
| Caelo | Clotrimazole | 21000121008 | 13 |
| Caelo | Clotrimazole | 21000121009 | 29 |
| Caelo | Clotrimazole | 21000121010 | 31 |
| Caelo | Clotrimazole | 210001210101 | 1 |
| Caelo | Clotrimazole | 21000121013 | 17 |
| Caelo | Clotrimazole | 21000123006 | 18 |
| Caelo | Clotrimazole | 21000123008 | 27 |
| Caelo | Clotrimazole | 21000123010 | 15 |
| Caelo | Clotrimazole | 21000123011 | 24 |
| Caelo | Clotrimazole | 21000211006 | 1 |
| Caelo | Clotrimazole | 210004116005 | 1 |
| Caelo | Clotrimazole | 2100117013 | 1 |
| Caelo | Clotrimazole | 2100121009 | 1 |
| Caelo | Clotrimazole | 21004116001 | 13 |
| Caelo | Clotrimazole | 21004116003 | 10 |
| Caelo | Clotrimazole | 21004116005 | 14 |
| Caelo | Clotrimazole | 21004116006 | 3 |
| Caelo | Clotrimazole | 21004116007 | 2 |
| Caelo | Clotrimazole | 21004116008 | 1 |
| Caelo | Clotrimazole | 21004116013 | 2 |
| Caelo | Clotrimazole | 21004116014 | 3 |
| Caelo | Clotrimazole | 21004117001 | 14 |
| Caelo | Clotrimazole | 21004117003 | 3 |
| Caelo | Clotrimazole | 21004117004 | 10 |
| Caelo | Clotrimazole | 21004117005 | 15 |
| Caelo | Clotrimazole | 21004117007 | 22 |
| Caelo | Clotrimazole | 21004117011 | 3 |
| Caelo | Clotrimazole | 21004117013 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Clotrimazole | 21004117016 | 17 |
| Caelo | Clotrimazole | 21004117017 | 5 |
| Caelo | Clotrimazole | 21004117018 | 6 |
| Caelo | Clotrimazole | 21004117019 | 3 |
| Caelo | Clotrimazole | 21004117022 | 2 |
| Caelo | Clotrimazole | 2100417005 | 1 |
| Caelo | Clotrimazole | 2103024-01 | 3 |
| Caelo | Clotrimazole | 210302402 | 2 |
| Caelo | Clotrimazole | 2103024-03 | 1 |
| Caelo | Clotrimazole | 21-24-B11-218638 | 1 |
| Caelo | Clotrimazole | 21H13-B14-213291 | 2 |
| Caelo | Clotrimazole | 2217Q-01276 | 1 |
| Caelo | Clotrimazole | 23001596002 | 2 |
| Caelo | Clotrimazole | 23001596008 | 1 |
| Caelo | Clotrimazole | 26071305 | 1 |
| Caelo | Clotrimazole | 310316-5-461 | 1 |
| Caelo | Clotrimazole | 311111 | 1 |
| Caelo | Clotrimazole | 3335 | 1 |
| Caelo | Clotrimazole | 3456575 | 1 |
| Caelo | Clotrimazole | 412091-2-P | 1 |
| Caelo | Clotrimazole | 415050-2-P | 1 |
| Caelo | Clotrimazole | 418072-1-P | 1 |
| Caelo | Clotrimazole | 5117E-01276 | 1 |
| Caelo | Clotrimazole | 54292100012113 | 1 |
| Caelo | Clotrimazole | 700135-0006 | 1 |
| Caelo | Clotrimazole | 8638446 | 2 |
| Caelo | Clotrimazole | 94006 | 1 |
| Caelo | Clotrimazole | 94008 | 1 |
| Caelo | Clotrimazole | AP1510003-01C | 1 |
| Caelo | Clotrimazole | AP201221-08 | 1 |
| Caelo | Clotrimazole | Fagron | 1 |
| Caelo | Clotrimazole | HCZ14218 | 1 |
| Caelo | Clotrimazole | HCZ20120 | 1 |
| Caelo | Clotrimazole | P-21091821/18147203 | 1 |
| Caelo | Clotrimazole | PC85 | 1 |
| Caeolo/Gehe | Clotrimazole | 16234521 | 1 |
| Caesar & Lorenz GmbH | Clotrimazole | 21004117016 | 1 |
| Caesar & Loretz /Phönix | Clotrimazole | 2000094004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117007 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121009 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016108 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000092006 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 18147211 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 200000094005 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000123008 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004116003 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117016 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016202 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 2100012301 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 2100121009 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016103 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117017 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004116014 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121009 | 1 |
| Caesar & Loretz GmbH Sana | Clotrimazole | 21004117011 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 18147203 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094003 | 3 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Clotrimazole | 20000094004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000123006 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000092006 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094002 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094003 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904003 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016205 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094008 | 1 |
| Caesar & Loretz GmbH/AEP | Clotrimazole | 21000121009 | 1 |
| Caesar & Loretz GmbH/AHD | Clotrimazole | 18147211 | 1 |
| Caesar & Loretz GmbH/AHD | Clotrimazole | 21000121010 | 1 |
| Caesar & Loretz GmbH/AHD | Clotrimazole | 21004117004 | 1 |
| Caesar & Loretz GmbH/AHD | Clotrimazole | 21004117017 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121009 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117011 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016105 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016106 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904005 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000123008 | 1 |
| Caesar & Loretz GmbH/GEHE | Clotrimazole | 18147211 | 1 |
| Caesar & Loretz GmbH/Gehe | Clotrimazole | 19016204 | 1 |
| Caesar & Loretz GmbH/Gehe | Clotrimazole | 20000092006 | 2 |
| Caesar & Loretz GmbH/Gehe | Clotrimazole | 20000092007 | 1 |
| Caesar & Loretz GmbH/GEHE | Clotrimazole | 20000094002 | 7 |
| Caesar & Loretz GmbH/GEHE | Clotrimazole | 20000094004 | 1 |
| Caesar & Loretz GmbH/Gehe | Clotrimazole | 21000123006 | 2 |
| Caesar & Loretz GmbH/Gehe | Clotrimazole | 21000123011 | 1 |
| Caesar & Loretz GmbH/Gehe | Clotrimazole | 21004116005 | 1 |
| Caesar & Loretz GmbH/Gehe | Clotrimazole | 21004117005 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000092006 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094008 | 3 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121013 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004116001 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016105 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016203 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121003 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016206 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904003 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121010 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000123011 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117016 | 1 |
| Caesar & Loretz GmbH/K | Clotrimazole | 20003904004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121006 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 18147102 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094002 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094005 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094008 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000123006 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121006 | 1 |
| Caesar & Loretz GmbH/Pho | Clotrimazole | 21000121004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121002 | 5 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000123008 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004116001 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004116003 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117022 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Clotrimazole | 20000094004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121009 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121013 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000123006 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117007 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904005 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121009 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016119 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016203 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 19016204 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000092005 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000092007 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094006 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 20003904004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121002 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121003 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121004 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121008 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121009 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | 21000121010 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 21004117007 | 2 |
| Caesar & Loretz GmbH... | Clotrimazole | AP210225-03 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | AP210622-01 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 16J07B02344817 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 17111604 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 17360204 | 3 |
| Caesar & Loretz GmbH | Clotrimazole | 17A19-B04 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 18147103 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 18147203 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 18147210 | 15 |
| Caesar & Loretz GmbH | Clotrimazole | 18147211 | 5 |
| Caesar & Loretz GmbH | Clotrimazole | 18147212 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 18147216 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 18147217 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 19016103 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 19016104 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 19016105 | 9 |
| Caesar & Loretz GmbH | Clotrimazole | 19016106 | 6 |
| Caesar & Loretz GmbH | Clotrimazole | 19016107 | 5 |
| Caesar & Loretz GmbH | Clotrimazole | 19016108 | 5 |
| Caesar & Loretz GmbH | Clotrimazole | 19016116 | 10 |
| Caesar & Loretz GmbH | Clotrimazole | 19016119 | 11 |
| Caesar & Loretz GmbH | Clotrimazole | 190162001 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 19016202 | 9 |
| Caesar & Loretz GmbH | Clotrimazole | 19016203 | 5 |
| Caesar & Loretz GmbH | Clotrimazole | 19016204 | 7 |
| Caesar & Loretz GmbH | Clotrimazole | 19016205 | 4 |
| Caesar & Loretz GmbH | Clotrimazole | 19016206 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 19016208 | 9 |
| Caesar & Loretz GmbH | Clotrimazole | 1902004-02 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 19076708 | 3 |
| Caesar & Loretz GmbH | Clotrimazole | 20000092002 | 7 |
| Caesar & Loretz GmbH | Clotrimazole | 20000092005 | 3 |
| Caesar & Loretz GmbH | Clotrimazole | 20000092006 | 16 |
| Caesar & Loretz GmbH | Clotrimazole | 20000092007 | 9 |
| Caesar & Loretz GmbH | Clotrimazole | 20000094002 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 20000094003 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 20000094004 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Clotrimazole | 20000094005 | 15 |
| Caesar & Loretz GmbH | Clotrimazole | 20000094006 | 13 |
| Caesar & Loretz GmbH | Clotrimazole | 20000094007 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 20000094008 | 9 |
| Caesar & Loretz GmbH | Clotrimazole | 20000094012 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 2000094004 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 2000094006 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 20003904002 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 20003904003 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 20003904004 | 13 |
| Caesar & Loretz GmbH | Clotrimazole | 20003904005 | 12 |
| Caesar & Loretz GmbH | Clotrimazole | 20003904008 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121002 | 4 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121003 | 13 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121004 | 15 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121005 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121006 | 23 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121008 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121009 | 13 |
| CAESAR & LORETZ GMBH | Clotrimazole | 21000121009 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121010 | 14 |
| Caesar & Loretz GmbH | Clotrimazole | 21000121013 | 9 |
| Caesar & Loretz GmbH | Clotrimazole | 21000123003 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 21000123006 | 17 |
| Caesar & Loretz GmbH | Clotrimazole | 21000123008 | 7 |
| Caesar & Loretz GmbH | Clotrimazole | 21000123010 | 5 |
| Caesar & Loretz GmbH | Clotrimazole | 21000123011 | 10 |
| Caesar & Loretz GmbH | Clotrimazole | 21004116001 | 16 |
| Caesar & Loretz GmbH | Clotrimazole | 21004116003 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 21004116005 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 21004116007 | 4 |
| Caesar & Loretz GmbH | Clotrimazole | 21004116014 | 6 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117001 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117003 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117004 | 9 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117005 | 10 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117007 | 12 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117011 | 3 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117013 | 1 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117016 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117017 | 3 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117018 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 21004117022 | 2 |
| Caesar & Loretz GmbH | Clotrimazole | 21I24-B11-213292 | 1 |
| Caesar & Loretz GmbH... | Clotrimazole | 20000094006 | 1 |
| Caesar & Loretz Hild... | Clotrimazole | 20003904003 | 1 |
| Caesar & Loretz Hilden | Clotrimazole | 18147211 | 1 |
| Caesar & Loretz Hilden | Clotrimazole | 19016204 | 1 |
| Caesar & Loretz Hilden | Clotrimazole | 20000094004 | 1 |
| Caesar & Loretz/Gehr | Clotrimazole | 18147211 | 2 |
| Caesar & Loretz/Geil... | Clotrimazole | 18147203 | 1 |
| Caesar & Loretz/Geil... | Clotrimazole | 20000092005 | 1 |
| Caesar & Loretz/Geil... | Clotrimazole | 21000121002 | 2 |
| Caesar & Loretz/Noweda | Clotrimazole | 20000094002 | 1 |
| Caesar & Loretz/Noweda | Clotrimazole | 20000094005 | 1 |
| Caesar & Loretz/Sanacorp | Clotrimazole | 18147210 | 1 |
| Caesar & Loretz | Clotrimazole | 16234504 | 1 |
| Caesar & Loretz | Clotrimazole | H20160502 | 1 |
| Caesar u Loretz | Clotrimazole | 15395613 | 1 |
| Caesar u Loretz | Clotrimazole | 16234501 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar&Lorenz / Gehe | Clotrimazole | 19016199 | 1 |
| Caesar&Lorenz | Clotrimazole | 21000121002 | 1 |
| Caesar&Loretz GmbH,1… | Clotrimazole | 16234509 | 1 |
| caesar&loretz GmbH,P… | Clotrimazole | 15395614 | 1 |
| Caesar&Loretz GmbH/ … | Clotrimazole | 16234522 | 1 |
| Caesar&Loretz GmbH/Anzag | Clotrimazole | 13184111 | 1 |
| Caesar&Loretz GmbH/Anzag | Clotrimazole | 14337807 | 1 |
| Caesar&Loretz GmbH | Clotrimazole | 14337814 | 1 |
| Caesar&loretz,Phoenix | Clotrimazole | 14144912 | 1 |
| Caesar&Loretz | Clotrimazole | 14337815 | 2 |
| Caesar&LoretzGmbH, P… | Clotrimazole | 18147212 | 1 |
| Caesar/Lorenz | Clotrimazole | 12320814 | 1 |
| Caesar/Lorenz | Clotrimazole | 13224201 | 3 |
| Caleo | Clotrimazole | 15395610 | 1 |
| CALO | Clotrimazole | 17360204 | 1 |
| Cealo/ Anzag | Clotrimazole | 1703028-01 | 2 |
| cealo/Gehe | Clotrimazole | 20003904003 | 2 |
| Cealo/Phoenix | Clotrimazole | 19016106 | 1 |
| Cealo/Sanacorp | Clotrimazole | 1902004-03 | 1 |
| Cealo/Sanacorp | Clotrimazole | 21000123011 | 3 |
| Cealo | Clotrimazole | 15395610 | 1 |
| Cealo | Clotrimazole | 17111612 | 1 |
| Cealo | Clotrimazole | 18147210 | 1 |
| Delta | Clotrimazole | 1607046-01 | 1 |
| E Plus | Clotrimazole | 1703028-02 | 1 |
| E Plus | Clotrimazole | 1808028-01 | 2 |
| EuRho / AHD | Clotrimazole | 2103024-01 | 2 |
| EuRho / Phoenix | Clotrimazole | 1703028-01 | 1 |
| EuRho / Phoenix | Clotrimazole | 2103024-02 | 4 |
| EuRho / Phönix | Clotrimazole | 2103024-01 | 1 |
| EuRho /Gehe | Clotrimazole | 1409027-02 | 1 |
| EuRho AHC | Clotrimazole | 1306036-01 | 1 |
| EuRho Noweda | Clotrimazole | 2007033-02 | 1 |
| EuRho Noweda | Clotrimazole | 2103024-01 | 1 |
| EuRho/ Anzag | Clotrimazole | 220629(2103024-01) | 1 |
| EuRho/ Fiebig | Clotrimazole | 2007033-01 | 1 |
| EuRho/ Phoenix | Clotrimazole | 160704602 | 1 |
| EuRho/ Phönix | Clotrimazole | 1703028-02 | 1 |
| EuRho/Anzag | Clotrimazole | 1902004-01 | 2 |
| EuRho/Gehe | Clotrimazole | 2007033-01 | 1 |
| EuRho/Gehe | Clotrimazole | 2103024-01 | 1 |
| EuRho/Jenne | Clotrimazole | 230117(2103024-01) | 1 |
| EuRho/Kehr | Clotrimazole | 1703028-02 | 1 |
| EuRho/Noweda | Clotrimazole | 2103024-02 | 1 |
| EuRho/Phoenix | Clotrimazole | 1210039-02 | 1 |
| EuRho/Phoenix | Clotrimazole | 1409027-01 | 1 |
| EuRho/Phoenix | Clotrimazole | 2007033-01 | 2 |
| EuRho/Phoenix | Clotrimazole | 2007033-03 | 1 |
| EuRho/Phönix | Clotrimazole | 1210039-2 | 1 |
| EuRho/Phönix | Clotrimazole | 1808028-01 | 1 |
| Eurho/Phönix | Clotrimazole | 200703302 | 1 |
| EuRho/Sanacorp | Clotrimazole | 16234522 | 1 |
| EuRho | Clotrimazole | 1108053-02 | 1 |
| EuRho | Clotrimazole | 1203040-02 | 3 |
| EuRho | Clotrimazole | 1203040-03 | 1 |
| EuRho | Clotrimazole | 1210039-02 | 2 |
| EuRho | Clotrimazole | 1306036-01 | 2 |
| eurho | Clotrimazole | 1309034-01 | 1 |
| EuRho | Clotrimazole | 1309034-02 | 1 |
| EuRho | Clotrimazole | 1409027-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Clotrimazole | 1703028-01 | 2 |
| Eurho | Clotrimazole | 1703028-02 | 2 |
| EuRho | Clotrimazole | 18080028-01 | 1 |
| EuRho | Clotrimazole | 1808028-01 | 3 |
| euRho | Clotrimazole | 190200401 | 1 |
| euRho | Clotrimazole | 1902004-01 | 1 |
| EuRho | Clotrimazole | 1902004-01 | 5 |
| EuRho | Clotrimazole | 1902004-02 | 3 |
| EuRho | Clotrimazole | 1902204-01 | 1 |
| EuRho | Clotrimazole | 2007033-01 | 2 |
| EuRho | Clotrimazole | 2007033-02 | 1 |
| Eurho | Clotrimazole | 2103024-01 | 3 |
| EuRho | Clotrimazole | 2103024-01 | 2 |
| EuRhoNoweda | Clotrimazole | 2103024-01 | 1 |
| EuRhoPh/Ph | Clotrimazole | 1902004-02 | 2 |
| EuRhoPh/Ph | Clotrimazole | 2007033-0130 | 1 |
| Euro /BAUMANN | Clotrimazole | 2007033-01 | 1 |
| Euro Gehe | Clotrimazole | 1808028-01 | 1 |
| Euro OCT Pharma/ Sanacorp | Clotrimazole | 1409027-04 | 1 |
| Euro OT/Gehe | Clotrimazole | 1409027-03 | 2 |
| Euro OTC | Clotrimazole | | 6 |
| Euro OTC | Clotrimazole | 1008028 | 1 |
| Euro OTC | Clotrimazole | 1105014-01 | 1 |
| Euro OTC | Clotrimazole | 110501402 | 1 |
| Euro OTC | Clotrimazole | 1105014-02 | 1 |
| Euro OTC | Clotrimazole | 1108053-01 | 1 |
| Euro OTC | Clotrimazole | 1108053-02 | 2 |
| Euro OTC | Clotrimazole | 11808028-01 | 1 |
| Euro OTC | Clotrimazole | 1202004-03 | 1 |
| Euro OTC | Clotrimazole | 1203040 | 1 |
| Euro OTC | Clotrimazole | 1203040-01 | 1 |
| Euro OTC | Clotrimazole | 120304002 | 1 |
| Euro OTC | Clotrimazole | 1203040-02 | 9 |
| Euro OTC | Clotrimazole | 1203040-03 | 9 |
| Euro OTC | Clotrimazole | 12082013C | 1 |
| Euro OTC | Clotrimazole | 1209211276 | 1 |
| Euro OTC | Clotrimazole | 121003901 | 3 |
| Euro OTC | Clotrimazole | 1210039-01 | 27 |
| Euro OTC | Clotrimazole | 1210039-02 | 22 |
| Euro OTC | Clotrimazole | 1306036 | 1 |
| Euro OTC | Clotrimazole | 130603601 | 3 |
| Euro OTC | Clotrimazole | 1306036-01 | 39 |
| Euro OTC | Clotrimazole | 1306306-01 | 1 |
| Euro OTC | Clotrimazole | 130636-01 | 2 |
| Euro OTC | Clotrimazole | 1309034 | 1 |
| Euro OTC | Clotrimazole | 130903401 | 5 |
| Euro OTC | Clotrimazole | 1309034-01 | 19 |
| Euro OTC | Clotrimazole | 130903402 | 1 |
| Euro OTC | Clotrimazole | 1309034-02 | 23 |
| Euro OTC | Clotrimazole | 1309054-02 | 1 |
| Euro OTC | Clotrimazole | 1314Q1276 | 1 |
| Euro OTC | Clotrimazole | 13224212 | 1 |
| Euro OTC | Clotrimazole | 13418014 | 1 |
| Euro OTC | Clotrimazole | 1409027 | 6 |
| Euro OTC | Clotrimazole | 1409027_03 | 1 |
| Euro OTC | Clotrimazole | 140902701 | 1 |
| Euro OTC | Clotrimazole | 1409027-01 | 30 |
| Euro OTC | Clotrimazole | 140902702 | 3 |
| Euro OTC | Clotrimazole | 1409027-02 | 46 |
| Euro OTC | Clotrimazole | 1409027-02Mg10g | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clotrimazole | 1409027-03 | 24 |
| Euro OTC | Clotrimazole | 1409027-04 | 32 |
| Euro OTC | Clotrimazole | 140927-01 | 1 |
| Euro OTC | Clotrimazole | 140927-02 | 1 |
| Euro OTC | Clotrimazole | 14144914 | 1 |
| Euro OTC | Clotrimazole | 14337829 | 2 |
| Euro OTC | Clotrimazole | 14C04-B31-291660 | 1 |
| Euro OTC | Clotrimazole | 150003-01 | 1 |
| Euro OTC | Clotrimazole | 150003-02 | 1 |
| Euro OTC | Clotrimazole | 15010003-01 | 1 |
| Euro OTC | Clotrimazole | 15042014C | 1 |
| Euro OTC | Clotrimazole | 15072014A | 1 |
| Euro OTC | Clotrimazole | 151000 | 1 |
| Euro OTC | Clotrimazole | 151000-01 | 1 |
| Euro OTC | Clotrimazole | 1510003_01 | 1 |
| Euro OTC | Clotrimazole | 151000301 | 1 |
| Euro OTC | Clotrimazole | 1510003-01 | 57 |
| Euro OTC | Clotrimazole | 1510003-02 | 24 |
| Euro OTC | Clotrimazole | 151003-01 | 1 |
| Euro OTC | Clotrimazole | 1605003C | 1 |
| Euro OTC | Clotrimazole | 1607045-01 | 1 |
| Euro OTC | Clotrimazole | 1607046 | 1 |
| Euro OTC | Clotrimazole | 1607046-0 | 1 |
| Euro OTC | Clotrimazole | 160704601 | 5 |
| Euro OTC | Clotrimazole | 1607046-01 | 72 |
| Euro OTC | Clotrimazole | 160704602 | 2 |
| Euro OTC | Clotrimazole | 1607046-02 | 42 |
| Euro OTC | Clotrimazole | 1607064-01 | 1 |
| Euro OTC | Clotrimazole | 16074046-01 | 1 |
| Euro OTC | Clotrimazole | 160802801 | 1 |
| Euro OTC | Clotrimazole | 1609046-01 | 1 |
| Euro OTC | Clotrimazole | 16234504 | 1 |
| Euro OTC | Clotrimazole | 16234505 | 1 |
| Euro OTC | Clotrimazole | 16234511 | 1 |
| Euro OTC | Clotrimazole | 16B11-B04-320088 | 1 |
| Euro OTC | Clotrimazole | 16J07-B02-341842 | 1 |
| Euro OTC | Clotrimazole | 170028-01 | 1 |
| Euro OTC | Clotrimazole | 1703025-03 | 1 |
| Euro OTC | Clotrimazole | 1703028 | 5 |
| Euro OTC | Clotrimazole | 1703028/03 | 1 |
| Euro OTC | Clotrimazole | 170302801 | 4 |
| Euro OTC | Clotrimazole | 1703028-01 | 118 |
| Euro OTC | Clotrimazole | 170302801-01 | 1 |
| Euro OTC | Clotrimazole | 170302802 | 1 |
| Euro OTC | Clotrimazole | 1703028-02 | 71 |
| Euro OTC | Clotrimazole | 1703028-02 | 1 |
| Euro OTC | Clotrimazole | 170302803 | 2 |
| Euro OTC | Clotrimazole | 1703028-03 | 62 |
| Euro OTC | Clotrimazole | 17053183 | 1 |
| Euro OTC | Clotrimazole | 170615C/1703028-01 | 1 |
| Euro OTC | Clotrimazole | 17111606 | 1 |
| Euro OTC | Clotrimazole | 17360201 | 1 |
| Euro OTC | Clotrimazole | 17A021 | 1 |
| Euro OTC | Clotrimazole | 17J25B06347476 | 1 |
| Euro OTC | Clotrimazole | 180002801 | 1 |
| Euro OTC | Clotrimazole | 180028-01 | 1 |
| Euro OTC | Clotrimazole | 1808018-01 | 1 |
| Euro OTC | Clotrimazole | 1808025-01 | 1 |
| Euro OTC | Clotrimazole | 1808028 | 4 |
| Euro OTC | Clotrimazole | 1808028_01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clotrimazole | 1808028_02 | 1 |
| Euro OTC | Clotrimazole | 180802801 | 5 |
| Euro OTC | Clotrimazole | 1808028-01 | 132 |
| Euro OTC | Clotrimazole | 180802802 | 1 |
| Euro OTC | Clotrimazole | 1808028-02 | 82 |
| Euro OTC | Clotrimazole | 1808828-01 | 1 |
| Euro OTC | Clotrimazole | 18147211 | 1 |
| Euro OTC | Clotrimazole | 1828028-01 | 1 |
| Euro OTC | Clotrimazole | 19016108 | 1 |
| Euro OTC | Clotrimazole | 1902001-01 | 1 |
| Euro OTC | Clotrimazole | 1902004 | 2 |
| Euro OTC | Clotrimazole | 1902004_01 | 1 |
| Euro OTC | Clotrimazole | 190200401 | 7 |
| Euro OTC | Clotrimazole | 1902004-01 | 170 |
| Euro OTC | Clotrimazole | 1902004-01HZC14218 | 1 |
| Euro OTC | Clotrimazole | 190200402 | 1 |
| Euro OTC | Clotrimazole | 1902004-02 | 80 |
| Euro OTC | Clotrimazole | 190200403 | 2 |
| Euro OTC | Clotrimazole | 1902004-03 | 58 |
| Euro OTC | Clotrimazole | 190202004-02 | 1 |
| Euro OTC | Clotrimazole | 190204-01 | 2 |
| Euro OTC | Clotrimazole | 190204-03 | 1 |
| Euro OTC | Clotrimazole | 19022004-01 | 1 |
| Euro OTC | Clotrimazole | 19024004-01 | 1 |
| Euro OTC | Clotrimazole | 1904004-02 | 1 |
| Euro OTC | Clotrimazole | 192004-01 | 2 |
| Euro OTC | Clotrimazole | 20007033-01 | 1 |
| Euro OTC | Clotrimazole | 2007003-01 | 1 |
| Euro OTC | Clotrimazole | 200703-02 | 1 |
| Euro OTC | Clotrimazole | 2007033 | 1 |
| Euro OTC | Clotrimazole | 2007033_01 | 1 |
| Euro OTC | Clotrimazole | 200703301 | 5 |
| Euro OTC | Clotrimazole | 2007033-01 | 134 |
| Euro OTC | Clotrimazole | 2007033-02 | 71 |
| Euro OTC | Clotrimazole | 2007033-03 | 10 |
| Euro OTC | Clotrimazole | 2007033-1 | 1 |
| Euro OTC | Clotrimazole | 200733-02 | 1 |
| Euro OTC | Clotrimazole | 20130512 | 1 |
| Euro OTC | Clotrimazole | 20160801 | 5 |
| Euro OTC | Clotrimazole | 203024-02 | 1 |
| Euro OTC | Clotrimazole | 206718 | 1 |
| Euro OTC | Clotrimazole | 2103021-01 | 1 |
| Euro OTC | Clotrimazole | 2103024 | 3 |
| Euro OTC | Clotrimazole | 2103024_02 | 1 |
| Euro OTC | Clotrimazole | 210302401 | 2 |
| Euro OTC | Clotrimazole | 2103024-01 | 87 |
| Euro OTC | Clotrimazole | 210302402 | 3 |
| Euro OTC | Clotrimazole | 2103024-02 | 51 |
| Euro OTC | Clotrimazole | 2103024-03 | 5 |
| Euro OTC | Clotrimazole | 2103024-04 | 1 |
| Euro OTC | Clotrimazole | 2103025-01 | 1 |
| Euro OTC | Clotrimazole | 21052015B | 1 |
| Euro OTC | Clotrimazole | 21122013A | 1 |
| Euro OTC | Clotrimazole | 213024-02 | 1 |
| Euro OTC | Clotrimazole | 220425D | 1 |
| Euro OTC | Clotrimazole | 22091806 | 1 |
| Euro OTC | Clotrimazole | 22122014B | 1 |
| Euro OTC | Clotrimazole | 2214A-01276 | 1 |
| Euro OTC | Clotrimazole | 2301055-01 | 5 |
| Euro OTC | Clotrimazole | 23121408 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Clotrimazole | 2313M01276 | 1 |
| Euro OTC | Clotrimazole | 2785 | 1 |
| Euro OTC | Clotrimazole | 2881 | 1 |
| Euro OTC | Clotrimazole | 30011402 | 1 |
| Euro OTC | Clotrimazole | 30062002 | 1 |
| Euro OTC | Clotrimazole | 3118A-01276 | 1 |
| Euro OTC | Clotrimazole | 3912E-01276 | 1 |
| Euro OTC | Clotrimazole | 40714/05 | 1 |
| Euro OTC | Clotrimazole | 41(1808028-01) | 1 |
| Euro OTC | Clotrimazole | 42(1902004-02) | 1 |
| Euro OTC | Clotrimazole | 4216M01276 | 1 |
| Euro OTC | Clotrimazole | 4216M-01276 | 2 |
| Euro OTC | Clotrimazole | 6051501 | 1 |
| Euro OTC | Clotrimazole | 700135 | 2 |
| Euro OTC | Clotrimazole | H20160502 | 1 |
| Euro OTC | Clotrimazole | HCZ00720 | 1 |
| Euro OTC | Clotrimazole | HCZ06718 | 3 |
| Euro OTC | Clotrimazole | HCZ07720 | 3 |
| Euro OTC | Clotrimazole | HCZ14218 | 5 |
| Euro OTC | Clotrimazole | HCZ20120 | 2 |
| euro//Noweda | Clotrimazole | 1808028-01 | 1 |
| Euro/Gehe | Clotrimazole | 1607046-02 | 1 |
| Euro/Gehe | Clotrimazole | 1703028-03 | 1 |
| Euro/Gehe | Clotrimazole | 18A18-B05-350778 | 1 |
| Euro/Noweda | Clotrimazole | 1510003-02 | 1 |
| EURO/Noweda | Clotrimazole | 190200401 | 1 |
| Euro/Phönix | Clotrimazole | 1510003-02 | 1 |
| Euro/Phönix | Clotrimazole | 1808028-01 | 1 |
| Euro/Phönix | Clotrimazole | 1902004-01 | 2 |
| Euro/Sanacorp | Clotrimazole | 149027-04 | 1 |
| Euro/Sanacorp | Clotrimazole | 1703028-02 | 1 |
| Euro/Sanacorp | Clotrimazole | 1808028-01 | 2 |
| Euro | Clotrimazole | 1510003-01 | 2 |
| Euro | Clotrimazole | 160704601 | 1 |
| Euroo / Phönix | Clotrimazole | 1409027-02 | 3 |
| Europ Ots Pharma | Clotrimazole | 13184105 | 1 |
| Europharm/Otto | Clotrimazole | 1203040-01 | 1 |
| Europharm/Otto | Clotrimazole | 1203040-02 | 1 |
| europharma | Clotrimazole | 1306036-01 | 1 |
| EuroTOC / Noweda | Clotrimazole | 1409027-03 | 1 |
| Fa.Phönix | Clotrimazole | 20h26-f05-373738 | 1 |
| Fa.Phönix | Clotrimazole | 21004117005 | 1 |
| Faggron | Clotrimazole | 21/24-B11-213293 | 2 |
| Fagron | Clotrimazole | | 5 |
| Fagron | Clotrimazole | 10G10B06-352427 | 1 |
| Fagron | Clotrimazole | 11-21329002 | 1 |
| Fagron | Clotrimazole | 11A05-N14 | 2 |
| Fagron | Clotrimazole | 11E17-N10 | 2 |
| Fagron | Clotrimazole | 11F30-N14 | 2 |
| Fagron | Clotrimazole | 11G15-N10 | 1 |
| Fagron | Clotrimazole | 11K21-N19 | 1 |
| Fagron | Clotrimazole | 11L12-N10 | 5 |
| Fagron | Clotrimazole | 12/21-N01 | 5 |
| Fagron | Clotrimazole | 12/21-N04 | 3 |
| Fagron | Clotrimazole | 1210039-01 | 1 |
| Fagron | Clotrimazole | 1221n04 | 1 |
| Fagron | Clotrimazole | 1221N04 | 1 |
| Fagron | Clotrimazole | 12721-N01 | 1 |
| Fagron | Clotrimazole | 12a05-n10 | 1 |
| Fagron | Clotrimazole | 12A05-N10 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clotrimazole | 12B27-N05 | 3 |
| Fagron | Clotrimazole | 12e02-N12 | 1 |
| Fagron | Clotrimazole | 12E02-N12 | 9 |
| Fagron | Clotrimazole | 12E30-N02 | 1 |
| Fagron | Clotrimazole | 12E30-N07 | 12 |
| Fagron | Clotrimazole | 12F02-N12 | 1 |
| Fagron | Clotrimazole | 12I16-N04 | 1 |
| Fagron | Clotrimazole | 12I21-N01 | 7 |
| Fagron | Clotrimazole | 12I21N04 | 1 |
| Fagron | Clotrimazole | 12I21-N04 | 7 |
| Fagron | Clotrimazole | 12K15-N01 | 1 |
| Fagron | Clotrimazole | 12l21-N04 | 2 |
| Fagron | Clotrimazole | 1309034-01 | 3 |
| Fagron | Clotrimazole | 13224201 | 1 |
| Fagron | Clotrimazole | 13C25-N10 | 10 |
| Fagron | Clotrimazole | 1409027-02 | 1 |
| Fagron | Clotrimazole | 14223201 | 1 |
| Fagron | Clotrimazole | 14337801 | 1 |
| Fagron | Clotrimazole | 14337818 | 1 |
| Fagron | Clotrimazole | 14337827 | 1 |
| Fagron | Clotrimazole | 14B05-B35 | 2 |
| Fagron | Clotrimazole | 14B05-B35-293542 | 3 |
| Fagron | Clotrimazole | 14B05-B35-293543 | 2 |
| Fagron | Clotrimazole | 14b05-b35-293544 | 1 |
| Fagron | Clotrimazole | 14B05-B35-293544 | 4 |
| Fagron | Clotrimazole | 14B05-B35-294932 | 1 |
| Fagron | Clotrimazole | 14b05-b35-294935 | 1 |
| Fagron | Clotrimazole | 14B05B35294935 | 1 |
| Fagron | Clotrimazole | 14B05-B35-294935 | 4 |
| Fagron | Clotrimazole | 14b05-b35-299941 | 1 |
| Fagron | Clotrimazole | 14B05-B35-299941 | 2 |
| Fagron | Clotrimazole | 14B05-B35-299944 | 3 |
| Fagron | Clotrimazole | 14B05-B36 | 7 |
| Fagron | Clotrimazole | 14B05B36291165 | 1 |
| Fagron | Clotrimazole | 14B05-B36-291165 | 2 |
| Fagron | Clotrimazole | 14b05b36291166 | 1 |
| Fagron | Clotrimazole | 14b05-b36-291166 | 2 |
| Fagron | Clotrimazole | 14B05-B36-291166 | 3 |
| Fagron | Clotrimazole | 14b05-B36-291167 | 1 |
| Fagron | Clotrimazole | 14B05B36291167 | 1 |
| Fagron | Clotrimazole | 14B05-B36-291167 | 5 |
| Fagron | Clotrimazole | 14B05-B36-291168 | 2 |
| Fagron | Clotrimazole | 14B05-B36-2991166 | 1 |
| Fagron | Clotrimazole | 14B06-B06 | 1 |
| Fagron | Clotrimazole | 14B06-B06-299942 | 1 |
| Fagron | Clotrimazole | 14B06-B06-299943 | 6 |
| Fagron | Clotrimazole | 14C04-B30 | 1 |
| Fagron | Clotrimazole | 14C04-B30-291656 | 8 |
| Fagron | Clotrimazole | 14C04-B30-291661 | 3 |
| Fagron | Clotrimazole | 14C04B31 | 1 |
| Fagron | Clotrimazole | 14C04-B31 | 8 |
| Fagron | Clotrimazole | 14C04-B312-299959 | 1 |
| Fagron | Clotrimazole | 14C04-B31-291660 | 4 |
| Fagron | Clotrimazole | 14C04-B31-294939 | 6 |
| Fagron | Clotrimazole | 14C04-B31-294940 | 1 |
| Fagron | Clotrimazole | 14C04-B31-294951 | 1 |
| Fagron | Clotrimazole | 14C04-B31-294952 | 1 |
| Fagron | Clotrimazole | 14C04-B31-299954 | 7 |
| Fagron | Clotrimazole | 14C04-B31-299955 | 1 |
| Fagron | Clotrimazole | 14C04-B31-299959 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clotrimazole | 14C04-B31-299960 | 7 |
| Fagron | Clotrimazole | 14C04B32291657 | 1 |
| Fagron | Clotrimazole | 14C04-B32-291657 | 1 |
| Fagron | Clotrimazole | 14E26-B02 | 1 |
| Fagron | Clotrimazole | 1510003-01 | 1 |
| Fagron | Clotrimazole | 15G14-B05 | 4 |
| Fagron | Clotrimazole | 15G14-B05-311100 | 12 |
| Fagron | Clotrimazole | 15G14-B05-311101 | 1 |
| Fagron | Clotrimazole | 15G14-B05-311102 | 4 |
| Fagron | Clotrimazole | 15G14-B05-311103 | 16 |
| Fagron | Clotrimazole | 15G14-B05-316483 | 1 |
| Fagron | Clotrimazole | 15G14-B06 | 1 |
| Fagron | Clotrimazole | 15G14-B06-211057 | 1 |
| Fagron | Clotrimazole | 15G14-B06-31105 | 1 |
| Fagron | Clotrimazole | 15g14-b06-311054 | 1 |
| Fagron | Clotrimazole | 15G14B06311054 | 1 |
| Fagron | Clotrimazole | 15G14B06-311054 | 1 |
| Fagron | Clotrimazole | 15G14-B06-311054 | 4 |
| Fagron | Clotrimazole | 15G14-B06-311056 | 2 |
| Fagron | Clotrimazole | 15G14-Bo5-311101 | 1 |
| Fagron | Clotrimazole | 160704602 | 1 |
| Fagron | Clotrimazole | 16234521 | 2 |
| Fagron | Clotrimazole | 16607-B02-333606 | 1 |
| Fagron | Clotrimazole | 16811-B04-320088 | 1 |
| Fagron | Clotrimazole | 16B09-B06 | 1 |
| Fagron | Clotrimazole | 16B09-B06-311506 | 4 |
| Fagron | Clotrimazole | 16B09-B06-311507 | 5 |
| Fagron | Clotrimazole | 16B09-B06-311785 | 3 |
| Fagron | Clotrimazole | 16B11B04 | 1 |
| Fagron | Clotrimazole | 16B11-B04 | 1 |
| Fagron | Clotrimazole | 16B11-B04-320088 | 6 |
| Fagron | Clotrimazole | 16B11-B04-322393 | 3 |
| Fagron | Clotrimazole | 16B11-B04-327611 | 6 |
| Fagron | Clotrimazole | 16BB11B04327611 | 1 |
| Fagron | Clotrimazole | 16E20-B10-317566 | 2 |
| Fagron | Clotrimazole | 16E20-B10-321597 | 2 |
| Fagron | Clotrimazole | 16E20-B10-321598 | 11 |
| Fagron | Clotrimazole | 16E20-B10-32197 | 1 |
| Fagron | Clotrimazole | 16E20-B10-324555 | 5 |
| Fagron | Clotrimazole | 16E20-B10-326010 | 3 |
| Fagron | Clotrimazole | 16E20-B10-327349 | 7 |
| Fagron | Clotrimazole | 16J07_B02 | 1 |
| Fagron | Clotrimazole | 16J07-B02 | 3 |
| Fagron | Clotrimazole | 16J07-B02-329385 | 4 |
| Fagron | Clotrimazole | 16J07-B02-329386 | 4 |
| Fagron | Clotrimazole | 16J07-B02-330216 | 7 |
| Fagron | Clotrimazole | 16J07-B02-330236 | 2 |
| Fagron | Clotrimazole | 16J07-B02-3335773 | 1 |
| Fagron | Clotrimazole | 16J07-B02-333606 | 3 |
| Fagron | Clotrimazole | 16J07-B02-335773 | 2 |
| Fagron | Clotrimazole | 16J07-B02-337573 | 3 |
| Fagron | Clotrimazole | 16J07-B02-338283 | 8 |
| Fagron | Clotrimazole | 16J07-B02-340511 | 2 |
| Fagron | Clotrimazole | 16j07-b02-340513 | 2 |
| Fagron | Clotrimazole | 16J07-B02-340513 | 7 |
| Fagron | Clotrimazole | 16J07-B02-340513-201 | 1 |
| Fagron | Clotrimazole | 16J07B02341842 | 2 |
| Fagron | Clotrimazole | 16J07-B02-341842 | 1 |
| Fagron | Clotrimazole | 16J07-B02-344816 | 3 |
| Fagron | Clotrimazole | 16J07-B02-344817 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clotrimazole | 16J07-B02-344818 | 8 |
| Fagron | Clotrimazole | 16J07B02347864 | 1 |
| Fagron | Clotrimazole | 16J07-B02-347864 | 4 |
| Fagron | Clotrimazole | 16J23-F06-365713 | 1 |
| Fagron | Clotrimazole | 1703028-01 | 1 |
| Fagron | Clotrimazole | 1703028-03 | 1 |
| Fagron | Clotrimazole | 17111613 | 1 |
| Fagron | Clotrimazole | 17360201 | 1 |
| Fagron | Clotrimazole | 17A19-804-38560 | 2 |
| Fagron | Clotrimazole | 17A19-B04_332114 | 1 |
| Fagron | Clotrimazole | 17A19-B04-332097 | 2 |
| Fagron | Clotrimazole | 17A19-B04332114 | 1 |
| Fagron | Clotrimazole | 17A19-B04-332114 | 2 |
| Fagron | Clotrimazole | 17A19-B04-334768 | 5 |
| Fagron | Clotrimazole | 17A19-B04-336568 | 1 |
| Fagron | Clotrimazole | 17A19-B04-336581 | 1 |
| Fagron | Clotrimazole | 17A19-B04-338560 | 5 |
| Fagron | Clotrimazole | 17A19-B04-338577 | 4 |
| Fagron | Clotrimazole | 17A19-B04-340476 | 1 |
| Fagron | Clotrimazole | 17A19-BO4-336568 | 1 |
| Fagron | Clotrimazole | 17A19-SB04-332097 | 1 |
| Fagron | Clotrimazole | 17J25-B06 | 3 |
| Fagron | Clotrimazole | 17J25-B06-345044 | 5 |
| Fagron | Clotrimazole | 17J25-B06-345045 | 2 |
| Fagron | Clotrimazole | 17J25-B06-345048 | 2 |
| Fagron | Clotrimazole | 17J25-B06-345049 | 1 |
| Fagron | Clotrimazole | 17J25-B06-345406 | 1 |
| Fagron | Clotrimazole | 17J25-B06-345407 | 5 |
| Fagron | Clotrimazole | 17J25-B06-347476 | 5 |
| Fagron | Clotrimazole | 17J25-B06-349130 | 2 |
| Fagron | Clotrimazole | 17j25-B06-349161 | 1 |
| Fagron | Clotrimazole | 17J25-B06-349161 | 6 |
| Fagron | Clotrimazole | 17J25-Bo6-345045 | 1 |
| Fagron | Clotrimazole | 17J25-BO6-349161 | 1 |
| Fagron | Clotrimazole | 18147101 | 1 |
| Fagron | Clotrimazole | 18147102 | 1 |
| Fagron | Clotrimazole | 18147217 | 1 |
| Fagron | Clotrimazole | 18610_B06 | 1 |
| Fagron | Clotrimazole | 18A18B05 | 1 |
| Fagron | Clotrimazole | 18A18-B05 | 3 |
| Fagron | Clotrimazole | 18A18-B05-344819 | 1 |
| Fagron | Clotrimazole | 18A18-B05-347865 | 10 |
| Fagron | Clotrimazole | 18a18-b05-348429 | 1 |
| Fagron | Clotrimazole | 18A18-B05348429 | 1 |
| Fagron | Clotrimazole | 18A18-B05-348429 | 4 |
| Fagron | Clotrimazole | 18A18-B05-349662 | 2 |
| Fagron | Clotrimazole | 18A18-B05-3496662 | 1 |
| Fagron | Clotrimazole | 18A18-B05-350778 | 7 |
| Fagron | Clotrimazole | 18A18-B05350780 | 1 |
| Fagron | Clotrimazole | 18A18-B05-350780 | 7 |
| Fagron | Clotrimazole | 18A18-B05-350781 | 2 |
| Fagron | Clotrimazole | 18A18B05352114 | 1 |
| Fagron | Clotrimazole | 18A18-B05-352114 | 4 |
| Fagron | Clotrimazole | 18a18-b05-352115 | 1 |
| Fagron | Clotrimazole | 18A18-B05-352115 | 5 |
| Fagron | Clotrimazole | 18A18B05353892 | 1 |
| Fagron | Clotrimazole | 18A18-B05-353892 | 5 |
| Fagron | Clotrimazole | 18A18-B05-355041 | 2 |
| Fagron | Clotrimazole | 18A18-B05-355042 | 1 |
| Fagron | Clotrimazole | 18G10-B06 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clotrimazole | 18G10-B06-352425 | 4 |
| Fagron | Clotrimazole | 18G10-B06-352426 | 2 |
| Fagron | Clotrimazole | 18G10-B06-352427 | 5 |
| Fagron | Clotrimazole | 18G10-B06352708 | 1 |
| Fagron | Clotrimazole | 18G10-B06-352708 | 5 |
| Fagron | Clotrimazole | 18G10-b06-353348 | 1 |
| Fagron | Clotrimazole | 18G10-B06-353348 | 4 |
| Fagron | Clotrimazole | 18G10-B06-354620 | 1 |
| Fagron | Clotrimazole | 18G10-B06-355382 | 2 |
| Fagron | Clotrimazole | 18G10-B06-355401 | 4 |
| Fagron | Clotrimazole | 18G10-B06-358825 | 16 |
| Fagron | Clotrimazole | 19/23-F06-367383 | 1 |
| Fagron | Clotrimazole | 1902004-01 | 1 |
| Fagron | Clotrimazole | 19814-B01-363547 | 2 |
| Fagron | Clotrimazole | 19B01363546 | 1 |
| Fagron | Clotrimazole | 19B14-B01 | 9 |
| Fagron | Clotrimazole | 19B14-B01_363546 | 1 |
| Fagron | Clotrimazole | 19B14-B01-259532 | 1 |
| Fagron | Clotrimazole | 19B14-B01-359531 | 7 |
| Fagron | Clotrimazole | 19b14-b01-359532 | 1 |
| Fagron | Clotrimazole | 19B14-B01-359532 | 5 |
| Fagron | Clotrimazole | 19b14-b01-359537 | 1 |
| Fagron | Clotrimazole | 19B14B01359537 | 1 |
| Fagron | Clotrimazole | 19B14-B01-359537 | 6 |
| Fagron | Clotrimazole | 19B14-B01-359538 | 3 |
| Fagron | Clotrimazole | 19B14-B01-359539 | 11 |
| Fagron | Clotrimazole | 19B14-B01-359540 | 1 |
| Fagron | Clotrimazole | 19b14-b01-361607 | 1 |
| Fagron | Clotrimazole | 19B14-B01-361607 | 8 |
| Fagron | Clotrimazole | 19B14-B01-361608 | 3 |
| Fagron | Clotrimazole | 19B14B01361609 | 1 |
| Fagron | Clotrimazole | 19B14-B01-361609 | 5 |
| Fagron | Clotrimazole | 19B14-B01-361610 | 1 |
| Fagron | Clotrimazole | 19B14-B01-363546 | 22 |
| Fagron | Clotrimazole | 19B14-B01-363546/4320 | 1 |
| Fagron | Clotrimazole | 19B14-B01-363547 | 11 |
| Fagron | Clotrimazole | 19B14-B01-363557 | 14 |
| Fagron | Clotrimazole | 19B14-B1-363557 | 1 |
| Fagron | Clotrimazole | 19B14-BO1-363557 | 1 |
| Fagron | Clotrimazole | 19J23 | 1 |
| Fagron | Clotrimazole | 19j23-06-367383 | 1 |
| Fagron | Clotrimazole | 19J23-F06_365713 | 1 |
| Fagron | Clotrimazole | 19J23-F06_367381 | 3 |
| Fagron | Clotrimazole | 19J23-F06-365713 | 10 |
| Fagron | Clotrimazole | 19J23-F06-3673803 | 2 |
| Fagron | Clotrimazole | 19J23-F06-367381 | 5 |
| Fagron | Clotrimazole | 19J23F06-367382 | 1 |
| Fagron | Clotrimazole | 19J23-F06-367382 | 7 |
| Fagron | Clotrimazole | 19j23-f06-367383 | 3 |
| Fagron | Clotrimazole | 19J23-F06367383 | 1 |
| Fagron | Clotrimazole | 19J23-F06-367383 | 14 |
| Fagron | Clotrimazole | 19J23-FO6-367383 | 2 |
| Fagron | Clotrimazole | 1A1-B05-34765 | 1 |
| Fagron | Clotrimazole | 2007033-01 | 3 |
| Fagron | Clotrimazole | 20111018 | 2 |
| Fagron | Clotrimazole | 20120603 | 3 |
| Fagron | Clotrimazole | 20151112-3 | 1 |
| Fagron | Clotrimazole | 20170427Ma9 | 1 |
| Fagron | Clotrimazole | 20171127Ma1 | 1 |
| Fagron | Clotrimazole | 20B27-F02 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clotrimazole | 20B27-F02_369401 | 1 |
| Fagron | Clotrimazole | 20B27-F02-0369401 | 1 |
| Fagron | Clotrimazole | 20B27-F02-369401 | 10 |
| Fagron | Clotrimazole | 20B27-F02-369402 | 5 |
| Fagron | Clotrimazole | 20b27f02369403 | 1 |
| Fagron | Clotrimazole | 20B27F02369403 | 2 |
| Fagron | Clotrimazole | 20B27-F02-369403 | 7 |
| Fagron | Clotrimazole | 20B27F02-370980 | 1 |
| Fagron | Clotrimazole | 20B27-F02-370980 | 1 |
| Fagron | Clotrimazole | 20H19-F01 | 1 |
| Fagron | Clotrimazole | 20H19-F01_37345 | 1 |
| Fagron | Clotrimazole | 20H19-F01-373455 | 3 |
| Fagron | Clotrimazole | 20H19-F01-373456 | 8 |
| Fagron | Clotrimazole | 20H26-F05 | 6 |
| Fagron | Clotrimazole | 20H26-F05-3737302 | 1 |
| Fagron | Clotrimazole | 20H26-F05-373732 | 3 |
| Fagron | Clotrimazole | 20H26-F05-373733 | 1 |
| Fagron | Clotrimazole | 20H26-F05-373736 | 4 |
| Fagron | Clotrimazole | 20H26-F05-373737 | 2 |
| Fagron | Clotrimazole | 20h26-f05-373738 | 1 |
| Fagron | Clotrimazole | 20H26F05373738 | 1 |
| Fagron | Clotrimazole | 20H26-F05-373738 | 3 |
| Fagron | Clotrimazole | 20H26-F05-373739 | 5 |
| Fagron | Clotrimazole | 20H26-F05-373740 | 2 |
| Fagron | Clotrimazole | 20H26-F06 | 1 |
| Fagron | Clotrimazole | 20H26-F06-373736 | 1 |
| Fagron | Clotrimazole | 20OH26-F05-373739 | 1 |
| Fagron | Clotrimazole | 21/24-B11-213289 | 1 |
| Fagron | Clotrimazole | 21/24-B11-213289Fag | 1 |
| Fagron | Clotrimazole | 21/24-B11-218638 | 1 |
| Fagron | Clotrimazole | 21124-B11-218638 | 2 |
| Fagron | Clotrimazole | 2124-B11 | 1 |
| Fagron | Clotrimazole | 21B12-B10-216242 | 1 |
| Fagron | Clotrimazole | 21D22-B03-217092 | 10 |
| Fagron | Clotrimazole | 21D22-B03-217713 | 1 |
| Fagron | Clotrimazole | 21h13-b14-213291 | 1 |
| Fagron | Clotrimazole | 21H13B14213291 | 1 |
| Fagron | Clotrimazole | 21H13-B14213291 | 1 |
| Fagron | Clotrimazole | 21H13-B14-213291 | 15 |
| Fagron | Clotrimazole | 21I24-B11-213289 | 2 |
| Fagron | Clotrimazole | 21I24B11213292 | 1 |
| Fagron | Clotrimazole | 21I24-B11-213292 | 6 |
| Fagron | Clotrimazole | 21I24-B11-213293 | 1 |
| Fagron | Clotrimazole | 21I24-B11-218638 | 4 |
| Fagron | Clotrimazole | 21l24-B11 | 1 |
| Fagron | Clotrimazole | 21l24-B11-218638 | 2 |
| Fagron | Clotrimazole | 22A21-B02-217360 | 8 |
| Fagron | Clotrimazole | 22A21-B02-217361 | 3 |
| Fagron | Clotrimazole | 22A21-B02-221730 | 2 |
| Fagron | Clotrimazole | 22A21-BO2 | 1 |
| Fagron | Clotrimazole | 22A21-BO2-217360 | 1 |
| Fagron | Clotrimazole | 23D11-B01-228693 | 1 |
| Fagron | Clotrimazole | 23H09-B07-230827 | 1 |
| Fagron | Clotrimazole | 23H09-B07-235131 | 1 |
| Fagron | Clotrimazole | 2616A-01276 | 1 |
| Fagron | Clotrimazole | 2OB27-FO2-369402 | 1 |
| Fagron | Clotrimazole | 2OB27-FO2-369403 | 1 |
| Fagron | Clotrimazole | 3716Q-01276 | 1 |
| Fagron | Clotrimazole | 4812E-01276(NP) | 1 |
| Fagron | Clotrimazole | 6C16MU1 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Clotrimazole | 700120-0003 | 2 |
| Fagron | Clotrimazole | 700135-0003 | 1 |
| Fagron | Clotrimazole | 8556777 | 1 |
| Fagron | Clotrimazole | 9041304 | 1 |
| Fagron | Clotrimazole | A21130J001 | 2 |
| Fagron | Clotrimazole | B01-3616009 | 1 |
| Fagron | Clotrimazole | B01-3635406 | 1 |
| Fagron | Clotrimazole | B01-3635507 | 1 |
| Fagron | Clotrimazole | B11-213289 | 1 |
| Fagron | Clotrimazole | C22H17CIN2 | 1 |
| Fagron | Clotrimazole | CLT/1307/0065A | 2 |
| Fagron | Clotrimazole | CLT/150570016b | 1 |
| Fagron | Clotrimazole | CLT/160/00058 | 1 |
| Fagron | Clotrimazole | CLT/1604/00227A | 1 |
| Fagron | Clotrimazole | CLT/1604/0027A | 2 |
| Fagron | Clotrimazole | CLT/1607/0060A | 2 |
| Fagron | Clotrimazole | CLT/1709/0067B | 1 |
| Fagron | Clotrimazole | CLT/1711/0077A | 2 |
| Fagron | Clotrimazole | CLT/1805/00468 | 2 |
| Fagron | Clotrimazole | CLT/1805/0046B | 2 |
| Fagron | Clotrimazole | CLT/1805/0064B | 3 |
| Fagron | Clotrimazole | CLT/1901/0002A | 5 |
| Fagron | Clotrimazole | CLT/2001/0006A | 1 |
| Fagron | Clotrimazole | CLT-1805-0046B | 1 |
| Fagron | Clotrimazole | CLT20010006A | 1 |
| Fagron | Clotrimazole | F01-3734506 | 2 |
| Fagron | Clotrimazole | F0236940001 | 1 |
| Fagron | Clotrimazole | F02-3694001 | 4 |
| Fagron | Clotrimazole | F02-3694002 | 1 |
| Fagron | Clotrimazole | F02-3709800 | 1 |
| Fagron | Clotrimazole | F05-3737302 | 1 |
| Fagron | Clotrimazole | F06-3657103 | 1 |
| Fagron | Clotrimazole | F06-3673801 | 2 |
| Fagron | Clotrimazole | F06-3673803 | 3 |
| Fagron | Clotrimazole | HCZ11520 | 4 |
| Fargon/ Phoenix | Clotrimazole | 18G10-B06-358825 | 1 |
| Fargon/Noweda | Clotrimazole | 18G-10-B06-355401 | 1 |
| Fargon/Noweda | Clotrimazole | 19B14-B01-363557 | 1 |
| Fargon/Phönix | Clotrimazole | 18147103 | 1 |
| Fargon | Clotrimazole | 16234511 | 1 |
| Fargon | Clotrimazole | 17J25-B06-345406 | 1 |
| Fargon | Clotrimazole | 18A18-B05-350778 | 1 |
| Fargon | Clotrimazole | 18g10-b06-355401 | 1 |
| Fargon | Clotrimazole | 18G10-B06-355401 | 1 |
| Fargon | Clotrimazole | 19B14-B01-363547 | 1 |
| Fargon | Clotrimazole | 20B27-F02-369403 | 1 |
| Fargron / Noweda | Clotrimazole | 16E20-B10-324555 | 1 |
| Fiebig 10.06.13 ek: 8,58EUR | Clotrimazole | 12E30-N07 | 1 |
| Fiebig | Clotrimazole | 1607046-01 | 1 |
| Fiebig | Clotrimazole | 1607046-02 | 1 |
| Fiebig | Clotrimazole | 1703028 | 1 |
| Fiebig | Clotrimazole | 1703028-03 | 1 |
| Fiebig | Clotrimazole | 1808028-02 | 1 |
| Fiebig | Clotrimazole | 18147101 | 1 |
| Fiebig | Clotrimazole | 20000092006 | 1 |
| Fiebig | Clotrimazole | 20000094008 | 1 |
| Fiebig | Clotrimazole | 23H09-B07230827 | 1 |
| Finteler Apotheke | Clotrimazole | 16234501 | 1 |
| Finteler Apotheke | Clotrimazole | 16234509 | 1 |
| Fischar/Gehe | Clotrimazole | 20111018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fragon/Phoenix | Clotrimazole | 18A18-B05-350778 | 2 |
| Fragon | Clotrimazole | 19B14-B01-363557 | 1 |
| Fragon | Clotrimazole | 21H13-B14-218610 | 1 |
| Fragron/noweda | Clotrimazole | 17A19-B04 | 1 |
| Fragron/noweda | Clotrimazole | CLT/1601/0005B | 1 |
| Gatt-Koller | Clotrimazole | 1801870 | 1 |
| Gatt-Koller | Clotrimazole | 201714s9 | 1 |
| Gehe amax | Clotrimazole | 14B05-B35-294935 | 1 |
| Gehe amax | Clotrimazole | 1607046-02 | 1 |
| Gehe amax | Clotrimazole | 16J07-B02-330216 | 1 |
| Gehe amax | Clotrimazole | 17111608 | 1 |
| Gehe amax | Clotrimazole | 1808028-01 | 1 |
| Gehe amax | Clotrimazole | 19J23-F06-365713 | 1 |
| Gehe amax | Clotrimazole | 20000092005 | 1 |
| Gehe/europharm | Clotrimazole | 2007033-02 | 2 |
| Gehe | Clotrimazole | 1108053-01 | 1 |
| Gehe | Clotrimazole | 11K21-N19 | 1 |
| Gehe | Clotrimazole | 12/21-N01 | 1 |
| Gehe | Clotrimazole | 121003902 | 1 |
| Gehe | Clotrimazole | 1306036-01 | 3 |
| Gehe | Clotrimazole | 1309034-01 | 1 |
| Gehe | Clotrimazole | 13184103 | 1 |
| Gehe | Clotrimazole | 13224216 | 1 |
| Gehe | Clotrimazole | 1409027-02 | 2 |
| Gehe | Clotrimazole | 14337815 | 2 |
| Gehe | Clotrimazole | 14337819 | 1 |
| Gehe | Clotrimazole | 14B05B35294935 | 1 |
| Gehe | Clotrimazole | 14B05-B35-294935 | 1 |
| Gehe | Clotrimazole | 14C04-B31-294952 | 1 |
| Gehe | Clotrimazole | 15G14-B05 | 1 |
| GEHE | Clotrimazole | 1607046-02 | 1 |
| Gehe | Clotrimazole | 16234505 | 1 |
| Gehe | Clotrimazole | 16234511 | 1 |
| Gehe | Clotrimazole | 16234513 | 1 |
| GEHE | Clotrimazole | 16234513 | 1 |
| Gehe | Clotrimazole | 16E20-B10-321598 | 2 |
| Gehe | Clotrimazole | 16J07/344817 | 1 |
| GEHE | Clotrimazole | 16J07-B02 | 1 |
| Gehe | Clotrimazole | 16j07-b02-330216 | 1 |
| Gehe | Clotrimazole | 16J07-B02-330216 | 1 |
| gehe | Clotrimazole | 1703028-01 | 2 |
| Gehe | Clotrimazole | 1703028-02 | 1 |
| Gehe | Clotrimazole | 17111603 | 1 |
| Gehe | Clotrimazole | 17111605 | 1 |
| Gehe | Clotrimazole | 17111616 | 1 |
| Gehe | Clotrimazole | 17360201 | 1 |
| GEHE | Clotrimazole | 17360202 | 1 |
| GEHE | Clotrimazole | 177111613 | 1 |
| Gehe | Clotrimazole | 17A19-B04 | 1 |
| Gehe | Clotrimazole | 17A19-B04-338560 | 1 |
| Gehe | Clotrimazole | 17J25-B06-0345044 | 1 |
| Gehe | Clotrimazole | 17J25-B06-345048 | 1 |
| Gehe | Clotrimazole | 17J25-B06-345407 | 1 |
| Gehe | Clotrimazole | 1808028-01 | 4 |
| Gehe | Clotrimazole | 1808028-02 | 1 |
| Gehe | Clotrimazole | 18147101 | 1 |
| Gehe | Clotrimazole | 18147103 | 1 |
| GEHE | Clotrimazole | 18147103 | 1 |
| GEHE | Clotrimazole | 18147210 | 2 |
| Gehe | Clotrimazole | 18A18-B05-350778 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Clotrimazole | 18G10-B06 | 2 |
| Gehe | Clotrimazole | 18G10-B06-0046B | 1 |
| Gehe | Clotrimazole | 18G10-B06-358825 | 1 |
| Gehe | Clotrimazole | 19016106 | 1 |
| Gehe | Clotrimazole | 19016108 | 1 |
| Gehe | Clotrimazole | 19016116 | 1 |
| Gehe | Clotrimazole | 1902004-02 | 2 |
| Gehe | Clotrimazole | 1902004-03 | 2 |
| Gehe | Clotrimazole | 200000094004 | 1 |
| gehe | Clotrimazole | 20000092002 | 1 |
| Gehe | Clotrimazole | 20000092006 | 1 |
| Gehe | Clotrimazole | 20000094003 | 2 |
| Gehe | Clotrimazole | 20000094006 | 1 |
| Gehe | Clotrimazole | 2007033-02 | 1 |
| Gehe | Clotrimazole | 21000121004 | 2 |
| Gehe | Clotrimazole | 21004116005 | 1 |
| Gehe | Clotrimazole | 21004116007 | 3 |
| Gehe | Clotrimazole | 21004116013 | 1 |
| Gehe | Clotrimazole | 21004116014 | 4 |
| gehe | Clotrimazole | 21004116016 | 1 |
| Gehe | Clotrimazole | 21004116016 | 1 |
| Gehe | Clotrimazole | 21004116017 | 1 |
| Gehe | Clotrimazole | 21004117003 | 1 |
| Gehe | Clotrimazole | 21004117007 | 1 |
| Gehe | Clotrimazole | 21004117016 | 1 |
| Gehe | Clotrimazole | 21004117018 | 1 |
| Gehe | Clotrimazole | 2103021-01 | 1 |
| Gehe | Clotrimazole | 2103024-01 | 1 |
| Gehe | Clotrimazole | 22A21-B02-217361 | 2 |
| Gehe | Clotrimazole | 22A21-B02-221731 | 2 |
| Gehe | Clotrimazole | 22A31-B02-221731 | 1 |
| Gehe | Clotrimazole | 23001596002 | 4 |
| GEHE | Clotrimazole | 23001596002 | 1 |
| Gehe | Clotrimazole | 23001596008 | 2 |
| gehe | Clotrimazole | 230105501 | 3 |
| Gehe | Clotrimazole | 2301055-01 | 3 |
| Gehe | Clotrimazole | 2301055-02 | 1 |
| Gehe | Clotrimazole | 24001098001 | 1 |
| Gehe | Clotrimazole | 2406013-01 | 1 |
| Gehe | Clotrimazole | 24E08-B10-002507 | 1 |
| Gehe | Clotrimazole | 24E08-B10-002511 | 3 |
| Gehe | Clotrimazole | CLT/1805/0046B | 1 |
| Gehe | Clotrimazole | HCZ14218 | 1 |
| Geilenkirchen | Clotrimazole | 17360204 | 1 |
| Geilenkirchen | Clotrimazole | 20000094004 | 1 |
| Guangzhou Hanpu Phar... | Clotrimazole | 14337819 | 1 |
| Guangzhou Hanpu Phar... | Clotrimazole | 1409027-03 | 1 |
| Guangzhou Hanpu Phar... | Clotrimazole | 1510003-01 | 1 |
| Guangzhou Hanpu Phar... | Clotrimazole | 1510003-02 | 1 |
| Guangzhou Hanpu Pharmac. | Clotrimazole | 1703028-02 | 1 |
| Halcycon Labs | Clotrimazole | 19016104 | 1 |
| Halcyon / Noweda | Clotrimazole | 18147210 | 1 |
| Halcyon Labs / Gehe ... | Clotrimazole | 18147103 | 1 |
| Halcyon Labs Pvt. Lt... | Clotrimazole | 20000094006 | 1 |
| Halcyon Labs Pvt.Ltd... | Clotrimazole | W8269 | 1 |
| Halcyon Labs Pvt.Ltd... | Clotrimazole | 18147101 | 1 |
| Halcyon Labs Pvt | Clotrimazole | 20003904004 | 1 |
| Halcyon Labs/ | Clotrimazole | 19016105 | 1 |
| Halcyon Labs | Clotrimazole | 1808028-02 | 1 |
| Halcyon Labs | Clotrimazole | 20000094005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Halcyon/Link & Eccius | Clotrimazole | W8269 | 1 |
| Halcyon/Noweda | Clotrimazole | 20000094008 | 1 |
| Halcyon/Noweda | Clotrimazole | HCZ14518 | 1 |
| Halcyon/Noweda | Clotrimazole | HCZ14718 | 1 |
| Halycon Labs / Fiebig | Clotrimazole | HCZ06718 | 1 |
| Hedinger/Gehe | Clotrimazole | 1703028-02 | 1 |
| Henry Lamotte oils GmbH | Clotrimazole | 18147203 | 1 |
| Holdermann | Clotrimazole | 21004117004 | 1 |
| Holdermann | Clotrimazole | 22A21-B02-221731 | 1 |
| Holdermann | Clotrimazole | 23001596003 | 1 |
| Jenne / Euro | Clotrimazole | 2103024-01 | 2 |
| Jenne | Clotrimazole | 18147103 | 1 |
| Jenne | Clotrimazole | 20000092006 | 1 |
| JENNE | Clotrimazole | 21004116007 | 1 |
| Jenne | Clotrimazole | 23001596002 | 1 |
| Jenne | Clotrimazole | 23001596009 | 2 |
| Jenne | Clotrimazole | 23003390005 | 2 |
| Jenne | Clotrimazole | 2301055-01 | 1 |
| Jenne | Clotrimazole | 241001(23003390006) | 1 |
| Kehr Holdermann | Clotrimazole | 2301055-04 | 2 |
| Kehr | Clotrimazole | 1808028-01 | 1 |
| Kehr | Clotrimazole | 18g10-b06-3533348 | 1 |
| Kehr | Clotrimazole | 18g10-b06-353348 | 1 |
| Kehr | Clotrimazole | 21004116005 | 1 |
| Kehr | Clotrimazole | 21004116013 | 1 |
| Kehr | Clotrimazole | 21004116014 | 1 |
| Kehr | Clotrimazole | 21004117022 | 1 |
| Kehr | Clotrimazole | 2103024-02 | 1 |
| Kehr | Clotrimazole | 23001596008 | 1 |
| Kehr | Clotrimazole | 23001596009 | 1 |
| Kehr | Clotrimazole | 23003390001 | 1 |
| Kehr | Clotrimazole | 2301055-01 | 2 |
| Kehr | Clotrimazole | 24001098001 | 1 |
| Kehr-Holdermann | Clotrimazole | 21004116014 | 1 |
| Klenk | Clotrimazole | 16B09-B06-311785 | 1 |
| Klosterring | Clotrimazole | 16234512 | 1 |
| Klosterring | Clotrimazole | 17111615 | 2 |
| Klosterring | Clotrimazole | 6234505 | 1 |
| Krieger | Clotrimazole | 2103024-02 | 1 |
| L12 | Clotrimazole | 16234512 | 1 |
| L12 | Clotrimazole | 17111606 | 1 |
| L12 | Clotrimazole | 17360204 | 1 |
| Link &Eccius (Halcyo... | Clotrimazole | W8269 | 1 |
| Maros Arznei GmbH | Clotrimazole | 13184105 | 1 |
| Martin Apo | Clotrimazole | 31117/1 | 1 |
| Max Jenne | Clotrimazole | 23001596009 | 1 |
| Midas | Clotrimazole | 1703028-01 | 1 |
| Midas | Clotrimazole | 1703028-03 | 1 |
| Midas | Clotrimazole | 1808028-02 | 1 |
| Mvda_15.01.2019 | Clotrimazole | 18147102 | 1 |
| Nachprüfung | Clotrimazole | 2082019-4 | 1 |
| Noveda | Clotrimazole | 20003904003 | 1 |
| Noweda 06.11.2019 | Clotrimazole | 19016119 | 1 |
| Noweda 07.07.2015 | Clotrimazole | 14144913 | 1 |
| Noweda 17.7.2019 | Clotrimazole | 19016105 | 1 |
| Noweda Fiebig 15.05.... | Clotrimazole | 20000092002 | 1 |
| Noweda Taucha | Clotrimazole | 19016206 | 1 |
| Noweda/EuRho | Clotrimazole | 2103024-01 | 1 |
| Noweda/Fargon | Clotrimazole | 17A19-B04-336568 | 1 |
| Noweda | Clotrimazole | 1203040-03 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Clotrimazole | 13224201 | 1 |
| Noweda | Clotrimazole | 13224217 | 1 |
| Noweda | Clotrimazole | 1409027 | 1 |
| Noweda | Clotrimazole | 1409027-02 | 1 |
| Noweda | Clotrimazole | 14337801 | 1 |
| Noweda | Clotrimazole | 14337816 | 1 |
| Noweda | Clotrimazole | 1510003-01 | 2 |
| Noweda | Clotrimazole | 15G14-B05-316483 | 2 |
| Noweda | Clotrimazole | 16234517 | 2 |
| Noweda | Clotrimazole | 16E20-BIO-321598 | 1 |
| Noweda | Clotrimazole | 16J07-B02-329386 | 1 |
| Noweda | Clotrimazole | 16j07-b02-341842 | 1 |
| Noweda | Clotrimazole | 1703028-01 | 1 |
| Noweda | Clotrimazole | 17111608 | 1 |
| Noweda | Clotrimazole | 17360201 | 1 |
| Noweda | Clotrimazole | 17360203 | 2 |
| Noweda | Clotrimazole | 17J25-B06-345044 | 1 |
| Noweda | Clotrimazole | 18147203 | 2 |
| Noweda | Clotrimazole | 18147211 | 1 |
| Noweda | Clotrimazole | 18147212 | 1 |
| Noweda | Clotrimazole | 18A18-B05 | 1 |
| Noweda | Clotrimazole | 18G10-B06 | 1 |
| Noweda | Clotrimazole | 18G10-B06-352425 | 1 |
| Noweda | Clotrimazole | 18G10-B06-358825 | 2 |
| Noweda | Clotrimazole | 19016104 | 1 |
| Noweda | Clotrimazole | 19016107 | 1 |
| Noweda | Clotrimazole | 19016202 | 2 |
| Noweda | Clotrimazole | 19016204 | 1 |
| Noweda | Clotrimazole | 19016208 | 1 |
| Noweda | Clotrimazole | 19020004-01 | 1 |
| Noweda | Clotrimazole | 1902004_01 | 1 |
| Noweda | Clotrimazole | 1902004-02 | 1 |
| Noweda | Clotrimazole | 19B14-B01-359539 | 1 |
| Noweda | Clotrimazole | 20000094005 | 1 |
| Noweda | Clotrimazole | 2007033-01 | 1 |
| Noweda | Clotrimazole | 2007033-02 | 2 |
| Noweda | Clotrimazole | 20111115 | 1 |
| Noweda | Clotrimazole | 20H26-F05-373738 | 1 |
| Noweda | Clotrimazole | 21000121002 | 1 |
| Noweda | Clotrimazole | 21000123008 | 1 |
| Noweda | Clotrimazole | 21000123011 | 1 |
| Noweda | Clotrimazole | 21004116003 | 2 |
| Noweda | Clotrimazole | 21004116007 | 2 |
| Noweda | Clotrimazole | 21004116008 | 1 |
| Noweda | Clotrimazole | 21004116013 | 2 |
| Noweda | Clotrimazole | 21004116014 | 1 |
| Noweda | Clotrimazole | 21004117001 | 1 |
| Noweda | Clotrimazole | 21004117016 | 1 |
| Noweda | Clotrimazole | 21004117017 | 1 |
| Noweda | Clotrimazole | 21004117018 | 3 |
| Noweda | Clotrimazole | 2103024-01 | 3 |
| Noweda | Clotrimazole | 2103024-02 | 1 |
| Noweda | Clotrimazole | 2103024-03 | 1 |
| Noweda | Clotrimazole | 22A21-B02-221730 | 1 |
| Noweda | Clotrimazole | 23001596002 | 5 |
| Noweda | Clotrimazole | 23001596010 | 1 |
| Noweda | Clotrimazole | 23003390001 | 1 |
| Noweda | Clotrimazole | 23003390004 | 2 |
| Noweda | Clotrimazole | 23003390005 | 2 |
| Noweda | Clotrimazole | 23003390006 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Clotrimazole | 2300390001 | 1 |
| Noweda | Clotrimazole | 2301055-01 | 2 |
| Noweda | Clotrimazole | 2301055-02 | 1 |
| Noweda | Clotrimazole | 2301055-04 | 2 |
| Noweda | Clotrimazole | 23D11-B01-228694 | 1 |
| Noweda | Clotrimazole | 23H09-B07-230826 | 1 |
| Noweda | Clotrimazole | 23H09-B07-235132 | 1 |
| Noweda | Clotrimazole | 2406013-01 | 1 |
| Oberlinden Apotheke | Clotrimazole | 201401300378 | 2 |
| p&m cosmetics/gehe | Clotrimazole | 16J07-B02-335773 | 2 |
| Phö/Dr.Wolff | Clotrimazole | 19016108 | 1 |
| Phoenix 23.10.14 5,50 | Clotrimazole | 1309034-02 | 1 |
| Phoenix 24.04.2017 | Clotrimazole | 1607046-02 | 1 |
| PHOENIX am 22.01.2014 | Clotrimazole | 1306036-01 | 1 |
| Phoenix | Clotrimazole | 12A05-N10 | 1 |
| Phoenix | Clotrimazole | 1309034-02 | 1 |
| Phoenix | Clotrimazole | 13224214 | 2 |
| Phoenix | Clotrimazole | 13224215 | 1 |
| Phoenix | Clotrimazole | 14337812 | 1 |
| Phoenix | Clotrimazole | 14c04b31 | 1 |
| Phoenix | Clotrimazole | 1607046-01 | 1 |
| Phoenix | Clotrimazole | 16234509 | 1 |
| phoenix | Clotrimazole | 16234512 | 1 |
| Phoenix | Clotrimazole | 16B11-B04-327611 | 1 |
| Phoenix | Clotrimazole | 17111601 | 1 |
| Phoenix | Clotrimazole | 17111603 | 1 |
| Phoenix | Clotrimazole | 18147102 | 1 |
| Phoenix | Clotrimazole | 1902004-01 | 1 |
| Phoenix | Clotrimazole | 1902004-02 | 2 |
| Phoenix | Clotrimazole | 191381012 | 1 |
| Phoenix | Clotrimazole | 20000092006 | 1 |
| Phoenix | Clotrimazole | 20000094003 | 1 |
| Phoenix | Clotrimazole | 20003904004 | 1 |
| Phoenix | Clotrimazole | 21000121002 | 1 |
| Phoenix | Clotrimazole | 21000121006 | 1 |
| Phoenix | Clotrimazole | 21004116013 | 2 |
| Phoenix | Clotrimazole | 21004116014 | 1 |
| Phoenix | Clotrimazole | 21004117004 | 1 |
| Phoenix | Clotrimazole | 21004117011 | 1 |
| Phoenix | Clotrimazole | 21004117016 | 1 |
| Phoenix | Clotrimazole | 21004117017 | 1 |
| Phoenix | Clotrimazole | 2103024-01 | 1 |
| Phoenix | Clotrimazole | 2103024-02 | 1 |
| Phoenix | Clotrimazole | 22A21-B02-217361 | 1 |
| Phoenix | Clotrimazole | 23001596002 | 8 |
| Phoenix | Clotrimazole | 23001596009 | 3 |
| Phoenix | Clotrimazole | 23001596010 | 1 |
| Phoenix | Clotrimazole | 23003390004 | 1 |
| Phoenix | Clotrimazole | 23003390005 | 1 |
| Phoenix | Clotrimazole | 2301055-01 | 2 |
| Phoenix | Clotrimazole | 3088 | 1 |
| Phoenix | Clotrimazole | 3237 | 1 |
| Phoenix | Clotrimazole | 79879 | 1 |
| Phönix Gotha | Clotrimazole | 14337811 | 1 |
| Phönix Gotha | Clotrimazole | 16J07-B02-344816 | 1 |
| Phönix WE:23.10.17 ... | Clotrimazole | 16234521 | 1 |
| Phönix | Clotrimazole | | 1 |
| phönix | Clotrimazole | 11305513 | 1 |
| Phönix | Clotrimazole | 13C25-N10 | 1 |
| Phönix | Clotrimazole | 1409027-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| phönix | Clotrimazole | 14337818 | 1 |
| Phönix | Clotrimazole | 15395618 | 1 |
| Phönix | Clotrimazole | 1607046-01 | 1 |
| Phönix | Clotrimazole | 16234505 | 1 |
| phönix | Clotrimazole | 16234512 | 1 |
| phönix | Clotrimazole | 16B11-B04-327611 | 1 |
| Phönix | Clotrimazole | 1703028-03 | 1 |
| Phönix | Clotrimazole | 17111603 | 1 |
| Phönix | Clotrimazole | 17111604 | 1 |
| Phönix | Clotrimazole | 17111608 | 2 |
| Phönix | Clotrimazole | 17360203 | 1 |
| Phönix | Clotrimazole | 18147103 | 1 |
| Phönix | Clotrimazole | 18147203 | 1 |
| PHÖNIX | Clotrimazole | 18147203 | 1 |
| Phönix | Clotrimazole | 18147212 | 1 |
| Phönix | Clotrimazole | 18G10-B06-354620 | 2 |
| PHÖNIX | Clotrimazole | 18G10-B06-358824 | 1 |
| Phönix | Clotrimazole | 19016104 | 1 |
| Phönix | Clotrimazole | 19016108 | 1 |
| Phönix | Clotrimazole | 19016116 | 1 |
| Phönix | Clotrimazole | 19016203 | 1 |
| Phönix | Clotrimazole | 19016205 | 1 |
| Phönix | Clotrimazole | 1902004-01 | 2 |
| Phönix | Clotrimazole | 1902004-02 | 1 |
| Phönix | Clotrimazole | 1902004-03 | 2 |
| PHÖNIX | Clotrimazole | 19b14b01363546 | 1 |
| Phönix | Clotrimazole | 20000092007 | 1 |
| Phönix | Clotrimazole | 2007033-01 | 1 |
| PHÖNIX | Clotrimazole | 200703301 | 1 |
| Phönix | Clotrimazole | 2007033-03 | 1 |
| Phönix | Clotrimazole | 200742407 | 1 |
| Phönix | Clotrimazole | 201033-01 | 1 |
| Phönix | Clotrimazole | 20160801 | 1 |
| Phönix | Clotrimazole | 21000121002 | 1 |
| phönix | Clotrimazole | 21004116007 | 1 |
| Phönix | Clotrimazole | 21004116007 | 4 |
| Phönix | Clotrimazole | 21004116013 | 1 |
| Phönix | Clotrimazole | 21004116014 | 2 |
| Phönix | Clotrimazole | 21004116016 | 1 |
| Phönix | Clotrimazole | 21004117018 | 1 |
| Phönix | Clotrimazole | 21004117022 | 1 |
| Phönix | Clotrimazole | 2103024-01 | 1 |
| Phönix | Clotrimazole | 2103024-02 | 4 |
| Phönix | Clotrimazole | 2103024-03 | 1 |
| phönix | Clotrimazole | 23001596002 | 3 |
| Phönix | Clotrimazole | 23001596002 | 5 |
| Phönix | Clotrimazole | 23001596003 | 2 |
| Phönix | Clotrimazole | 23001596009 | 2 |
| Phönix | Clotrimazole | 23003390001 | 2 |
| Phönix | Clotrimazole | 2300390001 | 1 |
| Phönix | Clotrimazole | 2301055-02 | 6 |
| Phönix | Clotrimazole | 2301055-03 | 3 |
| Phönix | Clotrimazole | 2406013-01 | 2 |
| Röntgen | Clotrimazole | 1808028-01 | 3 |
| Röntgen | Clotrimazole | 1902004-03 | 1 |
| Röntgen | Clotrimazole | 2007033-02 | 1 |
| Röntgen | Clotrimazole | 2103024-01 | 1 |
| Sanacorp/Caela | Clotrimazole | 17111603 | 1 |
| Sanacorp | Clotrimazole | 105/AKD1 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Clotrimazole | 109/AKD3 | 1 |
| Sanacorp | Clotrimazole | 109/AKD6 | 1 |
| Sanacorp | Clotrimazole | 1203040-03 | 1 |
| Sanacorp | Clotrimazole | 12159902 | 1 |
| Sanacorp | Clotrimazole | 1230805 | 1 |
| Sanacorp | Clotrimazole | 12320814 | 1 |
| Sanacorp | Clotrimazole | 13184105 | 1 |
| Sanacorp | Clotrimazole | 13224219 | 1 |
| Sanacorp | Clotrimazole | 14144905 | 1 |
| sanacorp | Clotrimazole | 14144918 | 1 |
| Sanacorp | Clotrimazole | 14337817 | 1 |
| Sanacorp | Clotrimazole | 15g14-b05-311100 | 1 |
| Sanacorp | Clotrimazole | 16E20-B10-327349 | 1 |
| Sanacorp | Clotrimazole | 16J07-B02-330216 | 1 |
| Sanacorp | Clotrimazole | 16J07-B02-338283 | 1 |
| Sanacorp | Clotrimazole | 1703028-02 | 1 |
| Sanacorp | Clotrimazole | 170302803 | 1 |
| Sanacorp | Clotrimazole | 17360201 | 1 |
| Sanacorp | Clotrimazole | 17360203 | 1 |
| Sanacorp | Clotrimazole | 17a19-b04-332114 | 1 |
| Sanacorp | Clotrimazole | 18147102 | 1 |
| Sanacorp | Clotrimazole | 18147203 | 3 |
| Sanacorp | Clotrimazole | 18147210 | 2 |
| Sanacorp | Clotrimazole | 18147211 | 1 |
| Sanacorp | Clotrimazole | 18147212 | 1 |
| Sanacorp | Clotrimazole | 1882321 | 1 |
| Sanacorp | Clotrimazole | 18A18-B05-349662 | 3 |
| Sanacorp | Clotrimazole | 18G10-B06 | 1 |
| Sanacorp | Clotrimazole | 19016116 | 1 |
| Sanacorp | Clotrimazole | 19016203 | 1 |
| Sanacorp | Clotrimazole | 19016208 | 2 |
| Sanacorp | Clotrimazole | 19B14-B01-359537 | 1 |
| Sanacorp | Clotrimazole | 20000094006 | 1 |
| Sanacorp | Clotrimazole | 20000094008 | 1 |
| sanacorp | Clotrimazole | 20003904004 | 1 |
| Sanacorp | Clotrimazole | 20003904005 | 1 |
| Sanacorp | Clotrimazole | 200703302 | 1 |
| Sanacorp | Clotrimazole | 20H19-F01 | 1 |
| Sanacorp | Clotrimazole | 20H26-F05 | 1 |
| Sanacorp | Clotrimazole | 20H26-F05-373739 | 4 |
| Sanacorp | Clotrimazole | 21000121006 | 2 |
| Sanacorp | Clotrimazole | 21000123008 | 1 |
| Sanacorp | Clotrimazole | 21000123010 | 1 |
| Sanacorp | Clotrimazole | 21004116005 | 1 |
| Sanacorp | Clotrimazole | 21004116007 | 1 |
| Sanacorp | Clotrimazole | 21004116013 | 1 |
| Sanacorp | Clotrimazole | 21004116014 | 2 |
| Sanacorp | Clotrimazole | 21004116017 | 1 |
| sanacorp | Clotrimazole | 21004117005 | 1 |
| Sanacorp | Clotrimazole | 21D22-B03-217092 | 2 |
| Sanacorp | Clotrimazole | 21H13-B14-213291 | 1 |
| Sanacorp | Clotrimazole | 22A21-B02-221671 | 1 |
| Sanacorp | Clotrimazole | 22A21-B02-221731 | 1 |
| Sanacorp | Clotrimazole | 23001596002 | 1 |
| Sanacorp | Clotrimazole | 23001596003 | 1 |
| Sanacorp | Clotrimazole | 23001596008 | 1 |
| Sanacorp | Clotrimazole | 23003390001 | 2 |
| Sanacorp | Clotrimazole | 2300339001 | 1 |
| sanacorp | Clotrimazole | 2301055-01 | 1 |
| Sanacorp | Clotrimazole | 2301055-01 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Clotrimazole | APCLT/1703/0016CC | 1 |
| Sanarcorp | Clotrimazole | 17a19-b04 | 1 |
| Sino Phyto | Clotrimazole | 13224210 | 2 |
| Stumpf | Clotrimazole | 12159902 | 1 |
| Test | Clotrimazole | Test | 1 |
| Vdl 14.07.14 | Clotrimazole | 13224225 | 1 |
| VDL;11.06.15;27,90EUR | Clotrimazole | 14337807 | 1 |
| WE Phönix.01.12.2016... | Clotrimazole | 15395618 | 1 |
| wepa/Sanaco | Clotrimazole | 14337819 | 1 |

- 249 201 spectra from 1666 *Apo-Ident* customers from a total of 51 162 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Clotrimazole* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Clotrimazole* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 540 | 0 | 157 786 |
| **Type B** | 0 | 680 | 0 | 212 260 |
| **Type C** | 0 | 7591 | 94 | 249 201 |

The substance/substance group *Clotrimazole* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8889 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.1176 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.7768 % (> 98.7378 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20794 | 22229 | 6.12 | 60.61 |
| 21087 | 23791 | 9.13 | 62.84 |
| 21114 | 23791 | 8.91 | 59.39 |
| 21207 | 25649 | 7.30 | 55.18 |
| 21259 | 25649 | 10.22 | 57.83 |
| 21264 | 25656 | 4.75 | 55.74 |
| 21352 | 22229 | 8.45 | 59.72 |
| 21353 | 22229 | 8.93 | 59.35 |
| 22229 | 22229 | 0.00 | 63.17 |
| 23791 | 23791 | 0.00 | 57.79 |
| 25649 | 25649 | 0.00 | 52.70 |
| 25656 | 25656 | 0.00 | 53.59 |
| 26137 | 25656 | 26.05 | 47.35 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Colistin sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20318-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Colistin sulfate; Colistin sulphate; Colistini sulfas

### Special notes

When selecting the *Colistin sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Colistin sulfate | 10 | 11 | 14 |

### Second-stage model

For differentiation of the substance/substance group *Colistin sulfate* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Colistin sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 30.18 | 18.73 |
| Bacitracin | 37.58 | 14.23 |
| Cannabis flower, CBD-dominant type | 51.86 | – |
| ⋮ | ⋮ | ⋮ |
| Calcium pantothenate | >50 | 37.39 |
| Amphotericin B | >50 | 49.82 |
| alpha-tocopheryl acetate dry concentrate | >50 | 52.09 |
| Cyanocobalamin | >50 | 58.55 |
| Riboflavin | >50 | 64.16 |
| Methylcobalamin | >50 | 69.02 |
| Nystatin | >50 | 70.59 |
| Gelatine, white | >50 | 73.14 |
| Estriol | >50 | 78.39 |
| Estradiol hemihydrate | >50 | 80.75 |
| Triamcinolone | >50 | 90.81 |
| Calcium glycerophosphate | >50 | 114.03 |
| Carmellose sodium | >50 | 128.10 |
| Hyoscine hydrobromide | >50 | 159.80 |
| SyrSpend® SF Alka | >50 | 200.61 |
| Tosylchloramide sodium | >50 | 202.92 |
| Rice starch | >50 | 226.86 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 286.83 |
| Oxalic acid | >50 | 317.17 |
| Corn starch | >50 | 322.32 |
| Acacia, dried dispersion | >50 | 326.52 |
| SyrSpend® SF pH4 | >50 | 398.71 |
| Maltodextrin | >50 | 447.94 |
| Potato starch | >50 | 450.31 |
| Wheat starch | >50 | 461.00 |
| Fructose | >50 | 547.69 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Colistin sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Colistin sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Colistin sulfate | APKB-CS-1602026C | 22974 | 40 | 20160418 |
| Audor Pharma | Colistin sulfate | APKB-CS-1602026C | 23027 | 40 | 20160418 |
| Euro OTC | Colistin sulfate | 1406001-01 | 21619 | 60 | 1508600 |
| Euro OTC | Colistin sulfate | 1507044 | 21852 | 60 | 20150817* |
| Euro OTC | Colistin sulfate | 1602021 | 22371 | 60 | 20160307* |
| Euro OTC | Colistin sulfate | 1606008 | 22695 | 40 | 20160704* |
| Euro OTC | Colistin sulfate | 2009035 | 25431 | 40 | 20200930* |
| Fagron | Colistin sulfate | 13G05-N01 | 20915 | 40 | 20130719 |
| Fagron | Colistin sulfate | 13G05-N01 | 21209 | 40 | 20130719 |
| Fagron | Colistin sulfate | 14E02-B03 | 21346 | 40 | 1501654 |
| Fagron | Colistin sulfate | 16F03-B01-324216 | 22973 | 40 | 20160706 |
| Fagron | Colistin sulfate | 20F18-B04-201974 | 25667 | 50 | 20200706 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 550 spectra of 12 reference samples from the substance/substance group *Colistin sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.
- 157 776 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 505 spectra of 14 reference samples from the substance/substance group *Colistin sulfate*.
- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Audor Pharma | Colistin sulfate | APKB-CS-1603034C | 23026 | 40 |
| Euro OTC | Colistin sulfate | 1406002-01 | 21700 | 45 |
| Euro OTC | Colistin sulfate | 1709009 | 23616 | 40 |
| Euro OTC | Colistin sulfate | 1710041 | 23866 | 40 |
| Euro OTC | Colistin sulfate | 1905016 | 24769 | 40 |
| Euro OTC | Colistin sulfate | 1908007 | 24836 | 40 |
| Euro OTC | Colistin sulfate | 2001039 | 25087 | 40 |
| Euro OTC | Colistin sulfate | 2301012 | 26653 | 40 |
| Fagron | Colistin sulfate | 22B14-B10-219015 | 26182 | 40 |
| Fagron | Colistin sulfate | 23D12-B10-230780 | 27382 | 40 |
| Fagron | Colistin sulfate | 24C13-B05-008621 | 27606 | 40 |
| Euro OTC | Colistin sulfate | 2301012 | 26653SI | 20 |
| Fagron | Colistin sulfate | 22B14-B10-219015 | 26182SI | 20 |
| Fagron | Colistin sulfate | 23D12-B10-230780 | 27382SI | 20 |

- 212 435 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 18 spectra from 8 *Apo-Ident* customers from 16 batches from the substance/substance group *Colistin sulfate*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Colistin sulfate | APKB-CS-1601026C | 1 |
| Audor Pharma | Colistin sulfate | APKB-CS-1603034C | 2 |
| Audor Pharma | Colistin sulfate | APKB-CS-1610012C | 1 |
| Caelo | Colistin sulfate | 1602021-01 | 1 |
| Euro OTC | Colistin sulfate | 1507044-01 | 1 |
| Fagron | Colistin sulfate | 15E15-B01-315340 | 1 |
| Fagron | Colistin sulfate | 16F03-B01 | 1 |
| Fagron | Colistin sulfate | 16F03-B01_322758 | 1 |
| Fagron | Colistin sulfate | 16f03-b01-324216 | 1 |
| Fagron | Colistin sulfate | 16F03-B01-324216 | 1 |
| Fagron | Colistin sulfate | 16J03-B10-330367 | 1 |
| Fagron | Colistin sulfate | 17E09-B04-342085 | 1 |
| Fagron | Colistin sulfate | 17j24-b03-342638 | 1 |
| Fagron | Colistin sulfate | 20K06-B03-202435 | 2 |
| Fagron | Colistin sulfate | 21G20_B09213652 | 1 |
| Fagron | Colistin sulfate | 21G20-B08-215430 | 1 |

- 256 868 spectra from 1666 *Apo-Ident* customers from a total of 52 137 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Colistin sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Colistin sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 510 | 40 | 157 776 |
| **Type B** | 0 | 505 | 0 | 212 435 |
| **Type C** | 0 | 18 | 0 | 256 868 |

The substance/substance group *Colistin sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 92.7273 % (> 92.1818 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8119 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20915 | 21619 | 8.78 | 49.83 |
| 21209 | 21619 | 8.05 | 45.54 |
| 21346 | 21346 | 0.00 | 37.34 |
| 21619 | 21619 | 0.00 | 46.43 |
| 21852 | 21852 | 0.00 | 37.22 |
| 22371 | 22371 | 0.00 | 53.94 |
| 22695 | 22695 | 0.00 | 38.34 |
| 22973 | 21852 | 3.23 | 36.80 |
| 22974 | 21852 | 16.49 | 35.99 |
| 23027 | 21346 | 16.99 | 35.69 |
| 25431 | 25431 | 0.00 | 59.60 |
| 25667 | 22695 | 24.61 | 37.58 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all

substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cyanocobalamin / Methylcobalamin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10003566-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cyanocobalamin / Methylcobalamin; Cyanocobalamin; Cyanocobalaminum; Methylcobalamin

### Special notes

When selecting the *Cyanocobalamin / Methylcobalamin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cyanocobalamin / Methylcobalamin | 17 | 12 | 33 |

### Second-stage model

For differentiation of the substance/substance group *Cyanocobalamin / Methylcobalamin* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cyanocobalamin / Methylcobalamin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Bacitracin | 40.90 | 14.37 |
| Polymyxin B sulfate | 45.40 | 24.18 |
| Cannabis flower, CBD-dominant type | 54.32 | – |
| ⋮ | ⋮ | ⋮ |
| Amphotericin B | >50 | 28.60 |
| Colistin sulfate | >50 | 31.18 |
| Calcium pantothenate | >50 | 43.17 |
| Nystatin | >50 | 45.00 |
| Gelatine, white | >50 | 55.45 |
| Estriol | >50 | 56.10 |
| Triamcinolone | >50 | 59.07 |
| alpha-tocopheryl acetate dry concentrate | >50 | 70.09 |
| Estradiol hemihydrate | >50 | 74.45 |
| Riboflavin | >50 | 78.57 |
| Hyoscine hydrobromide | >50 | 104.47 |
| Calcium glycerophosphate | >50 | 110.21 |
| Tosylchloramide sodium | >50 | 129.10 |
| SyrSpend® SF Alka | >50 | 158.58 |
| Carmellose sodium | >50 | 160.61 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 173.62 |
| Oxalic acid | >50 | 187.91 |
| Rice starch | >50 | 192.09 |
| SyrSpend® SF pH4 | >50 | 243.77 |
| Corn starch | >50 | 265.83 |
| Acacia, dried dispersion | >50 | 286.18 |
| Wheat starch | >50 | 360.48 |
| Potato starch | >50 | 364.80 |
| Maltodextrin | >50 | 389.41 |
| Fructose | >50 | 407.23 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cyanocobalamin / Methylcobalamin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cyanocobalamin / Methylcobalamin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Cyanocobalamin | 13342803 | 21299 | 40 | AR-15-FG-005429-01 |
| Caelo | Cyanocobalamin | 13342807 | 21479 | 60 | AR-15-FG-014917-01 |
| Caelo | Cyanocobalamin | 13342807 | 21479SI | 30 | AR-15-FG-014917-01 |
| Caelo | Cyanocobalamin | 160154 | 22441 | 60 | 20160309* |
| Caelo | Cyanocobalamin | 160154 | 22441SI | 60 | 20160309* |
| Euro OTC | Cyanocobalamin | 1305040-01 | 21635 | 60 | AR-15-FG-005214-01 |
| Euro OTC | Cyanocobalamin | 1506035 | 21867 | 60 | 20150708* |
| Euro OTC | Cyanocobalamin | 1506035 | 21867SI | 60 | 20150708* |
| Euro OTC | Cyanocobalamin | 1506035 | 21872 | 60 | 0000010479 |
| Euro OTC | Cyanocobalamin | 1506035 | 21872SI | 45 | 0000010479 |
| Euro OTC | Cyanocobalamin | 1604017 | 22536 | 30 | 20160509* |
| Euro OTC | Cyanocobalamin | 1604017 | 22536SI | 30 | 20160509* |
| Euro OTC | Cyanocobalamin | 1812011 | 24465 | 40 | 20190205* |
| Euro OTC | Methylcobalamin | 1207019-01 | 20743 | 40 | 1402501 |
| Euro OTC | Methylcobalamin | 1401032-01 | 21721 | 60 | 8778 |
| Euro OTC | Methylcobalamin | 1510002 | 22234 | 60 | 20151201* |
| Euro OTC | Methylcobalamin | 1401032 | 22239 | 60 | 20151201* |
| Euro OTC | Methylcobalamin | 1601043 | 22379 | 60 | 20160209* |
| Euro OTC | Methylcobalamin | 1804006 | 24072 | 40 | 20180420* |
| Euro OTC | Methylcobalamin | 1809001 | 24311 | 40 | 20180925* |
| Euro OTC | Methylcobalamin | 1904002 | 24775 | 40 | 20190806* |
| Euro OTC | Methylcobalamin | 2002014 | 25135 | 40 | 20200401* |
| Euro OTC | Methylcobalamin | 2502009 | 27668 | 40 | 20250520* |
| Euro OTC | Methylcobalamin | 2502009 | 27668SI | 20 | 20250520* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 1135 spectra of 24 reference samples from the substance/substance group *Cyanocobalamin / Methylcobalamin*. These samples are listed above in the *calibration samples* section. The reference samples come from 17 different batches.
- 157 191 spectra from a total of 2940 batches from further 495 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 830 spectra of 21 reference samples from the substance/substance group *Cyanocobalamin / Methylcobalamin*.
- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Cyanocobalamin | 16015411 | 23761 | 40 |
| Caelo | Cyanocobalamin | 162215 | 23790 | 40 |
| Caelo | Cyanocobalamin | 21001468003 | 25976 | 40 |
| Caelo | Cyanocobalamin | 24000619 | 27560 | 40 |
| Euro OTC | Cyanocobalamin | 1907030 | 24965 | 40 |
| Euro OTC | Cyanocobalamin | 2109009 | 25868 | 50 |
| Euro OTC | Cyanocobalamin | 2206015 | 26272 | 40 |
| Euro OTC | Cyanocobalamin | 2411013 | 27616 | 40 |
| Fagron | Cyanocobalamin | 23H14-B07-230965 | 27022 | 40 |
| Euro OTC | Methylcobalamin | 1711031 | 23885 | 40 |
| Euro OTC | Methylcobalamin | 2006003 | 25412 | 40 |
| Euro OTC | Methylcobalamin | 2202009 | 26097 | 40 |
| Caelo | Cyanocobalamin | 13342807 | 21479SI† | 30 |
| Caelo | Cyanocobalamin | 21001468003 | 25976SI | 40 |
| Caelo | Cyanocobalamin | 24000619 | 27560SI | 40 |
| Euro OTC | Cyanocobalamin | 1907030 | 24965SI | 40 |
| Euro OTC | Cyanocobalamin | 2109009 | 25868SI | 50 |
| Euro OTC | Cyanocobalamin | 2206015 | 26272SI | 40 |
| Euro OTC | Cyanocobalamin | 2411013 | 27616SI | 40 |
| Fagron | Cyanocobalamin | 23H14-B07-230965 | 27022SI | 40 |
| Euro OTC | Methylcobalamin | 2202009 | 26097SI | 20 |

- 212 110 spectra from a total of 4274 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 39 spectra from 25 *Apo-Ident* customers from 33 batches from the substance/substance group *Cyanocobalamin / Methylcobalamin*.
- Among them are spectra of independent samples from 33 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cyanocobalamin | 19I20-B04-1955509 | 1 |
| | Cyanocobalamin | 20D06-B02-2016102 | 1 |
| Caelo | Cyanocobalamin | 16015405 | 1 |
| Caelo | Cyanocobalamin | 1604017-01 | 1 |
| Caelo | Cyanocobalamin | 18016001 | 1 |
| Caelo | Cyanocobalamin | 18016010 | 1 |
| Caelo | Cyanocobalamin | 19088601 | 1 |
| Caelo | Cyanocobalamin | 19I20-B04 | 1 |
| Caelo | Cyanocobalamin | 21001468003 | 1 |
| Caelo | Cyanocobalamin | 21001468005 | 1 |
| Caelo | Cyanocobalamin | 9324102 | 1 |
| Caelo | Cyanocobalamin | 9324113 | 1 |
| Caelo | Cyanocobalamin | 9351704 | 1 |
| Caelo | Cyanocobalamin | 9373503 | 2 |
| Caesar & Loretz GmbH... | Cyanocobalamin | 9324102 | 1 |
| Caesar & Loretz GmbH | Cyanocobalamin | 16221501 | 1 |
| EuRho | Cyanocobalamin | 1812011-01 | 1 |
| Euro OTC | Methylcobalamin | 1601043-02 | 1 |
| Euro OTC | Methylcobalamin | 1711031-01 | 1 |
| Euro OTC | Methylcobalamin | 1804006-01 | 1 |
| Euro OTC | Methylcobalamin | 1809001-01 | 1 |
| Euro OTC | Methylcobalamin | 2002014-01 | 1 |
| Euro OTC | Methylcobalamin | 2006003-01 | 3 |
| Euro OTC | Methylcobalamin | 2006003-02 | 1 |
| Euro OTC | Cyanocobalamin | 5061204 | 1 |
| Fagron | Cyanocobalamin | 10K02-N05 | 2 |
| Fagron | Cyanocobalamin | 10K02-N05 | 1 |
| Fagron | Cyanocobalamin | 13124-B01-292062 | 1 |
| Fagron | Cyanocobalamin | 15H31-B02-315113 | 1 |
| Fagron | Cyanocobalamin | 17A27-B04 | 1 |
| Fagron | Cyanocobalamin | 17A27-B04-339672 | 2 |
| Fagron | Cyanocobalamin | B04-3396702 | 1 |
| faron | Cyanocobalamin | 18/10-B01-357181 | 1 |
| Spinnrad/Phoenix | Cyanocobalamin | 1217331032 | 1 |

- 256 847 spectra from 1666 *Apo-Ident* customers from a total of 52 120 batches from a further 723 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cyanocobalamin / Methylcobalamin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cyanocobalamin / Methylcobalamin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 1135 | 0 | 157 191 |
| **Type B** | 0 | 830 | 0 | 212 110 |
| **Type C** | 0 | 38 | 1 | 256 847 |

The substance/substance group *Cyanocobalamin / Methylcobalamin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.4714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2771 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.4359 % (> 89.7436 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20743 | 20743 | 0.00 | 72.39 |
| 21299 | 21299 | 0.00 | 52.79 |
| 21479 | 21479 | 0.00 | 58.25 |
| 21635 | 21635 | 0.00 | 45.62 |
| 21721 | 21721 | 0.00 | 108.86 |
| 21867 | 21867 | 0.00 | 47.41 |
| 21872 | 21872 | 0.00 | 61.96 |
| 22234 | 22234 | 0.00 | 40.90 |
| 22239 | 22239 | 0.00 | 68.68 |
| 22379 | 22379 | 0.00 | 56.66 |
| 22441 | 22441 | 0.00 | 97.69 |
| 22536 | 22536 | 0.00 | 90.10 |
| 24072 | 24072 | 0.00 | 52.62 |
| 24311 | 24311 | 0.00 | 61.25 |
| 24465 | 24465 | 0.00 | 75.94 |
| 24775 | 24775 | 0.00 | 74.13 |
| 25135 | 25135 | 0.00 | 102.68 |
| 27668 | 27668 | 0.00 | 77.12 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cyproheptadine hydrochloride 1.5 hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24437-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cyproheptadine hydrochloride 1.5 hydrate; Cyproheptadini hydrochloridum-1,5-hydricum

### Special notes

When selecting the *Cyproheptadine hydrochloride 1.5 hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cyproheptadine hydrochloride 1.5 hydrate | 3 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 136.04 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Cyproheptadine hydrochlor… | 16K07-B01-350645 | 24437 | 40 | 1906179 |
| Fagron | Cyproheptadine hydrochlor… | 21H10-B06-219299 | 26634 | 40 | 20211207 |
| Fagron | Cyproheptadine hydrochlor… | 23G20-B01-231484 | 27027 | 40 | 20231025 |
| Fagron | Cyproheptadine hydrochlor… | 23G20-B01-231484 | 27027SI | 20 | 20231025 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 140 spectra of 4 reference samples from the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.
- 158 186 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by


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this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Cyproheptadine hydrochlor… | 20K20-B05-202444 | 26076 | 40 |
| Fagron | Cyproheptadine hydrochlor… | 20K20-B05-202444 | 26076SI | 20 |
| Fagron | Cyproheptadine hydrochlor… | 21H10-B06-219299 | 26634SI† | 20 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*Cyproheptadine hydrochloride 1.5 hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 140 | 0 | 158 186 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Cyproheptadine hydrochloride 1.5 hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.7143 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24437 | 24437 | 0.00 | 193.87 |
| 26634 | 24437 | 23.73 | 194.56 |
| 27027 | 24437 | 26.06 | 194.19 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cyproterone acetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20593-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cyproterone acetate; Cyproteroni acetas

### Special notes

When selecting the *Cyproterone acetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cyproterone acetate | 8 | 9 | 93 |

### Second-stage model

For differentiation of the substance/substance group *Cyproterone acetate* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cyproterone acetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prilocaine hydrochloride | 66.67 | – |
| ⋮ | ⋮ | ⋮ |
| Oxybutynin hydrochloride | >50 | 83.75 |
| Prednicarbate | >50 | 98.17 |
| Amitriptyline hydrochloride | >50 | 115.91 |
| Capsaicin | >50 | 158.12 |
| Levocarnitine | >50 | 164.33 |
| Tetracaine | >50 | 204.11 |
| Sodium citrate | >50 | 205.43 |
| Valine | >50 | 239.74 |
| Methoxsalen | >50 | 339.92 |
| Norethisterone acetate | >50 | 374.34 |
| Alfatradiol | >50 | 386.26 |
| Quinine hydrochloride dihydrate | >50 | 387.63 |
| Ciprofloxacin hydrochloride | >50 | 496.73 |
| Pyridoxal-5-phosphate hydrate | >50 | 498.18 |
| Heparin sodium | >50 | 637.71 |
| Triclosan | >50 | 1524.47 |
| Amifampridine | >50 | 2173.70 |
| Sucrose | >50 | 2352.85 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cyproterone acetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cyproterone acetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Cyproterone acetate | APCPA140201CP | 23988 | 40 | 20140617 |
| Audor Pharma | Cyproterone acetate | APX03-181002-m0C | 24814 | 40 | 20181213 |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Cyproterone acetate | 1611003 | 22875 | 40 | 20161201* |
| Euro OTC | Cyproterone acetate | 1810017 | 24317 | 40 | 20181108* |
| Fagron | Cyproterone acetate | 13C11-N02 | 21262 | 40 | 1501534 |
| Fagron | Cyproterone acetate | 13J16-No4 | 21985 | 75 | 1602654 |
| Fagron | Cyproterone acetate | 15I11-B01-322117 | 22665 | 40 | 20150921 |
| Fagron | Cyproterone acetate | 17D11-B07-333693 | 23238 | 40 | 20170501 |
| Fagron | Cyproterone acetate | 17D11-B07-333693 | 23238SI | 20 | 20170501 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 375 spectra of 9 reference samples from the substance/substance group *Cyproterone acetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 951 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 771 spectra of 24 reference samples from the substance/substance group *Cyproterone acetate*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Cyproterone acetate | 1903011 | 24609 | 40 |
| Euro OTC | Cyproterone acetate | 1910022 | 24957 | 40 |
| Euro OTC | Cyproterone acetate | 2003045 | 25270 | 40 |
| Euro OTC | Cyproterone acetate | 2101023 | 25532 | 40 |
| Euro OTC | Cyproterone acetate | 2205022 | 26192 | 40 |
| Euro OTC | Cyproterone acetate | 2409015 | 27405 | 40 |
| Fagron | Cyproterone acetate | 18G25-B02-352728 | 24289 | 40 |
| Fagron | Cyproterone acetate | 22I13-B01-228645 | 26826 | 40 |
| Fagron | Cyproterone acetate | 24A08-B08-235276 | 27178 | 40 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Audor Pharma | Cyproterone acetate | APCPA140201CP | 23988SI† | 20 |
| Audor Pharma | Cyproterone acetate | APX03-181002-m0C | 24814SI† | 40 |
| Euro OTC | Cyproterone acetate | 1611003 | 22875SI† | 30 |
| Euro OTC | Cyproterone acetate | 1810017 | 24317SI† | 20 |
| Euro OTC | Cyproterone acetate | 1903011 | 24609SI | 20 |
| Euro OTC | Cyproterone acetate | 1910022 | 24957SI | 22 |
| Euro OTC | Cyproterone acetate | 2003045 | 25270SI | 30 |
| Euro OTC | Cyproterone acetate | 2101023 | 25532SI | 31 |
| Euro OTC | Cyproterone acetate | 2205022 | 26192SI | 32 |
| Euro OTC | Cyproterone acetate | 2409015 | 27405SI | 30 |
| Fagron | Cyproterone acetate | 13J16-No4 | 21985SI† | 23 |
| Fagron | Cyproterone acetate | 15I11-B01-322117 | 22665SI† | 33 |
| Fagron | Cyproterone acetate | 18G25-B02-352728 | 24289SI | 20 |
| Fagron | Cyproterone acetate | 22I13-B01-228645 | 26826SI | 30 |
| Fagron | Cyproterone acetate | 24A08-B08-235276 | 27178SI | 30 |

- 212 169 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 153 spectra from 74 *Apo-Ident* customers from 97 batches from the substance/substance group *Cyproterone acetate*.
- Among them are spectra of independent samples from 93 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cyproterone acetate | 21L17-B02-219584 | 1 |
| | Cyproterone acetate | 21L17-B02-221829 | 1 |
| | Cyproterone acetate | 21L17-B02-219884 | 1 |
| | Cyproterone acetate | 2205022-01 | 2 |
| | Cyproterone acetate | 22I13-B01-226125 | 1 |
| | Cyproterone acetate | 2409015-01 | 2 |
| | Cyproterone acetate | 24A08-B08-235276 | 1 |
| | Cyproterone acetate | 24A08-B08-237510 | 2 |
| | Cyproterone acetate | EU-CPA201104M | 1 |
| | Cyproterone acetate | EU-CPA240201M2 | 1 |
| Anzag | Cyproterone acetate | 21L17-B02-221828 | 2 |
| Audor Pharma | Cyproterone acetate | APCPA140201CP | 2 |
| Audor Pharma | Cyproterone acetate | APX03-181002-m0C | 1 |
| Audor Pharma | Cyproterone acetate | cpa140201cp | 1 |
| Audor Pharma | Cyproterone acetate | X03-181002-m0C | 1 |
| Caelo | Cyproterone acetate | 13j16-n04 | 1 |
| Caelo | Cyproterone acetate | 17D11-B07-334581 | 3 |
| Caelo | Cyproterone acetate | 18G25-B02-352728 | 1 |
| Caelo | Cyproterone acetate | CPA150301 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Ebert-Jacobi | Cyproterone acetate | 16K09-B04-329036 | 1 |
| Euro OTC | Cyproterone acetate | 1502038-01 | 1 |
| Euro OTC | Cyproterone acetate | 2003045-01 | 5 |
| Euro OTC | Cyproterone acetate | 2101023-01 | 2 |
| Fagron | Cyproterone acetate | 11L22-N02 | 1 |
| Fagron | Cyproterone acetate | 12D02-N13 | 1 |
| Fagron | Cyproterone acetate | 12F25-N09 | 3 |
| Fagron | Cyproterone acetate | 12J24-N02 | 1 |
| Fagron | Cyproterone acetate | 12L19-N05 | 3 |
| Fagron | Cyproterone acetate | 13/09-N03 | 1 |
| Fagron | Cyproterone acetate | 13/16-N04 | 2 |
| Fagron | Cyproterone acetate | 13j16n04 | 1 |
| Fagron | Cyproterone acetate | 13J16-N04 | 2 |
| Fagron | Cyproterone acetate | 13j16-no4 | 1 |
| Fagron | Cyproterone acetate | 15H04-B06-311064 | 1 |
| Fagron | Cyproterone acetate | 15I11-B01-315381 | 2 |
| Fagron | Cyproterone acetate | 16K09-B04-329037 | 1 |
| Fagron | Cyproterone acetate | 17D11-B07 | 1 |
| Fagron | Cyproterone acetate | 17D11-B07-336729 | 2 |
| Fagron | Cyproterone acetate | 17D11-B07-338440 | 1 |
| Fagron | Cyproterone acetate | 18041805 | 1 |
| Fagron | Cyproterone acetate | 18B05_B05_346309 | 1 |
| Fagron | Cyproterone acetate | 18B05-346308 | 1 |
| Fagron | Cyproterone acetate | 18B05-B05-346307 | 1 |
| Fagron | Cyproterone acetate | 18B05-B05-346309 | 3 |
| Fagron | Cyproterone acetate | 18G25-B02 | 1 |
| Fagron | Cyproterone acetate | 18G25-B02-352307 | 2 |
| Fagron | Cyproterone acetate | 18G25-B02-352728 | 3 |
| Fagron | Cyproterone acetate | 18G25-B02-354474 | 1 |
| Fagron | Cyproterone acetate | 18G25-B02-354475 | 3 |
| Fagron | Cyproterone acetate | 18G25-B02-354476 | 1 |
| Fagron | Cyproterone acetate | 18G25-B02-355388 | 2 |
| Fagron | Cyproterone acetate | 18G25-B02-358855 | 3 |
| Fagron | Cyproterone acetate | 18G25-B02-358856 | 4 |
| Fagron | Cyproterone acetate | 18G25-B02-358857 | 1 |
| Fagron | Cyproterone acetate | 19A23-B04 | 2 |
| Fagron | Cyproterone acetate | 19A23-B04_363300 | 1 |
| Fagron | Cyproterone acetate | 19A23-B04-363299 | 1 |
| Fagron | Cyproterone acetate | 19a23-b04-363300 | 1 |
| Fagron | Cyproterone acetate | 19A23-B04-363300 | 2 |
| Fagron | Cyproterone acetate | 19A23-B04-363301 | 1 |
| Fagron | Cyproterone acetate | 19A23-B04-363302 | 1 |
| Fagron | Cyproterone acetate | 19A23B04367910 | 1 |
| Fagron | Cyproterone acetate | 19A23-B04367910 | 1 |
| Fagron | Cyproterone acetate | 19A23-B04-367910 | 3 |
| Fagron | Cyproterone acetate | 19A23-BO4-363301 | 1 |
| Fagron | Cyproterone acetate | 19A23-BO4-367910 | 1 |
| Fagron | Cyproterone acetate | 20101807 | 1 |
| Fagron | Cyproterone acetate | 20K11-F01 | 1 |
| Fagron | Cyproterone acetate | 20K11-F01-376805 | 1 |
| Fagron | Cyproterone acetate | 20K11-F01-376807 | 1 |
| Fagron | Cyproterone acetate | 20K11-FO1-376807 | 1 |
| Fagron | Cyproterone acetate | 21F22-B04-213628 | 4 |
| Fagron | Cyproterone acetate | 21J12-B02-215671 | 1 |
| Fagron | Cyproterone acetate | 21L17-B02 | 4 |
| Fagron | Cyproterone acetate | 21L17-B02-217596 | 1 |
| Fagron | Cyproterone acetate | 21L17-B02-217628 | 1 |
| Fagron | Cyproterone acetate | 21L17-B02-219230 | 2 |
| Fagron | Cyproterone acetate | 21117-B02-221829 | 1 |
| Fagron | Cyproterone acetate | 21L17-B02-221829 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Cyproterone acetate | 21L17-B02-CPA201108M | 1 |
| Fagron | Cyproterone acetate | 22113-B01-228645 | 1 |
| Fagron | Cyproterone acetate | 2212-B01-228645 | 1 |
| Fagron | Cyproterone acetate | 2213-B01-228645 | 1 |
| Fagron | Cyproterone acetate | 22I13-B01-228645 | 1 |
| Fagron | Cyproterone acetate | 22K11-F01-376807 | 1 |
| Fagron | Cyproterone acetate | 2OK11-F01-376805 | 1 |
| Fagron | Cyproterone acetate | 2OK11-FO1-376805 | 1 |
| Fagron | Cyproterone acetate | 8B11-N06 | 1 |
| Fagron | Cyproterone acetate | B02-3527209 | 1 |
| Fagron | Cyproterone acetate | B0392/110020 | 3 |
| Fagron | Cyproterone acetate | B04-3664709 | 1 |
| Fagron | Cyproterone acetate | EU-CPA-170301 | 1 |
| Fagron | Cyproterone acetate | EUCPA200901M | 1 |
| Fagron | Cyproterone acetate | EU-CPA200901M | 2 |
| Fagron | Cyproterone acetate | EU-CPA201108M | 3 |
| Fagron | Cyproterone acetate | EU-CPA230202M | 1 |
| Fargon/Noweda | Cyproterone acetate | 18G25-B02-352729 | 1 |
| Fargon/Noweda | Cyproterone acetate | 18G25-B02-354476 | 1 |
| Gehe | Cyproterone acetate | 21L17-B02-217596 | 1 |
| Gehe | Cyproterone acetate | 21L17-B02-221829 | 1 |
| Gehe | Cyproterone acetate | 22I13-B01-228645 | 1 |
| Sanacorp | Cyproterone acetate | 18B05-B05-346307 | 1 |
| Sanacorp | Cyproterone acetate | 23H14-B03-234180 | 1 |
| Sanacorp | Cyproterone acetate | 23H14-BO3-234180 | 1 |

- 256 733 spectra from 1666 *Apo-Ident* customers from a total of 52 056 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cyproterone acetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cyproterone acetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 375 | 0 | 157 951 |
| **Type B** | 0 | 771 | 0 | 212 169 |
| **Type C** | 0 | 153 | 0 | 256 733 |

The substance/substance group *Cyproterone acetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2218 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 96.0784 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21262 | 21262 | 0.00 | 111.49 |
| 21985 | 21985 | 0.00 | 112.44 |
| 22665 | 21985 | 2.71 | 116.77 |
| 22875 | 22875 | 0.00 | 114.10 |
| 23238 | 21985 | 3.67 | 111.25 |
| 23988 | 21985 | 2.51 | 111.32 |
| 24317 | 24317 | 0.00 | 112.43 |
| 24814 | 21985 | 3.94 | 114.39 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cysteine hydrochloride monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20530-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cysteine hydrochloride monohydrate; Cysteini hydrochloridum monohydricum

### Special notes

When selecting the *Cysteine hydrochloride monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cysteine hydrochloride monohydrate | 9 | 5 | 4 |

### Second-stage model

For differentiation of the substance/substance group *Cysteine hydrochloride monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cysteine hydrochloride monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 103.11 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cysteine hydrochloride monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cysteine hydrochloride monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Cysteine hydrochloride mo… | 1701012 | 23003 | 40 | 20170207* |
| Euro OTC | Cysteine hydrochloride mo… | 1706023 | 23548 | 40 | 20170721* |
| Euro OTC | Cysteine hydrochloride mo… | 1807010-01 | 24188 | 40 | 20180808 |
| Euro OTC | Cysteine hydrochloride mo… | 1901012 | 24482 | 40 | 20190206* |
| Euro OTC | Cysteine hydrochloride mo… | 2010020 | 25453 | 40 | 20201216* |
| Euro OTC | Cysteine hydrochloride mo… | 2205018 | 26186 | 40 | 20220613* |
| Euro OTC | Cysteine hydrochloride mo… | 2205018 | 26186SI | 20 | 20220613* |
| Euro OTC | Cysteine hydrochloride mo… | 2301029 | 26863 | 40 | 20230728* |
| Euro OTC | Cysteine hydrochloride mo… | 2301029 | 26863SI | 20 | 20230728* |
| Euro OTC | Cysteine hydrochloride mo… | 2407009 | 27402 | 40 | 20241105* |
| Euro OTC | Cysteine hydrochloride mo… | 2407009 | 27402SI | 20 | 20241105* |
| Fagron | Cysteine hydrochloride mo… | 22J13-B02 | 26447 | 40 | 20221207* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 420 spectra of 12 reference samples from the substance/substance group *Cysteine hydrochloride monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 906 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 5 reference samples from the substance/substance group *Cysteine hydrochloride monohydrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Cysteine hydrochloride mo… | 1304019-01 | 21325 | 40 |
| Euro OTC | Cysteine hydrochloride mo… | 1507006 | 21840 | 60 |
| Euro OTC | Cysteine hydrochloride mo… | 1510015 | 21941 | 60 |
| Euro OTC | Cysteine hydrochloride mo… | 1603018 | 22516 | 40 |
| Euro OTC | Cysteine hydrochloride mo… | 2411018 | 27505 | 40 |

- 212 700 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 8 spectra from 4 *Apo-Ident* customers from 5 batches from the substance/substance group *Cysteine hydrochloride monohydrate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Cysteine hydrochloride mo… | 1304019-01 | 1 |
| Euro OTC | Cysteine hydrochloride mo… | 1807010-01 | 3 |
| Euro OTC | Cysteine hydrochloride mo… | 180710-01 | 1 |
| Euro OTC | Cysteine hydrochloride mo… | 1901012-01 | 1 |
| Euro OTC | Cysteine hydrochloride mo… | 2010020-01 | 2 |

- 256 878 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cysteine hydrochloride monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cysteine hydrochloride monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 8 | 0 | 256 878 |

The substance/substance group *Cysteine hydrochloride monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23003 | 23003 | 0.00 | 200.27 |
| 23548 | 23548 | 0.00 | 201.93 |

*continued on the next page*


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*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24188 | 24482 | 7.84 | 200.27 |
| 24482 | 24482 | 0.00 | 204.25 |
| 25453 | 25453 | 0.00 | 198.97 |
| 26186 | 26186 | 0.00 | 200.95 |
| 26447 | 26447 | 0.00 | 208.12 |
| 26863 | 26863 | 0.00 | 204.53 |
| 27402 | 27402 | 0.00 | 208.27 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Cystine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20515-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Cystine; Cystinum

### Special notes

When selecting the *Cystine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Cystine | 8 | 5 | 18 |

### Second-stage model

For differentiation of the substance/substance group *Cystine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Cystine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Lysine hydrochloride | 89.18 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Cystine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Cystine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Cystine | 1307052-01 | 21328 | 40 | 20130918 |
| Euro OTC | Cystine | 1408016-01 | 21715 | 60 | 20140911 |
| Euro OTC | Cystine | 1603010 | 22523 | 40 | 20160406* |
| Euro OTC | Cystine | 1610013 | 22863 | 40 | 20161110* |
| Euro OTC | Cystine | 1801016 | 23879 | 40 | 20180126* |
| Euro OTC | Cystine | 2009038 | 25411 | 40 | 20201020* |
| Euro OTC | Cystine | 2305001 | 26876 | 40 | 20230802* |
| Fagron | Cystine | 15F08-B05-310685 | 23767 | 40 | 20150616 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 340 spectra of 8 reference samples from the substance/substance group *Cystine*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 157 986 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 230 spectra of 7 reference samples from the substance/substance group *Cystine*.
- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Cystine | 1811005 | 24332 | 40 |
| Euro OTC | Cystine | 1904022 | 24617 | 40 |
| Euro OTC | Cystine | 1910028 | 24933 | 40 |
| Euro OTC | Cystine | 2202004 | 26036 | 40 |
| Euro OTC | Cystine | 2207020 | 26435 | 40 |
| Euro OTC | Cystine | 2202004 | 26036SI | 10 |
| Euro OTC | Cystine | 2305001 | 26876SI† | 20 |

- 212 710 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 37 spectra from 9 *Apo-Ident* customers from 19 batches from the substance/substance group *Cystine*.
- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cystine | 2207020-01 | 2 |
| | Cystine | 2305001-01 | 2 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cystine | 2305001-02 | 1 |
| Caelo | Cystine | 190402201 | 1 |
| Euro OTC | Cystine | 1204090 | 1 |
| Euro OTC | Cystine | 1207013-01 | 2 |
| Euro OTC | Cystine | 1801016-01 | 3 |
| Euro OTC | Cystine | 1811005-01 | 2 |
| Euro OTC | Cystine | 1904022-01 | 1 |
| Euro OTC | Cystine | 1910028-01 | 1 |
| Euro OTC | Cystine | 2009038-01 | 4 |
| Euro OTC | Cystine | 2009038-02 | 3 |
| Euro OTC | Cystine | 2081301 | 1 |
| Euro OTC | Cystine | 2202004-01 | 3 |
| Euro OTC | Cystine | 26081408 | 1 |
| Euro OTC | Cystine | 30041809 | 1 |
| Euro OTC | Cystine | 3021502 | 1 |
| Fagron | Cystine | 12D26-B04-285823 | 2 |
| Fagron | Cystine | 15F08-B05-310685 | 1 |
| Fagron | Cystine | 1904022-01 | 1 |
| Fagron | Cystine | 1910028-01 | 3 |

- 256 849 spectra from 1666 *Apo-Ident* customers from a total of 52 135 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Cystine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Cystine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 340 | 0 | 157 986 |
| **Type B** | 0 | 230 | 0 | 212 710 |
| **Type C** | 0 | 37 | 0 | 256 849 |

The substance/substance group *Cystine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2353 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.3913 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 83.7838 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21328 | 23879 | 5.87 | 150.70 |
| 21715 | 22523 | 5.16 | 149.25 |
| 22523 | 22523 | 0.00 | 151.92 |
| 22863 | 22863 | 0.00 | 155.47 |
| 23767 | 23879 | 12.20 | 154.29 |
| 23879 | 23879 | 0.00 | 154.51 |
| 25411 | 25411 | 0.00 | 148.61 |
| 26876 | 26876 | 0.00 | 168.60 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Dequalinium chloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20350-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Dequalinium chloride; Dequalinii chloridum

### Special notes

When selecting the *Dequalinium chloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Dequalinium chloride | 13 | 8 | 141 |

### Second-stage model

For differentiation of the substance/substance group *Dequalinium chloride* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Dequalinium chloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 72.37 | – |
| ⋮ | ⋮ | ⋮ |
| Dithranol | >50 | 59.83 |
| Eosin Y | >50 | 96.32 |
| Oxytetracycline hydrochloride | >50 | 133.02 |
| Sodium salicylate | >50 | 143.24 |
| Levothyroxin sodium | >50 | 184.62 |
| Tannin | >50 | 252.26 |
| Acetylsalicylic acid | >50 | 255.42 |
| Benzoic acid | >50 | 433.75 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Dequalinium chloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Dequalinium chloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Dequalinium chloride | 12361908 | 21296 | 40 | 1412076 |
| Caelo | Dequalinium chloride | 12361906 | 21387 | 60 | 20121228 |
| Caelo | Dequalinium chloride | 15218406 | 22953 | 40 | 20150622 |
| Caelo | Dequalinium chloride | 15402803 | 23121 | 40 | 1707614 |
| Caelo | Dequalinium chloride | 154028 | 23362 | 40 | 20160219* |
| Caelo | Dequalinium chloride | 154028 | 24403 | 40 | 20160219* |
| Caelo | Dequalinium chloride | 191314 | 25205 | 40 | 20190626* |
| Euro OTC | Dequalinium chloride | 1405012-01 | 21617 | 60 | 20140623 |
| Euro OTC | Dequalinium chloride | 1512032 | 22295 | 60 | 20160121* |
| Euro OTC | Dequalinium chloride | 1512032-02 | 24142 | 40 | 1809202 |
| Euro OTC | Dequalinium chloride | 2003008 | 25156 | 40 | 20200528* |
| Euro OTC | Dequalinium chloride | 2103018 | 25687 | 40 | 20210421* |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Dequalinium chloride | 13I26-N10 | 21269 | 40 | 20130121 |
| Fagron | Dequalinium chloride | 15B16-B04-332113 | 23266 | 40 | 20150226 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 620 spectra of 14 reference samples from the substance/substance group *Dequalinium chloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 13 different batches.

- 157 706 spectra from a total of 2944 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 540 spectra of 13 reference samples from the substance/substance group *Dequalinium chloride*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Dequalinium chloride | 180794 | 24011 | 40 |
| Caelo | Dequalinium chloride | 22001564 | 26243 | 40 |
| Caelo | Dequalinium chloride | 24001318 | 27314 | 40 |
| Euro OTC | Dequalinium chloride | 1804009 | 24082 | 40 |
| Euro OTC | Dequalinium chloride | 2310016 | 27194 | 40 |
| Euro OTC | Dequalinium chloride | 2501010 | 27490 | 40 |
| Fagron | Dequalinium chloride | 11D29-N11 | 20660 | 80 |
| Fagron | Dequalinium chloride | 19J16-B08-197304 | 25177 | 40 |
| Caelo | Dequalinium chloride | 12361906 | 21386 | 60 |
| Caelo | Dequalinium chloride | 12361906 | 21387† | 60 |
| Caelo | Dequalinium chloride | 22001564 | 26243SI | 20 |
| Caelo | Dequalinium chloride | 24001318 | 27314SI | 20 |
| Euro OTC | Dequalinium chloride | 2310016 | 27194SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 400 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 538 spectra from 326 *Apo-Ident* customers from 150 batches from the substance/substance group *Dequalinium chloride*.

- Among them are spectra of independent samples from 136 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Dequalinium chloride | 1512032-01 | 1 |
| | Dequalinium chloride | 20003344009 | 1 |
| | Dequalinium chloride | 20003344010 | 2 |
| | Dequalinium chloride | 2103018-01 | 5 |
| | Dequalinium chloride | 22001564003 | 2 |
| | Dequalinium chloride | 22001564004 | 3 |
| | Dequalinium chloride | 22001564008 | 3 |
| | Dequalinium chloride | 22001564013 | 1 |
| | Dequalinium chloride | 2310016-01 | 1 |
| | Dequalinium chloride | 24001318002 | 1 |
| AHD | Dequalinium chloride | 15218401 | 1 |
| AHD | Dequalinium chloride | 1804009-02 | 1 |
| Alliance H. | Dequalinium chloride | 1512032-01 | 1 |
| Alliance Health | Dequalinium chloride | 12077508 | 1 |
| Alliance Healthcare | Dequalinium chloride | 19131402 | 1 |
| Alliance Healthcare | Dequalinium chloride | 2003008-01 | 1 |
| Allianz Healthcare | Dequalinium chloride | 1512032-01 | 1 |
| Anzag ek:7.89EUR | Dequalinium chloride | 11166204 | 1 |
| Anzag | Dequalinium chloride | 15B16-B04-340177 | 1 |
| Anzag | Dequalinium chloride | 230417(2103018-01) | 1 |
| Anzag | Dequalinium chloride | 250410(2310016-01) | 1 |
| apomix | Dequalinium chloride | 1804009-01 | 1 |
| Caelo | Dequalinium chloride | | 1 |
| Caelo | Dequalinium chloride | 10879409 | 1 |
| Caelo | Dequalinium chloride | 11166203 | 1 |
| Caelo | Dequalinium chloride | 11166204 | 2 |
| Caelo | Dequalinium chloride | 11166209 | 1 |
| Caelo | Dequalinium chloride | 12077508 | 2 |
| Caelo | Dequalinium chloride | 12077510 | 7 |
| Caelo | Dequalinium chloride | 1210008-03 | 1 |
| Caelo | Dequalinium chloride | 12361906 | 3 |
| Caelo | Dequalinium chloride | 12361908 | 2 |
| Caelo | Dequalinium chloride | 12361911 | 3 |
| Caelo | Dequalinium chloride | 12G05-N07 | 1 |
| Caelo | Dequalinium chloride | 13/26-N10 | 1 |
| Caelo | Dequalinium chloride | 13348805 | 2 |
| Caelo | Dequalinium chloride | 13A23-N02 | 2 |
| Caelo | Dequalinium chloride | 1405012-02 | 1 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dequalinium chloride | 14072901 | 1 |
| Caelo | Dequalinium chloride | 14C10-B03 | 1 |
| Caelo | Dequalinium chloride | 151203202 | 1 |
| Caelo | Dequalinium chloride | 1512032-02 | 3 |
| Caelo | Dequalinium chloride | 152184 | 1 |
| Caelo | Dequalinium chloride | 15218401 | 7 |
| Caelo | Dequalinium chloride | 15218402 | 1 |
| Caelo | Dequalinium chloride | 15218404 | 2 |
| Caelo | Dequalinium chloride | 15218406 | 6 |
| Caelo | Dequalinium chloride | 15218407 | 1 |
| Caelo | Dequalinium chloride | 15218410 | 1 |
| Caelo | Dequalinium chloride | 15402801 | 3 |
| Caelo | Dequalinium chloride | 15402803 | 4 |
| Caelo | Dequalinium chloride | 15402805 | 2 |
| Caelo | Dequalinium chloride | 15402806 | 2 |
| Caelo | Dequalinium chloride | 15402807 | 2 |
| Caelo | Dequalinium chloride | 15B16-B04 | 1 |
| Caelo | Dequalinium chloride | 15B16-B04-326872 | 1 |
| Caelo | Dequalinium chloride | 15B16-B04-337594 | 1 |
| Caelo | Dequalinium chloride | 15B16-B04-342302 | 1 |
| Caelo | Dequalinium chloride | 18015801 | 2 |
| Caelo | Dequalinium chloride | 18015802 | 2 |
| Caelo | Dequalinium chloride | 1804009-03 | 2 |
| Caelo | Dequalinium chloride | 18079402 | 1 |
| Caelo | Dequalinium chloride | 18079403 | 6 |
| Caelo | Dequalinium chloride | 18079404 | 3 |
| Caelo | Dequalinium chloride | 18079405 | 1 |
| Caelo | Dequalinium chloride | 18079407 | 3 |
| Caelo | Dequalinium chloride | 18079408 | 1 |
| Caelo | Dequalinium chloride | 18079410 | 1 |
| Caelo | Dequalinium chloride | 18079411 | 3 |
| Caelo | Dequalinium chloride | 191314003 | 8 |
| Caelo | Dequalinium chloride | 191314004 | 6 |
| Caelo | Dequalinium chloride | 191314005 | 1 |
| Caelo | Dequalinium chloride | 191314006 | 2 |
| Caelo | Dequalinium chloride | 19131402 | 12 |
| Caelo | Dequalinium chloride | 20003344004 | 7 |
| Caelo | Dequalinium chloride | 20003344006 | 1 |
| Caelo | Dequalinium chloride | 20003344007 | 3 |
| Caelo | Dequalinium chloride | 20003344009 | 2 |
| Caelo | Dequalinium chloride | 20003344012 | 3 |
| Caelo | Dequalinium chloride | 2000334404 | 1 |
| Caelo | Dequalinium chloride | 2003008-01 | 2 |
| Caelo | Dequalinium chloride | 215I-01325 | 1 |
| Caelo | Dequalinium chloride | 22001564002 | 1 |
| Caelo | Dequalinium chloride | 220812K2 | 1 |
| Caelo | Dequalinium chloride | 3613A-01325 | 1 |
| Caelo | Dequalinium chloride | 5315I-01325 | 1 |
| Caesar & Loretz GmbH... | Dequalinium chloride | 18079411 | 1 |
| Caesar & Loretz GmbH... | Dequalinium chloride | 191314007 | 1 |
| Caesar & Loretz GmbH... | Dequalinium chloride | 191314007 | 1 |
| Caesar & Loretz GmbH... | Dequalinium chloride | 20003344012 | 1 |
| Caesar & Loretz GmbH... | Dequalinium chloride | 20003344003 | 1 |
| Caesar & Loretz GmbH... | Dequalinium chloride | 20003344007 | 1 |
| Caesar & Loretz GmbH | Dequalinium chloride | 18079404 | 2 |
| Caesar & Loretz GmbH | Dequalinium chloride | 18079410 | 1 |
| Caesar & Loretz GmbH | Dequalinium chloride | 18079411 | 1 |
| Caesar & Loretz GmbH | Dequalinium chloride | 191314003 | 3 |
| Caesar & Loretz GmbH | Dequalinium chloride | 191314004 | 1 |
| Caesar & Loretz GmbH | Dequalinium chloride | 191314006 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Dequalinium chloride | 191314007 | 3 |
| Caesar & Loretz GmbH | Dequalinium chloride | 19131402 | 5 |
| Caesar & Loretz GmbH | Dequalinium chloride | 20003344004 | 2 |
| Caesar & Loretz GmbH | Dequalinium chloride | 210008690091 | 1 |
| Caesar & Loretz GmbH | Dequalinium chloride | 22001564002 | 1 |
| Cealo / Anzag | Dequalinium chloride | 230221(2103018-01) | 1 |
| Cealo, GEHE | Dequalinium chloride | 2003008-01 | 1 |
| Eurho Sanacorp | Dequalinium chloride | 2003008-01 | 1 |
| EuRho/ Anzag | Dequalinium chloride | 220627(2103018-01) | 1 |
| EuRho/ Anzag | Dequalinium chloride | 80(1804009-01) | 1 |
| Eurho/Jenne | Dequalinium chloride | 1407020-01 | 1 |
| EuRho/Phoenix | Dequalinium chloride | 2103018-01 | 1 |
| EuRho | Dequalinium chloride | 1110002-01 | 1 |
| EuRho | Dequalinium chloride | 2003008-01 | 1 |
| Euro OTC | Dequalinium chloride | | 3 |
| Euro OTC | Dequalinium chloride | 1010022-01 | 2 |
| Euro OTC | Dequalinium chloride | 1103045-01 | 1 |
| Euro OTC | Dequalinium chloride | 11091701 | 1 |
| Euro OTC | Dequalinium chloride | 1110002-01 | 2 |
| Euro OTC | Dequalinium chloride | 1210008-01 | 2 |
| Euro OTC | Dequalinium chloride | 1210008-02 | 2 |
| Euro OTC | Dequalinium chloride | 1210008-03 | 2 |
| Euro OTC | Dequalinium chloride | 1405012-01 | 5 |
| Euro OTC | Dequalinium chloride | 1405012-02 | 6 |
| Euro OTC | Dequalinium chloride | 1407029-01 | 7 |
| Euro OTC | Dequalinium chloride | 1407029-02 | 6 |
| Euro OTC | Dequalinium chloride | 15061204 | 1 |
| Euro OTC | Dequalinium chloride | 1512031-01 | 1 |
| Euro OTC | Dequalinium chloride | 151203201 | 1 |
| Euro OTC | Dequalinium chloride | 1512032-01 | 21 |
| Euro OTC | Dequalinium chloride | 1512032-02 | 14 |
| Euro OTC | Dequalinium chloride | 180400901 | 1 |
| Euro OTC | Dequalinium chloride | 1804009-01 | 22 |
| Euro OTC | Dequalinium chloride | 1804009-02 | 4 |
| Euro OTC | Dequalinium chloride | 1804009-03 | 22 |
| Euro OTC | Dequalinium chloride | 18040092-02 | 1 |
| Euro OTC | Dequalinium chloride | 18044009-01 | 1 |
| Euro OTC | Dequalinium chloride | 2000300801 | 1 |
| Euro OTC | Dequalinium chloride | 20030008-01 | 1 |
| Euro OTC | Dequalinium chloride | 2003008-01 | 26 |
| Euro OTC | Dequalinium chloride | 2103018-01 | 24 |
| Euro OTC | Dequalinium chloride | 210318-01 | 1 |
| Euro OTC | Dequalinium chloride | 211118(2003008) | 1 |
| Euro OTC | Dequalinium chloride | 220809(2103018-01) | 1 |
| Euro OTC | Dequalinium chloride | 804009-021 | 1 |
| Euro OTC | Dequalinium chloride | 81(1804009-01) | 1 |
| Euro OTC | Dequalinium chloride | 82(1804009-01 | 1 |
| Euro OTC | Dequalinium chloride | 83(1804009-03) | 1 |
| Euro OTC | Dequalinium chloride | EuroOTC | 1 |
| Euro/Sanacorp | Dequalinium chloride | 1407029-02 | 1 |
| Euro/Sanacorp | Dequalinium chloride | 1512032-01 | 2 |
| Euro/Sanacorp | Dequalinium chloride | 1512032-02 | 1 |
| Euro/Spangro | Dequalinium chloride | 1512032-02 | 1 |
| Fa.Phönix | Dequalinium chloride | 11166204 | 1 |
| Fag / Noweda | Dequalinium chloride | 15B16-B04-321326 | 1 |
| Fagron | Dequalinium chloride | | 5 |
| Fagron | Dequalinium chloride | 10H05-N07 | 1 |
| Fagron | Dequalinium chloride | 12B14-N01 | 1 |
| Fagron | Dequalinium chloride | 12D05-N09 | 1 |
| Fagron | Dequalinium chloride | 12G05-N07 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Dequalinium chloride | 13A23-N02 | 3 |
| Fagron | Dequalinium chloride | 13D26-N06 | 3 |
| Fagron | Dequalinium chloride | 13I26-N10 | 1 |
| Fagron | Dequalinium chloride | 1407029-01 | 2 |
| Fagron | Dequalinium chloride | 14C10-B03 | 1 |
| Fagron | Dequalinium chloride | 14C10B03292286 | 1 |
| Fagron | Dequalinium chloride | 14C10-B03-292286 | 4 |
| Fagron | Dequalinium chloride | 15B16-B04 | 2 |
| Fagron | Dequalinium chloride | 15B16B04304432 | 1 |
| Fagron | Dequalinium chloride | 15B16-B04-304432 | 2 |
| Fagron | Dequalinium chloride | 15B16-B04-316267 | 4 |
| Fagron | Dequalinium chloride | 15B16B04321326 | 1 |
| Fagron | Dequalinium chloride | 15B16-B04-321326 | 1 |
| Fagron | Dequalinium chloride | 15B16-B04-326872 | 2 |
| Fagron | Dequalinium chloride | 15B16-B04-332113 | 3 |
| Fagron | Dequalinium chloride | 15B16B04337594 | 1 |
| Fagron | Dequalinium chloride | 15B16-B04-340177 | 1 |
| Fagron | Dequalinium chloride | 15B16-B04-342302 | 2 |
| Fagron | Dequalinium chloride | 15B16-B04-346969 | 4 |
| Fagron | Dequalinium chloride | 15B16-B04-352989 | 2 |
| Fagron | Dequalinium chloride | 15B16-B04-354618 | 2 |
| Fagron | Dequalinium chloride | 18B16-B04-356149 | 1 |
| Fagron | Dequalinium chloride | 19J16-B08 | 4 |
| Fagron | Dequalinium chloride | 19J16B08197304 | 2 |
| Fagron | Dequalinium chloride | 19J16-B08-197304 | 8 |
| Fagron | Dequalinium chloride | 19JI-B08-197304 | 1 |
| Fagron | Dequalinium chloride | 20F19-B03-201436 | 6 |
| Fagron | Dequalinium chloride | 20I18-B01-202442 | 2 |
| Fagron | Dequalinium chloride | B03_2014306 | 1 |
| Fagron | Dequalinium chloride | B03-2014306 | 4 |
| Fiebig | Dequalinium chloride | 2003008-01 | 1 |
| Gatt-Koller | Dequalinium chloride | 1800212 | 1 |
| GEHE/ EuRho | Dequalinium chloride | 2103018-01 | 1 |
| Gehe/EuRho | Dequalinium chloride | 9245-90125 | 1 |
| Gehe | Dequalinium chloride | 1512032-01 | 1 |
| GEHE | Dequalinium chloride | 1804009-01 | 1 |
| Gehe | Dequalinium chloride | 22001564004 | 1 |
| Gehe | Dequalinium chloride | 240212(2103018-01) | 1 |
| GUMO | Dequalinium chloride | 191314003 | 1 |
| Jenne | Dequalinium chloride | 230503(2103018-01) | 1 |
| Jenne | Dequalinium chloride | 2310016-01 | 1 |
| Klosterring | Dequalinium chloride | 15B16-B04-321326 | 1 |
| L30 | Dequalinium chloride | 1804009-01 | 1 |
| Lamotte/Spangroh | Dequalinium chloride | 15218404 | 1 |
| Lebsa/AHD | Dequalinium chloride | 1405012-01 | 1 |
| LEBSA/Phoenix | Dequalinium chloride | 1210008-03 | 1 |
| LEBSA | Dequalinium chloride | | 1 |
| Lebsa | Dequalinium chloride | 2003008-01 | 2 |
| Nachprüfung | Dequalinium chloride | 2082019-10 | 1 |
| Noweda/Schönbuch | Dequalinium chloride | 24001318001 | 1 |
| Noweda | Dequalinium chloride | 12b14-n05 | 1 |
| Noweda | Dequalinium chloride | 2103018-01 | 1 |
| Ph.Euro/Noweda | Dequalinium chloride | 2103018-01 | 1 |
| Phoenix | Dequalinium chloride | 191314006 | 1 |
| Phönix/EuRo | Dequalinium chloride | 2003008-01 | 1 |
| Phönix/Fagon | Dequalinium chloride | 15B16-B04-316267 | 1 |
| Phönix | Dequalinium chloride | 10127-N02Retest | 1 |
| Phönix | Dequalinium chloride | 1110002-01 | 1 |
| Phönix | Dequalinium chloride | 13D26-N06 | 1 |
| Phönix | Dequalinium chloride | 151203201 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Dequalinium chloride | 1804009-01 | 1 |
| phönix | Dequalinium chloride | 2103018-01 | 1 |
| Raben-Apotheke Mildenau | Dequalinium chloride | 1405012-01 | 1 |
| S.Binder | Dequalinium chloride | 1210008-04 | 1 |
| Sanacorp | Dequalinium chloride | 18079407 | 2 |
| Sanacorp | Dequalinium chloride | 19131402 | 1 |
| Sanacorp | Dequalinium chloride | 2103018-01 | 1 |
| Th. Geyer | Dequalinium chloride | 15B16-B04-354618 | 1 |
| Wepa Apothekenbedarf | Dequalinium chloride | 151203202 | 1 |

- 256 348 spectra from 1666 *Apo-Ident* customers from a total of 52 005 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Dequalinium chloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Dequalinium chloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 620 | 0 | 157 706 |
| **Type B** | 0 | 540 | 0 | 212 400 |
| **Type C** | 0 | 537 | 1 | 256 348 |

The substance/substance group *Dequalinium chloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0323 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8889 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8141 % (> 99.2565 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21269 | 21296 | 51.14 | 149.95 |
| 21296 | 21296 | 0.00 | 171.43 |
| 21387 | 21296 | 13.82 | 175.52 |
| 21617 | 21296 | 28.49 | 191.19 |
| 22295 | 22295 | 0.00 | 203.38 |
| 22953 | 21296 | 38.94 | 153.30 |
| 23121 | 23121 | 0.00 | 267.85 |
| 23266 | 23362 | 41.13 | 233.37 |
| 23362 | 23362 | 0.00 | 213.81 |
| 24142 | 24142 | 0.00 | 145.68 |
| 24403 | 24403 | 0.00 | 164.30 |
| 25156 | 25156 | 0.00 | 257.75 |
| 25205 | 25205 | 0.00 | 153.40 |
| 25687 | 25687 | 0.00 | 245.96 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Dexamethasone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20009-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Dexamethasone; Dexamethasonum

### Special notes

When selecting the *Dexamethasone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Dexamethasone | 10 | 17 | 409 |

### Second-stage model

For differentiation of the substance/substance group *Dexamethasone* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Dexamethasone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 67.66 | – |
| ⋮ | ⋮ | ⋮ |
| Betamethasone | >50 | 34.36 |
| Prednisolone | >50 | 39.87 |
| Fluocinolone acetonide | >50 | 51.18 |
| Triamcinolone acetonide | >50 | 57.26 |
| Methylprednisolone | >50 | 68.95 |
| Tyrothricin | >50 | 135.68 |
| Gramicidin | >50 | 184.52 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Dexamethasone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Dexamethasone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Dexamethasone | 13084315 | 21403 | 60 | AR-15-FG-006810-01 |
| Caelo | Dexamethasone | 15054627 | 23169 | 40 | 20150420 |
| Caelo | Dexamethasone | 190221 | 24504 | 40 | 20190214* |
| Caelo | Dexamethasone | 190221 | 24504SI | 40 | 20190214* |
| Caelo | Dexamethasone | 23002226 | 26967 | 40 | 20230922* |
| Euro OTC | Dexamethasone | 1303007-01 | 21289 | 40 | 1407432 |
| Euro OTC | Dexamethasone | 1303007-01 | 21850 | 60 | 20130328 |
| Euro OTC | Dexamethasone | 1601052 | 22364 | 45 | 20160225* |
| Euro OTC | Dexamethasone | 1601052 | 22364SI | 45 | 20160225* |
| Euro OTC | Dexamethasone | 1611001 | 22914 | 40 | 20161212* |
| Euro OTC | Dexamethasone | 1611001 | 22914SI | 37 | 20161212* |
| Euro OTC | Dexamethasone | 2005024 | 25301 | 40 | 20200824* |
| Fagron | Dexamethasone | 16F02-B05-324844 | 23168 | 40 | 20160711 |
| Fagron | Dexamethasone | 19A24-B01-361445 | 24705 | 40 | 20190403 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 607 spectra of 14 reference samples from the substance/substance group *Dexamethasone*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.
- 157 719 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1518 spectra of 38 reference samples from the substance/substance group *Dexamethasone*.
- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Dexamethasone | 13084306 | 21062 | 60 |
| Caelo | Dexamethasone | 171042 | 23331 | 40 |
| Caelo | Dexamethasone | 172856 | 23841 | 40 |
| Caelo | Dexamethasone | 190865 | 24742 | 40 |
| Caelo | Dexamethasone | 20002251 | 25633 | 40 |
| Caelo | Dexamethasone | 21001380 | 25795 | 40 |
| Caelo | Dexamethasone | 22000049 | 25996 | 40 |
| Caelo | Dexamethasone | 22002762 | 26476 | 40 |
| Euro OTC | Dexamethasone | 1209008-02 | 21078 | 60 |
| Euro OTC | Dexamethasone | 1708004 | 23692 | 40 |
| Euro OTC | Dexamethasone | 1806023 | 24136 | 40 |
| Euro OTC | Dexamethasone | 1909011 | 24839 | 40 |
| Euro OTC | Dexamethasone | 1708004-02 | 24867 | 40 |
| Euro OTC | Dexamethasone | 2109019 | 25874 | 50 |
| Euro OTC | Dexamethasone | 2208005 | 26264 | 40 |
| Fagron | Dexamethasone | 19A24-B01-359626 | 24573 | 40 |
| Fagron | Dexamethasone | 22A17-B06-218167 | 26074 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Dexamethasone | 15054627 | 23169SI† | 20 |
| Caelo | Dexamethasone | 171042 | 23331SI | 24 |
| Caelo | Dexamethasone | 172856 | 23841SI | 40 |
| Caelo | Dexamethasone | 190865 | 24742SI | 40 |
| Caelo | Dexamethasone | 20002251 | 25633SI | 40 |
| Caelo | Dexamethasone | 21001380 | 25795SI | 40 |
| Caelo | Dexamethasone | 22000049 | 25996SI | 40 |
| Caelo | Dexamethasone | 22002762 | 26476SI | 40 |
| Caelo | Dexamethasone | 23002226 | 26967SI† | 40 |
| Euro OTC | Dexamethasone | 1303007-01 | 21850SI† | 45 |
| Euro OTC | Dexamethasone | 1708004 | 23692SI | 26 |
| Euro OTC | Dexamethasone | 1806023 | 24136SI | 33 |
| Euro OTC | Dexamethasone | 1909011 | 24839SI | 40 |
| Euro OTC | Dexamethasone | 1708004-02 | 24867SI | 40 |
| Euro OTC | Dexamethasone | 2005024 | 25301SI† | 40 |
| Euro OTC | Dexamethasone | 2109019 | 25874SI | 50 |
| Euro OTC | Dexamethasone | 2208005 | 26264SI | 40 |
| Fagron | Dexamethasone | 16F02-B05-324844 | 23168SI† | 30 |
| Fagron | Dexamethasone | 19A24-B01-359626 | 24573SI | 40 |
| Fagron | Dexamethasone | 19A24-B01-361445 | 24705SI† | 40 |
| Fagron | Dexamethasone | 22A17-B06-218167 | 26074SI | 40 |

- 211 422 spectra from a total of 4264 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3184 spectra from 1046 *Apo-Ident* customers from 422 batches from the substance/substance group *Dexamethasone*.

- Among them are spectra of independent samples from 407 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Dexamethasone | 15054628 | 1 |
| | Dexamethasone | 156547896 | 1 |
| | Dexamethasone | 19086503 | 1 |
| | Dexamethasone | 2005024-03 | 1 |
| | Dexamethasone | 2109019 | 1 |
| | Dexamethasone | 2109019-01 | 3 |
| | Dexamethasone | 2109019-03 | 19 |
| | Dexamethasone | 22000049004 | 2 |
| | Dexamethasone | 22000049005 | 4 |
| | Dexamethasone | 22000049009 | 2 |
| | Dexamethasone | 22000049011 | 2 |
| | Dexamethasone | 220002762015 | 1 |
| | Dexamethasone | 220002762016 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Dexamethasone | 2200043005 | 1 |
| | Dexamethasone | 2200276005 | 1 |
| | Dexamethasone | 22002762003 | 9 |
| | Dexamethasone | 22002762004 | 3 |
| | Dexamethasone | 22002762005 | 2 |
| | Dexamethasone | 22002762008 | 14 |
| | Dexamethasone | 22002762009 | 8 |
| | Dexamethasone | 22002762010 | 7 |
| | Dexamethasone | 22002762011 | 2 |
| | Dexamethasone | 22002762014 | 3 |
| | Dexamethasone | 22002762015 | 17 |
| | Dexamethasone | 22002762016 | 22 |
| | Dexamethasone | 22002762017 | 16 |
| | Dexamethasone | 22002762019 | 2 |
| | Dexamethasone | 2202762005 | 1 |
| | Dexamethasone | 2202762015 | 1 |
| | Dexamethasone | 2202762017 | 2 |
| | Dexamethasone | 2208005 | 1 |
| | Dexamethasone | 220800501 | 1 |
| | Dexamethasone | 2208005-01 | 23 |
| | Dexamethasone | 2208005-02 | 9 |
| | Dexamethasone | 2208005-0262/24P | 1 |
| | Dexamethasone | 2208005-03 | 8 |
| | Dexamethasone | 2208005-04 | 2 |
| | Dexamethasone | 22B26-B06-222195 | 2 |
| | Dexamethasone | 23/13-B14-007283 | 1 |
| | Dexamethasone | 23002226001 | 1 |
| | Dexamethasone | 23003262002 | 4 |
| | Dexamethasone | 23003262003 | 2 |
| | Dexamethasone | 23B23-B03220800 | 1 |
| | Dexamethasone | 23B-23-B03-220800 | 1 |
| | Dexamethasone | 23B23-B03-227238 | 3 |
| 07.2021 | Dexamethasone | 1909011 | 1 |
| AHC | Dexamethasone | 22002762016 | 1 |
| AHD | Dexamethasone | 17104210 | 1 |
| AHD | Dexamethasone | 17104211 | 1 |
| AHD | Dexamethasone | 17L19-B03-344099 | 1 |
| AHD | Dexamethasone | 1806023-01 | 1 |
| AHD | Dexamethasone | 19022108 | 1 |
| AHD | Dexamethasone | 1909011-01 | 1 |
| AHD | Dexamethasone | 21001380002 | 1 |
| AHD | Dexamethasone | 22002762008 | 1 |
| AHD | Dexamethasone | 22002762009 | 1 |
| AHD | Dexamethasone | 22002762015 | 1 |
| AHD | Dexamethasone | 2208005-01 | 1 |
| ALH | Dexamethasone | 15054617 | 2 |
| Allaince Healthcare | Dexamethasone | 22002762017 | 1 |
| Alliance Healthcare | Dexamethasone | 20003905004 | 1 |
| Alliance/Caeolo | Dexamethasone | 19086503 | 1 |
| Alliance/EuRho | Dexamethasone | 1909011-02 | 1 |
| Alliance | Dexamethasone | 22002762005 | 2 |
| alliance | Dexamethasone | 22002762008 | 1 |
| Alliance | Dexamethasone | 22002762016 | 1 |
| Alliance | Dexamethasone | 22B26-B06-222196 | 1 |
| Anzag | Dexamethasone | 1233305 | 1 |
| Anzag | Dexamethasone | 17332404 | 1 |
| Anzag | Dexamethasone | 2200004909 | 1 |
| Anzag | Dexamethasone | 22002762005 | 1 |
| Anzag | Dexamethasone | 22002762015 | 1 |
| Anzag | Dexamethasone | 2208005-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Apo ident | Dexamethasone | 2005024-03 | 1 |
| apo-ident | Dexamethasone | 1909011-02 | 2 |
| apomix | Dexamethasone | 1611001-01 | 1 |
| Bombastus | Dexamethasone | 150546629 | 1 |
| Bombastus | Dexamethasone | 17332418 | 1 |
| Bombastus | Dexamethasone | 1806023-01 | 1 |
| BUFA | Dexamethasone | 97A29FP-101103 | 2 |
| Cael / GEHE | Dexamethasone | 19086513 | 1 |
| Caelo | Dexamethasone | | 3 |
| Caelo | Dexamethasone | 10369920 | 8 |
| Caelo | Dexamethasone | 10369921 | 2 |
| Caelo | Dexamethasone | 11105502 | 1 |
| Caelo | Dexamethasone | 111055-02 | 1 |
| Caelo | Dexamethasone | 117019022107 | 1 |
| Caelo | Dexamethasone | 117117332419 | 1 |
| Caelo | Dexamethasone | 1203304788 | 1 |
| Caelo | Dexamethasone | 12033301 | 3 |
| Caelo | Dexamethasone | 12033303 | 1 |
| Caelo | Dexamethasone | 12033304 | 1 |
| Caelo | Dexamethasone | 12033305 | 4 |
| Caelo | Dexamethasone | 12033307 | 6 |
| Caelo | Dexamethasone | 12033308 | 2 |
| Caelo | Dexamethasone | 12033312 | 2 |
| Caelo | Dexamethasone | 12033314 | 7 |
| Caelo | Dexamethasone | 12033315 | 4 |
| Caelo | Dexamethasone | 12033317 | 5 |
| Caelo | Dexamethasone | 12033318 | 5 |
| Caelo | Dexamethasone | 1209008-01 | 1 |
| Caelo | Dexamethasone | 12091306 | 1 |
| Caelo | Dexamethasone | 12165803 | 1 |
| Caelo | Dexamethasone | 12165804 | 1 |
| Caelo | Dexamethasone | 1303007-03 | 1 |
| Caelo | Dexamethasone | 13084304 | 2 |
| Caelo | Dexamethasone | 13084305 | 5 |
| Caelo | Dexamethasone | 13084306 | 3 |
| Caelo | Dexamethasone | 13084307 | 2 |
| Caelo | Dexamethasone | 13084308 | 2 |
| Caelo | Dexamethasone | 13084309 | 1 |
| Caelo | Dexamethasone | 13084310 | 8 |
| Caelo | Dexamethasone | 13084313 | 4 |
| Caelo | Dexamethasone | 13084316 | 4 |
| Caelo | Dexamethasone | 13084317 | 7 |
| Caelo | Dexamethasone | 13084319 | 5 |
| Caelo | Dexamethasone | 13084320 | 2 |
| Caelo | Dexamethasone | 130854306 | 1 |
| Caelo | Dexamethasone | 13342310 | 1 |
| Caelo | Dexamethasone | 1335213 | 1 |
| Caelo | Dexamethasone | 13352302 | 9 |
| Caelo | Dexamethasone | 13352303 | 1 |
| Caelo | Dexamethasone | 13352304 | 1 |
| Caelo | Dexamethasone | 13352308 | 7 |
| Caelo | Dexamethasone | 13352309 | 2 |
| Caelo | Dexamethasone | 13352310 | 17 |
| Caelo | Dexamethasone | 13352311 | 1 |
| Caelo | Dexamethasone | 13352312 | 15 |
| Caelo | Dexamethasone | 13352315 | 2 |
| Caelo | Dexamethasone | 13D12-N09 | 1 |
| Caelo | Dexamethasone | 14196402 | 3 |
| Caelo | Dexamethasone | 1504610 | 1 |
| Caelo | Dexamethasone | 1504618 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dexamethasone | 1504631 | 1 |
| Caelo | Dexamethasone | 15054506 | 1 |
| Caelo | Dexamethasone | 15054602 | 11 |
| Caelo | Dexamethasone | 15054603 | 3 |
| Caelo | Dexamethasone | 15054605 | 11 |
| Caelo | Dexamethasone | 15054606 | 14 |
| Caelo | Dexamethasone | 15054609 | 5 |
| Caelo | Dexamethasone | 15054610 | 1 |
| Caelo | Dexamethasone | 15054611 | 8 |
| Caelo | Dexamethasone | 15054614 | 5 |
| Caelo | Dexamethasone | 15054616 | 6 |
| Caelo | Dexamethasone | 15054617 | 11 |
| Caelo | Dexamethasone | 15054618 | 3 |
| Caelo | Dexamethasone | 15054620/170314D | 1 |
| Caelo | Dexamethasone | 15054621 | 9 |
| Caelo | Dexamethasone | 15054622 | 35 |
| Caelo | Dexamethasone | 15054623 | 11 |
| Caelo | Dexamethasone | 15054627 | 2 |
| Caelo | Dexamethasone | 15054628 | 11 |
| Caelo | Dexamethasone | 15054629 | 20 |
| Caelo | Dexamethasone | 15054631 | 6 |
| Caelo | Dexamethasone | 1505623 | 1 |
| Caelo | Dexamethasone | 15215601 | 1 |
| Caelo | Dexamethasone | 15A05-B01-304637 | 1 |
| Caelo | Dexamethasone | 15I04-B04-315528 | 1 |
| Caelo | Dexamethasone | 15K17-B07-321457 | 1 |
| Caelo | Dexamethasone | 1601052-01 | 1 |
| Caelo | Dexamethasone | 1601052-02 | 3 |
| Caelo | Dexamethasone | 16012207 | 1 |
| Caelo | Dexamethasone | 160821D | 1 |
| Caelo | Dexamethasone | 161001-01 | 1 |
| Caelo | Dexamethasone | 161100101 | 2 |
| Caelo | Dexamethasone | 1611001-01 | 3 |
| Caelo | Dexamethasone | 16K24-B05-330281 | 1 |
| Caelo | Dexamethasone | 1704203 | 1 |
| Caelo | Dexamethasone | 1704204 | 1 |
| Caelo | Dexamethasone | 1708004-01 | 6 |
| Caelo | Dexamethasone | 17081716 | 1 |
| Caelo | Dexamethasone | 1708804-01 | 1 |
| Caelo | Dexamethasone | 17104201 | 1 |
| Caelo | Dexamethasone | 17104202 | 2 |
| Caelo | Dexamethasone | 17104203 | 6 |
| Caelo | Dexamethasone | 17104204 | 9 |
| Caelo | Dexamethasone | 17104205 | 8 |
| Caelo | Dexamethasone | 17104210 | 24 |
| Caelo | Dexamethasone | 17104211 | 30 |
| Caelo | Dexamethasone | 17104212 | 2 |
| Caelo | Dexamethasone | 17104216 | 12 |
| Caelo | Dexamethasone | 171042165511 | 1 |
| Caelo | Dexamethasone | 171042165585 | 1 |
| Caelo | Dexamethasone | 1714203 | 1 |
| Caelo | Dexamethasone | 173322402 | 1 |
| Caelo | Dexamethasone | 17332402 | 14 |
| Caelo | Dexamethasone | 17332403 | 37 |
| Caelo | Dexamethasone | 17332404 | 15 |
| Caelo | Dexamethasone | 17332406 | 8 |
| Caelo | Dexamethasone | 17332407 | 6 |
| Caelo | Dexamethasone | 17332408 | 19 |
| Caelo | Dexamethasone | 17332411 | 3 |
| Caelo | Dexamethasone | 17332412 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dexamethasone | 17332413 | 8 |
| Caelo | Dexamethasone | 17332414 | 8 |
| Caelo | Dexamethasone | 17332415 | 8 |
| Caelo | Dexamethasone | 17332415-D20180115Ma | 1 |
| Caelo | Dexamethasone | 17332416 | 4 |
| Caelo | Dexamethasone | 17332417 | 3 |
| Caelo | Dexamethasone | 17332418 | 3 |
| Caelo | Dexamethasone | 17332419 | 26 |
| Caelo | Dexamethasone | 17e31-b01-338016 | 1 |
| Caelo | Dexamethasone | 1806023-01 | 4 |
| Caelo | Dexamethasone | 18121709 | 1 |
| Caelo | Dexamethasone | 190022101 | 1 |
| Caelo | Dexamethasone | 1902210 | 1 |
| Caelo | Dexamethasone | 19022101 | 51 |
| Caelo | Dexamethasone | 19022102 | 3 |
| Caelo | Dexamethasone | 19022103 | 9 |
| Caelo | Dexamethasone | 19022104 | 8 |
| Caelo | Dexamethasone | 19022107 | 20 |
| Caelo | Dexamethasone | 190221070 | 1 |
| Caelo | Dexamethasone | 19022108 | 5 |
| Caelo | Dexamethasone | 19022109 | 1 |
| Caelo | Dexamethasone | 19022112 | 6 |
| Caelo | Dexamethasone | 190222112 | 1 |
| Caelo | Dexamethasone | 19056503 | 1 |
| Caelo | Dexamethasone | 190865001 | 16 |
| Caelo | Dexamethasone | 190865005 | 1 |
| Caelo | Dexamethasone | 19086501 | 7 |
| Caelo | Dexamethasone | 19086502 | 29 |
| Caelo | Dexamethasone | 19086503 | 53 |
| Caelo | Dexamethasone | 19086504 | 19 |
| Caelo | Dexamethasone | 19086508 | 6 |
| Caelo | Dexamethasone | 19086513 | 29 |
| Caelo | Dexamethasone | 190901101 | 1 |
| Caelo | Dexamethasone | 1909011-01 | 1 |
| Caelo | Dexamethasone | 19096503 | 1 |
| Caelo | Dexamethasone | 191072709 | 1 |
| Caelo | Dexamethasone | 192245004 | 1 |
| Caelo | Dexamethasone | 192876001 | 39 |
| Caelo | Dexamethasone | 192876002 | 1 |
| Caelo | Dexamethasone | 192876004 | 32 |
| Caelo | Dexamethasone | 192876005 | 21 |
| Caelo | Dexamethasone | 192876008 | 2 |
| Caelo | Dexamethasone | 192876009 | 14 |
| Caelo | Dexamethasone | 200002251001 | 2 |
| Caelo | Dexamethasone | 200002251002 | 2 |
| Caelo | Dexamethasone | 200002551001 | 1 |
| Caelo | Dexamethasone | 200003905003 | 1 |
| Caelo | Dexamethasone | 20002251001 | 26 |
| Caelo | Dexamethasone | 20002251002 | 11 |
| Caelo | Dexamethasone | 200039005004 | 1 |
| Caelo | Dexamethasone | 20003905001 | 3 |
| Caelo | Dexamethasone | 20003905002 | 18 |
| Caelo | Dexamethasone | 20003905003 | 19 |
| Caelo | Dexamethasone | 20003905004 | 11 |
| Caelo | Dexamethasone | 20003905005 | 21 |
| Caelo | Dexamethasone | 2000395004 | 2 |
| Caelo | Dexamethasone | 2005024-01 | 3 |
| Caelo | Dexamethasone | 2005024-02 | 1 |
| Caelo | Dexamethasone | 2005024-03 | 1 |
| Caelo | Dexamethasone | 200529SM | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dexamethasone | 2100130011 | 1 |
| Caelo | Dexamethasone | 21001380001 | 4 |
| Caelo | Dexamethasone | 21001380002 | 29 |
| Caelo | Dexamethasone | 21001380003 | 11 |
| Caelo | Dexamethasone | 21001380004 | 17 |
| Caelo | Dexamethasone | 21001380008 | 4 |
| Caelo | Dexamethasone | 21001380009 | 15 |
| Caelo | Dexamethasone | 21001380009I | 1 |
| Caelo | Dexamethasone | 21001380010 | 13 |
| Caelo | Dexamethasone | 21001380011 | 9 |
| Caelo | Dexamethasone | 2100138003 | 1 |
| Caelo | Dexamethasone | 2100138009 | 3 |
| Caelo | Dexamethasone | 2100138009x2 | 2 |
| Caelo | Dexamethasone | 2109019-01 | 1 |
| Caelo | Dexamethasone | 2109019-02 | 1 |
| Caelo | Dexamethasone | 22000019003 | 1 |
| Caelo | Dexamethasone | 22000049002 | 3 |
| Caelo | Dexamethasone | 22000049003 | 22 |
| Caelo | Dexamethasone | 22000049004 | 10 |
| Caelo | Dexamethasone | 22000049005 | 7 |
| Caelo | Dexamethasone | 22000049009 | 1 |
| Caelo | Dexamethasone | 22000049010 | 8 |
| Caelo | Dexamethasone | 22000049011 | 7 |
| Caelo | Dexamethasone | 2200049003 | 1 |
| Caelo | Dexamethasone | 2200049004 | 1 |
| Caelo | Dexamethasone | 2200049009 | 1 |
| Caelo | Dexamethasone | 22002762001 | 1 |
| Caelo | Dexamethasone | 22002762002 | 1 |
| Caelo | Dexamethasone | 22002762003 | 21 |
| Caelo | Dexamethasone | 22002762004 | 7 |
| Caelo | Dexamethasone | 22002762005 | 2 |
| Caelo | Dexamethasone | 22002762008 | 3 |
| Caelo | Dexamethasone | 22002762009 | 1 |
| Caelo | Dexamethasone | 22002762010 | 1 |
| Caelo | Dexamethasone | 22002762014 | 1 |
| Caelo | Dexamethasone | 22002762017 | 2 |
| Caelo | Dexamethasone | 2202762008 | 1 |
| Caelo | Dexamethasone | 2884 | 1 |
| Caelo | Dexamethasone | 3084310 | 1 |
| Caelo | Dexamethasone | 6(19086504) | 1 |
| Caelo | Dexamethasone | 9383631 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22000049005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 17104211 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone | 19022101 | 3 |
| Caesar & Loretz GmbH... | Dexamethasone | 19022107 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22002762004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 17332416 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 17332419 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380003 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086513 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 10369922 | 1 |
| Caesar & Loretz GmbH/ AHD | Dexamethasone | 192876005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20002251001 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19022101 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876004 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20002251002 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380002 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone | 20003905004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Dexamethasone | 20003905002 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22002762004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380004 | 1 |
| Caesar & Loretz GmbH/AHD | Dexamethasone | 19086502 | 1 |
| Caesar & Loretz GmbH/AHD | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH/AHD | Dexamethasone | 22000049005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19022107 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086504 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086513 | 1 |
| Caesar & Loretz GmbH/Gehe | Dexamethasone | 19086502 | 2 |
| Caesar & Loretz GmbH/GEHE | Dexamethasone | 19086508 | 1 |
| Caesar & Loretz GmbH/GEHE | Dexamethasone | 192876004 | 2 |
| Caesar & Loretz GmbH/Gehe | Dexamethasone | 20003905002 | 1 |
| Caesar & Loretz GmbH/Gehe | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH/GEHE | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH/Gehe | Dexamethasone | 21001380009 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19022103 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20003905004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22000049004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22002762009 | 1 |
| Caesar & Loretz GmbH/Gö | Dexamethasone | 192876004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380009 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22000049005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 1806023-02 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19022103 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20002251002 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380002 | 1 |
| Caesar & Loretz GmbH/Kehr | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH/Kehr | Dexamethasone | 22000049003 | 1 |
| Caesar & Loretz GmbH/Krie | Dexamethasone | 19086503 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086502 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876005 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086503 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876009 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22000049011 | 1 |
| Caesar & Loretz GmbH/Ph | Dexamethasone | 21001380010 | 1 |
| Caesar & Loretz GmbH/Pho | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20003905003 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19022112 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086502 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086503 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 19086508 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380002 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380003 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 21001380004 | 2 |
| Caesar & Loretz GmbH/Sa | Dexamethasone | 192876004 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone | 1909011-01 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 192876009 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 20002251002 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone | 22000049003 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 15054622 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 161100102 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 17332408 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 17332414 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 17332415 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 17332419 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Dexamethasone | 19022101 | 11 |
| Caesar & Loretz GmbH | Dexamethasone | 19022103 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 19022104 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 19022107 | 5 |
| Caesar & Loretz GmbH | Dexamethasone | 19022108 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 190865001 | 2 |
| Caesar & Loretz GmbH | Dexamethasone | 19086502 | 8 |
| Caesar & Loretz GmbH | Dexamethasone | 19086503 | 6 |
| Caesar & Loretz GmbH | Dexamethasone | 19086504 | 7 |
| Caesar & Loretz GmbH | Dexamethasone | 19086513 | 3 |
| Caesar & Loretz GmbH | Dexamethasone | 1909011-01 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 192876001 | 11 |
| Caesar & Loretz GmbH | Dexamethasone | 192876002 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 192876004 | 12 |
| Caesar & Loretz GmbH | Dexamethasone | 192876005 | 7 |
| Caesar & Loretz GmbH | Dexamethasone | 192876008 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 192876009 | 6 |
| Caesar & Loretz GmbH | Dexamethasone | 20002251001 | 10 |
| Caesar & Loretz GmbH | Dexamethasone | 20002251002 | 4 |
| Caesar & Loretz GmbH | Dexamethasone | 20003905001 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 20003905002 | 10 |
| Caesar & Loretz GmbH | Dexamethasone | 20003905003 | 6 |
| Caesar & Loretz GmbH | Dexamethasone | 20003905004 | 5 |
| Caesar & Loretz GmbH | Dexamethasone | 20003905005 | 6 |
| Caesar & Loretz GmbH | Dexamethasone | 21001380002 | 14 |
| Caesar & Loretz GmbH | Dexamethasone | 21001380003 | 5 |
| Caesar & Loretz GmbH | Dexamethasone | 21001380004 | 5 |
| Caesar & Loretz GmbH | Dexamethasone | 21001380008 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 21001380009 | 10 |
| Caesar & Loretz GmbH | Dexamethasone | 21001380010 | 6 |
| Caesar & Loretz GmbH | Dexamethasone | 21001380011 | 3 |
| Caesar & Loretz GmbH | Dexamethasone | 22000049003 | 3 |
| Caesar & Loretz GmbH | Dexamethasone | 22000049004 | 5 |
| Caesar & Loretz GmbH | Dexamethasone | 22000049005 | 5 |
| Caesar & Loretz GmbH | Dexamethasone | 22000049009 | 4 |
| Caesar & Loretz GmbH | Dexamethasone | 22000049010 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 22000049011 | 2 |
| Caesar & Loretz GmbH | Dexamethasone | 22002762002 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 22002762003 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 22002762004 | 4 |
| Caesar & Loretz GmbH | Dexamethasone | 22002762005 | 3 |
| Caesar & Loretz GmbH | Dexamethasone | 22002762009 | 1 |
| Caesar & Loretz GmbH | Dexamethasone | 22002762014 | 1 |
| Caesar & Loretz Hilden | Dexamethasone | 17332419 | 1 |
| Caesar & Loretz Hilden | Dexamethasone | 19086503 | 1 |
| Caesar & Loretz Hilden | Dexamethasone | 192876001 | 2 |
| Caesar & Loretz Hilden | Dexamethasone | 20003905005 | 1 |
| Caesar & Loretz/AHD | Dexamethasone | 19086503 | 1 |
| Caesar & Loretz/Noweda | Dexamethasone | 13084319 | 1 |
| Caesar & Loretz/Noweda | Dexamethasone | 20002251001 | 1 |
| Caesar & Loretz | Dexamethasone | 21001380009 | 1 |
| Caesar / Gehe | Dexamethasone | 17332403 | 1 |
| Caesar& Loretz/Geile... | Dexamethasone | 19022104 | 1 |
| Caesar&Loretz GmbH,1... | Dexamethasone | 15054622 | 3 |
| caesar&loretz GmbH,P... | Dexamethasone | 15054606 | 2 |
| Caesar&Loretz GmbH | Dexamethasone | 20002251002 | 1 |
| Caesar&Loretz GmbH | Dexamethasone | 20003905005 | 1 |
| Caesar&Loretz GmbH | Dexamethasone | 22000049003 | 1 |
| Caesar/Gehe | Dexamethasone | 190865001 | 2 |
| caesar | Dexamethasone | 15054617 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| calo | Dexamethasone | 17332403 | 1 |
| Cealo | Dexamethasone | 17332404 | 1 |
| Ebert & Jacobi | Dexamethasone | 1303007-03 | 1 |
| Ebert&Jacobi | Dexamethasone | 1601052-01 | 1 |
| Ebert-Jacobi | Dexamethasone | 1611001-01 | 1 |
| EuRho / Phoenix | Dexamethasone | 1303007-03 | 1 |
| EuRho / Phoenix | Dexamethasone | 15054631 | 1 |
| EuRho / Phönix | Dexamethasone | | 1 |
| EuRho / Phönix | Dexamethasone | 2109019-01 | 1 |
| EuRho Anzag | Dexamethasone | 1601052-02 | 1 |
| EuRho Gehe | Dexamethasone | 1909011-02 | 1 |
| EuRho Pharma | Dexamethasone | 2109019-02 | 1 |
| EuRho/ Gehe | Dexamethasone | 1708004-01 | 1 |
| EuRho/ Noweda | Dexamethasone | 2109019-02 | 1 |
| EuRho/Gehe | Dexamethasone | 1806023-01 | 1 |
| EuRho/Noweda | Dexamethasone | 17008004-01 | 1 |
| EuRho/Noweda | Dexamethasone | 1806023-01 | 1 |
| EuRho/Noweda | Dexamethasone | 1806023-03 | 1 |
| EuRho/Noweda | Dexamethasone | 1909011-02 | 1 |
| EuRho/Noweda | Dexamethasone | 21090-02 | 1 |
| euRho/Noweda | Dexamethasone | 2109019-01 | 2 |
| EuRho/Phoenix | Dexamethasone | 1909011-02 | 1 |
| EuRho/Sanacorp | Dexamethasone | 2005024-02 | 1 |
| EuRho | Dexamethasone | 1303007-03 | 1 |
| EuRho | Dexamethasone | 1708004-01 | 1 |
| EuRho | Dexamethasone | 1806023_04 | 1 |
| EuRho | Dexamethasone | 1806023-01 | 1 |
| EuRho | Dexamethasone | 1909011-01 | 1 |
| EuRho | Dexamethasone | 1909011-02 | 2 |
| eurho | Dexamethasone | 2005024-01 | 1 |
| EuRho | Dexamethasone | 2005024-01 | 3 |
| EuRho | Dexamethasone | 2005024-02 | 1 |
| EuRho | Dexamethasone | 2005024-03 | 2 |
| EuRho | Dexamethasone | 2109019-01 | 1 |
| EuRho | Dexamethasone | 2109019-02 | 1 |
| EuRho | Dexamethasone | NUD180601 | 1 |
| Eurho-Pharma | Dexamethasone | 1909011-02 | 1 |
| Euro OTC | Dexamethasone | | 4 |
| Euro OTC | Dexamethasone | 1107006-01 | 1 |
| Euro OTC | Dexamethasone | 111105501 | 1 |
| Euro OTC | Dexamethasone | 1111055-01 | 5 |
| Euro OTC | Dexamethasone | 1111055-02 | 2 |
| Euro OTC | Dexamethasone | 1200008-01 | 1 |
| Euro OTC | Dexamethasone | 1203032-01 | 4 |
| Euro OTC | Dexamethasone | 1203032-02 | 3 |
| Euro OTC | Dexamethasone | 1209008-01 | 11 |
| Euro OTC | Dexamethasone | 120900802 | 2 |
| Euro OTC | Dexamethasone | 1209008-02 | 26 |
| Euro OTC | Dexamethasone | 13030007 | 1 |
| Euro OTC | Dexamethasone | 13030007-01 | 1 |
| Euro OTC | Dexamethasone | 1303007 | 1 |
| Euro OTC | Dexamethasone | 130300701 | 4 |
| Euro OTC | Dexamethasone | 1303007-01 | 34 |
| Euro OTC | Dexamethasone | 130300702 | 2 |
| Euro OTC | Dexamethasone | 1303007-02 | 10 |
| Euro OTC | Dexamethasone | 130300703 | 2 |
| Euro OTC | Dexamethasone | 1303007-03 | 30 |
| Euro OTC | Dexamethasone | 1303007-04 | 2 |
| Euro OTC | Dexamethasone | 13352309 | 1 |
| Euro OTC | Dexamethasone | 14D11-B01-294031 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Dexamethasone | 15054621 | 1 |
| Euro OTC | Dexamethasone | 1512211327 | 1 |
| Euro OTC | Dexamethasone | 160105201 | 2 |
| Euro OTC | Dexamethasone | 1601052-01 | 27 |
| Euro OTC | Dexamethasone | 160105202 | 2 |
| Euro OTC | Dexamethasone | 1601052-02 | 37 |
| Euro OTC | Dexamethasone | 1601052-21 | 1 |
| Euro OTC | Dexamethasone | 1611001 | 2 |
| Euro OTC | Dexamethasone | 161100101 | 3 |
| Euro OTC | Dexamethasone | 1611001-01 | 58 |
| Euro OTC | Dexamethasone | 1611001-02 | 2 |
| Euro OTC | Dexamethasone | 161101-01 | 1 |
| Euro OTC | Dexamethasone | 1702004-01 | 1 |
| Euro OTC | Dexamethasone | 17080004-01 | 1 |
| Euro OTC | Dexamethasone | 1708004 | 1 |
| Euro OTC | Dexamethasone | 170800401 | 2 |
| Euro OTC | Dexamethasone | 1708004-01 | 96 |
| Euro OTC | Dexamethasone | 1708004-02 | 6 |
| Euro OTC | Dexamethasone | 1708804-01 | 1 |
| Euro OTC | Dexamethasone | 17104203 | 1 |
| Euro OTC | Dexamethasone | 17104204 | 1 |
| Euro OTC | Dexamethasone | 17104210 | 1 |
| Euro OTC | Dexamethasone | 17104211 | 1 |
| Euro OTC | Dexamethasone | 17332403 | 1 |
| Euro OTC | Dexamethasone | 180208D/1611001-01 | 1 |
| Euro OTC | Dexamethasone | 1806023 | 2 |
| Euro OTC | Dexamethasone | 1806023_03 | 1 |
| Euro OTC | Dexamethasone | 180602301 | 2 |
| Euro OTC | Dexamethasone | 1806023-01 | 57 |
| Euro OTC | Dexamethasone | 1806023-010 | 1 |
| Euro OTC | Dexamethasone | 180602302 | 2 |
| Euro OTC | Dexamethasone | 1806023-02 | 18 |
| Euro OTC | Dexamethasone | 1806023-03 | 7 |
| Euro OTC | Dexamethasone | 1806023-04 | 19 |
| Euro OTC | Dexamethasone | 1806023-24 | 1 |
| Euro OTC | Dexamethasone | 1806032-02 | 1 |
| Euro OTC | Dexamethasone | 19022103 | 1 |
| Euro OTC | Dexamethasone | 1905014-01 | 1 |
| Euro OTC | Dexamethasone | 190701 | 1 |
| Euro OTC | Dexamethasone | 19086503 | 1 |
| Euro OTC | Dexamethasone | 1909011 | 3 |
| Euro OTC | Dexamethasone | 190901101 | 2 |
| Euro OTC | Dexamethasone | 1909011-01 | 46 |
| Euro OTC | Dexamethasone | 190901102 | 1 |
| Euro OTC | Dexamethasone | 1909011-02 | 33 |
| Euro OTC | Dexamethasone | 1909011-02P200622-1 | 1 |
| Euro OTC | Dexamethasone | 19909011-02 | 1 |
| Euro OTC | Dexamethasone | 20005024-01 | 1 |
| Euro OTC | Dexamethasone | 2002024-01 | 2 |
| Euro OTC | Dexamethasone | 2005021-03 | 1 |
| Euro OTC | Dexamethasone | 2005024 | 1 |
| Euro OTC | Dexamethasone | 2005024_04 | 1 |
| Euro OTC | Dexamethasone | 200502401 | 1 |
| Euro OTC | Dexamethasone | 2005024-01 | 56 |
| Euro OTC | Dexamethasone | 200502402 | 1 |
| Euro OTC | Dexamethasone | 2005024-02 | 32 |
| Euro OTC | Dexamethasone | 200502403 | 2 |
| Euro OTC | Dexamethasone | 2005024-03 | 40 |
| Euro OTC | Dexamethasone | 2005024-04 | 5 |
| Euro OTC | Dexamethasone | 21001215017 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Dexamethasone | 21009019-01 | 1 |
| Euro OTC | Dexamethasone | 2109012-01 | 1 |
| Euro OTC | Dexamethasone | 2109018-02 | 1 |
| Euro OTC | Dexamethasone | 210901901 | 1 |
| Euro OTC | Dexamethasone | 2109019-01 | 44 |
| Euro OTC | Dexamethasone | 21090-19-01 | 1 |
| Euro OTC | Dexamethasone | 2109019-02 | 14 |
| Euro OTC | Dexamethasone | 2109019-03 | 4 |
| Euro OTC | Dexamethasone | 2109019-0306 | 1 |
| Euro OTC | Dexamethasone | 21090919-01 | 1 |
| Euro OTC | Dexamethasone | 2208005-01 | 1 |
| Euro OTC | Dexamethasone | 4914501 | 1 |
| Euro OTC | Dexamethasone | 5213A1327 | 1 |
| Euro OTC | Dexamethasone | 700107 | 3 |
| Euro OTC | Dexamethasone | DB003/0213 | 3 |
| Euro OTC | Dexamethasone | DZ11005K | 1 |
| Euro OTC | Dexamethasone | L53613 | 1 |
| Euro OTC | Dexamethasone | T45290 | 2 |
| Euro RHO/Jenne | Dexamethasone | 1909011-02 | 1 |
| Euro Rho/Jenne | Dexamethasone | 2005024-03 | 1 |
| Euro/ Gehe | Dexamethasone | 1909011-03 | 1 |
| Euro/ Gehe | Dexamethasone | 19G25-B02-363757 | 1 |
| Euro/ Sanacorp | Dexamethasone | 1601052-01 | 2 |
| Euro/Gehe | Dexamethasone | 1611001-01 | 1 |
| Euro/Gehe | Dexamethasone | 1708004-01 | 2 |
| Euro/Noweda | Dexamethasone | 1806023-01 | 1 |
| Euro/Sana | Dexamethasone | 2109019-01 | 1 |
| EuRoh/Fiebig | Dexamethasone | 1806023-01 | 1 |
| EuRoh/Gehe | Dexamethasone | 1806023 | 1 |
| Fagron | Dexamethasone | 11D26-N10 | 3 |
| Fagron | Dexamethasone | 11F30-N02 | 1 |
| Fagron | Dexamethasone | 11L08-N01 | 4 |
| Fagron | Dexamethasone | 1209008-01 | 1 |
| Fagron | Dexamethasone | 12A24-B01-35964 | 1 |
| Fagron | Dexamethasone | 12B06-N12 | 2 |
| Fagron | Dexamethasone | 12D26-N09 | 2 |
| Fagron | Dexamethasone | 12H21-N11 | 2 |
| Fagron | Dexamethasone | 1303007-03 | 1 |
| Fagron | Dexamethasone | 13D12-N09 | 5 |
| Fagron | Dexamethasone | 13D12-N19 | 1 |
| Fagron | Dexamethasone | 13G08-N13 | 5 |
| Fagron | Dexamethasone | 13L30-B34-289691 | 2 |
| Fagron | Dexamethasone | 14A22-B03 | 2 |
| Fagron | Dexamethasone | 14A22-B03-290700 | 1 |
| Fagron | Dexamethasone | 14A22-B03-290701 | 1 |
| Fagron | Dexamethasone | 14A22-B03-294030 | 1 |
| Fagron | Dexamethasone | 14D11-B01-294031 | 2 |
| Fagron | Dexamethasone | 14D11-B01-294032 | 1 |
| Fagron | Dexamethasone | 15/04-B04-315528 | 1 |
| Fagron | Dexamethasone | 15054603 | 1 |
| Fagron | Dexamethasone | 15054614 | 1 |
| Fagron | Dexamethasone | 15A05-B01 | 1 |
| Fagron | Dexamethasone | 15A05-B01-034636 | 1 |
| Fagron | Dexamethasone | 15a05-b01-304636 | 1 |
| Fagron | Dexamethasone | 15A05-B01-304636 | 3 |
| Fagron | Dexamethasone | 15a05-b01-304637 | 1 |
| Fagron | Dexamethasone | 15A05-B01-304637 | 1 |
| Fagron | Dexamethasone | 15C16-B07 | 1 |
| Fagron | Dexamethasone | 15C16-B07-308252 | 1 |
| Fagron | Dexamethasone | 15I04-B04-315528 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Dexamethasone | 15K17-B07-321457 | 3 |
| Fagron | Dexamethasone | 16/06-B03-327323 | 1 |
| Fagron | Dexamethasone | 1601052-01 | 1 |
| Fagron | Dexamethasone | 16I06-B03-327323 | 3 |
| Fagron | Dexamethasone | 16I06-B03-327488 | 3 |
| Fagron | Dexamethasone | 16K24B05330281 | 1 |
| Fagron | Dexamethasone | 16K24-B05-330281 | 1 |
| Fagron | Dexamethasone | 1708004-01 | 2 |
| Fagron | Dexamethasone | 17104203 | 1 |
| Fagron | Dexamethasone | 17332414 | 1 |
| Fagron | Dexamethasone | 17C13-B07-332461 | 5 |
| Fagron | Dexamethasone | 17E31-B01-331860 | 1 |
| Fagron | Dexamethasone | 17E31-B01-338016 | 1 |
| Fagron | Dexamethasone | 17E31B01338017 | 1 |
| Fagron | Dexamethasone | 17L19-B03 | 1 |
| Fagron | Dexamethasone | 17L19-B03-344099 | 2 |
| Fagron | Dexamethasone | 17L19B03-344100 | 1 |
| Fagron | Dexamethasone | 17L19-B03-344100 | 2 |
| Fagron | Dexamethasone | 17L19-B03-344396 | 1 |
| Fagron | Dexamethasone | 18D09-B06 | 1 |
| Fagron | Dexamethasone | 18D09-B06-348185 | 3 |
| Fagron | Dexamethasone | 18E08-B05-350243 | 4 |
| Fagron | Dexamethasone | 18H07-B00-355632 | 1 |
| Fagron | Dexamethasone | 18H07-B02-355632 | 1 |
| Fagron | Dexamethasone | 18H07-B02-356113 | 1 |
| Fagron | Dexamethasone | 19A24B01 | 1 |
| Fagron | Dexamethasone | 19A24-B01 | 1 |
| Fagron | Dexamethasone | 19A24-B01-359624 | 4 |
| Fagron | Dexamethasone | 19A24-B01-359625 | 1 |
| Fagron | Dexamethasone | 19A24-B01-359626 | 3 |
| Fagron | Dexamethasone | 19A24-B01-361445 | 1 |
| Fagron | Dexamethasone | 19G25-B02-363751 | 3 |
| Fagron | Dexamethasone | 19G25-B02-363755 | 1 |
| Fagron | Dexamethasone | 2005024-01 | 1 |
| Fagron | Dexamethasone | 20B04-F06-369866 | 2 |
| Fagron | Dexamethasone | 20B04-F06-369867 | 1 |
| Fagron | Dexamethasone | 20E08-F04-370660 | 1 |
| Fagron | Dexamethasone | 20F19-F08 | 1 |
| Fagron | Dexamethasone | 20F19-F08-371577 | 4 |
| Fagron | Dexamethasone | 20F19-F08-371578 | 1 |
| Fagron | Dexamethasone | 20K05-F04-375225 | 2 |
| Fagron | Dexamethasone | 21C11-F03-377848 | 5 |
| Fagron | Dexamethasone | 21C11-F03-378501 | 5 |
| Fagron | Dexamethasone | 21H13-B20-216247 | 1 |
| Fagron | Dexamethasone | 22A17-B06-216246 | 6 |
| Fagron | Dexamethasone | 22B26-B06-220498 | 1 |
| Fagron | Dexamethasone | 22B26-B06-222196 | 1 |
| Fagron | Dexamethasone | 22B26-B06 | 1 |
| Fagron | Dexamethasone | 2314A-01327 | 1 |
| Fagron | Dexamethasone | 700107-0002 | 1 |
| Fagron | Dexamethasone | DZ11005K12B06-N12 | 1 |
| Fagron | Dexamethasone | F03-3778408 | 1 |
| Fagron | Dexamethasone | F06-3698606 | 2 |
| Fagron | Dexamethasone | NUD160702 | 1 |
| Fagron | Dexamethasone | NUD180601 | 1 |
| Fargon/Noweda | Dexamethasone | 19A24-B01 | 2 |
| Fiebig | Dexamethasone | 19086513 | 1 |
| Fiebig | Dexamethasone | 20003905002 | 1 |
| Gatt-Koller | Dexamethasone | 1801087 | 1 |
| GEHE 12.03.2014 | Dexamethasone | 13084306 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe 8.04.2014 | Dexamethasone | 13084310 | 2 |
| Gehe amax | Dexamethasone | 1806023-02 | 2 |
| Gehe amax | Dexamethasone | 1806023-04 | 1 |
| Gehe amax | Dexamethasone | 2005024-01 | 3 |
| Gehe Rostock | Dexamethasone | 22002762004 | 1 |
| Gehe, Tianyao pharma… | Dexamethasone | 1909011-01 | 1 |
| Gehe/ Euro | Dexamethasone | 2005024-01 | 1 |
| Gehe | Dexamethasone | 1203032-02 | 1 |
| Gehe | Dexamethasone | 120900802 | 1 |
| Gehe | Dexamethasone | 13084317 | 1 |
| Gehe | Dexamethasone | 15054621 | 1 |
| Gehe | Dexamethasone | 15054629 | 1 |
| Gehe | Dexamethasone | 15054631 | 1 |
| Gehe | Dexamethasone | 1601052-02 | 1 |
| Gehe | Dexamethasone | 1611001-01 | 3 |
| Gehe | Dexamethasone | 17104210 | 1 |
| Gehe | Dexamethasone | 17104212 | 1 |
| Gehe | Dexamethasone | 17332404 | 1 |
| GEHE | Dexamethasone | 17L19-B03-344099 | 1 |
| GEHE | Dexamethasone | 18H07-B02 | 1 |
| Gehe | Dexamethasone | 19086501 | 1 |
| Gehe | Dexamethasone | 192876004 | 1 |
| Gehe | Dexamethasone | 20003905003 | 1 |
| Gehe | Dexamethasone | 2005024-01 | 1 |
| Gehe | Dexamethasone | 2005024-04 | 1 |
| Gehe | Dexamethasone | 2109019-03 | 1 |
| Gehe | Dexamethasone | 2200004901 | 1 |
| Gehe | Dexamethasone | 22002762003 | 2 |
| gehe | Dexamethasone | 220800501 | 1 |
| gehe | Dexamethasone | 2208005-02 | 1 |
| Gehe | Dexamethasone | 2208005-03 | 1 |
| Gehe | Dexamethasone | F03-3785001 | 1 |
| Geibo | Dexamethasone | 22002762015 | 1 |
| Geilenkirchen | Dexamethasone | 17104205 | 1 |
| Henry Lamotte Oils GmbH | Dexamethasone | 13084304 | 1 |
| Holdermann | Dexamethasone | 22002762003 | 1 |
| Holdermann | Dexamethasone | 22002762016 | 1 |
| Jenne | Dexamethasone | 1806023-01 | 1 |
| Jenne | Dexamethasone | 1806023-02 | 1 |
| Jenne | Dexamethasone | 1909011-01 | 1 |
| Jenne | Dexamethasone | 20002251002 | 1 |
| Jenne | Dexamethasone | 2005024-03 | 1 |
| Jenne | Dexamethasone | 22002762003 | 1 |
| Jenne | Dexamethasone | 22002762008 | 1 |
| Jenne | Dexamethasone | 22002762016 | 3 |
| Kehr/Fargon | Dexamethasone | 1806023-01 | 2 |
| Kehr | Dexamethasone | 17104205 | 1 |
| Kehr | Dexamethasone | 17104210 | 1 |
| Kehr | Dexamethasone | 19086508 | 1 |
| Kehr | Dexamethasone | 2109019-03 | 1 |
| Kehr | Dexamethasone | 22002762004 | 1 |
| Kehr | Dexamethasone | 2208005-01 | 1 |
| Krieger | Dexamethasone | 17332406 | 1 |
| L10 | Dexamethasone | 1708004-01 | 1 |
| Noweda 02.12.2019 | Dexamethasone | 1806023-04 | 1 |
| Noweda Taucha | Dexamethasone | 2109019-01 | 2 |
| Noweda | Dexamethasone | 1303007-03 | 1 |
| Noweda | Dexamethasone | 1708004-01 | 3 |
| Noweda | Dexamethasone | 1708004-02 | 1 |
| Noweda | Dexamethasone | 17104204 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Dexamethasone | 1806023-01 | 1 |
| Noweda | Dexamethasone | 1806023-04 | 1 |
| Noweda | Dexamethasone | 19022101 | 2 |
| Noweda | Dexamethasone | 19086503 | 1 |
| Noweda | Dexamethasone | 1909011-01 | 1 |
| Noweda | Dexamethasone | 20002251001 | 2 |
| Noweda | Dexamethasone | 20003905002 | 1 |
| Noweda | Dexamethasone | 200039050022003905003 | 1 |
| Noweda | Dexamethasone | 20003905003 | 1 |
| Noweda | Dexamethasone | 200502404 | 1 |
| Noweda | Dexamethasone | 21001380003 | 1 |
| Noweda | Dexamethasone | 2109019-02 | 2 |
| Noweda | Dexamethasone | 2109019-03 | 3 |
| Noweda | Dexamethasone | 22000049005 | 2 |
| Noweda | Dexamethasone | 22002762003 | 1 |
| Noweda | Dexamethasone | 22002762005 | 1 |
| Noweda | Dexamethasone | 22002762008 | 1 |
| Noweda | Dexamethasone | 22002762010 | 1 |
| Noweda | Dexamethasone | 22002762014 | 1 |
| Noweda | Dexamethasone | 22002762016 | 1 |
| Noweda | Dexamethasone | 2208005-01 | 5 |
| Noweda | Dexamethasone | 2208005-03 | 2 |
| PH Euro 8,0 | Dexamethasone | 15054610 | 1 |
| Pharmacia / Gehe | Dexamethasone | M62488 | 1 |
| Pharmacia&Upjohn Comp | Dexamethasone | 1209008-02 | 1 |
| Pharmacia&Upjohn Com… | Dexamethasone | 1601052-02 | 1 |
| Phoenix Goettin | Dexamethasone | 117113352302 | 1 |
| Phoenix | Dexamethasone | 10369928 | 1 |
| Phoenix | Dexamethasone | 13084313 | 2 |
| Phoenix | Dexamethasone | 13g08n13 | 1 |
| Phoenix | Dexamethasone | 15I04-B04 | 1 |
| Phoenix | Dexamethasone | 17332406 | 1 |
| Phoenix | Dexamethasone | 17332416 | 1 |
| Phoenix | Dexamethasone | 17332419 | 1 |
| Phoenix | Dexamethasone | 19086503 | 1 |
| Phoenix | Dexamethasone | 1909011-01 | 2 |
| Phoenix | Dexamethasone | 20002251002 | 1 |
| Phoenix | Dexamethasone | 20004529003 | 1 |
| Phoenix | Dexamethasone | 200622506 | 1 |
| Phoenix | Dexamethasone | 2109019-01 | 1 |
| Phoenix | Dexamethasone | 220002762016 | 1 |
| Phoenix | Dexamethasone | 22002762003 | 2 |
| Phoenix | Dexamethasone | 22002762016 | 11 |
| Phoenix | Dexamethasone | 2208005-01 | 1 |
| Phoenix | Dexamethasone | 2208005-03 | 1 |
| Phoenix | Dexamethasone | 23003262003 | 1 |
| Phoenix | Dexamethasone | 3110723 | 1 |
| Phoenix | Dexamethasone | 3405 | 1 |
| Phönix Euro 23.6.21 | Dexamethasone | 2005024-03 | 1 |
| Phönix Gotha | Dexamethasone | 12033315 | 1 |
| Phönix Gotha | Dexamethasone | 13352311 | 1 |
| Phönix Gotha | Dexamethasone | 17332408 | 1 |
| Phönix | Dexamethasone | 12033314 | 1 |
| PHÖNIX | Dexamethasone | 15K17-B07 | 1 |
| Phönix | Dexamethasone | 1601052-02 | 3 |
| Phönix | Dexamethasone | 1806023-01 | 1 |
| Phönix | Dexamethasone | 19022101 | 1 |
| Phönix | Dexamethasone | 1909011-01 | 1 |
| Phönix | Dexamethasone | 1909011-02 | 1 |
| Phönix | Dexamethasone | 192876005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Dexamethasone | 2005024-03 | 1 |
| PHönix | Dexamethasone | 2005024-03 | 1 |
| phönix | Dexamethasone | 21001380009 | 1 |
| Phönix | Dexamethasone | 2109019-03 | 1 |
| Phönix | Dexamethasone | 22002762003 | 1 |
| Phönix | Dexamethasone | 22002762008 | 2 |
| Phönix | Dexamethasone | 22002762010 | 1 |
| Phönix | Dexamethasone | 22002762016 | 4 |
| Phönix | Dexamethasone | 2208005-01 | 1 |
| Raben-Apotheke Mildenau | Dexamethasone | 1303007-01 | 2 |
| Sanacorp | Dexamethasone | 13084308 | 1 |
| Sanacorp | Dexamethasone | 13352309 | 1 |
| Sanacorp | Dexamethasone | 1601052-01 | 1 |
| Sanacorp | Dexamethasone | 17104211 | 1 |
| Sanacorp | Dexamethasone | 17332402 | 1 |
| Sanacorp | Dexamethasone | 2005024-01 | 1 |
| Sanacorp | Dexamethasone | 21001380011 | 1 |
| Sanacorp | Dexamethasone | 22002762004 | 2 |
| Sanacorp | Dexamethasone | 22002762008 | 1 |
| Sanacorp | Dexamethasone | 22002762009 | 1 |
| Sanacorp | Dexamethasone | 22002762014 | 1 |
| Sanacorp | Dexamethasone | 2208005-03 | 1 |
| Sanofi-Chimie FR/Noweda | Dexamethasone | 15054606 | 2 |
| Sanofi-Chimie, FR/ Noweda | Dexamethasone | 12033308 | 1 |
| Symbiotica/Noweda | Dexamethasone | 1601052-02 | 1 |
| Symbiotica | Dexamethasone | 1303007-01 | 1 |
| Symbiotica | Dexamethasone | 1303007-03 | 2 |
| Symbiotika | Dexamethasone | 1303007-03 | 1 |
| Tianijin Tianyao / Gehe | Dexamethasone | 17332408 | 1 |
| Tianjin Tianyao Pharm/AHD | Dexamethasone | 1806023-01 | 1 |
| Tianjin Tianyao Phar… | Dexamethasone | 200502404 | 1 |
| Tianjin/Noweda | Dexamethasone | NUD170802 | 1 |
| Tianjin/Phoenix | Dexamethasone | NUD190701 | 1 |
| Tianjin/Phoenix | Dexamethasone | NUD200402 | 1 |
| unbekannt | Dexamethasone | 12D26-N09 | 1 |

- 253 702 spectra from 1666 *Apo-Ident* customers from a total of 51 740 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Dexamethasone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Dexamethasone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 607 | 0 | 157 719 |
| **Type B** | 0 | 1518 | 0 | 211 422 |
| **Type C** | 0 | 3122 | 62 | 253 702 |

The substance/substance group *Dexamethasone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0115 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6047 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.0528 % (> 97.9585 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21289 | 21289 | 0.00 | 167.86 |
| 21403 | 21403 | 0.00 | 96.61 |
| 21850 | 21289 | 16.62 | 168.61 |
| 22364 | 22364 | 0.00 | 85.48 |
| 22914 | 22914 | 0.00 | 90.21 |
| 23168 | 24504 | 9.62 | 172.32 |
| 23169 | 22364 | 7.22 | 85.73 |
| 24504 | 24504 | 0.00 | 173.43 |
| 24705 | 24504 | 9.16 | 171.90 |
| 25301 | 25301 | 0.00 | 173.74 |
| 26967 | 26967 | 0.00 | 174.92 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Dexamethasone acetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20313-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Dexamethasone acetate; Dexamethasoni acetas

### Special notes

When selecting the *Dexamethasone acetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Dexamethasone acetate | 7 | 3 | 123 |

### Second-stage model

For differentiation of the substance/substance group *Dexamethasone acetate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Dexamethasone acetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 57.53 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Dexamethasone acetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Dexamethasone acetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Dexamethasone acetate | 13260703 | 21301 | 40 | 1412430 |
| Caelo | Dexamethasone acetate | 13260706 | 21593 | 60 | 1502537 |
| Caelo | Dexamethasone acetate | 14200207 | 21815 | 60 | 20140807 |
| Caelo | Dexamethasone acetate | 14200207 | 21815SI | 30 | 20140807 |
| Caelo | Dexamethasone acetate | 20002252 | 25448 | 40 | 2102142 |
| Caelo | Dexamethasone acetate | 20002252 | 25448SI | 34 | 2102142 |
| Caelo | Dexamethasone acetate | 23000428 | 26942 | 40 | 20230907* |
| Caelo | Dexamethasone acetate | 23000428 | 26942SI | 40 | 20230907* |
| Euro OTC | Dexamethasone acetate | 1405024-01 | 21614 | 60 | 20140620 |
| Euro OTC | Dexamethasone acetate | 1405024-01 | 21614SI | 45 | 20140620 |
| Euro OTC | Dexamethasone acetate | 1708011 | 23693 | 40 | 20171002* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 489 spectra of 11 reference samples from the substance/substance group *Dexamethasone acetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 837 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 281 spectra of 8 reference samples from the substance/substance group *Dexamethasone acetate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Dexamethasone acetate | 161066 | 22437 | 60 |
| Caelo | Dexamethasone acetate | 181730 | 24253 | 40 |
| Caelo | Dexamethasone acetate | 191192 | 24734 | 40 |
| Caelo | Dexamethasone acetate | 14200207 | 21815SI† | 15 |
| Caelo | Dexamethasone acetate | 161066 | 22437SI | 42 |
| Caelo | Dexamethasone acetate | 181730 | 24253SI | 20 |
| Caelo | Dexamethasone acetate | 191192 | 24734SI | 40 |
| Euro OTC | Dexamethasone acetate | 1708011 | 23693SI† | 24 |

- 212 659 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 567 spectra from 297 *Apo-Ident* customers from 127 batches from the substance/substance group *Dexamethasone acetate*.

- Among them are spectra of independent samples from 123 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Dexamethasone acetate | 20004529006 | 1 |
| | Dexamethasone acetate | 20004529009 | 2 |
| | Dexamethasone acetate | 20004529015 | 1 |
| | Dexamethasone acetate | 20004529018 | 3 |
| | Dexamethasone acetate | 2000459003 | 1 |
| | Dexamethasone acetate | 23000428003 | 2 |
| | Dexamethasone acetate | 23000428004 | 1 |
| | Dexamethasone acetate | 23000428005 | 10 |
| | Dexamethasone acetate | 24000144001 | 1 |
| AHD | Dexamethasone acetate | 1405024-03 | 1 |
| AHD | Dexamethasone acetate | 18173002 | 1 |
| Alliance | Dexamethasone acetate | 20004529014 | 1 |
| alliance | Dexamethasone acetate | 20004529019 | 1 |
| apomix | Dexamethasone acetate | 1405024-03 | 1 |
| Bombastus | Dexamethasone acetate | 16106616 | 1 |
| Caelo | Dexamethasone acetate | 11093210 | 1 |
| Caelo | Dexamethasone acetate | 11093211 | 1 |
| Caelo | Dexamethasone acetate | 11093215 | 1 |
| Caelo | Dexamethasone acetate | 11093217 | 1 |
| Caelo | Dexamethasone acetate | 12021801 | 2 |
| Caelo | Dexamethasone acetate | 12021803 | 3 |
| Caelo | Dexamethasone acetate | 12021811 | 1 |
| Caelo | Dexamethasone acetate | 12021814 | 2 |
| Caelo | Dexamethasone acetate | 13100401 | 1 |
| Caelo | Dexamethasone acetate | 13100403 | 5 |
| Caelo | Dexamethasone acetate | 13100404 | 3 |
| Caelo | Dexamethasone acetate | 13100406 | 1 |
| Caelo | Dexamethasone acetate | 13100407 | 4 |
| Caelo | Dexamethasone acetate | 13100408 | 2 |
| Caelo | Dexamethasone acetate | 13260701 | 4 |
| Caelo | Dexamethasone acetate | 13260702 | 1 |
| Caelo | Dexamethasone acetate | 13260703 | 3 |
| Caelo | Dexamethasone acetate | 13260705 | 1 |
| Caelo | Dexamethasone acetate | 1405024-01 | 1 |
| Caelo | Dexamethasone acetate | 140502403 | 1 |
| Caelo | Dexamethasone acetate | 14200201 | 3 |
| Caelo | Dexamethasone acetate | 14200205 | 3 |
| Caelo | Dexamethasone acetate | 14200207 | 1 |
| Caelo | Dexamethasone acetate | 14200208 | 2 |
| Caelo | Dexamethasone acetate | 14379601 | 1 |
| Caelo | Dexamethasone acetate | 14379602 | 2 |
| Caelo | Dexamethasone acetate | 14379607 | 5 |
| Caelo | Dexamethasone acetate | 14379608 | 1 |
| Caelo | Dexamethasone acetate | 14379609 | 3 |
| Caelo | Dexamethasone acetate | 14379611 | 3 |
| Caelo | Dexamethasone acetate | 14379615 | 4 |
| Caelo | Dexamethasone acetate | 14379616 | 5 |
| Caelo | Dexamethasone acetate | 14379617 | 1 |
| Caelo | Dexamethasone acetate | 15243201 | 5 |
| Caelo | Dexamethasone acetate | 15243202 | 4 |
| Caelo | Dexamethasone acetate | 15243203 | 1 |
| Caelo | Dexamethasone acetate | 16106601 | 1 |
| Caelo | Dexamethasone acetate | 16106602 | 3 |
| Caelo | Dexamethasone acetate | 16106603 | 6 |
| Caelo | Dexamethasone acetate | 16106603/171025DM | 1 |
| Caelo | Dexamethasone acetate | 16106604 | 2 |
| Caelo | Dexamethasone acetate | 16106607 | 4 |
| Caelo | Dexamethasone acetate | 16106608 | 5 |
| Caelo | Dexamethasone acetate | 16106609 | 1 |
| Caelo | Dexamethasone acetate | 16106610 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dexamethasone acetate | 16106611 | 2 |
| Caelo | Dexamethasone acetate | 16106612 | 2 |
| Caelo | Dexamethasone acetate | 16106613 | 4 |
| Caelo | Dexamethasone acetate | 16106615 | 2 |
| Caelo | Dexamethasone acetate | 16106616 | 8 |
| Caelo | Dexamethasone acetate | 161066165624 | 1 |
| Caelo | Dexamethasone acetate | 16106617 | 6 |
| Caelo | Dexamethasone acetate | 16106619 | 5 |
| Caelo | Dexamethasone acetate | 1610662 | 1 |
| Caelo | Dexamethasone acetate | 16106622 | 2 |
| Caelo | Dexamethasone acetate | 16106623 | 1 |
| Caelo | Dexamethasone acetate | 16106624 | 2 |
| Caelo | Dexamethasone acetate | 1708011-01 | 1 |
| Caelo | Dexamethasone acetate | 18041813 | 1 |
| Caelo | Dexamethasone acetate | 18173001 | 8 |
| Caelo | Dexamethasone acetate | 18173002 | 12 |
| Caelo | Dexamethasone acetate | 18173004 | 5 |
| Caelo | Dexamethasone acetate | 18173007 | 3 |
| Caelo | Dexamethasone acetate | 18173008 | 6 |
| Caelo | Dexamethasone acetate | 18173010 | 1 |
| Caelo | Dexamethasone acetate | 18173011 | 7 |
| Caelo | Dexamethasone acetate | 18173012 | 12 |
| Caelo | Dexamethasone acetate | 18173014 | 2 |
| Caelo | Dexamethasone acetate | 1873011 | 1 |
| Caelo | Dexamethasone acetate | 1911201 | 1 |
| Caelo | Dexamethasone acetate | 19119021 | 1 |
| Caelo | Dexamethasone acetate | 191192001 | 9 |
| Caelo | Dexamethasone acetate | 191192002 | 8 |
| Caelo | Dexamethasone acetate | 191192003 | 1 |
| Caelo | Dexamethasone acetate | 191192004 | 8 |
| Caelo | Dexamethasone acetate | 191192005 | 5 |
| Caelo | Dexamethasone acetate | 19119201 | 9 |
| Caelo | Dexamethasone acetate | 19119202 | 15 |
| Caelo | Dexamethasone acetate | 19119204 | 4 |
| Caelo | Dexamethasone acetate | 191192040 | 1 |
| Caelo | Dexamethasone acetate | 191192201 | 1 |
| Caelo | Dexamethasone acetate | 20002252001 | 8 |
| Caelo | Dexamethasone acetate | 200045290008 | 1 |
| Caelo | Dexamethasone acetate | 20004529001 | 10 |
| Caelo | Dexamethasone acetate | 20004529002 | 9 |
| Caelo | Dexamethasone acetate | 20004529003 | 12 |
| Caelo | Dexamethasone acetate | 20004529006 | 5 |
| Caelo | Dexamethasone acetate | 20004529008 | 7 |
| Caelo | Dexamethasone acetate | 20004529009 | 3 |
| Caelo | Dexamethasone acetate | 20004529010 | 4 |
| Caelo | Dexamethasone acetate | 20004529012 | 1 |
| Caelo | Dexamethasone acetate | 20004529014 | 1 |
| Caelo | Dexamethasone acetate | 20004529015 | 2 |
| Caelo | Dexamethasone acetate | 20004529016 | 4 |
| Caelo | Dexamethasone acetate | 20004529017 | 1 |
| Caelo | Dexamethasone acetate | 20004529018 | 2 |
| Caelo | Dexamethasone acetate | 20004529019 | 1 |
| Caelo | Dexamethasone acetate | 2004529003 | 1 |
| Caelo | Dexamethasone acetate | 2004529017 | 1 |
| Caelo | Dexamethasone acetate | 211118(20004529002) | 1 |
| Caelo | Dexamethasone acetate | 22/AKD2 | 1 |
| Caelo | Dexamethasone acetate | 3913Q-01326 | 1 |
| Caelo | Dexamethasone acetate | 4113I-01326 | 1 |
| Caelo | Dexamethasone acetate | 5/AD1 | 1 |
| Caelo | Dexamethasone acetate | 50(18173001) | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dexamethasone acetate | 51(19119204) | 1 |
| Caelo | Dexamethasone acetate | 8173004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 18173004 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 18173008 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 18173012 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 191192004 | 3 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 18173012 | 2 |
| Caesar & Loretz GmbH/Gehe | Dexamethasone acetate | 20004529001 | 1 |
| Caesar & Loretz GmbH/Gehe | Dexamethasone acetate | 20004529009 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 20004529001 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 20004529001 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 18173008 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 191192002 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 19119202 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 20004529015 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 19119202 | 2 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 18173011 | 1 |
| Caesar & Loretz GmbH... | Dexamethasone acetate | 19119202 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 18173001 | 3 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 18173002 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 18173007 | 2 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 18173008 | 3 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 18173010 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 18173012 | 6 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 191192001 | 7 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 191192004 | 2 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 191192005 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 19119202 | 2 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 19119203 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20002252001 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529001 | 4 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529002 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529003 | 4 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529006 | 2 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529008 | 1 |
| CAESAR & LORETZ GMBH | Dexamethasone acetate | 20004529008 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529009 | 1 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529010 | 3 |
| Caesar & Loretz GmbH | Dexamethasone acetate | 20004529015 | 4 |
| Caesar & Loretz Hilden | Dexamethasone acetate | 19119202 | 1 |
| Caesar und Loretz GmbH | Dexamethasone acetate | 18173011 | 1 |
| ERho | Dexamethasone acetate | 1405024-02 | 1 |
| EuRho/Jenne | Dexamethasone acetate | 1708011-02 | 1 |
| EuRho/Noweda | Dexamethasone acetate | 1708011-01 | 2 |
| Eurho/Sanacorp | Dexamethasone acetate | 1708011-01 | 1 |
| EuRho | Dexamethasone acetate | 1110007-01 | 1 |
| Euro OTC | Dexamethasone acetate | 1110007-01 | 4 |
| Euro OTC | Dexamethasone acetate | 1110007-02 | 5 |
| Euro OTC | Dexamethasone acetate | 1110007-03 | 1 |
| Euro OTC | Dexamethasone acetate | 1405024 | 1 |
| Euro OTC | Dexamethasone acetate | 1405024-01 | 1 |
| Euro OTC | Dexamethasone acetate | 140502402 | 1 |
| Euro OTC | Dexamethasone acetate | 1405024-02 | 9 |
| Euro OTC | Dexamethasone acetate | 140502403 | 1 |
| Euro OTC | Dexamethasone acetate | 1405024-03 | 20 |
| Euro OTC | Dexamethasone acetate | 1405024-04 | 2 |
| Euro OTC | Dexamethasone acetate | 1708011-01 | 25 |
| Euro OTC | Dexamethasone acetate | 1708011-02 | 6 |
| europharma | Dexamethasone acetate | 1110007-01 | 1 |
| Fagron | Dexamethasone acetate | 1110007 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Dexamethasone acetate | 1110007-01 | 1 |
| Fagron | Dexamethasone acetate | 14200207 | 1 |
| Fagron | Dexamethasone acetate | 1708011-01 | 2 |
| Fagron | Dexamethasone acetate | 18173002 | 1 |
| Fiebig | Dexamethasone acetate | 23000428005 | 1 |
| Geha | Dexamethasone acetate | 191192001 | 1 |
| Gehe | Dexamethasone acetate | 16106609 | 1 |
| Gehe | Dexamethasone acetate | 16106613 | 1 |
| Gehe | Dexamethasone acetate | 16106619 | 1 |
| Gehe | Dexamethasone acetate | 1708011-01 | 1 |
| Gehe | Dexamethasone acetate | 18173007 | 1 |
| Gehe | Dexamethasone acetate | 18173012 | 1 |
| gehe | Dexamethasone acetate | 19119021 | 1 |
| Gehe | Dexamethasone acetate | 20004529016 | 1 |
| Jenne | Dexamethasone acetate | 231128(20004529008) | 1 |
| Jenne | Dexamethasone acetate | 250701(24000144014) | 1 |
| Noweda | Dexamethasone acetate | 1110007-02 | 1 |
| Noweda | Dexamethasone acetate | 13100406 | 1 |
| Noweda | Dexamethasone acetate | 1708011-02 | 1 |
| Noweda | Dexamethasone acetate | 18173010 | 1 |
| Noweda | Dexamethasone acetate | 20004529015 | 1 |
| Noweda | Dexamethasone acetate | 23000428005 | 1 |
| Phoenix | Dexamethasone acetate | 20004529018 | 1 |
| Phoenix | Dexamethasone acetate | 23000428005 | 1 |
| Phönix | Dexamethasone acetate | | 1 |
| Phönix | Dexamethasone acetate | 16106603 | 1 |
| Sanacorp | Dexamethasone acetate | 14379611 | 1 |
| Sanacorp | Dexamethasone acetate | 16106613 | 1 |
| Sanacorp | Dexamethasone acetate | 1708011-01 | 1 |
| Sanacorp | Dexamethasone acetate | 1708011-02 | 1 |
| Sanacorp | Dexamethasone acetate | 29994529018 | 1 |
| Sanofi Chimie/ Gehe | Dexamethasone acetate | 18173004 | 1 |

- 256 319 spectra from 1666 *Apo-Ident* customers from a total of 52 028 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Dexamethasone acetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Dexamethasone acetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 489 | 0 | 157 837 |
| **Type B** | 0 | 281 | 0 | 212 659 |
| **Type C** | 0 | 535 | 32 | 256 319 |

The substance/substance group *Dexamethasone acetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7730 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.8648 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 94.3563 % (> 93.8272 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21301 | 21301 | 0.00 | 153.16 |
| 21593 | 21593 | 0.00 | 154.71 |
| 21614 | 21301 | 8.01 | 155.35 |
| 21815 | 21593 | 12.72 | 153.79 |
| 23693 | 23693 | 0.00 | 162.45 |
| 25448 | 25448 | 0.00 | 196.30 |
| 26942 | 26942 | 0.00 | 229.07 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Dextromethorphan hydrobromide monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22318-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Dextromethorphan hydrobromide monohydrate; Dextromethorphani hydrobromidum monohydricum

### Special notes

When selecting the *Dextromethorphan hydrobromide monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Dextromethorphan hydrobromide monohydrate | 7 | 3 | 10 |

### Second-stage model

For differentiation of the substance/substance group *Dextromethorphan hydrobromide monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Dextromethorphan hydrobromide monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 102.36 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Dextromethorphan hydrobromide monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Dextromethorphan hydrobromide monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Dextromethorphan hydrobro… | 15D23-B07-308849 | 22318 | 60 | AR-16-FG-008487-02 |
| Fagron | Dextromethorphan hydrobro… | 15D23-B07-308849 | 22326 | 60 | 20150508 |
| Fagron | Dextromethorphan hydrobro… | 16A22-B03-321371 | 23103 | 40 | 20160205 |
| Fagron | Dextromethorphan hydrobro… | 17B28-B01-341594 | 23780 | 40 | 20170612 |
| Fagron | Dextromethorphan hydrobro… | 19A08-B03-363561 | 24949 | 40 | 20190201 |
| Fagron | Dextromethorphan hydrobro… | 21F02-B05-221069 | 26283 | 40 | 20210909 |
| Fagron | Dextromethorphan hydrobro… | 21F02-B05-221069 | 26283SI | 20 | 20210909 |
| Fagron | Dextromethorphan hydrobro… | 23A21-B02-225362 | 26633 | 40 | 20230222 |
| Fagron | Dextromethorphan hydrobro… | 23E30-B01-230367 | 26817 | 40 | 20230616 |
| Fagron | Dextromethorphan hydrobro… | 23E30-B01-230367 | 26817SI | 20 | 20230616 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 400 spectra of 10 reference samples from the substance/substance group *Dextromethorphan hydrobromide monohydrate*. These samples are listed above in the *calibration samples* section.


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The reference samples come from 7 different batches.

- 157 926 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Dextromethorphan hydrobromide monohydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Dextromethorphan hydrobro… | 16E23-B02-329706 | 23593 | 40 |
| Fagron | Dextromethorphan hydrobro… | 18B09-B02-350261 | 24288 | 40 |
| Fagron | Dextromethorphan hydrobro… | 23L12-B03-234621 | 27166 | 40 |
| Fagron | Dextromethorphan hydrobro… | 23A21-B02-225362 | 26633SI† | 20 |

- 212 800 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 27 spectra from 10 *Apo-Ident* customers from 14 batches from the substance/substance group *Dextromethorphan hydrobromide monohydrate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Dextromethorphan hydrobro… | 23A21-B02-225362 | 1 |
| Anzag | Dextromethorphan hydrobro… | 23L12-B03-123621 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag | Dextromethorphan hydrobro… | 23L2-B03-234621 | 1 |
| Caelo | Dextromethorphan hydrobro… | 17B28-B01-345398 | 1 |
| Fagron | Dextromethorphan hydrobro… | 14H27-B04-299502 | 7 |
| Fagron | Dextromethorphan hydrobro… | 16A22-B03-319331 | 1 |
| Fagron | Dextromethorphan hydrobro… | 16A22-B03-321371 | 5 |
| Fagron | Dextromethorphan hydrobro… | 18809-B02-358862 | 1 |
| Fagron | Dextromethorphan hydrobro… | 18B09-B02-350261 | 1 |
| Fagron | Dextromethorphan hydrobro… | 18B09-B02-358862 | 1 |
| Fagron | Dextromethorphan hydrobro… | 19A08-B03-363561 | 1 |
| Fagron | Dextromethorphan hydrobro… | 23L12-B03-234621 | 3 |
| Gehe | Dextromethorphan hydrobro… | 23A21-B02-225362 | 1 |
| Gehe | Dextromethorphan hydrobro… | 23E30-B01-230367 | 1 |
| Phoenix | Dextromethorphan hydrobro… | 19A08-B03-363562 | 1 |

- 256 859 spectra from 1666 *Apo-Ident* customers from a total of 52 140 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Dextromethorphan hydrobromide monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Dextromethorphan hydrobromide monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 27 | 0 | 256 859 |

The substance/substance group *Dextromethorphan hydrobromide monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 77.7778 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22318 | 22318 | 0.00 | 130.50 |
| 22326 | 22318 | 4.54 | 130.27 |
| 23103 | 22318 | 7.03 | 130.70 |
| 23780 | 22318 | 10.76 | 130.91 |
| 24949 | 22318 | 13.46 | 132.64 |
| 26283 | 22318 | 10.15 | 130.98 |
| 26633 | 22318 | 12.57 | 131.57 |
| 26817 | 22318 | 14.33 | 131.21 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Diclofenac sodium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20022-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Diclofenac sodium; Diclofenacum natricum

### Special notes

When selecting the *Diclofenac sodium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Diclofenac sodium | 7 | 10 | 201 |

### Second-stage model

For differentiation of the substance/substance group *Diclofenac sodium* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Diclofenac sodium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 141.05 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Diclofenac sodium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Diclofenac sodium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Diclofenac sodium | 12214219 | 20883 | 20 | 20120815 |
| Caelo | Diclofenac sodium | 13214311 | 21467 | 60 | 20130826 |
| Caelo | Diclofenac sodium | 13214311 | 21470 | 60 | 20130826 |
| Caelo | Diclofenac sodium | 163492 | 23037 | 40 | 20170112* |
| Euro OTC | Diclofenac sodium | 1403013-01 | 21330 | 40 | 20140401 |
| Euro OTC | Diclofenac sodium | 1607016 | 22694 | 40 | 20160808* |
| Fagron | Diclofenac sodium | 13E03-N02 | 20886 | 40 | 20130515 |
| Fagron | Diclofenac sodium | 12L28-B05 | 21261 | 40 | 20130123 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 340 spectra of 8 reference samples from the substance/substance group *Diclofenac sodium*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 986 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 470 spectra of 13 reference samples from the substance/substance group *Diclofenac sodium*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Diclofenac sodium | 21000065 | 25860 | 50 |
| Caelo | Diclofenac sodium | 25000032 | 27556 | 40 |
| Euro OTC | Diclofenac sodium | 1711026 | 23872 | 40 |
| Euro OTC | Diclofenac sodium | 1904008 | 24618 | 40 |
| Euro OTC | Diclofenac sodium | 2009027 | 25416 | 40 |
| Euro OTC | Diclofenac sodium | 2307012 | 26857 | 30 |
| Euro OTC | Diclofenac sodium | 2411004 | 27493 | 40 |
| Fagron | Diclofenac sodium | 15D14-B04-307452 | 21979 | 60 |
| Fagron | Diclofenac sodium | 19L02-F02-367737 | 25176 | 40 |
| Fagron | Diclofenac sodium | 22L20-B04-230962 | 27167 | 40 |
| Caelo | Diclofenac sodium | 21000065 | 25860SI | 10 |
| Euro OTC | Diclofenac sodium | 2307012 | 26857SI | 20 |
| Fagron | Diclofenac sodium | 22L20-B04-230962 | 27167SI | 20 |

- 212 470 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 823 spectra from 373 *Apo-Ident* customers from 210 batches from the substance/substance group *Diclofenac sodium*.

- Among them are spectra of independent samples from 200 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Diclofenac sodium | 2009027 | 2 |
| | Diclofenac sodium | 2009027-02 | 3 |
| | Diclofenac sodium | 2009027-03 | 2 |
| | Diclofenac sodium | 2009027-05 | 8 |
| | Diclofenac sodium | 21000065011 | 1 |
| | Diclofenac sodium | 21000065016 | 2 |
| | Diclofenac sodium | 21I29-B06 | 1 |
| | Diclofenac sodium | 21I29-B06-213571 | 1 |
| | Diclofenac sodium | 21I29-B06-221805 | 6 |
| | Diclofenac sodium | 21l29-B06-213571 | 1 |
| | Diclofenac sodium | 22L20_B04-230962 | 1 |
| | Diclofenac sodium | 22L20-B01-230962 | 1 |
| | Diclofenac sodium | 22L20-B04-230962 | 6 |
| | Diclofenac sodium | 22L20-B04-239660 | 1 |
| | Diclofenac sodium | 23000021001 | 1 |
| | Diclofenac sodium | 23000021006 | 1 |
| | Diclofenac sodium | 23000021007 | 4 |
| | Diclofenac sodium | 230701201 | 1 |
| | Diclofenac sodium | 2307012-01 | 12 |
| | Diclofenac sodium | 2307012-02 | 1 |
| | Diclofenac sodium | 24000148006 | 2 |
| | Diclofenac sodium | 24000148007 | 1 |
| | Diclofenac sodium | 24F24-B09-004650 | 3 |
| | Diclofenac sodium | 8/0206A | 1 |
| | Diclofenac sodium | 80423750002 | 1 |
| | Diclofenac sodium | A22370D230 | 1 |
| | Diclofenac sodium | RDS/2108/0206A | 2 |
| | Diclofenac sodium | RDS21080206A | 1 |
| AHD | Diclofenac sodium | 1503014-01 | 1 |
| AHD | Diclofenac sodium | 15D14B04314450 | 1 |
| Aliance Healthcare | Diclofenac sodium | 2009027-03 | 1 |
| Amoli/Phoenix | Diclofenac sodium | 20J01-F09 | 1 |
| Amoli/Phoenix | Diclofenac sodium | RDS/1807/0134A | 1 |
| Amoli | Diclofenac sodium | 1503014-01 | 1 |
| Bombastus | Diclofenac sodium | 1711026-01 | 1 |
| Caeli/Alliance | Diclofenac sodium | 18202602 | 1 |
| Caelo | Diclofenac sodium | 11091201 | 1 |
| Caelo | Diclofenac sodium | 12214202 | 1 |
| Caelo | Diclofenac sodium | 12214205 | 1 |
| Caelo | Diclofenac sodium | 12214206 | 1 |
| Caelo | Diclofenac sodium | 12214219 | 2 |
| Caelo | Diclofenac sodium | 12L28-B05 | 1 |
| Caelo | Diclofenac sodium | 13214303 | 2 |
| Caelo | Diclofenac sodium | 13214304 | 1 |
| Caelo | Diclofenac sodium | 13214308 | 4 |
| Caelo | Diclofenac sodium | 13214309 | 3 |
| Caelo | Diclofenac sodium | 13214311 | 8 |
| Caelo | Diclofenac sodium | 13214312 | 2 |
| Caelo | Diclofenac sodium | 13214316 | 1 |
| Caelo | Diclofenac sodium | 13214317 | 5 |
| Caelo | Diclofenac sodium | 13214318 | 4 |
| Caelo | Diclofenac sodium | 140301301 | 1 |
| Caelo | Diclofenac sodium | 1503014-01 | 3 |
| Caelo | Diclofenac sodium | 15169604 | 7 |
| Caelo | Diclofenac sodium | 15169609 | 2 |
| Caelo | Diclofenac sodium | 15169613 | 2 |
| Caelo | Diclofenac sodium | 15169615 | 1 |
| Caelo | Diclofenac sodium | 15169617 | 1 |
| Caelo | Diclofenac sodium | 15169675 | 1 |
| Caelo | Diclofenac sodium | 15278501 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Diclofenac sodium | 15278502 | 2 |
| Caelo | Diclofenac sodium | 15278505 | 2 |
| Caelo | Diclofenac sodium | 15278506 | 3 |
| Caelo | Diclofenac sodium | 15278507 | 1 |
| Caelo | Diclofenac sodium | 15K23-B03-318519 | 2 |
| Caelo | Diclofenac sodium | 15K23-B03-325753 | 2 |
| Caelo | Diclofenac sodium | 15K23-B03-325753 | 1 |
| Caelo | Diclofenac sodium | 16/29-B04-334699 | 1 |
| Caelo | Diclofenac sodium | 1607016-03 | 1 |
| Caelo | Diclofenac sodium | 16349207 | 3 |
| Caelo | Diclofenac sodium | 16349208 | 1 |
| Caelo | Diclofenac sodium | 1711026-01 | 1 |
| Caelo | Diclofenac sodium | 1711026-02 | 1 |
| Caelo | Diclofenac sodium | 1711026-03 | 1 |
| Caelo | Diclofenac sodium | 17J19-B01-345397 | 1 |
| Caelo | Diclofenac sodium | 17J19-B01-352716 | 1 |
| Caelo | Diclofenac sodium | 18039202 | 1 |
| Caelo | Diclofenac sodium | 18039203 | 3 |
| Caelo | Diclofenac sodium | 18039208 | 1 |
| Caelo | Diclofenac sodium | 18039210 | 2 |
| Caelo | Diclofenac sodium | 182026003 | 1 |
| Caelo | Diclofenac sodium | 182026004 | 5 |
| Caelo | Diclofenac sodium | 18202602 | 3 |
| Caelo | Diclofenac sodium | 18202606 | 1 |
| Caelo | Diclofenac sodium | 18202609 | 7 |
| Caelo | Diclofenac sodium | 20003803001 | 3 |
| Caelo | Diclofenac sodium | 20003803002 | 3 |
| Caelo | Diclofenac sodium | 20003803004 | 2 |
| Caelo | Diclofenac sodium | 2000383002 | 1 |
| Caelo | Diclofenac sodium | 2100005012 | 1 |
| Caelo | Diclofenac sodium | 21000065003 | 1 |
| Caelo | Diclofenac sodium | 21000065004 | 2 |
| Caelo | Diclofenac sodium | 21000065006 | 2 |
| Caelo | Diclofenac sodium | 21000065009 | 3 |
| Caelo | Diclofenac sodium | 2100006501 | 1 |
| Caelo | Diclofenac sodium | 21000065012 | 4 |
| Caelo | Diclofenac sodium | 21I29-B06-221805 | 1 |
| Caelo | Diclofenac sodium | 5081501 | 1 |
| Caesar & Loretz GmbH... | Diclofenac sodium | 23000021002 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 18039210 | 2 |
| Caesar & Loretz GmbH | Diclofenac sodium | 182026004 | 2 |
| Caesar & Loretz GmbH | Diclofenac sodium | 18202601 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 18202602 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 18202606 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 18202609 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 20003803001 | 3 |
| Caesar & Loretz GmbH | Diclofenac sodium | 20003803002 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 20003803004 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 21000065002 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 21000065006 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 21000065012 | 3 |
| Caesar & Loretz GmbH | Diclofenac sodium | 21000065013 | 1 |
| Caesar & Loretz GmbH | Diclofenac sodium | 21000065015 | 2 |
| Cealo | Diclofenac sodium | 160701601 | 1 |
| Euph/Sanacorp | Diclofenac sodium | 171102603 | 1 |
| EuRho / Gehe | Diclofenac sodium | 2009027-02 | 2 |
| EuRho /Gumo | Diclofenac sodium | 1711028-03 | 1 |
| EuRho/Anzag | Diclofenac sodium | 1904008-02 | 1 |
| EuRho/Jenne | Diclofenac sodium | 1(1711026-03) | 1 |
| EuRho/Noweda | Diclofenac sodium | 2009027 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Eurho/Noweda | Diclofenac sodium | 2009027-02 | 1 |
| EuRho/Noweda | Diclofenac sodium | 2009027-02 | 2 |
| EuRho/Sanacorp | Diclofenac sodium | 1711026-02 | 2 |
| EuRho/Sanacorp | Diclofenac sodium | 1904008-02 | 1 |
| EuRho/Sanacorp | Diclofenac sodium | 2009027-01 | 1 |
| EuRho/Spangro | Diclofenac sodium | 1607016-03 | 5 |
| EuRho/Spangro | Diclofenac sodium | 1711026-02 | 2 |
| EuRho | Diclofenac sodium | 1206026-02 | 1 |
| EuRho | Diclofenac sodium | 1503014-01 | 1 |
| EuRho | Diclofenac sodium | 2009027-02 | 1 |
| Euro OTC | Diclofenac sodium | 11091404 | 1 |
| Euro OTC | Diclofenac sodium | 1111040-01 | 2 |
| Euro OTC | Diclofenac sodium | 12060250 | 1 |
| Euro OTC | Diclofenac sodium | 1206026 | 1 |
| Euro OTC | Diclofenac sodium | 1206026-01 | 7 |
| Euro OTC | Diclofenac sodium | 1206026-02 | 3 |
| Euro OTC | Diclofenac sodium | 12214220 | 1 |
| Euro OTC | Diclofenac sodium | 13111203 | 1 |
| Euro OTC | Diclofenac sodium | 140301301 | 1 |
| Euro OTC | Diclofenac sodium | 1403013-01 | 5 |
| Euro OTC | Diclofenac sodium | 1403013-02 | 7 |
| Euro OTC | Diclofenac sodium | 1403013-03 | 3 |
| Euro OTC | Diclofenac sodium | 1503014-01 | 12 |
| Euro OTC | Diclofenac sodium | 1503014-02 | 6 |
| Euro OTC | Diclofenac sodium | 15169606 | 1 |
| Euro OTC | Diclofenac sodium | 15K23-B03-321673 | 1 |
| Euro OTC | Diclofenac sodium | 16067016-03 | 1 |
| Euro OTC | Diclofenac sodium | 1607016-01 | 33 |
| Euro OTC | Diclofenac sodium | 1607016-02 | 17 |
| Euro OTC | Diclofenac sodium | 1607016-03 | 24 |
| Euro OTC | Diclofenac sodium | 1711023-03 | 1 |
| Euro OTC | Diclofenac sodium | 1711026 | 2 |
| Euro OTC | Diclofenac sodium | 1711026-01 | 17 |
| Euro OTC | Diclofenac sodium | 171102602 | 2 |
| Euro OTC | Diclofenac sodium | 1711026-02 | 17 |
| Euro OTC | Diclofenac sodium | 171102603 | 3 |
| Euro OTC | Diclofenac sodium | 1711026-03 | 41 |
| Euro OTC | Diclofenac sodium | 1711026-1 | 1 |
| Euro OTC | Diclofenac sodium | 17111026_01 | 1 |
| Euro OTC | Diclofenac sodium | 17J19-B01-350960 | 2 |
| Euro OTC | Diclofenac sodium | 1807016-01 | 1 |
| Euro OTC | Diclofenac sodium | 182026004 | 2 |
| Euro OTC | Diclofenac sodium | 1904008 | 2 |
| Euro OTC | Diclofenac sodium | 190400801 | 3 |
| Euro OTC | Diclofenac sodium | 1904008-01 | 16 |
| Euro OTC | Diclofenac sodium | 1904008-02 | 31 |
| Euro OTC | Diclofenac sodium | 1904008-1 | 1 |
| Euro OTC | Diclofenac sodium | 1904008-2 | 1 |
| Euro OTC | Diclofenac sodium | 194008-02 | 1 |
| Euro OTC | Diclofenac sodium | 19404008-01 | 1 |
| Euro OTC | Diclofenac sodium | 2009027 | 1 |
| Euro OTC | Diclofenac sodium | 2009027-01 | 18 |
| Euro OTC | Diclofenac sodium | 2009027-02 | 38 |
| Euro OTC | Diclofenac sodium | 2009027-03 | 12 |
| Euro OTC | Diclofenac sodium | 2009027-04 | 1 |
| Euro OTC | Diclofenac sodium | 2009027-05 | 1 |
| Euro OTC | Diclofenac sodium | 2091715 | 1 |
| Euro OTC | Diclofenac sodium | 21031703 | 1 |
| Euro OTC | Diclofenac sodium | 23051814 | 1 |
| Euro OTC | Diclofenac sodium | 25041403 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Diclofenac sodium | 301180730-21 | 1 |
| Euro OTC | Diclofenac sodium | 301200712-52 | 1 |
| Euro OTC | Diclofenac sodium | 31101802 | 1 |
| Euro OTC | Diclofenac sodium | 8051812 | 1 |
| Euro OTC | Diclofenac sodium | AP201218-03 | 1 |
| Euro OTC | Diclofenac sodium | AP210516-20 | 1 |
| EURO/all | Diclofenac sodium | 135796 | 1 |
| Euro/Anzag | Diclofenac sodium | 1607016-03 | 1 |
| Euro/L10 | Diclofenac sodium | 1711026031904008-01 | 1 |
| EURO/Noweda | Diclofenac sodium | 140301301 | 1 |
| Euro/Phönix | Diclofenac sodium | 1711026 | 1 |
| Euro/Phönix | Diclofenac sodium | 2009027-02 | 1 |
| Europharm/Otto | Diclofenac sodium | 135796 | 1 |
| EurRho/ Anzag | Diclofenac sodium | 1403013-03 | 1 |
| Fagron | Diclofenac sodium | | 1 |
| Fagron | Diclofenac sodium | 10031505 | 1 |
| Fagron | Diclofenac sodium | 12L28-B05-289773 | 2 |
| Fagron | Diclofenac sodium | 135796-0002 | 1 |
| Fagron | Diclofenac sodium | 13E03-N02 | 1 |
| Fagron | Diclofenac sodium | 13H22-N10 | 1 |
| Fagron | Diclofenac sodium | 14031411 | 1 |
| Fagron | Diclofenac sodium | 14G17-B08-0159A | 1 |
| Fagron | Diclofenac sodium | 14G17B08297032 | 1 |
| Fagron | Diclofenac sodium | 14G17-B08-297032 | 6 |
| Fagron | Diclofenac sodium | 15D14-B04 | 1 |
| Fagron | Diclofenac sodium | 15D14-B04-307452 | 1 |
| Fagron | Diclofenac sodium | 15D14-B04-314450 | 4 |
| Fagron | Diclofenac sodium | 15D14-B04-315835 | 1 |
| Fagron | Diclofenac sodium | 15K23-B03 | 1 |
| Fagron | Diclofenac sodium | 15K23-B03-318519 | 2 |
| Fagron | Diclofenac sodium | 15K23-B03-321673 | 6 |
| Fagron | Diclofenac sodium | 15K23-B03-324025 | 6 |
| Fagron | Diclofenac sodium | 15K23-B03-325753 | 5 |
| Fagron | Diclofenac sodium | 15K23-B03-327802 | 5 |
| Fagron | Diclofenac sodium | 16/29-B04-332372 | 1 |
| Fagron | Diclofenac sodium | 1607016-03 | 3 |
| Fagron | Diclofenac sodium | 16I29-B04 | 1 |
| Fagron | Diclofenac sodium | 16I29-B04-332372 | 4 |
| Fagron | Diclofenac sodium | 16l29 | 1 |
| Fagron | Diclofenac sodium | 17F02 | 1 |
| Fagron | Diclofenac sodium | 17F02-B05 | 1 |
| Fagron | Diclofenac sodium | 17F02-B05-338797 | 8 |
| Fagron | Diclofenac sodium | 17J19-B01 | 1 |
| Fagron | Diclofenac sodium | 17j19-B01-342310 | 1 |
| Fagron | Diclofenac sodium | 17J19-B01-342310 | 4 |
| Fagron | Diclofenac sodium | 17J19-B01-345397 | 2 |
| Fagron | Diclofenac sodium | 17J19-B01-350960 | 3 |
| Fagron | Diclofenac sodium | 17J19-B01-352716 | 3 |
| Fagron | Diclofenac sodium | 17j19-b01-354796 | 1 |
| Fagron | Diclofenac sodium | 17j19-B01-354796 | 1 |
| Fagron | Diclofenac sodium | 17J19-B01-354796 | 2 |
| Fagron | Diclofenac sodium | 17J19-B01B350960 | 1 |
| Fagron | Diclofenac sodium | 18H24-B07 | 2 |
| Fagron | Diclofenac sodium | 18H24-B07-357416 | 5 |
| Fagron | Diclofenac sodium | 18H24-B07-358891 | 5 |
| Fagron | Diclofenac sodium | 19L02-F02 | 1 |
| Fagron | Diclofenac sodium | 19L02-F02-367737 | 5 |
| Fagron | Diclofenac sodium | 19L02-F02-368388 | 3 |
| Fagron | Diclofenac sodium | 19L02-f02-369055 | 1 |
| Fagron | Diclofenac sodium | 19L02-F02-369055 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Diclofenac sodium | 19L02-F02-367737 | 1 |
| Fagron | Diclofenac sodium | 20J01-F090 | 1 |
| Fagron | Diclofenac sodium | 20J01-F09-0043A | 1 |
| Fagron | Diclofenac sodium | 20J01-F09-374507 | 6 |
| Fagron | Diclofenac sodium | 21129-B06-221805 | 1 |
| Fagron | Diclofenac sodium | 21129-BO6-221805 | 1 |
| Fagron | Diclofenac sodium | 21C26-F04-377842 | 5 |
| Fagron | Diclofenac sodium | 21I29-B06-221805 | 12 |
| Fagron | Diclofenac sodium | 314450 | 1 |
| Fagron | Diclofenac sodium | 5041401 | 1 |
| Fagron | Diclofenac sodium | F02-3677307 | 1 |
| Fagron | Diclofenac sodium | F02-367737 | 1 |
| Fagron | Diclofenac sodium | F02-3683808 | 2 |
| Fagron | Diclofenac sodium | f04-3778402 | 1 |
| Fagron | Diclofenac sodium | F09-3745007 | 2 |
| Fagron | Diclofenac sodium | RDS/1405/0159A | 1 |
| Fagron | Diclofenac sodium | RDS/1607/334699 | 1 |
| Fargon GmbH & Co.KG | Diclofenac sodium | 15K23-B03-325753 | 1 |
| Fargron | Diclofenac sodium | 14G17-B08-297032 | 1 |
| FIEBIG | Diclofenac sodium | 20003803002 | 1 |
| Fischar/Phönix | Diclofenac sodium | 13214311 | 1 |
| Fragon/Sanacorp | Diclofenac sodium | 19L02-F02-3699055 | 1 |
| Gehe | Diclofenac sodium | 1206026-01 | 1 |
| Gehe | Diclofenac sodium | 15278502 | 1 |
| Gehe | Diclofenac sodium | 1711026-03 | 1 |
| GEHE | Diclofenac sodium | 17J19-B01-342310 | 1 |
| Gehe | Diclofenac sodium | 1904008-01 | 2 |
| Gehe | Diclofenac sodium | 547718202609 | 1 |
| Gehe | Diclofenac sodium | A22370D230 | 1 |
| Geilenkirchen | Diclofenac sodium | 15278502 | 2 |
| Hedinger/Phoenix | Diclofenac sodium | 15278506 | 3 |
| Hubei Gedian Humanwe... | Diclofenac sodium | 1711026-02 | 1 |
| JENNE | Diclofenac sodium | 17J19-B01 | 1 |
| Kehr | Diclofenac sodium | 1711026-03 | 1 |
| kehr | Diclofenac sodium | 2009027-03 | 1 |
| kehr | Diclofenac sodium | 230701201 | 1 |
| L11 | Diclofenac sodium | 15278506 | 1 |
| L12 | Diclofenac sodium | 18039202 | 1 |
| Noveda | Diclofenac sodium | 30120071252 | 1 |
| Noweda/EuRho | Diclofenac sodium | 1904008-02 | 1 |
| Noweda | Diclofenac sodium | 11G12-N06 | 1 |
| Noweda | Diclofenac sodium | 1403013-01 | 1 |
| Noweda | Diclofenac sodium | 15278504 | 1 |
| Noweda | Diclofenac sodium | 1711026-03 | 1 |
| Noweda | Diclofenac sodium | 18039202 | 1 |
| Noweda | Diclofenac sodium | 18202602 | 1 |
| Noweda | Diclofenac sodium | 1904008-01 | 1 |
| Noweda | Diclofenac sodium | 19L02-F02-367737 | 1 |
| Noweda | Diclofenac sodium | 2009027-03 | 3 |
| NOWEDA | Diclofenac sodium | 2009027-05 | 1 |
| Noweda | Diclofenac sodium | 23000021007 | 1 |
| Noweda | Diclofenac sodium | 2307012-01 | 1 |
| Noweda | Diclofenac sodium | 24000148006 | 1 |
| Phoenix | Diclofenac sodium | 15K23-B03 | 1 |
| Phoenix | Diclofenac sodium | 1711026-02 | 1 |
| Phoenix | Diclofenac sodium | 19L02-F02-368388 | 1 |
| Phönix | Diclofenac sodium | 1403013-03 | 1 |
| Phönix | Diclofenac sodium | 1607016-02 | 1 |
| Phönix | Diclofenac sodium | 1711026-03 | 1 |
| PHÖNIX | Diclofenac sodium | 17F02-B05 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Diclofenac sodium | 17F02-B05-338797 | 1 |
| Phönix | Diclofenac sodium | 21i29-b06-213571 | 1 |
| Phönix | Diclofenac sodium | F02-3677307 | 1 |
| sana | Diclofenac sodium | 2009027-03 | 1 |
| Sanacorp | Diclofenac sodium | 1206026-01 | 1 |
| SANACORP | Diclofenac sodium | 18039204 | 1 |
| SANACORP | Diclofenac sodium | 18202606 | 1 |
| Sanacorp | Diclofenac sodium | 2009027-03 | 1 |
| Sanacorp | Diclofenac sodium | 3616Q-02994 | 1 |
| siehe Protokoll | Diclofenac sodium | 15169617 | 1 |

- 256 063 spectra from 1666 *Apo-Ident* customers from a total of 51 943 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Diclofenac sodium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Diclofenac sodium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 340 | 0 | 157 986 |
| **Type B** | 0 | 470 | 0 | 212 470 |
| **Type C** | 0 | 820 | 3 | 256 063 |

The substance/substance group *Diclofenac sodium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2353 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7234 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6355 % (> 99.2710 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20883 | 23037 | 10.88 | 318.72 |
| 20886 | 23037 | 24.55 | 326.51 |
| 21261 | 23037 | 29.62 | 317.71 |
| 21330 | 23037 | 18.01 | 326.46 |
| 21467 | 23037 | 16.55 | 323.47 |
| 21470 | 23037 | 6.99 | 329.73 |
| 22694 | 22694 | 0.00 | 257.13 |
| 23037 | 23037 | 0.00 | 321.60 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Diltiazem hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20043-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Diltiazem hydrochloride; Diltiazemi hydrochloridum

### Special notes

When selecting the *Diltiazem hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Diltiazem hydrochloride | 6 | 6 | 692 |

### Second-stage model

For differentiation of the substance/substance group *Diltiazem hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Diltiazem hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cocaine hydrochloride | 73.08 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Diltiazem hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Diltiazem hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Diltiazem hydrochloride | 13346914 | 21300 | 40 | 20131028 |
| Caelo | Diltiazem hydrochloride | 13346914 | 21406 | 60 | 20131028 |
| Caelo | Diltiazem hydrochloride | 13346914 | 21407 | 60 | 20131028 |
| Caelo | Diltiazem hydrochloride | 161908 | 22631 | 40 | 20160715* |
| Caelo | Diltiazem hydrochloride | 170432 | 23325 | 40 | 20170331* |
| Fagron | Diltiazem hydrochloride | 14C12-B04 | 21270 | 40 | 20140417 |
| Fagron | Diltiazem hydrochloride | 16G20-B03-328133 | 23015 | 40 | 20160829 |
| Fagron | Diltiazem hydrochloride | 16G20-B03-328133 | 23016 | 40 | 20160829 |
| Fagron | Diltiazem hydrochloride | 20C12-F03-371907 | 25365 | 40 | 20200713 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 9 reference samples from the substance/substance group *Diltiazem hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 926 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 300 spectra of 9 reference samples from the substance/substance group *Diltiazem hydrochloride*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Diltiazem hydrochloride | 173370 | 23826 | 40 |
| Caelo | Diltiazem hydrochloride | 183011 | 24389 | 40 |
| Caelo | Diltiazem hydrochloride | 190841 | 24505 | 40 |
| Caelo | Diltiazem hydrochloride | 22001215 | 26115 | 40 |
| Caelo | Diltiazem hydrochloride | 23001896 | 26950 | 40 |
| Fagron | Diltiazem hydrochloride | 23H17-B02-238695 | 27376 | 40 |
| Caelo | Diltiazem hydrochloride | 22001215 | 26115SI | 20 |
| Caelo | Diltiazem hydrochloride | 23001896 | 26950SI | 20 |
| Fagron | Diltiazem hydrochloride | 23H17-B02-238695 | 27376SI | 20 |

- 212 640 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 5042 spectra from 1264 *Apo-Ident* customers from 749 batches from the substance/substance group *Diltiazem hydrochloride*.

- Among them are spectra of independent samples from 691 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Diltiazem hydrochloride | | 1 |
| | Diltiazem hydrochloride | 135968-0009 | 1 |
| | Diltiazem hydrochloride | 181023/6 | 1 |
| | Diltiazem hydrochloride | 20000622015 | 2 |
| | Diltiazem hydrochloride | 20C12-F03-371907 | 1 |
| | Diltiazem hydrochloride | 21000035016 | 1 |
| | Diltiazem hydrochloride | 21000035017 | 1 |
| | Diltiazem hydrochloride | 21D26-F02-378333 | 1 |
| | Diltiazem hydrochloride | 21F11-B03-218832 | 1 |
| | Diltiazem hydrochloride | 21F11B03218858 | 1 |
| | Diltiazem hydrochloride | 21F11-B03-218858 | 2 |
| | Diltiazem hydrochloride | 21F11-B03-221071 | 1 |
| | Diltiazem hydrochloride | 21F11-B03-223064 | 7 |
| | Diltiazem hydrochloride | 21F11-BB03-221071 | 1 |
| | Diltiazem hydrochloride | 21F11-Bo3-221072 | 1 |
| | Diltiazem hydrochloride | 22/13-B07-223063 | 2 |
| | Diltiazem hydrochloride | 22/13-B07225364 | 1 |
| | Diltiazem hydrochloride | 22001215001 | 4 |
| | Diltiazem hydrochloride | 22001215002 | 1 |
| | Diltiazem hydrochloride | 22001215009 | 1 |
| | Diltiazem hydrochloride | 22001215011 | 2 |
| | Diltiazem hydrochloride | 22001215012 | 10 |
| | Diltiazem hydrochloride | 22001215013 | 1 |
| | Diltiazem hydrochloride | 22001215015 | 4 |
| | Diltiazem hydrochloride | 22001215017 | 3 |
| | Diltiazem hydrochloride | 22001215018 | 6 |
| | Diltiazem hydrochloride | 22001215019 | 12 |
| | Diltiazem hydrochloride | 22001215024 | 17 |
| | Diltiazem hydrochloride | 22001215026 | 12 |
| | Diltiazem hydrochloride | 22001215028 | 2 |
| | Diltiazem hydrochloride | 22001215029 | 36 |
| | Diltiazem hydrochloride | 22001215030 | 68 |
| | Diltiazem hydrochloride | 2200121512 | 1 |
| | Diltiazem hydrochloride | 2201215029 | 1 |
| | Diltiazem hydrochloride | 22113-B07-220363 | 1 |
| | Diltiazem hydrochloride | 22113-B07-223063 | 2 |
| | Diltiazem hydrochloride | 22113-B07-223065 | 1 |
| | Diltiazem hydrochloride | 227683 | 1 |
| | Diltiazem hydrochloride | 22I13-B07-223063 | 18 |
| | Diltiazem hydrochloride | 22I13-B07-223065 | 1 |
| | Diltiazem hydrochloride | 22I13-B07-225364 | 13 |
| | Diltiazem hydrochloride | 22I13-B07-225365 | 3 |
| | Diltiazem hydrochloride | 22I13-B07-225366 | 2 |
| | Diltiazem hydrochloride | 22I13-BO7-223063 | 1 |
| | Diltiazem hydrochloride | 22I13-BO7-225364 | 1 |
| | Diltiazem hydrochloride | 22l13-B07-223063 | 1 |
| | Diltiazem hydrochloride | 2300189008 | 1 |
| | Diltiazem hydrochloride | 23001896001 | 1 |
| | Diltiazem hydrochloride | 23001896002 | 8 |
| | Diltiazem hydrochloride | 23001896006 | 4 |
| | Diltiazem hydrochloride | 23001896007 | 43 |
| | Diltiazem hydrochloride | 23001896008 | 10 |
| | Diltiazem hydrochloride | 23C20B01230369 | 1 |
| | Diltiazem hydrochloride | 23C20-B01-230369 | 3 |
| | Diltiazem hydrochloride | 23C20-B02-227683 | 11 |
| | Diltiazem hydrochloride | 23C20-B02-227685 | 1 |
| | Diltiazem hydrochloride | 23C20-B02-228330 | 1 |
| | Diltiazem hydrochloride | 23G06-B07-232368 | 1 |
| | Diltiazem hydrochloride | 23G06-B07-234623 | 6 |
| | Diltiazem hydrochloride | 23G06-B07-234624 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Diltiazem hydrochloride | 23G06-B07-2347623 | 1 |
| | Diltiazem hydrochloride | 23G06-B08-236814 | 1 |
| | Diltiazem hydrochloride | 23H17-B02-002187 | 2 |
| | Diltiazem hydrochloride | 23H17-B02-003148 | 1 |
| | Diltiazem hydrochloride | 23H17B02238694 | 1 |
| | Diltiazem hydrochloride | 23H17-B02-238694 | 15 |
| | Diltiazem hydrochloride | 23H17-B02-238695 | 2 |
| | Diltiazem hydrochloride | 23H-B02-238694 | 1 |
| | Diltiazem hydrochloride | 24000125003 | 3 |
| | Diltiazem hydrochloride | 24000125004 | 5 |
| | Diltiazem hydrochloride | 24000125005 | 6 |
| | Diltiazem hydrochloride | 24000125006 | 11 |
| | Diltiazem hydrochloride | 24000125007 | 24 |
| | Diltiazem hydrochloride | 2400012500754/24P | 1 |
| | Diltiazem hydrochloride | 24000125013 | 1 |
| | Diltiazem hydrochloride | 24000125014 | 5 |
| | Diltiazem hydrochloride | 24000125016 | 4 |
| | Diltiazem hydrochloride | 24000125017 | 2 |
| | Diltiazem hydrochloride | 24F24-B04-006623 | 4 |
| | Diltiazem hydrochloride | 25D02-B12-011126 | 1 |
| | Diltiazem hydrochloride | AZ-0260423 | 1 |
| | Diltiazem hydrochloride | Az-0350522 | 1 |
| | Diltiazem hydrochloride | AZ-0350522 | 2 |
| | Diltiazem hydrochloride | AZ-0440321 | 1 |
| | Diltiazem hydrochloride | AZ-0941022 | 1 |
| | Diltiazem hydrochloride | AZ-0951022 | 2 |
| | Diltiazem hydrochloride | B01-2303906 | 1 |
| | Diltiazem hydrochloride | B02-2276803 | 9 |
| | Diltiazem hydrochloride | B07-2230603 | 2 |
| | Diltiazem hydrochloride | B07-2253604 | 1 |
| | Diltiazem hydrochloride | BO4-0096705 | 1 |
| | Diltiazem hydrochloride | Dil17052023 | 1 |
| 11.08.14 Phoenix | Diltiazem hydrochloride | 13346901 | 1 |
| AEP | Diltiazem hydrochloride | 22001215013 | 2 |
| AEP | Diltiazem hydrochloride | 22001215019 | 1 |
| AEP | Diltiazem hydrochloride | 23001896007 | 1 |
| AHD | Diltiazem hydrochloride | 14C12-B04-292757 | 1 |
| AHD | Diltiazem hydrochloride | 15230514 | 5 |
| AHD | Diltiazem hydrochloride | 15G20-B08-314375 | 1 |
| AHD | Diltiazem hydrochloride | 17043210 | 1 |
| AHD | Diltiazem hydrochloride | 17337010 | 3 |
| AHD | Diltiazem hydrochloride | 17337017 | 2 |
| AHD | Diltiazem hydrochloride | 18301108 | 3 |
| AHD | Diltiazem hydrochloride | 18A29-B01-345623 | 2 |
| AHD | Diltiazem hydrochloride | 20000622010 | 1 |
| AHD | Diltiazem hydrochloride | 21000035021 | 1 |
| AHD | Diltiazem hydrochloride | 22001215029 | 1 |
| AHD | Diltiazem hydrochloride | 22001215030 | 1 |
| AHD | Diltiazem hydrochloride | 23001896008 | 1 |
| AHD | Diltiazem hydrochloride | 23H17-B02-003150 | 1 |
| AHD | Diltiazem hydrochloride | 24000125006 | 1 |
| ALH | Diltiazem hydrochloride | 15414319 | 1 |
| Aliance Health Care | Diltiazem hydrochloride | 22001215029 | 1 |
| Alliance Health | Diltiazem hydrochloride | 13A02-N05 | 1 |
| Alliance Healthcare | Diltiazem hydrochloride | 12I12-N02 | 1 |
| Alliance Healthcare | Diltiazem hydrochloride | 22001215007 | 1 |
| Alliance Healthcare | Diltiazem hydrochloride | 23H17-B02-238694 | 1 |
| Alliance | Diltiazem hydrochloride | 12133008 | 1 |
| Alliance | Diltiazem hydrochloride | 12133009 | 1 |
| Alliance | Diltiazem hydrochloride | 22001215026 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance | Diltiazem hydrochloride | 22I13-B07-223065 | 1 |
| allianz | Diltiazem hydrochloride | 15230512 | 1 |
| Allince Healthcare | Diltiazem hydrochloride | 16C14-B11-320849 | 1 |
| Anzag | Diltiazem hydrochloride | 13346915 | 1 |
| anzag | Diltiazem hydrochloride | 15414319 | 2 |
| Anzag | Diltiazem hydrochloride | 17043203 | 1 |
| Anzag | Diltiazem hydrochloride | 22001215024 | 1 |
| Anzag | Diltiazem hydrochloride | 230811(22001215024) | 1 |
| Anzag | Diltiazem hydrochloride | 250217(24000125007) | 1 |
| apomix | Diltiazem hydrochloride | 13346903 | 1 |
| apomix | Diltiazem hydrochloride | 14C12-B04-292759 | 1 |
| Athenstaedt | Diltiazem hydrochloride | 17337005 | 2 |
| Bomastus / Alliance ... | Diltiazem hydrochloride | 17043219 | 1 |
| Bombastus | Diltiazem hydrochloride | 16190813 | 1 |
| Caelo | Diltiazem hydrochloride | | 4 |
| Caelo | Diltiazem hydrochloride | 10069509 | 1 |
| Caelo | Diltiazem hydrochloride | 1020617/16190813 | 1 |
| Caelo | Diltiazem hydrochloride | 10212404 | 1 |
| Caelo | Diltiazem hydrochloride | 10212413 | 1 |
| Caelo | Diltiazem hydrochloride | 1090917/17043203 | 1 |
| Caelo | Diltiazem hydrochloride | 1091503 | 1 |
| Caelo | Diltiazem hydrochloride | 11091301 | 1 |
| Caelo | Diltiazem hydrochloride | 11134113 | 1 |
| Caelo | Diltiazem hydrochloride | 11134117 | 4 |
| Caelo | Diltiazem hydrochloride | 11L20-N06 | 1 |
| Caelo | Diltiazem hydrochloride | 12/12-N02 | 1 |
| Caelo | Diltiazem hydrochloride | 12051802 | 1 |
| Caelo | Diltiazem hydrochloride | 12133006 | 1 |
| Caelo | Diltiazem hydrochloride | 12133008 | 2 |
| Caelo | Diltiazem hydrochloride | 12133009 | 7 |
| Caelo | Diltiazem hydrochloride | 12133010 | 12 |
| Caelo | Diltiazem hydrochloride | 12133011 | 3 |
| Caelo | Diltiazem hydrochloride | 12133014 | 2 |
| Caelo | Diltiazem hydrochloride | 12133022 | 11 |
| Caelo | Diltiazem hydrochloride | 12133023 | 1 |
| Caelo | Diltiazem hydrochloride | 12133028 | 4 |
| Caelo | Diltiazem hydrochloride | 12133029 | 4 |
| Caelo | Diltiazem hydrochloride | 12176801 | 1 |
| Caelo | Diltiazem hydrochloride | 12176804 | 1 |
| Caelo | Diltiazem hydrochloride | 12177101 | 13 |
| Caelo | Diltiazem hydrochloride | 1250417 | 1 |
| Caelo | Diltiazem hydrochloride | 12D05-N07 | 3 |
| Caelo | Diltiazem hydrochloride | 13031501 | 1 |
| Caelo | Diltiazem hydrochloride | 13102004 | 1 |
| Caelo | Diltiazem hydrochloride | 1319604 | 1 |
| Caelo | Diltiazem hydrochloride | 13196103 | 2 |
| Caelo | Diltiazem hydrochloride | 13196104 | 7 |
| Caelo | Diltiazem hydrochloride | 13196105 | 17 |
| Caelo | Diltiazem hydrochloride | 13196107 | 3 |
| Caelo | Diltiazem hydrochloride | 1334609 | 1 |
| Caelo | Diltiazem hydrochloride | 13346901 | 8 |
| Caelo | Diltiazem hydrochloride | 13346902 | 5 |
| Caelo | Diltiazem hydrochloride | 13346903 | 10 |
| Caelo | Diltiazem hydrochloride | 13346904 | 5 |
| Caelo | Diltiazem hydrochloride | 13346905 | 9 |
| Caelo | Diltiazem hydrochloride | 13346908 | 1 |
| Caelo | Diltiazem hydrochloride | 13346914 | 6 |
| Caelo | Diltiazem hydrochloride | 13346915 | 8 |
| Caelo | Diltiazem hydrochloride | 1396103 | 1 |
| Caelo | Diltiazem hydrochloride | 13A02-N05 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Diltiazem hydrochloride | 13G16-N05 | 1 |
| Caelo | Diltiazem hydrochloride | 13G16-No5 | 1 |
| Caelo | Diltiazem hydrochloride | 13J24-B04-286569 | 1 |
| Caelo | Diltiazem hydrochloride | 13j24-b04-286571 | 1 |
| Caelo | Diltiazem hydrochloride | 1405904 | 1 |
| Caelo | Diltiazem hydrochloride | 14059133 | 1 |
| Caelo | Diltiazem hydrochloride | 140595 | 1 |
| Caelo | Diltiazem hydrochloride | 14059502 | 1 |
| Caelo | Diltiazem hydrochloride | 14059503 | 3 |
| Caelo | Diltiazem hydrochloride | 14059504 | 3 |
| Caelo | Diltiazem hydrochloride | 14059513 | 18 |
| Caelo | Diltiazem hydrochloride | 14059514 | 17 |
| Caelo | Diltiazem hydrochloride | 140595143 | 1 |
| Caelo | Diltiazem hydrochloride | 14059515 | 3 |
| Caelo | Diltiazem hydrochloride | 14059521 | 2 |
| Caelo | Diltiazem hydrochloride | 14318402 | 4 |
| Caelo | Diltiazem hydrochloride | 14318403 | 4 |
| Caelo | Diltiazem hydrochloride | 14318409 | 14 |
| Caelo | Diltiazem hydrochloride | 14318410 | 3 |
| Caelo | Diltiazem hydrochloride | 14318412 | 18 |
| Caelo | Diltiazem hydrochloride | 14318413 | 3 |
| Caelo | Diltiazem hydrochloride | 14318414 | 3 |
| Caelo | Diltiazem hydrochloride | 14318416 | 2 |
| Caelo | Diltiazem hydrochloride | 1459513 | 1 |
| Caelo | Diltiazem hydrochloride | 14C12-B04 | 2 |
| Caelo | Diltiazem hydrochloride | 14C12-B04-292757 | 1 |
| Caelo | Diltiazem hydrochloride | 14C12-B04-294133 | 1 |
| Caelo | Diltiazem hydrochloride | 14C12-B04-294135 | 1 |
| Caelo | Diltiazem hydrochloride | 14g22b08299781 | 1 |
| Caelo | Diltiazem hydrochloride | 14G22-B08-299781 | 1 |
| Caelo | Diltiazem hydrochloride | 15/246/DI | 1 |
| Caelo | Diltiazem hydrochloride | 15212801 | 12 |
| Caelo | Diltiazem hydrochloride | 15212802 | 8 |
| Caelo | Diltiazem hydrochloride | 15212806 | 2 |
| Caelo | Diltiazem hydrochloride | 1521806 | 1 |
| Caelo | Diltiazem hydrochloride | 15230000000000000000 | 1 |
| Caelo | Diltiazem hydrochloride | 15230501 | 7 |
| Caelo | Diltiazem hydrochloride | 15230502 | 14 |
| Caelo | Diltiazem hydrochloride | 15230503 | 12 |
| Caelo | Diltiazem hydrochloride | 15230504 | 3 |
| Caelo | Diltiazem hydrochloride | 15230507 | 3 |
| Caelo | Diltiazem hydrochloride | 15230510 | 3 |
| Caelo | Diltiazem hydrochloride | 15230512 | 19 |
| Caelo | Diltiazem hydrochloride | 15230513 | 1 |
| Caelo | Diltiazem hydrochloride | 15230514 | 3 |
| Caelo | Diltiazem hydrochloride | 15230515 | 1 |
| Caelo | Diltiazem hydrochloride | 15230516 | 1 |
| Caelo | Diltiazem hydrochloride | 152341904111 | 1 |
| Caelo | Diltiazem hydrochloride | 154114319 | 1 |
| Caelo | Diltiazem hydrochloride | 15414301 | 21 |
| Caelo | Diltiazem hydrochloride | 15414302 | 15 |
| Caelo | Diltiazem hydrochloride | 15414303 | 1 |
| Caelo | Diltiazem hydrochloride | 15414304 | 1 |
| Caelo | Diltiazem hydrochloride | 15414305 | 4 |
| Caelo | Diltiazem hydrochloride | 15414309 | 2 |
| Caelo | Diltiazem hydrochloride | 15414310 | 1 |
| Caelo | Diltiazem hydrochloride | 15414312 | 1 |
| Caelo | Diltiazem hydrochloride | 15414313 | 17 |
| Caelo | Diltiazem hydrochloride | 15414318 | 1 |
| Caelo | Diltiazem hydrochloride | 15414319 | 32 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Diltiazem hydrochloride | 15414320 | 1 |
| Caelo | Diltiazem hydrochloride | 15414321 | 2 |
| Caelo | Diltiazem hydrochloride | 15435807 | 1 |
| Caelo | Diltiazem hydrochloride | 15B12-B01-305399 | 1 |
| Caelo | Diltiazem hydrochloride | 15B12-B01-305400 | 1 |
| Caelo | Diltiazem hydrochloride | 15B12-B01-305401 | 1 |
| Caelo | Diltiazem hydrochloride | 15G20B-08-312065 | 1 |
| Caelo | Diltiazem hydrochloride | 15G20-B08-314375 | 2 |
| Caelo | Diltiazem hydrochloride | 160415D | 1 |
| Caelo | Diltiazem hydrochloride | 161908 | 1 |
| Caelo | Diltiazem hydrochloride | 16190801 | 4 |
| Caelo | Diltiazem hydrochloride | 16190805 | 3 |
| Caelo | Diltiazem hydrochloride | 16190806 | 16 |
| Caelo | Diltiazem hydrochloride | 16190807 | 3 |
| Caelo | Diltiazem hydrochloride | 16190810 | 11 |
| Caelo | Diltiazem hydrochloride | 16190813 | 17 |
| Caelo | Diltiazem hydrochloride | 16190814 | 13 |
| Caelo | Diltiazem hydrochloride | 16190815 | 1 |
| Caelo | Diltiazem hydrochloride | 16190817 | 2 |
| Caelo | Diltiazem hydrochloride | 16190818 | 1 |
| Caelo | Diltiazem hydrochloride | 16A18-B07-31667 | 1 |
| Caelo | Diltiazem hydrochloride | 16A18-B07-318732 | 2 |
| Caelo | Diltiazem hydrochloride | 16A18-B07-318733 | 1 |
| Caelo | Diltiazem hydrochloride | 16A18-B07-319570 | 1 |
| Caelo | Diltiazem hydrochloride | 16C14_B11_322642 | 1 |
| Caelo | Diltiazem hydrochloride | 16C14-B11-320849 | 1 |
| Caelo | Diltiazem hydrochloride | 16G20_B03_325903 | 1 |
| Caelo | Diltiazem hydrochloride | 16G20-B03-328133 | 2 |
| Caelo | Diltiazem hydrochloride | 16L19-B01-330365 | 3 |
| Caelo | Diltiazem hydrochloride | 170043217 | 1 |
| Caelo | Diltiazem hydrochloride | 170430204 | 1 |
| Caelo | Diltiazem hydrochloride | 1704317 | 1 |
| Caelo | Diltiazem hydrochloride | 170432 | 1 |
| Caelo | Diltiazem hydrochloride | 17043202 | 27 |
| Caelo | Diltiazem hydrochloride | 17043203 | 15 |
| Caelo | Diltiazem hydrochloride | 17043204 | 13 |
| Caelo | Diltiazem hydrochloride | 17043205 | 9 |
| Caelo | Diltiazem hydrochloride | 17043207 | 1 |
| Caelo | Diltiazem hydrochloride | 17043208 | 1 |
| Caelo | Diltiazem hydrochloride | 17043210 | 2 |
| Caelo | Diltiazem hydrochloride | 17043212 | 1 |
| Caelo | Diltiazem hydrochloride | 17043213 | 2 |
| Caelo | Diltiazem hydrochloride | 17043215 | 19 |
| Caelo | Diltiazem hydrochloride | 17043216 | 32 |
| Caelo | Diltiazem hydrochloride | 17043217 | 30 |
| Caelo | Diltiazem hydrochloride | 17043218 | 18 |
| Caelo | Diltiazem hydrochloride | 17043219 | 29 |
| Caelo | Diltiazem hydrochloride | 17043223 | 9 |
| Caelo | Diltiazem hydrochloride | 17043224 | 9 |
| Caelo | Diltiazem hydrochloride | 17043227 | 1 |
| Caelo | Diltiazem hydrochloride | 17043228 | 5 |
| Caelo | Diltiazem hydrochloride | 17043230 | 5 |
| Caelo | Diltiazem hydrochloride | 17053181 | 1 |
| Caelo | Diltiazem hydrochloride | 170602DH/16190813 | 1 |
| Caelo | Diltiazem hydrochloride | 170729181 | 1 |
| Caelo | Diltiazem hydrochloride | 17331012 | 1 |
| Caelo | Diltiazem hydrochloride | 17332021 | 1 |
| Caelo | Diltiazem hydrochloride | 173327027 | 1 |
| Caelo | Diltiazem hydrochloride | 173337018 | 1 |
| Caelo | Diltiazem hydrochloride | 173337026 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Diltiazem hydrochloride | 17337004 | 14 |
| Caelo | Diltiazem hydrochloride | 17337005 | 33 |
| Caelo | Diltiazem hydrochloride | 17337007 | 2 |
| Caelo | Diltiazem hydrochloride | 17337009 | 51 |
| Caelo | Diltiazem hydrochloride | 1733701 | 1 |
| Caelo | Diltiazem hydrochloride | 17337010 | 6 |
| Caelo | Diltiazem hydrochloride | 17337011 | 16 |
| Caelo | Diltiazem hydrochloride | 17337012 | 23 |
| Caelo | Diltiazem hydrochloride | 17337014 | 14 |
| Caelo | Diltiazem hydrochloride | 17337016 | 10 |
| Caelo | Diltiazem hydrochloride | 17337017 | 3 |
| Caelo | Diltiazem hydrochloride | 17337018 | 39 |
| Caelo | Diltiazem hydrochloride | 17337025 | 28 |
| Caelo | Diltiazem hydrochloride | 17337026 | 43 |
| Caelo | Diltiazem hydrochloride | 17337027 | 31 |
| Caelo | Diltiazem hydrochloride | 1733712 | 1 |
| Caelo | Diltiazem hydrochloride | 17D11-B11-333704 | 1 |
| Caelo | Diltiazem hydrochloride | 17D11-B11-333705 | 2 |
| Caelo | Diltiazem hydrochloride | 17D11-B11-334837 | 3 |
| Caelo | Diltiazem hydrochloride | 17H25-B01-340697 | 2 |
| Caelo | Diltiazem hydrochloride | 17h25-b01340699 | 1 |
| Caelo | Diltiazem hydrochloride | 17H25-B01-343273 | 1 |
| Caelo | Diltiazem hydrochloride | 180320DHC/17043218 | 1 |
| Caelo | Diltiazem hydrochloride | 18041802 | 1 |
| Caelo | Diltiazem hydrochloride | 18061511 | 1 |
| Caelo | Diltiazem hydrochloride | 18259501 | 1 |
| Caelo | Diltiazem hydrochloride | 18301108 | 1 |
| Caelo | Diltiazem hydrochloride | 18301109 | 7 |
| Caelo | Diltiazem hydrochloride | 1830111 | 1 |
| Caelo | Diltiazem hydrochloride | 18301110 | 15 |
| Caelo | Diltiazem hydrochloride | 18301111 | 36 |
| Caelo | Diltiazem hydrochloride | 1831110 | 1 |
| Caelo | Diltiazem hydrochloride | 18A29_B01_345623 | 1 |
| Caelo | Diltiazem hydrochloride | 18A29-B01 | 2 |
| Caelo | Diltiazem hydrochloride | 18A29-B01-345624 | 1 |
| Caelo | Diltiazem hydrochloride | 18A29-B01-346694 | 3 |
| Caelo | Diltiazem hydrochloride | 18a29-b01-347886 | 1 |
| Caelo | Diltiazem hydrochloride | 18A29-B01-347886 | 2 |
| Caelo | Diltiazem hydrochloride | 18A29-B01-348861 | 4 |
| Caelo | Diltiazem hydrochloride | 18A29-B01-352907 | 1 |
| Caelo | Diltiazem hydrochloride | 18A29-B01-352909 | 1 |
| Caelo | Diltiazem hydrochloride | 18A29-B01-348861 | 1 |
| Caelo | Diltiazem hydrochloride | 18H09-B03 | 2 |
| Caelo | Diltiazem hydrochloride | 18H09-B03-352908 | 1 |
| Caelo | Diltiazem hydrochloride | 18H09-B03-358917 | 4 |
| Caelo | Diltiazem hydrochloride | 18H09-B03-358918 | 1 |
| Caelo | Diltiazem hydrochloride | 18H09-B03-362596 | 2 |
| Caelo | Diltiazem hydrochloride | 18H09-B03-366217 | 1 |
| Caelo | Diltiazem hydrochloride | 18H09-B03-366218 | 1 |
| Caelo | Diltiazem hydrochloride | 18h09-b03-366219 | 1 |
| Caelo | Diltiazem hydrochloride | 1904108 | 1 |
| Caelo | Diltiazem hydrochloride | 190840108 | 1 |
| Caelo | Diltiazem hydrochloride | 190841002 | 9 |
| Caelo | Diltiazem hydrochloride | 190841004 | 3 |
| Caelo | Diltiazem hydrochloride | 190841005 | 26 |
| Caelo | Diltiazem hydrochloride | 190841006 | 33 |
| Caelo | Diltiazem hydrochloride | 190841007 | 32 |
| Caelo | Diltiazem hydrochloride | 19084103 | 7 |
| Caelo | Diltiazem hydrochloride | 19084104 | 17 |
| Caelo | Diltiazem hydrochloride | 19084105 | 33 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Diltiazem hydrochloride | 19084106 | 42 |
| Caelo | Diltiazem hydrochloride | 19084107 | 32 |
| Caelo | Diltiazem hydrochloride | 19084108 | 42 |
| Caelo | Diltiazem hydrochloride | 19084110 | 21 |
| Caelo | Diltiazem hydrochloride | 19084110P-191028-1 | 1 |
| Caelo | Diltiazem hydrochloride | 19084110P-200217-2 | 1 |
| Caelo | Diltiazem hydrochloride | 19084111 | 9 |
| Caelo | Diltiazem hydrochloride | 19084115 | 22 |
| Caelo | Diltiazem hydrochloride | 190941007/3720 | 1 |
| Caelo | Diltiazem hydrochloride | 19841006 | 1 |
| Caelo | Diltiazem hydrochloride | 19H09-B03-366217 | 1 |
| Caelo | Diltiazem hydrochloride | 20000622003 | 16 |
| Caelo | Diltiazem hydrochloride | 20000622007 | 2 |
| Caelo | Diltiazem hydrochloride | 20000622008 | 8 |
| Caelo | Diltiazem hydrochloride | 20000622009 | 16 |
| Caelo | Diltiazem hydrochloride | 20000622010 | 38 |
| Caelo | Diltiazem hydrochloride | 20000622011 | 24 |
| Caelo | Diltiazem hydrochloride | 20000622014 | 2 |
| Caelo | Diltiazem hydrochloride | 20000622015 | 12 |
| Caelo | Diltiazem hydrochloride | 2000622011 | 1 |
| Caelo | Diltiazem hydrochloride | 2000622015 | 1 |
| Caelo | Diltiazem hydrochloride | 2001215007 | 1 |
| Caelo | Diltiazem hydrochloride | 20C12-F03-371907 | 1 |
| Caelo | Diltiazem hydrochloride | 20C-12-F03-371907 | 1 |
| Caelo | Diltiazem hydrochloride | 20J01F11374760 | 1 |
| Caelo | Diltiazem hydrochloride | 20J01-F11-374763 | 1 |
| Caelo | Diltiazem hydrochloride | 210000035001 | 1 |
| Caelo | Diltiazem hydrochloride | 210000035012 | 1 |
| Caelo | Diltiazem hydrochloride | 21000035001 | 21 |
| Caelo | Diltiazem hydrochloride | 21000035002 | 30 |
| Caelo | Diltiazem hydrochloride | 21000035003 | 31 |
| Caelo | Diltiazem hydrochloride | 21000035004 | 3 |
| Caelo | Diltiazem hydrochloride | 210000350069 | 1 |
| Caelo | Diltiazem hydrochloride | 21000035008 | 14 |
| Caelo | Diltiazem hydrochloride | 21000035009 | 27 |
| Caelo | Diltiazem hydrochloride | 21000035010 | 29 |
| Caelo | Diltiazem hydrochloride | 21000035011 | 16 |
| Caelo | Diltiazem hydrochloride | 21000035012 | 19 |
| Caelo | Diltiazem hydrochloride | 21000035013 | 3 |
| Caelo | Diltiazem hydrochloride | 21000035016 | 10 |
| Caelo | Diltiazem hydrochloride | 21000035017 | 26 |
| Caelo | Diltiazem hydrochloride | 21000035018 | 1 |
| Caelo | Diltiazem hydrochloride | 21000035021 | 11 |
| Caelo | Diltiazem hydrochloride | 21000035023 | 3 |
| Caelo | Diltiazem hydrochloride | 2100003509 | 1 |
| Caelo | Diltiazem hydrochloride | 2100003510 | 1 |
| Caelo | Diltiazem hydrochloride | 21000035100 | 1 |
| Caelo | Diltiazem hydrochloride | 21000035101 | 1 |
| Caelo | Diltiazem hydrochloride | 2100003517 | 1 |
| Caelo | Diltiazem hydrochloride | 2100003521 | 1 |
| Caelo | Diltiazem hydrochloride | 2100035003 | 2 |
| Caelo | Diltiazem hydrochloride | 2100035010 | 1 |
| Caelo | Diltiazem hydrochloride | 2100035017 | 1 |
| Caelo | Diltiazem hydrochloride | 2100035021 | 2 |
| Caelo | Diltiazem hydrochloride | 21D26-F02-378333 | 3 |
| Caelo | Diltiazem hydrochloride | 21F11-B03-221071 | 1 |
| Caelo | Diltiazem hydrochloride | 22000062009 | 1 |
| Caelo | Diltiazem hydrochloride | 22001215001 | 1 |
| Caelo | Diltiazem hydrochloride | 22001215003 | 25 |
| Caelo | Diltiazem hydrochloride | 22001215007 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Diltiazem hydrochloride | 22001215008 | 22 |
| Caelo | Diltiazem hydrochloride | 22001215009 | 15 |
| Caelo | Diltiazem hydrochloride | 22001215011 | 3 |
| Caelo | Diltiazem hydrochloride | 22001215012 | 5 |
| Caelo | Diltiazem hydrochloride | 22001215013 | 8 |
| Caelo | Diltiazem hydrochloride | 22001215015 | 10 |
| Caelo | Diltiazem hydrochloride | 22001215018 | 1 |
| Caelo | Diltiazem hydrochloride | 22001215019 | 9 |
| Caelo | Diltiazem hydrochloride | 22001215026 | 1 |
| Caelo | Diltiazem hydrochloride | 22001215029 | 1 |
| Caelo | Diltiazem hydrochloride | 22001215030 | 4 |
| Caelo | Diltiazem hydrochloride | 2200125007 | 1 |
| Caelo | Diltiazem hydrochloride | 2200125015 | 1 |
| Caelo | Diltiazem hydrochloride | 2201215008 | 1 |
| Caelo | Diltiazem hydrochloride | 221001215008 | 1 |
| Caelo | Diltiazem hydrochloride | 22L13-B07-223063 | 1 |
| Caelo | Diltiazem hydrochloride | 23001896002 | 1 |
| Caelo | Diltiazem hydrochloride | 23001896007 | 1 |
| Caelo | Diltiazem hydrochloride | 23051818 | 1 |
| Caelo | Diltiazem hydrochloride | 2310213562 | 1 |
| Caelo | Diltiazem hydrochloride | 23121402 | 1 |
| Caelo | Diltiazem hydrochloride | 23C20-BO1-230369 | 1 |
| Caelo | Diltiazem hydrochloride | 24000125007 | 1 |
| Caelo | Diltiazem hydrochloride | 24000125016 | 1 |
| Caelo | Diltiazem hydrochloride | 24061706 | 1 |
| Caelo | Diltiazem hydrochloride | 25041401 | 1 |
| Caelo | Diltiazem hydrochloride | 251422/1 | 1 |
| Caelo | Diltiazem hydrochloride | 261115DHC | 1 |
| Caelo | Diltiazem hydrochloride | 27101706 | 1 |
| Caelo | Diltiazem hydrochloride | 27101803 | 1 |
| Caelo | Diltiazem hydrochloride | 2760181 | 1 |
| Caelo | Diltiazem hydrochloride | 2818A-03562 | 1 |
| Caelo | Diltiazem hydrochloride | 3313U-03562 | 1 |
| Caelo | Diltiazem hydrochloride | 3442 | 1 |
| Caelo | Diltiazem hydrochloride | 4(190841006) | 1 |
| Caelo | Diltiazem hydrochloride | 514I-03562 | 1 |
| Caelo | Diltiazem hydrochloride | 6031302 | 1 |
| Caelo | Diltiazem hydrochloride | 7082005 | 1 |
| Caelo | Diltiazem hydrochloride | 8726 | 1 |
| Caelo | Diltiazem hydrochloride | DIL/M-04511 | 1 |
| Caelo | Diltiazem hydrochloride | DIL/M-19911 | 1 |
| Caelo | Diltiazem hydrochloride | RT297 | 1 |
| Caeol/Noweda | Diltiazem hydrochloride | 17337018 | 1 |
| Caesar & Lorenz GmbH | Diltiazem hydrochloride | 17043218 | 1 |
| Caesar & Lorenz GmbH | Diltiazem hydrochloride | 190841007 | 1 |
| Caesar & Loretz / AHD | Diltiazem hydrochloride | 19084107 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035018 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841007 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084107 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035002 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035014 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084103 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622014 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035004 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 220012150009 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 22001215013 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 22001215015 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622007 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084106 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084105 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622011 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035010 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841007 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 1908410 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841007 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035002 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035021 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841005 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084110 | 1 |
| Caesar & Loretz GmbH/AEP | Diltiazem hydrochloride | 19084107 | 1 |
| Caesar & Loretz GmbH/AHD | Diltiazem hydrochloride | 20000622010 | 2 |
| Caesar & Loretz GmbH/AHD | Diltiazem hydrochloride | 21000035010 | 1 |
| Caesar & Loretz GmbH/AHD | Diltiazem hydrochloride | 21000035023 | 1 |
| Caesar & Loretz GmbH/AHD | Diltiazem hydrochloride | 22001215026 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 22001215008 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 22001215015 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841006 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035002 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035010 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 2100003509 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035024 | 2 |
| Caesar & Loretz GmbH/E | Diltiazem hydrochloride | 20000622010 | 1 |
| Caesar & Loretz GmbH/E | Diltiazem hydrochloride | 21000035011 | 1 |
| Caesar & Loretz GmbH/E | Diltiazem hydrochloride | 22001215003 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 17337027 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035017 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035021 | 1 |
| Caesar & Loretz GmbH/G | Diltiazem hydrochloride | 21000035003 | 1 |
| Caesar & Loretz GmbH/G | Diltiazem hydrochloride | 21000035017 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 190841007 | 2 |
| Caesar & Loretz GmbH/GEHE | Diltiazem hydrochloride | 19084105 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 19084106 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 19084107 | 1 |
| Caesar & Loretz GmbH/gehe | Diltiazem hydrochloride | 19084108 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 20000622010 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 20000622014 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 21000035010 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 21000035011 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 21000035017 | 4 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 21000035021 | 1 |
| Caesar & Loretz GmbH/gehe | Diltiazem hydrochloride | 22001215008 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 22001215011 | 1 |
| Caesar & Loretz GmbH/Gehe | Diltiazem hydrochloride | 22001215019 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622008 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622015 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035011 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084104 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084106 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035009 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035011 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 22001215015 | 1 |
| Caesar & Loretz GmbH/K | Diltiazem hydrochloride | 21000035009 | 1 |
| Caesar & Loretz GmbH/Kehr | Diltiazem hydrochloride | 21000035023 | 1 |
| Caesar & Loretz GmbH/Kehr | Diltiazem hydrochloride | 22001215011 | 3 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841007 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084105 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084115 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035012 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 22001215007 | 7 |
| Caesar & Loretz GmbH/Ph | Diltiazem hydrochloride | 19084108 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Ph | Diltiazem hydrochloride | 20000622009 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084108 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084115 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19268401 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622003 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622008 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622015 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035003 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035004 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035017 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035021 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841004 | 5 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 190841007 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084105 | 2 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 19084106 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622009 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 20000622010 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035003 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035009 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035011 | 3 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 21000035017 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | AP220802-01 | 1 |
| Caesar & Loretz GmbH... | Diltiazem hydrochloride | 17337027 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 12133010 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17043218 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17043219 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17337009 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17337014 | 2 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17337018 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17337025 | 5 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17337026 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 17337027 | 4 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 18301109 | 4 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 18301110 | 3 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 18301111 | 8 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 190841002 | 3 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 190841005 | 5 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 190841006 | 8 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 190841007 | 9 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084103 | 9 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084104 | 2 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084105 | 7 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084106 | 9 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084107 | 7 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084108 | 10 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084110 | 2 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084111 | 7 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19084115 | 7 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 19135410 | 4 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20000622003 | 4 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20000622007 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20000622008 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20000622009 | 8 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20000622010 | 8 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20000622011 | 10 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20000622015 | 5 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 2000622003 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 20C12-F03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035001 | 11 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035002 | 10 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035003 | 12 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035004 | 2 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035008 | 6 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035009 | 9 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035010 | 10 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035011 | 8 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035012 | 5 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035013 | 4 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035016 | 5 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035017 | 11 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035021 | 7 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035023 | 9 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 21000035024 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 220001215007 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215002 | 2 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215003 | 10 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215007 | 7 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215008 | 5 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215009 | 10 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215011 | 3 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215012 | 2 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215013 | 4 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215015 | 9 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215019 | 5 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | 22001215030 | 2 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | B03-3662107 | 1 |
| Caesar & Loretz GmbH | Diltiazem hydrochloride | F03-3719008 | 2 |
| Caesar & Loretz GmbH… | Diltiazem hydrochloride | 21000035021 | 1 |
| Caesar & Loretz GmbH… | Diltiazem hydrochloride | 22001215015 | 1 |
| Caesar & Loretz/Geil… | Diltiazem hydrochloride | 190841006 | 1 |
| Caesar & Loretz/Geil… | Diltiazem hydrochloride | 20000622011 | 1 |
| Caesar & Loretz/Geil… | Diltiazem hydrochloride | 21000035010 | 1 |
| Caesar & Loretz/Noweda | Diltiazem hydrochloride | 19084108 | 1 |
| Caesar & Loretz/Noweda | Diltiazem hydrochloride | 21000035003 | 1 |
| Caesar & Loretz | Diltiazem hydrochloride | 16190806 | 1 |
| Caesar & Loretz | Diltiazem hydrochloride | 17043202 | 1 |
| Caesar & Loretz | Diltiazem hydrochloride | 17043216 | 1 |
| Caesar & Loretz | Diltiazem hydrochloride | 17337012 | 1 |
| CAESAR & LORETZ | Diltiazem hydrochloride | 19084105 | 1 |
| Caesar / Gehe | Diltiazem hydrochloride | 16190806 | 1 |
| Caesar&Loretz GmbH /Anzag | Diltiazem hydrochloride | 15414302 | 1 |
| Caesar&Loretz GmbH/Anzag | Diltiazem hydrochloride | 14318412 | 1 |
| Caesar&Loretz GmbH | Diltiazem hydrochloride | 20000622010 | 1 |
| Caesar&Loretz GmbH | Diltiazem hydrochloride | 20000622011 | 1 |
| Caesar&Loretz GmbH | Diltiazem hydrochloride | 21000035003 | 1 |
| Caesar&Loretz GmbH | Diltiazem hydrochloride | 21000035016 | 1 |
| Caeser und Loretz GmbH | Diltiazem hydrochloride | 19084108 | 1 |
| Caleo/ Noweda | Diltiazem hydrochloride | 17043218 | 2 |
| Caleo/ Noweda | Diltiazem hydrochloride | 17337027 | 2 |
| Caleo/gehe | Diltiazem hydrochloride | 18301111 | 1 |
| Caleo | Diltiazem hydrochloride | 17043202 | 1 |
| Cealo/Sanacorp | Diltiazem hydrochloride | 14059514 | 1 |
| Cealo/Sanacorp | Diltiazem hydrochloride | 190841006 | 1 |
| Cealo | Diltiazem hydrochloride | 22001215008 | 1 |
| Chiesi/Phoenix | Diltiazem hydrochloride | 15230502 | 1 |
| Divis Laboratories … | Diltiazem hydrochloride | 20J01-F11_374760 | 1 |
| EuRho/Phönix | Diltiazem hydrochloride | 14059514 | 1 |
| Euro OTC | Diltiazem hydrochloride | 16A18B07 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Diltiazem hydrochloride | 17043216 | 1 |
| Euro OTC | Diltiazem hydrochloride | 17043228 | 1 |
| Euro OTC | Diltiazem hydrochloride | 17337005 | 1 |
| Euro OTC | Diltiazem hydrochloride | 17337027 | 1 |
| Europharm / Gehe | Diltiazem hydrochloride | 17H25-B01-343273 | 1 |
| Fa.Phönix | Diltiazem hydrochloride | 17331026 | 1 |
| Fagon/Noweda | Diltiazem hydrochloride | 18H09-B03-354798 | 1 |
| Fagron | Diltiazem hydrochloride | | 2 |
| Fagron | Diltiazem hydrochloride | 10808-N01 | 1 |
| Fagron | Diltiazem hydrochloride | 10D28-N23 | 1 |
| Fagron | Diltiazem hydrochloride | 11/01-N08 | 1 |
| Fagron | Diltiazem hydrochloride | 11-01-N08 | 1 |
| Fagron | Diltiazem hydrochloride | 11C14-N18 | 1 |
| Fagron | Diltiazem hydrochloride | 11E18-N04 | 3 |
| Fagron | Diltiazem hydrochloride | 11I01-N08 | 1 |
| Fagron | Diltiazem hydrochloride | 11J28-N05 | 1 |
| Fagron | Diltiazem hydrochloride | 12/12-N02 | 4 |
| Fagron | Diltiazem hydrochloride | 12/12-NO2 | 1 |
| Fagron | Diltiazem hydrochloride | 12d05-n07 | 1 |
| Fagron | Diltiazem hydrochloride | 12D05-N07 | 11 |
| Fagron | Diltiazem hydrochloride | 12D05-N070 | 1 |
| Fagron | Diltiazem hydrochloride | 12F19-N10 | 3 |
| Fagron | Diltiazem hydrochloride | 12F19-N100102/574 | 1 |
| Fagron | Diltiazem hydrochloride | 12I12-N02 | 2 |
| Fagron | Diltiazem hydrochloride | 12K07-N02 | 2 |
| Fagron | Diltiazem hydrochloride | 12l12-N02 | 1 |
| Fagron | Diltiazem hydrochloride | 13346902 | 1 |
| Fagron | Diltiazem hydrochloride | 13346915 | 1 |
| Fagron | Diltiazem hydrochloride | 135968-0009 | 2 |
| Fagron | Diltiazem hydrochloride | 13a02-n05 | 1 |
| Fagron | Diltiazem hydrochloride | 13A02N05 | 3 |
| Fagron | Diltiazem hydrochloride | 13A02-N05 | 9 |
| Fagron | Diltiazem hydrochloride | 13C14-B11-322642 | 1 |
| Fagron | Diltiazem hydrochloride | 13F13-N05 | 10 |
| Fagron | Diltiazem hydrochloride | 13G16_N05 | 1 |
| Fagron | Diltiazem hydrochloride | 13G16-N05 | 23 |
| Fagron | Diltiazem hydrochloride | 13J24-B04 | 3 |
| Fagron | Diltiazem hydrochloride | 13j24-b04-286569 | 1 |
| Fagron | Diltiazem hydrochloride | 13J24B04286569 | 3 |
| Fagron | Diltiazem hydrochloride | 13J24-B04-286569 | 11 |
| Fagron | Diltiazem hydrochloride | 13J24-B04-286570 | 1 |
| Fagron | Diltiazem hydrochloride | 13J24-B04-286571 | 2 |
| Fagron | Diltiazem hydrochloride | 13J24-B04-289432 | 3 |
| Fagron | Diltiazem hydrochloride | 14C12_B04_292757 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12_B04-294133 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12B04 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12-B04 | 5 |
| Fagron | Diltiazem hydrochloride | 14C12-B04_294133 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12-B04-292757 | 23 |
| Fagron | Diltiazem hydrochloride | 14c12-b04-292759 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12-B04-292759 | 4 |
| Fagron | Diltiazem hydrochloride | 14C12-B04294133 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12-B04-294133 | 6 |
| Fagron | Diltiazem hydrochloride | 14c12-b04-294134 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12-B04-294134 | 1 |
| Fagron | Diltiazem hydrochloride | 14C12-B04-294135 | 2 |
| Fagron | Diltiazem hydrochloride | 14G22B08 | 1 |
| Fagron | Diltiazem hydrochloride | 14G22-B08 | 3 |
| Fagron | Diltiazem hydrochloride | 14g22-b08-299781 | 1 |
| Fagron | Diltiazem hydrochloride | 14G22-B08299781 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Diltiazem hydrochloride | 14G22-B08-299781 | 13 |
| Fagron | Diltiazem hydrochloride | 14G22-B08-299782 | 6 |
| Fagron | Diltiazem hydrochloride | 14G22-B08-299783 | 1 |
| Fagron | Diltiazem hydrochloride | 15414313 | 1 |
| Fagron | Diltiazem hydrochloride | 15B12/B01305399 | 1 |
| Fagron | Diltiazem hydrochloride | 15B12-b01 | 1 |
| Fagron | Diltiazem hydrochloride | 15B12-B01 | 8 |
| Fagron | Diltiazem hydrochloride | 15B12-B01_305399 | 1 |
| Fagron | Diltiazem hydrochloride | 15B12-B01-305299 | 1 |
| Fagron | Diltiazem hydrochloride | 15b12-b01-305399 | 2 |
| Fagron | Diltiazem hydrochloride | 15B12B01305399 | 2 |
| Fagron | Diltiazem hydrochloride | 15B12-B01-305399 | 27 |
| Fagron | Diltiazem hydrochloride | 15b12-b01-305400 | 2 |
| Fagron | Diltiazem hydrochloride | 15B12B01305400 | 1 |
| Fagron | Diltiazem hydrochloride | 15B12-B01-305400 | 8 |
| Fagron | Diltiazem hydrochloride | 15B12-B01-305401 | 3 |
| Fagron | Diltiazem hydrochloride | 15G20-B02-310792 | 1 |
| Fagron | Diltiazem hydrochloride | 15G20-B08 | 3 |
| Fagron | Diltiazem hydrochloride | 15G20-B08-310792 | 1 |
| Fagron | Diltiazem hydrochloride | 15G20-B08-312065 | 15 |
| Fagron | Diltiazem hydrochloride | 15g20-b08-314375 | 1 |
| Fagron | Diltiazem hydrochloride | 15G20-B08-314375 | 7 |
| Fagron | Diltiazem hydrochloride | 16A14-B11-322153 | 1 |
| Fagron | Diltiazem hydrochloride | 16A18-B07 | 5 |
| Fagron | Diltiazem hydrochloride | 16A18B07316667 | 1 |
| Fagron | Diltiazem hydrochloride | 16A18-B07-316667 | 13 |
| Fagron | Diltiazem hydrochloride | 16A18B07316668 | 1 |
| Fagron | Diltiazem hydrochloride | 16a18-b07-318732 | 2 |
| Fagron | Diltiazem hydrochloride | 16A18-B07318732 | 1 |
| Fagron | Diltiazem hydrochloride | 16A18-B07-318732 | 16 |
| Fagron | Diltiazem hydrochloride | 16A18-B07-318733 | 3 |
| Fagron | Diltiazem hydrochloride | 16A18-B07-319570 | 3 |
| Fagron | Diltiazem hydrochloride | 16C14-B11 | 4 |
| Fagron | Diltiazem hydrochloride | 16c14-b11-211642 | 1 |
| Fagron | Diltiazem hydrochloride | 16C14B11320568 | 2 |
| Fagron | Diltiazem hydrochloride | 16C14-B11-320568 | 5 |
| Fagron | Diltiazem hydrochloride | 16c14-b11-320849 | 1 |
| Fagron | Diltiazem hydrochloride | 16C14B11320849 | 1 |
| Fagron | Diltiazem hydrochloride | 16C14-B11-320849 | 16 |
| Fagron | Diltiazem hydrochloride | 16c14-b11-322152 | 1 |
| Fagron | Diltiazem hydrochloride | 16C14B11322152 | 1 |
| Fagron | Diltiazem hydrochloride | 16C14-B11-322152 | 7 |
| Fagron | Diltiazem hydrochloride | 16C14-B11-322153 | 8 |
| Fagron | Diltiazem hydrochloride | 16C14-B11-322642 | 17 |
| Fagron | Diltiazem hydrochloride | 16G20-B03 | 4 |
| Fagron | Diltiazem hydrochloride | 16g20-b03-325903 | 1 |
| Fagron | Diltiazem hydrochloride | 16G20B03325903 | 1 |
| Fagron | Diltiazem hydrochloride | 16G20B03-325903 | 1 |
| Fagron | Diltiazem hydrochloride | 16G20-B03-325903 | 24 |
| Fagron | Diltiazem hydrochloride | 16G20-B03-328133 | 11 |
| Fagron | Diltiazem hydrochloride | 16G20-B03-328253 | 4 |
| Fagron | Diltiazem hydrochloride | 16GH20-B03-325903 | 1 |
| Fagron | Diltiazem hydrochloride | 16L19-B01 | 1 |
| Fagron | Diltiazem hydrochloride | 16L19-B01_330396 | 1 |
| Fagron | Diltiazem hydrochloride | 16l19-b01-330365 | 1 |
| Fagron | Diltiazem hydrochloride | 16L19-B01-330365 | 9 |
| Fagron | Diltiazem hydrochloride | 16L19-B01-330395 | 2 |
| Fagron | Diltiazem hydrochloride | 16L19B01330396 | 1 |
| Fagron | Diltiazem hydrochloride | 16L19-B01-330396 | 8 |
| Fagron | Diltiazem hydrochloride | 17043203 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Diltiazem hydrochloride | 17043215 | 3 |
| Fagron | Diltiazem hydrochloride | 17337026 | 1 |
| Fagron | Diltiazem hydrochloride | 17D11-B11 | 6 |
| Fagron | Diltiazem hydrochloride | 17D11-B11-333704 | 16 |
| Fagron | Diltiazem hydrochloride | 17D-11-B11-333704 | 1 |
| Fagron | Diltiazem hydrochloride | 17D11-B11-333705 | 3 |
| Fagron | Diltiazem hydrochloride | 17D11-B11-334192 | 7 |
| Fagron | Diltiazem hydrochloride | 17d11b11334837 | 1 |
| Fagron | Diltiazem hydrochloride | 17D11-B11-334837 | 19 |
| Fagron | Diltiazem hydrochloride | 17d11-b11-336727 | 1 |
| Fagron | Diltiazem hydrochloride | 17D11B11336727 | 1 |
| Fagron | Diltiazem hydrochloride | 17D11-B11-336727 | 7 |
| Fagron | Diltiazem hydrochloride | 17H25-B01 | 5 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-340697 | 18 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-340698 | 5 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-340699 | 2 |
| Fagron | Diltiazem hydrochloride | 17h25-b01-341596 | 1 |
| Fagron | Diltiazem hydrochloride | 17H25-B01341596 | 1 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-341596 | 16 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-341597 | 3 |
| Fagron | Diltiazem hydrochloride | 17H25B01-341598 | 1 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-341598 | 2 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-343272 | 1 |
| Fagron | Diltiazem hydrochloride | 17H25-B01-343273 | 11 |
| Fagron | Diltiazem hydrochloride | 17H25-Bo1-340697 | 1 |
| Fagron | Diltiazem hydrochloride | 18301111 | 2 |
| Fagron | Diltiazem hydrochloride | 18A29_B01_348861 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-01-347886 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01 | 16 |
| Fagron | Diltiazem hydrochloride | 18A-29-B01 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-32907 | 1 |
| Fagron | Diltiazem hydrochloride | 18a29b01345623 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-345623 | 17 |
| Fagron | Diltiazem hydrochloride | 18a29-b01-345624 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-345624 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-345625 | 2 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-346694 | 9 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-346695 | 4 |
| Fagron | Diltiazem hydrochloride | 18A29B01347886 | 2 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-347886 | 20 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-347887 | 5 |
| Fagron | Diltiazem hydrochloride | 18a29-b01-348861 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29B01348861 | 2 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-348861 | 29 |
| Fagron | Diltiazem hydrochloride | 18A29B01350964 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-350964 | 5 |
| Fagron | Diltiazem hydrochloride | 18A29B01-352722 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-352722 | 3 |
| Fagron | Diltiazem hydrochloride | 18A-29-B01-352722 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-352723 | 6 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-352907 | 18 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-352909 | 4 |
| Fagron | Diltiazem hydrochloride | 18A29-B01-358861 | 1 |
| Fagron | Diltiazem hydrochloride | 18A29-Bo1-345623 | 1 |
| Fagron | Diltiazem hydrochloride | 18A-B01 | 1 |
| Fagron | Diltiazem hydrochloride | 18A-B01-352907 | 1 |
| Fagron | Diltiazem hydrochloride | 18H03-B03-358920 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09_B03_354798 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09_B03_358918 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09_B03_362595 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Diltiazem hydrochloride | 18H09-B03 | 33 |
| Fagron | Diltiazem hydrochloride | 18H09-B03_354798 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03_366219 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-0008 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-326596 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-352908 | 2 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-354798 | 20 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-357183 | 8 |
| Fagron | Diltiazem hydrochloride | 18H09B03357184 | 2 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-357184 | 5 |
| Fagron | Diltiazem hydrochloride | 18h09-b03-358917 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-b03-358917 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09B03358917 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-358917 | 33 |
| Fagron | Diltiazem hydrochloride | 18H-09-B03-358917 | 2 |
| Fagron | Diltiazem hydrochloride | 18h09b03358918 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09B03358918 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-358918 | 21 |
| Fagron | Diltiazem hydrochloride | 18H09B03358919 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09B03-358919 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-358919 | 9 |
| Fagron | Diltiazem hydrochloride | 18H09B03358920 | 2 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-358920 | 5 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-3589818 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-3625905 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-3625909 | 1 |
| Fagron | Diltiazem hydrochloride | 18h09-b03-362595 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-362595 | 30 |
| Fagron | Diltiazem hydrochloride | 18H09B03-362596 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-362596 | 23 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-362596/AZ-0560718 | 1 |
| Fagron | Diltiazem hydrochloride | 18h09-b03-362599 | 2 |
| Fagron | Diltiazem hydrochloride | 18H09-B03362599 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-362599 | 14 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-362600 | 3 |
| Fagron | Diltiazem hydrochloride | 18H09B03366217 | 2 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-366217 | 47 |
| Fagron | Diltiazem hydrochloride | 18-H09-B03-366217 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03366218 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-366218 | 12 |
| Fagron | Diltiazem hydrochloride | 18-H09B03366218 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-366219 | 8 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-58918 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-B03-654798 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-BO3-354798 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-BO3-362596 | 1 |
| Fagron | Diltiazem hydrochloride | 18H09-BO3-366218 | 1 |
| Fagron | Diltiazem hydrochloride | 18H19-B03-358918 | 2 |
| Fagron | Diltiazem hydrochloride | 18H-B03 | 1 |
| Fagron | Diltiazem hydrochloride | 18HO9-B03-366219 | 1 |
| Fagron | Diltiazem hydrochloride | 190312702 | 1 |
| Fagron | Diltiazem hydrochloride | 190841308 | 1 |
| Fagron | Diltiazem hydrochloride | 19H09-B03-357184 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12F03 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12-F03 | 11 |
| Fagron | Diltiazem hydrochloride | 20C12-F03_371907 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12-F03-3719007 | 1 |
| Fagron | Diltiazem hydrochloride | 20c12f03371907 | 1 |
| Fagron | Diltiazem hydrochloride | 20c12-f03-371907 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12F03371907 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Diltiazem hydrochloride | 20C12-F03-371907 | 39 |
| Fagron | Diltiazem hydrochloride | 20C12-F03-371908 | 4 |
| Fagron | Diltiazem hydrochloride | 20C12-F03-3733809 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12F03373389 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12-F03-373389 | 7 |
| Fagron | Diltiazem hydrochloride | 20c12-f03-374171 | 2 |
| Fagron | Diltiazem hydrochloride | 20c12-F03-374171 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12F03374171 | 1 |
| Fagron | Diltiazem hydrochloride | 20C12-F03-374171 | 14 |
| Fagron | Diltiazem hydrochloride | 20C12-FO3-371907 | 3 |
| Fagron | Diltiazem hydrochloride | 20J01-F11 | 5 |
| Fagron | Diltiazem hydrochloride | 20j01-f11-374760 | 3 |
| Fagron | Diltiazem hydrochloride | 20j01-F11-374760 | 1 |
| Fagron | Diltiazem hydrochloride | 20J01-F11-374760 | 30 |
| Fagron | Diltiazem hydrochloride | 20J01-F11-3747600 | 1 |
| Fagron | Diltiazem hydrochloride | 20J01F11374761 | 2 |
| Fagron | Diltiazem hydrochloride | 20J01-F11-374761 | 11 |
| Fagron | Diltiazem hydrochloride | 20J01-F11374763 | 1 |
| Fagron | Diltiazem hydrochloride | 20J01-F11-374763 | 11 |
| Fagron | Diltiazem hydrochloride | 20J01-F11-374764 | 12 |
| Fagron | Diltiazem hydrochloride | 20J01-F11-374765 | 1 |
| Fagron | Diltiazem hydrochloride | 212F11-803-216679 | 1 |
| Fagron | Diltiazem hydrochloride | 21D26-F02 | 3 |
| Fagron | Diltiazem hydrochloride | 21D26-F02-378333 | 33 |
| Fagron | Diltiazem hydrochloride | 21D26-F03-378339 | 3 |
| Fagron | Diltiazem hydrochloride | 21F11 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11_b03_216679 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-803 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-803-216679 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-b03 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-B03 | 10 |
| Fagron | Diltiazem hydrochloride | 21F11-B03_221072 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-213610 | 5 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-213611 | 12 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-216679 | 35 |
| Fagron | Diltiazem hydrochloride | 21F11B03216762 | 2 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-216762 | 10 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-218832 | 3 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-218858 | 7 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-218922 | 4 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-2210071 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-221071 | 26 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-221072 | 2 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-221073 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-B03-223064 | 2 |
| Fagron | Diltiazem hydrochloride | 21f11-bo3-216679 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-BO3-216679 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-BO3-216762 | 2 |
| Fagron | Diltiazem hydrochloride | 21F11-BO3-218832 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-BO3-221071 | 1 |
| Fagron | Diltiazem hydrochloride | 21F11-BO3-223064 | 1 |
| Fagron | Diltiazem hydrochloride | 22/13-B07-223063 | 1 |
| Fagron | Diltiazem hydrochloride | 22082014A | 1 |
| Fagron | Diltiazem hydrochloride | 22113-B07 | 1 |
| Fagron | Diltiazem hydrochloride | 22113-B07-223063 | 1 |
| Fagron | Diltiazem hydrochloride | 2213-B07-223063 | 1 |
| Fagron | Diltiazem hydrochloride | 221D-F02-378333 | 1 |
| Fagron | Diltiazem hydrochloride | 22I12-B07-223063 | 1 |
| Fagron | Diltiazem hydrochloride | 22i13-b07 | 1 |
| Fagron | Diltiazem hydrochloride | 22I13-B07 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Diltiazem hydrochloride | 22i13-B07-223063 | 1 |
| Fagron | Diltiazem hydrochloride | 22I13-B07-223063 | 19 |
| Fagron | Diltiazem hydrochloride | 22I13-B07-223065 | 3 |
| Fagron | Diltiazem hydrochloride | 22I13-B07-225364 | 1 |
| Fagron | Diltiazem hydrochloride | 22l13-B07 | 1 |
| Fagron | Diltiazem hydrochloride | 23C20-B02-227683 | 1 |
| Fagron | Diltiazem hydrochloride | 23C20-B02-228330 | 2 |
| Fagron | Diltiazem hydrochloride | 2798 | 1 |
| Fagron | Diltiazem hydrochloride | 3046333 | 1 |
| Fagron | Diltiazem hydrochloride | 362596 | 1 |
| Fagron | Diltiazem hydrochloride | 3713M-03562 | 1 |
| Fagron | Diltiazem hydrochloride | 371907 | 1 |
| Fagron | Diltiazem hydrochloride | 612213562 | 1 |
| Fagron | Diltiazem hydrochloride | 9J14-N17 | 1 |
| Fagron | Diltiazem hydrochloride | AT-0810520 | 1 |
| Fagron | Diltiazem hydrochloride | AZ-0100716 | 1 |
| Fagron | Diltiazem hydrochloride | AZ-0150120 | 4 |
| Fagron | Diltiazem hydrochloride | AZ-0350522 | 2 |
| Fagron | Diltiazem hydrochloride | AZ-0440321 | 4 |
| Fagron | Diltiazem hydrochloride | AZ-0440321/21F11-B03-221071 | 1 |
| Fagron | Diltiazem hydrochloride | AZ-04600321 | 1 |
| Fagron | Diltiazem hydrochloride | AZ-0460321 | 4 |
| Fagron | Diltiazem hydrochloride | AZ-0470321 | 1 |
| Fagron | Diltiazem hydrochloride | AZ0560718 | 1 |
| Fagron | Diltiazem hydrochloride | AZ-0560718 | 20 |
| Fagron | Diltiazem hydrochloride | AZ-0631216 | 10 |
| Fagron | Diltiazem hydrochloride | AZ-0641216 | 4 |
| Fagron | Diltiazem hydrochloride | az-0810520 | 1 |
| Fagron | Diltiazem hydrochloride | AZ-0810520 | 9 |
| Fagron | Diltiazem hydrochloride | AZ3500522 | 1 |
| Fagron | Diltiazem hydrochloride | AZ-C150120 | 1 |
| Fagron | Diltiazem hydrochloride | B03_2167602 | 1 |
| Fagron | Diltiazem hydrochloride | B03-3625909 | 1 |
| Fagron | Diltiazem hydrochloride | B03-3662107 | 4 |
| Fagron | Diltiazem hydrochloride | B03-3662108 | 4 |
| Fagron | Diltiazem hydrochloride | B07-2230603 | 1 |
| Fagron | Diltiazem hydrochloride | Bo3-3626000 | 1 |
| Fagron | Diltiazem hydrochloride | DIL/M-01314 | 1 |
| Fagron | Diltiazem hydrochloride | DIL/M-0314 | 1 |
| Fagron | Diltiazem hydrochloride | DIL/M-10515 | 2 |
| Fagron | Diltiazem hydrochloride | DIL/M-13114 | 1 |
| Fagron | Diltiazem hydrochloride | DIL/M-20215 | 1 |
| Fagron | Diltiazem hydrochloride | DIL/M-21816 | 4 |
| Fagron | Diltiazem hydrochloride | Dilt09122022 | 1 |
| Fagron | Diltiazem hydrochloride | F01-3783303 | 1 |
| Fagron | Diltiazem hydrochloride | F02-3783303 | 2 |
| Fagron | Diltiazem hydrochloride | F03-3719007 | 10 |
| Fagron | Diltiazem hydrochloride | F03-3719008 | 1 |
| Fagron | Diltiazem hydrochloride | F03-3733809 | 1 |
| Fagron | Diltiazem hydrochloride | F03-3741701 | 2 |
| Fagron | Diltiazem hydrochloride | F03-374171 | 1 |
| Fagron | Diltiazem hydrochloride | F11-3747600 | 5 |
| Fagron | Diltiazem hydrochloride | F11-3747601 | 1 |
| Fagron | Diltiazem hydrochloride | F11-3747603 | 1 |
| Fagron | Diltiazem hydrochloride | F11-3747605 | 1 |
| Fagron | Diltiazem hydrochloride | F11-374764 | 1 |
| Fagron | Diltiazem hydrochloride | P-07041629/305400 | 1 |
| Fagron | Diltiazem hydrochloride | P-09101821/348861 | 1 |
| Fargon/AEP | Diltiazem hydrochloride | 20C12-F03-371907 | 1 |
| Fargon/AHD | Diltiazem hydrochloride | 18A29-B01-352907 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fargon/Kehr | Diltiazem hydrochloride | 16G20-B03-328133 | 1 |
| Fargon/Krieger | Diltiazem hydrochloride | 17H25-B1-340697 | 1 |
| Fargon/Krieger | Diltiazem hydrochloride | 18A29-B01-352907 | 1 |
| Fargon/Krieger | Diltiazem hydrochloride | 18H09-B03-354798 | 1 |
| Fargon/Krieger | Diltiazem hydrochloride | 18H09-B03-362595 | 1 |
| Fargon/Noweda | Diltiazem hydrochloride | 18H09-B03 | 1 |
| Fargon/Phönix | Diltiazem hydrochloride | 18H09-B03-358917 | 1 |
| Fargon/Phönix | Diltiazem hydrochloride | 20C12-F03-374171 | 1 |
| Fargon/Phönix | Diltiazem hydrochloride | 21F11-B03-216820 | 1 |
| Fargon | Diltiazem hydrochloride | 16C14-B11-320849 | 1 |
| Fargon | Diltiazem hydrochloride | 18A29-B01-348861 | 1 |
| Fargon | Diltiazem hydrochloride | 18A29-B01-352907 | 1 |
| Fargon | Diltiazem hydrochloride | 18H09-B03-362595 | 1 |
| Fargon | Diltiazem hydrochloride | AZ-0810520 | 1 |
| Fargon | Diltiazem hydrochloride | B03-3625905 | 1 |
| Fargon | Diltiazem hydrochloride | F03-3719007 | 1 |
| FGagron7Noweda | Diltiazem hydrochloride | B03-2136101 | 1 |
| Fgron / Gehe | Diltiazem hydrochloride | 17H25B01341596 | 1 |
| Fiebig ek:12.27 01.08.12 | Diltiazem hydrochloride | 11/01-N08 | 1 |
| Fiebig | Diltiazem hydrochloride | 16G20-B03-328133 | 1 |
| Fiebig | Diltiazem hydrochloride | 17043227 | 1 |
| fiebig | Diltiazem hydrochloride | 22001215030 | 1 |
| Fiebig | Diltiazem hydrochloride | 24000125006 | 1 |
| Fragon/ Gehe | Diltiazem hydrochloride | 18h09b03366217 | 1 |
| Fragon/Alliance | Diltiazem hydrochloride | 21F11-Bo3-216679 | 1 |
| Fragon/Noweda | Diltiazem hydrochloride | 16L19-B01-330396 | 1 |
| Fragon/Sanacorp | Diltiazem hydrochloride | 18H09-B03-358918 | 1 |
| Gatt-Koller | Diltiazem hydrochloride | 22J02643 | 1 |
| Gehe amax | Diltiazem hydrochloride | 18H09-B03-354798 | 1 |
| Gehe amax | Diltiazem hydrochloride | 18H09-B03-366218 | 1 |
| Gehe amax | Diltiazem hydrochloride | 190841005 | 2 |
| Gehe amax | Diltiazem hydrochloride | 19084106 | 1 |
| Gehe | Diltiazem hydrochloride | 12133009 | 1 |
| Gehe | Diltiazem hydrochloride | 12133022 | 1 |
| Gehe | Diltiazem hydrochloride | 13346915 | 1 |
| Gehe | Diltiazem hydrochloride | 14C12-B04-292757 | 1 |
| Gehe | Diltiazem hydrochloride | 14G22-B08-299781 | 1 |
| Gehe | Diltiazem hydrochloride | 15230503 | 1 |
| Gehe | Diltiazem hydrochloride | 15414319 | 1 |
| Gehe | Diltiazem hydrochloride | 15B12-B01-305399 | 2 |
| Gehe | Diltiazem hydrochloride | 16190806 | 1 |
| Gehe | Diltiazem hydrochloride | 16190813 | 1 |
| GEHE | Diltiazem hydrochloride | 16190813 | 1 |
| Gehe | Diltiazem hydrochloride | 16L-19-B01-330365 | 1 |
| Gehe | Diltiazem hydrochloride | 17043202 | 1 |
| GEHE | Diltiazem hydrochloride | 17043217 | 1 |
| Gehe | Diltiazem hydrochloride | 17043218 | 1 |
| Gehe | Diltiazem hydrochloride | 17043219 | 1 |
| GEHE | Diltiazem hydrochloride | 17337004 | 2 |
| Gehe | Diltiazem hydrochloride | 17337005 | 1 |
| GEHE | Diltiazem hydrochloride | 17337025 | 2 |
| Gehe | Diltiazem hydrochloride | 17337026 | 1 |
| Gehe | Diltiazem hydrochloride | 17337027 | 1 |
| Gehe | Diltiazem hydrochloride | 17D11-B11 | 1 |
| Gehe | Diltiazem hydrochloride | 17d11-b11-334837 | 1 |
| Gehe | Diltiazem hydrochloride | 18301111 | 1 |
| Gehe | Diltiazem hydrochloride | 18A29-B01 | 1 |
| Gehe | Diltiazem hydrochloride | 18A29-B01-348861 | 1 |
| Gehe | Diltiazem hydrochloride | 18A29-B01-352907 | 1 |
| Gehe | Diltiazem hydrochloride | 18H09-B03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Diltiazem hydrochloride | 18H09-B03-358917 | 1 |
| Gehe | Diltiazem hydrochloride | 18H09-B03-358918 | 1 |
| Gehe | Diltiazem hydrochloride | 18H09-B03-362599 | 1 |
| GEHE | Diltiazem hydrochloride | 19084110 | 1 |
| Gehe | Diltiazem hydrochloride | 20000622009 | 1 |
| Gehe | Diltiazem hydrochloride | 20C12-F03 | 1 |
| Gehe | Diltiazem hydrochloride | 20C12-F03-371907 | 1 |
| Gehe | Diltiazem hydrochloride | 20J01-F11-374760 | 1 |
| Gehe | Diltiazem hydrochloride | 21000035002 | 1 |
| Gehe | Diltiazem hydrochloride | 21000035016 | 1 |
| Gehe | Diltiazem hydrochloride | 21D26-F02-378333 | 1 |
| Gehe | Diltiazem hydrochloride | 21F11-B03-213610 | 1 |
| Gehe | Diltiazem hydrochloride | 21F11-B03-221071 | 2 |
| Gehe | Diltiazem hydrochloride | 22001215009 | 1 |
| Gehe | Diltiazem hydrochloride | 22001215012 | 1 |
| Gehe | Diltiazem hydrochloride | 22001215018 | 1 |
| GEHE | Diltiazem hydrochloride | 22001215018 | 1 |
| Gehe | Diltiazem hydrochloride | 22001215024 | 1 |
| Gehe | Diltiazem hydrochloride | 22I13-B07-223063 | 2 |
| GEHE | Diltiazem hydrochloride | 22I13-B07-223063 | 1 |
| Gehe | Diltiazem hydrochloride | 23C20-B02 | 1 |
| Gehe | Diltiazem hydrochloride | 23C20-B02-227683 | 2 |
| Gehe | Diltiazem hydrochloride | 23C20-B02-228330 | 1 |
| Gehe | Diltiazem hydrochloride | 23G06-B07-234623 | 2 |
| Gehe | Diltiazem hydrochloride | 23H17-B02-238694 | 1 |
| Gehe | Diltiazem hydrochloride | F11-3747600 | 1 |
| Geilenkirchen | Diltiazem hydrochloride | 17043218 | 1 |
| Geilenkirchen | Diltiazem hydrochloride | 19084108 | 1 |
| Hedinger GmbH | Diltiazem hydrochloride | 16G20-B03 | 1 |
| Jenne | Diltiazem hydrochloride | 15414313 | 1 |
| Jenne | Diltiazem hydrochloride | 21000035017 | 1 |
| Jenne | Diltiazem hydrochloride | 22001215019 | 1 |
| Jenne | Diltiazem hydrochloride | 22001215030 | 1 |
| Jenne | Diltiazem hydrochloride | 23001896007 | 1 |
| Kehr | Diltiazem hydrochloride | 17043228 | 1 |
| Kehr | Diltiazem hydrochloride | 21F11-B03-218858 | 1 |
| Kehr | Diltiazem hydrochloride | 21F11-B03-221071 | 1 |
| Kehr | Diltiazem hydrochloride | 22001215003 | 2 |
| Kehr | Diltiazem hydrochloride | 2213-B07-225364 | 1 |
| kehr | Diltiazem hydrochloride | 22I13B07223063 | 1 |
| kehr | Diltiazem hydrochloride | 22I13-B07-225364 | 1 |
| Kehr | Diltiazem hydrochloride | 23001896007 | 1 |
| Kehr | Diltiazem hydrochloride | 23C20-B02-228330 | 1 |
| kehr | Diltiazem hydrochloride | 23g06b07234623 | 1 |
| Kehr | Diltiazem hydrochloride | 24000125007 | 1 |
| Klenk | Diltiazem hydrochloride | 18A29-B01-347886 | 1 |
| Klosterring | Diltiazem hydrochloride | 16190806 | 1 |
| Krieger/Phönix | Diltiazem hydrochloride | AZ-0460321 | 1 |
| Krieger | Diltiazem hydrochloride | 22i13-B07-223063 | 1 |
| Kuerzel | Diltiazem hydrochloride | 13G16-N05 | 1 |
| Lusochimica S.P.A. I... | Diltiazem hydrochloride | 15230507 | 2 |
| M/s.Piramal Enterpri... | Diltiazem hydrochloride | 190841005 | 1 |
| M/s.Piramal Enterpri... | Diltiazem hydrochloride | 19084108 | 1 |
| M/s/Noweda | Diltiazem hydrochloride | DIL/M-03519 | 4 |
| Ms Piramal/Noweda | Diltiazem hydrochloride | DIL/M-02820 | 4 |
| Nachprüfung | Diltiazem hydrochloride | | 1 |
| Noveda | Diltiazem hydrochloride | 18A29-B01-348861 | 1 |
| Noveda | Diltiazem hydrochloride | 20000622011 | 1 |
| Noweda 17.09.2019 | Diltiazem hydrochloride | 19084105 | 1 |
| Noweda | Diltiazem hydrochloride | 12133010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Diltiazem hydrochloride | 12133022 | 1 |
| Noweda | Diltiazem hydrochloride | 12133029 | 1 |
| Noweda | Diltiazem hydrochloride | 12176801 | 1 |
| Noweda | Diltiazem hydrochloride | 13346901 | 1 |
| Noweda | Diltiazem hydrochloride | 14318409 | 1 |
| Noweda | Diltiazem hydrochloride | 15230503 | 1 |
| Noweda | Diltiazem hydrochloride | 15414319 | 1 |
| Noweda | Diltiazem hydrochloride | 16190812 | 1 |
| Noweda | Diltiazem hydrochloride | 16L19-B01-330365 | 2 |
| Noweda | Diltiazem hydrochloride | 17334012 | 1 |
| Noweda | Diltiazem hydrochloride | 17337026 | 1 |
| Noweda | Diltiazem hydrochloride | 17D11-B11-334837 | 1 |
| Noweda | Diltiazem hydrochloride | 18H09B03358918 | 1 |
| Noweda | Diltiazem hydrochloride | 18H09-B03-362595 | 1 |
| Noweda | Diltiazem hydrochloride | 19084104 | 1 |
| Noweda | Diltiazem hydrochloride | 20000622011 | 1 |
| Noweda | Diltiazem hydrochloride | 20J01-F11-374760 | 1 |
| Noweda | Diltiazem hydrochloride | 21000035002 | 1 |
| Noweda | Diltiazem hydrochloride | 21000035003 | 1 |
| Noweda | Diltiazem hydrochloride | 21000035017 | 1 |
| Noweda | Diltiazem hydrochloride | 2100035010 | 1 |
| Noweda | Diltiazem hydrochloride | 21F11-B03 | 1 |
| Noweda | Diltiazem hydrochloride | 21F11-B03-221071 | 1 |
| Noweda | Diltiazem hydrochloride | 22001215007 | 2 |
| Noweda | Diltiazem hydrochloride | 22001215009 | 1 |
| Noweda | Diltiazem hydrochloride | 22001215011 | 3 |
| Noweda | Diltiazem hydrochloride | 22001215012 | 1 |
| Noweda | Diltiazem hydrochloride | 22001215015 | 1 |
| Noweda | Diltiazem hydrochloride | 22001215018 | 1 |
| Noweda | Diltiazem hydrochloride | 22001215019 | 1 |
| Noweda | Diltiazem hydrochloride | 22001215024 | 5 |
| Noweda | Diltiazem hydrochloride | 22001215030 | 1 |
| NOWEDA | Diltiazem hydrochloride | 22001215030 | 1 |
| Noweda | Diltiazem hydrochloride | 2201215030 | 1 |
| Noweda | Diltiazem hydrochloride | 22113-B07-225364 | 1 |
| Noweda | Diltiazem hydrochloride | 22I13-B07-223063 | 1 |
| Noweda | Diltiazem hydrochloride | 22I13-B07-223065 | 2 |
| Noweda | Diltiazem hydrochloride | 22I13-B07-225364 | 1 |
| Noweda | Diltiazem hydrochloride | 22l13-B07-225365 | 1 |
| Noweda | Diltiazem hydrochloride | 23001896001 | 1 |
| Noweda | Diltiazem hydrochloride | 23001896002 | 1 |
| Noweda | Diltiazem hydrochloride | 23C20-B01-230369 | 2 |
| Noweda | Diltiazem hydrochloride | 23G06-B07-234623 | 1 |
| Noweda | Diltiazem hydrochloride | 23H17-B02-238694 | 1 |
| Noweda | Diltiazem hydrochloride | 24000125005 | 2 |
| Noweda | Diltiazem hydrochloride | 24000125007 | 3 |
| Noweda | Diltiazem hydrochloride | 24000125015 | 1 |
| Noweda | Diltiazem hydrochloride | AZ-0941022 | 1 |
| p&m cosmetics/gehe | Diltiazem hydrochloride | 17043217 | 1 |
| Phoenix 14.03.2019 15,21EUR | Diltiazem hydrochloride | 18A29-B01-345623 | 1 |
| phoenix | Diltiazem hydrochloride | 11/01-N08 | 1 |
| Phoenix | Diltiazem hydrochloride | 13346902 | 1 |
| Phoenix | Diltiazem hydrochloride | 13346914 | 1 |
| phoenix | Diltiazem hydrochloride | 14318412 | 1 |
| Phoenix | Diltiazem hydrochloride | 15230503 | 1 |
| Phoenix | Diltiazem hydrochloride | 17337005 | 1 |
| Phoenix | Diltiazem hydrochloride | 17337018 | 1 |
| Phoenix | Diltiazem hydrochloride | 18h09-b03 | 1 |
| Phoenix | Diltiazem hydrochloride | 18H09-B03-357183 | 1 |
| Phoenix | Diltiazem hydrochloride | 20000622014 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Diltiazem hydrochloride | 200101601 | 1 |
| Phoenix | Diltiazem hydrochloride | 20J01-F11 | 1 |
| Phoenix | Diltiazem hydrochloride | 20j01-f11-374763 | 1 |
| Phoenix | Diltiazem hydrochloride | 21000035003 | 1 |
| Phoenix | Diltiazem hydrochloride | 21000035013 | 3 |
| Phoenix | Diltiazem hydrochloride | 2100035004 | 1 |
| Phoenix | Diltiazem hydrochloride | 22001215024 | 1 |
| Phoenix | Diltiazem hydrochloride | 22001215030 | 2 |
| Phoenix | Diltiazem hydrochloride | 2200125029 | 1 |
| Phoenix | Diltiazem hydrochloride | 22I13-B07-223063 | 1 |
| Phoenix | Diltiazem hydrochloride | 22l13-B07-223063 | 1 |
| Phoenix | Diltiazem hydrochloride | 23001896007 | 1 |
| PHOENIX | Diltiazem hydrochloride | 23001896007 | 2 |
| Phoenix | Diltiazem hydrochloride | 23g06-b07-234623 | 1 |
| Phoenix | Diltiazem hydrochloride | 23G06-B07-234623 | 1 |
| Phoenix | Diltiazem hydrochloride | 23H17-B02-003150 | 1 |
| Phoenix | Diltiazem hydrochloride | AZ-0260423 | 1 |
| Phoenix | Diltiazem hydrochloride | B03-3625906 | 1 |
| Phöix | Diltiazem hydrochloride | 23C20-B02-227683 | 1 |
| Phönix Berlin | Diltiazem hydrochloride | 22001215019 | 1 |
| Phönix Gotha | Diltiazem hydrochloride | 15230503 | 1 |
| Phönix, Caesar&Loret… | Diltiazem hydrochloride | 19084115 | 1 |
| Phönix/Fagon | Diltiazem hydrochloride | 16A18-B07_318732 | 1 |
| Phönix/Fargon | Diltiazem hydrochloride | 18H09-B03-358917 | 1 |
| Phönix/Fargon | Diltiazem hydrochloride | AZ-0560718 | 1 |
| Phönix/Fargon | Diltiazem hydrochloride | F03-3719007 | 1 |
| Phönix | Diltiazem hydrochloride | 13196106 | 1 |
| Phönix | Diltiazem hydrochloride | 13F13-N05 | 1 |
| phönix | Diltiazem hydrochloride | 14059514 | 1 |
| Phönix | Diltiazem hydrochloride | 15212801 | 1 |
| Phönix | Diltiazem hydrochloride | 15414302 | 1 |
| Phönix | Diltiazem hydrochloride | 15G20-B08-310792 | 1 |
| phönix | Diltiazem hydrochloride | 16G20-B03-328133 | 1 |
| PHÖNIX | Diltiazem hydrochloride | 17043215 | 2 |
| Phönix | Diltiazem hydrochloride | 17043219 | 1 |
| Phönix | Diltiazem hydrochloride | 17d11-b11-334837 | 1 |
| Phönix | Diltiazem hydrochloride | 18A29-B01-347886 | 1 |
| Phönix | Diltiazem hydrochloride | 18A29-B01-348861 | 1 |
| Phönix | Diltiazem hydrochloride | 18h09-b03-358917 | 1 |
| Phönix | Diltiazem hydrochloride | 18H09-B03358917 | 1 |
| Phönix | Diltiazem hydrochloride | 18H09-B03-362595 | 1 |
| Phönix | Diltiazem hydrochloride | 18H09-B03-366217 | 2 |
| Phönix | Diltiazem hydrochloride | 19084106 | 1 |
| Phönix | Diltiazem hydrochloride | 19084108 | 1 |
| PHÖNIX | Diltiazem hydrochloride | 19084108 | 1 |
| Phönix | Diltiazem hydrochloride | 20000622015 | 1 |
| Phönix | Diltiazem hydrochloride | 2000622003 | 1 |
| Phönix | Diltiazem hydrochloride | 20C12-F03-373389 | 1 |
| Phönix | Diltiazem hydrochloride | 21F11B03213611 | 1 |
| phönix | Diltiazem hydrochloride | 21F11-B03-221071 | 2 |
| Phönix | Diltiazem hydrochloride | 22001215024 | 3 |
| Phönix | Diltiazem hydrochloride | 22001215030 | 4 |
| PHönix | Diltiazem hydrochloride | 22001215030 | 1 |
| Phönix | Diltiazem hydrochloride | 2200121530 | 1 |
| Phönix | Diltiazem hydrochloride | 22I13-B07_223063 | 1 |
| Phönix | Diltiazem hydrochloride | 23001896007 | 2 |
| phönix | Diltiazem hydrochloride | 23C20-B02-227683 | 3 |
| Phönix | Diltiazem hydrochloride | 23C20-B02-227683 | 1 |
| Phönix | Diltiazem hydrochloride | AZ-0350522 | 2 |
| Phönix | Diltiazem hydrochloride | AZ-0560718 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Diltiazem hydrochloride | AZ-0951022 | 1 |
| Phönix | Diltiazem hydrochloride | b03-3625906 | 1 |
| Phönix | Diltiazem hydrochloride | f11-3747600 | 1 |
| Piramal Healthcare L... | Diltiazem hydrochloride | 12/12-N02 | 1 |
| Piramaral Healthcare LTD. | Diltiazem hydrochloride | 12F19-N10 | 1 |
| Röntgen | Diltiazem hydrochloride | 18A29-B01-350964 | 1 |
| Sanacop | Diltiazem hydrochloride | 14059523 | 1 |
| Sanacorp /Fargron | Diltiazem hydrochloride | 16G20-B03-325903 | 1 |
| Sanacorp WE 17.02.17... | Diltiazem hydrochloride | 16190806 | 1 |
| Sanacorp, 18.02.17, ... | Diltiazem hydrochloride | 16190807 | 1 |
| Sanacorp | Diltiazem hydrochloride | 11134115 | 4 |
| Sanacorp | Diltiazem hydrochloride | 11134121 | 2 |
| Sanacorp | Diltiazem hydrochloride | 11J28-04511 | 1 |
| Sanacorp | Diltiazem hydrochloride | 12/12-N02 | 2 |
| Sanacorp | Diltiazem hydrochloride | 12133010 | 1 |
| Sanacorp | Diltiazem hydrochloride | 12I12-N02 | 1 |
| Sanacorp | Diltiazem hydrochloride | 13j24-b04-286569 | 1 |
| Sanacorp | Diltiazem hydrochloride | 14c12-b04-292757 | 1 |
| Sanacorp | Diltiazem hydrochloride | 17043217 | 1 |
| Sanacorp | Diltiazem hydrochloride | 17337005 | 1 |
| Sanacorp | Diltiazem hydrochloride | 17337009 | 1 |
| Sanacorp | Diltiazem hydrochloride | 17337026 | 2 |
| Sanacorp | Diltiazem hydrochloride | 18301111 | 2 |
| Sanacorp | Diltiazem hydrochloride | 18H09-B03 | 2 |
| Sanacorp | Diltiazem hydrochloride | 190841006 | 1 |
| Sanacorp | Diltiazem hydrochloride | 19084104 | 1 |
| Sanacorp | Diltiazem hydrochloride | 19084106 | 1 |
| Sanacorp | Diltiazem hydrochloride | 19084107 | 1 |
| Sanacorp | Diltiazem hydrochloride | 21000035003 | 1 |
| Sanacorp | Diltiazem hydrochloride | 21000035009 | 1 |
| Sanacorp | Diltiazem hydrochloride | 22001215007 | 2 |
| Sanacorp | Diltiazem hydrochloride | 22001215009 | 1 |
| sanacorp | Diltiazem hydrochloride | 22001215012 | 2 |
| Sanacorp | Diltiazem hydrochloride | 22001215012 | 1 |
| Sanacorp | Diltiazem hydrochloride | 22001215019 | 1 |
| Sanacorp | Diltiazem hydrochloride | 22001215026 | 1 |
| Sanacorp | Diltiazem hydrochloride | 22001215029 | 1 |
| Sanacorp | Diltiazem hydrochloride | 22I13-B07-223063 | 1 |
| sanacorp | Diltiazem hydrochloride | 23001896006 | 1 |
| Sanacorp | Diltiazem hydrochloride | 23G06-B07-234623 | 1 |
| Sanacorp | Diltiazem hydrochloride | 24000125007 | 1 |
| Sanacorp | Diltiazem hydrochloride | 3216679 | 1 |
| Sanacorp | Diltiazem hydrochloride | Fargon | 1 |
| sittig | Diltiazem hydrochloride | 14G22-B08-299781 | 1 |
| VDL;18.02.15;15,95EUR | Diltiazem hydrochloride | 14059514 | 1 |
| Wepa / Wepa | Diltiazem hydrochloride | 17043218 | 1 |

- 251 844 spectra from 1666 *Apo-Ident* customers from a total of 51 408 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Diltiazem hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Diltiazem hydrochloride*

and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 300 | 0 | 212 640 |
| **Type C** | 0 | 4868 | 174 | 251 844 |

The substance/substance group *Diltiazem hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 96.5490 % (> 96.4895 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21270 | 22631 | 27.43 | 88.88 |
| 21300 | 22631 | 12.80 | 89.55 |
| 21406 | 22631 | 12.05 | 89.21 |
| 21407 | 22631 | 12.41 | 97.38 |
| 22631 | 22631 | 0.00 | 101.13 |
| 23015 | 23325 | 22.45 | 95.00 |
| 23016 | 22631 | 26.70 | 97.09 |
| 23325 | 23325 | 0.00 | 96.55 |
| 25365 | 22631 | 17.35 | 102.80 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Diphenhydramine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20186-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Diphenhydramine hydrochloride; Diphenhydramini hydrochloridum

### Special notes

When selecting the *Diphenhydramine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Diphenhydramine hydrochloride | 7 | 5 | 67 |

### Second-stage model

For differentiation of the substance/substance group *Diphenhydramine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Diphenhydramine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Doxepin hydrochloride | 73.70 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Diphenhydramine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Diphenhydramine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Diphenhydramine hydrochloride | 12329816 | 21304 | 40 | 20121119 |
| Caelo | Diphenhydramine hydrochloride | 12329816 | 21464 | 60 | 20121119 |
| Caelo | Diphenhydramine hydrochloride | 16004901 | 23235 | 40 | 20160122 |
| Caelo | Diphenhydramine hydrochloride | 180082 | 24755 | 40 | 20180126* |
| Caelo | Diphenhydramine hydrochloride | 22002760 | 26361 | 30 | 20220923* |
| Caelo | Diphenhydramine hydrochloride | 22002760 | 26361SI | 20 | 20220923* |
| Fagron | Diphenhydramine hydrochloride | 16C25-B03-331026 | 23262 | 40 | AR-17-FG-015432-02 |
| Fagron | Diphenhydramine hydrochloride | 18K28-B02-358954 | 24702 | 40 | 20181219 |
| Fagron | Diphenhydramine hydrochloride | 20G03-F08-374141 | 25746 | 50 | 20200928 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *Diphenhydramine - hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 7 reference samples from the substance/substance group *Diphenhydramine - hydrochloride*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Diphenhydramine hydrochloride | 15072617 | 23206 | 40 |
| Caelo | Diphenhydramine hydrochloride | 172276 | 23803 | 40 |
| Caelo | Diphenhydramine hydrochloride | 183010 | 24390 | 40 |
| Caelo | Diphenhydramine hydrochloride | 22003785 | 26717 | 40 |
| Caelo | Diphenhydramine hydrochloride | 23001022 | 26836 | 40 |
| Caelo | Diphenhydramine hydrochloride | 22003785 | 26717SI | 20 |
| Caelo | Diphenhydramine hydrochloride | 23001022 | 26836SI | 20 |

- 212 700 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 215 spectra from 112 *Apo-Ident* customers from 69 batches from the substance/substance group *Diphenhydramine hydrochloride*.

- Among them are spectra of independent samples from 67 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Diphenhydramine hydrochloride | 21000109013 | 2 |
| | Diphenhydramine hydrochloride | 22002760004 | 4 |
| | Diphenhydramine hydrochloride | 22002760007 | 1 |
| | Diphenhydramine hydrochloride | 22003785002 | 1 |
| | Diphenhydramine hydrochloride | 24001421004 | 1 |
| Caelo | Diphenhydramine hydrochloride | | 1 |
| Caelo | Diphenhydramine hydrochloride | 10122030 | 1 |
| Caelo | Diphenhydramine hydrochloride | 12007702 | 1 |
| Caelo | Diphenhydramine hydrochloride | 12007713 | 2 |
| Caelo | Diphenhydramine hydrochloride | 12007715 | 2 |
| Caelo | Diphenhydramine hydrochloride | 12007716 | 1 |
| Caelo | Diphenhydramine hydrochloride | 12007721 | 2 |
| Caelo | Diphenhydramine hydrochloride | 12329805 | 1 |
| Caelo | Diphenhydramine hydrochloride | 12329815 | 2 |
| Caelo | Diphenhydramine hydrochloride | 13100462 | 1 |
| Caelo | Diphenhydramine hydrochloride | 13331810 | 2 |
| Caelo | Diphenhydramine hydrochloride | 13331813 | 1 |
| Caelo | Diphenhydramine hydrochloride | 13343104 | 1 |
| Caelo | Diphenhydramine hydrochloride | 15072602 | 4 |
| Caelo | Diphenhydramine hydrochloride | 15072603 | 5 |
| Caelo | Diphenhydramine hydrochloride | 15072608 | 1 |
| Caelo | Diphenhydramine hydrochloride | 15072609 | 6 |
| Caelo | Diphenhydramine hydrochloride | 15072614 | 13 |
| Caelo | Diphenhydramine hydrochloride | 15072617 | 3 |
| Caelo | Diphenhydramine hydrochloride | 15072630 | 1 |
| Caelo | Diphenhydramine hydrochloride | 15220402 | 1 |
| Caelo | Diphenhydramine hydrochloride | 15220403 | 8 |
| Caelo | Diphenhydramine hydrochloride | 15220404 | 3 |
| Caelo | Diphenhydramine hydrochloride | 15220405 | 3 |
| Caelo | Diphenhydramine hydrochloride | 16004905 | 1 |
| Caelo | Diphenhydramine hydrochloride | 16004908 | 3 |
| Caelo | Diphenhydramine hydrochloride | 16004910 | 8 |
| Caelo | Diphenhydramine hydrochloride | 18008201 | 5 |
| Caelo | Diphenhydramine hydrochloride | 18008202 | 1 |
| Caelo | Diphenhydramine hydrochloride | 18008205 | 5 |
| Caelo | Diphenhydramine hydrochloride | 18008208 | 10 |
| Caelo | Diphenhydramine hydrochloride | 18108407 | 1 |
| Caelo | Diphenhydramine hydrochloride | 1814A-01339 | 1 |
| Caelo | Diphenhydramine hydrochloride | 18168403 | 3 |
| Caelo | Diphenhydramine hydrochloride | 18168407 | 17 |
| Caelo | Diphenhydramine hydrochloride | 1912I-01339 | 1 |
| Caelo | Diphenhydramine hydrochloride | 2000239001 | 1 |
| Caelo | Diphenhydramine hydrochloride | 20002393001 | 4 |
| Caelo | Diphenhydramine hydrochloride | 20071502 | 1 |
| Caelo | Diphenhydramine hydrochloride | 2041403 | 1 |
| Caelo | Diphenhydramine hydrochloride | 21000108002 | 1 |
| Caelo | Diphenhydramine hydrochloride | 21000109007 | 2 |
| Caelo | Diphenhydramine hydrochloride | 21000109013 | 1 |
| Caelo | Diphenhydramine hydrochloride | 22003785002 | 1 |
| Caelo | Diphenhydramine hydrochloride | 2215I-01339 | 1 |
| Caelo | Diphenhydramine hydrochloride | 25071306 | 1 |
| Caelo | Diphenhydramine hydrochloride | 2517M-01339 | 1 |
| Caelo | Diphenhydramine hydrochloride | 2818A-01339 | 1 |
| Caelo | Diphenhydramine hydrochloride | 3071715 | 1 |
| Caelo | Diphenhydramine hydrochloride | 31031508 | 1 |
| Caelo | Diphenhydramine hydrochloride | 5121204 | 1 |
| Caelo | Diphenhydramine hydrochloride | 8072001 | 1 |
| Caeolo | Diphenhydramine hydrochloride | 18008205 | 1 |
| Caesar & Loretz GmbH... | Diphenhydramine hydrochloride | 18168407 | 2 |
| Caesar & Loretz GmbH... | Diphenhydramine hydrochloride | 18168407 | 1 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Diphenhydramine hydrochloride | 21000108002 | 1 |
| Caesar & Loretz GmbH... | Diphenhydramine hydrochloride | 21000109007 | 2 |
| Caesar & Loretz GmbH | Diphenhydramine hydrochloride | 18008208 | 1 |
| Caesar & Loretz GmbH | Diphenhydramine hydrochloride | 18168407 | 13 |
| Caesar & Loretz GmbH | Diphenhydramine hydrochloride | 20002393004 | 1 |
| Caesar & Loretz GmbH | Diphenhydramine hydrochloride | 21000108003 | 2 |
| Caesar & Loretz GmbH | Diphenhydramine hydrochloride | 21000109003 | 1 |
| Caesar & Loretz GmbH | Diphenhydramine hydrochloride | 21000109007 | 4 |
| Caesar & Loretz GmbH | Diphenhydramine hydrochloride | 21000109013 | 1 |
| Caesar & Loretz Hilden | Diphenhydramine hydrochloride | 16004905 | 1 |
| Caesar & Loretz Hilden | Diphenhydramine hydrochloride | 18008202 | 2 |
| Caesar & Loretz Hilden | Diphenhydramine hydrochloride | 18008205 | 1 |
| Caesar & Loretz Hilden | Diphenhydramine hydrochloride | 18168403 | 1 |
| Caesar & Loretz Hilden | Diphenhydramine hydrochloride | 18168407 | 2 |
| Caesar & Loretz Hilden | Diphenhydramine hydrochloride | 20002393001 | 2 |
| Caesar/Noweda | Diphenhydramine hydrochloride | 12007714 | 1 |
| Fagron | Diphenhydramine hydrochloride | 12F28-N01 | 1 |
| Fagron | Diphenhydramine hydrochloride | 12J04-N02 | 1 |
| Fagron | Diphenhydramine hydrochloride | 13A14-B40-293346 | 1 |
| Fagron | Diphenhydramine hydrochloride | 15072614 | 1 |
| Fagron | Diphenhydramine hydrochloride | 16C25-B03-331026 | 1 |
| Finze | Diphenhydramine hydrochloride | 9F05-N04 | 2 |
| Gatt-Koller | Diphenhydramine hydrochloride | 21J02410 | 1 |
| Gatt-Koller | Diphenhydramine hydrochloride | 606030315 | 1 |
| Gehe | Diphenhydramine hydrochloride | 12329815 | 1 |
| Gehe | Diphenhydramine hydrochloride | 22003785002 | 1 |
| Jenne | Diphenhydramine hydrochloride | 18008208 | 1 |
| L30 | Diphenhydramine hydrochloride | 18008201 | 1 |
| Noweda | Diphenhydramine hydrochloride | 12007716 | 1 |
| Noweda | Diphenhydramine hydrochloride | 15220402 | 1 |
| PHOENIX 29.01.2013 | Diphenhydramine hydrochloride | 120208 | 1 |
| Phönix WE: 07.01.14 ... | Diphenhydramine hydrochloride | 12329805 | 1 |
| Recordati/Noweda | Diphenhydramine hydrochloride | 17100490 | 1 |
| Sanacorp | Diphenhydramine hydrochloride | 12329805 | 1 |
| Sanacorp | Diphenhydramine hydrochloride | 15072608 | 1 |
| Sanacorp | Diphenhydramine hydrochloride | 15072617 | 1 |
| Sanacorp | Diphenhydramine hydrochloride | 16004908 | 1 |
| Sanacorp | Diphenhydramine hydrochloride | 2200276000 | 1 |
| Supriya/Noweda | Diphenhydramine hydrochloride | 20002393004 | 1 |

- 256 671 spectra from 1666 *Apo-Ident* customers from a total of 52 085 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Diphenhydramine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Diphenhydramine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 202 | 13 | 256 671 |

The substance/substance group *Diphenhydramine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 93.9535 % (> 92.5581 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21304 | 23262 | 18.91 | 101.51 |
| 21464 | 23262 | 16.23 | 101.34 |
| 23235 | 23262 | 18.30 | 101.07 |
| 23262 | 23262 | 0.00 | 108.65 |
| 24702 | 23262 | 9.04 | 106.65 |
| 24755 | 24755 | 0.00 | 100.69 |
| 25746 | 23262 | 10.12 | 101.64 |
| 26361 | 26361 | 0.00 | 101.64 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Diphenylcyclopropenone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10003690-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Diphenylcyclopropenone; Diphenylcyclopropenonum

### Special notes

When selecting the *Diphenylcyclopropenone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Diphenylcyclopropenone | 7 | 3 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Diphenylcyclopropenone* the following second-stage model is used:

- Submodel 18

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Diphenylcyclopropenone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium benzoate | 44.89 | 27.24 |
| Dithranol | 114.88 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Diphenylcyclopropenone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Diphenylcyclopropenone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Diphenylcyclopropenone | 12L17-N07 | 20934 | 40 | 1407599 |
| Fagron | Diphenylcyclopropenone | 13I26-N12 | 21342 | 40 | 1504598 |
| Fagron | Diphenylcyclopropenone | 13I26-N12 | 21539 | 35 | 20130920 |
| Fagron | Diphenylcyclopropenone | 16F02-B10-329708 | 23070 | 40 | 1902476 |
| Fagron | Diphenylcyclopropenone | 16F02-B10-326265 | 23071 | 40 | 20160822 |
| Fagron | Diphenylcyclopropenone | 20I09-F02-374243 | 25585 | 40 | 20201016 |
| Fagron | Diphenylcyclopropenone | 20J27-F06-374823 | 25741 | 50 | 20201109 |
| Fagron | Diphenylcyclopropenone | 22D27-B01-226151 | 26540 | 40 | 20220630 |
| Fagron | Diphenylcyclopropenone | 22D27-B01-226151 | 26540SI | 20 | 20220630 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 345 spectra of 9 reference samples from the substance/substance group *Diphenylcyclopropenone*.


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These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 981 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 3 reference samples from the substance/substance group *Diphenylcyclopropenone*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Diphenylcyclopropenone | 15J12-B01-316620 | 22362 | 60 |
| Fagron | Diphenylcyclopropenone | 18I03-B04-356833 | 24582 | 40 |
| Fagron | Diphenylcyclopropenone | 19K26-F01-367396 | 25189 | 40 |

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 16 spectra from 13 *Apo-Ident* customers from 13 batches from the substance/substance group *Diphenylcyclopropenone*.
- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Diphenylcyclopropenone | 17B-13B02-334769 | 1 |
| Fagron | Diphenylcyclopropenone | 1(17B13-B02-34977) | 1 |
| Fagron | Diphenylcyclopropenone | 16F02B10324263 | 1 |
| Fagron | Diphenylcyclopropenone | 16F02-B10-327812 | 3 |
| Fagron | Diphenylcyclopropenone | 18I03B04 | 1 |
| Fagron | Diphenylcyclopropenone | 18I-03-B04 | 1 |
| Fagron | Diphenylcyclopropenone | 18I03-B04_356833 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Diphenylcyclopropenone | 19K26-F01-367396 | 1 |
| Fagron | Diphenylcyclopropenone | 20J27-F06-374823 | 1 |
| Fagron | Diphenylcyclopropenone | 35-16-I-95P3117 | 1 |
| Fagron | Diphenylcyclopropenone | 35-17-II-57P3503 | 1 |
| Fiebig | Diphenylcyclopropenone | 17B13-B02-334769 | 1 |
| Frago/Noweda | Diphenylcyclopropenone | 16F02-B10-324263 | 2 |

- 256 870 spectra from 1666 *Apo-Ident* customers from a total of 52 140 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Diphenylcyclopropenone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Diphenylcyclopropenone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 345 | 0 | 157 981 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 16 | 0 | 256 870 |

The substance/substance group *Diphenylcyclopropenone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2609 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20934 | 20934 | 0.00 | 102.20 |
| 21342 | 21342 | 0.00 | 274.70 |
| 21539 | 21342 | 4.54 | 282.93 |
| 23070 | 23070 | 0.00 | 92.29 |
| 23071 | 21342 | 63.96 | 277.02 |
| 25585 | 20934 | 36.12 | 113.44 |
| 25741 | 20934 | 12.45 | 107.26 |
| 26540 | 20934 | 38.83 | 95.44 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Dithranol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20032-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Dithranol; Dithranolum

### Special notes

When selecting the *Dithranol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Dithranol | 11 | 5 | 178 |

### Second-stage model

For differentiation of the substance/substance group *Dithranol* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Dithranol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 114.22 | – |
| ⋮ | ⋮ | ⋮ |
| Sodium salicylate | >50 | 34.64 |
| Dequalinium chloride | >50 | 36.10 |
| Acetylsalicylic acid | >50 | 51.98 |
| Benzoic acid | >50 | 59.17 |
| Eosin Y | >50 | 161.16 |
| Oxytetracycline hydrochloride | >50 | 269.52 |
| Levothyroxin sodium | >50 | 567.21 |
| Tannin | >50 | 1207.10 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Dithranol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Dithranol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Dithranol | 18115302 | 24169 | 40 | 1811302 |
| Caelo | Dithranol | 18190604 | 24429 | 40 | 1904372 |
| Caelo | Dithranol | 190868 | 24501 | 40 | 20190426* |
| Caelo | Dithranol | 190550 | 24503 | 40 | 20190426* |
| Caelo | Dithranol | 20002967002 | 25429 | 30 | 2102141 |
| Caelo | Dithranol | 20002967 | 25646 | 40 | 20201021* |
| Euro OTC | Dithranol | 1702022-01 | 24153 | 40 | 1809448 |
| Euro OTC | Dithranol | 2201006 | 25960 | 40 | 20220209* |
| Fagron | Dithranol | 18B23-B05-348137 | 24172 | 40 | 20180430 |
| Fagron | Dithranol | 20K20-B04-203566 | 25502 | 40 | 20201127 |
| Fagron | Dithranol | 22F11-B02-223754 | 26452 | 40 | 230502386 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 430 spectra of 11 reference samples from the substance/substance group *Dithranol*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 896 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 250 spectra of 8 reference samples from the substance/substance group *Dithranol*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Audor Pharma | Dithranol | APOP_DNL/11/17/001D | 24173 | 40 |
| Caelo | Dithranol | 24000565 | 27320 | 40 |
| Euro OTC | Dithranol | 2001025 | 25101 | 40 |
| Euro OTC | Dithranol | 2004028 | 25472 | 40 |
| Euro OTC | Dithranol | 2409010 | 27455 | 40 |
| Caelo | Dithranol | 24000565 | 27320SI | 20 |
| Euro OTC | Dithranol | 2201006 | 25960SI† | 10 |
| Euro OTC | Dithranol | 2409010 | 27455SI | 20 |

- 212 690 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 688 spectra from 448 *Apo-Ident* customers from 193 batches from the substance/substance group *Dithranol*.
- Among them are spectra of independent samples from 177 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Dithranol | 17970168 | 1 |
| | Dithranol | 20000213003 | 1 |
| | Dithranol | 2000024300 | 1 |
| | Dithranol | 21000824004301221/4 | 1 |
| | Dithranol | 21000824007 | 1 |
| | Dithranol | 21I17-B01-213565 | 3 |
| | Dithranol | 22001422005 | 21 |
| | Dithranol | 22001422009 | 2 |
| | Dithranol | 22001422012 | 1 |
| | Dithranol | 2200142205 | 1 |
| | Dithranol | 2201006-01 | 1 |
| | Dithranol | 2201006-03 | 2 |
| | Dithranol | 2201006-04 | 10 |
| | Dithranol | 2201006-05 | 21 |
| | Dithranol | 22F11-B02 | 1 |
| | Dithranol | 22F11-B02-219586 | 2 |
| | Dithranol | 22F11-B02-226170 | 9 |
| | Dithranol | 230725(22001422005) | 1 |
| | Dithranol | 23F15-B01-231257 | 2 |
| | Dithranol | 23F15-BO1-231257 | 1 |
| | Dithranol | 23H22-B11-237978 | 2 |
| | Dithranol | 24000565004 | 7 |
| | Dithranol | 2409010-01 | 4 |
| | Dithranol | 24F28-B29-002278 | 1 |
| | Dithranol | 24F28-B29-002279 | 3 |
| | Dithranol | 24F28-B29-007014 | 1 |
| | Dithranol | 829-0022708 | 1 |
| | Dithranol | B01-2312507 | 1 |
| | Dithranol | B11-2379708 | 1 |
| | Dithranol | B11-2407809 | 2 |
| | Dithranol | B29-0022708 | 1 |
| | Dithranol | OP-DNL-C1-001/22 | 1 |
| | Dithranol | OPF28-B29-0022789 | 1 |
| 11,41 | Dithranol | 23F15-B01-231257 | 1 |
| 31.08.2021 | Dithranol | 2001025-01 | 2 |
| AHC | Dithranol | 2201006-01 | 1 |
| AHD | Dithranol | 1702022-04 | 1 |
| AHD | Dithranol | 21000824001 | 1 |
| AHD | Dithranol | 22001422005 | 1 |
| AHD | Dithranol | APDT/386/2012D | 1 |
| Alliance Healthcare | Dithranol | 2201006-05 | 2 |
| Alliance Healthcare | Dithranol | 24000565004 | 1 |
| Alliance | Dithranol | 21000824005 | 1 |
| Alliance | Dithranol | 22001006-05 | 1 |
| Alliance | Dithranol | 22001422005 | 1 |
| Alliance | Dithranol | 2201006-05 | 1 |
| Anzag | Dithranol | 120302502 | 1 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Dithranol | | 18 |
| Audor Pharma | Dithranol | 11/11/002D | 1 |
| Audor Pharma | Dithranol | 28(APOP-DNL/11/17/0 | 1 |
| Audor Pharma | Dithranol | AOOP-DNL/11/17002S | 1 |
| Audor Pharma | Dithranol | APDT/351/2010D | 1 |
| Audor Pharma | Dithranol | APDT/365/2011 | 2 |
| Audor Pharma | Dithranol | APDT/365/2011D | 1 |
| Audor Pharma | Dithranol | APDT/375/2012D | 8 |
| Audor Pharma | Dithranol | APDT/450/2016D | 1 |
| Audor Pharma | Dithranol | APDT/471/2017D | 5 |
| Audor Pharma | Dithranol | APDT3752012D | 1 |
| Audor Pharma | Dithranol | APDT3902013D | 1 |
| Audor Pharma | Dithranol | APO-DNL/11/17/001-1D | 1 |
| Audor Pharma | Dithranol | APOP-DNL/11/17/0002 | 1 |
| Audor Pharma | Dithranol | ApOPDNL/11/17/001 | 1 |
| Audor Pharma | Dithranol | APOP-DNL/11/17/001 | 2 |
| Audor Pharma | Dithranol | APOP-DNL/11/17/001-1 | 3 |
| Audor Pharma | Dithranol | APOPDNL/11/17/001-1D | 1 |
| Audor Pharma | Dithranol | APOP-DNL/11/17/001D | 4 |
| Audor Pharma | Dithranol | APOP-DNL/11/17/001-D | 4 |
| Audor Pharma | Dithranol | APOP-DNL/11/17/002 | 4 |
| Audor Pharma | Dithranol | apop-dnl/11/17/002d | 1 |
| Audor Pharma | Dithranol | APOP-DNL/11/17/002D | 2 |
| Audor Pharma | Dithranol | APOP-DNL/11/17001-1 | 1 |
| Audor Pharma | Dithranol | APOP-DNL/11/17001-1D | 1 |
| Audor Pharma | Dithranol | APOP-DNL11170011D | 1 |
| Audor Pharma | Dithranol | APOPDNL1117002D | 1 |
| Audor Pharma | Dithranol | APQP-DNL/11/17/002D | 1 |
| Audor Pharma | Dithranol | DT/351/2010D | 1 |
| Audor Pharma | Dithranol | DT/375/2012D | 2 |
| Audor Pharma | Dithranol | OP-DNL/11/17/0001 | 1 |
| Audor Pharma | Dithranol | OP-DNL/11/17/001 | 1 |
| Audor Pharma | Dithranol | OP-DNL/11/17/001-1D | 1 |
| Caelo | Dithranol | | 2 |
| Caelo | Dithranol | 11064501 | 1 |
| Caelo | Dithranol | 12014502 | 1 |
| Caelo | Dithranol | 12014504 | 2 |
| Caelo | Dithranol | 1203025-02 | 1 |
| Caelo | Dithranol | 1212I-01274 | 1 |
| Caelo | Dithranol | 12236809 | 1 |
| Caelo | Dithranol | 12236811 | 4 |
| Caelo | Dithranol | 12375302 | 4 |
| Caelo | Dithranol | 12375305 | 1 |
| Caelo | Dithranol | 12375403 | 1 |
| Caelo | Dithranol | 12375601 | 1 |
| Caelo | Dithranol | 13120502 | 1 |
| Caelo | Dithranol | 13120503 | 1 |
| Caelo | Dithranol | 13120504 | 1 |
| Caelo | Dithranol | 13120702 | 1 |
| Caelo | Dithranol | 14101715 | 1 |
| Caelo | Dithranol | 1702022-01 | 1 |
| Caelo | Dithranol | 1702022-04 | 1 |
| Caelo | Dithranol | 18055001 | 1 |
| Caelo | Dithranol | 18115302 | 3 |
| Caelo | Dithranol | 18115306 | 3 |
| Caelo | Dithranol | 18115308 | 3 |
| Caelo | Dithranol | 18B23-B05-348137 | 1 |
| Caelo | Dithranol | 19055001 | 7 |
| Caelo | Dithranol | 19086804 | 3 |
| Caelo | Dithranol | 19204604 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dithranol | 19204605 | 5 |
| Caelo | Dithranol | 192939004 | 11 |
| Caelo | Dithranol | 192939005 | 3 |
| Caelo | Dithranol | 200000243003 | 1 |
| Caelo | Dithranol | 20000243003 | 13 |
| Caelo | Dithranol | 200004097004 | 1 |
| Caelo | Dithranol | 20001097004 | 1 |
| Caelo | Dithranol | 20002967002 | 1 |
| Caelo | Dithranol | 20004097001 | 6 |
| Caelo | Dithranol | 20004097002 | 1 |
| Caelo | Dithranol | 20004097004 | 8 |
| Caelo | Dithranol | 210000824001 | 1 |
| Caelo | Dithranol | 210008240007 | 1 |
| Caelo | Dithranol | 21000824001 | 20 |
| Caelo | Dithranol | 21000824002 | 2 |
| Caelo | Dithranol | 21000824004 | 26 |
| Caelo | Dithranol | 21000824007 | 17 |
| Caelo | Dithranol | 2100824004 | 1 |
| Caelo | Dithranol | 27111206 | 1 |
| Caelo | Dithranol | 7/2020 | 1 |
| Caelo | Dithranol | APDT/3652011D | 1 |
| Caelo | Dithranol | APDT/375/2012D | 3 |
| Caelo | Dithranol | APOP-DNL/11/17/001-1 | 1 |
| Caelo | Dithranol | B04-2035606 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 192939004 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 21000824004 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 192939004 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 20004097001 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 20000243002 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 21000824004 | 1 |
| Caesar & Loretz GmbH/Gehe | Dithranol | 21000824001 | 1 |
| Caesar & Loretz GmbH/Gehe | Dithranol | 21000824004 | 1 |
| Caesar & Loretz GmbH/Gehe | Dithranol | 21000824007 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 20004097001 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 21000824002 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 20000243004 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 20004097001 | 1 |
| Caesar & Loretz GmbH... | Dithranol | 21000824007 | 2 |
| Caesar & Loretz GmbH | Dithranol | 1702022-04 | 1 |
| Caesar & Loretz GmbH | Dithranol | 19055001 | 2 |
| Caesar & Loretz GmbH | Dithranol | 19086804 | 1 |
| CAESAR & LORETZ GMBH | Dithranol | 192939004 | 1 |
| Caesar & Loretz GmbH | Dithranol | 192939005 | 1 |
| Caesar & Loretz GmbH | Dithranol | 20000243003 | 3 |
| Caesar & Loretz GmbH | Dithranol | 20000243004 | 1 |
| Caesar & Loretz GmbH | Dithranol | 20002967002 | 1 |
| Caesar & Loretz GmbH | Dithranol | 20004097001 | 7 |
| Caesar & Loretz GmbH | Dithranol | 20004097002 | 2 |
| Caesar & Loretz GmbH | Dithranol | 20004097004 | 5 |
| Caesar & Loretz GmbH | Dithranol | 21000824001 | 6 |
| Caesar & Loretz GmbH | Dithranol | 21000824003 | 1 |
| Caesar & Loretz GmbH | Dithranol | 21000824004 | 8 |
| Caesar & Loretz GmbH | Dithranol | 21000824007 | 4 |
| Caesar & Loretz GmbH | Dithranol | 22001422002 | 1 |
| Caesar & Loretz GmbH | Dithranol | 22001422005 | 1 |
| Cealo / Anzag | Dithranol | 221129(21000824007) | 1 |
| Cealo | Dithranol | 20004097004 | 2 |
| Ceasar & Loretz GmbH... | Dithranol | 19204605 | 1 |
| EuRho / Noweda | Dithranol | 2004028-01 | 1 |
| EuRho/ Sanacorp | Dithranol | 2201006-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| eurho/noweda | Dithranol | 2201006-04 | 1 |
| EuRho/Phoenix | Dithranol | 2001025-01 | 2 |
| EuRho/Sanacorp | Dithranol | 2004028 | 1 |
| EuRho | Dithranol | 1203025-01 | 1 |
| EuRho | Dithranol | 2201006-02 | 1 |
| EuRho | Dithranol | 2201006-03 | 1 |
| Euro OTC | Dithranol | | 1 |
| Euro OTC | Dithranol | 1008011-01 | 1 |
| Euro OTC | Dithranol | 1008011-02 | 2 |
| Euro OTC | Dithranol | 1203025-01 | 2 |
| Euro OTC | Dithranol | 1203025-02 | 14 |
| Euro OTC | Dithranol | 1311029-01 | 1 |
| Euro OTC | Dithranol | 1702002-04 | 1 |
| Euro OTC | Dithranol | 17020022-02 | 1 |
| Euro OTC | Dithranol | 170202-01 | 1 |
| Euro OTC | Dithranol | 1702021 | 1 |
| Euro OTC | Dithranol | 1702021-02 | 2 |
| Euro OTC | Dithranol | 170202103 | 1 |
| Euro OTC | Dithranol | 1702021-03 | 14 |
| Euro OTC | Dithranol | 1702021-0301/2021 | 1 |
| Euro OTC | Dithranol | 1702022-01 | 2 |
| Euro OTC | Dithranol | 1702022-02 | 3 |
| Euro OTC | Dithranol | 1702022-04 | 12 |
| Euro OTC | Dithranol | 20004097002 | 1 |
| Euro OTC | Dithranol | 200102501 | 2 |
| Euro OTC | Dithranol | 2001025-01 | 25 |
| Euro OTC | Dithranol | 200402801 | 1 |
| Euro OTC | Dithranol | 2004028-01 | 6 |
| Euro OTC | Dithranol | 2004028-02 | 9 |
| Euro OTC | Dithranol | 2201006-01 | 6 |
| Euro OTC | Dithranol | 2201006-02 | 1 |
| Euro OTC | Dithranol | 2201006-03 | 10 |
| Euro OTC | Dithranol | 2201006-04 | 1 |
| Euro OTC | Dithranol | 2201006-05 | 2 |
| Euro OTC | Dithranol | 29(1702022-04) | 1 |
| Euro OTC | Dithranol | 56/11072013 | 1 |
| Euro OTC | Dithranol | DT/370/2012 | 1 |
| Euro OTC | Dithranol | DTHX-094 | 1 |
| Euro/ AHC | Dithranol | 2201006-03 | 1 |
| Euro/ Gehe | Dithranol | APOP-DNL/11/17/002 | 1 |
| Euro/Jenne | Dithranol | 1702022-04 | 1 |
| Euro/Noweda | Dithranol | 2201006-03 | 1 |
| Fagron | Dithranol | 11L20-N13 | 1 |
| Fagron | Dithranol | 1-21883004 | 1 |
| Fagron | Dithranol | 1218834 | 1 |
| Fagron | Dithranol | 13A30-N01 | 4 |
| Fagron | Dithranol | 17710I-01274 | 1 |
| Fagron | Dithranol | 18823-B50-35511 | 1 |
| Fagron | Dithranol | 18B23-B50-355511 | 2 |
| Fagron | Dithranol | 20C20-B07-200565 | 1 |
| Fagron | Dithranol | 20G27-B01-200443 | 2 |
| Fagron | Dithranol | 20K20-B04 | 1 |
| Fagron | Dithranol | 20K20-B04-203566 | 1 |
| Fagron | Dithranol | 20k20-B04-210534 | 1 |
| Fagron | Dithranol | 20K20-B04-210534 | 1 |
| Fagron | Dithranol | 21/17-B01-213565 | 1 |
| Fagron | Dithranol | 21/17-B01-218834 | 6 |
| Fagron | Dithranol | 21117-801-218834 | 1 |
| Fagron | Dithranol | 21117B01-218834 | 1 |
| Fagron | Dithranol | 2117B01218834 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Dithranol | 21I17-b01-218834 | 1 |
| Fagron | Dithranol | 21I17-B01-218834 | 4 |
| Fagron | Dithranol | 220100603 | 1 |
| Fagron | Dithranol | 22F11-B02-226170 | 3 |
| Fagron | Dithranol | 22F11-BO2-226170 | 1 |
| Fagron | Dithranol | 9K10-N19 | 1 |
| Fagron | Dithranol | B01-2188304 | 2 |
| Fagron | Dithranol | BO1-2188304 | 1 |
| Fagron | Dithranol | OP-DNL-C1-002/21 | 1 |
| fiebig | Dithranol | 22001422005 | 1 |
| Fiebig | Dithranol | 22001422005 | 1 |
| Gehe/Audar | Dithranol | APDT3752012D | 1 |
| Gehe/Euro | Dithranol | 2201006-03 | 1 |
| Gehe | Dithranol | 1311029-01 | 1 |
| Gehe | Dithranol | 21/17-B01-218834 | 1 |
| Gehe | Dithranol | 2201006-04 | 2 |
| Gehe | Dithranol | 2201006-05 | 1 |
| GEHE | Dithranol | 220100605 | 1 |
| gehe | Dithranol | 22F11-B02-226170 | 1 |
| Gehe | Dithranol | 22F11-B02-226170 | 2 |
| Gehe | Dithranol | 23F15-B01-231257 | 2 |
| Gehe | Dithranol | 23H22-B11-237978 | 1 |
| Gehe | Dithranol | 240418(2201006-05) | 1 |
| Gehe | Dithranol | APOP-DNL/11/17/001 | 1 |
| Jenne / Optimus | Dithranol | 2004028-01 | 1 |
| jenne | Dithranol | 2201006-5 | 1 |
| Jenne | Dithranol | 23F15-B01-231257 | 1 |
| Jenne | Dithranol | 250207(2409010-01) | 1 |
| Jenne | Dithranol | 250502(2409010-01) | 1 |
| kehr | Dithranol | 22011006-05 | 1 |
| Kehr | Dithranol | 22F11-B02-226170 | 1 |
| Kehr | Dithranol | 23F15-B01-235539 | 1 |
| Kehr | Dithranol | 24F28-B29-002279 | 1 |
| Noweda, EuRho | Dithranol | 2201006-03 | 1 |
| Noweda | Dithranol | 1203025-02 | 1 |
| Noweda | Dithranol | 1702022-02 | 1 |
| Noweda | Dithranol | 2201006-03 | 1 |
| Noweda | Dithranol | 2201006-04 | 1 |
| Noweda | Dithranol | 2201006-05 | 1 |
| Noweda | Dithranol | 22F11-B02-219586 | 1 |
| Noweda | Dithranol | 23H22-B11-240789 | 2 |
| Noweda | Dithranol | APDT/375/2012 | 1 |
| Noweda | Dithranol | DT/375/2012D | 1 |
| Optimus Drugs/Phoenix | Dithranol | APOPDNL/11/17/001-1D | 1 |
| Optimus Pharma | Dithranol | | 1 |
| Optimus/Phönix | Dithranol | APOP-DNL11/17/002D | 1 |
| Pala | Dithranol | DTHX-097 | 1 |
| Phoenix/Noweda | Dithranol | APOP-DNL/11/17/002D | 1 |
| Phoenix | Dithranol | 1701030-01 | 1 |
| Phoenix | Dithranol | apopdnl1117002d | 1 |
| phönix | Dithranol | 21000824007 | 1 |
| Phönix | Dithranol | 2201006-05 | 1 |
| Phönix | Dithranol | Caelo | 1 |
| Sanacorp | Dithranol | | 1 |
| Sanacorp | Dithranol | 1702022-04 | 1 |
| Sanacorp | Dithranol | 2001025-01 | 2 |
| Sanacorp | Dithranol | 20K20-B04-210534 | 1 |
| Sanacorp | Dithranol | 21I17B01-213565 | 1 |
| Sanacorp | Dithranol | 22001422005 | 2 |
| Sanacorp | Dithranol | 2201006-03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Dithranol | 23F15-B01-235539 | 1 |
| Sanacorp | Dithranol | APDT/375/2012 | 1 |
| Sanacorp | Dithranol | APOP-DNL/11/17/001-D | 1 |

- 256 198 spectra from 1666 *Apo-Ident* customers from a total of 51 961 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Dithranol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Dithranol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 430 | 0 | 157 896 |
| **Type B** | 0 | 250 | 0 | 212 690 |
| **Type C** | 0 | 647 | 41 | 256 198 |

The substance/substance group *Dithranol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6047 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 94.0407 % (> 93.6047 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24153 | 24153 | 0.00 | 156.75 |
| 24169 | 24169 | 0.00 | 150.82 |
| 24172 | 24169 | 5.55 | 150.27 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24429 | 24429 | 0.00 | 172.18 |
| 24501 | 24501 | 0.00 | 148.66 |
| 24503 | 24503 | 0.00 | 150.98 |
| 25429 | 25429 | 0.00 | 166.94 |
| 25502 | 24153 | 30.66 | 146.89 |
| 25646 | 25646 | 0.00 | 176.11 |
| 25960 | 25960 | 0.00 | 212.52 |
| 26452 | 26452 | 0.00 | 154.16 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **DL-Methionine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10004593-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

DL-Methionine; DL-Methioninum

### Special notes

When selecting the *DL-Methionine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| DL-Methionine | 3 | 1 | 2 |

### Second-stage model

For differentiation of the substance/substance group *DL-Methionine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *DL-Methionine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Ornithine aspartate | 80.79 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *DL-Methionine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *DL-Methionine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | DL-Methionine | 172575 | 25449 | 40 | 20171024* |
| Caelo | DL-Methionine | 190211 | 25450 | 40 | 20190306* |
| Caelo | DL-Methionine | 23000413 | 26714 | 40 | 20230323* |
| Caelo | DL-Methionine | 23000413 | 26714SI | 20 | 20230323* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 140 spectra of 4 reference samples from the substance/substance group *DL-Methionine*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 186 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *DL-Methionine*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | DL-Methionine | 193073 | 25451 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3 spectra from 2 *Apo-Ident* customers from 2 batches from the substance/substance group *DL-Methionine*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | DL-Methionine | 16274007 | 1 |
| Caelo | DL-Methionine | 21000019005 | 2 |

- 256 883 spectra from 1666 *Apo-Ident* customers from a total of 52 151 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *DL-Methionine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *DL-Methionine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 140 | 0 | 158 186 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 3 | 0 | 256 883 |

The substance/substance group *DL-Methionine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.7143 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9030 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25449 | 25449 | 0.00 | 120.92 |
| 25450 | 25450 | 0.00 | 117.05 |
| 26714 | 26714 | 0.00 | 128.34 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Doxepin hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005411-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Doxepin hydrochloride; Doxepini hydrochloridum

### Special notes

When selecting the *Doxepin hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Doxepin hydrochloride | 6 | 4 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Doxepin hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Doxepin hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Benzydamine hydrochloride | 80.11 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Doxepin hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Doxepin hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Dipharma | Doxepin hydrochloride | 1909145 | 25812 | 50 | 20190716 |
| Dipharma | Doxepin hydrochloride | 2003479 | 25814 | 50 | 20200312 |
| Dipharma | Doxepin hydrochloride | 1909145 | 25815 | 50 | 2204026 |
| Dipharma | Doxepin hydrochloride | 2207952 | 26321 | 40 | 20220628 |
| Fagron | Doxepin hydrochloride | 18A30-B01-361389 | 25816 | 50 | 20190617 |
| Fagron | Doxepin hydrochloride | 21G23-B04-222859 | 26387 | 40 | 20211005 |
| Fagron | Doxepin hydrochloride | 23H22-B15-008605 | 27605 | 40 | 20231027 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 7 reference samples from the substance/substance group *Doxepin hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 290 spectra of 13 reference samples from the substance/substance group *Doxepin hydrochloride*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Dipharma | Doxepin hydrochloride | 1904946 | 25813 | 50 |
| Dipharma | Doxepin hydrochloride | 2112869 | 25897 | 50 |
| Fagron | Doxepin hydrochloride | 20C26-F01-371195 | 25720 | 40 |
| Fagron | Doxepin hydrochloride | 21G23-B05-215698 | 25910 | 40 |
| Dipharma | Doxepin hydrochloride | 1909145 | 25812SI† | 10 |
| Dipharma | Doxepin hydrochloride | 1904946 | 25813SI | 10 |
| Dipharma | Doxepin hydrochloride | 2003479 | 25814SI† | 10 |
| Dipharma | Doxepin hydrochloride | 1909145 | 25815SI† | 10 |
| Dipharma | Doxepin hydrochloride | 2112869 | 25897SI | 10 |
| Dipharma | Doxepin hydrochloride | 2207952 | 26321SI† | 20 |
| Fagron | Doxepin hydrochloride | 18A30-B01-361389 | 25816SI† | 10 |
| Fagron | Doxepin hydrochloride | 21G23-B05-215698 | 25910SI | 10 |
| Fagron | Doxepin hydrochloride | 21G23-B04-222859 | 26387SI† | 20 |

- 212 650 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Doxepin hydrochloride*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Doxepin hydrochloride | 21G23 | 1 |

- 256 885 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Doxepin hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Doxepin hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 290 | 0 | 212 650 |
| **Type C** | 0 | 1 | 0 | 256 885 |

The substance/substance group *Doxepin hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.9310 %) |
| **Type C** | 100.0000 % (> 99.9038 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25812 | 25815 | 12.82 | 112.87 |
| 25814 | 25815 | 18.30 | 127.00 |
| 25815 | 25815 | 0.00 | 119.96 |
| 25816 | 25815 | 12.88 | 147.32 |
| 26321 | 25815 | 10.72 | 110.64 |
| 26387 | 25815 | 13.63 | 113.66 |
| 27605 | 25815 | 25.08 | 134.37 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Doxycycline hyclate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20796-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Doxycycline hyclate; Doxycyclini hyclas

### Special notes

When selecting the *Doxycycline hyclate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Doxycycline hyclate | 6 | 3 | 32 |

### Second-stage model

For differentiation of the substance/substance group *Doxycycline hyclate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Doxycycline hyclate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 74.43 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Doxycycline hyclate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Doxycycline hyclate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Doxycycline hyclate | 12G12-N15 | 20796 | 40 | 1404233 |
| Fagron | Doxycycline hyclate | 12G12-N15 | 20821 | 40 | 20120807 |
| Fagron | Doxycycline hyclate | 14K28-B05-312218 | 22242 | 60 | 20150216 |
| Fagron | Doxycycline hyclate | 19A30-B01-360207 | 24820 | 40 | 20190412 |
| Fagron | Doxycycline hyclate | 19I12-F01-366406 | 24946 | 40 | 20191204 |
| Fagron | Doxycycline hyclate | 21I10-B02-219301 | 26328 | 40 | 20211117 |
| Fagron | Doxycycline hyclate | 21I10-B02-219301 | 26328SI | 20 | 20211117 |
| Fagron | Doxycycline hyclate | 23L01-B01-004244 | 27469 | 40 | 20231219 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 8 reference samples from the substance/substance group *Doxycycline hyclate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 5 reference samples from the substance/substance group *Doxycycline hyclate*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Doxycycline hyclate | 16I06-B02-330167 | 23118 | 40 |
| Fagron | Doxycycline hyclate | 18D18-B01-349567 | 24170 | 40 |
| Fagron | Doxycycline hyclate | 21I15-F01-380126 | 25905 | 40 |
| Fagron | Doxycycline hyclate | 21I15-F01-380126 | 25905SI | 10 |
| Fagron | Doxycycline hyclate | 23L01-B01-004244 | 27469SI† | 20 |

- 212 790 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 41 spectra from 27 *Apo-Ident* customers from 34 batches from the substance/substance group *Doxycycline hyclate*.
- Among them are spectra of independent samples from 32 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Doxycycline hyclate | 2115-F01-380126 | 1 |
| | Doxycycline hyclate | 21I10-B02-221825 | 1 |
| | Doxycycline hyclate | B02-2218205 | 1 |
| | Doxycycline hyclate | H202106006 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AHD | Doxycycline hyclate | 18D18-B01-353701 | 1 |
| Caelo | Doxycycline hyclate | 16I06-B02-335675 | 1 |
| Caelo | Doxycycline hyclate | 16I06-B02-341857 | 1 |
| Fagron | Doxycycline hyclate | 12G12-N15 | 1 |
| Fagron | Doxycycline hyclate | 13D24-B40-298948 | 1 |
| Fagron | Doxycycline hyclate | 14K28-B05_312218 | 1 |
| Fagron | Doxycycline hyclate | 14K28-B05-312010 | 1 |
| Fagron | Doxycycline hyclate | 16/06-B02-341857 | 1 |
| Fagron | Doxycycline hyclate | 1603008 | 1 |
| Fagron | Doxycycline hyclate | 1606B02330167 | 1 |
| Fagron | Doxycycline hyclate | 16106-Bo2 | 1 |
| Fagron | Doxycycline hyclate | 16E04-B07-231917 | 1 |
| Fagron | Doxycycline hyclate | 16I06-B02 | 1 |
| Fagron | Doxycycline hyclate | 16I06-B02-330167 | 1 |
| Fagron | Doxycycline hyclate | 16I06-B02-341857 | 4 |
| Fagron | Doxycycline hyclate | 16l06-B02-330167 | 1 |
| Fagron | Doxycycline hyclate | 17112201 | 1 |
| Fagron | Doxycycline hyclate | 18D18_B01_349567 | 1 |
| Fagron | Doxycycline hyclate | 18D18-B01-349567 | 2 |
| Fagron | Doxycycline hyclate | 18D18B01353701 | 1 |
| Fagron | Doxycycline hyclate | 18D18-B01-353701 | 1 |
| Fagron | Doxycycline hyclate | 18D18-B01-353801 | 1 |
| Fagron | Doxycycline hyclate | 19A30-B01 | 1 |
| Fagron | Doxycycline hyclate | 19A30-B01-360207 | 1 |
| Fagron | Doxycycline hyclate | 20101701 | 1 |
| Fagron | Doxycycline hyclate | 20A30-F01-368711 | 1 |
| Fagron | Doxycycline hyclate | 21/10-B02-221825 | 1 |
| Fagron | Doxycycline hyclate | F01-3687101 | 1 |
| Fragron/Sanacorp | Doxycycline hyclate | 16l06-B02-335675 | 1 |
| Löwen City-Apotheke … | Doxycycline hyclate | 10022014 | 1 |
| Löwen City-Apotheke … | Doxycycline hyclate | 2042015 | 1 |
| Merck | Doxycycline hyclate | 22022019 | 1 |
| Sanacorp | Doxycycline hyclate | 16I06-B02-335675 | 1 |

- 256 845 spectra from 1666 *Apo-Ident* customers from a total of 52 120 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Doxycycline hyclate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Doxycycline hyclate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 40 | 1 | 256 845 |

The substance/substance group *Doxycycline hyclate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.5610 % (> 90.2439 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20796 | 20796 | 0.00 | 153.87 |
| 20821 | 20796 | 9.37 | 152.53 |
| 22242 | 20796 | 21.51 | 154.52 |
| 24820 | 20796 | 19.00 | 157.54 |
| 24946 | 20796 | 17.54 | 161.45 |
| 26328 | 20796 | 22.75 | 154.68 |
| 27469 | 20796 | 12.56 | 157.39 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Doxylamine hydrogen succinate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20315-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Doxylamine hydrogen succinate; Doxylamine succinate; Doxylamini hydrogenosuccinas

### Special notes

When selecting the *Doxylamine hydrogen succinate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Doxylamine hydrogen succinate | 6 | 6 | 74 |

### Second-stage model

For differentiation of the substance/substance group *Doxylamine hydrogen succinate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Doxylamine hydrogen succinate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Doxepin hydrochloride | 76.36 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Doxylamine hydrogen succinate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Doxylamine hydrogen succinate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Doxylamine hydrogen succinate | 15203906 | 23085 | 40 | 20151112 |
| Caelo | Doxylamine hydrogen succinate | 15203906 | 23086 | 40 | 20151112 |
| Caelo | Doxylamine hydrogen succinate | 183312 | 24535 | 40 | 20190219* |
| Fagron | Doxylamine hydrogen succinate | 14F03-B01-293498 | 21542 | 60 | 1410524 |
| Fagron | Doxylamine hydrogen succinate | 15F01-B04-309189 | 22601 | 40 | AR-16-FG-011361-01 |
| Fagron | Doxylamine hydrogen succinate | 20B19-F06-370985 | 25518 | 40 | 20200320 |
| Fagron | Doxylamine hydrogen succinate | 20K05-F03-375371 | 25838 | 50 | 20201207 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 310 spectra of 7 reference samples from the substance/substance group *Doxylamine hydrogen succinate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 016 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 300 spectra of 9 reference samples from the substance/substance group *Doxylamine hydrogen succinate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Doxylamine hydrogen succinate | 172047 | 23626 | 40 |
| Caelo | Doxylamine hydrogen succinate | 181277 | 24536 | 40 |
| Caelo | Doxylamine hydrogen succinate | 20002147003 | 25514 | 40 |
| Caelo | Doxylamine hydrogen succinate | 22000214 | 26114 | 40 |
| Caelo | Doxylamine hydrogen succinate | 23003003 | 27119 | 40 |
| Caelo | Doxylamine hydrogen succinate | 24000843 | 27239 | 40 |
| Caelo | Doxylamine hydrogen succinate | 22000214 | 26114SI | 20 |
| Caelo | Doxylamine hydrogen succinate | 23003003 | 27119SI | 20 |
| Caelo | Doxylamine hydrogen succinate | 24000843 | 27239SI | 20 |

- 212 640 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 169 spectra from 34 *Apo-Ident* customers from 77 batches from the substance/substance group *Doxylamine hydrogen succinate*.

- Among them are spectra of independent samples from 70 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Doxylamine hydrogen succinate | 22K09-B06-228678 | 1 |
| | Doxylamine hydrogen succinate | 23003003002 | 1 |
| | Doxylamine hydrogen succinate | 23003003010 | 1 |
| | Doxylamine hydrogen succinate | B06_2286708 | 1 |
| Caelo | Doxylamine hydrogen succinate | | 1 |
| Caelo | Doxylamine hydrogen succinate | 14k27-B07 | 1 |
| Caelo | Doxylamine hydrogen succinate | 15F01-B04-309189 | 2 |
| Caelo | Doxylamine hydrogen succinate | 15F01-B04-317385 | 2 |
| Caelo | Doxylamine hydrogen succinate | 15K04B01327356 | 1 |
| Caelo | Doxylamine hydrogen succinate | 16F06-B02-338804 | 2 |
| Caelo | Doxylamine hydrogen succinate | 16F06-B02-357986 | 1 |
| Caelo | Doxylamine hydrogen succinate | 18331201 | 1 |
| Caelo | Doxylamine hydrogen succinate | 18331206 | 1 |
| Caelo | Doxylamine hydrogen succinate | 21C19-F04-377749 | 1 |
| Euro OTC | Doxylamine hydrogen succinate | 16F06-B02-348869 | 1 |
| Fagron | Doxylamine hydrogen succinate | | 5 |
| Fagron | Doxylamine hydrogen succinate | 11G20-N10 | 1 |
| Fagron | Doxylamine hydrogen succinate | 11K17-N04 | 3 |
| Fagron | Doxylamine hydrogen succinate | 12811328003 | 1 |
| Fagron | Doxylamine hydrogen succinate | 12811420001 | 1 |
| Fagron | Doxylamine hydrogen succinate | 12811625003 | 6 |
| Fagron | Doxylamine hydrogen succinate | 12E04-N04 | 3 |
| Fagron | Doxylamine hydrogen succinate | 12G10-N03 | 6 |
| Fagron | Doxylamine hydrogen succinate | 12K21-N01 | 2 |
| Fagron | Doxylamine hydrogen succinate | 13/26-N14 | 1 |
| Fagron | Doxylamine hydrogen succinate | 13A04-N02 | 7 |
| Fagron | Doxylamine hydrogen succinate | 13E29-N03 | 4 |
| Fagron | Doxylamine hydrogen succinate | 14F03B01293498 | 1 |
| Fagron | Doxylamine hydrogen succinate | 14F03-B01-296845 | 1 |
| Fagron | Doxylamine hydrogen succinate | 14K27-B07 | 1 |
| Fagron | Doxylamine hydrogen succinate | 14K27-B07-303356 | 1 |
| Fagron | Doxylamine hydrogen succinate | 15F01-B04-308354 | 1 |
| Fagron | Doxylamine hydrogen succinate | 15F01-B04-309189 | 1 |
| Fagron | Doxylamine hydrogen succinate | 15K04-B01 | 1 |
| Fagron | Doxylamine hydrogen succinate | 15K04-B01-317386 | 1 |
| Fagron | Doxylamine hydrogen succinate | 15K04-B01-318794 | 5 |
| Fagron | Doxylamine hydrogen succinate | 15K04-B01-322165 | 7 |
| Fagron | Doxylamine hydrogen succinate | 15K04-B01-327356 | 2 |
| Fagron | Doxylamine hydrogen succinate | 15k04b01327357 | 1 |
| Fagron | Doxylamine hydrogen succinate | 15K04-B01-327357 | 8 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02 | 2 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B-02-338804 | 1 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02-338805 | 4 |
| Fagron | Doxylamine hydrogen succinate | 16-F06-B02-338805 | 1 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02-341879 | 7 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02-348870 | 2 |
| Fagron | Doxylamine hydrogen succinate | 16F-06-B02-348870 | 1 |
| Fagron | Doxylamine hydrogen succinate | 16F-06-B02-3488760 | 1 |
| Fagron | Doxylamine hydrogen succinate | 16F-06-B02-351516 | 1 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02-353930 | 3 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02-353931 | 1 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02-357510 | 2 |
| Fagron | Doxylamine hydrogen succinate | 16F06-B02-357986 | 2 |
| Fagron | Doxylamine hydrogen succinate | 18041818 | 1 |
| Fagron | Doxylamine hydrogen succinate | 19C14-B01 | 1 |
| Fagron | Doxylamine hydrogen succinate | 19C14-B01-362199 | 2 |
| Fagron | Doxylamine hydrogen succinate | 19C14-B01-362200 | 2 |
| Fagron | Doxylamine hydrogen succinate | 19C14-B01-364554 | 1 |
| Fagron | Doxylamine hydrogen succinate | 19C14-B01-364555 | 2 |
| Fagron | Doxylamine hydrogen succinate | 19C14-B01-364557 | 1 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Doxylamine hydrogen succinate | 19C14-B01-364888 | 1 |
| Fagron | Doxylamine hydrogen succinate | 20B19-F06-368886 | 2 |
| Fagron | Doxylamine hydrogen succinate | 20B19-F06-370985 | 2 |
| Fagron | Doxylamine hydrogen succinate | 20B19-F06-370986 | 1 |
| Fagron | Doxylamine hydrogen succinate | 20B19-F06-370987 | 1 |
| Fagron | Doxylamine hydrogen succinate | 20K05-F03 | 2 |
| Fagron | Doxylamine hydrogen succinate | 21C19-F04-377750 | 2 |
| Fagron | Doxylamine hydrogen succinate | 21C19-F04-377751 | 1 |
| Fagron | Doxylamine hydrogen succinate | 2oko5-F03-375372 | 1 |
| Fagron | Doxylamine hydrogen succinate | 351516 | 1 |
| Fagron | Doxylamine hydrogen succinate | 483875887 | 1 |
| Fagron | Doxylamine hydrogen succinate | F06-B02-351516/34887 | 1 |
| L10 | Doxylamine hydrogen succinate | 16F06B02338805 | 1 |
| L10 | Doxylamine hydrogen succinate | 16F06-B02-341879 | 2 |
| L10 | Doxylamine hydrogen succinate | 16F06-B02-351516 | 1 |
| L12 | Doxylamine hydrogen succinate | 15K04-B01-332765 | 3 |
| L12 | Doxylamine hydrogen succinate | 16F06-B02-338805 | 5 |
| L12 | Doxylamine hydrogen succinate | 16F06-B02-343936 | 5 |
| L12 | Doxylamine hydrogen succinate | 16F06-B02-348870 | 4 |
| L12 | Doxylamine hydrogen succinate | 16F06-B02-353931 | 4 |
| L30 | Doxylamine hydrogen succinate | 16F06-b02-334258 | 1 |

- 256 717 spectra from 1666 *Apo-Ident* customers from a total of 52 076 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Doxylamine hydrogen succinate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Doxylamine hydrogen succinate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 310 | 0 | 158 016 |
| **Type B** | 0 | 300 | 0 | 212 640 |
| **Type C** | 0 | 168 | 1 | 256 717 |

The substance/substance group *Doxylamine hydrogen succinate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0645 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.4083 % (> 97.6331 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to

exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21542 | 21542 | 0.00 | 122.29 |
| 22601 | 22601 | 0.00 | 109.95 |
| 23085 | 24535 | 21.25 | 107.07 |
| 23086 | 24535 | 20.21 | 107.34 |
| 24535 | 24535 | 0.00 | 104.45 |
| 25518 | 22601 | 28.88 | 107.19 |
| 25838 | 21542 | 11.35 | 112.90 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **EDTA calcium disodium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10003685-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

EDTA calcium disodium; Natrii calcii edetas; Sodium calcium edetate

### Special notes

When selecting the *EDTA calcium disodium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| EDTA calcium disodium | 6 | 3 | 3 |

### Second-stage model

For differentiation of the substance/substance group *EDTA calcium disodium* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *EDTA calcium disodium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 71.82 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *EDTA calcium disodium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *EDTA calcium disodium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | EDTA calcium disodium | 1807024 | 24145 | 40 | 20180725* |
| Euro OTC | EDTA calcium disodium | 1901028 | 24467 | 40 | 20190218* |
| Euro OTC | EDTA calcium disodium | 1910014 | 24955 | 40 | 20191119* |
| Euro OTC | EDTA calcium disodium | 2003032 | 25242 | 40 | 20200527* |
| Euro OTC | EDTA calcium disodium | 2207022 | 26266 | 40 | 20220818* |
| Euro OTC | EDTA calcium disodium | 2207022 | 26266SI | 20 | 20220818* |
| Euro OTC | EDTA calcium disodium | 2301043 | 26593 | 40 | 20230309* |
| Euro OTC | EDTA calcium disodium | 2301043 | 26593SI | 20 | 20230309* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 280 spectra of 8 reference samples from the substance/substance group *EDTA calcium disodium*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *EDTA calcium disodium*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | EDTA calcium disodium | 1705029 | 23434 | 40 |
| Euro OTC | EDTA calcium disodium | 2311016 | 27072 | 40 |
| Euro OTC | EDTA calcium disodium | 2504009 | 27669 | 40 |
| Euro OTC | EDTA calcium disodium | 2311016 | 27072SI | 20 |

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6 spectra from 1 *Apo-Ident* customers from 4 batches from the substance/substance group *EDTA calcium disodium*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | EDTA calcium disodium | 1901028-01Retest | 1 |
| Euro OTC | EDTA calcium disodium | 1910014-01 | 1 |
| Euro OTC | EDTA calcium disodium | 2003032 | 1 |
| Euro OTC | EDTA calcium disodium | 2010022-01 | 3 |

- 256 880 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *EDTA calcium disodium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *EDTA calcium disodium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 6 | 0 | 256 880 |

The substance/substance group *EDTA calcium disodium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24145 | 24145 | 0.00 | 187.06 |
| 24467 | 24467 | 0.00 | 130.56 |
| 24955 | 24955 | 0.00 | 211.33 |
| 25242 | 25242 | 0.00 | 181.02 |
| 26266 | 26266 | 0.00 | 206.35 |
| 26593 | 26593 | 0.00 | 211.94 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at


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least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Enalapril maleate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10003565-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Enalapril maleate; Enalaprili maleas

### Special notes

When selecting the *Enalapril maleate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Enalapril maleate | 6 | 3 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Enalapril maleate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Enalapril maleate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 102.54 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Enalapril maleate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Enalapril maleate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Enalapril maleate | 16K14-B02-336220 | 23716 | 40 | 1801425 |
| Fagron | Enalapril maleate | 17J18-B03-347278 | 24096 | 40 | 20171208 |
| Fagron | Enalapril maleate | 20F26-F02-372725 | 25444 | 40 | 20200812 |
| Fagron | Enalapril maleate | 22F29-B02-223143 | 26377 | 40 | 20220713 |
| Fagron | Enalapril maleate | 22F29-B02-223143 | 26377SI | 20 | 20220713 |
| Fagron | Enalapril maleate | 23C23-B01-227968 | 26683 | 40 | 20230427 |
| Fagron | Enalapril maleate | 23H22-B08-232432 | 27031 | 40 | 20230919 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 7 reference samples from the substance/substance group *Enalapril maleate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 170 spectra of 5 reference samples from the substance/substance group *Enalapril maleate*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Enalapril maleate | 19H27-F02-364744 | 24945 | 40 |
| Fagron | Enalapril maleate | 21B19-F03-377278 | 25840 | 50 |
| Fagron | Enalapril maleate | 21G22-B04-218923 | 26329 | 40 |
| Fagron | Enalapril maleate | 21G22-B04-218923 | 26329SI | 20 |
| Fagron | Enalapril maleate | 23C23-B01-227968 | 26683SI† | 20 |

- 212 770 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 53 spectra from 38 *Apo-Ident* customers from 19 batches from the substance/substance group *Enalapril maleate*.
- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Enalapril maleate | 21G22-B04-218923 | 1 |
| | Enalapril maleate | 23C23-B01-227968 | 10 |
| | Enalapril maleate | 24D10B09004552 | 1 |
| | Enalapril maleate | 3012-2210-012 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Enalapril maleate | 305-02001 | 1 |
| | Enalapril maleate | B08-2324302 | 1 |
| Fagron | Enalapril maleate | 19H27-F02-364744 | 2 |
| Fagron | Enalapril maleate | 1G22-B04-218923 | 1 |
| Fagron | Enalapril maleate | 20F26-F02 | 1 |
| Fagron | Enalapril maleate | 20F26-F02-372725 | 14 |
| Fagron | Enalapril maleate | 21B19-F03-3772708 | 1 |
| Fagron | Enalapril maleate | 21B19-F03-377278 | 5 |
| Fagron | Enalapril maleate | 21G22-B04 | 2 |
| Fagron | Enalapril maleate | 21G22-B04-218923 | 3 |
| Fagron | Enalapril maleate | 22F29-B02-223143 | 2 |
| Fagron | Enalapril maleate | 20F26-F02-372725 | 1 |
| Fagron | Enalapril maleate | 3012-2004-008 | 1 |
| Fagron | Enalapril maleate | 811-01000 | 1 |
| Fagron | Enalapril maleate | F02-3272005 | 1 |
| Jenne | Enalapril maleate | 23C23-B01-227968 | 1 |
| Nachprüfung | Enalapril maleate | AP200615-11 | 1 |
| Noweda | Enalapril maleate | 22F29-B02-223143 | 1 |

- 256 833 spectra from 1666 *Apo-Ident* customers from a total of 52 134 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Enalapril maleate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Enalapril maleate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 170 | 0 | 212 770 |
| **Type C** | 0 | 53 | 0 | 256 833 |

The substance/substance group *Enalapril maleate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.4706 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 88.6792 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23716 | 23716 | 0.00 | 222.07 |
| 24096 | 23716 | 6.70 | 228.43 |
| 25444 | 23716 | 11.00 | 222.68 |
| 26377 | 23716 | 9.14 | 222.89 |
| 26683 | 23716 | 11.65 | 221.41 |
| 27031 | 23716 | 18.44 | 228.59 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Eosin Y** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20571-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Eosin Y; Eosinum natricum

### Special notes

When selecting the *Eosin Y* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Eosin Y | 7 | 4 | 63 |

### Second-stage model

For differentiation of the substance/substance group *Eosin Y* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Eosin Y* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 58.77 | – |
| ⋮ | ⋮ | ⋮ |
| Dequalinium chloride | >50 | 58.19 |
| Levothyroxin sodium | >50 | 62.34 |
| Oxytetracycline hydrochloride | >50 | 91.58 |
| Tannin | >50 | 127.44 |
| Sodium salicylate | >50 | 276.47 |
| Dithranol | >50 | 302.29 |
| Acetylsalicylic acid | >50 | 341.36 |
| Benzoic acid | >50 | 380.65 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Eosin Y* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Eosin Y*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Eosin Y | 12E25-N01 | 20900 | 60 | 20120607 |
| Fagron | Eosin Y | 15G01-T03-025958 | 22261 | 60 | 1604114 |
| Fagron | Eosin Y | 13F14-T01-017395 | 22534 | 40 | 1608469 |
| Fagron | Eosin Y | 13F14-T01-017395 | 22535 | 40 | 20141219 |
| Fagron | Eosin Y | 13F14-T01-017395 | 22660 | 40 | 1801115 |
| Fagron | Eosin Y | 13F14-T01-017395 | 22816 | 40 | 1705197 |
| Fagron | Eosin Y | 17K21-T07-042542 | 23975 | 40 | 1805338 |
| Fagron | Eosin Y | 19J25-B06-196532 | 25187 | 40 | 20191216 |
| Fagron | Eosin Y | 20G07-B02-200510 | 25503 | 40 | 20200730 |
| Fagron | Eosin Y | 23E10-B02-228749 | 26822 | 40 | 20230619 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 440 spectra of 10 reference samples from the substance/substance group *Eosin Y*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 886 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 260 spectra of 8 reference samples from the substance/substance group *Eosin Y*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Eosin Y | 13I11-N03 | 20932 | 40 |
| Fagron | Eosin Y | 20J13-B01-201856 | 25754 | 40 |
| Fagron | Eosin Y | 21L20-B06-213987 | 26063 | 40 |
| Fagron | Eosin Y | 23I20-B08-010410 | 27639 | 40 |
| Fagron | Eosin Y | 13I11-N03 | 21208 | 40 |
| Fagron | Eosin Y | 21L20-B06-213987 | 26063SI | 20 |
| Fagron | Eosin Y | 23E10-B02-228749 | 26822SI† | 20 |
| Fagron | Eosin Y | 23I20-B08-010410 | 27639SI | 20 |

- 212 680 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 234 spectra from 196 *Apo-Ident* customers from 76 batches from the substance/substance group *Eosin Y*.

- Among them are spectra of independent samples from 63 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Eosin Y | 21L20-B06 | 1 |
| | Eosin Y | 21L20-B06-213987 | 2 |
| | Eosin Y | 21L20-BO6-213987 | 1 |
| | Eosin Y | 22127-B01-223849 | 1 |
| | Eosin Y | 22I27-B01-223849 | 5 |
| | Eosin Y | 22I27-B01-223850 | 1 |
| | Eosin Y | 23E10-B02-001497 | 1 |
| | Eosin Y | 23e10-b02-228749 | 1 |
| | Eosin Y | 23E10-B02-228749 | 7 |
| | Eosin Y | 23E10-B02-235703 | 1 |
| | Eosin Y | B02-2287409 | 8 |
| | Eosin Y | B06-1965302 | 1 |
| | Eosin Y | B06-2139807 | 2 |
| | Eosin Y | BO2-2287409 | 2 |
| | Eosin Y | EYWS/03/22 | 1 |
| Cael Sanacorp 05.02.2016 | Eosin Y | 13F14-T01-017395 | 1 |
| Caelo | Eosin Y | 12e25n01 | 1 |
| Caelo | Eosin Y | 12e25-n01 | 1 |
| Caelo | Eosin Y | 13F14-T01-017395 | 1 |
| Caelo | Eosin Y | 13I11-N03 | 1 |
| Caelo | Eosin Y | 14H28-M05 | 1 |
| Caelo | Eosin Y | 15G01-T03-025958 | 1 |
| Caelo | Eosin Y | 17K21-T07 | 1 |
| Caelo | Eosin Y | 20J13-BO1-201856 | 1 |
| Fa.Phönix | Eosin Y | 17k21-t07-062160 | 1 |
| Fagron | Eosin Y | 1(20G0-B02-200510) | 1 |
| Fagron | Eosin Y | 11E25-N01 | 1 |
| Fagron | Eosin Y | 11F21-N10 | 1 |
| Fagron | Eosin Y | 12A02-N09 | 2 |
| Fagron | Eosin Y | 12E25-N01 | 4 |
| Fagron | Eosin Y | 12H28-N08 | 3 |
| Fagron | Eosin Y | 13/11-N03 | 3 |
| Fagron | Eosin Y | 13/11-NO3 | 1 |
| Fagron | Eosin Y | 13F14-T01-017395 | 6 |
| Fagron | Eosin Y | 13fF14-T01-017395 | 1 |
| Fagron | Eosin Y | 14H28-M05 | 4 |
| Fagron | Eosin Y | 14H28-M09 | 2 |
| Fagron | Eosin Y | 15G01-T03 | 1 |
| Fagron | Eosin Y | 15G01-T03-025958 | 5 |
| Fagron | Eosin Y | 15G01T03025959 | 1 |
| Fagron | Eosin Y | 15G01-T03-027933 | 2 |
| Fagron | Eosin Y | 15G01-T03-034438 | 1 |
| Fagron | Eosin Y | 17372-87-1 | 2 |
| Fagron | Eosin Y | 17K21-T0-054710 | 1 |
| Fagron | Eosin Y | 17K21-T07 | 4 |
| Fagron | Eosin Y | 17K21-T07_062160 | 1 |
| Fagron | Eosin Y | 17K21-T07-042542 | 4 |
| Fagron | Eosin Y | 17K21T07-054710 | 1 |
| Fagron | Eosin Y | 17K21-T07-054710 | 9 |
| Fagron | Eosin Y | 17K21-T07-057542 | 4 |
| Fagron | Eosin Y | 17K21-T07-057543 | 1 |
| Fagron | Eosin Y | 17K21T07060102 | 1 |
| Fagron | Eosin Y | 17K21-T07-060102 | 7 |
| Fagron | Eosin Y | 17K21-T07-060103 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Eosin Y | 17K21-T07-062160 | 14 |
| Fagron | Eosin Y | 19j25-b06-196532 | 2 |
| Fagron | Eosin Y | 19J25-B06-196532 | 11 |
| Fagron | Eosin Y | 201856 | 1 |
| Fagron | Eosin Y | 20g07-b02-200510 | 1 |
| Fagron | Eosin Y | 20G07-B02-200510 | 7 |
| Fagron | Eosin Y | 20G07-B02-200567 | 1 |
| Fagron | Eosin Y | 20J13_B01_201856 | 1 |
| Fagron | Eosin Y | 20J13-B01 | 2 |
| Fagron | Eosin Y | 20J13-B01-201856 | 19 |
| Fagron | Eosin Y | 20J13-BO1 | 1 |
| Fagron | Eosin Y | 20J13-BO1-201856 | 1 |
| Fagron | Eosin Y | 2125848 | 1 |
| Fagron | Eosin Y | 21L20-B06 | 1 |
| Fagron | Eosin Y | 21L20-B06-213987 | 12 |
| Fagron | Eosin Y | 2200510 | 1 |
| Fagron | Eosin Y | 54710 | 1 |
| Fagron | Eosin Y | 701074-0001 | 1 |
| Fagron | Eosin Y | B01-2018506 | 1 |
| Fagron | Eosin Y | B06-1965302 | 5 |
| Fagron | Eosin Y | EYWS/02/20 | 1 |
| Fagron | Eosin Y | EYWS/03/22 | 1 |
| Fagron | Eosin Y | EYWS/09/17 | 1 |
| Fagron | Eosin Y | EYWS/12/19 | 2 |
| Fagron | Eosin Y | EYWS/15/13 | 1 |
| Fagron | Eosin Y | EYWS/16/11 | 2 |
| Fagron | Eosin Y | EYWS/16/9 | 1 |
| Fagron | Eosin Y | T07-0621600 | 1 |
| Fargon/noweda | Eosin Y | 21L20-B06-213987 | 1 |
| Fargon/Sanacorp | Eosin Y | 13/11-No3 | 1 |
| Fargon | Eosin Y | 19J25-B06-196532 | 2 |
| Fiebig | Eosin Y | 13F14-T01-017395 | 1 |
| Fiebig | Eosin Y | EYWS/16/19 | 1 |
| Gehe | Eosin Y | 14H28-M05 | 1 |
| Gehe | Eosin Y | 19j25-b06-196532 | 1 |
| Gehe | Eosin Y | 20J13-BO1-201856 | 1 |
| Gilbert/Gehe | Eosin Y | 1K21-T07-062160 | 1 |
| JPN Pharma Pvt Ltd | Eosin Y | 21L20-B06 | 1 |
| Kehr | Eosin Y | 23E10-B02-228749 | 1 |
| L12 | Eosin Y | 17K21-T07-054710 | 1 |
| Noweda | Eosin Y | 20J13B01201856 | 1 |
| Noweda | Eosin Y | 21L20-B06 | 1 |
| Noweda | Eosin Y | 23E10-B02-228749 | 1 |
| Sanacorp | Eosin Y | 12E25-N01 | 1 |
| sanacorp | Eosin Y | 14H28-M05 | 1 |
| Sanacorp | Eosin Y | 22127-B01-223849 | 1 |
| Sanacorp | Eosin Y | T07-0621600 | 1 |

- 256 652 spectra from 1666 *Apo-Ident* customers from a total of 52 077 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Eosin Y* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all

relevant spectra of the various substances were compared with *Eosin Y* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 260 | 0 | 212 680 |
| **Type C** | 0 | 230 | 4 | 256 652 |

The substance/substance group *Eosin Y* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6923 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.2906 % (> 97.0085 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20900 | 22534 | 57.83 | 191.69 |
| 22261 | 22261 | 0.00 | 165.12 |
| 22534 | 22534 | 0.00 | 155.87 |
| 22535 | 22660 | 2.21 | 221.18 |
| 22660 | 22660 | 0.00 | 221.95 |
| 22816 | 22816 | 0.00 | 219.38 |
| 23975 | 23975 | 0.00 | 169.29 |
| 25187 | 22660 | 45.84 | 197.36 |
| 25503 | 22660 | 79.74 | 205.48 |
| 26822 | 22534 | 118.36 | 191.12 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ephedrine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20993-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ephedrine hydrochloride; Ephedrini hydrochloridum

### Special notes

When selecting the *Ephedrine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ephedrine hydrochloride | 6 | 4 | 68 |

### Second-stage model

For differentiation of the substance/substance group *Ephedrine hydrochloride* the following second-stage model is used:

- Submodel 08

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ephedrine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 148.72 | – |
| ⋮ | ⋮ | ⋮ |
| Prednisone | >50 | 33.07 |
| Prednisolone acetate | >50 | 51.44 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ephedrine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ephedrine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ephedrine hydrochloride | 12017217 | 20993 | 40 | 1511635 |
| Caelo | Ephedrine hydrochloride | 13323305 | 21322 | 40 | 20131113 |
| Caelo | Ephedrine hydrochloride | 14378502 | 21803 | 60 | 20150106 |
| Caelo | Ephedrine hydrochloride | 161197 | 22436 | 60 | 20160420* |
| Caelo | Ephedrine hydrochloride | 21000335008 | 25729 | 40 | 20210125 |
| Caelo | Ephedrine hydrochloride | 21000335008 | 25729SI | 40 | 20210125 |
| Fagron | Ephedrine hydrochloride | 15H28-B02-316349 | 23073 | 40 | 20150924 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 320 spectra of 7 reference samples from the substance/substance group *Ephedrine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 250 spectra of 7 reference samples from the substance/substance group *Ephedrine hydrochloride*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ephedrine hydrochloride | 171736 | 23672 | 40 |
| Caelo | Ephedrine hydrochloride | 22001784 | 26372 | 40 |
| Caelo | Ephedrine hydrochloride | 23001657 | 26841 | 30 |
| Fagron | Ephedrine hydrochloride | 20H07-B01-202226 | 25970 | 40 |
| Caelo | Ephedrine hydrochloride | 22001784 | 26372SI | 30 |
| Caelo | Ephedrine hydrochloride | 23001657 | 26841SI | 30 |
| Fagron | Ephedrine hydrochloride | 20H07-B01-202226 | 25970SI | 40 |

- 212 690 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 138 spectra from 55 *Apo-Ident* customers from 73 batches from the substance/substance group *Ephedrine hydrochloride*.

- Among them are spectra of independent samples from 68 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ephedrine hydrochloride | 2400466005 | 1 |
| Alliance healfcare | Ephedrine hydrochloride | 18213109 | 1 |
| Alliance healfcare | Ephedrine hydrochloride | 18213115 | 1 |
| Anzag | Ephedrine hydrochloride | 18213113 | 1 |
| C&L | Ephedrine hydrochloride | 21000335008 | 1 |
| Caelo | Ephedrine hydrochloride | | 1 |
| Caelo | Ephedrine hydrochloride | 10103425 | 1 |
| Caelo | Ephedrine hydrochloride | 10119709 | 1 |
| Caelo | Ephedrine hydrochloride | 11126407 | 1 |
| Caelo | Ephedrine hydrochloride | 12017207 | 1 |
| Caelo | Ephedrine hydrochloride | 12017209 | 2 |
| Caelo | Ephedrine hydrochloride | 12017215 | 1 |
| Caelo | Ephedrine hydrochloride | 12017217 | 1 |
| Caelo | Ephedrine hydrochloride | 12017223 | 1 |
| Caelo | Ephedrine hydrochloride | 13323302 | 1 |
| Caelo | Ephedrine hydrochloride | 13323305 | 2 |
| Caelo | Ephedrine hydrochloride | 13323310 | 1 |
| Caelo | Ephedrine hydrochloride | 13323316 | 1 |
| Caelo | Ephedrine hydrochloride | 13323321 | 1 |
| Caelo | Ephedrine hydrochloride | 14378502 | 1 |
| Caelo | Ephedrine hydrochloride | 14378506 | 2 |
| Caelo | Ephedrine hydrochloride | 14378507 | 1 |
| Caelo | Ephedrine hydrochloride | 14378508 | 1 |
| Caelo | Ephedrine hydrochloride | 14378510 | 1 |
| Caelo | Ephedrine hydrochloride | 15179302 | 2 |
| Caelo | Ephedrine hydrochloride | 151J9304 | 1 |
| Caelo | Ephedrine hydrochloride | 16119702 | 3 |
| Caelo | Ephedrine hydrochloride | 16119703 | 1 |
| Caelo | Ephedrine hydrochloride | 16119704 | 1 |
| Caelo | Ephedrine hydrochloride | 16119709 | 2 |
| Caelo | Ephedrine hydrochloride | 16119710 | 1 |
| Caelo | Ephedrine hydrochloride | 16119715 | 5 |
| Caelo | Ephedrine hydrochloride | 16119715200218P301 | 1 |
| Caelo | Ephedrine hydrochloride | 1619704 | 1 |
| Caelo | Ephedrine hydrochloride | 1713601 | 1 |
| Caelo | Ephedrine hydrochloride | 17173601 | 1 |
| Caelo | Ephedrine hydrochloride | 17173604 | 1 |
| Caelo | Ephedrine hydrochloride | 18006701 | 4 |
| Caelo | Ephedrine hydrochloride | 18006702 | 1 |
| Caelo | Ephedrine hydrochloride | 18006708 | 1 |
| Caelo | Ephedrine hydrochloride | 18006709 | 1 |
| Caelo | Ephedrine hydrochloride | 1813113 | 1 |
| Caelo | Ephedrine hydrochloride | 1821 | 1 |
| Caelo | Ephedrine hydrochloride | 182131002 | 1 |
| Caelo | Ephedrine hydrochloride | 182131003 | 6 |
| Caelo | Ephedrine hydrochloride | 18213103 | 6 |
| Caelo | Ephedrine hydrochloride | 18213104 | 2 |
| Caelo | Ephedrine hydrochloride | 18213105 | 1 |
| Caelo | Ephedrine hydrochloride | 18213109 | 2 |
| Caelo | Ephedrine hydrochloride | 18213111 | 1 |
| Caelo | Ephedrine hydrochloride | 18213112 | 1 |
| Caelo | Ephedrine hydrochloride | 18213113 | 2 |
| Caelo | Ephedrine hydrochloride | 18213115 | 6 |
| Caelo | Ephedrine hydrochloride | 192679004 | 2 |
| Caelo | Ephedrine hydrochloride | 21000335002 | 1 |
| Caelo | Ephedrine hydrochloride | 21000335004 | 3 |
| Caelo | Ephedrine hydrochloride | 21000335009 | 1 |
| Caelo | Ephedrine hydrochloride | 21000335011 | 1 |
| Caelo | Ephedrine hydrochloride | 21000335012 | 2 |
| Caelo | Ephedrine hydrochloride | 21000335013 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ephedrine hydrochloride | 22001784007 | 1 |
| Caesar & Loretz GmbH… | Ephedrine hydrochloride | 11126411 | 1 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 14378503 | 1 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 18213103 | 1 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 18213104 | 2 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 18213109 | 1 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 18213113 | 3 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 18213115 | 2 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 192679004 | 2 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 21000335002 | 1 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 21000335011 | 3 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 21000335012 | 2 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 22001784003 | 1 |
| Caesar & Loretz GmbH | Ephedrine hydrochloride | 22001784011 | 2 |
| Caesar & Loretz Hilden | Ephedrine hydrochloride | 18213103 | 1 |
| Cealo, GEHE | Ephedrine hydrochloride | 21000335001 | 1 |
| Fagron | Ephedrine hydrochloride | 12017220 | 1 |
| Fagron | Ephedrine hydrochloride | 13B19-N04 | 1 |
| Fagron | Ephedrine hydrochloride | 13L30-B36 | 1 |
| Gatt-Koller / Phoenix | Ephedrine hydrochloride | 18502141114 | 1 |
| GATT-KOLLER/PHOENIX | Ephedrine hydrochloride | 915/03141314 | 2 |
| Gehe am 04.03.14 | Ephedrine hydrochloride | 13323303 | 1 |
| LandSiegfried Pharma… | Ephedrine hydrochloride | 17242077 | 5 |
| LandSiegfried Pharma… | Ephedrine hydrochloride | 19212002 | 1 |
| Noweda | Ephedrine hydrochloride | 22001784003 | 1 |
| Phoenix 04.03.14 | Ephedrine hydrochloride | 1332303 | 1 |
| PHOENIX 10.03.2014 | Ephedrine hydrochloride | 13323302 | 1 |
| Phönix | Ephedrine hydrochloride | 13323315 | 1 |

- 256 748 spectra from 1666 *Apo-Ident* customers from a total of 52 081 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ephedrine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ephedrine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 210 | 40 | 212 690 |
| **Type C** | 0 | 138 | 0 | 256 748 |

The substance/substance group *Ephedrine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 84.0000 % (> 82.8000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 95.6522 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20993 | 20993 | 0.00 | 217.29 |
| 21322 | 22436 | 7.53 | 215.07 |
| 21803 | 22436 | 4.82 | 216.04 |
| 22436 | 22436 | 0.00 | 218.64 |
| 23073 | 20993 | 5.40 | 216.73 |
| 25729 | 22436 | 5.85 | 215.11 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Epinephrine hydrogen tartrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20689-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Epinephrine hydrogen tartrate; Adrenaline hydrogen tartrate; Adrenalini tartras

### Special notes

When selecting the *Epinephrine hydrogen tartrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Epinephrine hydrogen tartrate | 7 | 5 | 35 |

### Second-stage model

For differentiation of the substance/substance group *Epinephrine hydrogen tartrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Epinephrine hydrogen tartrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 100.66 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Epinephrine hydrogen tartrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Epinephrine hydrogen tartrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Epinephrine hydrogen tartrate | 12120202 | 20689 | 40 | 1405614 |
| Caelo | Epinephrine hydrogen tartrate | 12337804 | 21058 | 40 | 20121128 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21489 | 60 | 1603180 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21489SI | 60 | 1603180 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21490 | 60 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21491 | 20 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21492 | 20 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21493 | 20 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21494 | 60 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21495 | 20 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21496 | 20 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21497 | 20 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21498 | 20 | 20140130 |
| Caelo | Epinephrine hydrogen tartrate | 20004277006 | 25728 | 40 | 20201214 |
| Caelo | Epinephrine hydrogen tartrate | 20004277006 | 25728SI | 40 | 20201214 |
| Caelo | Epinephrine hydrogen tartrate | 21004241 | 26299 | 40 | 20220622* |
| Caelo | Epinephrine hydrogen tartrate | 21004241 | 26299SI | 40 | 20220622* |
| Fagron | Epinephrine hydrogen tartrate | 12L22-N04 | 20749 | 40 | 20120106 |
| Fagron | Epinephrine hydrogen tartrate | 18K30-B03-358514 | 24706 | 40 | 20190320 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 700 spectra of 19 reference samples from the substance/substance group *Epinephrine hydrogen tartrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 626 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 720 spectra of 21 reference samples from the substance/substance group *Epinephrine hydrogen tartrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Epinephrine hydrogen tartrate | 162764 | 22777 | 40 |
| Caelo | Epinephrine hydrogen tartrate | 171115 | 23323 | 40 |
| Caelo | Epinephrine hydrogen tartrate | 181795 | 24260 | 40 |
| Caelo | Epinephrine hydrogen tartrate | 22002542002 | 26553 | 40 |
| Caelo | Epinephrine hydrogen tartrate | 24000754 | 27466 | 40 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21490SI† | 60 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21491SI† | 20 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21492SI† | 20 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21493SI† | 20 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21495SI† | 20 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21496SI† | 20 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21497SI† | 20 |
| Caelo | Epinephrine hydrogen tartrate | 14007802 | 21498SI† | 20 |
| Caelo | Epinephrine hydrogen tartrate | 162764 | 22777SI | 40 |
| Caelo | Epinephrine hydrogen tartrate | 171115 | 23323SI | 40 |
| Caelo | Epinephrine hydrogen tartrate | 171115 | 23326 | 40 |
| Caelo | Epinephrine hydrogen tartrate | 171115 | 23326SI | 40 |
| Caelo | Epinephrine hydrogen tartrate | 181795 | 24260SI | 40 |
| Caelo | Epinephrine hydrogen tartrate | 22002542002 | 26553SI | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Epinephrine hydrogen tartrate | 24000754 | 27466SI | 40 |
| Fagron | Epinephrine hydrogen tartrate | 18K30-B03-358514 | 24706SI† | 40 |

- 212 220 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 70 spectra from 38 *Apo-Ident* customers from 39 batches from the substance/substance group *Epinephrine hydrogen tartrate*.

- Among them are spectra of independent samples from 34 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Epinephrine hydrogen tartrate | 22002542007 | 2 |
| AHD 17.11.14 EK 7,60 | Epinephrine hydrogen tartrate | | 1 |
| Alliance Health 12.03.14 | Epinephrine hydrogen tartrate | 12337805 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 10237109 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 12120202 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 123337805 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 12337801 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 12337805 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 14007808 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 14301002 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 15194102 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 15194104 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 15239701 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 15239703 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 162746402 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 16276402 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 16276406 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 17111503 | 3 |
| Caelo | Epinephrine hydrogen tartrate | 181795003 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 18179503 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 18179504 | 5 |
| Caelo | Epinephrine hydrogen tartrate | 18179505 | 2 |
| Caelo | Epinephrine hydrogen tartrate | 20004277006 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 210316-1 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 210316-3 | 1 |
| Caelo | Epinephrine hydrogen tartrate | 22002542002 | 2 |
| Caesar & Loretz GmbH... | Epinephrine hydrogen tartrate | 20004277006 | 1 |
| Caesar & Loretz GmbH | Epinephrine hydrogen tartrate | 18179505 | 1 |
| Caesar & Loretz GmbH | Epinephrine hydrogen tartrate | 20004277006 | 2 |
| Caesar & Loretz GmbH | Epinephrine hydrogen tartrate | 22002542002 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 12/02-N03 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 12011902 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 12G11-N07 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Epinephrine hydrogen tartrate | 12G11-No70076/130 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 13I04-N03 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 13I04-N03 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 14E12-B02 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 15A13-B02-305559 | 2 |
| Fagron | Epinephrine hydrogen tartrate | 16e09-b11-319882 | 1 |
| Fagron | Epinephrine hydrogen tartrate | 16E09-B11-319882 | 2 |
| Fagron | Epinephrine hydrogen tartrate | E80-18002 | 4 |
| Fagron | Epinephrine hydrogen tartrate | E80-18D02 | 1 |
| Fargon GmbH & CoKG | Epinephrine hydrogen tartrate | 16E09-B11-319882 | 2 |
| Gehe | Epinephrine hydrogen tartrate | 17111503 | 1 |
| GEHE | Epinephrine hydrogen tartrate | 18179504 | 1 |
| Phoenix 22.5.14 | Epinephrine hydrogen tartrate | 12337804 | 1 |
| Wuhan/Noweda | Epinephrine hydrogen tartrate | C38-190902 | 1 |

- 256 816 spectra from 1666 *Apo-Ident* customers from a total of 52 114 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Epinephrine hydrogen tartrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Epinephrine hydrogen tartrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 700 | 0 | 157 626 |
| **Type B** | 0 | 720 | 0 | 212 220 |
| **Type C** | 0 | 70 | 0 | 256 816 |

The substance/substance group *Epinephrine hydrogen tartrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1429 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.1667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 91.4286 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20689 | 20689 | 0.00 | 232.54 |
| 20749 | 21489 | 18.61 | 225.64 |
| 21058 | 20689 | 5.18 | 231.99 |
| 21489 | 21489 | 0.00 | 244.77 |
| 21490 | 21489 | 4.99 | 260.71 |
| 21491 | 21489 | 2.90 | 244.13 |
| 21492 | 21489 | 6.39 | 229.30 |
| 21493 | 21489 | 2.22 | 239.47 |
| 21494 | 21489 | 9.44 | 236.88 |
| 21495 | 21489 | 3.84 | 244.75 |
| 21496 | 21489 | 6.55 | 232.16 |
| 21497 | 20689 | 8.78 | 229.18 |
| 21498 | 21489 | 2.96 | 242.48 |
| 24706 | 20689 | 6.50 | 234.74 |
| 25728 | 21489 | 9.02 | 240.42 |
| 26299 | 26299 | 0.00 | 234.49 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Erythromycin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20011-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Erythromycin; Erythromycinum

### Special notes

When selecting the *Erythromycin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Erythromycin | 9 | 17 | 962 |

### Second-stage model

For differentiation of the substance/substance group *Erythromycin* the following second-stage model is used:

- Submodel 07

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Erythromycin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 76.26 | – |
| ⋮ | ⋮ | ⋮ |
| Budesonide | >50 | 16.44 |
| Betamethasone valerate | >50 | 19.99 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Erythromycin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Erythromycin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Erythromycin | 13175601 | 21323 | 40 | 20130620 |
| Caelo | Erythromycin | 160792 | 22438 | 60 | 20160408* |
| Euro OTC | Erythromycin | 1308016-02 | 21651 | 60 | 1412542 |
| Euro OTC | Erythromycin | 1508034 | 21890 | 60 | 20150925* |
| Euro OTC | Erythromycin | 1607038 | 22832 | 40 | 20160831* |
| Euro OTC | Erythromycin | 1705038 | 23438 | 40 | 20170705* |
| Euro OTC | Erythromycin | 1811019 | 24420 | 40 | 20190114* |
| Fagron | Erythromycin | 12E24-N04 | 21056 | 60 | 20120607 |
| Fagron | Erythromycin | 14B06-B35-290872 | 21669 | 60 | 20140225 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 460 spectra of 9 reference samples from the substance/substance group *Erythromycin*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 866 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 840 spectra of 21 reference samples from the substance/substance group *Erythromycin*.

- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Erythromycin | 160795 | 22439 | 60 |
| Caelo | Erythromycin | 160797 | 22440 | 60 |
| Caelo | Erythromycin | 160796 | 22442 | 60 |
| Caelo | Erythromycin | 21002046 | 25858 | 50 |
| Caelo | Erythromycin | 21002044 | 25859 | 50 |
| Caelo | Erythromycin | 22001550 | 26629 | 40 |
| Euro OTC | Erythromycin | 1906032 | 24781 | 40 |
| Euro OTC | Erythromycin | 2002018 | 25121 | 40 |
| Euro OTC | Erythromycin | 2002038 | 25123 | 40 |
| Euro OTC | Erythromycin | 2007017 | 25432 | 40 |
| Euro OTC | Erythromycin | 2010015 | 25574 | 40 |
| Euro OTC | Erythromycin | 2010014 | 25575 | 40 |
| Euro OTC | Erythromycin | 2206001 | 26206 | 40 |
| Euro OTC | Erythromycin | 2301053 | 26602 | 40 |
| Euro OTC | Erythromycin | 2308010 | 26940 | 40 |
| Euro OTC | Erythromycin | 2407014 | 27369 | 40 |
| Fagron | Erythromycin | 23D27-B01-227928 | 26824 | 40 |
| Caelo | Erythromycin | 22001550 | 26629SI | 20 |
| Euro OTC | Erythromycin | 2206001 | 26206SI | 20 |
| Euro OTC | Erythromycin | 2301053 | 26602SI | 20 |
| Euro OTC | Erythromycin | 2407014 | 27369SI | 20 |

- 212 100 spectra from a total of 4270 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6974 spectra from 1445 *Apo-Ident* customers from 1011 batches from the substance/substance group *Erythromycin*.

- Among them are spectra of independent samples from 958 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Erythromycin | | 1 |
| | Erythromycin | 1308016-02 | 1 |
| | Erythromycin | 181023/17 | 1 |
| | Erythromycin | 2007017-01 | 2 |
| | Erythromycin | 2010015-03 | 1 |
| | Erythromycin | 21/13-B02-213864 | 1 |
| | Erythromycin | 21002041001 | 1 |
| | Erythromycin | 21002041004 | 1 |
| | Erythromycin | 21002041006 | 1 |
| | Erythromycin | 21002041007 | 1 |
| | Erythromycin | 21002041009 | 2 |
| | Erythromycin | 21002041010 | 5 |
| | Erythromycin | 21002041011 | 3 |
| | Erythromycin | 21002041014 | 6 |
| | Erythromycin | 21002042001 | 1 |
| | Erythromycin | 21002053002 | 11 |
| | Erythromycin | 2113-B02-213864 | 1 |
| | Erythromycin | 21A26-F01-376731 | 1 |
| | Erythromycin | 21A26-F01-376732 | 3 |
| | Erythromycin | 21F02-F02-379295 | 1 |
| | Erythromycin | 21I13-B02-213864 | 1 |
| | Erythromycin | 21I13-B02-213865 | 8 |
| | Erythromycin | 21l13-B02-213865 | 1 |
| | Erythromycin | 22001550001 | 5 |
| | Erythromycin | 22001550002 | 13 |
| | Erythromycin | 22001550003 | 8 |
| | Erythromycin | 22001550005 | 17 |
| | Erythromycin | 22001550006 | 9 |
| | Erythromycin | 2200155003 | 1 |
| | Erythromycin | 2200155005 | 1 |
| | Erythromycin | 22002199001 | 14 |
| | Erythromycin | 22002199002 | 11 |
| | Erythromycin | 22002199003 | 5 |
| | Erythromycin | 22002200001 | 4 |
| | Erythromycin | 22002200002 | 6 |
| | Erythromycin | 22002200003 | 7 |
| | Erythromycin | 22002200004 | 27 |
| | Erythromycin | 22002200005 | 17 |
| | Erythromycin | 22002202001 | 2 |
| | Erythromycin | 22002202002 | 4 |
| | Erythromycin | 22002202003 | 21 |
| | Erythromycin | 22002203001 | 7 |
| | Erythromycin | 2202200005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Erythromycin | 2202202003 | 1 |
| | Erythromycin | 2206001-01 | 18 |
| | Erythromycin | 2208001-01 | 1 |
| | Erythromycin | 221/13-B02-213770 | 1 |
| | Erythromycin | 2-21386004 | 1 |
| | Erythromycin | 22C2200P | 1 |
| | Erythromycin | 22C2300P | 1 |
| | Erythromycin | 22C230P | 2 |
| | Erythromycin | 23003351001 | 6 |
| | Erythromycin | 23003351002 | 17 |
| | Erythromycin | 23003351003 | 4 |
| | Erythromycin | 23003351004 | 9 |
| | Erythromycin | 23003352001 | 3 |
| | Erythromycin | 23003352002 | 3 |
| | Erythromycin | 23003387001 | 16 |
| | Erythromycin | 23003387002 | 16 |
| | Erythromycin | 23003531002 | 1 |
| | Erythromycin | 2301052-02 | 1 |
| | Erythromycin | 230105301 | 1 |
| | Erythromycin | 2301053-01 | 42 |
| | Erythromycin | 2301053-02 | 20 |
| | Erythromycin | 23027-B01-227930 | 2 |
| | Erythromycin | 2308010-01 | 35 |
| | Erythromycin | 2308010-02 | 4 |
| | Erythromycin | 2308010-03 | 9 |
| | Erythromycin | 2308010-04 | 2 |
| | Erythromycin | 2308010-10 | 1 |
| | Erythromycin | 231053-01 | 1 |
| | Erythromycin | 23d27_b01_227795 | 1 |
| | Erythromycin | 23D27-B01-227795 | 4 |
| | Erythromycin | 23D27-B01-227928 | 6 |
| | Erythromycin | 23D27-B01-227929 | 8 |
| | Erythromycin | 23D27-B01-227930 | 4 |
| | Erythromycin | 23H23-B04-231446 | 4 |
| | Erythromycin | 2407014-01 | 5 |
| | Erythromycin | 24C25-B34-001108 | 2 |
| | Erythromycin | 24C25-B34-001113 | 12 |
| | Erythromycin | 24C25-B34-001114 | 6 |
| | Erythromycin | 24C25-B34-004227 | 5 |
| | Erythromycin | 324464 | 1 |
| | Erythromycin | 4H21P | 2 |
| | Erythromycin | A000586(Campus) | 1 |
| | Erythromycin | B01-2277905 | 1 |
| | Erythromycin | B01-2279300 | 2 |
| | Erythromycin | B01-2279301 | 1 |
| | Erythromycin | B04-2368406 | 1 |
| | Erythromycin | B34-0011103 | 1 |
| | Erythromycin | CEPEB004H21P | 1 |
| | Erythromycin | CEPEB022C22P | 3 |
| | Erythromycin | CEPEB022C23P | 1 |
| | Erythromycin | intern | 1 |
| ,0+ | Erythromycin | 180964001 | 1 |
| 24.03.2016 Phoenix 19,54EUR | Erythromycin | 15245101 | 2 |
| AbZ | Erythromycin | 18F05-B01-350908 | 1 |
| AEP | Erythromycin | 22001550003 | 1 |
| AEP | Erythromycin | 22002200004 | 1 |
| AEP | Erythromycin | 23003351002 | 1 |
| AEP | Erythromycin | 23003352002 | 1 |
| AEP | Erythromycin | 23003387002 | 1 |
| AHC 04.07.13 EK38,50 | Erythromycin | 12156207 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AHD 13.10.2014 18,68 | Erythromycin | 14044005 | 2 |
| AHD 26.02.16 13,15EUR | Erythromycin | 14I30-B01-308789 | 1 |
| AHD/EuRho | Erythromycin | 1906032-01 | 1 |
| AHD | Erythromycin | 1409019-02 | 1 |
| AHD | Erythromycin | 180964005 | 1 |
| AHD | Erythromycin | 18110119-01 | 1 |
| AHD | Erythromycin | 21002041002 | 1 |
| AHD | Erythromycin | 22001550002 | 1 |
| AHD | Erythromycin | 22002199001 | 2 |
| AHD | Erythromycin | 22002200005 | 2 |
| AHD | Erythromycin | 22002202003 | 1 |
| AHD | Erythromycin | 23003351002 | 1 |
| ahd | Erythromycin | 2301053-01 | 1 |
| AHD | Erythromycin | 2301053-01 | 1 |
| AHD | Erythromycin | 2301053-02 | 4 |
| AHD | Erythromycin | 2308010-01 | 1 |
| AHD | Erythromycin | 23D27-B01-227928 | 2 |
| ahd | Erythromycin | 23H23-B04-231446 | 1 |
| ahd | Erythromycin | 23H23-BO4-236846 | 1 |
| AlH | Erythromycin | 15042902 | 1 |
| Alliance Health | Erythromycin | 120503502 | 1 |
| Alliance Healthcare | Erythromycin | 12E24-N04 | 1 |
| Alliance Healthcare | Erythromycin | 13F12-N21 | 1 |
| Alliance Healthcare | Erythromycin | 1607038-02 | 1 |
| Alliance healthcare | Erythromycin | 20003732007 | 1 |
| Alliance Healthcare | Erythromycin | 20E18-F06-371571 | 1 |
| Alliance Healthcare | Erythromycin | 21002041006 | 1 |
| Alliance Healthcare | Erythromycin | 22002200004 | 1 |
| Alliance Healthcare | Erythromycin | 23H23-B04-231446 | 1 |
| Alliance Healthcare | Erythromycin | CEPEB003D20P | 1 |
| Alliance Healthcare13,31 | Erythromycin | 24C25-B34-001113 | 1 |
| Alliance | Erythromycin | 22001550002 | 1 |
| Alliance | Erythromycin | 2206001-01 | 1 |
| alliance | Erythromycin | 2301053-01 | 1 |
| Alliance | Erythromycin | 2301053-012 | 1 |
| Alliance | Erythromycin | 23D27-B01-227929 | 1 |
| Allianz Healthcare | Erythromycin | 16079602 | 1 |
| Allianz Healthcare | Erythromycin | 1811019-02 | 1 |
| Alte Apotheke | Erythromycin | 16079206 | 1 |
| Anuh Pharma Itd (site) | Erythromycin | 20I07-F06-375516 | 1 |
| Anuh Pharma Itd/ AHD | Erythromycin | 19C21-B03-361400 | 1 |
| Anuh Pharma Itd/ AHD | Erythromycin | 19C21-B03-361725 | 1 |
| Anuh Pharma Itd/ AHD | Erythromycin | 19C-B03-361400 | 1 |
| Anuh Pharma/Sanacorp | Erythromycin | 19L18-F02-3677709 | 1 |
| Anuh Pharma | Erythromycin | 18Fo5-B01-354817 | 1 |
| Anzag 23.11.12 ek:26,49 | Erythromycin | 1205035-01 | 1 |
| Anzag | Erythromycin | 12152206 | 1 |
| Anzag | Erythromycin | 13175506 | 1 |
| Anzag | Erythromycin | 14044001 | 1 |
| Anzag | Erythromycin | 16079501 | 1 |
| Anzag | Erythromycin | 2010014-01 | 1 |
| Anzag | Erythromycin | 21002041006 | 2 |
| Anzag | Erythromycin | 22002199001 | 1 |
| Anzag | Erythromycin | 22002200005 | 1 |
| Anzag | Erythromycin | 23003387001 | 2 |
| Anzag | Erythromycin | 2308010-02 | 1 |
| Apo-Ident / Phoenix | Erythromycin | EBS/1701-BM-001 | 1 |
| Apoident/ Phoenix | Erythromycin | 1906032-01 | 1 |
| apo-ident/Alliance | Erythromycin | 2007017-01 | 1 |
| apo-ident/Phoenix | Erythromycin | 190292002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| apo-ident/Phönix | Erythromycin | 2010014-01 | 1 |
| apo-ident/Phönix | Erythromycin | 2010015-01 | 1 |
| apo-ident | Erythromycin | 1607038-01 | 1 |
| Apo-ident | Erythromycin | 1607038-01 | 3 |
| apo-ident | Erythromycin | 1607038-02 | 1 |
| apo-ident | Erythromycin | 1705038-01 | 1 |
| Audor Pharma | Erythromycin | 13175602 | 1 |
| Audor Pharma | Erythromycin | 2002018-01 | 1 |
| Audor Pharma | Erythromycin | 2010015-01 | 1 |
| Audor Pharma | Erythromycin | APEB022/17E | 1 |
| Audor Pharma | Erythromycin | APEB022I17E | 1 |
| Audor Pharma | Erythromycin | EB022I17E | 1 |
| Biomed / Gehe | Erythromycin | 1508034-01 | 1 |
| Biomed / Gehe | Erythromycin | 1508034-02 | 1 |
| Biomed / Gehe | Erythromycin | 1705038-03 | 1 |
| Biomed/Phönix | Erythromycin | 1607038-01 | 1 |
| Biomed | Erythromycin | 1508035-01 | 1 |
| Bionorica Ethics | Erythromycin | 1906032-01EBS/19-022 | 1 |
| Bombastus | Erythromycin | 14B06-B35-290873 | 1 |
| Bombastus | Erythromycin | 14F13-B02 | 1 |
| Bombastus | Erythromycin | 15042603 | 1 |
| Bombastus | Erythromycin | 15042705 | 2 |
| Bombastus | Erythromycin | 16079606 | 1 |
| Bombastus | Erythromycin | 1705038-03 | 1 |
| Bombastus | Erythromycin | 17088402 | 1 |
| Caeelo | Erythromycin | 17088013 | 1 |
| Caelo | Erythromycin | | 4 |
| Caelo | Erythromycin | 10079203 | 1 |
| Caelo | Erythromycin | 1008018-02 | 1 |
| Caelo | Erythromycin | 10091502 | 1 |
| Caelo | Erythromycin | 10217101 | 1 |
| Caelo | Erythromycin | 10788402 | 1 |
| Caelo | Erythromycin | 10896403 | 1 |
| Caelo | Erythromycin | 1091801 | 1 |
| Caelo | Erythromycin | 1102024-01 | 1 |
| Caelo | Erythromycin | 11092001 | 1 |
| Caelo | Erythromycin | 1114Q-01362 | 1 |
| Caelo | Erythromycin | 11195306 | 1 |
| Caelo | Erythromycin | 11195402 | 3 |
| Caelo | Erythromycin | 11195405 | 1 |
| Caelo | Erythromycin | 11195407 | 3 |
| Caelo | Erythromycin | 11195408 | 1 |
| Caelo | Erythromycin | 1171116 | 1 |
| Caelo | Erythromycin | 1181116 | 1 |
| Caelo | Erythromycin | 1195407 | 1 |
| Caelo | Erythromycin | 11j06-n05 | 1 |
| Caelo | Erythromycin | 1205036-01 | 2 |
| Caelo | Erythromycin | 12051801 | 1 |
| Caelo | Erythromycin | 12152101 | 3 |
| Caelo | Erythromycin | 12152102 | 3 |
| Caelo | Erythromycin | 12152104 | 2 |
| Caelo | Erythromycin | 12152105 | 3 |
| Caelo | Erythromycin | 12152107 | 1 |
| Caelo | Erythromycin | 12152108 | 3 |
| Caelo | Erythromycin | 12152109 | 10 |
| Caelo | Erythromycin | 1215219 | 1 |
| Caelo | Erythromycin | 12152201 | 8 |
| Caelo | Erythromycin | 12152202 | 3 |
| Caelo | Erythromycin | 12152203 | 1 |
| Caelo | Erythromycin | 12152205 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 12152206 | 9 |
| Caelo | Erythromycin | 12152208 | 4 |
| Caelo | Erythromycin | 12156201 | 3 |
| Caelo | Erythromycin | 12156202 | 7 |
| Caelo | Erythromycin | 12156203 | 2 |
| Caelo | Erythromycin | 12156204 | 4 |
| Caelo | Erythromycin | 12156206 | 2 |
| Caelo | Erythromycin | 12156207 | 3 |
| Caelo | Erythromycin | 12156208 | 6 |
| Caelo | Erythromycin | 12E24-N04 | 1 |
| Caelo | Erythromycin | 13011810 | 1 |
| Caelo | Erythromycin | 1308016-01 | 2 |
| Caelo | Erythromycin | 1308016-02 | 1 |
| Caelo | Erythromycin | 13145504 | 1 |
| Caelo | Erythromycin | 1315501 | 1 |
| Caelo | Erythromycin | 13175501 | 6 |
| Caelo | Erythromycin | 13175502 | 4 |
| Caelo | Erythromycin | 13175503 | 8 |
| Caelo | Erythromycin | 13175504 | 6 |
| Caelo | Erythromycin | 13175504-3413310132 | 1 |
| Caelo | Erythromycin | 13175505 | 4 |
| Caelo | Erythromycin | 13175506 | 4 |
| Caelo | Erythromycin | 13175506-3559412014 | 1 |
| Caelo | Erythromycin | 13175601 | 8 |
| Caelo | Erythromycin | 131756017 | 1 |
| Caelo | Erythromycin | 13175603 | 11 |
| Caelo | Erythromycin | 13175604 | 7 |
| Caelo | Erythromycin | 13175607 | 8 |
| Caelo | Erythromycin | 13175608 | 6 |
| Caelo | Erythromycin | 13175610 | 1 |
| Caelo | Erythromycin | 13175611 | 5 |
| Caelo | Erythromycin | 13175612 | 2 |
| Caelo | Erythromycin | 13175801 | 10 |
| Caelo | Erythromycin | 13175802 | 8 |
| Caelo | Erythromycin | 13175803 | 8 |
| Caelo | Erythromycin | 13175804 | 2 |
| Caelo | Erythromycin | 13175808 | 2 |
| Caelo | Erythromycin | 13175809 | 5 |
| Caelo | Erythromycin | 13175810 | 4 |
| Caelo | Erythromycin | 13175811 | 8 |
| Caelo | Erythromycin | 13178756tzgklhj | 1 |
| Caelo | Erythromycin | 13189001 | 8 |
| Caelo | Erythromycin | 13189002 | 7 |
| Caelo | Erythromycin | 13189004 | 5 |
| Caelo | Erythromycin | 13189006 | 3 |
| Caelo | Erythromycin | 13189007 | 2 |
| Caelo | Erythromycin | 132152108 | 1 |
| Caelo | Erythromycin | 13A02-N06 | 1 |
| Caelo | Erythromycin | 13D30-N01 | 1 |
| Caelo | Erythromycin | 13H22-N07 | 1 |
| Caelo | Erythromycin | 14/30-B01-300059 | 1 |
| Caelo | Erythromycin | 140044203 | 1 |
| Caelo | Erythromycin | 140440006 | 1 |
| Caelo | Erythromycin | 14044001 | 10 |
| Caelo | Erythromycin | 14044002 | 10 |
| Caelo | Erythromycin | 14044004 | 11 |
| Caelo | Erythromycin | 140440044 | 1 |
| Caelo | Erythromycin | 14044005 | 9 |
| Caelo | Erythromycin | 14044006 | 6 |
| Caelo | Erythromycin | 14044007 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 14044008 | 4 |
| Caelo | Erythromycin | 14044009 | 3 |
| Caelo | Erythromycin | 14044010 | 4 |
| Caelo | Erythromycin | 14044011 | 2 |
| Caelo | Erythromycin | 14044012 | 3 |
| Caelo | Erythromycin | 14044014 | 3 |
| Caelo | Erythromycin | 1404409 | 1 |
| Caelo | Erythromycin | 14044101 | 7 |
| Caelo | Erythromycin | 14044105 | 4 |
| Caelo | Erythromycin | 14044106 | 3 |
| Caelo | Erythromycin | 14044107 | 3 |
| Caelo | Erythromycin | 14044109 | 5 |
| Caelo | Erythromycin | 14044110 | 1 |
| Caelo | Erythromycin | 14044114 | 6 |
| Caelo | Erythromycin | 14044115 | 6 |
| Caelo | Erythromycin | 14044116 | 1 |
| Caelo | Erythromycin | 14044118 | 3 |
| Caelo | Erythromycin | 1404414 | 1 |
| Caelo | Erythromycin | 1404418 | 1 |
| Caelo | Erythromycin | 14044201 | 5 |
| Caelo | Erythromycin | 14044202 | 3 |
| Caelo | Erythromycin | 14044205 | 4 |
| Caelo | Erythromycin | 14044206 | 3 |
| Caelo | Erythromycin | 14044207 | 2 |
| Caelo | Erythromycin | 1409019 | 1 |
| Caelo | Erythromycin | 1409019-01 | 2 |
| Caelo | Erythromycin | 140901902 | 2 |
| Caelo | Erythromycin | 1409019-02 | 5 |
| Caelo | Erythromycin | 140930E | 1 |
| Caelo | Erythromycin | 1414M-01362 | 1 |
| Caelo | Erythromycin | 1430b01300059 | 1 |
| Caelo | Erythromycin | 14B06-B35-290866 | 2 |
| Caelo | Erythromycin | 14B06-B35-290872 | 1 |
| Caelo | Erythromycin | 14B06-B35-290873 | 1 |
| Caelo | Erythromycin | 14b06-b35-293508 | 1 |
| Caelo | Erythromycin | 14F13-B02-296464 | 2 |
| Caelo | Erythromycin | 14F13-B02-300061 | 1 |
| Caelo | Erythromycin | 14I30-B01 | 1 |
| Caelo | Erythromycin | 14I30-B01-308789 | 1 |
| Caelo | Erythromycin | 150242813 | 1 |
| Caelo | Erythromycin | 15042601 | 2 |
| Caelo | Erythromycin | 15042602 | 8 |
| Caelo | Erythromycin | 15042603 | 6 |
| Caelo | Erythromycin | 15042604 | 3 |
| Caelo | Erythromycin | 15042605 | 9 |
| Caelo | Erythromycin | 15042606 | 1 |
| Caelo | Erythromycin | 15042608 | 3 |
| Caelo | Erythromycin | 15042609 | 8 |
| Caelo | Erythromycin | 15042610 | 10 |
| Caelo | Erythromycin | 15042611 | 5 |
| Caelo | Erythromycin | 15042611-20160504Ma1 | 1 |
| Caelo | Erythromycin | 15042612 | 7 |
| Caelo | Erythromycin | 15042613 | 4 |
| Caelo | Erythromycin | 15042701 | 12 |
| Caelo | Erythromycin | 15042702 | 4 |
| Caelo | Erythromycin | 15042703 | 9 |
| Caelo | Erythromycin | 15042704 | 8 |
| Caelo | Erythromycin | 15042705 | 10 |
| Caelo | Erythromycin | 15042706 | 10 |
| Caelo | Erythromycin | 15042707 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 15042711 | 14 |
| Caelo | Erythromycin | 150427704 | 1 |
| Caelo | Erythromycin | 150428 | 1 |
| Caelo | Erythromycin | 15042802 | 3 |
| Caelo | Erythromycin | 15042803 | 15 |
| Caelo | Erythromycin | 15042804 | 1 |
| Caelo | Erythromycin | 15042806 | 12 |
| Caelo | Erythromycin | 15042808 | 1 |
| Caelo | Erythromycin | 15042809 | 3 |
| Caelo | Erythromycin | 15042810 | 6 |
| Caelo | Erythromycin | 15042811 | 3 |
| Caelo | Erythromycin | 15042812 | 1 |
| Caelo | Erythromycin | 15042813 | 15 |
| Caelo | Erythromycin | 15042814 | 11 |
| Caelo | Erythromycin | 15042815 | 3 |
| Caelo | Erythromycin | 15042816 | 7 |
| Caelo | Erythromycin | 15042901 | 10 |
| Caelo | Erythromycin | 15042902 | 2 |
| Caelo | Erythromycin | 1504812 | 1 |
| Caelo | Erythromycin | 1504813 | 1 |
| Caelo | Erythromycin | 150803401 | 1 |
| Caelo | Erythromycin | 1508034-01 | 1 |
| Caelo | Erythromycin | 1508034-02 | 3 |
| Caelo | Erythromycin | 1524002 | 1 |
| Caelo | Erythromycin | 1524004 | 1 |
| Caelo | Erythromycin | 15245002 | 22 |
| Caelo | Erythromycin | 15245003 | 9 |
| Caelo | Erythromycin | 15245004 | 13 |
| Caelo | Erythromycin | 15245005 | 2 |
| Caelo | Erythromycin | 15245007 | 3 |
| Caelo | Erythromycin | 15245008 | 3 |
| Caelo | Erythromycin | 15245008I-041016-3 | 1 |
| Caelo | Erythromycin | 15245101 | 9 |
| Caelo | Erythromycin | 154042602 | 1 |
| Caelo | Erythromycin | 16/24-B10-341876 | 1 |
| Caelo | Erythromycin | 16017088303 | 1 |
| Caelo | Erythromycin | 1607038 | 1 |
| Caelo | Erythromycin | 160703801 | 2 |
| Caelo | Erythromycin | 1607038-01 | 4 |
| Caelo | Erythromycin | 1607038-02 | 10 |
| Caelo | Erythromycin | 16073038-02 | 1 |
| Caelo | Erythromycin | 160738-01 | 1 |
| Caelo | Erythromycin | 16076903 | 1 |
| Caelo | Erythromycin | 16079201 | 10 |
| Caelo | Erythromycin | 16079202 | 12 |
| Caelo | Erythromycin | 16079203 | 21 |
| Caelo | Erythromycin | 16079204 | 14 |
| Caelo | Erythromycin | 16079205 | 6 |
| Caelo | Erythromycin | 16079206 | 3 |
| Caelo | Erythromycin | 16079207 | 8 |
| Caelo | Erythromycin | 16079208 | 10 |
| Caelo | Erythromycin | 16079209 | 1 |
| Caelo | Erythromycin | 16079210 | 9 |
| Caelo | Erythromycin | 16079213 | 14 |
| Caelo | Erythromycin | 16079214 | 11 |
| Caelo | Erythromycin | 16079214-20170704Ma1 | 1 |
| Caelo | Erythromycin | 16079214-20171127Ma6 | 1 |
| Caelo | Erythromycin | 16079214-24417/1 | 1 |
| Caelo | Erythromycin | 16079216 | 8 |
| Caelo | Erythromycin | 16079501 | 20 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 16079502 | 15 |
| Caelo | Erythromycin | 16079503 | 8 |
| Caelo | Erythromycin | 16079505 | 3 |
| Caelo | Erythromycin | 16079506 | 7 |
| Caelo | Erythromycin | 16079507 | 1 |
| Caelo | Erythromycin | 16079509 | 29 |
| Caelo | Erythromycin | 16079510 | 9 |
| Caelo | Erythromycin | 16079511 | 10 |
| Caelo | Erythromycin | 16079512 | 5 |
| Caelo | Erythromycin | 16079513 | 11 |
| Caelo | Erythromycin | 16079514 | 1 |
| Caelo | Erythromycin | 16079515 | 1 |
| Caelo | Erythromycin | 160796 | 1 |
| Caelo | Erythromycin | 16079602 | 5 |
| Caelo | Erythromycin | 16079603 | 16 |
| Caelo | Erythromycin | 16079604 | 5 |
| Caelo | Erythromycin | 16079605 | 2 |
| Caelo | Erythromycin | 16079606 | 7 |
| Caelo | Erythromycin | 16079607 | 1 |
| Caelo | Erythromycin | 16079608 | 21 |
| Caelo | Erythromycin | 16079609 | 8 |
| Caelo | Erythromycin | 16079610 | 1 |
| Caelo | Erythromycin | 16079612 | 16 |
| Caelo | Erythromycin | 16079613 | 2 |
| Caelo | Erythromycin | 16079614 | 6 |
| Caelo | Erythromycin | 16079701 | 1 |
| Caelo | Erythromycin | 16079702 | 9 |
| Caelo | Erythromycin | 16079704 | 4 |
| Caelo | Erythromycin | 16091712 | 1 |
| Caelo | Erythromycin | 16979201 | 1 |
| Caelo | Erythromycin | 16G06-803 | 1 |
| Caelo | Erythromycin | 16G06-B03-324463 | 1 |
| Caelo | Erythromycin | 16G06-B03-324464 | 1 |
| Caelo | Erythromycin | 16G06-B03-324465 | 1 |
| Caelo | Erythromycin | 16G06-B03-324466 | 2 |
| Caelo | Erythromycin | 16G06B03329150 | 1 |
| Caelo | Erythromycin | 16G06-B03-329150 | 1 |
| Caelo | Erythromycin | 16i24-B10 | 1 |
| Caelo | Erythromycin | 16j24b1033673 | 1 |
| Caelo | Erythromycin | 16J24-B10-336735 | 2 |
| Caelo | Erythromycin | 16J24-B10-339487 | 1 |
| Caelo | Erythromycin | 16J24-B10-341875 | 1 |
| Caelo | Erythromycin | 16J24-B10-341876 | 1 |
| Caelo | Erythromycin | 16J24-B-341876 | 1 |
| Caelo | Erythromycin | 1705037-01 | 1 |
| Caelo | Erythromycin | 1705038 | 2 |
| Caelo | Erythromycin | 1705038_02 | 1 |
| Caelo | Erythromycin | 170503801 | 1 |
| Caelo | Erythromycin | 1705038-01 | 9 |
| Caelo | Erythromycin | 170503802 | 1 |
| Caelo | Erythromycin | 1705038-02 | 4 |
| Caelo | Erythromycin | 17068309 | 1 |
| Caelo | Erythromycin | 170718A | 1 |
| Caelo | Erythromycin | 1708/8308 | 1 |
| Caelo | Erythromycin | 17086301 | 1 |
| Caelo | Erythromycin | 17088001 | 4 |
| Caelo | Erythromycin | 17088002 | 19 |
| Caelo | Erythromycin | 17088003 | 12 |
| Caelo | Erythromycin | 17088004 | 14 |
| Caelo | Erythromycin | 17088005 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 17088007 | 11 |
| Caelo | Erythromycin | 17088008 | 15 |
| Caelo | Erythromycin | 17088008-20180206Ma2 | 1 |
| Caelo | Erythromycin | 17088008-E20180112Ma | 1 |
| Caelo | Erythromycin | 17088009 | 11 |
| Caelo | Erythromycin | 17088010 | 14 |
| Caelo | Erythromycin | 17088010-20180404Ma2 | 1 |
| Caelo | Erythromycin | 170880103 | 1 |
| Caelo | Erythromycin | 17088011 | 1 |
| Caelo | Erythromycin | 17088013 | 35 |
| Caelo | Erythromycin | 17088013/1250418 | 1 |
| Caelo | Erythromycin | 1708807 | 1 |
| Caelo | Erythromycin | 1708808 | 2 |
| Caelo | Erythromycin | 17088203 | 21 |
| Caelo | Erythromycin | 17088204 | 48 |
| Caelo | Erythromycin | 17088206 | 1 |
| Caelo | Erythromycin | 17088207 | 9 |
| Caelo | Erythromycin | 17088208 | 2 |
| Caelo | Erythromycin | 17088210 | 37 |
| Caelo | Erythromycin | 17088210-E20181115Ma | 1 |
| Caelo | Erythromycin | 17088212 | 1 |
| Caelo | Erythromycin | 17088301 | 68 |
| Caelo | Erythromycin | 17088302 | 4 |
| Caelo | Erythromycin | 17088303 | 7 |
| Caelo | Erythromycin | 17088304 | 1 |
| Caelo | Erythromycin | 17088305 | 28 |
| Caelo | Erythromycin | 17088305031110172 | 1 |
| Caelo | Erythromycin | 17088306 | 41 |
| Caelo | Erythromycin | 17088308 | 12 |
| Caelo | Erythromycin | 17088309 | 23 |
| Caelo | Erythromycin | 17088401 | 8 |
| Caelo | Erythromycin | 17088402 | 17 |
| Caelo | Erythromycin | 17088403 | 25 |
| Caelo | Erythromycin | 17088403-20180619Ma1 | 1 |
| Caelo | Erythromycin | 17088403-E2081115Ma1 | 1 |
| Caelo | Erythromycin | 17088404 | 25 |
| Caelo | Erythromycin | 17088405 | 19 |
| Caelo | Erythromycin | 17088406 | 11 |
| Caelo | Erythromycin | 170888309 | 1 |
| Caelo | Erythromycin | 1709038-01 | 1 |
| Caelo | Erythromycin | 17219705 | 1 |
| Caelo | Erythromycin | 1780210 | 1 |
| Caelo | Erythromycin | 178824 | 1 |
| Caelo | Erythromycin | 1788402 | 1 |
| Caelo | Erythromycin | 180096302 | 1 |
| Caelo | Erythromycin | 18094606 | 1 |
| Caelo | Erythromycin | 18095303 | 1 |
| Caelo | Erythromycin | 1809604 | 1 |
| Caelo | Erythromycin | 180960405 | 1 |
| Caelo | Erythromycin | 18096201 | 25 |
| Caelo | Erythromycin | 180962011905013-04 | 1 |
| Caelo | Erythromycin | 18096202 | 14 |
| Caelo | Erythromycin | 18096203 | 1 |
| Caelo | Erythromycin | 18096204 | 5 |
| Caelo | Erythromycin | 18096205 | 26 |
| Caelo | Erythromycin | 18096206 | 1 |
| Caelo | Erythromycin | 18096207 | 2 |
| Caelo | Erythromycin | 18096208 | 17 |
| Caelo | Erythromycin | 18096209 | 27 |
| Caelo | Erythromycin | 18096210 | 12 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 18096211 | 11 |
| Caelo | Erythromycin | 1809630 | 1 |
| Caelo | Erythromycin | 18096302 | 20 |
| Caelo | Erythromycin | 18096303 | 16 |
| Caelo | Erythromycin | 18096304 | 5 |
| Caelo | Erythromycin | 18096305 | 3 |
| Caelo | Erythromycin | 180964001 | 28 |
| Caelo | Erythromycin | 180964002 | 7 |
| Caelo | Erythromycin | 180964003 | 16 |
| Caelo | Erythromycin | 180964004 | 7 |
| Caelo | Erythromycin | 180964005 | 4 |
| Caelo | Erythromycin | 18096401 | 35 |
| Caelo | Erythromycin | 18096403 | 13 |
| Caelo | Erythromycin | 18096404 | 9 |
| Caelo | Erythromycin | 18096405 | 24 |
| Caelo | Erythromycin | 18096406 | 30 |
| Caelo | Erythromycin | 180964403 | 1 |
| Caelo | Erythromycin | 1811019-01 | 6 |
| Caelo | Erythromycin | 1811019-02 | 1 |
| Caelo | Erythromycin | 18215001 | 3 |
| Caelo | Erythromycin | 18F05-B01-350907 | 1 |
| Caelo | Erythromycin | 18F05-B01-350908 | 1 |
| Caelo | Erythromycin | 18F05-B01-35096 | 1 |
| Caelo | Erythromycin | 18F05-B01-353588 | 2 |
| Caelo | Erythromycin | 18F05-B01-356705 | 1 |
| Caelo | Erythromycin | 18F05-B01-356706 | 2 |
| Caelo | Erythromycin | 18F05-B01-358087 | 1 |
| Caelo | Erythromycin | 19011908 | 1 |
| Caelo | Erythromycin | 1903060E | 1 |
| Caelo | Erythromycin | 1906032-01 | 6 |
| Caelo | Erythromycin | 19071306 | 1 |
| Caelo | Erythromycin | 19096406 | 1 |
| Caelo | Erythromycin | 19C21B03361400 | 1 |
| Caelo | Erythromycin | 19C21-B03-361724 | 2 |
| Caelo | Erythromycin | 19L18-F02-367776 | 1 |
| Caelo | Erythromycin | 19L18-F02367779 | 1 |
| Caelo | Erythromycin | 200002258002 | 2 |
| Caelo | Erythromycin | 200002259007 | 1 |
| Caelo | Erythromycin | 200003731001 | 1 |
| Caelo | Erythromycin | 200003731004 | 1 |
| Caelo | Erythromycin | 200022259008 | 1 |
| Caelo | Erythromycin | 20002250002 | 1 |
| Caelo | Erythromycin | 20002258001 | 3 |
| Caelo | Erythromycin | 20002258002 | 20 |
| Caelo | Erythromycin | 20002258003 | 2 |
| Caelo | Erythromycin | 20002259002 | 23 |
| Caelo | Erythromycin | 20002259003 | 23 |
| Caelo | Erythromycin | 20002259003/4620 | 1 |
| Caelo | Erythromycin | 20002259004 | 4 |
| Caelo | Erythromycin | 20002259005 | 10 |
| Caelo | Erythromycin | 20002259006 | 25 |
| Caelo | Erythromycin | 20002259007 | 15 |
| Caelo | Erythromycin | 20002259008 | 2 |
| Caelo | Erythromycin | 20003431004 | 1 |
| Caelo | Erythromycin | 2000373007 | 1 |
| Caelo | Erythromycin | 2000373008 | 1 |
| Caelo | Erythromycin | 2000373009 | 1 |
| Caelo | Erythromycin | 20003731001 | 23 |
| Caelo | Erythromycin | 20003731002 | 3 |
| Caelo | Erythromycin | 20003731003 | 25 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 20003731004 | 29 |
| Caelo | Erythromycin | 20003731005 | 28 |
| Caelo | Erythromycin | 20003732001 | 16 |
| Caelo | Erythromycin | 20003732002 | 7 |
| Caelo | Erythromycin | 20003732004 | 13 |
| Caelo | Erythromycin | 20003732005 | 6 |
| Caelo | Erythromycin | 20003732006 | 1 |
| Caelo | Erythromycin | 20003732007 | 11 |
| Caelo | Erythromycin | 20003732008 | 19 |
| Caelo | Erythromycin | 20003732009 | 31 |
| Caelo | Erythromycin | 20003732010 | 39 |
| Caelo | Erythromycin | 20003732011 | 3 |
| Caelo | Erythromycin | 20003733001 | 8 |
| Caelo | Erythromycin | 2000373731004 | 1 |
| Caelo | Erythromycin | 2000373732010 | 1 |
| Caelo | Erythromycin | 20003762010 | 1 |
| Caelo | Erythromycin | 20004278008 | 1 |
| Caelo | Erythromycin | 2002258002 | 1 |
| Caelo | Erythromycin | 2003731005 | 1 |
| Caelo | Erythromycin | 2003732011 | 1 |
| Caelo | Erythromycin | 2003733001 | 1 |
| Caelo | Erythromycin | 2007017-01 | 3 |
| Caelo | Erythromycin | 2010015-01 | 3 |
| Caelo | Erythromycin | 2010015-03 | 1 |
| Caelo | Erythromycin | 20122013D | 1 |
| Caelo | Erythromycin | 20270912-3 | 1 |
| Caelo | Erythromycin | 20E18-F05-371567 | 1 |
| Caelo | Erythromycin | 20E18-F06 | 1 |
| Caelo | Erythromycin | 20E18-F06-372104 | 3 |
| Caelo | Erythromycin | 20I07-F06 | 1 |
| Caelo | Erythromycin | 2100100204 | 1 |
| Caelo | Erythromycin | 210020410002 | 1 |
| Caelo | Erythromycin | 21002041001 | 9 |
| Caelo | Erythromycin | 21002041002 | 15 |
| Caelo | Erythromycin | 21002041003 | 3 |
| Caelo | Erythromycin | 21002041006 | 5 |
| Caelo | Erythromycin | 21002041007 | 17 |
| Caelo | Erythromycin | 21002041008 | 2 |
| Caelo | Erythromycin | 21002041009 | 8 |
| Caelo | Erythromycin | 21002041010 | 8 |
| Caelo | Erythromycin | 21002041012 | 1 |
| Caelo | Erythromycin | 21002042001 | 22 |
| Caelo | Erythromycin | 21002044001 | 2 |
| Caelo | Erythromycin | 21002044002 | 3 |
| Caelo | Erythromycin | 210020441004 | 1 |
| Caelo | Erythromycin | 21002046001 | 3 |
| Caelo | Erythromycin | 21002053002 | 4 |
| Caelo | Erythromycin | 2100242001 | 1 |
| Caelo | Erythromycin | 21A26-F01 | 1 |
| Caelo | Erythromycin | 21A26-F01-376731 | 1 |
| Caelo | Erythromycin | 22001550001 | 4 |
| Caelo | Erythromycin | 22001550002 | 5 |
| Caelo | Erythromycin | 22001550003 | 3 |
| Caelo | Erythromycin | 22001550005 | 2 |
| Caelo | Erythromycin | 22002199001 | 2 |
| Caelo | Erythromycin | 2200219901 | 1 |
| Caelo | Erythromycin | 22002200001 | 13 |
| Caelo | Erythromycin | 22002200002 | 5 |
| Caelo | Erythromycin | 22002200003 | 1 |
| Caelo | Erythromycin | 22002200005 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Erythromycin | 2200220005 | 1 |
| Caelo | Erythromycin | 22002202001 | 1 |
| Caelo | Erythromycin | 2201550002 | 1 |
| Caelo | Erythromycin | 22041302 | 1 |
| Caelo | Erythromycin | 23003387002 | 1 |
| Caelo | Erythromycin | 23021710 | 1 |
| Caelo | Erythromycin | 24071402 | 1 |
| Caelo | Erythromycin | 24101312 | 1 |
| Caelo | Erythromycin | 26011402 | 1 |
| Caelo | Erythromycin | 27071202 | 1 |
| Caelo | Erythromycin | 2761 | 1 |
| Caelo | Erythromycin | 28041505 | 1 |
| Caelo | Erythromycin | 28101405 | 1 |
| Caelo | Erythromycin | 30011505 | 1 |
| Caelo | Erythromycin | 3081601 | 1 |
| Caelo | Erythromycin | 3092014B | 1 |
| Caelo | Erythromycin | 3110195 | 1 |
| Caelo | Erythromycin | 3317 | 1 |
| Caelo | Erythromycin | 4316E-01362 | 1 |
| Caelo | Erythromycin | 5042604 | 1 |
| Caelo | Erythromycin | 5052015D | 1 |
| Caelo | Erythromycin | 511111 | 1 |
| Caelo | Erythromycin | 59/AKD59 | 1 |
| Caelo | Erythromycin | 60/AKD4 | 1 |
| Caelo | Erythromycin | 618E-01362 | 1 |
| Caelo | Erythromycin | 80963021 | 1 |
| Caelo | Erythromycin | Caelo | 1 |
| Caelo | Erythromycin | EB06/14 | 1 |
| Caelo | Erythromycin | I31032016/1 | 1 |
| Caeolo/Krieger | Erythromycin | 17088004 | 1 |
| Caeolo/Noweda | Erythromycin | 13189007 | 1 |
| Caeolo/Noweda | Erythromycin | 16079603 | 1 |
| Caesa / Alliance Hea… | Erythromycin | 17088309 | 1 |
| Caesar & Lorenz GmbH | Erythromycin | 15042611 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 20003732009 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096405 | 2 |
| Caesar & Loretz GmbH… | Erythromycin | 20002259003 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 20003731005 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096211 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096401 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096406 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 20003731001 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 20003731004 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 20003732008 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 21002041009 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 17088404 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096201 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096208 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096406 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 22001550002 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 20003732002 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 180964005 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 18096401 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 10217208 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 13189002 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 17088003 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 16079207 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 21002041002 | 1 |
| Caesar & Loretz GmbH/ G | Erythromycin | 18096201 | 1 |
| Caesar & Loretz GmbH… | Erythromycin | 20003732010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/ GTH | Erythromycin | 18096209 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041010 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731004 | 3 |
| Caesar & Loretz GmbH... | Erythromycin | 180964001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731004 | 1 |
| Caesar & Loretz GmbH/AEP | Erythromycin | 18096302 | 2 |
| Caesar & Loretz GmbH/AEP | Erythromycin | 22002200002 | 1 |
| Caesar & Loretz GmbH/AHD | Erythromycin | 20002259005 | 1 |
| Caesar & Loretz GmbH/AHD | Erythromycin | 20003733001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 17088303 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731004 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732008 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732010 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259006 | 2 |
| Caesar & Loretz GmbH/E | Erythromycin | 21002041001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 18096404 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732007 | 1 |
| Caesar & Loretz GmbH/G | Erythromycin | 20002258002 | 1 |
| Caesar & Loretz GmbH/Gehe | Erythromycin | 18096208 | 1 |
| Caesar & Loretz GmbH/Gehe | Erythromycin | 18096209 | 1 |
| Caesar & Loretz GmbH/Gehe | Erythromycin | 180964002 | 1 |
| Caesar & Loretz GmbH/Gehe | Erythromycin | 18096401 | 1 |
| Caesar & Loretz GmbH/Gehe | Erythromycin | 18096405 | 1 |
| Caesar & Loretz GmbH/Gehe | Erythromycin | 18096406 | 3 |
| Caesar & Loretz GmbH/Gehe | Erythromycin | 22002199001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002258003 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732002 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041008 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259002 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731004 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732010 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041009 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 18096302 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259002 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731004 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002042001 | 1 |
| Caesar & Loretz GmbH/Kehr | Erythromycin | F05-3715605 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731003 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 200201801 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 18096405 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259007 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732007 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732008 | 2 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041002 | 1 |
| Caesar & Loretz GmbH/Ph | Erythromycin | 1906032-01 | 1 |
| Caesar & Loretz GmbH/Phoe | Erythromycin | 20002258003 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 22002199001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 180964003 | 2 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259003 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259005 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259007 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003731005 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732007 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732008 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732009 | 2 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732010 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 18096209 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 180964001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Erythromycin | 18096403 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002258002 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20002259003 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732008 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 20003732009 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041002 | 2 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041006 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002041007 | 2 |
| Caesar & Loretz GmbH... | Erythromycin | 21002042001 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | AP220827-07 | 1 |
| Caesar & Loretz GmbH... | Erythromycin | 21002044001 | 1 |
| Caesar & Loretz GmbH/Wepa | Erythromycin | 180964003 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 15042814 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 16079509 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 17088005 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 17088305 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 17088306 | 3 |
| Caesar & Loretz GmbH | Erythromycin | 17088308 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 17088309 | 8 |
| Caesar & Loretz GmbH | Erythromycin | 17088403 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 17088404 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 18096201 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 18096203 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 18096204 | 3 |
| Caesar & Loretz GmbH | Erythromycin | 18096205 | 5 |
| Caesar & Loretz GmbH | Erythromycin | 18096207 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 18096208 | 3 |
| Caesar & Loretz GmbH | Erythromycin | 18096209 | 8 |
| Caesar & Loretz GmbH | Erythromycin | 18096210 | 6 |
| Caesar & Loretz GmbH | Erythromycin | 18096211 | 3 |
| Caesar & Loretz GmbH | Erythromycin | 18096302 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 18096303 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 18096304 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 18096305 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 180964001 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 180964002 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 180964003 | 8 |
| Caesar & Loretz GmbH | Erythromycin | 180964005 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 18096401 | 18 |
| Caesar & Loretz GmbH | Erythromycin | 18096403 | 6 |
| Caesar & Loretz GmbH | Erythromycin | 18096404 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 18096405 | 6 |
| Caesar & Loretz GmbH | Erythromycin | 18096406 | 6 |
| Caesar & Loretz GmbH | Erythromycin | 20002258001 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 20002258002 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 20002259002 | 4 |
| Caesar & Loretz GmbH | Erythromycin | 20002259003 | 8 |
| Caesar & Loretz GmbH | Erythromycin | 20002259005 | 6 |
| Caesar & Loretz GmbH | Erythromycin | 20002259006 | 12 |
| Caesar & Loretz GmbH | Erythromycin | 20002259007 | 4 |
| Caesar & Loretz GmbH | Erythromycin | 20002259008 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 20003731001 | 12 |
| Caesar & Loretz GmbH | Erythromycin | 20003731002 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 20003731003 | 6 |
| Caesar & Loretz GmbH | Erythromycin | 20003731004 | 6 |
| Caesar & Loretz GmbH | Erythromycin | 20003731005 | 10 |
| Caesar & Loretz GmbH | Erythromycin | 20003732001 | 3 |
| Caesar & Loretz GmbH | Erythromycin | 20003732002 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 20003732004 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 20003732007 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Erythromycin | 20003732008 | 17 |
| Caesar & Loretz GmbH | Erythromycin | 20003732009 | 7 |
| Caesar & Loretz GmbH | Erythromycin | 20003732010 | 18 |
| Caesar & Loretz GmbH | Erythromycin | 20003732011 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 20003733001 | 8 |
| Caesar & Loretz GmbH | Erythromycin | 2002259005 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 21002041002 | 8 |
| Caesar & Loretz GmbH | Erythromycin | 21002041003 | 5 |
| Caesar & Loretz GmbH | Erythromycin | 21002041004 | 5 |
| Caesar & Loretz GmbH | Erythromycin | 21002041008 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 21002041009 | 5 |
| Caesar & Loretz GmbH | Erythromycin | 21002041010 | 3 |
| Caesar & Loretz GmbH | Erythromycin | 21002041011 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 21002041012 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 21002041014 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 21002042001 | 9 |
| Caesar & Loretz GmbH | Erythromycin | 21002044001 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 21002046001 | 2 |
| Caesar & Loretz GmbH | Erythromycin | 22001550001 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 22001550003 | 1 |
| Caesar & Loretz GmbH | Erythromycin | 22002200001 | 3 |
| Caesar & Loretz GmbH | Erythromycin | 2206001-01 | 1 |
| Caesar & Loretz GmbH | Erythromycin | F02-3677709 | 3 |
| Caesar & Loretz Hild… | Erythromycin | 180964001 | 1 |
| Caesar & Loretz Hilden | Erythromycin | 17088305 | 1 |
| Caesar & Loretz Hilden | Erythromycin | 18096208 | 1 |
| Caesar & Loretz/AHC | Erythromycin | 15042813 | 1 |
| Caesar & Loretz/AHD | Erythromycin | 20002258002 | 1 |
| Caesar & Loretz/Geil… | Erythromycin | 17088210 | 2 |
| Caesar & Loretz/Phönix | Erythromycin | 20003732004 | 1 |
| Caesar & Loretz/Sanacorp | Erythromycin | 18096201 | 2 |
| Caesar & Loretz | Erythromycin | 20003732004 | 1 |
| Caesar / Gehe | Erythromycin | 15042705 | 1 |
| Caesar / Gehe | Erythromycin | 17088402 | 1 |
| Caesar u. Loretz/Noweda | Erythromycin | 16079209 | 1 |
| Caesar und Loretz | Erythromycin | 17088210 | 1 |
| Caesar& Loretz GmbH | Erythromycin | 17088305 | 1 |
| Caesar&Lorenz/AHD | Erythromycin | 18096303 | 1 |
| Caesar&Loretz GmbH /Anzag | Erythromycin | 15042610 | 1 |
| Caesar&Loretz GmbH | Erythromycin | 15042807 | 1 |
| Caesar&Loretz GmbH | Erythromycin | 20002259001 | 1 |
| Caesar&Loretz GmbH | Erythromycin | 21002044002 | 1 |
| Caesar&loretz,Phoenix | Erythromycin | 13175602 | 1 |
| Caesar&loretz,Phoenix | Erythromycin | 14044004 | 1 |
| caesar&loretz,phönix | Erythromycin | 15042603 | 1 |
| Caesar/Loretz/Noweda | Erythromycin | 15042610 | 1 |
| Calo/AHD | Erythromycin | 15042605 | 1 |
| Cealo / Noweda | Erythromycin | 1205036-02 | 1 |
| Cealo/ Phoenix | Erythromycin | 17088210 | 1 |
| Cealo/Alliance Healthcare | Erythromycin | 17088309 | 1 |
| Cealo/Sanacorp | Erythromycin | 180964003 | 1 |
| Cealo | Erythromycin | 16079513 | 1 |
| Cealo | Erythromycin | 16079603 | 2 |
| Celo/Kehr | Erythromycin | 16079608 | 1 |
| Ebert & Jacobi | Erythromycin | 15042611 | 1 |
| Ebert & Jacobi | Erythromycin | 15245007 | 1 |
| Eigenherstellung | Erythromycin | 14044006 | 1 |
| EuRho / Alliance | Erythromycin | 2007017-01 | 1 |
| EuRho / Noweda | Erythromycin | 700770 | 1 |
| EuRho 08.08.2013Alli… | Erythromycin | 1205036-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho/ AHD | Erythromycin | 1705038-01 | 1 |
| EuRho/ Anzag | Erythromycin | 211124(2010014-01) | 1 |
| EuRho/ NOWEDA | Erythromycin | 1906032-01 | 1 |
| EuRho/ Noweda | Erythromycin | 2010015-02 | 1 |
| EuRho/Gehe | Erythromycin | 1409019-01 | 1 |
| EuRho/Gehe | Erythromycin | 1811019-01 | 1 |
| EuRho/Gehe | Erythromycin | 1906032-01 | 1 |
| EuRho/Gehe | Erythromycin | 2010014-01 | 1 |
| EuRho/Noweda | Erythromycin | 1508034-02 | 1 |
| EuRho/Noweda | Erythromycin | 1705038-01 | 1 |
| EuRho/Noweda | Erythromycin | 2002018-01 | 1 |
| EuRho/Noweda | Erythromycin | 2206001-01 | 1 |
| EuRho/Phönix | Erythromycin | 1106036-05 | 1 |
| EuRho/Phönix | Erythromycin | 1205035 | 1 |
| EuRho/Phönix | Erythromycin | 1308016-02 | 1 |
| EuRho/Phönix | Erythromycin | 1811019-01 | 1 |
| EuRho/Phönix | Erythromycin | 2002018-01 | 1 |
| Eurho/Phönix | Erythromycin | 2010014-02 | 1 |
| EuRho/Sanacorp | Erythromycin | 2010014-01 | 1 |
| EuRho/Sanacorp | Erythromycin | 2301053-01 | 1 |
| EuRho | Erythromycin | 1205035-01 | 1 |
| EuRho | Erythromycin | 1205035-02 | 1 |
| EuRho | Erythromycin | 1205036-01 | 1 |
| EuRho | Erythromycin | 1308016-02 | 1 |
| EuRho | Erythromycin | 1705038-01 | 3 |
| EuRho | Erythromycin | 1705038-02 | 1 |
| EuRho | Erythromycin | 1705038-03 | 1 |
| EuRho | Erythromycin | 1811019-01 | 2 |
| EuRho | Erythromycin | 1906032-01 | 1 |
| EuRho | Erythromycin | 2002018-01 | 1 |
| EuRho | Erythromycin | 2007017-01 | 2 |
| EuRho | Erythromycin | 2010014-02 | 1 |
| euRho | Erythromycin | 2010015-01 | 1 |
| Eurho | Erythromycin | 2010015-01 | 1 |
| EuRho | Erythromycin | 2010015-01 | 1 |
| EuRho | Erythromycin | 2010015-03 | 2 |
| Eurho | Erythromycin | 2206001-01 | 1 |
| Euro CT Phönix | Erythromycin | 13175604 | 1 |
| Euro OCT / Krieger | Erythromycin | 2007017-01 | 1 |
| Euro OCT / Krieger | Erythromycin | 2010014-01 | 1 |
| Euro Oct/Phoenix | Erythromycin | 1705038-03 | 1 |
| EURO OGT / Anzag | Erythromycin | 1409019-01 | 1 |
| Euro OT | Erythromycin | 1409019-02 | 1 |
| Euro OTC | Erythromycin | 100(2002018-01) | 1 |
| Euro OTC | Erythromycin | 101(2007017-01) | 1 |
| Euro OTC | Erythromycin | 1013u-01362 | 1 |
| Euro OTC | Erythromycin | 1106036-04 | 1 |
| Euro OTC | Erythromycin | 1106036-05 | 6 |
| Euro OTC | Erythromycin | 111811019-02 | 1 |
| Euro OTC | Erythromycin | 1205035-01 | 13 |
| Euro OTC | Erythromycin | 120503502 | 1 |
| Euro OTC | Erythromycin | 1205035-02 | 17 |
| Euro OTC | Erythromycin | 1205036/02 | 1 |
| Euro OTC | Erythromycin | 120503601 | 1 |
| Euro OTC | Erythromycin | 1205036-01 | 7 |
| Euro OTC | Erythromycin | 120503602 | 2 |
| Euro OTC | Erythromycin | 1205036-02 | 9 |
| Euro OTC | Erythromycin | 12A02-N06 | 1 |
| Euro OTC | Erythromycin | 130801601 | 6 |
| Euro OTC | Erythromycin | 1308016-01 | 24 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Erythromycin | 130801602 | 2 |
| Euro OTC | Erythromycin | 1308016-02 | 28 |
| Euro OTC | Erythromycin | 13175505 | 1 |
| Euro OTC | Erythromycin | 14044205 | 1 |
| Euro OTC | Erythromycin | 140901901 | 3 |
| Euro OTC | Erythromycin | 1409019-01 | 30 |
| Euro OTC | Erythromycin | 1409019-01Mg100g | 1 |
| Euro OTC | Erythromycin | 140901902 | 1 |
| Euro OTC | Erythromycin | 1409019-02 | 56 |
| Euro OTC | Erythromycin | 1409019-02Gehe | 1 |
| Euro OTC | Erythromycin | 14090-9-01 | 1 |
| Euro OTC | Erythromycin | 140919-02 | 2 |
| Euro OTC | Erythromycin | 15042704 | 2 |
| Euro OTC | Erythromycin | 15042810 | 1 |
| Euro OTC | Erythromycin | 15080-01 | 1 |
| Euro OTC | Erythromycin | 1508034 | 1 |
| Euro OTC | Erythromycin | 150803401 | 1 |
| Euro OTC | Erythromycin | 1508034-01 | 38 |
| Euro OTC | Erythromycin | 1508034-02 | 19 |
| Euro OTC | Erythromycin | 1508034-02Mg100g | 1 |
| Euro OTC | Erythromycin | 150834-01 | 1 |
| Euro OTC | Erythromycin | 15245002 | 1 |
| Euro OTC | Erythromycin | 15245008 | 1 |
| Euro OTC | Erythromycin | 15245101 | 1 |
| Euro OTC | Erythromycin | 1607038 | 2 |
| Euro OTC | Erythromycin | 1607038/01 | 1 |
| Euro OTC | Erythromycin | 160703801 | 5 |
| Euro OTC | Erythromycin | 1607038-01 | 81 |
| Euro OTC | Erythromycin | 160703802 | 2 |
| Euro OTC | Erythromycin | 1607038-02 | 93 |
| Euro OTC | Erythromycin | 1607038-2 | 1 |
| Euro OTC | Erythromycin | 16079206 | 1 |
| Euro OTC | Erythromycin | 167038-01 | 1 |
| Euro OTC | Erythromycin | 167038-02 | 1 |
| Euro OTC | Erythromycin | 16G06-B03-329150 | 1 |
| Euro OTC | Erythromycin | 170503038-03 | 1 |
| Euro OTC | Erythromycin | 1705037-01 | 1 |
| Euro OTC | Erythromycin | 1705038 | 3 |
| Euro OTC | Erythromycin | 1705038_01 | 1 |
| Euro OTC | Erythromycin | 170503801 | 2 |
| Euro OTC | Erythromycin | 1705038-01 | 140 |
| Euro OTC | Erythromycin | 170503802 | 1 |
| Euro OTC | Erythromycin | 1705038-02 | 37 |
| Euro OTC | Erythromycin | 170503803 | 2 |
| Euro OTC | Erythromycin | 1705038-03 | 57 |
| Euro OTC | Erythromycin | 1705038-04 | 1 |
| Euro OTC | Erythromycin | 1705039-01 | 1 |
| Euro OTC | Erythromycin | 170538-03 | 1 |
| Euro OTC | Erythromycin | 17088005 | 1 |
| Euro OTC | Erythromycin | 17088203 | 2 |
| Euro OTC | Erythromycin | 17088204 | 2 |
| Euro OTC | Erythromycin | 17088210 | 1 |
| Euro OTC | Erythromycin | 180201E/1705038-01 | 1 |
| Euro OTC | Erythromycin | 181019-01 | 1 |
| Euro OTC | Erythromycin | 18110019-01 | 1 |
| Euro OTC | Erythromycin | 1811019_02 | 1 |
| Euro OTC | Erythromycin | 1811019-01 | 104 |
| Euro OTC | Erythromycin | 181101902 | 1 |
| Euro OTC | Erythromycin | 1811019-02 | 13 |
| Euro OTC | Erythromycin | 1811019-2 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Erythromycin | 18111019 | 1 |
| Euro OTC | Erythromycin | 181119-01 | 1 |
| Euro OTC | Erythromycin | 19006032-01 | 1 |
| Euro OTC | Erythromycin | 1906032 | 3 |
| Euro OTC | Erythromycin | 190603201 | 7 |
| Euro OTC | Erythromycin | 1906032-01 | 109 |
| Euro OTC | Erythromycin | 1906032-02 | 19 |
| Euro OTC | Erythromycin | 1906032-03 | 3 |
| Euro OTC | Erythromycin | 190603301 | 1 |
| Euro OTC | Erythromycin | 190632-01 | 1 |
| Euro OTC | Erythromycin | 1909032-01 | 1 |
| Euro OTC | Erythromycin | 200201801 | 2 |
| Euro OTC | Erythromycin | 2002018-01 | 102 |
| Euro OTC | Erythromycin | 2002018-1 | 1 |
| Euro OTC | Erythromycin | 2002038-01 | 2 |
| Euro OTC | Erythromycin | 20022018-01 | 2 |
| Euro OTC | Erythromycin | 2007017 | 1 |
| Euro OTC | Erythromycin | 20070170-01 | 1 |
| Euro OTC | Erythromycin | 200701701 | 4 |
| Euro OTC | Erythromycin | 2007017-01 | 101 |
| Euro OTC | Erythromycin | 2007017-04 | 1 |
| Euro OTC | Erythromycin | 20100014-01 | 1 |
| Euro OTC | Erythromycin | 2010012-01 | 1 |
| Euro OTC | Erythromycin | 201001401 | 3 |
| Euro OTC | Erythromycin | 2010014-01 | 78 |
| Euro OTC | Erythromycin | 2010014-02 | 33 |
| Euro OTC | Erythromycin | 201001501 | 1 |
| Euro OTC | Erythromycin | 2010015-01 | 59 |
| Euro OTC | Erythromycin | 2010015-02 | 15 |
| Euro OTC | Erythromycin | 201001503 | 2 |
| Euro OTC | Erythromycin | 2010015-03 | 22 |
| Euro OTC | Erythromycin | 201004-01 | 1 |
| Euro OTC | Erythromycin | 220600-01 | 1 |
| Euro OTC | Erythromycin | 2206001-01 | 31 |
| Euro OTC | Erythromycin | 220712(2010014-02) | 1 |
| Euro OTC | Erythromycin | 2301053-01 | 6 |
| Euro OTC | Erythromycin | 230327(2206001-01) | 1 |
| Euro OTC | Erythromycin | 31K190P | 1 |
| Euro OTC | Erythromycin | 3613A1362 | 1 |
| Euro OTC | Erythromycin | 4112Q-01362 | 1 |
| Euro OTC | Erythromycin | 4914659 | 1 |
| Euro OTC | Erythromycin | 700770 | 1 |
| Euro OTC | Erythromycin | 80616-4 | 1 |
| Euro OTC | Erythromycin | 95(1705038-02 | 1 |
| Euro OTC | Erythromycin | 96(1811019-01) | 1 |
| Euro OTC | Erythromycin | 97(1811019-02) | 1 |
| Euro OTC | Erythromycin | 98(1906032-01) | 1 |
| Euro OTC | Erythromycin | 99(2002018-01) | 1 |
| Euro OTC | Erythromycin | CEPEB022C22P | 1 |
| Euro OTC | Erythromycin | EBC/20-016 | 1 |
| Euro OTC | Erythromycin | EBS/1205-M-040 | 1 |
| Euro OTC | Erythromycin | EBS/1307-BM-001 | 1 |
| Euro OTC | Erythromycin | EBS/1701-BM-001 | 4 |
| Euro OTC | Erythromycin | EBS/18-M-003 | 1 |
| Euro OTC | Erythromycin | EBS/19-022 | 5 |
| Euro OTC | Erythromycin | EBS/20-016 | 1 |
| Euro OTC | Erythromycin | EBS/20-040 | 1 |
| Euro OTC | Erythromycin | EBS/20-041 | 1 |
| Euro OTC | Erythromycin | EBS18M003 | 1 |
| Euro OTC | Erythromycin | EM04022021 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Erythromycin | F02-3687508 | 1 |
| Euro/ANZAG | Erythromycin | 1705038-03 | 1 |
| Euro/Gehe | Erythromycin | 1508034-01 | 1 |
| Euro/Gehe | Erythromycin | 1607038-02 | 1 |
| Euro/Gehe | Erythromycin | 1705038-01 | 2 |
| Euro/Krieger | Erythromycin | 1607038-01 | 1 |
| Euro/Krieger | Erythromycin | 1906032-01 | 2 |
| Euro/Noweda | Erythromycin | 1607038-01 | 2 |
| Euro/Noweda | Erythromycin | 1811019-01 | 2 |
| Euro/Phönix | Erythromycin | 1705038-02 | 1 |
| Euro/Phönix | Erythromycin | 1811019-01 | 1 |
| Euro/Phönix | Erythromycin | 2007017-01 | 1 |
| Euro/Sanacorp | Erythromycin | 1607038-02 | 1 |
| Euro/Sanacorp | Erythromycin | 1705038-01 | 1 |
| Euro | Erythromycin | 1308016-02 | 1 |
| euroct/gehe | Erythromycin | 1308016-01 | 1 |
| euroct/gehe | Erythromycin | 1308016-02 | 2 |
| Euroct/Gehe | Erythromycin | 1409019-01 | 2 |
| Europharm/Otto | Erythromycin | 1106036-05 | 2 |
| EuroTOC / Noweda | Erythromycin | 1409019-02 | 1 |
| Eurp | Erythromycin | 1308016-01 | 2 |
| Fa.Phönix | Erythromycin | 16079216 | 1 |
| Fa.Phönix | Erythromycin | 17088301 | 1 |
| Fa.Phönix | Erythromycin | 17088309 | 1 |
| Fa.Phönix | Erythromycin | 20003731001 | 1 |
| Fa.Phönix | Erythromycin | 20003731004 | 2 |
| Fa.Phönix | Erythromycin | 20003732008 | 1 |
| Fa.Phönix | Erythromycin | 2206001-01 | 1 |
| fagr | Erythromycin | 13A02-N06 | 1 |
| Fagron | Erythromycin | | 6 |
| Fagron | Erythromycin | 114-07-8 | 1 |
| Fagron | Erythromycin | 11D13-N09 | 2 |
| Fagron | Erythromycin | 11J06-N05 | 2 |
| Fagron | Erythromycin | 11J06-No5 | 1 |
| Fagron | Erythromycin | 1205036-01 | 1 |
| Fagron | Erythromycin | 12E24-N04 | 14 |
| Fagron | Erythromycin | 12E24-No4 | 1 |
| Fagron | Erythromycin | 12J30-N01 | 13 |
| Fagron | Erythromycin | 13175503 | 1 |
| Fagron | Erythromycin | 13175602 | 1 |
| Fagron | Erythromycin | 13175608 | 1 |
| Fagron | Erythromycin | 13175803 | 1 |
| Fagron | Erythromycin | 13175810 | 1 |
| Fagron | Erythromycin | 13A02N06 | 1 |
| Fagron | Erythromycin | 13A02-N06 | 9 |
| Fagron | Erythromycin | 13A02-N-06 | 1 |
| Fagron | Erythromycin | 13A02-N060571/680 | 1 |
| Fagron | Erythromycin | 13A02-No6 | 1 |
| Fagron | Erythromycin | 13d30-n01 | 1 |
| Fagron | Erythromycin | 13D30N01 | 1 |
| Fagron | Erythromycin | 13D30-N01 | 25 |
| Fagron | Erythromycin | 13D30-N01003/456 | 1 |
| Fagron | Erythromycin | 13D30-N010278/730 | 1 |
| Fagron | Erythromycin | 13D30-N010336/730 | 1 |
| Fagron | Erythromycin | 13f12-n21 | 1 |
| Fagron | Erythromycin | 13F12-N21 | 24 |
| Fagron | Erythromycin | 13H22-N07 | 7 |
| Fagron | Erythromycin | 13H22-N070126/246 | 1 |
| Fagron | Erythromycin | 13H22-N070228/246 | 1 |
| Fagron | Erythromycin | 14/30-B01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Erythromycin | 14/30-B01_308790 | 1 |
| Fagron | Erythromycin | 14/30B01300060 | 1 |
| Fagron | Erythromycin | 14/30-B01-300060 | 3 |
| Fagron | Erythromycin | 14/30B0130050 | 1 |
| Fagron | Erythromycin | 14/30-B01-303884 | 1 |
| Fagron | Erythromycin | 14/30-B01-308189 | 5 |
| Fagron | Erythromycin | 14/30-B01-308789 | 3 |
| Fagron | Erythromycin | 1409019-02 | 3 |
| Fagron | Erythromycin | 1430B01300059 | 1 |
| Fagron | Erythromycin | 1430-b01-300060 | 1 |
| Fagron | Erythromycin | 1430B01303884 | 1 |
| Fagron | Erythromycin | 1430-B01-303884 | 1 |
| Fagron | Erythromycin | 1430-B01-308789 | 1 |
| Fagron | Erythromycin | 14806-B35-290874 | 1 |
| Fagron | Erythromycin | 14B06-35-290873 | 1 |
| Fagron | Erythromycin | 14B06-B35 | 11 |
| Fagron | Erythromycin | 14B06-B35-290866 | 2 |
| Fagron | Erythromycin | 14b06-b35-290872 | 1 |
| Fagron | Erythromycin | 14B06-B35-290872 | 5 |
| Fagron | Erythromycin | 14B06-B35290873 | 1 |
| Fagron | Erythromycin | 14B06-B35-290873 | 4 |
| Fagron | Erythromycin | 14B06-B35-290874 | 3 |
| Fagron | Erythromycin | 14B06-B35-290875 | 8 |
| Fagron | Erythromycin | 14B06-B35-293508 | 2 |
| Fagron | Erythromycin | 14b06-b35-293509 | 1 |
| Fagron | Erythromycin | 14B06-B35-293509 | 7 |
| Fagron | Erythromycin | 14b06b5293508 | 1 |
| Fagron | Erythromycin | 14F13-B02 | 2 |
| Fagron | Erythromycin | 14F13-B02-293487 | 1 |
| Fagron | Erythromycin | 14F13-B02-293488 | 3 |
| Fagron | Erythromycin | 14F13-B02-293490 | 2 |
| Fagron | Erythromycin | 14F13-B02-293511 | 3 |
| Fagron | Erythromycin | 14F13-B02-296464 | 3 |
| Fagron | Erythromycin | 14F13-B02-300061 | 4 |
| Fagron | Erythromycin | 14F13-B12-300061 | 1 |
| Fagron | Erythromycin | 14I30B01 | 1 |
| Fagron | Erythromycin | 14I30-B01 | 5 |
| Fagron | Erythromycin | 14I30-B01-3000060 | 1 |
| Fagron | Erythromycin | 14I30-B01-300050 | 2 |
| Fagron | Erythromycin | 14i30b01-300059 | 1 |
| Fagron | Erythromycin | 14I30-B01-300059 | 1 |
| Fagron | Erythromycin | 14I30-B01-300060 | 2 |
| Fagron | Erythromycin | 14I30-B01-300062 | 3 |
| Fagron | Erythromycin | 14I30-B01-300063 | 1 |
| Fagron | Erythromycin | 14i30-b01-303884 | 1 |
| Fagron | Erythromycin | 14I30-B01-303884 | 7 |
| Fagron | Erythromycin | 14I30-B01-306927 | 3 |
| Fagron | Erythromycin | 14I30-B01-308188 | 4 |
| Fagron | Erythromycin | 14I30B01308189 | 1 |
| Fagron | Erythromycin | 14I30-B01-308189 | 1 |
| Fagron | Erythromycin | 14I30-B01-308789 | 1 |
| Fagron | Erythromycin | 14i30-b01-311166 | 1 |
| Fagron | Erythromycin | 14I30-B01-311166 | 2 |
| Fagron | Erythromycin | 1508034-01 | 2 |
| Fagron | Erythromycin | 16/24-B10-329155 | 1 |
| Fagron | Erythromycin | 16/24-B10-329158 | 1 |
| Fagron | Erythromycin | 16/24-B10-339487 | 2 |
| Fagron | Erythromycin | 16/24-B10-341875 | 1 |
| Fagron | Erythromycin | 16/24-B10-341876 | 1 |
| Fagron | Erythromycin | 16079208 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Erythromycin | 16079608 | 1 |
| Fagron | Erythromycin | 16G06_B03_324466 | 1 |
| Fagron | Erythromycin | 16G06-B03 | 11 |
| Fagron | Erythromycin | 16G06-B03_0003 | 1 |
| Fagron | Erythromycin | 16G06-B03-324462 | 3 |
| Fagron | Erythromycin | 16g06-b03-324463 | 2 |
| Fagron | Erythromycin | 16G06-B03-324463 | 12 |
| Fagron | Erythromycin | 16G06-B03324464 | 1 |
| Fagron | Erythromycin | 16G06-B03-324464 | 15 |
| Fagron | Erythromycin | 16G06-B03-324465 | 7 |
| Fagron | Erythromycin | 16G06-B03-324466 | 7 |
| Fagron | Erythromycin | 16G06B03-329149 | 1 |
| Fagron | Erythromycin | 16G06-B03-329149 | 4 |
| Fagron | Erythromycin | 16g06-b03-329150 | 1 |
| Fagron | Erythromycin | 16G06-B03-329150 | 6 |
| Fagron | Erythromycin | 16G06-B03-329152 | 2 |
| Fagron | Erythromycin | 16G06-B03-329157 | 6 |
| Fagron | Erythromycin | 16G06-B03-324463 | 1 |
| Fagron | Erythromycin | 16G08-B03 | 1 |
| Fagron | Erythromycin | 16J24_B10_339487 | 1 |
| Fagron | Erythromycin | 16j24-b10 | 1 |
| Fagron | Erythromycin | 16J24-B10 | 8 |
| Fagron | Erythromycin | 16J24-B10-329154 | 3 |
| Fagron | Erythromycin | 16j24-b10-329155 | 1 |
| Fagron | Erythromycin | 16J24-b10-329155 | 1 |
| Fagron | Erythromycin | 16J24-B10-329155 | 5 |
| Fagron | Erythromycin | 16J24-B10-329156 | 10 |
| Fagron | Erythromycin | 16j24-b10-329158 | 1 |
| Fagron | Erythromycin | 16J24-B10-329158 | 3 |
| Fagron | Erythromycin | 16J24-B10-336735 | 5 |
| Fagron | Erythromycin | 16j24-b10-336736 | 1 |
| Fagron | Erythromycin | 16J24-B10-336736 | 4 |
| Fagron | Erythromycin | 16J24-B10-3367363 | 1 |
| Fagron | Erythromycin | 16J24-B10338558 | 1 |
| Fagron | Erythromycin | 16J24-B10-338558 | 1 |
| Fagron | Erythromycin | 16J24-B10-338559 | 1 |
| Fagron | Erythromycin | 16j24-b10-339487 | 1 |
| Fagron | Erythromycin | 16J24-B10-339487 | 12 |
| Fagron | Erythromycin | 16J24-B10-339488 | 3 |
| Fagron | Erythromycin | 16J24-B10-341875 | 8 |
| Fagron | Erythromycin | 16J24-B10-341876 | 1 |
| Fagron | Erythromycin | 16J24-B10-341877 | 1 |
| Fagron | Erythromycin | 16-j24-B10-346206 | 1 |
| Fagron | Erythromycin | 16J24-B10-346206 | 4 |
| Fagron | Erythromycin | 16J24-B10-358088 | 1 |
| Fagron | Erythromycin | 16J25-B10-329155 | 1 |
| Fagron | Erythromycin | 1705038-01 | 3 |
| Fagron | Erythromycin | 17088005 | 1 |
| Fagron | Erythromycin | 17088211 | 1 |
| Fagron | Erythromycin | 17088402 | 1 |
| Fagron | Erythromycin | 18096205 | 1 |
| Fagron | Erythromycin | 18096208 | 2 |
| Fagron | Erythromycin | 1811019-01 | 1 |
| Fagron | Erythromycin | 18f01-b0a-353587 | 1 |
| Fagron | Erythromycin | 18F05 | 1 |
| Fagron | Erythromycin | 18F058-B01-352501 | 1 |
| Fagron | Erythromycin | 18f05-b01 | 1 |
| Fagron | Erythromycin | 18F05-B01 | 7 |
| Fagron | Erythromycin | 18F-05-B01 | 1 |
| Fagron | Erythromycin | 18F05-B01-350897 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Erythromycin | 18F05-B01-350906 | 11 |
| Fagron | Erythromycin | 18F05-B01-350907 | 5 |
| Fagron | Erythromycin | 18f05-b01-350908 | 1 |
| Fagron | Erythromycin | 18F05-B01-350908 | 12 |
| Fagron | Erythromycin | 18F05-B01-350909 | 2 |
| Fagron | Erythromycin | 18F05-B01-352500 | 7 |
| Fagron | Erythromycin | 18f05-b01-352501 | 1 |
| Fagron | Erythromycin | 18F05-B01-352501 | 3 |
| Fagron | Erythromycin | 18F05-B01-35358 | 1 |
| Fagron | Erythromycin | 18f05-b01-353586 | 1 |
| Fagron | Erythromycin | 18F05-B01-353586 | 8 |
| Fagron | Erythromycin | 18F05-B01-353587 | 8 |
| Fagron | Erythromycin | 18F05-B01-353588 | 1 |
| Fagron | Erythromycin | 18F05-B01-35387 | 1 |
| Fagron | Erythromycin | 18F05-B01-354817 | 2 |
| Fagron | Erythromycin | 18F05-B01-354818 | 1 |
| Fagron | Erythromycin | 18F05-B01-355773 | 1 |
| Fagron | Erythromycin | 18F05-B01-356076 | 1 |
| Fagron | Erythromycin | 18f05-b01-356705 | 1 |
| Fagron | Erythromycin | 18F05-B01-356705 | 5 |
| Fagron | Erythromycin | 18F05-B01-356706 | 2 |
| Fagron | Erythromycin | 18F05-B01-356707 | 8 |
| Fagron | Erythromycin | 18f05-b01-358087 | 1 |
| Fagron | Erythromycin | 18F05-B01-358087 | 4 |
| Fagron | Erythromycin | 18F05-B01-358088 | 7 |
| Fagron | Erythromycin | 18F05-B01-358362 | 1 |
| Fagron | Erythromycin | 18F05-B01-3586707 | 1 |
| Fagron | Erythromycin | 18F05-b01-359011 | 1 |
| Fagron | Erythromycin | 18F05-B01-359011 | 1 |
| Fagron | Erythromycin | 19C21 | 1 |
| Fagron | Erythromycin | 19C21_B03_361400 | 1 |
| Fagron | Erythromycin | 19C21_B03_361402 | 1 |
| Fagron | Erythromycin | 19C21_B03B19 | 1 |
| Fagron | Erythromycin | 19c21b03 | 1 |
| Fagron | Erythromycin | 19C21-B03 | 11 |
| Fagron | Erythromycin | 19C21-B03-0003 | 1 |
| Fagron | Erythromycin | 19c21b03361400 | 1 |
| Fagron | Erythromycin | 19C21-B03-361400 | 13 |
| Fagron | Erythromycin | 19c21b03361401 | 1 |
| Fagron | Erythromycin | 19C21-B03-361401 | 9 |
| Fagron | Erythromycin | 19C21-B03-361402 | 12 |
| Fagron | Erythromycin | 19c21b03361724 | 1 |
| Fagron | Erythromycin | 19C21B03361724 | 2 |
| Fagron | Erythromycin | 19C21-B03-361724 | 13 |
| Fagron | Erythromycin | 19C21-B03361725 | 1 |
| Fagron | Erythromycin | 19C21-B03-361725 | 12 |
| Fagron | Erythromycin | 19C21-B03-361726 | 3 |
| Fagron | Erythromycin | 19C21-B03-361726 | 1 |
| Fagron | Erythromycin | 19L18/F02/367780 | 1 |
| Fagron | Erythromycin | 19L18-F02 | 9 |
| Fagron | Erythromycin | 19L-18F02 | 1 |
| Fagron | Erythromycin | 19L18-F02-3677 | 1 |
| Fagron | Erythromycin | 19L18-F02-36776 | 1 |
| Fagron | Erythromycin | 19L18-F02-367776 | 1 |
| Fagron | Erythromycin | 19L18-F02-367777 | 9 |
| Fagron | Erythromycin | 19L18F02367778 | 1 |
| Fagron | Erythromycin | 19L18-F02-367778 | 11 |
| Fagron | Erythromycin | 19L18-F02-367779 | 14 |
| Fagron | Erythromycin | 19L18-F02-36778 | 2 |
| Fagron | Erythromycin | 19L18F02367780 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Erythromycin | 19L18-F02-367780 | 2 |
| Fagron | Erythromycin | 19L18-F02-3677803 | 1 |
| Fagron | Erythromycin | 19L18-F02-367783 | 1 |
| Fagron | Erythromycin | 19L18-F02-367784 | 4 |
| Fagron | Erythromycin | 19L18-F02-368758 | 6 |
| Fagron | Erythromycin | 19L18-F02P-200319-4 | 1 |
| Fagron | Erythromycin | 19L18-FO2 | 1 |
| Fagron | Erythromycin | 19L18-FO2-367776 | 1 |
| Fagron | Erythromycin | 19L18-FO2-367778 | 1 |
| Fagron | Erythromycin | 19L18-Fo2-367779 | 1 |
| Fagron | Erythromycin | 19L18-FO2-367779 | 3 |
| Fagron | Erythromycin | 19L18-FO2-367784 | 2 |
| Fagron | Erythromycin | 19L18-FO2-368758 | 1 |
| Fagron | Erythromycin | 20/07-F06-375516 | 3 |
| Fagron | Erythromycin | 2002018-01 | 2 |
| Fagron | Erythromycin | 20107-F06 | 1 |
| Fagron | Erythromycin | 20107F06373880 | 1 |
| Fagron | Erythromycin | 20107-F06-373880 | 1 |
| Fagron | Erythromycin | 20107-F06375516 | 1 |
| Fagron | Erythromycin | 20107-F06-375516 | 4 |
| Fagron | Erythromycin | 20E18-F01-371571 | 1 |
| Fagron | Erythromycin | 20E18-F05 | 1 |
| Fagron | Erythromycin | 20E18-F05-371563 | 6 |
| Fagron | Erythromycin | 20E18-F05-371564 | 4 |
| Fagron | Erythromycin | 20E18-F05371565 | 3 |
| Fagron | Erythromycin | 20E18-F05-371565 | 6 |
| Fagron | Erythromycin | 20E18-F05-371566 | 4 |
| Fagron | Erythromycin | 20E18-F05-371567 | 1 |
| Fagron | Erythromycin | 20E18-F06 | 9 |
| Fagron | Erythromycin | 20E18-F06-371204 | 1 |
| Fagron | Erythromycin | 20E18F06371570 | 1 |
| Fagron | Erythromycin | 20E18-F06371570 | 1 |
| Fagron | Erythromycin | 20E18-F06-371570 | 3 |
| Fagron | Erythromycin | 20E18-F06371571 | 1 |
| Fagron | Erythromycin | 20E18-F06-371571 | 7 |
| Fagron | Erythromycin | 20e18-F06-371572 | 1 |
| Fagron | Erythromycin | 20E18-F06-371572 | 2 |
| Fagron | Erythromycin | 20E18F06371573 | 1 |
| Fagron | Erythromycin | 20E18-F06-371573 | 7 |
| Fagron | Erythromycin | 20E18-F06-371573 | 1 |
| Fagron | Erythromycin | 20E18-F06-372103 | 12 |
| Fagron | Erythromycin | 20E18-F06-372104 | 30 |
| Fagron | Erythromycin | 20E18-FO6 | 1 |
| Fagron | Erythromycin | 20I07-F06-373880 | 3 |
| Fagron | Erythromycin | 20I07-F06-3755106 | 1 |
| Fagron | Erythromycin | 20I07-f06-375516 | 1 |
| Fagron | Erythromycin | 20I07-F06-375516 | 8 |
| Fagron | Erythromycin | 20I07-FO6-375516 | 1 |
| Fagron | Erythromycin | 20I17-F06-375516 | 1 |
| Fagron | Erythromycin | 20l07-F06-375516 | 1 |
| Fagron | Erythromycin | 21/13-B02 | 1 |
| Fagron | Erythromycin | 21/13-B02-213864 | 5 |
| Fagron | Erythromycin | 21/13-B02-213865 | 1 |
| Fagron | Erythromycin | 21/13-BO2-213864 | 1 |
| Fagron | Erythromycin | 21113-B02-213864 | 1 |
| Fagron | Erythromycin | 21113b02213865 | 1 |
| Fagron | Erythromycin | 21A26-F01 | 3 |
| Fagron | Erythromycin | 21A26-F01-37631 | 1 |
| Fagron | Erythromycin | 21A26-F01-376729 | 1 |
| Fagron | Erythromycin | 21A26-F01-376730 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Erythromycin | 21A26-F01376731 | 2 |
| Fagron | Erythromycin | 21A26-F01-376731 | 21 |
| Fagron | Erythromycin | 21a26-f01-376732 | 1 |
| Fagron | Erythromycin | 21A26-F01-376732 | 17 |
| Fagron | Erythromycin | 21A26-F01-376734 | 5 |
| Fagron | Erythromycin | 21A26-Fo1-376731 | 2 |
| Fagron | Erythromycin | 21A26-FO1-376732 | 1 |
| Fagron | Erythromycin | 21F02-F02-379295 | 6 |
| Fagron | Erythromycin | 21I13-B02-213770 | 2 |
| Fagron | Erythromycin | 21I13-B02-213864 | 8 |
| Fagron | Erythromycin | 21I13-B02-213865 | 3 |
| Fagron | Erythromycin | 21113-B02-213864 | 2 |
| Fagron | Erythromycin | 21113-BO2-213864 | 1 |
| Fagron | Erythromycin | 21113-BO2-213865 | 1 |
| Fagron | Erythromycin | 220401E | 1 |
| Fagron | Erythromycin | 22102001 | 1 |
| Fagron | Erythromycin | 23D27-B01-227928 | 1 |
| Fagron | Erythromycin | 23D27-B01-227929 | 1 |
| Fagron | Erythromycin | 23D27-Bo1-227928 | 1 |
| Fagron | Erythromycin | 23D27-BO1-227929 | 1 |
| Fagron | Erythromycin | 2OE18-F06-372104 | 1 |
| Fagron | Erythromycin | 3000-50 | 1 |
| Fagron | Erythromycin | 300059 | 1 |
| Fagron | Erythromycin | 31K1900P | 1 |
| Fagron | Erythromycin | 3D2000P | 1 |
| Fagron | Erythromycin | 4212E-01362 | 1 |
| Fagron | Erythromycin | 4H21P | 1 |
| Fagron | Erythromycin | 510211362 | 1 |
| Fagron | Erythromycin | 700770-0002 | 1 |
| Fagron | Erythromycin | 700770-0007P-190312 | 1 |
| Fagron | Erythromycin | B01-3590101 | 1 |
| Fagron | Erythromycin | B02-2138604 | 2 |
| Fagron | Erythromycin | B02-213864 | 1 |
| Fagron | Erythromycin | BO2-2138604 | 1 |
| Fagron | Erythromycin | CEFEB001E18 | 1 |
| Fagron | Erythromycin | cepb001e18 | 1 |
| Fagron | Erythromycin | CEPEB001E18 | 2 |
| Fagron | Erythromycin | CEPEB003D20P | 4 |
| Fagron | Erythromycin | CEPEB004H21P | 2 |
| Fagron | Erythromycin | CEPEB032B19 | 1 |
| Fagron | Erythromycin | cepeb039g20p | 1 |
| Fagron | Erythromycin | CEPEB039G20P | 2 |
| Fagron | Erythromycin | CEPEB084A21 | 1 |
| Fagron | Erythromycin | E-030613-1 | 1 |
| Fagron | Erythromycin | E18F06-372104 | 1 |
| Fagron | Erythromycin | E-250213-2 | 1 |
| Fagron | Erythromycin | EB022E14 | 2 |
| Fagron | Erythromycin | EB032J13 | 4 |
| Fagron | Erythromycin | EB068/14 | 1 |
| Fagron | Erythromycin | EB06814 | 1 |
| Fagron | Erythromycin | EB078B13 | 1 |
| Fagron | Erythromycin | EBS/1201-008 | 2 |
| Fagron | Erythromycin | f02-3677707 | 1 |
| Fagron | Erythromycin | F02-3677709 | 2 |
| Fagron | Erythromycin | F02-3677803 | 1 |
| Fagron | Erythromycin | F02-3677804 | 6 |
| Fagron | Erythromycin | F05-3715606 | 1 |
| Fagron | Erythromycin | F06-3715700 | 3 |
| Fagron | Erythromycin | F06-3715703 | 2 |
| Fagron | Erythromycin | F06-3721004 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Erythromycin | F06-3738800 | 1 |
| Fagron | Erythromycin | F06-3755106 | 4 |
| Fagron | Erythromycin | F06-3715701 | 1 |
| Fagron | Erythromycin | OEBA/0010516 | 2 |
| Fagron | Erythromycin | OEBA/0020516 | 2 |
| Fagron | Erythromycin | P-26041922/356705 | 1 |
| Fargon/GEHE | Erythromycin | 19C21-B03 | 1 |
| Fargon/Gehe | Erythromycin | 19C21-B03-361725 | 1 |
| Fargon/GEHE | Erythromycin | 19C21-B03-361725 | 1 |
| Fargon/Noweda | Erythromycin | 18F05-B01-356705 | 1 |
| Fargon/Noweda | Erythromycin | 18F05-B01-358088 | 2 |
| Fargon/Sanacorp | Erythromycin | 16J24-B10-329158 | 1 |
| Fargon | Erythromycin | 19c21-b03-361725 | 1 |
| Fargon | Erythromycin | 20E18-F05-371566 | 1 |
| Fargron / Gehe | Erythromycin | 18F05-B01-350907 | 1 |
| Fiebig | Erythromycin | 1409019-02 | 1 |
| Fiebig | Erythromycin | 1607038-02 | 1 |
| Fiebig | Erythromycin | 1705038 | 1 |
| Fiebig | Erythromycin | 17088005 | 2 |
| Fiebig | Erythromycin | 19L18-F02-367780 | 1 |
| fiebig | Erythromycin | 21002053002 | 1 |
| Fiebig | Erythromycin | 2301053-01 | 1 |
| Fiebig | Erythromycin | 2308010-01 | 2 |
| Fiebig | Erythromycin | 2308010-02 | 1 |
| Fiebig | Erythromycin | 2407014-01 | 1 |
| Fiebig05.2021 | Erythromycin | 1607038-02 | 1 |
| Finteler Apotheke | Erythromycin | 1607038-02 | 1 |
| Fragon/ Gehe | Erythromycin | 20E18-F06-371571 | 1 |
| Gatt-Koller | Erythromycin | 1803029 | 2 |
| GEHE 21.05.2014 | Erythromycin | 1308016-01 | 1 |
| Gehe amax | Erythromycin | 16079213 | 1 |
| Gehe Rostock | Erythromycin | 2007017-01 | 1 |
| Gehe//EuRho | Erythromycin | 2002018-01 | 1 |
| Gehe/EuRho | Erythromycin | 2002018-01 | 1 |
| Gehe/Euro | Erythromycin | 1409019-02 | 2 |
| Gehe | Erythromycin | 1106036-05 | 1 |
| Gehe | Erythromycin | 11D13-N09 | 1 |
| Gehe | Erythromycin | 12152105 | 1 |
| Gehe | Erythromycin | 12152108 | 1 |
| Gehe | Erythromycin | 12E24-N04 | 1 |
| Gehe | Erythromycin | 1308016-01 | 3 |
| Gehe | Erythromycin | 1308016-02 | 1 |
| Gehe | Erythromycin | 13189001 | 2 |
| Gehe | Erythromycin | 13F12-N21 | 1 |
| Gehe | Erythromycin | 140901901 | 1 |
| Gehe | Erythromycin | 1409019-01 | 3 |
| Gehe | Erythromycin | 1409019-02 | 2 |
| Gehe | Erythromycin | 15042603 | 1 |
| Gehe | Erythromycin | 15042611 | 1 |
| Gehe | Erythromycin | 15042705 | 1 |
| Gehe | Erythromycin | 150803401 | 1 |
| Gehe | Erythromycin | 1508034-01 | 1 |
| Gehe | Erythromycin | 15245004 | 1 |
| Gehe | Erythromycin | 1607038-01 | 2 |
| gehe | Erythromycin | 1607038-02 | 2 |
| Gehe | Erythromycin | 1607038-02 | 5 |
| Gehe | Erythromycin | 16079204 | 1 |
| GEHE | Erythromycin | 16079208 | 1 |
| Gehe | Erythromycin | 16079209 | 1 |
| GEHE | Erythromycin | 16079213 | 2 |

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|---|---|---|---|
| Gehe | Erythromycin | 16079505 | 1 |
| Gehe | Erythromycin | 16079510 | 1 |
| GEHE | Erythromycin | 16079512 | 1 |
| GEHE | Erythromycin | 16079609 | 2 |
| Gehe | Erythromycin | 16G06-B03 | 1 |
| Gehe | Erythromycin | 16J24-B10-336735 | 1 |
| Gehe | Erythromycin | 1705038-02 | 1 |
| Gehe | Erythromycin | 1705038-03 | 1 |
| GEHE | Erythromycin | 17088008 | 1 |
| Gehe | Erythromycin | 17088010 | 1 |
| GEHE | Erythromycin | 17088203 | 2 |
| Gehe | Erythromycin | 17088204 | 2 |
| Gehe | Erythromycin | 17088210 | 1 |
| Gehe | Erythromycin | 17088301 | 2 |
| Gehe | Erythromycin | 18096202 | 1 |
| GEHE | Erythromycin | 18096202 | 2 |
| GEHE | Erythromycin | 18096210 | 1 |
| Gehe | Erythromycin | 180964003 | 1 |
| Gehe | Erythromycin | 1811019-01 | 1 |
| Gehe | Erythromycin | 18F05-B01-352501 | 1 |
| Gehe | Erythromycin | 18F05-B01-358088 | 1 |
| Gehe | Erythromycin | 1906032-01 | 1 |
| Gehe | Erythromycin | 19C21-B03-361400 | 1 |
| Gehe | Erythromycin | 19C21-B03-361401 | 1 |
| Gehe | Erythromycin | 19C21-B03-361725 | 2 |
| Gehe | Erythromycin | 19L18-F02-36778 | 1 |
| Gehe | Erythromycin | 20002259007 | 3 |
| Gehe | Erythromycin | 20003732002 | 1 |
| Gehe | Erythromycin | 20003732010 | 1 |
| Gehe | Erythromycin | 2002018-01 | 1 |
| Gehe | Erythromycin | 2007017-01 | 2 |
| Gehe | Erythromycin | 2010014-01 | 1 |
| Gehe | Erythromycin | 20E18-F06-372103 | 1 |
| Gehe | Erythromycin | 21/13-B02-213864 | 1 |
| Gehe | Erythromycin | 21A26-F01 | 1 |
| GEHE | Erythromycin | 21I13-B02-213865 | 1 |
| Gehe | Erythromycin | 22001550002 | 1 |
| GEHE | Erythromycin | 22001550002 | 1 |
| Gehe | Erythromycin | 22001550005 | 1 |
| Gehe | Erythromycin | 22002200001 | 1 |
| Gehe | Erythromycin | 22002200003 | 1 |
| Gehe | Erythromycin | 22002202003 | 1 |
| Gehe | Erythromycin | 23003351002 | 1 |
| Gehe | Erythromycin | 23003351004 | 1 |
| Gehe | Erythromycin | 2301053-01 | 1 |
| GEHE | Erythromycin | 2301053-01 | 3 |
| Gehe | Erythromycin | 2308010-01 | 2 |
| Gehe | Erythromycin | 2308010-04 | 1 |
| Gehe | Erythromycin | 240822(22002199003) | 1 |
| Gehe | Erythromycin | 3D200P | 1 |
| Gehe | Erythromycin | f02-3677707 | 1 |
| Geibo | Erythromycin | 20002259003 | 1 |
| Geilenkirchen | Erythromycin | 16J24B10-339488 | 1 |
| Geilenkirchen | Erythromycin | 17088309 | 1 |
| Geilenkirchen | Erythromycin | 18096205 | 1 |
| Geilenkirchen | Erythromycin | 19L18-F02-367780 | 1 |
| gepepharm GmbH | Erythromycin | 13175502 | 1 |
| GUMO | Erythromycin | 19C21-B03-361725 | 1 |
| GUMO | Erythromycin | 19L18-F02-3677708 | 1 |
| GUMO | Erythromycin | 19L18-F02-3687508 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| GUMO | Erythromycin | 20E18-F06 | 1 |
| GUMO | Erythromycin | F02-3677708 | 1 |
| Gutenberg-Apotheke | Erythromycin | 13175608 | 1 |
| Holdermann | Erythromycin | 21002041010 | 1 |
| Ichthyol-Gesellschaft | Erythromycin | 161020E/1607038-01 | 1 |
| Jenapharm/Phönix | Erythromycin | 1607036-01 | 1 |
| Jenne | Erythromycin | 20003732007 | 1 |
| Jenne | Erythromycin | 2010014-02 | 1 |
| Jenne | Erythromycin | 22002202003 | 2 |
| Jenne | Erythromycin | 23003351004 | 1 |
| Jenne | Erythromycin | 230911(22002199002) | 1 |
| Kehr | Erythromycin | 1705038-01 | 1 |
| Kehr | Erythromycin | 21002041010 | 1 |
| Kehr | Erythromycin | 21002041014 | 3 |
| Kehr | Erythromycin | 22002200004 | 2 |
| Kehr | Erythromycin | 226001-01 | 1 |
| Kehr | Erythromycin | 23003387002 | 2 |
| Kehr | Erythromycin | 2301053-01 | 1 |
| kehr | Erythromycin | 230105302 | 1 |
| Kehr | Erythromycin | 2308010-01 | 1 |
| Klenk | Erythromycin | EB068I14 | 1 |
| Klosterring | Erythromycin | CEPEB001E18 | 1 |
| Krieger | Erythromycin | 16G06-B03-329150 | 1 |
| Krieger | Erythromycin | 16J24-B10-336735 | 1 |
| Krieger | Erythromycin | 16J24-B10-341876 | 1 |
| Krieger | Erythromycin | 3402 | 1 |
| L12 | Erythromycin | 16079206 | 2 |
| L12 | Erythromycin | 18096203 | 1 |
| L20 | Erythromycin | 2308010-01 | 1 |
| L30 | Erythromycin | 17088208 | 1 |
| Lamotte | Erythromycin | 18096406 | 1 |
| Max Jenne | Erythromycin | 22002200001 | 1 |
| Max Jenne | Erythromycin | 22002200004 | 2 |
| Midas | Erythromycin | 16079609 | 1 |
| Mikrobiell | Erythromycin | 1705038-01 | 1 |
| Mömerzheim | Erythromycin | 17088001 | 1 |
| Nachprüfung | Erythromycin | 13175810 | 1 |
| Noweda 23.08.2019 | Erythromycin | 1811019-01 | 1 |
| Noweda Essen | Erythromycin | 2308010-01 | 1 |
| Noweda Taucha | Erythromycin | 21002041001 | 1 |
| Noweda/Fragron | Erythromycin | 18F05-B01-359011 | 1 |
| Noweda/Gehe | Erythromycin | 14B06-B35-293508 | 1 |
| Noweda | Erythromycin | 11195411 | 2 |
| Noweda | Erythromycin | 11195413 | 1 |
| Noweda | Erythromycin | 12152108 | 2 |
| Noweda | Erythromycin | 12152201 | 1 |
| Noweda | Erythromycin | 12E24-N04 | 1 |
| Noweda | Erythromycin | 1308016-01 | 1 |
| Noweda | Erythromycin | 130801602 | 2 |
| Noweda | Erythromycin | 13175603 | 2 |
| Noweda | Erythromycin | 13175608 | 1 |
| Noweda | Erythromycin | 14044006 | 1 |
| Noweda | Erythromycin | 14044114 | 1 |
| Noweda | Erythromycin | 150803401 | 1 |
| Noweda | Erythromycin | 15245101 | 1 |
| Noweda | Erythromycin | 160703801 | 1 |
| Noweda | Erythromycin | 1607038-02 | 1 |
| Noweda | Erythromycin | 16079502 | 1 |
| Noweda | Erythromycin | 16079606 | 1 |
| Noweda | Erythromycin | 16J24-B10 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Erythromycin | 16J24-B10-329156 | 1 |
| Noweda | Erythromycin | 1705038-02 | 2 |
| Noweda | Erythromycin | 17088001 | 1 |
| Noweda | Erythromycin | 17088003 | 1 |
| Noweda | Erythromycin | 17088004 | 1 |
| Noweda | Erythromycin | 17088013 | 1 |
| Noweda | Erythromycin | 17088208 | 1 |
| Noweda | Erythromycin | 17088404 | 1 |
| Noweda | Erythromycin | 17088405 | 2 |
| Noweda | Erythromycin | 18096201 | 1 |
| Noweda | Erythromycin | 18096203 | 1 |
| Noweda | Erythromycin | 18096302 | 1 |
| Noweda | Erythromycin | 180964001 | 1 |
| Noweda | Erythromycin | 1811019-01 | 1 |
| Noweda | Erythromycin | 1906032-01 | 3 |
| Noweda | Erythromycin | 19C21-B03-361400 | 1 |
| Noweda | Erythromycin | 20002259004 | 1 |
| Noweda | Erythromycin | 20002259006 | 1 |
| Noweda | Erythromycin | 20003731001 | 2 |
| Noweda | Erythromycin | 20003731003 | 1 |
| Noweda | Erythromycin | 20003731004 | 1 |
| Noweda | Erythromycin | 20003731005 | 1 |
| Noweda | Erythromycin | 20003732010 | 2 |
| Noweda | Erythromycin | 2010014-01 | 1 |
| Noweda | Erythromycin | 20I07-F06-375516 | 1 |
| Noweda | Erythromycin | 21002041004 | 7 |
| noweda | Erythromycin | 21002041009 | 1 |
| Noweda | Erythromycin | 22001550003 | 1 |
| Noweda | Erythromycin | 22002199001 | 1 |
| Noweda | Erythromycin | 220022000002 | 1 |
| noweda | Erythromycin | 22002200001 | 1 |
| Noweda | Erythromycin | 22002200002 | 1 |
| Noweda | Erythromycin | 22002200004 | 2 |
| Noweda | Erythromycin | 22002202003 | 5 |
| Noweda | Erythromycin | 22002203001 | 1 |
| Noweda | Erythromycin | 2206001-01 | 3 |
| Noweda | Erythromycin | 23003351001 | 1 |
| Noweda | Erythromycin | 23003351002 | 1 |
| Noweda | Erythromycin | 23003352002 | 1 |
| Noweda | Erythromycin | 2300337001 | 1 |
| Noweda | Erythromycin | 2301053-01 | 3 |
| Noweda | Erythromycin | 2301053010 | 1 |
| Noweda | Erythromycin | 2301053-02 | 2 |
| Noweda | Erythromycin | 2308010-01 | 1 |
| Noweda | Erythromycin | 2308010-02 | 1 |
| Noweda | Erythromycin | 23D27-B01-227929 | 2 |
| NOWEDA | Erythromycin | 23D27-B01-227929 | 2 |
| Noweda | Erythromycin | 23D27-B1-227929 | 1 |
| Noweda | Erythromycin | P2019/92 | 1 |
| Noweda12/2025 | Erythromycin | 22002200002 | 1 |
| Noweda21.04.2015 | Erythromycin | 14044110 | 1 |
| OTG/Gehe | Erythromycin | 1409019-01 | 1 |
| Otto Fischar | Erythromycin | 16G06-B03-329150 | 1 |
| Parthe Apotheke | Erythromycin | 147/19 | 1 |
| Parthe Apotheke | Erythromycin | 56/21 | 1 |
| ph.Eur | Erythromycin | 2301053-01 | 1 |
| Ph.Euro/Noweda | Erythromycin | 2010015-01 | 1 |
| Phagron | Erythromycin | | 1 |
| PHOENIX 08.05.2014 | Erythromycin | 13175604 | 1 |
| PHOENIX 08.05.2014 | Erythromycin | 13175608 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix 10.02.2020 | Erythromycin | 1906032-01 | 1 |
| Phoenix 25.09.19 8,14EUR | Erythromycin | 18096209 | 2 |
| Phoenix 28.11.2018 | Erythromycin | 17088004 | 1 |
| Phoenix/Cealo | Erythromycin | 17088004/0918E-01362 | 1 |
| Phoenix | Erythromycin | 12152201 | 2 |
| Phoenix | Erythromycin | 13175608 | 1 |
| Phoenix | Erythromycin | 14044106 | 1 |
| Phoenix | Erythromycin | 15042609 | 1 |
| Phoenix | Erythromycin | 15042811 | 1 |
| Phoenix | Erythromycin | 16079501 | 1 |
| Phoenix | Erythromycin | 1705038-01 | 1 |
| Phoenix | Erythromycin | 17088403 | 1 |
| Phoenix | Erythromycin | 18096205 | 1 |
| Phoenix | Erythromycin | 18096302 | 1 |
| Phoenix | Erythromycin | 180964003 | 1 |
| Phoenix | Erythromycin | 18096401 | 2 |
| Phoenix | Erythromycin | 1906032-01 | 2 |
| PHOENIX | Erythromycin | 19C21-B03 | 1 |
| Phoenix | Erythromycin | 20002259002 | 2 |
| Phoenix | Erythromycin | 20003731001 | 1 |
| Phoenix | Erythromycin | 20003731004 | 4 |
| Phoenix | Erythromycin | 2002018-01 | 1 |
| Phoenix | Erythromycin | 2007017-01 | 1 |
| Phoenix | Erythromycin | 201001501 | 1 |
| Phoenix | Erythromycin | 2010015-1 | 1 |
| Phoenix | Erythromycin | 21002041014 | 1 |
| Phoenix | Erythromycin | 2113-B02-213864 | 1 |
| Phoenix | Erythromycin | 22001550005 | 1 |
| Phoenix | Erythromycin | 22002200004 | 3 |
| Phoenix | Erythromycin | 22002202003 | 3 |
| Phoenix | Erythromycin | 22002203001 | 1 |
| Phoenix | Erythromycin | 2206001-01 | 1 |
| Phoenix | Erythromycin | 23003351002 | 1 |
| Phoenix | Erythromycin | 23003387001 | 1 |
| Phoenix | Erythromycin | 23003387002 | 2 |
| Phoenix | Erythromycin | 2308010-03 | 1 |
| Phoenix | Erythromycin | 23D27-B01-227929 | 1 |
| Phoenix | Erythromycin | 3104 | 1 |
| Phoenix | Erythromycin | 3207 | 1 |
| Phönix WE: 23.09.17… | Erythromycin | 16079604 | 1 |
| Phönix Eurho | Erythromycin | 2002018-01 | 1 |
| Phönix Gotha | Erythromycin | 18096303 | 1 |
| Phönix Gotha | Erythromycin | 18096403 | 1 |
| Phönix WE:30.07.2016… | Erythromycin | 15245101 | 1 |
| Phönix | Erythromycin | | 1 |
| Phönix | Erythromycin | 1205036-02 | 1 |
| Phönix | Erythromycin | 121427016 | 1 |
| Phönix | Erythromycin | 14044201 | 1 |
| Phönix | Erythromycin | 14B06-B35 | 1 |
| Phönix | Erythromycin | 14F13-B02-293511 | 1 |
| phönix | Erythromycin | 15042611 | 1 |
| phönix | Erythromycin | 15042813 | 1 |
| Phönix | Erythromycin | 15042813 | 2 |
| phönix | Erythromycin | 15245101 | 1 |
| phönix | Erythromycin | 16079203 | 1 |
| Phönix | Erythromycin | 16079205 | 1 |
| Phönix | Erythromycin | 16079210 | 1 |
| Phönix | Erythromycin | 1705038-01 | 3 |
| Phönix | Erythromycin | 1705038-03 | 1 |
| PHÖNIX | Erythromycin | 1705038-03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Erythromycin | 17088002 | 1 |
| Phonix | Erythromycin | 17088005 | 1 |
| Phönix | Erythromycin | 17088301 | 1 |
| Phönix | Erythromycin | 17088306 | 1 |
| Phönix | Erythromycin | 17088404 | 1 |
| Phönix | Erythromycin | 18096209 | 1 |
| Phönix | Erythromycin | 1811019-01 | 3 |
| PHÖNIX | Erythromycin | 1906032 | 1 |
| Phönix | Erythromycin | 1906032-01 | 4 |
| Phönix | Erythromycin | 19C21-B03-361724 | 2 |
| Phönix | Erythromycin | 19118-F02-367779 | 1 |
| Phönix | Erythromycin | 200202018-01 | 1 |
| Phönix | Erythromycin | 200952209 | 1 |
| Phönix | Erythromycin | 2010014-01 | 1 |
| PHÖNIX | Erythromycin | 2010014-01 | 1 |
| Phönix | Erythromycin | 2010015-01 | 1 |
| Phönix | Erythromycin | 20E18-F06-372103 | 1 |
| Phönix | Erythromycin | 21002041009 | 1 |
| Phönix | Erythromycin | 21002041010 | 1 |
| Phönix | Erythromycin | 21002041014 | 2 |
| Phönix | Erythromycin | 21I13-B02-213864 | 1 |
| Phönix | Erythromycin | 22001550002 | 1 |
| Phönix | Erythromycin | 22001550005 | 1 |
| phönix | Erythromycin | 22002199001 | 1 |
| Phönix | Erythromycin | 22002199001 | 1 |
| Phönix | Erythromycin | 22002200002 | 2 |
| Phönix | Erythromycin | 22002200004 | 7 |
| Phönix | Erythromycin | 22002200005 | 1 |
| Phönix | Erythromycin | 22002202003 | 3 |
| Phönix | Erythromycin | 23003351022 | 1 |
| Phönix | Erythromycin | 2301053-01 | 2 |
| Phönix | Erythromycin | 2301053-02 | 1 |
| Phönix | Erythromycin | 23D27-B01-227928 | 1 |
| Raben-Apotheke Mildenau | Erythromycin | 13175601 | 2 |
| Rondell Apotheke | Erythromycin | 15042803 | 1 |
| Röntgen | Erythromycin | 2002018-01 | 2 |
| Röntgen | Erythromycin | 2007017-01 | 1 |
| Röntgen | Erythromycin | 2010014-01 | 3 |
| Sa / EuRho | Erythromycin | 2010014-01 | 1 |
| Sanacopr | Erythromycin | | 1 |
| Sanacorp, 35,50EUR, 24.1.17 | Erythromycin | 1607038-01 | 2 |
| Sanacorp/apo-ident | Erythromycin | 1705038-03 | 1 |
| Sanacorp/EuRho | Erythromycin | 17088306 | 1 |
| Sanacorp | Erythromycin | | 1 |
| Sanacorp | Erythromycin | 1106036-04 | 1 |
| Sanacorp | Erythromycin | 1205035-02 | 1 |
| Sanacorp | Erythromycin | 12152202 | 1 |
| Sanacorp | Erythromycin | 12156208 | 1 |
| Sanacorp | Erythromycin | 1308016-01 | 1 |
| Sanacorp | Erythromycin | 1308016-02 | 1 |
| Sanacorp | Erythromycin | 13H22-N07 | 1 |
| Sanacorp | Erythromycin | 1409019-01 | 1 |
| Sanacorp | Erythromycin | 16079612 | 1 |
| Sanacorp | Erythromycin | 16079702 | 1 |
| Sanacorp | Erythromycin | 16J24-B10 | 2 |
| Sanacorp | Erythromycin | 16J24B10-338559 | 1 |
| Sanacorp | Erythromycin | 16J24-B10-338559 | 1 |
| Sanacorp | Erythromycin | 1705038-03 | 1 |
| Sanacorp | Erythromycin | 17088002 | 1 |
| Sanacorp | Erythromycin | 17088010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Erythromycin | 170880403 | 1 |
| Sanacorp | Erythromycin | 17088302 | 1 |
| Sanacorp | Erythromycin | 17088402 | 1 |
| Sanacorp | Erythromycin | 17088404 | 1 |
| Sanacorp | Erythromycin | 18096204 | 1 |
| Sanacorp | Erythromycin | 18096210 | 1 |
| Sanacorp | Erythromycin | 18096404 | 1 |
| Sanacorp | Erythromycin | 18096405 | 1 |
| sanacorp | Erythromycin | 18096406 | 1 |
| Sanacorp | Erythromycin | 181101901 | 1 |
| Sanacorp | Erythromycin | 18F05-B01-350908 | 2 |
| sanacorp | Erythromycin | 1906032-01 | 1 |
| Sanacorp | Erythromycin | 1906032-01 | 1 |
| Sanacorp | Erythromycin | 19C21-B03 | 1 |
| Sanacorp | Erythromycin | 19C21-B03-361401 | 1 |
| Sanacorp | Erythromycin | 19C21-B03-361725 | 1 |
| Sanacorp | Erythromycin | 19L18-F02-368758 | 1 |
| Sanacorp | Erythromycin | 20071017-01 | 1 |
| Sanacorp | Erythromycin | 20100114-01 | 1 |
| Sanacorp | Erythromycin | 2010014-02 | 1 |
| Sanacorp | Erythromycin | 20E18-F06-3721004 | 1 |
| Sanacorp | Erythromycin | 20E18-F06-372104 | 1 |
| Sanacorp | Erythromycin | 21002041004 | 1 |
| Sanacorp | Erythromycin | 21002041014 | 1 |
| Sanacorp | Erythromycin | 21002046001 | 1 |
| Sanacorp | Erythromycin | 21A26-F01-376731 | 5 |
| Sanacorp | Erythromycin | 21f02-f02-379295 | 1 |
| Sanacorp | Erythromycin | 21I13-B02-213865 | 1 |
| Sanacorp | Erythromycin | 22001550003 | 1 |
| Sanacorp | Erythromycin | 22001550005 | 2 |
| Sanacorp | Erythromycin | 22002199002 | 2 |
| Sanacorp | Erythromycin | 22002200004 | 2 |
| Sanacorp | Erythromycin | 22002202003 | 2 |
| Sanacorp | Erythromycin | 2206001-01 | 1 |
| Sanacorp | Erythromycin | 23003351002 | 1 |
| Sanacorp | Erythromycin | 23003387001 | 1 |
| Sanacorp | Erythromycin | 2301053-01 | 3 |
| Sanacorp | Erythromycin | 23H23-B04-231446 | 2 |
| Sanacorp | Erythromycin | 23H23-B04-236846 | 1 |
| Sanacorp | Erythromycin | 31K190P | 1 |
| Sanacorp | Erythromycin | 59/AKD51 | 1 |
| Sanacorp | Erythromycin | 60/AKD52 | 1 |
| Sanacorp;19.03.15;30,50EUR | Erythromycin | 1409019-01 | 1 |
| Sm Biomed / Gehe | Erythromycin | 15245002 | 1 |
| Sm Biomed / Gehe | Erythromycin | 16079202 | 1 |
| Sm Biomed / Gehe | Erythromycin | 17088013 | 1 |
| SM Biomed Sdn Bhd/Phoenix | Erythromycin | 2010015-01 | 1 |
| SM Biomed Sdn. Bhd | Erythromycin | 20020018-01 | 1 |
| SM Biomed Sdn | Erythromycin | 18096405 | 1 |
| SM Biomed/Noweda | Erythromycin | EBD/18-003 | 2 |
| SM Biomed/Noweda | Erythromycin | EBD/20-003 | 1 |
| SM Biomed | Erythromycin | 2010014-02 | 1 |
| Spangro | Erythromycin | 16079205 | 1 |
| Spangro | Erythromycin | 16G06-B-03-329151 | 1 |
| Spangro_21.05.2019 | Erythromycin | 1705038-03 | 1 |
| Unisan | Erythromycin | 140901902 | 1 |
| VDL | Erythromycin | 11195407 | 1 |
| VDL | Erythromycin | 160703801 | 1 |
| wepa | Erythromycin | 2206001-01 | 1 |
| Wolff/AHD | Erythromycin | 15245004 | 1 |


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- 249 912 spectra from 1666 *Apo-Ident* customers from a total of 51 156 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Erythromycin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Erythromycin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 460 | 0 | 157 866 |
| **Type B** | 0 | 840 | 0 | 212 100 |
| **Type C** | 0 | 6794 | 180 | 249 912 |

The substance/substance group *Erythromycin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6957 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2857 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.4190 % (> 97.3760 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21056 | 21890 | 11.15 | 120.93 |
| 21323 | 22438 | 6.07 | 122.06 |
| 21651 | 21651 | 0.00 | 137.01 |
| 21669 | 21651 | 14.87 | 126.88 |
| 21890 | 21890 | 0.00 | 123.42 |
| 22438 | 22438 | 0.00 | 123.68 |
| 22832 | 22832 | 0.00 | 119.87 |
| 23438 | 23438 | 0.00 | 119.66 |
| 24420 | 24420 | 0.00 | 137.47 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Estradiol benzoate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20098-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Estradiol benzoate; Estradioli benzoas

### Special notes

When selecting the *Estradiol benzoate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Estradiol benzoate | 7 | 5 | 137 |

### Second-stage model

For differentiation of the substance/substance group *Estradiol benzoate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Estradiol benzoate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 132.34 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Estradiol benzoate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Estradiol benzoate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Estradiol benzoate | 15078608 | 23218 | 40 | 20150415 |
| Caelo | Estradiol benzoate | 181444 | 24254 | 40 | 20180614* |
| Caelo | Estradiol benzoate | 21004177006 | 26314 | 40 | 20220112 |
| Caelo | Estradiol benzoate | 21004177006 | 26314SI | 40 | 20220112 |
| Euro OTC | Estradiol benzoate | 1301006-02 | 21290 | 40 | 1507405 |
| Euro OTC | Estradiol benzoate | 1507009 | 21869 | 60 | 0000010566 |
| Euro OTC | Estradiol benzoate | 1507009 | 21869SI | 60 | 0000010566 |
| Fagron | Estradiol benzoate | 12H02-N02 | 20889 | 40 | 20120817 |
| Fagron | Estradiol benzoate | 12H02-N02 | 20889SI | 60 | 20120817 |
| Fagron | Estradiol benzoate | 14B20-B02 | 21257 | 40 | 20140327 |
| Fagron | Estradiol benzoate | 14B20-B02 | 21257SI | 60 | 20140327 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 520 spectra of 11 reference samples from the substance/substance group *Estradiol benzoate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 806 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 440 spectra of 11 reference samples from the substance/substance group *Estradiol benzoate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Estradiol benzoate | 13277607 | 21324 | 40 |
| Euro OTC | Estradiol benzoate | 1611004 | 22873 | 40 |
| Euro OTC | Estradiol benzoate | 1412033 | 24139 | 40 |
| Euro OTC | Estradiol benzoate | 2001032 | 25113 | 40 |
| Fagron | Estradiol benzoate | 24B26-B06-228380 | 27184 | 40 |
| Caelo | Estradiol benzoate | 15078608 | 23218SI† | 40 |
| Caelo | Estradiol benzoate | 181444 | 24254SI† | 40 |
| Euro OTC | Estradiol benzoate | 1611004 | 22873SI | 40 |
| Euro OTC | Estradiol benzoate | 1412033 | 24139SI | 40 |
| Euro OTC | Estradiol benzoate | 2001032 | 25113SI | 40 |
| Fagron | Estradiol benzoate | 24B26-B06-228380 | 27184SI | 40 |

- 212 500 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 970 spectra from 589 *Apo-Ident* customers from 146 batches from the substance/substance group *Estradiol benzoate*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 136 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Estradiol benzoate | 2001032 | 1 |
| | Estradiol benzoate | 2001032-03 | 2 |
| | Estradiol benzoate | 21004177005 | 1 |
| | Estradiol benzoate | 21004177006 | 1 |
| | Estradiol benzoate | 2209014-01 | 1 |
| | Estradiol benzoate | 2300012002 | 1 |
| | Estradiol benzoate | 23000121002 | 9 |
| | Estradiol benzoate | 23000121003 | 18 |
| | Estradiol benzoate | 23000121005 | 17 |
| | Estradiol benzoate | 23003603002 | 2 |
| | Estradiol benzoate | 3919E-01946 | 1 |
| A.H. 07.06.13 ek: 24,14EUR | Estradiol benzoate | 1201019-02 | 1 |
| AHC | Estradiol benzoate | 18144408 | 1 |
| AHD | Estradiol benzoate | 14B20-B02-292001 | 1 |
| AHD | Estradiol benzoate | 1611004-02 | 1 |
| AHD | Estradiol benzoate | 18144404 | 1 |
| AHD | Estradiol benzoate | 23000121005 | 1 |
| aliance healthcare 5... | Estradiol benzoate | 10118576 | 1 |
| Alliance Healthcare | Estradiol benzoate | 1301006-01 | 1 |
| apo-ident | Estradiol benzoate | 18144405 | 1 |
| Bayer Pharma AG / Noweda | Estradiol benzoate | 14B20-B02 | 1 |
| Bayer Pharma/Noweda | Estradiol benzoate | 14B20-B02-292001 | 1 |
| Bayer-Schering | Estradiol benzoate | 1007037-03 | 1 |
| Caelo | Estradiol benzoate | | 4 |
| Caelo | Estradiol benzoate | 10124909 | 5 |
| Caelo | Estradiol benzoate | 10124912 | 1 |
| Caelo | Estradiol benzoate | 10124915 | 2 |
| Caelo | Estradiol benzoate | 10124918 | 2 |
| Caelo | Estradiol benzoate | 10124919 | 1 |
| Caelo | Estradiol benzoate | 10124921 | 1 |
| Caelo | Estradiol benzoate | 1100417 | 1 |
| Caelo | Estradiol benzoate | 111004-02 | 1 |
| Caelo | Estradiol benzoate | 1149 | 1 |
| Caelo | Estradiol benzoate | 1201019-02 | 1 |
| Caelo | Estradiol benzoate | 12255904 | 10 |
| Caelo | Estradiol benzoate | 12255905 | 10 |
| Caelo | Estradiol benzoate | 1301006-02 | 1 |
| Caelo | Estradiol benzoate | 13276401 | 6 |
| Caelo | Estradiol benzoate | 13277602 | 8 |
| Caelo | Estradiol benzoate | 13277603 | 2 |
| Caelo | Estradiol benzoate | 13277605 | 4 |
| Caelo | Estradiol benzoate | 13277607 | 3 |
| Caelo | Estradiol benzoate | 1401001-01 | 1 |
| Caelo | Estradiol benzoate | 1412033-02 | 1 |
| Caelo | Estradiol benzoate | 1507009-01 | 1 |
| Caelo | Estradiol benzoate | 1507806 | 1 |
| Caelo | Estradiol benzoate | 15078602 | 10 |
| Caelo | Estradiol benzoate | 15078603 | 22 |
| Caelo | Estradiol benzoate | 15078604 | 21 |
| Caelo | Estradiol benzoate | 15078606 | 6 |
| Caelo | Estradiol benzoate | 15078608 | 16 |
| Caelo | Estradiol benzoate | 15078609 | 1 |
| Caelo | Estradiol benzoate | 150918EB | 1 |
| Caelo | Estradiol benzoate | 15C10B04305523 | 1 |
| Caelo | Estradiol benzoate | 15C10-B04-305523 | 2 |
| Caelo | Estradiol benzoate | 16003701 | 7 |
| Caelo | Estradiol benzoate | 16003702 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Estradiol benzoate | 16003707 | 22 |
| Caelo | Estradiol benzoate | 1611004-01 | 1 |
| Caelo | Estradiol benzoate | 1611004-02 | 2 |
| Caelo | Estradiol benzoate | 17357602 | 8 |
| Caelo | Estradiol benzoate | 17357604 | 2 |
| Caelo | Estradiol benzoate | 17357605 | 12 |
| Caelo | Estradiol benzoate | 1814402 | 1 |
| Caelo | Estradiol benzoate | 1814404 | 1 |
| Caelo | Estradiol benzoate | 1814405 | 1 |
| Caelo | Estradiol benzoate | 1814408 | 1 |
| Caelo | Estradiol benzoate | 18144402 | 23 |
| Caelo | Estradiol benzoate | 18144404 | 19 |
| Caelo | Estradiol benzoate | 18144405 | 31 |
| Caelo | Estradiol benzoate | 18144406 | 17 |
| Caelo | Estradiol benzoate | 18144406P-191101-1 | 1 |
| Caelo | Estradiol benzoate | 18144408 | 22 |
| Caelo | Estradiol benzoate | 181444404 | 1 |
| Caelo | Estradiol benzoate | 181444405 | 1 |
| Caelo | Estradiol benzoate | 181444406 | 1 |
| Caelo | Estradiol benzoate | 1844406 | 1 |
| Caelo | Estradiol benzoate | 200000164001 | 2 |
| Caelo | Estradiol benzoate | 20000164001 | 53 |
| Caelo | Estradiol benzoate | 2000016401 | 2 |
| Caelo | Estradiol benzoate | 2000164001 | 2 |
| Caelo | Estradiol benzoate | 2001032-01 | 3 |
| Caelo | Estradiol benzoate | 2001032-02 | 3 |
| Caelo | Estradiol benzoate | 21000144002 | 1 |
| Caelo | Estradiol benzoate | 21000145001 | 18 |
| Caelo | Estradiol benzoate | 21000145003 | 6 |
| Caelo | Estradiol benzoate | 21004177003 | 19 |
| Caelo | Estradiol benzoate | 21004177004 | 4 |
| Caelo | Estradiol benzoate | 21004177005 | 13 |
| Caelo | Estradiol benzoate | 21004177006 | 14 |
| Caelo | Estradiol benzoate | 21004177008 | 13 |
| Caelo | Estradiol benzoate | 2100417704 | 1 |
| Caelo | Estradiol benzoate | 21121204 | 1 |
| Caelo | Estradiol benzoate | 227051-08-08 | 1 |
| Caelo | Estradiol benzoate | 23000121002 | 3 |
| Caelo | Estradiol benzoate | 23000121005 | 1 |
| Caelo | Estradiol benzoate | 32308779 | 1 |
| Caelo | Estradiol benzoate | 6091305 | 1 |
| Caelo | Estradiol benzoate | 81403700 | 1 |
| Caelo | Estradiol benzoate | 84303830 | 2 |
| Caelo | Estradiol benzoate | 92137389 | 1 |
| Caelo | Estradiol benzoate | eucerin | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21004177003 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 18144404 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21004177008 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 20000164001 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21000145003 | 1 |
| Caesar & Loretz GmbH/AHD | Estradiol benzoate | 21004177006 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 18144404 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21000145001 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21000145001 | 1 |
| Caesar & Loretz GmbH/Gehe | Estradiol benzoate | 18144405 | 1 |
| Caesar & Loretz GmbH/GEHE | Estradiol benzoate | 18144405 | 1 |
| Caesar & Loretz GmbH/GEHE | Estradiol benzoate | 18144406 | 1 |
| Caesar & Loretz GmbH/Gehe | Estradiol benzoate | 20000164001 | 1 |
| Caesar & Loretz GmbH/Gehe | Estradiol benzoate | 21004177004 | 2 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 20000164001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Kehr | Estradiol benzoate | 20000164001 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 18144402 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21000145001 | 1 |
| Caesar & Loretz GmbH/Ph | Estradiol benzoate | 18144408 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 20000164001 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 18144404 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21004177005 | 1 |
| Caesar & Loretz GmbH... | Estradiol benzoate | 21004177003 | 1 |
| Caesar & Loretz GmbH | Estradiol benzoate | 17357605 | 4 |
| Caesar & Loretz GmbH | Estradiol benzoate | 18144402 | 1 |
| Caesar & Loretz GmbH | Estradiol benzoate | 18144405 | 12 |
| Caesar & Loretz GmbH | Estradiol benzoate | 18144406 | 9 |
| Caesar & Loretz GmbH | Estradiol benzoate | 18144408 | 4 |
| Caesar & Loretz GmbH | Estradiol benzoate | 20000164001 | 8 |
| Caesar & Loretz GmbH | Estradiol benzoate | 21000145001 | 6 |
| Caesar & Loretz GmbH | Estradiol benzoate | 21000145003 | 5 |
| Caesar & Loretz GmbH | Estradiol benzoate | 21004177003 | 5 |
| Caesar & Loretz GmbH | Estradiol benzoate | 21004177004 | 4 |
| Caesar & Loretz GmbH | Estradiol benzoate | 21004177005 | 3 |
| Caesar & Loretz GmbH | Estradiol benzoate | 21004177006 | 18 |
| Caesar & Loretz GmbH | Estradiol benzoate | 21004177008 | 2 |
| Caesar & Loretz GmbH | Estradiol benzoate | 23000121002 | 3 |
| Caesar & Loretz | Estradiol benzoate | 17357605 | 1 |
| Caesar / Gehe | Estradiol benzoate | 16003707 | 1 |
| Caesar L / Sanacorp | Estradiol benzoate | 18144408 | 1 |
| Caesar&Lorenz / Gehe | Estradiol benzoate | 18144405 | 1 |
| Caesar&Lorenz | Estradiol benzoate | 21000145001 | 1 |
| Cealo/Noweda | Estradiol benzoate | 18144405 | 1 |
| Cealo | Estradiol benzoate | 15078604 | 1 |
| EuRho/Noweda | Estradiol benzoate | 2001032-03 | 6 |
| EuRho/Sanacorp | Estradiol benzoate | 1201019-02 | 1 |
| EuRho | Estradiol benzoate | 84303830 | 1 |
| Euro OCT/Noweda | Estradiol benzoate | 1301006-02 | 4 |
| Euro OTC | Estradiol benzoate | 1007037-02 | 1 |
| Euro OTC | Estradiol benzoate | 1201019-01 | 7 |
| Euro OTC | Estradiol benzoate | 1201019-02 | 9 |
| Euro OTC | Estradiol benzoate | 121019-01 | 1 |
| Euro OTC | Estradiol benzoate | 130100601 | 1 |
| Euro OTC | Estradiol benzoate | 1301006-01 | 2 |
| Euro OTC | Estradiol benzoate | 1301006-02 | 7 |
| Euro OTC | Estradiol benzoate | 14010001-01 | 1 |
| Euro OTC | Estradiol benzoate | 1401001-01 | 10 |
| Euro OTC | Estradiol benzoate | 140101-01 | 1 |
| Euro OTC | Estradiol benzoate | 1412033-01 | 9 |
| Euro OTC | Estradiol benzoate | 1412033-02 | 6 |
| Euro OTC | Estradiol benzoate | 150700901 | 2 |
| Euro OTC | Estradiol benzoate | 1507009-01 | 16 |
| Euro OTC | Estradiol benzoate | 1507009-01I-0401016 | 1 |
| Euro OTC | Estradiol benzoate | 16003707 | 1 |
| Euro OTC | Estradiol benzoate | 1611004-01 | 11 |
| Euro OTC | Estradiol benzoate | 161100402 | 2 |
| Euro OTC | Estradiol benzoate | 1611004-02 | 22 |
| Euro OTC | Estradiol benzoate | 1611004-028638831 | 1 |
| Euro OTC | Estradiol benzoate | 16110047-02 | 1 |
| Euro OTC | Estradiol benzoate | 16111004-01 | 1 |
| Euro OTC | Estradiol benzoate | 1807161 | 1 |
| Euro OTC | Estradiol benzoate | 2001032-01 | 13 |
| Euro OTC | Estradiol benzoate | 2001032-02 | 5 |
| Euro OTC | Estradiol benzoate | 2001032-03 | 3 |
| Euro OTC | Estradiol benzoate | 21000145003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Estradiol benzoate | 8011422 | 1 |
| Euro OTC | Estradiol benzoate | 83101340 | 1 |
| Euro OTC | Estradiol benzoate | 84303830 | 2 |
| EURO Pharma | Estradiol benzoate | 84303830 | 1 |
| Euro/Krieger | Estradiol benzoate | 1611004-02 | 1 |
| Fa.Phönix | Estradiol benzoate | 16003707 | 1 |
| Fa.Phönix | Estradiol benzoate | 20000164001 | 1 |
| Fagron | Estradiol benzoate | 11H01-N12 | 1 |
| Fagron | Estradiol benzoate | 11L23-N01 | 2 |
| Fagron | Estradiol benzoate | 12B08-N05 | 1 |
| Fagron | Estradiol benzoate | 12D20N06 | 1 |
| Fagron | Estradiol benzoate | 12H02-N02 | 3 |
| Fagron | Estradiol benzoate | 12H02-N052 | 1 |
| Fagron | Estradiol benzoate | 12L14-N02 | 1 |
| Fagron | Estradiol benzoate | 13/11-N01 | 2 |
| Fagron | Estradiol benzoate | 13C15-B07-288645 | 1 |
| Fagron | Estradiol benzoate | 13I11N01 | 1 |
| Fagron | Estradiol benzoate | 13I11-N01 | 1 |
| Fagron | Estradiol benzoate | 1412033-01 | 1 |
| Fagron | Estradiol benzoate | 14820-B02-294949 | 1 |
| Fagron | Estradiol benzoate | 14B20-B02 | 3 |
| Fagron | Estradiol benzoate | 14B20-B02-2920001 | 1 |
| Fagron | Estradiol benzoate | 14B20-B02-292001 | 6 |
| Fagron | Estradiol benzoate | 14b20-b02-294949 | 1 |
| Fagron | Estradiol benzoate | 14B20-B02-294949 | 3 |
| Fagron | Estradiol benzoate | 15c10-b04-305523 | 1 |
| Fagron | Estradiol benzoate | 15C10-B04-305523 | 6 |
| Fagron | Estradiol benzoate | 15E08-B08 | 1 |
| Fagron | Estradiol benzoate | 15E08-B08-311705 | 13 |
| Fagron | Estradiol benzoate | 17357602 | 1 |
| Fagron | Estradiol benzoate | 17L01-B05-3434714 | 1 |
| Fagron | Estradiol benzoate | 17L01B05343714 | 1 |
| Fagron | Estradiol benzoate | 17L01-B05-343714 | 4 |
| Fagron | Estradiol benzoate | 17L01-B05-348601 | 1 |
| Fagron | Estradiol benzoate | 2001032-01 | 1 |
| Fagron | Estradiol benzoate | 20D16-F08-370349 | 1 |
| Fagron | Estradiol benzoate | 2x12L14-N02 | 1 |
| Fagron | Estradiol benzoate | 81403680 | 1 |
| Fagron | Estradiol benzoate | 81403690 | 3 |
| Fagron | Estradiol benzoate | 83101340 | 2 |
| Fagron | Estradiol benzoate | 84303830 | 1 |
| Fagron | Estradiol benzoate | 84303840 | 1 |
| Fargon/AHD | Estradiol benzoate | 15E08-B08-311705 | 2 |
| Fiebig | Estradiol benzoate | 20000164001 | 1 |
| Gehe | Estradiol benzoate | 11L23-N01 | 1 |
| Gehe | Estradiol benzoate | 15078606 | 1 |
| GEHE | Estradiol benzoate | 15078609 | 1 |
| Gehe | Estradiol benzoate | 16003702 | 1 |
| Gehe | Estradiol benzoate | 17L01-B05-343714 | 1 |
| Gehe | Estradiol benzoate | 18144408 | 1 |
| Gehe | Estradiol benzoate | 20000164001 | 1 |
| Gehe | Estradiol benzoate | 2001032-02 | 2 |
| Gehe | Estradiol benzoate | 21004177005 | 1 |
| Gehe | Estradiol benzoate | 21004177006 | 2 |
| Gehe | Estradiol benzoate | 23000121002 | 2 |
| GUMO | Estradiol benzoate | 21000145001 | 1 |
| Holdermann | Estradiol benzoate | 23000121003 | 1 |
| Jenne/Caesar & Loret… | Estradiol benzoate | 21004177004 | 1 |
| Kehr | Estradiol benzoate | 18144404 | 1 |
| Kehr | Estradiol benzoate | 23000121003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Estradiol benzoate | 8(18144402) | 1 |
| Krieger | Estradiol benzoate | 3401 | 1 |
| Nachprüfung | Estradiol benzoate | 123456 | 1 |
| Noweda | Estradiol benzoate | 1003040-01 | 2 |
| Noweda | Estradiol benzoate | 13277603 | 1 |
| Noweda | Estradiol benzoate | 15078603 | 1 |
| Noweda | Estradiol benzoate | 15078608 | 1 |
| Noweda | Estradiol benzoate | 18144402 | 1 |
| Noweda | Estradiol benzoate | 2001032-01 | 1 |
| Noweda | Estradiol benzoate | 21000145001 | 2 |
| Noweda | Estradiol benzoate | 21004177003 | 1 |
| Noweda | Estradiol benzoate | 21004177004 | 1 |
| Phoenix 1.10.2018 | Estradiol benzoate | 17357602 | 1 |
| Phoenix WE:20.11.17 … | Estradiol benzoate | 16003702 | 1 |
| Phoenix/Cealo | Estradiol benzoate | 1611004-01 | 1 |
| Phoenix | Estradiol benzoate | 15078608 | 1 |
| Phoenix | Estradiol benzoate | 18144402 | 1 |
| Phoenix | Estradiol benzoate | 18144405 | 2 |
| Phoenix | Estradiol benzoate | 20d16-f08-373007 | 1 |
| Phoenix | Estradiol benzoate | 8638831 | 1 |
| phönix | Estradiol benzoate | 14B20-B02-294949 | 1 |
| Phönix | Estradiol benzoate | 16003707 | 2 |
| phönix | Estradiol benzoate | 21004177004 | 1 |
| Sanacorp 04.07.19 Ek… | Estradiol benzoate | 18144404 | 1 |
| Sanacorp | Estradiol benzoate | 10/AKD24 | 1 |
| sanacorp | Estradiol benzoate | 15078604 | 1 |
| Sanacorp | Estradiol benzoate | 16003707 | 1 |
| Sanacorp | Estradiol benzoate | 17L01-B05 | 2 |
| Sanacorp | Estradiol benzoate | 17L01-B05-343714 | 1 |
| Sanacorp | Estradiol benzoate | 180625/2 | 1 |
| Sanacorp | Estradiol benzoate | 1814402 | 1 |
| Sanacorp | Estradiol benzoate | 21004177005 | 1 |
| Sanacorp | Estradiol benzoate | 23000121002 | 2 |
| Valdepharm/Phoenix | Estradiol benzoate | ESB002-3E | 1 |
| VDl 16.10.14 12,70 euro | Estradiol benzoate | | 1 |
| VDL | Estradiol benzoate | 1507009-01 | 1 |
| WE:Phönix 21.09.2012 | Estradiol benzoate | 12B08-N05 | 1 |

- 255 916 spectra from 1666 *Apo-Ident* customers from a total of 52 012 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Estradiol benzoate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Estradiol benzoate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 520 | 0 | 157 806 |
| **Type B** | 0 | 440 | 0 | 212 500 |
| **Type C** | 0 | 956 | 14 | 255 916 |


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The substance/substance group *Estradiol benzoate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8462 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6364 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.5567 % (> 98.2474 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20889 | 21290 | 10.56 | 215.27 |
| 21257 | 21290 | 4.39 | 213.10 |
| 21290 | 21290 | 0.00 | 213.29 |
| 21869 | 21869 | 0.00 | 216.72 |
| 23218 | 21869 | 10.32 | 215.90 |
| 24254 | 24254 | 0.00 | 215.68 |
| 26314 | 21869 | 12.43 | 215.94 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Estradiol hemihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20497-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Estradiol hemihydrate; Estradiolum hemihydricum

### Special notes

When selecting the *Estradiol hemihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Estradiol hemihydrate | 11 | 28 | 159 |

### Second-stage model

For differentiation of the substance/substance group *Estradiol hemihydrate* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Estradiol hemihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 52.65 | – |
| ⋮ | ⋮ | ⋮ |
| Estriol | >50 | 20.53 |
| Polymyxin B sulfate | >50 | 37.61 |
| Bacitracin | >50 | 42.19 |
| Cyanocobalamin | >50 | 58.11 |
| Riboflavin | >50 | 59.76 |
| Colistin sulfate | >50 | 59.92 |
| Amphotericin B | >50 | 61.36 |
| Nystatin | >50 | 73.85 |
| Triamcinolone | >50 | 75.71 |
| Calcium glycerophosphate | >50 | 91.11 |
| alpha-tocopheryl acetate dry concentrate | >50 | 96.57 |
| Methylcobalamin | >50 | 141.09 |
| Calcium pantothenate | >50 | 143.23 |
| Gelatine, white | >50 | 165.88 |
| SyrSpend® SF Alka | >50 | 171.16 |
| Hyoscine hydrobromide | >50 | 198.85 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 202.50 |
| Tosylchloramide sodium | >50 | 205.51 |
| Carmellose sodium | >50 | 214.39 |
| Rice starch | >50 | 288.68 |
| Corn starch | >50 | 329.90 |
| Oxalic acid | >50 | 337.11 |
| Acacia, dried dispersion | >50 | 487.56 |
| Wheat starch | >50 | 491.85 |
| SyrSpend® SF pH4 | >50 | 498.19 |
| Maltodextrin | >50 | 521.56 |
| Potato starch | >50 | 568.24 |
| Fructose | >50 | 707.54 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Estradiol hemihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Estradiol hemihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Estradiol hemihydrate | 12268016 | 21302 | 40 | 1410502 |
| Caelo | Estradiol hemihydrate | 13285802 | 21499 | 60 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21500 | 60 | 1510622 |
| Caelo | Estradiol hemihydrate | 13285802 | 21501 | 20 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21502 | 20 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21503 | 20 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21504 | 20 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21505 | 20 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21506 | 20 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21507 | 20 | 20130913 |
| Caelo | Estradiol hemihydrate | 13285802 | 21508 | 60 | 1410504 |
| Euro OTC | Estradiol hemihydrate | 1208022-01 | 21291 | 40 | 20121012 |
| Euro OTC | Estradiol hemihydrate | 1507013 | 21847 | 60 | 1510623 |
| Euro OTC | Estradiol hemihydrate | 1507013 | 21847SI | 60 | 1510623 |
| Euro OTC | Estradiol hemihydrate | 1510039 | 21945 | 60 | 20151103* |
| Euro OTC | Estradiol hemihydrate | 1510039 | 21945SI | 89 | 20151103* |
| Euro OTC | Estradiol hemihydrate | 1601017 | 22307 | 45 | 20160122* |
| Euro OTC | Estradiol hemihydrate | 1612008 | 22913 | 40 | 20170117* |
| Euro OTC | Estradiol hemihydrate | 1612008 | 22913SI | 40 | 20170117* |
| Euro OTC | Estradiol hemihydrate | 2009029 | 25402 | 40 | 20201012* |
| Euro OTC | Estradiol hemihydrate | 2103014 | 25608 | 40 | 20210406* |
| Euro OTC | Estradiol hemihydrate | 2103014 | 25608SI | 40 | 20210406* |
| Fagron | Estradiol hemihydrate | 14G24-B04-297404 | 21667 | 55 | 20140825 |
| Fagron | Estradiol hemihydrate | 16H04-B01-328738 | 23184 | 40 | 20160915 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 1009 spectra of 24 reference samples from the substance/substance group *Estradiol hemihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.
- 157 317 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 2544 spectra of 67 reference samples from the substance/substance group *Estradiol hemihydrate*.
- Among them are spectra of independent samples from 28 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Estradiol hemihydrate | 170582 | 23339 | 40 |
| Caelo | Estradiol hemihydrate | 181443 | 24257 | 40 |
| Caelo | Estradiol hemihydrate | 21003879006 | 26315 | 40 |
| Caelo | Estradiol hemihydrate | 23003532003 | 27577 | 40 |
| Euro OTC | Estradiol hemihydrate | 1607003 | 22712 | 40 |
| Euro OTC | Estradiol hemihydrate | 1612008-01 | 23099 | 40 |
| Euro OTC | Estradiol hemihydrate | 1705018 | 23431 | 40 |
| Euro OTC | Estradiol hemihydrate | 1710031 | 23779 | 40 |
| Euro OTC | Estradiol hemihydrate | 1802013 | 24083 | 40 |
| Euro OTC | Estradiol hemihydrate | 1802012 | 24086 | 40 |
| Euro OTC | Estradiol hemihydrate | 1809022 | 24319 | 40 |
| Euro OTC | Estradiol hemihydrate | 1808032 | 24322 | 40 |
| Euro OTC | Estradiol hemihydrate | 1905001 | 24639 | 40 |
| Euro OTC | Estradiol hemihydrate | 1906013 | 24772 | 40 |
| Euro OTC | Estradiol hemihydrate | 1910006 | 24973 | 40 |
| Euro OTC | Estradiol hemihydrate | 1911010 | 24983 | 40 |
| Euro OTC | Estradiol hemihydrate | 2002008 | 25108 | 40 |
| Euro OTC | Estradiol hemihydrate | 2002009 | 25109 | 40 |
| Euro OTC | Estradiol hemihydrate | 2002007 | 25114 | 40 |
| Euro OTC | Estradiol hemihydrate | 2006023 | 25257 | 40 |
| Euro OTC | Estradiol hemihydrate | 2006024 | 25266 | 40 |
| Euro OTC | Estradiol hemihydrate | 2006022 | 25284 | 40 |
| Euro OTC | Estradiol hemihydrate | 2009028 | 25403 | 40 |
| Euro OTC | Estradiol hemihydrate | 2201041 | 25966 | 40 |
| Euro OTC | Estradiol hemihydrate | 2303010 | 26656 | 40 |
| Euro OTC | Estradiol hemihydrate | 2405012 | 27278 | 40 |
| Fagron | Estradiol hemihydrate | 13K22-N01 | 21263 | 40 |
| Fagron | Estradiol hemihydrate | 22I23-B01-225111 | 26374 | 40 |
| Caelo | Estradiol hemihydrate | 13285802 | 21499SI† | 60 |
| Caelo | Estradiol hemihydrate | 13285802 | 21500SI† | 60 |
| Caelo | Estradiol hemihydrate | 13285802 | 21501SI† | 20 |
| Caelo | Estradiol hemihydrate | 13285802 | 21502SI† | 20 |
| Caelo | Estradiol hemihydrate | 13285802 | 21503SI† | 20 |
| Caelo | Estradiol hemihydrate | 13285802 | 21504SI† | 20 |
| Caelo | Estradiol hemihydrate | 13285802 | 21505SI† | 20 |
| Caelo | Estradiol hemihydrate | 13285802 | 21506SI† | 20 |
| Caelo | Estradiol hemihydrate | 13285802 | 21507SI† | 20 |
| Caelo | Estradiol hemihydrate | 170582 | 23339SI | 30 |
| Caelo | Estradiol hemihydrate | 181443 | 24257SI | 40 |
| Caelo | Estradiol hemihydrate | 21003879006 | 26315SI | 40 |
| Caelo | Estradiol hemihydrate | 23003532003 | 27577SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1601017 | 22307SI† | 45 |
| Euro OTC | Estradiol hemihydrate | 1607003 | 22712SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1612008-01 | 23099SI | 30 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Estradiol hemihydrate | 1705018 | 23431SI | 30 |
| Euro OTC | Estradiol hemihydrate | 1710031 | 23779SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1802013 | 24083SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1802012 | 24086SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1809022 | 24319SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1808032 | 24322SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1905001 | 24639SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1906013 | 24772SI | 39 |
| Euro OTC | Estradiol hemihydrate | 1910006 | 24973SI | 40 |
| Euro OTC | Estradiol hemihydrate | 1911010 | 24983SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2002008 | 25108SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2002009 | 25109SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2002007 | 25114SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2006023 | 25257SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2006024 | 25266SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2006022 | 25284SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2009029 | 25402SI† | 40 |
| Euro OTC | Estradiol hemihydrate | 2009028 | 25403SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2201041 | 25966SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2303010 | 26656SI | 40 |
| Euro OTC | Estradiol hemihydrate | 2405012 | 27278SI | 40 |
| Fagron | Estradiol hemihydrate | 16H04-B01-328738 | 23184SI† | 30 |
| Fagron | Estradiol hemihydrate | 22I23-B01-225111 | 26374SI | 40 |

- 210 396 spectra from a total of 4255 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 604 spectra from 226 *Apo-Ident* customers from 167 batches from the substance/substance group *Estradiol hemihydrate*.

- Among them are spectra of independent samples from 159 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Estradiol hemihydrate | 21003879006 | 2 |
| | Estradiol hemihydrate | 21003879009 | 2 |
| | Estradiol hemihydrate | 2103014-02 | 1 |
| | Estradiol hemihydrate | 22000384017 | 1 |
| | Estradiol hemihydrate | 22123-B01 | 1 |
| | Estradiol hemihydrate | 23000120001 | 4 |
| | Estradiol hemihydrate | 2300020001 | 1 |
| | Estradiol hemihydrate | 2303010-01 | 7 |
| Anzag; 12.72EUR; 7.10.2015 | Estradiol hemihydrate | 15038004 | 1 |
| Audor Pharma | Estradiol hemihydrate | 1911010-01 | 1 |
| Bayer Pharma AG | Estradiol hemihydrate | 1411024-01 | 2 |
| Bayer Pharma | Estradiol hemihydrate | 13K22-N01 | 2 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Estradiol hemihydrate | 108082101 | 1 |
| Caelo | Estradiol hemihydrate | 11078104 | 1 |
| Caelo | Estradiol hemihydrate | 11078105 | 1 |
| Caelo | Estradiol hemihydrate | 11078113 | 1 |
| Caelo | Estradiol hemihydrate | 12172003 | 2 |
| Caelo | Estradiol hemihydrate | 12268003 | 1 |
| Caelo | Estradiol hemihydrate | 12268012 | 5 |
| Caelo | Estradiol hemihydrate | 12F29-N03 | 1 |
| Caelo | Estradiol hemihydrate | 13285801 | 1 |
| Caelo | Estradiol hemihydrate | 13285802 | 4 |
| Caelo | Estradiol hemihydrate | 13285804 | 1 |
| Caelo | Estradiol hemihydrate | 13285811 | 4 |
| Caelo | Estradiol hemihydrate | 13K22-N01 | 1 |
| Caelo | Estradiol hemihydrate | 15038004 | 5 |
| Caelo | Estradiol hemihydrate | 1503801 | 1 |
| Caelo | Estradiol hemihydrate | 15038010 | 2 |
| Caelo | Estradiol hemihydrate | 15038014 | 2 |
| Caelo | Estradiol hemihydrate | 15038016 | 2 |
| Caelo | Estradiol hemihydrate | 15385406 | 1 |
| Caelo | Estradiol hemihydrate | 15385410 | 4 |
| Caelo | Estradiol hemihydrate | 15385411 | 1 |
| Caelo | Estradiol hemihydrate | 15385415 | 2 |
| Caelo | Estradiol hemihydrate | 15D01-B02-319032 | 1 |
| Caelo | Estradiol hemihydrate | 1601017-01 | 5 |
| Caelo | Estradiol hemihydrate | 1612008-01 | 1 |
| Caelo | Estradiol hemihydrate | 1705018-01 | 3 |
| Caelo | Estradiol hemihydrate | 17058205 | 4 |
| Caelo | Estradiol hemihydrate | 18082101 | 3 |
| Caelo | Estradiol hemihydrate | 18082101P-180904-1 | 1 |
| Caelo | Estradiol hemihydrate | 18082103 | 1 |
| Caelo | Estradiol hemihydrate | 18082104 | 4 |
| Caelo | Estradiol hemihydrate | 18082105 | 6 |
| Caelo | Estradiol hemihydrate | 18144306 | 2 |
| Caelo | Estradiol hemihydrate | 18144308 | 1 |
| Caelo | Estradiol hemihydrate | 18144309 | 3 |
| Caelo | Estradiol hemihydrate | 18144314 | 3 |
| Caelo | Estradiol hemihydrate | 18F18-B01-351946 | 1 |
| Caelo | Estradiol hemihydrate | 19051501 | 1 |
| Caelo | Estradiol hemihydrate | 193089002 | 3 |
| Caelo | Estradiol hemihydrate | 193089003 | 1 |
| Caelo | Estradiol hemihydrate | 193089007 | 5 |
| Caelo | Estradiol hemihydrate | 193089010 | 5 |
| Caelo | Estradiol hemihydrate | 193089011 | 2 |
| Caelo | Estradiol hemihydrate | 19308910 | 1 |
| Caelo | Estradiol hemihydrate | 20I18-F03-374511 | 1 |
| Caelo | Estradiol hemihydrate | 21000148001 | 7 |
| Caelo | Estradiol hemihydrate | 21003879001 | 1 |
| Caelo | Estradiol hemihydrate | 21003879006 | 3 |
| Caelo | Estradiol hemihydrate | 22101301 | 1 |
| Caelo | Estradiol hemihydrate | 84201560 | 1 |
| Caelo | Estradiol hemihydrate | 9248916 | 2 |
| Caesar & Loretz GmbH... | Estradiol hemihydrate | 18144309 | 1 |
| Caesar & Loretz GmbH... | Estradiol hemihydrate | 21003879006 | 1 |
| Caesar & Loretz GmbH... | Estradiol hemihydrate | 193089011 | 1 |
| Caesar & Loretz GmbH/Sana | Estradiol hemihydrate | 193089010 | 1 |
| Caesar & Loretz GmbH... | Estradiol hemihydrate | 193089011 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 15385415 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 18082104 | 5 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 18082105 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 18144306 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Estradiol hemihydrate | 18144309 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 193089002 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 193089006 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 193089007 | 2 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 193089011 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 21000148001 | 2 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 21000148003 | 1 |
| Caesar & Loretz GmbH | Estradiol hemihydrate | 21003879006 | 5 |
| ESD | Estradiol hemihydrate | ESD-20010 | 1 |
| EuRho/Sanacorp | Estradiol hemihydrate | 1911010-01 | 1 |
| Eurho | Estradiol hemihydrate | 2002007-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 1308003-01 | 2 |
| Euro OTC | Estradiol hemihydrate | 1374814 | 1 |
| Euro OTC | Estradiol hemihydrate | 1404030-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 1411024-01 | 2 |
| Euro OTC | Estradiol hemihydrate | 1504034-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 1507013-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 1510039-01 | 11 |
| Euro OTC | Estradiol hemihydrate | 15D01-B02 | 1 |
| Euro OTC | Estradiol hemihydrate | 1601017-01 | 10 |
| Euro OTC | Estradiol hemihydrate | 1607003-01 | 29 |
| Euro OTC | Estradiol hemihydrate | 1607003-0101374814 | 1 |
| Euro OTC | Estradiol hemihydrate | 1612008_01 | 1 |
| Euro OTC | Estradiol hemihydrate | 1612008-01 | 26 |
| Euro OTC | Estradiol hemihydrate | 1705018-01 | 18 |
| Euro OTC | Estradiol hemihydrate | 17058205 | 1 |
| Euro OTC | Estradiol hemihydrate | 1802012-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 1802013-01 | 3 |
| Euro OTC | Estradiol hemihydrate | 1808032-01 | 23 |
| Euro OTC | Estradiol hemihydrate | 1809022-01 | 7 |
| Euro OTC | Estradiol hemihydrate | 180902202 | 1 |
| Euro OTC | Estradiol hemihydrate | 1809022-02 | 6 |
| Euro OTC | Estradiol hemihydrate | 1906013-01 | 3 |
| Euro OTC | Estradiol hemihydrate | 1910006-01 | 4 |
| Euro OTC | Estradiol hemihydrate | 1911010-01 | 4 |
| Euro OTC | Estradiol hemihydrate | 2002009-01 | 4 |
| Euro OTC | Estradiol hemihydrate | 2006022-01 | 15 |
| Euro OTC | Estradiol hemihydrate | 2006023-01 | 12 |
| Euro OTC | Estradiol hemihydrate | 2006024-01 | 14 |
| Euro OTC | Estradiol hemihydrate | 2006024-02 | 1 |
| Euro OTC | Estradiol hemihydrate | 20090028-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 2009028-01 | 18 |
| Euro OTC | Estradiol hemihydrate | 2009029 | 10 |
| Euro OTC | Estradiol hemihydrate | 2009029-01 | 20 |
| Euro OTC | Estradiol hemihydrate | 2103014-0 | 2 |
| Euro OTC | Estradiol hemihydrate | 210301401 | 1 |
| Euro OTC | Estradiol hemihydrate | 2103014-01 | 19 |
| Euro OTC | Estradiol hemihydrate | 2201041-01 | 8 |
| Euro OTC | Estradiol hemihydrate | 2303010-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 2405012-01 | 1 |
| Euro OTC | Estradiol hemihydrate | 27061714 | 1 |
| Euro OTC | Estradiol hemihydrate | 701634 | 1 |
| Euro/ Phönix | Estradiol hemihydrate | 3417M-02845 | 1 |
| Fagron | Estradiol hemihydrate | | 1 |
| Fagron | Estradiol hemihydrate | 110314O1 | 1 |
| Fagron | Estradiol hemihydrate | 11A21-N01 | 1 |
| Fagron | Estradiol hemihydrate | 11H23-N02 | 1 |
| Fagron | Estradiol hemihydrate | 12F29-N03 | 6 |
| Fagron | Estradiol hemihydrate | 12L19-N07 | 7 |
| Fagron | Estradiol hemihydrate | 12L29-N07 | 1 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Estradiol hemihydrate | 13E07-N02 | 4 |
| Fagron | Estradiol hemihydrate | 13k22n01 | 1 |
| Fagron | Estradiol hemihydrate | 13K22N01 | 1 |
| Fagron | Estradiol hemihydrate | 13K22-N01 | 5 |
| Fagron | Estradiol hemihydrate | 14G24-B04 | 1 |
| Fagron | Estradiol hemihydrate | 14G24-B04-297402 | 3 |
| Fagron | Estradiol hemihydrate | 14G24-B04-297404 | 1 |
| Fagron | Estradiol hemihydrate | 14G24-B04-297405 | 1 |
| Fagron | Estradiol hemihydrate | 14G24-B04-297406 | 1 |
| Fagron | Estradiol hemihydrate | 14G24-B04-302446 | 3 |
| Fagron | Estradiol hemihydrate | 15D01-B02-308190 | 1 |
| Fagron | Estradiol hemihydrate | 15D01-B02-308568 | 2 |
| Fagron | Estradiol hemihydrate | 15D01-B02-312068 | 3 |
| Fagron | Estradiol hemihydrate | 15D01-B02-319032 | 4 |
| Fagron | Estradiol hemihydrate | 16D12-B01-322022 | 1 |
| Fagron | Estradiol hemihydrate | 16D12B01326783 | 1 |
| Fagron | Estradiol hemihydrate | 16D12-B01-326783 | 6 |
| Fagron | Estradiol hemihydrate | 16h04-b01-328738 | 1 |
| Fagron | Estradiol hemihydrate | 16H04-B01-328738 | 1 |
| Fagron | Estradiol hemihydrate | 16h04-b01-334200 | 1 |
| Fagron | Estradiol hemihydrate | 16H04-B01-334200 | 4 |
| Fagron | Estradiol hemihydrate | 16H04-B01-334592 | 1 |
| Fagron | Estradiol hemihydrate | 16h04-b01-337595 | 1 |
| Fagron | Estradiol hemihydrate | 16H04-B01-33795 | 1 |
| Fagron | Estradiol hemihydrate | 16H04-B01-339490 | 1 |
| Fagron | Estradiol hemihydrate | 1802012-01 | 1 |
| Fagron | Estradiol hemihydrate | 1802013-01 | 3 |
| Fagron | Estradiol hemihydrate | 18F18-B01 | 2 |
| Fagron | Estradiol hemihydrate | 18F18-B01-351789 | 1 |
| Fagron | Estradiol hemihydrate | 18F18-B01-351790 | 1 |
| Fagron | Estradiol hemihydrate | 18F18-B01-351946 | 2 |
| Fagron | Estradiol hemihydrate | 18F18-B01-354821 | 1 |
| Fagron | Estradiol hemihydrate | 18F18-B01-355586 | 1 |
| Fagron | Estradiol hemihydrate | 18F18-B01-357641 | 2 |
| Fagron | Estradiol hemihydrate | 18F18-B01-359015 | 2 |
| Fagron | Estradiol hemihydrate | 18F18B01360269 | 1 |
| Fagron | Estradiol hemihydrate | 18F18-B01-360269 | 1 |
| Fagron | Estradiol hemihydrate | 18F18-B01-363586 | 3 |
| Fagron | Estradiol hemihydrate | 18F18-B01-363587 | 2 |
| Fagron | Estradiol hemihydrate | 20B07-F02-369198 | 1 |
| Fagron | Estradiol hemihydrate | 20b07-f02-369199 | 1 |
| Fagron | Estradiol hemihydrate | 20B07-F02-369529 | 1 |
| Fagron | Estradiol hemihydrate | 20I18-F03-374511 | 1 |
| Fagron | Estradiol hemihydrate | 20I18-FO3-374511 | 2 |
| Fagron | Estradiol hemihydrate | 20l18-F03-374511 | 1 |
| Fagron | Estradiol hemihydrate | 21E12-F07-378251 | 2 |
| Fagron | Estradiol hemihydrate | 21E12-F07-378252 | 1 |
| Fagron | Estradiol hemihydrate | 21E12-F07-378866 | 2 |
| Fagron | Estradiol hemihydrate | 302446 | 1 |
| Fagron | Estradiol hemihydrate | 83100820 | 2 |
| Fagron | Estradiol hemihydrate | 84201170 | 1 |
| Fagron | Estradiol hemihydrate | 84201560 | 1 |
| Fagron | Estradiol hemihydrate | 9G07N01 | 1 |
| Fagron | Estradiol hemihydrate | 9J27-N05 | 1 |
| Fagron | Estradiol hemihydrate | F02-3695209 | 1 |
| Fagron | Estradiol hemihydrate | UN80044 | 1 |
| Fargon | Estradiol hemihydrate | 2B07-369198 | 1 |
| Fargon | Estradiol hemihydrate | B01-3635806 | 1 |
| Fargon | Estradiol hemihydrate | f02-3691908 | 1 |
| Fargron/ Sanacorp | Estradiol hemihydrate | 14G24-b04-297402 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fiebig | Estradiol hemihydrate | 16H04-B01 | 1 |
| Gatt-Koller | Estradiol hemihydrate | 1801604 | 2 |
| Gehe | Estradiol hemihydrate | 15038016 | 1 |
| Gehe | Estradiol hemihydrate | 82404160 | 1 |
| Henry Lamotte/AHD | Estradiol hemihydrate | 18082101 | 1 |
| La Chandra /Noweda | Estradiol hemihydrate | 210301401 | 1 |
| Noweda | Estradiol hemihydrate | 12268008 | 1 |
| Noweda | Estradiol hemihydrate | 15038004 | 1 |
| Noweda | Estradiol hemihydrate | 18F18-B01_351946 | 1 |
| Noweda | Estradiol hemihydrate | 21003879006 | 1 |
| Phoenix | Estradiol hemihydrate | 22I23-B01 | 1 |
| phönix | Estradiol hemihydrate | 13285802 | 1 |
| Phönix | Estradiol hemihydrate | 21003879002 | 1 |
| phönix | Estradiol hemihydrate | 21003879009 | 3 |
| Phönix | Estradiol hemihydrate | 23000120001 | 1 |
| Röntgen | Estradiol hemihydrate | 18082105 | 1 |
| Röntgen | Estradiol hemihydrate | 193089002 | 1 |
| Sanacorp /Fargron | Estradiol hemihydrate | 15D01-B02-312068 | 1 |
| Sanacorp | Estradiol hemihydrate | 15038010 | 1 |
| Sanacorp | Estradiol hemihydrate | 18F18-B01 | 1 |
| Sanacorp | Estradiol hemihydrate | 21E12-F07-379952 | 2 |
| Symbiotec/Phoenix | Estradiol hemihydrate | 20/18-F03 | 1 |
| vDL | Estradiol hemihydrate | 2103014-02 | 1 |

- 256 282 spectra from 1666 *Apo-Ident* customers from a total of 51 988 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Estradiol hemihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Estradiol hemihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 1009 | 0 | 157 317 |
| **Type B** | 0 | 2544 | 0 | 210 396 |
| **Type C** | 0 | 603 | 1 | 256 282 |

The substance/substance group *Estradiol hemihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.4054 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.7642 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8344 % (> 99.3377 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21291 | 21945 | 4.77 | 107.38 |
| 21302 | 21302 | 0.00 | 122.37 |
| 21499 | 21847 | 6.35 | 102.83 |
| 21500 | 21500 | 0.00 | 97.09 |
| 21501 | 21302 | 5.61 | 118.17 |
| 21502 | 21302 | 5.72 | 116.70 |
| 21503 | 21302 | 11.07 | 116.59 |
| 21504 | 21302 | 6.81 | 117.55 |
| 21505 | 21302 | 9.83 | 116.30 |
| 21506 | 21945 | 9.58 | 110.50 |
| 21507 | 21302 | 5.78 | 121.10 |
| 21508 | 21508 | 0.00 | 126.97 |
| 21667 | 21945 | 2.95 | 109.14 |
| 21847 | 21847 | 0.00 | 103.11 |
| 21945 | 21945 | 0.00 | 111.56 |
| 22307 | 22307 | 0.00 | 115.00 |
| 22913 | 22913 | 0.00 | 115.97 |
| 23184 | 22307 | 4.16 | 119.11 |
| 25402 | 25402 | 0.00 | 117.24 |
| 25608 | 25608 | 0.00 | 113.56 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Estradiol valerate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20330-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Estradiol valerate; Estradioli valeras

### Special notes

When selecting the *Estradiol valerate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Estradiol valerate | 6 | 4 | 147 |

### Second-stage model

For differentiation of the substance/substance group *Estradiol valerate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Estradiol valerate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 89.30 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Estradiol valerate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Estradiol valerate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Estradiol valerate | 13264001 | 21411 | 60 | 1410503 |
| Caelo | Estradiol valerate | 13264001 | 21411SI | 45 | 1410503 |
| Caelo | Estradiol valerate | 13264001 | 21416 | 120 | 1510624 |
| Caelo | Estradiol valerate | 13264001 | 21416SI | 45 | 1510624 |
| Caelo | Estradiol valerate | 13264001 | 21417 | 20 | 20130920 |
| Caelo | Estradiol valerate | 13264001 | 21418 | 20 | 20130920 |
| Caelo | Estradiol valerate | 13264001 | 21419 | 20 | 20130920 |
| Caelo | Estradiol valerate | 13264001 | 21422 | 20 | 20130920 |
| Caelo | Estradiol valerate | 13264001 | 21423 | 20 | 20130920 |
| Caelo | Estradiol valerate | 13264001 | 21424 | 60 | 1410503 |
| Caelo | Estradiol valerate | 13264001 | 21425 | 20 | 20130920 |
| Caelo | Estradiol valerate | 13264001 | 21426 | 20 | 20130920 |
| Caelo | Estradiol valerate | 15194802 | 21989 | 60 | 20150708 |
| Caelo | Estradiol valerate | 15194802 | 21989SI | 30 | 20150708 |
| Caelo | Estradiol valerate | 163277 | 23056 | 40 | 20161221* |
| Caelo | Estradiol valerate | 163277 | 23056SI | 40 | 20161221* |
| Caelo | Estradiol valerate | 22000384013 | 26741 | 40 | 20220407 |
| Fagron | Estradiol valerate | 12D18-N02 | 20651 | 40 | 20120426 |
| Fagron | Estradiol valerate | 12D18-N02 | 21266 | 40 | 20120118 |
| Fagron | Estradiol valerate | 14E26-B02-294846 | 21646 | 60 | 20140616 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 820 spectra of 20 reference samples from the substance/substance group *Estradiol valerate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 506 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 467 spectra of 16 reference samples from the substance/substance group *Estradiol valerate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Estradiol valerate | 180674 | 24030 | 40 |
| Caelo | Estradiol valerate | 20002389004 | 25427 | 40 |
| Caelo | Estradiol valerate | 24000954 | 27231 | 40 |
| Fagron | Estradiol valerate | 20J16-F01-375199 | 25753 | 40 |
| Caelo | Estradiol valerate | 13264001 | 21417SI† | 14 |
| Caelo | Estradiol valerate | 13264001 | 21418SI† | 15 |
| Caelo | Estradiol valerate | 13264001 | 21419SI† | 15 |
| Caelo | Estradiol valerate | 13264001 | 21422SI† | 17 |
| Caelo | Estradiol valerate | 13264001 | 21423SI† | 15 |
| Caelo | Estradiol valerate | 13264001 | 21425SI† | 15 |
| Caelo | Estradiol valerate | 13264001 | 21426SI† | 16 |
| Caelo | Estradiol valerate | 180674 | 24030SI | 40 |
| Caelo | Estradiol valerate | 20002389004 | 25427SI | 40 |
| Caelo | Estradiol valerate | 22000384013 | 26741SI† | 40 |
| Caelo | Estradiol valerate | 24000954 | 27231SI | 40 |
| Fagron | Estradiol valerate | 20J16-F01-375199 | 25753SI | 40 |

- 212 473 spectra from a total of 4281 batches from further 872 substances. These spectra were

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 550 spectra from 223 *Apo-Ident* customers from 157 batches from the substance/substance group *Estradiol valerate*.
- Among them are spectra of independent samples from 147 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Estradiol valerate | 22000384002 | 2 |
| | Estradiol valerate | 22000384005 | 2 |
| | Estradiol valerate | 22000384007 | 1 |
| | Estradiol valerate | 22000384010 | 4 |
| | Estradiol valerate | 22000384011 | 3 |
| | Estradiol valerate | 22000384015 | 4 |
| | Estradiol valerate | 22000384017 | 3 |
| | Estradiol valerate | 22000384020 | 1 |
| | Estradiol valerate | 22000384021 | 1 |
| | Estradiol valerate | 23I13-B13-231047 | 1 |
| | Estradiol valerate | 23I13-B13-235334 | 1 |
| | Estradiol valerate | 24000954001 | 3 |
| | Estradiol valerate | 24000954003 | 8 |
| | Estradiol valerate | 24000954006 | 1 |
| | Estradiol valerate | 24000954007 | 3 |
| | Estradiol valerate | ESV003-1A | 1 |
| | Estradiol valerate | F01-3751904 | 1 |
| | Estradiol valerate | F01-3760807 | 1 |
| Bayer Pharma / Gehe | Estradiol valerate | 84404140 | 1 |
| Bayer Pharma AG | Estradiol valerate | 15C10-B05-305395 | 1 |
| Bayer Pharma GmbH | Estradiol valerate | 82201620 | 1 |
| Bayer/Gehe | Estradiol valerate | 15C10-B05-309186 | 2 |
| Beiersdorf/AHD | Estradiol valerate | 12A20-N10 | 1 |
| Caelo | Estradiol valerate | 10E07-N04 | 1 |
| Caelo | Estradiol valerate | 12G05-N09 | 2 |
| Caelo | Estradiol valerate | 13264001 | 1 |
| Caelo | Estradiol valerate | 13264002 | 1 |
| Caelo | Estradiol valerate | 13264003 | 1 |
| Caelo | Estradiol valerate | 14E26-B02-294844 | 1 |
| Caelo | Estradiol valerate | 14E26-B02-294845 | 1 |
| Caelo | Estradiol valerate | 15194808 | 1 |
| Caelo | Estradiol valerate | 15C10-805 | 1 |
| Caelo | Estradiol valerate | 15C10-B05 | 2 |
| Caelo | Estradiol valerate | 15c10-B05-305396 | 1 |
| Caelo | Estradiol valerate | 15C10B05308851 | 1 |
| Caelo | Estradiol valerate | 15c10-b05-314840 | 1 |
| Caelo | Estradiol valerate | 15C10-B05-314840 | 1 |
| Caelo | Estradiol valerate | 15C10-B05-321675 | 1 |
| Caelo | Estradiol valerate | 15C10-B05-326087 | 1 |
| Caelo | Estradiol valerate | 16327702 | 5 |
| Caelo | Estradiol valerate | 16327703 | 2 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Estradiol valerate | 16327706 | 4 |
| Caelo | Estradiol valerate | 16327709 | 5 |
| Caelo | Estradiol valerate | 16327710 | 1 |
| Caelo | Estradiol valerate | 16327711 | 3 |
| Caelo | Estradiol valerate | 16F09-B01-332756 | 1 |
| Caelo | Estradiol valerate | 18062402 | 1 |
| Caelo | Estradiol valerate | 18067402 | 11 |
| Caelo | Estradiol valerate | 18067403 | 1 |
| Caelo | Estradiol valerate | 18067404 | 1 |
| Caelo | Estradiol valerate | 18067405 | 2 |
| Caelo | Estradiol valerate | 18067407 | 8 |
| Caelo | Estradiol valerate | 18067408 | 2 |
| Caelo | Estradiol valerate | 18067409 | 7 |
| Caelo | Estradiol valerate | 18067410 | 1 |
| Caelo | Estradiol valerate | 18067410P-181228-1 | 1 |
| Caelo | Estradiol valerate | 18067411 | 1 |
| Caelo | Estradiol valerate | 18067412 | 3 |
| Caelo | Estradiol valerate | 18067413 | 2 |
| Caelo | Estradiol valerate | 18067415P-190718-2 | 1 |
| Caelo | Estradiol valerate | 18067416 | 6 |
| Caelo | Estradiol valerate | 18067417 | 1 |
| Caelo | Estradiol valerate | 18067417P-200217-3 | 1 |
| Caelo | Estradiol valerate | 1810013 | 1 |
| Caelo | Estradiol valerate | 190615001 | 4 |
| Caelo | Estradiol valerate | 190615003 | 1 |
| Caelo | Estradiol valerate | 190615004 | 15 |
| Caelo | Estradiol valerate | 190615007 | 3 |
| Caelo | Estradiol valerate | 19061501 | 2 |
| Caelo | Estradiol valerate | 19061503 | 4 |
| Caelo | Estradiol valerate | 19061506 | 5 |
| Caelo | Estradiol valerate | 19061507 | 10 |
| Caelo | Estradiol valerate | 2(190615501) | 1 |
| Caelo | Estradiol valerate | 200004423006 | 1 |
| Caelo | Estradiol valerate | 20002389002 | 19 |
| Caelo | Estradiol valerate | 20002389003 | 9 |
| Caelo | Estradiol valerate | 20004423001 | 12 |
| Caelo | Estradiol valerate | 20004423003 | 5 |
| Caelo | Estradiol valerate | 20004423005 | 3 |
| Caelo | Estradiol valerate | 20004423006 | 15 |
| Caelo | Estradiol valerate | 2000443001 | 1 |
| Caelo | Estradiol valerate | 2002389002 | 1 |
| Caelo | Estradiol valerate | 218U-03259 | 1 |
| Caelo | Estradiol valerate | 22000384004 | 2 |
| Caelo | Estradiol valerate | 22000384007 | 3 |
| Caelo | Estradiol valerate | 22000384010 | 2 |
| Caelo | Estradiol valerate | 22000384015 | 4 |
| Caelo | Estradiol valerate | 222000384020 | 1 |
| Caelo | Estradiol valerate | 3(190615004) | 1 |
| Caelo | Estradiol valerate | 4(20002389002) | 1 |
| Caelo | Estradiol valerate | 4214U-03259 | 1 |
| Caelo | Estradiol valerate | 5218Q-03259 | 1 |
| Caelo | Estradiol valerate | 5315A-03259 | 1 |
| Caelo | Estradiol valerate | test | 1 |
| Caesar & Lorenz | Estradiol valerate | 10123258 | 1 |
| Caesar & Loretz GmbH… | Estradiol valerate | 20004423003 | 1 |
| Caesar & Loretz GmbH… | Estradiol valerate | 20004423006 | 1 |
| Caesar & Loretz GmbH… | Estradiol valerate | 22000384004 | 1 |
| Caesar & Loretz GmbH… | Estradiol valerate | 20002389003 | 2 |
| Caesar & Loretz GmbH… | Estradiol valerate | 20004423005 | 1 |
| Caesar & Loretz GmbH/Gehe | Estradiol valerate | 190615 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Estradiol valerate | 190615004 | 1 |
| Caesar & Loretz GmbH/Kehr | Estradiol valerate | 18067409 | 1 |
| Caesar & Loretz GmbH/Kehr | Estradiol valerate | 18067416 | 1 |
| Caesar & Loretz GmbH... | Estradiol valerate | 20004423005 | 1 |
| Caesar & Loretz GmbH... | Estradiol valerate | 19061501 | 1 |
| Caesar & Loretz GmbH... | Estradiol valerate | 19061507 | 4 |
| Caesar & Loretz GmbH... | Estradiol valerate | 20002389002 | 1 |
| Caesar & Loretz GmbH | Estradiol valerate | 18067416 | 1 |
| Caesar & Loretz GmbH | Estradiol valerate | 18067417 | 1 |
| CAESAR & LORETZ GMBH | Estradiol valerate | 190615001 | 1 |
| CAESAR & LORETZ GMBH | Estradiol valerate | 190615003 | 2 |
| Caesar & Loretz GmbH | Estradiol valerate | 190615004 | 4 |
| Caesar & Loretz GmbH | Estradiol valerate | 19061503 | 2 |
| Caesar & Loretz GmbH | Estradiol valerate | 19061507 | 1 |
| Caesar & Loretz GmbH | Estradiol valerate | 20002389002 | 5 |
| Caesar & Loretz GmbH | Estradiol valerate | 20002389003 | 2 |
| Caesar & Loretz GmbH | Estradiol valerate | 20004423001 | 5 |
| Caesar & Loretz GmbH | Estradiol valerate | 20004423003 | 4 |
| Caesar & Loretz GmbH | Estradiol valerate | 20004423005 | 1 |
| Caesar & Loretz GmbH | Estradiol valerate | 20004423006 | 8 |
| Caesar & Loretz GmbH | Estradiol valerate | 22000384002 | 4 |
| Caesar & Loretz GmbH | Estradiol valerate | 22000384004 | 5 |
| Caesar & Loretz GmbH | Estradiol valerate | 22000384005 | 1 |
| Cealo/Sanacorp | Estradiol valerate | 20004423006 | 1 |
| Euro OTC | Estradiol valerate | 15C10-b05 | 1 |
| Euro OTC | Estradiol valerate | 1606022-01 | 1 |
| Fagro | Estradiol valerate | 15C10-B05-318405 | 1 |
| Fagron | Estradiol valerate | 11G18-N04 | 1 |
| Fagron | Estradiol valerate | 11J13-N09 | 1 |
| Fagron | Estradiol valerate | 11J13-No9 | 1 |
| Fagron | Estradiol valerate | 11k04-n04 | 1 |
| Fagron | Estradiol valerate | 11K04-N04 | 1 |
| Fagron | Estradiol valerate | 12A20-N10 | 2 |
| Fagron | Estradiol valerate | 12D18-N02 | 3 |
| Fagron | Estradiol valerate | 12G05N09 | 1 |
| Fagron | Estradiol valerate | 12G05-N09 | 2 |
| Fagron | Estradiol valerate | 12K05-N02 | 3 |
| Fagron | Estradiol valerate | 13A07-N11 | 6 |
| Fagron | Estradiol valerate | 13D16N10 | 1 |
| Fagron | Estradiol valerate | 13D16-N10 | 4 |
| Fagron | Estradiol valerate | 13g09-n05 | 1 |
| Fagron | Estradiol valerate | 13G09N05 | 1 |
| Fagron | Estradiol valerate | 13G09-N05 | 5 |
| Fagron | Estradiol valerate | 13I13-N02 | 2 |
| Fagron | Estradiol valerate | 13J13-N02 | 1 |
| Fagron | Estradiol valerate | 14E26B02 | 2 |
| Fagron | Estradiol valerate | 14E26-B02-294844 | 1 |
| Fagron | Estradiol valerate | 14E26-B02-294845 | 3 |
| Fagron | Estradiol valerate | 14E26-B02-294847 | 1 |
| Fagron | Estradiol valerate | 14E26-B02-296348 | 7 |
| Fagron | Estradiol valerate | 14E26-B02-302873 | 3 |
| Fagron | Estradiol valerate | 15C10-B05 | 2 |
| Fagron | Estradiol valerate | 15C10-B05_314840 | 1 |
| Fagron | Estradiol valerate | 15C10-B05-305395 | 6 |
| Fagron | Estradiol valerate | 15C10-B05-305396 | 1 |
| Fagron | Estradiol valerate | 15C10-B05-308851 | 9 |
| Fagron | Estradiol valerate | 15c10-b05-309186 | 1 |
| Fagron | Estradiol valerate | 15C10-B05-309186 | 1 |
| Fagron | Estradiol valerate | 15C10-B05-313568 | 1 |
| Fagron | Estradiol valerate | 15c10-b05-314840 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Estradiol valerate | 15C10-B05-314840 | 5 |
| Fagron | Estradiol valerate | 15C10-B05-318405 | 1 |
| Fagron | Estradiol valerate | 15C10B05321675 | 1 |
| Fagron | Estradiol valerate | 15C10-B05-321675 | 11 |
| Fagron | Estradiol valerate | 15c10-b05-324956 | 1 |
| Fagron | Estradiol valerate | 15C10-B05-324956 | 3 |
| Fagron | Estradiol valerate | 15C10B05-326087 | 1 |
| Fagron | Estradiol valerate | 15C10-B05-326087 | 5 |
| Fagron | Estradiol valerate | 16F09-B01 | 2 |
| Fagron | Estradiol valerate | 16F09-B01_332756 | 1 |
| Fagron | Estradiol valerate | 16F09-B01-328135 | 8 |
| Fagron | Estradiol valerate | 16F09-B01-329621 | 1 |
| Fagron | Estradiol valerate | 16F09-B01-332756 | 5 |
| Fagron | Estradiol valerate | 16F09-B01-332757 | 2 |
| Fagron | Estradiol valerate | 16F09Bo1328135 | 1 |
| Fagron | Estradiol valerate | 18067405 | 1 |
| Fagron | Estradiol valerate | 18g05-b02 | 1 |
| Fagron | Estradiol valerate | 18G05-B02 | 2 |
| Fagron | Estradiol valerate | 18G05-B02-353985 | 13 |
| Fagron | Estradiol valerate | 18G05-B02353986 | 1 |
| Fagron | Estradiol valerate | 18G05-B02-353986 | 3 |
| Fagron | Estradiol valerate | 18G5-B02-253985 | 1 |
| Fagron | Estradiol valerate | 190615001 | 1 |
| Fagron | Estradiol valerate | 19c10-b05-318405 | 1 |
| Fagron | Estradiol valerate | 20002389003 | 1 |
| Fagron | Estradiol valerate | 20J16-F01 | 2 |
| Fagron | Estradiol valerate | 20J16-F01-3760807 | 1 |
| Fagron | Estradiol valerate | 20J16F01376087 | 2 |
| Fagron | Estradiol valerate | 20J16-F01-376087 | 3 |
| Fagron | Estradiol valerate | 23A30-B05-224547 | 1 |
| Fagron | Estradiol valerate | 24052014a | 1 |
| Fagron | Estradiol valerate | 27061710 | 1 |
| Fagron | Estradiol valerate | 814M-03259 | 1 |
| Fagron | Estradiol valerate | 82201620 | 1 |
| Fagron | Estradiol valerate | 84404140 | 4 |
| Fagron | Estradiol valerate | ESV003-1A | 2 |
| Fagron | Estradiol valerate | ESVOO3-1A | 1 |
| Fagron | Estradiol valerate | F01-3751904 | 1 |
| Fagron | Estradiol valerate | VFM002-1C | 2 |
| Fargon / AHD | Estradiol valerate | 18G05-B02-353985 | 2 |
| fargon/Phoenix | Estradiol valerate | 16F09-B01-332756 | 2 |
| Fargon | Estradiol valerate | 10123264 | 1 |
| Frago/Gehe | Estradiol valerate | 15C10-B0508561040 | 1 |
| Frago/Noweda | Estradiol valerate | 16F09-B01 | 2 |
| Frago/Noweda | Estradiol valerate | 16F09-B01-329621 | 1 |
| Frago/Noweda | Estradiol valerate | 16F09-B01-332757 | 1 |
| Fragon | Estradiol valerate | 15C10-B05-5314840 | 1 |
| Gehe | Estradiol valerate | 14E26-B02-296348 | 1 |
| Gehe | Estradiol valerate | 14E26-B02-302872 | 1 |
| Gehe | Estradiol valerate | 16327703 | 1 |
| Gehe | Estradiol valerate | 16327712 | 1 |
| Gehe | Estradiol valerate | 16F09-B01-332756 | 1 |
| GEHE | Estradiol valerate | 16F09-B01-332757 | 1 |
| Gehe | Estradiol valerate | 190615001 | 1 |
| Gehe | Estradiol valerate | 22000384015 | 2 |
| Gehe | Estradiol valerate | 22000384020 | 1 |
| Hedinger/Noweda | Estradiol valerate | 15C10-B05 | 1 |
| L10 | Estradiol valerate | 24000954003 | 1 |
| Noweda | Estradiol valerate | 12A20-N10 | 1 |
| Noweda | Estradiol valerate | 19061506 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Estradiol valerate | 20002389003 | 2 |
| noweda | Estradiol valerate | 2200034007 | 1 |
| Noweda | Estradiol valerate | 22000384015 | 1 |
| Phoenix | Estradiol valerate | 13G09-N05 | 1 |
| Phoenix | Estradiol valerate | 20002389002 | 1 |
| Phoenix | Estradiol valerate | 20J16-F01-375194 | 1 |
| Phönix/Fargon | Estradiol valerate | 979-32-8 | 1 |
| Phönix | Estradiol valerate | 15C10-B05-326087 | 1 |
| phönix | Estradiol valerate | 20J16-F01 | 1 |
| Sanacorp | Estradiol valerate | 13264002 | 1 |
| Sanacorp | Estradiol valerate | 20J16-F01-375194 | 1 |
| Sanacorp | Estradiol valerate | 22000384005 | 1 |
| Sanacorp | Estradiol valerate | 22000384011 | 1 |
| Sanacorp | Estradiol valerate | 22000384015 | 1 |
| THC/Phönix | Estradiol valerate | 18067402 | 1 |

- 256 336 spectra from 1666 *Apo-Ident* customers from a total of 51 999 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Estradiol valerate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Estradiol valerate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 820 | 0 | 157 506 |
| **Type B** | 0 | 467 | 0 | 212 473 |
| **Type C** | 0 | 541 | 9 | 256 336 |

The substance/substance group *Estradiol valerate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.2683 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7152 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.3636 % (> 97.8182 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20651 | 21411 | 5.61 | 126.32 |
| 21266 | 21416 | 6.30 | 128.54 |
| 21411 | 21411 | 0.00 | 125.44 |
| 21416 | 21416 | 0.00 | 128.41 |
| 21417 | 21416 | 2.64 | 128.92 |
| 21418 | 21416 | 5.01 | 126.70 |
| 21419 | 21416 | 1.87 | 128.85 |
| 21422 | 21416 | 3.71 | 129.30 |
| 21423 | 21416 | 3.00 | 127.79 |
| 21424 | 21424 | 0.00 | 128.79 |
| 21425 | 21416 | 2.40 | 129.50 |
| 21426 | 21416 | 1.87 | 128.90 |
| 21646 | 21416 | 5.51 | 129.05 |
| 21989 | 21416 | 2.72 | 129.76 |
| 23056 | 23056 | 0.00 | 128.37 |
| 26741 | 21416 | 10.35 | 127.15 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Estriol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20878-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Estriol; Estriolum

### Special notes

When selecting the *Estriol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Estriol | 8 | 21 | 206 |

### Second-stage model

For differentiation of the substance/substance group *Estriol* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Estriol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 58.53 | – |
| ⋮ | ⋮ | ⋮ |
| Polymyxin B sulfate | >50 | 35.19 |
| Estradiol hemihydrate | >50 | 53.18 |
| Bacitracin | >50 | 53.32 |
| Riboflavin | >50 | 78.36 |
| Colistin sulfate | >50 | 78.93 |
| Amphotericin B | >50 | 82.68 |
| Cyanocobalamin | >50 | 118.26 |
| Triamcinolone | >50 | 132.60 |
| Nystatin | >50 | 141.60 |
| Calcium pantothenate | >50 | 145.01 |
| alpha-tocopheryl acetate dry concentrate | >50 | 167.31 |
| Calcium glycerophosphate | >50 | 171.98 |
| Tosylchloramide sodium | >50 | 208.87 |
| Hyoscine hydrobromide | >50 | 228.06 |
| Methylcobalamin | >50 | 228.37 |
| Gelatine, white | >50 | 258.48 |
| Carmellose sodium | >50 | 312.64 |
| SyrSpend® SF Alka | >50 | 381.62 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 395.88 |
| Oxalic acid | >50 | 411.03 |
| Rice starch | >50 | 537.08 |
| Corn starch | >50 | 595.94 |
| Acacia, dried dispersion | >50 | 619.87 |
| Wheat starch | >50 | 623.02 |
| Maltodextrin | >50 | 818.83 |
| SyrSpend® SF pH4 | >50 | 858.98 |
| Potato starch | >50 | 868.50 |
| Fructose | >50 | 1013.07 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Estriol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Estriol*:


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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Estriol | 12298706 | 20878 | 40 | 20121106 |
| Caelo | Estriol | 13256001 | 21390 | 55 | 1511155 |
| Caelo | Estriol | 13256001 | 21390SI | 60 | 1511155 |
| Caelo | Estriol | 13256001 | 21391 | 60 | 20130821 |
| Caelo | Estriol | 13256001 | 21392 | 20 | 20130821 |
| Caelo | Estriol | 13256001 | 21393 | 60 | 20130821 |
| Caelo | Estriol | 13256001 | 21394 | 20 | 20130821 |
| Caelo | Estriol | 13256001 | 21395 | 20 | 20130821 |
| Caelo | Estriol | 13256001 | 21399 | 20 | 20130821 |
| Caelo | Estriol | 13256001 | 21400 | 20 | 20130821 |
| Caelo | Estriol | 13256001 | 21401 | 20 | 20130821 |
| Caelo | Estriol | 13256001 | 21404 | 20 | 20130821 |
| Euro OTC | Estriol | 1507026 | 21848 | 60 | 0000010671 |
| Euro OTC | Estriol | 1507026 | 21848SI | 60 | 0000010671 |
| Euro OTC | Estriol | 1509042 | 21939 | 60 | 20151009* |
| Euro OTC | Estriol | 1509042 | 21939SI | 60 | 20151009* |
| Euro OTC | Estriol | 1703044 | 23181 | 40 | 20170502* |
| Fagron | Estriol | 11J13-N07 | 21255 | 40 | 1412180 |
| Fagron | Estriol | 16D15-B03-322957 | 22889 | 40 | 20160711 |
| Fagron | Estriol | 16D15-B03-322957 | 22889SI | 40 | 20160711 |
| Fagron | Estriol | 16I19-B01-331468 | 23172 | 40 | 20170301 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 855 spectra of 21 reference samples from the substance/substance group *Estriol*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 471 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1937 spectra of 51 reference samples from the substance/substance group *Estriol*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- Among them are spectra of independent samples from 21 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Estriol | 161382 | 22633 | 40 |
| Caelo | Estriol | 2010002 | 25400 | 40 |
| Caelo | Estriol | 22003580 | 26715 | 39 |
| Caelo | Estriol | 24002295002 | 27653 | 40 |
| Euro OTC | Estriol | 1310002-01 | 21292 | 40 |
| Euro OTC | Estriol | 1606044 | 22711 | 40 |
| Euro OTC | Estriol | 1610035 | 22850 | 40 |
| Euro OTC | Estriol | 1710022 | 23731 | 40 |
| Euro OTC | Estriol | 1710030 | 23733 | 40 |
| Euro OTC | Estriol | 1803011 | 24073 | 40 |
| Euro OTC | Estriol | 1903035 | 24604 | 40 |
| Euro OTC | Estriol | 2002010 | 25107 | 40 |
| Euro OTC | Estriol | 2007001 | 25237 | 40 |
| Euro OTC | Estriol | 2103007 | 25610 | 40 |
| Euro OTC | Estriol | 2107006 | 25706 | 50 |
| Euro OTC | Estriol | 2111005 | 25884 | 50 |
| Euro OTC | Estriol | 2302018 | 26660 | 40 |
| Euro OTC | Estriol | 2312004 | 27158 | 39 |
| Euro OTC | Estriol | 2402025 | 27286 | 40 |
| Euro OTC | Estriol | 2502007 | 27615 | 40 |
| Fagron | Estriol | 22H12-B05-224456 | 26455 | 40 |
| Caelo | Estriol | 13256001 | 21391SI† | 60 |
| Caelo | Estriol | 13256001 | 21392SI† | 20 |
| Caelo | Estriol | 13256001 | 21394SI† | 20 |
| Caelo | Estriol | 13256001 | 21395SI† | 20 |
| Caelo | Estriol | 13256001 | 21399SI† | 20 |
| Caelo | Estriol | 13256001 | 21400SI† | 20 |
| Caelo | Estriol | 13256001 | 21401SI† | 20 |
| Caelo | Estriol | 13256001 | 21404SI† | 20 |
| Caelo | Estriol | 161382 | 22633SI | 40 |
| Caelo | Estriol | 2010002 | 25400SI | 40 |
| Caelo | Estriol | 22003580 | 26715SI | 40 |
| Caelo | Estriol | 24002295002 | 27653SI | 40 |
| Euro OTC | Estriol | 1606044 | 22711SI | 40 |
| Euro OTC | Estriol | 1610035 | 22850SI | 40 |
| Euro OTC | Estriol | 1703044 | 23181SI† | 40 |
| Euro OTC | Estriol | 1710022 | 23731SI | 40 |
| Euro OTC | Estriol | 1710030 | 23733SI | 40 |
| Euro OTC | Estriol | 1803011 | 24073SI | 40 |
| Euro OTC | Estriol | 1903035 | 24604SI | 40 |
| Euro OTC | Estriol | 2002010 | 25107SI | 40 |
| Euro OTC | Estriol | 2007001 | 25237SI | 40 |
| Euro OTC | Estriol | 2103007 | 25610SI | 40 |
| Euro OTC | Estriol | 2107006 | 25706SI | 50 |
| Euro OTC | Estriol | 2111005 | 25884SI | 50 |
| Euro OTC | Estriol | 2302018 | 26660SI | 40 |
| Euro OTC | Estriol | 2312004 | 27158SI | 30 |
| Euro OTC | Estriol | 2402025 | 27286SI | 40 |
| Euro OTC | Estriol | 2502007 | 27615SI | 40 |
| Fagron | Estriol | 16I19-B01-331468 | 23172SI† | 30 |
| Fagron | Estriol | 22H12-B05-224456 | 26455SI | 39 |

- 211 003 spectra from a total of 4263 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 670 spectra from 324 *Apo-Ident* customers from 215 batches from the substance/substance group *Estriol*.
- Among them are spectra of independent samples from 196 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Estriol | 20G10-f06-372935 | 1 |
| | Estriol | 20G10-F06-372935 | 1 |
| | Estriol | 20G10-F06-372958 | 1 |
| | Estriol | 21002272024 | 1 |
| | Estriol | 210700601 | 1 |
| | Estriol | 2111005-01 | 2 |
| | Estriol | 22003580003 | 3 |
| | Estriol | 22003680002 | 1 |
| | Estriol | 22H12-B06-222366 | 3 |
| | Estriol | 22K19-B04-226402 | 2 |
| | Estriol | 23A30-B01-227260 | 1 |
| | Estriol | 23A30-B01-227261 | 1 |
| | Estriol | 23E15-B03-229441 | 2 |
| | Estriol | 23H03-B06-233745 | 1 |
| | Estriol | 23H03-B06-236102 | 1 |
| | Estriol | 24/10-B04-002960 | 1 |
| | Estriol | 240202025-01 | 1 |
| | Estriol | 2402025-01 | 4 |
| | Estriol | B06-2223606 | 1 |
| | Estriol | ESTZ01A011 | 1 |
| | Estriol | L00048288 | 1 |
| AHD | Estriol | 16I19-B01-331466 | 1 |
| Alliance Healthcare | Estriol | 20G10-F06-372958 | 1 |
| apomix | Estriol | 14077904 | 1 |
| Apotheke am Luisenho... | Estriol | 20000085004 | 2 |
| Audor Pharma | Estriol | | 16 |
| Audor Pharma | Estriol | 2002010-01 | 1 |
| Audor Pharma | Estriol | AP20780041010218E | 1 |
| Audor Pharma | Estriol | AP20780041020218E | 3 |
| Audor Pharma | Estriol | APL000036940E | 1 |
| Audor Pharma | Estriol | APL00036940E | 2 |
| Audor Pharma | Estriol | APL00037293 | 1 |
| Audor Pharma | Estriol | APL00037293E | 1 |
| Aufor/AHD | Estriol | | 1 |
| Bayer Pharma GmbH / ... | Estriol | 15297804 | 1 |
| Bombastus | Estriol | 5128 | 1 |
| Caelo | Estriol | 10053206 | 1 |
| Caelo | Estriol | 10H30-N06 | 1 |
| Caelo | Estriol | 11254402 | 1 |
| Caelo | Estriol | 11254410 | 1 |
| Caelo | Estriol | 11254412 | 1 |
| Caelo | Estriol | 12032503 | 4 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Estriol | 12032504 | 2 |
| Caelo | Estriol | 12032507 | 5 |
| Caelo | Estriol | 12298702 | 2 |
| Caelo | Estriol | 12298704 | 6 |
| Caelo | Estriol | 12298706 | 1 |
| Caelo | Estriol | 12298707 | 2 |
| Caelo | Estriol | 12H06N02 | 1 |
| Caelo | Estriol | 12H06-N02 | 1 |
| Caelo | Estriol | 13256001 | 1 |
| Caelo | Estriol | 13256004 | 9 |
| Caelo | Estriol | 14077901 | 1 |
| Caelo | Estriol | 14077903 | 2 |
| Caelo | Estriol | 14077904 | 10 |
| Caelo | Estriol | 1409018-01 | 1 |
| Caelo | Estriol | 14272101 | 3 |
| Caelo | Estriol | 14272104 | 5 |
| Caelo | Estriol | 1477904 | 1 |
| Caelo | Estriol | 14j20-b07 | 1 |
| Caelo | Estriol | 15008902 | 1 |
| Caelo | Estriol | 15028901 | 4 |
| Caelo | Estriol | 15028904 | 8 |
| Caelo | Estriol | 15028905 | 1 |
| Caelo | Estriol | 15297804 | 17 |
| Caelo | Estriol | 15297805 | 1 |
| Caelo | Estriol | 16/19-B01-331467 | 1 |
| Caelo | Estriol | 16053404 | 1 |
| Caelo | Estriol | 16053405 | 2 |
| Caelo | Estriol | 16053408 | 5 |
| Caelo | Estriol | 16053409 | 1 |
| Caelo | Estriol | 16138204 | 4 |
| Caelo | Estriol | 16317701 | 5 |
| Caelo | Estriol | 16317702 | 6 |
| Caelo | Estriol | 16317703 | 4 |
| Caelo | Estriol | 17042014B | 1 |
| Caelo | Estriol | 1710030-01 | 2 |
| Caelo | Estriol | 17133703 | 2 |
| Caelo | Estriol | 17133704 | 9 |
| Caelo | Estriol | 17133705 | 4 |
| Caelo | Estriol | 17133706 | 21 |
| Caelo | Estriol | 17133709 | 6 |
| Caelo | Estriol | 17133710 | 8 |
| Caelo | Estriol | 17133711 | 6 |
| Caelo | Estriol | 1713373 | 1 |
| Caelo | Estriol | 1733706 | 1 |
| Caelo | Estriol | 17348701 | 17 |
| Caelo | Estriol | 17348702 | 10 |
| Caelo | Estriol | 17348706 | 10 |
| Caelo | Estriol | 17348707 | 8 |
| Caelo | Estriol | 18041811 | 1 |
| Caelo | Estriol | 18247101 | 4 |
| Caelo | Estriol | 19035606 | 3 |
| Caelo | Estriol | 19035607 | 11 |
| Caelo | Estriol | 19035609 | 2 |
| Caelo | Estriol | 200000085004 | 1 |
| Caelo | Estriol | 20000085004 | 16 |
| Caelo | Estriol | 20000085005 | 1 |
| Caelo | Estriol | 20000085006 | 6 |
| Caelo | Estriol | 20G10-F06 | 1 |
| Caelo | Estriol | 20G10-F06-372934 | 1 |
| Caelo | Estriol | 20G10-F06-372958 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Estriol | 24031501 | 1 |
| Caelo | Estriol | 27061303 | 1 |
| Caelo | Estriol | 9071801 | 1 |
| Caelo | Estriol | L00047276 | 1 |
| Caesar & Loretz GmbH... | Estriol | 20000085004 | 1 |
| Caesar & Loretz GmbH... | Estriol | 20000085006 | 1 |
| Caesar & Loretz GmbH... | Estriol | 19035607 | 1 |
| Caesar & Loretz GmbH... | Estriol | 20000085006 | 1 |
| Caesar & Loretz GmbH... | Estriol | 20000085006 | 1 |
| Caesar & Loretz GmbH | Estriol | 15028901 | 1 |
| Caesar & Loretz GmbH | Estriol | 15028904 | 1 |
| Caesar & Loretz GmbH | Estriol | 17133704 | 1 |
| Caesar & Loretz GmbH | Estriol | 17348701 | 1 |
| Caesar & Loretz GmbH | Estriol | 19035607 | 1 |
| Caesar & Loretz GmbH | Estriol | 19035609 | 2 |
| Caesar & Loretz GmbH | Estriol | 20000085004 | 2 |
| Caesar & Loretz GmbH | Estriol | 20000085006 | 2 |
| Caesar & Loretz GmbH | Estriol | 21001836002 | 1 |
| Caesar § Lorenz GmbH | Estriol | 12298712 | 1 |
| Caesar&Loretz,AHC, 1... | Estriol | 15297804 | 1 |
| Cealo/ Sanacorp | Estriol | 17133706 | 2 |
| Cealo/GEHE | Estriol | 17348702 | 1 |
| Ensbona/ Sanacorp | Estriol | 16053405 | 1 |
| EuRho | Estriol | 1710030-01 | 1 |
| Euro OTC | Estriol | 1201020-01 | 1 |
| Euro OTC | Estriol | 1310002-01 | 1 |
| Euro OTC | Estriol | 1403011-01 | 2 |
| Euro OTC | Estriol | 1409018-01 | 1 |
| Euro OTC | Estriol | 15028904 | 1 |
| Euro OTC | Estriol | 1507026-01 | 1 |
| Euro OTC | Estriol | 1509042-01 | 3 |
| Euro OTC | Estriol | 1606044-01 | 14 |
| Euro OTC | Estriol | 1610035-01 | 5 |
| Euro OTC | Estriol | 1703044-01 | 1 |
| Euro OTC | Estriol | 170344-01 | 1 |
| Euro OTC | Estriol | 1710030-01 | 3 |
| Euro OTC | Estriol | 17133706 | 1 |
| Euro OTC | Estriol | 1803011-01 | 1 |
| Euro OTC | Estriol | 1903035-01 | 1 |
| Euro OTC | Estriol | 2002010-01 | 1 |
| Euro OTC | Estriol | 2007001-01 | 6 |
| Euro OTC | Estriol | 2010002-01 | 4 |
| Euro OTC | Estriol | 2010002-02 | 1 |
| Euro OTC | Estriol | 2010002-03 | 3 |
| Euro OTC | Estriol | 2103007-01 | 8 |
| Euro OTC | Estriol | 2107006-01 | 5 |
| Euro/Phönix | Estriol | 1509042-01 | 1 |
| Fagon/Gehe | Estriol | 24110-B04-005727 | 1 |
| Fagron | Estriol | | 2 |
| Fagron | Estriol | 11D13-N11 | 1 |
| Fagron | Estriol | 11J13-N07 | 3 |
| Fagron | Estriol | 12A26-N02 | 2 |
| Fagron | Estriol | 12F08-N06 | 1 |
| Fagron | Estriol | 12H06-N02 | 5 |
| Fagron | Estriol | 12H06-No2 | 2 |
| Fagron | Estriol | 12K07-N15 | 2 |
| Fagron | Estriol | 13C15-N04 | 4 |
| Fagron | Estriol | 13D19-N02 | 1 |
| Fagron | Estriol | 13H28-N01 | 4 |
| Fagron | Estriol | 14B06-B11-291563 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Estriol | 14b06b11291565 | 1 |
| Fagron | Estriol | 14B06-B11-291565 | 1 |
| Fagron | Estriol | 14B06-B11-294565 | 1 |
| Fagron | Estriol | 14E13-B01-294033 | 1 |
| Fagron | Estriol | 14E13-B01-294034 | 3 |
| Fagron | Estriol | 14H29-B02-298072 | 3 |
| Fagron | Estriol | 15297804 | 2 |
| Fagron | Estriol | 15A15-B07-312064 | 2 |
| Fagron | Estriol | 15A15-B07-314241 | 2 |
| Fagron | Estriol | 16/19-B01-332862 | 1 |
| Fagron | Estriol | 16/19-B01-336394 | 1 |
| Fagron | Estriol | 16/19-B01-340536 | 3 |
| Fagron | Estriol | 16/19-B01-3430535 | 1 |
| Fagron | Estriol | 16/19-B01-348555 | 1 |
| Fagron | Estriol | 16/19-B01-351346 | 3 |
| Fagron | Estriol | 1619B01351346 | 1 |
| Fagron | Estriol | 1629-b01-3363964 | 1 |
| Fagron | Estriol | 16D15-B03-323016 | 2 |
| Fagron | Estriol | 16D15-B03-323017 | 1 |
| Fagron | Estriol | 16I19-B01 | 2 |
| Fagron | Estriol | 16I19-B01-331466 | 1 |
| Fagron | Estriol | 16I19-B01-331467 | 1 |
| Fagron | Estriol | 16I19-B01-331468 | 1 |
| Fagron | Estriol | 16I19-B01-332862 | 1 |
| Fagron | Estriol | 16I19-B01-340535 | 2 |
| Fagron | Estriol | 16I19-B01-348555 | 1 |
| Fagron | Estriol | 16I19-B01-351346 | 1 |
| Fagron | Estriol | 16I9-B01 | 1 |
| Fagron | Estriol | 19C28-B01 | 1 |
| Fagron | Estriol | 19C28-B01-361787 | 3 |
| Fagron | Estriol | 19C28-B01-361788 | 1 |
| Fagron | Estriol | 20F16-F02 | 1 |
| Fagron | Estriol | 20F16-F02-372831 | 1 |
| Fagron | Estriol | 20f16-f02-372833 | 1 |
| Fagron | Estriol | 20G10-F06 | 7 |
| Fagron | Estriol | 20G10-F06-3729304 | 1 |
| Fagron | Estriol | 20G10-F06-372933 | 1 |
| Fagron | Estriol | 20g10-f06-372934 | 1 |
| Fagron | Estriol | 20g10-F06-372934 | 1 |
| Fagron | Estriol | 20G10-F06-372934 | 16 |
| Fagron | Estriol | 20G10-F06-372936 | 1 |
| Fagron | Estriol | 20G10-F06372958 | 1 |
| Fagron | Estriol | 20G10-F06-372958 | 29 |
| Fagron | Estriol | 20G10-F06-379234 | 1 |
| Fagron | Estriol | 20G10-FO6-372935 | 1 |
| Fagron | Estriol | 20G10-FO6-372958 | 1 |
| Fagron | Estriol | 21B26-F01 | 1 |
| Fagron | Estriol | 21B26-F01-378475 | 1 |
| Fagron | Estriol | 21B26-F01-379597 | 1 |
| Fagron | Estriol | 21B26-F01-380778 | 1 |
| Fagron | Estriol | 22A10-F03-381434 | 2 |
| Fagron | Estriol | 22A10-F03-381730 | 1 |
| Fagron | Estriol | 22H12-B05-224456 | 1 |
| Fagron | Estriol | 22H12-B06 | 1 |
| Fagron | Estriol | 22H12-B06-222365 | 3 |
| Fagron | Estriol | 22H12-B06-222366 | 1 |
| Fagron | Estriol | 22H12-BO6-222366 | 1 |
| Fagron | Estriol | 23A30-B01-227262 | 1 |
| Fagron | Estriol | 23H03-B06-233745 | 1 |
| Fagron | Estriol | 24I10-B04-002952 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Estriol | 20G10-F06-372934 | 1 |
| Fagron | Estriol | 20G10-F06-372934 | 1 |
| Fagron | Estriol | 700194-0001 | 1 |
| Fagron | Estriol | 81100490 | 1 |
| Fagron | Estriol | 86200800 | 3 |
| Fagron | Estriol | F02-3728302 | 1 |
| Fagron | Estriol | F06_3729508 | 1 |
| Fagron | Estriol | F06-3729303 | 1 |
| Fagron | Estriol | F06-3729304 | 3 |
| Fagron | Estriol | F06-372933 | 1 |
| Fagron | Estriol | F06-3729508 | 3 |
| Fagron | Estriol | L00047276 | 11 |
| fargon | Estriol | 12a26-n02 | 1 |
| Fargron/ Gehe | Estriol | 20000085004 | 2 |
| Fiebig | Estriol | 17133711 | 2 |
| Fiebig | Estriol | 22K19-B04-226402 | 1 |
| Gehe 30.12.14 | Estriol | 14B06-B11-291563 | 1 |
| Gehe | Estriol | 16053405 | 1 |
| Gehe | Estriol | 17133706 | 1 |
| Gehe | Estriol | 17348701 | 2 |
| Geilenkirchen | Estriol | 17133706 | 1 |
| Geilenkirchen | Estriol | 17133710 | 1 |
| Geilenkirchen | Estriol | 17348701 | 1 |
| Haihang Industry | Estriol | 20130824 | 1 |
| Jenne | Estriol | F06-3729508 | 1 |
| Kehr | Estriol | 17133704 | 1 |
| Kehr | Estriol | 18247101 | 1 |
| Noweda 19.05.2015 | Estriol | 14272104 | 1 |
| Noweda | Estriol | 11J13-No7 | 1 |
| Noweda | Estriol | 12032504 | 1 |
| Noweda | Estriol | 16I19-B01 | 1 |
| Noweda | Estriol | 19C28-B01-361786 | 1 |
| Noweda | Estriol | 20G10-F06 | 1 |
| Noweda | Estriol | 20G10-F06-372933 | 2 |
| Noweda | Estriol | 2103007 | 1 |
| NWM CHina | Estriol | ES150304 | 1 |
| Phoenix | Estriol | 17348701 | 1 |
| Phoenix | Estriol | 20G10-F06-372958 | 1 |
| Phoenix | Estriol | 3032 | 1 |
| Phönix /euro | Estriol | 1803011-01 | 1 |
| Phönix | Estriol | 16/19-B01331467 | 1 |
| Phönix | Estriol | 23A30-B01-227261 | 1 |
| Sanacoro | Estriol | 22H12-B06-222366 | 3 |
| Sanacorp | Estriol | 13256004 | 1 |
| Sanacorp | Estriol | 16317701 | 1 |
| Sanacorp | Estriol | 16317702 | 1 |
| Sanacorp | Estriol | 19035606 | 1 |
| sanacorp | Estriol | 2103007-01 | 1 |
| Sanacorp | Estriol | 2111005-01 | 1 |
| Sanacorp | Estriol | 23A30-B01-227261 | 1 |
| Sanacorp | Estriol | 23E15-B03-229441 | 1 |
| Shandong Northwest M... | Estriol | ETL160302 | 1 |
| Shandong Northwest M... | Estriol | ETL160419 | 1 |
| VDL | Estriol | 13256004 | 1 |

- 256 216 spectra from 1666 *Apo-Ident* customers from a total of 51 941 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Estriol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Estriol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 855 | 0 | 157 471 |
| **Type B** | 0 | 1937 | 0 | 211 003 |
| **Type C** | 0 | 662 | 8 | 256 216 |

The substance/substance group *Estriol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.2982 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6902 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8060 % (> 98.3582 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20878 | 21255 | 5.86 | 174.23 |
| 21255 | 21255 | 0.00 | 173.05 |
| 21390 | 21390 | 0.00 | 196.42 |
| 21391 | 21390 | 4.99 | 197.57 |
| 21392 | 21939 | 5.35 | 189.37 |
| 21393 | 21848 | 5.67 | 196.11 |
| 21394 | 21939 | 4.82 | 187.75 |
| 21395 | 21848 | 2.43 | 198.91 |
| 21399 | 21939 | 2.91 | 169.86 |
| 21400 | 21939 | 4.61 | 173.68 |
| 21401 | 21390 | 3.56 | 199.65 |
| 21404 | 21939 | 3.20 | 163.29 |
| 21848 | 21848 | 0.00 | 198.97 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21939 | 21939 | 0.00 | 173.10 |
| 22889 | 23181 | 3.08 | 145.72 |
| 23172 | 21939 | 3.79 | 154.73 |
| 23181 | 23181 | 0.00 | 148.25 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ethacridine lactate monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20750-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ethacridine lactate monohydrate; Ethacridini lactas monohydricus

### Special notes

When selecting the *Ethacridine lactate monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ethacridine lactate monohydrate | 7 | 5 | 94 |

### Second-stage model

For differentiation of the substance/substance group *Ethacridine lactate monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ethacridine lactate monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 76.91 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ethacridine lactate monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ethacridine lactate monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ethacridine lactate monoh… | 12149507 | 20750 | 40 | 20120619 |
| Caelo | Ethacridine lactate monoh… | 16273403 | 23247 | 40 | 20161122 |
| Caelo | Ethacridine lactate monoh… | 22001737 | 26357 | 40 | 20220819* |
| Euro OTC | Ethacridine lactate monoh… | 1206016-02 | 21636 | 60 | 20121019 |
| Euro OTC | Ethacridine lactate monoh… | 1412034-02 | 22733 | 40 | 20150223 |
| Fagron | Ethacridine lactate monoh… | 13I24-N03 | 21265 | 40 | AR-15-FG-007011-02 |
| Fagron | Ethacridine lactate monoh… | 15A29-B02-306219 | 22500 | 40 | 20150205 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 7 reference samples from the substance/substance group *Ethacridine lactate monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 026 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 280 spectra of 9 reference samples from the substance/substance group *Ethacridine lactate monohydrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ethacridine lactate monoh… | 172476 | 23671 | 40 |
| Caelo | Ethacridine lactate monoh… | 183146 | 24355 | 40 |
| Caelo | Ethacridine lactate monoh… | 20001048 | 25203 | 40 |
| Caelo | Ethacridine lactate monoh… | 21001424012 | 25925 | 40 |
| Fagron | Ethacridine lactate monoh… | 21C17-B01-215098 | 26065 | 40 |
| Caelo | Ethacridine lactate monoh… | 172476 | 23798 | 40 |
| Caelo | Ethacridine lactate monoh… | 21001424012 | 25925SI | 10 |
| Caelo | Ethacridine lactate monoh… | 22001737 | 26357SI† | 20 |
| Fagron | Ethacridine lactate monoh… | 21C17-B01-215098 | 26065SI | 10 |

- 212 660 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 477 spectra from 288 *Apo-Ident* customers from 101 batches from the substance/substance group *Ethacridine lactate monohydrate*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 94 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ethacridine lactate monoh... | 22001737005 | 2 |
| | Ethacridine lactate monoh... | 22001737011 | 3 |
| | Ethacridine lactate monoh... | 22001737016 | 1 |
| AHD | Ethacridine lactate monoh... | 22001737016 | 1 |
| AHL | Ethacridine lactate monoh... | 141101 | 1 |
| Alliance Healthcare | Ethacridine lactate monoh... | 141234-04 | 1 |
| Anzag | Ethacridine lactate monoh... | 111201 | 1 |
| Anzag | Ethacridine lactate monoh... | 18314601 | 1 |
| Bombastus | Ethacridine lactate monoh... | 13/24-N03 | 1 |
| Bombastus | Ethacridine lactate monoh... | 14A15-B04-300493 | 1 |
| cae | Ethacridine lactate monoh... | 16272410 | 1 |
| cae | Ethacridine lactate monoh... | 20004177003 | 1 |
| Caelo | Ethacridine lactate monoh... | 10288702 | 1 |
| Caelo | Ethacridine lactate monoh... | 11J07-N05 | 1 |
| Caelo | Ethacridine lactate monoh... | 1206016-03 | 1 |
| Caelo | Ethacridine lactate monoh... | 12149507 | 3 |
| Caelo | Ethacridine lactate monoh... | 12268407 | 3 |
| Caelo | Ethacridine lactate monoh... | 12G02-N13 | 2 |
| Caelo | Ethacridine lactate monoh... | 13/24-N03 | 1 |
| Caelo | Ethacridine lactate monoh... | 141203401 | 1 |
| Caelo | Ethacridine lactate monoh... | 1412034-01 | 1 |
| Caelo | Ethacridine lactate monoh... | 1412034-02 | 1 |
| Caelo | Ethacridine lactate monoh... | 1412034-03 | 2 |
| Caelo | Ethacridine lactate monoh... | 141203404 | 1 |
| Caelo | Ethacridine lactate monoh... | 1412034-04 | 2 |
| Caelo | Ethacridine lactate monoh... | 15/214/R | 1 |
| Caelo | Ethacridine lactate monoh... | 15177603 | 4 |
| Caelo | Ethacridine lactate monoh... | 15177608 | 2 |
| Caelo | Ethacridine lactate monoh... | 15177612 | 1 |
| Caelo | Ethacridine lactate monoh... | 15438003 | 6 |
| Caelo | Ethacridine lactate monoh... | 15438007 | 4 |
| Caelo | Ethacridine lactate monoh... | 15438009 | 2 |
| Caelo | Ethacridine lactate monoh... | 16272401 | 1 |
| Caelo | Ethacridine lactate monoh... | 16272406 | 1 |
| Caelo | Ethacridine lactate monoh... | 16272408 | 3 |
| Caelo | Ethacridine lactate monoh... | 16272410 | 3 |
| Caelo | Ethacridine lactate monoh... | 16272412 | 1 |
| Caelo | Ethacridine lactate monoh... | 16272413 | 1 |
| Caelo | Ethacridine lactate monoh... | 162734 | 1 |
| Caelo | Ethacridine lactate monoh... | 16273403 | 8 |
| Caelo | Ethacridine lactate monoh... | 16273411 | 9 |
| Caelo | Ethacridine lactate monoh... | 1627412 | 1 |
| Caelo | Ethacridine lactate monoh... | 17247605 | 14 |
| Caelo | Ethacridine lactate monoh... | 17247606 | 1 |
| Caelo | Ethacridine lactate monoh... | 17332303 | 4 |
| Caelo | Ethacridine lactate monoh... | 17332304 | 16 |
| Caelo | Ethacridine lactate monoh... | 17332312 | 4 |
| Caelo | Ethacridine lactate monoh... | 17332314 | 12 |
| Caelo | Ethacridine lactate monoh... | 17332316 | 6 |
| Caelo | Ethacridine lactate monoh... | 1814607 | 1 |
| Caelo | Ethacridine lactate monoh... | 183146004 | 4 |
| Caelo | Ethacridine lactate monoh... | 183146005 | 6 |
| Caelo | Ethacridine lactate monoh... | 18314601 | 9 |
| Caelo | Ethacridine lactate monoh... | 18314603 | 1 |
| Caelo | Ethacridine lactate monoh... | 18314605 | 1 |
| Caelo | Ethacridine lactate monoh... | 18314607 | 28 |
| Caelo | Ethacridine lactate monoh... | 18314608 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ethacridine lactate monoh… | 20001048002 | 9 |
| Caelo | Ethacridine lactate monoh… | 20001048004 | 1 |
| Caelo | Ethacridine lactate monoh… | 20004177003 | 10 |
| Caelo | Ethacridine lactate monoh… | 21001424004 | 16 |
| Caelo | Ethacridine lactate monoh… | 21001424012 | 2 |
| Caelo | Ethacridine lactate monoh… | 21001424013 | 1 |
| Caelo | Ethacridine lactate monoh… | 21001424014 | 9 |
| Caelo | Ethacridine lactate monoh… | 22001737003 | 11 |
| Caelo | Ethacridine lactate monoh… | 22001737005 | 3 |
| Caelo | Ethacridine lactate monoh… | 22001737008 | 1 |
| Caelo | Ethacridine lactate monoh… | 22001737011 | 1 |
| Caelo | Ethacridine lactate monoh… | 22001737013 | 1 |
| Caelo | Ethacridine lactate monoh… | 22001737016 | 1 |
| Caelo | Ethacridine lactate monoh… | 2201737003 | 1 |
| Caelo | Ethacridine lactate monoh… | 7247805 | 1 |
| Caesar & Lorenz GmbH | Ethacridine lactate monoh… | 18314601 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 18314601 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 17332304 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 17332314 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 18314601 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 20004177003 | 1 |
| Caesar & Loretz GmbH/AHD | Ethacridine lactate monoh… | 20001048002 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 22001737003 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 17332316 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 20001048002 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 18314607 | 1 |
| Caesar & Loretz GmbH/Kehr | Ethacridine lactate monoh… | 21001424004 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 22001737003 | 1 |
| Caesar & Loretz GmbH… | Ethacridine lactate monoh… | 20001048 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 17332314 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 183146002 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 183146005 | 3 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 18314601 | 3 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 18314607 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 20001048002 | 4 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 20001048003 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 20001048006 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 20004177003 | 2 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 21001424004 | 2 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 21001424012 | 2 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 21001424013 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 22001737005 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | 22001737008 | 1 |
| Caesar & Loretz GmbH | Ethacridine lactate monoh… | caelo | 1 |
| Caesar & Loretz/Gehe | Ethacridine lactate monoh… | 20001048002 | 1 |
| Caleo/ Noweda | Ethacridine lactate monoh… | 17332312 | 1 |
| Cealo/Sanacorp | Ethacridine lactate monoh… | 21001424013 | 1 |
| Chinosol/Anzag | Ethacridine lactate monoh… | 2112A-02196 | 1 |
| Chinosol/Anzag | Ethacridine lactate monoh… | 914E-02196 | 1 |
| Dermapharm | Ethacridine lactate monoh… | 100201 | 1 |
| Dermapharm | Ethacridine lactate monoh… | 111201 | 5 |
| Dermapharm | Ethacridine lactate monoh… | 130201 | 8 |
| Dermapharm | Ethacridine lactate monoh… | 141101 | 11 |
| Dermopharm | Ethacridine lactate monoh… | 130201 | 1 |
| Dermopharm | Ethacridine lactate monoh… | 141101 | 1 |
| E Plus | Ethacridine lactate monoh… | 17332314 | 1 |
| E+J, 28.09.2016 | Ethacridine lactate monoh… | 141101 | 2 |
| Ebert & Jacobi | Ethacridine lactate monoh… | 15177608 | 1 |
| Euro OTC | Ethacridine lactate monoh… | 1206016-02 | 4 |
| Euro OTC | Ethacridine lactate monoh… | 1206016-03 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Ethacridine lactate monoh… | 13/24-N03 | 1 |
| Euro OTC | Ethacridine lactate monoh… | 1412034-01 | 5 |
| Euro OTC | Ethacridine lactate monoh… | 1412034-02 | 2 |
| Euro OTC | Ethacridine lactate monoh… | 1412034-03 | 13 |
| Euro OTC | Ethacridine lactate monoh… | 141203404 | 2 |
| Euro OTC | Ethacridine lactate monoh… | 1412034-04 | 4 |
| Euro OTC | Ethacridine lactate monoh… | 15438007 | 1 |
| Euro OTC | Ethacridine lactate monoh… | 17332304 | 2 |
| Euro OTC | Ethacridine lactate monoh… | 1807013-01 | 9 |
| Euro OTC | Ethacridine lactate monoh… | 1807013-02 | 5 |
| Euro OTC | Ethacridine lactate monoh… | 20001048002 | 1 |
| Euro OTC | Ethacridine lactate monoh… | 2905007-01 | 1 |
| Euro OTC | Ethacridine lactate monoh… | 2905007v-03 | 1 |
| Euro OTC | Ethacridine lactate monoh… | 2905007V-03 | 1 |
| Euro OTC | Ethacridine lactate monoh… | A201801002 | 1 |
| Fagron | Ethacridine lactate monoh… | 11/07-N05 | 1 |
| Fagron | Ethacridine lactate monoh… | 12/24-N04 | 2 |
| Fagron | Ethacridine lactate monoh… | 12324N03 | 1 |
| Fagron | Ethacridine lactate monoh… | 12A02-N10 | 1 |
| Fagron | Ethacridine lactate monoh… | 12C30-N07 | 1 |
| Fagron | Ethacridine lactate monoh… | 12G02-N13 | 5 |
| Fagron | Ethacridine lactate monoh… | 12G02-N135-15 | 1 |
| Fagron | Ethacridine lactate monoh… | 12J24-N04 | 1 |
| Fagron | Ethacridine lactate monoh… | 13/24-N03 | 5 |
| Fagron | Ethacridine lactate monoh… | 13/24-NO3 | 1 |
| Fagron | Ethacridine lactate monoh… | 13I24-N03 | 7 |
| Fagron | Ethacridine lactate monoh… | 13l24-N03 | 1 |
| Fagron | Ethacridine lactate monoh… | 1412034-04 | 1 |
| Fagron | Ethacridine lactate monoh… | 14A15-B04 | 2 |
| Fagron | Ethacridine lactate monoh… | 14A15-B04-300493 | 6 |
| Fagron | Ethacridine lactate monoh… | 16273411 | 1 |
| Fagron | Ethacridine lactate monoh… | 16e20-b11-322514 | 1 |
| Fagron | Ethacridine lactate monoh… | 16E20-B11-322514 | 5 |
| Fagron | Ethacridine lactate monoh… | 16E20-B11-326633 | 1 |
| Fagron | Ethacridine lactate monoh… | 16E20-B11-328430 | 1 |
| Fagron | Ethacridine lactate monoh… | 201205001 | 2 |
| Finze | Ethacridine lactate monoh… | 90601 | 1 |
| Gehe amax | Ethacridine lactate monoh… | 18314607 | 1 |
| Gehe | Ethacridine lactate monoh… | 13I24-N03 | 1 |
| Gehe | Ethacridine lactate monoh… | 141101 | 1 |
| Gehe | Ethacridine lactate monoh… | 1412034-03 | 1 |
| Gehe | Ethacridine lactate monoh… | 17247605 | 2 |
| Gehe | Ethacridine lactate monoh… | 21001424014 | 1 |
| Gehe | Ethacridine lactate monoh… | 22001737008 | 1 |
| Kehr | Ethacridine lactate monoh… | 22001737014 | 1 |
| Kehr | Ethacridine lactate monoh… | 22001737016 | 1 |
| Liaoyuang Silver Eag… | Ethacridine lactate monoh… | 1412034-02 | 1 |
| Noweda | Ethacridine lactate monoh… | 183146005 | 1 |
| Noweda | Ethacridine lactate monoh… | 18314601 | 1 |
| Noweda | Ethacridine lactate monoh… | 18314607 | 2 |
| Noweda | Ethacridine lactate monoh… | 20001048002 | 2 |
| Noweda | Ethacridine lactate monoh… | 22001737011 | 4 |
| Noweda | Ethacridine lactate monoh… | 3785846 | 1 |
| phoenix 18.11.2014 | Ethacridine lactate monoh… | 13/24-N03 | 1 |
| Phoenix | Ethacridine lactate monoh… | 100201 | 1 |
| Phoenix | Ethacridine lactate monoh… | 1412034-03 | 1 |
| Phoenix | Ethacridine lactate monoh… | 22001737016 | 1 |
| Phönix | Ethacridine lactate monoh… | 111201 | 1 |
| Phonix | Ethacridine lactate monoh… | 13I24-N03 | 1 |
| Phönix | Ethacridine lactate monoh… | 20001048002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Ethacridine lactate monoh… | 22001737016 | 1 |
| Rezepturlager - Verl… | Ethacridine lactate monoh… | 121/15 | 1 |
| Rezepturlager - Verl… | Ethacridine lactate monoh… | 220/17 | 1 |
| Sanacorp HST | Ethacridine lactate monoh… | 17247605 | 1 |
| Sanacorp/EuRho | Ethacridine lactate monoh… | 1412034-03 | 1 |
| Sanacorp | Ethacridine lactate monoh… | 22001737005 | 1 |

- 256 409 spectra from 1666 *Apo-Ident* customers from a total of 52 054 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ethacridine lactate monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ethacridine lactate monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 280 | 0 | 212 660 |
| **Type C** | 0 | 471 | 6 | 256 409 |

The substance/substance group *Ethacridine lactate monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.8571 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.7421 % (> 98.1132 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20750 | 21265 | 6.12 | 150.35 |
| 21265 | 21265 | 0.00 | 148.62 |
| 21636 | 21265 | 8.40 | 152.00 |
| 22500 | 21265 | 11.29 | 149.75 |
| 22733 | 21265 | 12.89 | 148.63 |
| 23247 | 21265 | 11.98 | 150.28 |
| 26357 | 26357 | 0.00 | 159.73 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ethinylestradiol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20950-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ethinylestradiol; Ethinylestradiolum

### Special notes

When selecting the *Ethinylestradiol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ethinylestradiol | 6 | 2 | 19 |

### Second-stage model

For differentiation of the substance/substance group *Ethinylestradiol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ethinylestradiol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 109.29 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ethinylestradiol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ethinylestradiol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ethinylestradiol | 13I09-N04 | 20950 | 40 | 1402058 |
| Fagron | Ethinylestradiol | 14E15-B03-296049 | 21705 | 55 | 1507109 |
| Fagron | Ethinylestradiol | 14E15-B03-296049 | 21705SI | 56 | 1507109 |
| Fagron | Ethinylestradiol | 14E15-B03-310270 | 21916 | 60 | 20140708 |
| Fagron | Ethinylestradiol | 14E15-B03-310270 | 21916SI | 60 | 20140708 |
| Fagron | Ethinylestradiol | 14E15-B03-310270 | 21958 | 60 | 20140708 |
| Fagron | Ethinylestradiol | 18E25-B01-355721 | 24584 | 40 | 20180810 |
| Fagron | Ethinylestradiol | 19J11-F01-367137 | 25045 | 40 | 2007191 |
| Fagron | Ethinylestradiol | 22A18-F02-382202 | 26327 | 40 | 20220429 |
| Fagron | Ethinylestradiol | 22A18-F02-382202 | 26327SI | 40 | 20220429 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 491 spectra of 10 reference samples from the substance/substance group *Ethinylestradiol*. These samples are listed above in the *calibration samples* section. The reference samples come from 6


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different batches.

- 157 835 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 312 spectra of 7 reference samples from the substance/substance group *Ethinylestradiol*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Ethinylestradiol | 16B17-B01-329904 | 23075 | 40 |
| Fagron | Ethinylestradiol | 23E16-B04-234620 | 27053 | 40 |
| Fagron | Ethinylestradiol | 14E15-B03-310270 | 21958SI† | 43 |
| Fagron | Ethinylestradiol | 16B17-B01-329904 | 23075SI | 30 |
| Fagron | Ethinylestradiol | 18E25-B01-355721 | 24584SI† | 40 |
| Fagron | Ethinylestradiol | 19J11-F01-367137 | 25045SI† | 40 |
| Fagron | Ethinylestradiol | 23E16-B04-234620 | 27053SI | 79 |

- 212 628 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 36 spectra from 28 *Apo-Ident* customers from 23 batches from the substance/substance group *Ethinylestradiol*.

- Among them are spectra of independent samples from 19 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ethinylestradiol | 18E25-B01-0001 | 1 |
| Fagron | Ethinylestradiol | 12D19-N04 | 1 |
| Fagron | Ethinylestradiol | 1367138 | 2 |
| Fagron | Ethinylestradiol | 13G03-N04 | 1 |
| Fagron | Ethinylestradiol | 13I09-N04 | 1 |
| Fagron | Ethinylestradiol | 14e15b03296049 | 1 |
| Fagron | Ethinylestradiol | 16B17-B01 | 1 |
| Fagron | Ethinylestradiol | 16B17-B01-320666 | 1 |
| Fagron | Ethinylestradiol | 16B17-B01-333326 | 1 |
| Fagron | Ethinylestradiol | 18E25-B01 | 2 |
| Fagron | Ethinylestradiol | 18E25-B01-351832 | 2 |
| Fagron | Ethinylestradiol | 18E25-B01-352721 | 1 |
| Fagron | Ethinylestradiol | 18E25-B01-353920 | 3 |
| Fagron | Ethinylestradiol | 18E25-B01-355721 | 4 |
| Fagron | Ethinylestradiol | 19J11-F01-367137 | 1 |
| Fagron | Ethinylestradiol | 19J11-F01-367138 | 5 |
| Fagron | Ethinylestradiol | 19J11-F01-373282 | 2 |
| Fagron | Ethinylestradiol | 22A18-F02-382202 | 1 |
| Fagron | Ethinylestradiol | 22A18-FO2-382202 | 1 |
| Fagron | Ethinylestradiol | 84100720 | 1 |
| Fagron | Ethinylestradiol | 8561175 | 1 |
| Fagron | Ethinylestradiol | F01-3671308 | 1 |
| Fagron | Ethinylestradiol | UN803HA | 1 |

- 256 850 spectra from 1666 *Apo-Ident* customers from a total of 52 130 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ethinylestradiol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ethinylestradiol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 491 | 0 | 157 835 |
| **Type B** | 0 | 312 | 0 | 212 628 |
| **Type C** | 0 | 36 | 0 | 256 850 |

The substance/substance group *Ethinylestradiol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7780 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0769 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 83.3333 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to


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exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20950 | 20950 | 0.00 | 173.46 |
| 21705 | 21705 | 0.00 | 209.10 |
| 21916 | 21705 | 9.62 | 190.63 |
| 21958 | 21705 | 8.59 | 193.84 |
| 24584 | 20950 | 40.10 | 160.23 |
| 25045 | 25045 | 0.00 | 217.11 |
| 26327 | 20950 | 30.23 | 170.96 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ethosuximide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24100-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ethosuximide; Ethosuximidum

### Special notes

When selecting the *Ethosuximide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ethosuximide | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Ethosuximide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ethosuximide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 73.46 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ethosuximide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ethosuximide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Katwijk Ch... | Ethosuximide | 451717 | 24100 | 40 | 20180509 |
| Katwijk Ch... | Ethosuximide | 451645 | 24101 | 40 | 1807457 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 80 spectra of 2 reference samples from the substance/substance group *Ethosuximide*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

- 158 246 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *Ethosuximide*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Katwijk Chemie BV | Ethosuximide | 451644 | 24102 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Ethosuximide*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ethosuximide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ethosuximide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 80 | 0 | 158 246 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Ethosuximide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 92.5000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24100 | 24101 | 31.71 | 118.35 |
| 24101 | 24101 | 0.00 | 120.17 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Fampridine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20902-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Fampridine; Fampridinum

### Special notes

When selecting the *Fampridine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Fampridine | 9 | 5 | 48 |

### Second-stage model

For differentiation of the substance/substance group *Fampridine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Fampridine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 153.69 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Fampridine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Fampridine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Fampridine | 16276001 | 22881 | 40 | 20161024 |
| Caelo | Fampridine | 16276001 | 22905 | 40 | 20161024 |
| Caelo | Fampridine | 16276001 | 23074 | 40 | 20161024 |
| Caelo | Fampridine | 16276001 | 23237 | 40 | 20161024 |
| Caelo | Fampridine | 190675 | 24724 | 40 | 20190506* |
| Caelo | Fampridine | 180219 | 24756 | 40 | 20180214* |
| Caelo | Fampridine | 180219 | 24756SI | 40 | 20180214* |
| Caelo | Fampridine | 20003524 | 25559 | 40 | 20201126* |
| Caelo | Fampridine | 20003524 | 25559SI | 40 | 20201126* |
| Fagron | Fampridine | 13G26-N06 | 20902 | 40 | 1402686 |
| Fagron | Fampridine | 14D11-B06-293750 | 21541 | 60 | 20140113 |
| Fagron | Fampridine | 16D11-B07-318220 | 22491 | 40 | AR-16-FG-011566-01 |
| Fagron | Fampridine | 16E25-B03-324097 | 22894 | 40 | 20160609 |
| Fagron | Fampridine | 16E25-B03-324097 | 22945 | 40 | 20160609 |
| Fagron | Fampridine | 17K20-B02-349165 | 24439 | 40 | 20180103 |
| Fagron | Fampridine | 17K20-B02-349165 | 24439SI | 40 | 20180103 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 660 spectra of 16 reference samples from the substance/substance group *Fampridine*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 666 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 440 spectra of 11 reference samples from the substance/substance group *Fampridine*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Fampridine | 172170 | 23653 | 40 |
| Caelo | Fampridine | 19000755 | 25197 | 40 |
| Caelo | Fampridine | 22001045 | 26119 | 40 |
| Fagron | Fampridine | 19G24-B02-363769 | 24823 | 40 |
| Fagron | Fampridine | 22I21-B07-223809 | 26385 | 40 |
| Caelo | Fampridine | 190675 | 24724SI† | 40 |
| Caelo | Fampridine | 19000755 | 25197SI | 40 |
| Caelo | Fampridine | 22001045 | 26119SI | 40 |
| Fagron | Fampridine | 16E25-B03-324097 | 22894SI† | 40 |
| Fagron | Fampridine | 19G24-B02-363769 | 24823SI | 40 |
| Fagron | Fampridine | 22I21-B07-223809 | 26385SI | 40 |

- 212 500 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 85 spectra from 25 *Apo-Ident* customers from 50 batches from the substance/substance group *Fampridine*.
- Among them are spectra of independent samples from 48 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Fampridine | 22K17-B03-228705 | 3 |
| | Fampridine | 24H29-B08-008257 | 1 |
| | Fampridine | 353033 | 1 |
| Caelo | Fampridine | 15350001 | 1 |
| Caelo | Fampridine | 15350002 | 1 |
| Caelo | Fampridine | 16276001 | 1 |
| Caelo | Fampridine | 16276002 | 3 |
| Caelo | Fampridine | 17217002 | 1 |
| Caelo | Fampridine | 17217003 | 2 |
| Caelo | Fampridine | 17217004 | 1 |
| Caelo | Fampridine | 17217005 | 1 |
| Caelo | Fampridine | 18021901 | 1 |
| Caelo | Fampridine | 18021903 | 2 |
| Caelo | Fampridine | 18021907 | 3 |
| Caelo | Fampridine | 19000755005 | 2 |
| Caelo | Fampridine | 19000755007 | 1 |
| Caelo | Fampridine | 19067501 | 1 |
| Caelo | Fampridine | 19067504 | 1 |
| Caelo | Fampridine | 24111801 | 1 |
| Caesar & Loretz GmbH/Gehe | Fampridine | 22001045001 | 2 |
| Fagron | Fampridine | 13C07-B02-289395 | 1 |
| Fagron | Fampridine | 14D11-B06-296110 | 1 |
| Fagron | Fampridine | 14D11-B40-301641 | 1 |
| Fagron | Fampridine | 14D11-B40-304961 | 1 |
| Fagron | Fampridine | 16/19-Bo4-330727 | 1 |
| Fagron | Fampridine | 16D11-B07 | 1 |
| Fagron | Fampridine | 17/19-B01 | 2 |
| Fagron | Fampridine | 17/19-B01-339467 | 1 |
| Fagron | Fampridine | 17D19-B01-333745 | 1 |
| Fagron | Fampridine | 17K20_B02_344609 | 1 |
| Fagron | Fampridine | 17K20-B02 | 4 |
| Fagron | Fampridine | 17K20-B02-344609 | 2 |
| Fagron | Fampridine | 17K20-B02-349165 | 1 |
| Fagron | Fampridine | 17K20-B02-349165/0000254876 | 1 |
| Fagron | Fampridine | 18121801 | 1 |
| Fagron | Fampridine | 18H01-B08 | 1 |
| Fagron | Fampridine | 19G24-B02 | 4 |
| Fagron | Fampridine | 19G24-B02-363768 | 5 |
| Fagron | Fampridine | 19g24-b02-363769 | 1 |
| Fagron | Fampridine | 19G24-B02-363770 | 9 |
| Fagron | Fampridine | 20D06-F07-370084 | 2 |
| Fagron | Fampridine | 20D06-F07-370086 | 2 |
| Fagron | Fampridine | 22C25-B07-215458 | 1 |
| Fagron | Fampridine | 22C25-B07-215459 | 3 |
| Fagron | Fampridine | 22k17-b03-226121 | 1 |
| Fagron | Fampridine | 22121-B07-223809 | 1 |
| Fagron | Fampridine | 254876 | 1 |
| Inresa | Fampridine | 220825 | 1 |
| Inresa | Fampridine | 236761 | 1 |
| Noweda | Fampridine | 17K20-B02-349165 | 1 |
| PHÖNIX | Fampridine | 20210217-2 | 1 |


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- 256 801 spectra from 1666 *Apo-Ident* customers from a total of 52 103 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Fampridine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Fampridine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 660 | 0 | 157 666 |
| **Type B** | 0 | 440 | 0 | 212 500 |
| **Type C** | 0 | 84 | 1 | 256 801 |

The substance/substance group *Fampridine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0909 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6364 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8235 % (> 95.2941 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20902 | 20902 | 0.00 | 267.07 |
| 21541 | 20902 | 7.36 | 269.47 |
| 22491 | 22491 | 0.00 | 291.88 |
| 22881 | 20902 | 33.67 | 269.88 |
| 22894 | 22491 | 7.50 | 289.03 |
| 22905 | 20902 | 31.43 | 270.42 |
| 22945 | 22491 | 12.09 | 287.11 |
| 23074 | 20902 | 35.47 | 269.59 |

*continued on the next page*

*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23237 | 22491 | 36.42 | 270.19 |
| 24439 | 22491 | 7.87 | 292.10 |
| 24724 | 24724 | 0.00 | 264.79 |
| 24756 | 24756 | 0.00 | 265.66 |
| 25559 | 25559 | 0.00 | 254.15 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ferrous gluconate hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24166-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ferrous gluconate hydrate; Ferrosi gluconas hydricus

### Special notes

When selecting the *Ferrous gluconate hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ferrous gluconate hydrate | 4 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Ferrous gluconate hydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ferrous gluconate hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 66.78 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ferrous gluconate hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ferrous gluconate hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Ferrous gluconate hydrate | 2008035 | 25378 | 40 | 20201015* |
| Euro OTC | Ferrous gluconate hydrate | 2103004 | 25604 | 40 | 20210329* |
| Euro OTC | Ferrous gluconate hydrate | 2201008 | 26085 | 40 | 20220425* |
| Euro OTC | Ferrous gluconate hydrate | 2307024 | 26859 | 40 | 20230821* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 160 spectra of 4 reference samples from the substance/substance group *Ferrous gluconate hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 166 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Ferrous gluconate hydrate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Ferrous gluconate hydrate | 1805025 | 24166 | 40 |
| Euro OTC | Ferrous gluconate hydrate | 2201008 | 26085SI† | 20 |
| Euro OTC | Ferrous gluconate hydrate | 2307024 | 26859SI† | 20 |

- 212 860 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Ferrous gluconate hydrate*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

### Validation results

The validation runs checked whether the substance/substance group *Ferrous gluconate hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ferrous gluconate hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 160 | 0 | 158 166 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Ferrous gluconate hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.2500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25378 | 25378 | 0.00 | 413.73 |
| 25604 | 25604 | 0.00 | 403.48 |
| 26085 | 26085 | 0.00 | 405.09 |
| 26859 | 26859 | 0.00 | 403.42 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Finasteride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20955-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Finasteride; Finasteridum

### Special notes

When selecting the *Finasteride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Finasteride | 7 | 14 | 34 |

### Second-stage model

For differentiation of the substance/substance group *Finasteride* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Finasteride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 107.19 | 134.61 |
| ⋮ | ⋮ | ⋮ |
| Riboflavin sodium phosphate hydrate | >50 | 159.81 |
| Magnesium citrate | >50 | 360.61 |
| Mg-Ca-K colamine phosphate | >50 | 360.89 |
| Gentamicin sulfate | >50 | 685.28 |
| Tobramycin sulfate | >50 | 963.85 |
| Neomycin sulfate | >50 | 1121.65 |
| Zinc gluconate | >50 | 1635.84 |
| Sodium tetraborate | >50 | 2072.30 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Finasteride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Finasteride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Finasteride | 1403016-01 | 21626 | 60 | 1506004 |
| Euro OTC | Finasteride | 1403016-02 | 21750 | 60 | 20140505 |
| Euro OTC | Finasteride | 1403016-02 | 21750SI | 51 | 20140505 |
| Euro OTC | Finasteride | 1605020 | 22565 | 40 | 20160613* |
| Euro OTC | Finasteride | 1605020 | 22565SI | 40 | 20160613* |
| Euro OTC | Finasteride | 1610012 | 22856 | 40 | 20161116* |
| Euro OTC | Finasteride | 1610012 | 22856SI | 33 | 20161116* |
| Euro OTC | Finasteride | 2101024 | 25527 | 40 | 20210217* |
| Euro OTC | Finasteride | 2101024 | 25527SI | 34 | 20210217* |
| Fagron | Finasteride | 13I03-N01 | 20955 | 40 | 1411272 |
| Fagron | Finasteride | 14A16-B40-295980 | 21742 | 60 | 20140317 |
| Fagron | Finasteride | 14A16-B40-295980 | 21742SI | 45 | 20140317 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 543 spectra of 12 reference samples from the substance/substance group *Finasteride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.
- 157 783 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1132 spectra of 29 reference samples from the substance/substance group *Finasteride*.
- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Finasteride | 1704004 | 23151 | 40 |
| Euro OTC | Finasteride | 1804010 | 24129 | 40 |
| Euro OTC | Finasteride | 1809019 | 24342 | 40 |
| Euro OTC | Finasteride | 2003027 | 25355 | 40 |
| Euro OTC | Finasteride | 2111004 | 25913 | 40 |
| Euro OTC | Finasteride | 2210013 | 26421 | 40 |
| Euro OTC | Finasteride | 2210015 | 26438 | 40 |
| Euro OTC | Finasteride | 2301045 | 26576 | 40 |
| Euro OTC | Finasteride | 2403004 | 27291 | 40 |
| Euro OTC | Finasteride | 2407022 | 27367 | 30 |
| Euro OTC | Finasteride | 2501025 | 27519 | 40 |
| Fagron | Finasteride | 15J15-B02-320084 | 22594 | 40 |
| Fagron | Finasteride | 22B14-B09-217630 | 26078 | 40 |
| Fagron | Finasteride | 23J19-B04-233067 | 27039 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Finasteride | 1804010 | 24129SI | 40 |
| Euro OTC | Finasteride | 1809019 | 24342SI | 31 |
| Euro OTC | Finasteride | 2003027 | 25355SI | 39 |
| Euro OTC | Finasteride | 2111004 | 25913SI | 40 |
| Euro OTC | Finasteride | 2210013 | 26421SI | 40 |
| Euro OTC | Finasteride | 2210015 | 26438SI | 40 |
| Euro OTC | Finasteride | 2301045 | 26576SI | 40 |
| Euro OTC | Finasteride | 2403004 | 27291SI | 40 |
| Euro OTC | Finasteride | 2407022 | 27367SI | 38 |
| Euro OTC | Finasteride | 2501025 | 27519SI | 40 |
| Fagron | Finasteride | 15J15-B02-320084 | 22594SI | 40 |
| Fagron | Finasteride | 15J15-B02-320084 | 22595 | 40 |
| Fagron | Finasteride | 15J15-B02-320084 | 22595SI | 40 |
| Fagron | Finasteride | 22B14-B09-217630 | 26078SI | 40 |
| Fagron | Finasteride | 23J19-B04-233067 | 27039SI | 34 |

- 211 808 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 68 spectra from 22 *Apo-Ident* customers from 36 batches from the substance/substance group *Finasteride*.

- Among them are spectra of independent samples from 34 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Finasteride | 2210013-01 | 2 |
| | Finasteride | 2301045-01 | 7 |
| Caelo | Finasteride | 17112-B07-340606 | 1 |
| Caelo | Finasteride | 1809019-01 | 1 |
| Crystal | Finasteride | 141100801 | 1 |
| Euro OTC | Finasteride | 1403016-02 | 1 |
| Euro OTC | Finasteride | 1411008-01 | 1 |
| Euro OTC | Finasteride | 1605020-01 | 1 |
| Euro OTC | Finasteride | 1610012-01 | 2 |
| Euro OTC | Finasteride | 1704004-01 | 5 |
| Euro OTC | Finasteride | 1804010-01 | 2 |
| Euro OTC | Finasteride | 1809019-01 | 2 |
| Euro OTC | Finasteride | 18090919-01 | 1 |
| Euro OTC | Finasteride | 20B11-F03-373005 | 1 |
| Euro OTC | Finasteride | 2101024-01 | 6 |
| Euro OTC | Finasteride | 2210013-01 | 1 |
| Euro OTC | Finasteride | C1012/116010 | 1 |
| Fagron | Finasteride | 13I03-N01 | 2 |
| Fagron | Finasteride | 14111305 | 1 |
| Fagron | Finasteride | 14L23-B02-306981 | 1 |
| Fagron | Finasteride | 15I01-B03 | 1 |
| Fagron | Finasteride | 15I01-B03-314476 | 1 |
| Fagron | Finasteride | 17011303 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Finasteride | 17I12-B07-340606 | 4 |
| Fagron | Finasteride | 17I12-B07-355068 | 1 |
| Fagron | Finasteride | 17I12-B07-356321 | 1 |
| Fagron | Finasteride | 18041810 | 1 |
| Fagron | Finasteride | 18L13-B05-356320 | 1 |
| Fagron | Finasteride | 18L13-B05-356321 | 2 |
| Fagron | Finasteride | 19041707 | 1 |
| Fagron | Finasteride | 19D10-B01-362337 | 3 |
| Fagron | Finasteride | 20181101 | 1 |
| Fagron | Finasteride | 20190301 | 1 |
| Fagron | Finasteride | 20190702 | 1 |
| Fagron | Finasteride | 20B11-F03-373005 | 1 |
| Fagron | Finasteride | 20J01-F05-374980 | 1 |
| Fagron | Finasteride | 22B14-B09-217630 | 3 |
| Fagron | Finasteride | F03-3730005 | 1 |
| Phoenix | Finasteride | 1804010-01 | 1 |
| Shandong Northwest M… | Finasteride | FNA160604 | 1 |

- 256 818 spectra from 1666 *Apo-Ident* customers from a total of 52 117 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Finasteride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Finasteride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 543 | 0 | 157 783 |
| **Type B** | 0 | 1132 | 0 | 211 808 |
| **Type C** | 0 | 68 | 0 | 256 818 |

The substance/substance group *Finasteride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8950 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4700 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 91.1765 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20955 | 20955 | 0.00 | 187.01 |
| 21626 | 21626 | 0.00 | 178.64 |
| 21742 | 21626 | 24.74 | 177.99 |
| 21750 | 21626 | 20.67 | 177.06 |
| 22565 | 22565 | 0.00 | 181.98 |
| 22856 | 22856 | 0.00 | 184.88 |
| 25527 | 25527 | 0.00 | 187.87 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Fluocinolone acetonide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21031-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Fluocinolone acetonide; Fluocinoloni acetonidum

### Special notes

When selecting the *Fluocinolone acetonide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Fluocinolone acetonide | 6 | 3 | 45 |

### Second-stage model

For differentiation of the substance/substance group *Fluocinolone acetonide* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Fluocinolone acetonide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Triamcinolone acetonide | 59.76 | 36.51 |
| ⋮ | ⋮ | ⋮ |
| Betamethasone | >50 | 65.70 |
| Dexamethasone | >50 | 73.91 |
| Methylprednisolone | >50 | 82.43 |
| Tyrothricin | >50 | 87.41 |
| Prednisolone | >50 | 87.53 |
| Gramicidin | >50 | 153.42 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Fluocinolone acetonide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Fluocinolone acetonide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Fluocinolone acetonide | 12035003 | 21756 | 60 | 20120321 |
| Caelo | Fluocinolone acetonide | 12035003 | 21756SI | 48 | 20120321 |
| Caelo | Fluocinolone acetonide | 162281 | 22637 | 40 | 20160907* |
| Caelo | Fluocinolone acetonide | 162281 | 22637SI | 30 | 20160907* |
| Euro OTC | Fluocinolone acetonide | 2804013E-01 | 21031 | 60 | 1404008 |
| Euro OTC | Fluocinolone acetonide | 2804013E-01 | 21077 | 60 | 20121206 |
| Euro OTC | Fluocinolone acetonide | 2804013E-01 | 21822 | 60 | 20121206 |
| Euro OTC | Fluocinolone acetonide | 2804013E-01 | 21822SI | 60 | 20121206 |
| Fagron | Fluocinolone acetonide | 14L19-B04-307101 | 22267 | 45 | 20150219 |
| Fagron | Fluocinolone acetonide | 14L19-B04-307101 | 22267SI | 45 | 20150219 |
| Fagron | Fluocinolone acetonide | 14L19-B04-307101 | 23080 | 40 | 20150219 |
| Fagron | Fluocinolone acetonide | 17F14-B08-350105 | 24700 | 40 | 20171221 |
| Fagron | Fluocinolone acetonide | 20K03-F03-375403 | 25750 | 40 | 2111539 |
| Fagron | Fluocinolone acetonide | 20K03-F03-375403 | 25750SI | 40 | 2111539 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 668 spectra of 14 reference samples from the substance/substance group *Fluocinolone acetonide*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 658 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 378 spectra of 10 reference samples from the substance/substance group *Fluocinolone acetonide*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Fluocinolone acetonide | 172130 | 23674 | 40 |
| Fagron | Fluocinolone acetonide | 21K03-B06-217656 | 26069 | 40 |
| Fagron | Fluocinolone acetonide | 22D11-B02-221847 | 26325 | 40 |
| Caelo | Fluocinolone acetonide | 172130 | 23674SI | 12 |
| Euro OTC | Fluocinolone acetonide | 2804013E-01 | 21823 | 60 |
| Euro OTC | Fluocinolone acetonide | 2804013E-01 | 21823SI | 46 |
| Fagron | Fluocinolone acetonide | 14L19-B04-307101 | 23080SI† | 20 |
| Fagron | Fluocinolone acetonide | 17F14-B08-350105 | 24700SI† | 40 |
| Fagron | Fluocinolone acetonide | 21K03-B06-217656 | 26069SI | 40 |
| Fagron | Fluocinolone acetonide | 22D11-B02-221847 | 26325SI | 40 |

- 212 562 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 77 spectra from 45 *Apo-Ident* customers from 50 batches from the substance/substance group *Fluocinolone acetonide*.
- Among them are spectra of independent samples from 45 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Fluocinolone acetonide | 20K03-F03-375404 | 1 |
| | Fluocinolone acetonide | 22D11-B02-221848 | 1 |
| | Fluocinolone acetonide | 22D11-BO2-221848 | 1 |
| | Fluocinolone acetonide | 23D01-B03-231001 | 2 |
| Caelo | Fluocinolone acetonide | 12035003 | 1 |
| Caelo | Fluocinolone acetonide | 1408022-02 | 2 |
| Caelo | Fluocinolone acetonide | 16228108 | 2 |
| Caelo | Fluocinolone acetonide | 18073203 | 1 |
| Caelo | Fluocinolone acetonide | 18073206 | 1 |
| Caelo | Fluocinolone acetonide | 18073303 | 2 |
| Caelo | Fluocinolone acetonide | 2804013V-03 | 1 |
| Caesar & Loretz Hilden | Fluocinolone acetonide | 18073301 | 1 |
| Eurho | Fluocinolone acetonide | 1408022-04 | 1 |
| Euro OTC | Fluocinolone acetonide | 1408022-02 | 2 |
| Euro OTC | Fluocinolone acetonide | 1408022-03 | 1 |
| Euro OTC | Fluocinolone acetonide | 2804013E-01 | 1 |
| Fagro/Noweda | Fluocinolone acetonide | 15K06-B02-336730 | 1 |
| Fagron | Fluocinolone acetonide | 1(18I19-B05-363303) | 1 |
| Fagron | Fluocinolone acetonide | 13E22-N10 | 1 |
| Fagron | Fluocinolone acetonide | 13L30B35295489 | 1 |
| Fagron | Fluocinolone acetonide | 13L30-B35-295489 | 1 |
| Fagron | Fluocinolone acetonide | 14l19-b04 | 1 |
| Fagron | Fluocinolone acetonide | 14L19-B04 | 4 |
| Fagron | Fluocinolone acetonide | 14L19-B04-317248 | 2 |
| Fagron | Fluocinolone acetonide | 14L19-B04-615699 | 1 |
| Fagron | Fluocinolone acetonide | 15K06-B02 | 1 |
| Fagron | Fluocinolone acetonide | 15k06-b02-326488 | 1 |
| Fagron | Fluocinolone acetonide | 15k06-b02-332955 | 1 |
| Fagron | Fluocinolone acetonide | 15K06-B02-336730 | 1 |
| Fagron | Fluocinolone acetonide | 17f14-b08-346965 | 1 |
| Fagron | Fluocinolone acetonide | 17F14-B08-346965 | 1 |
| Fagron | Fluocinolone acetonide | 17F14-B08-350106 | 3 |
| Fagron | Fluocinolone acetonide | 18/19-B05-359031 | 1 |
| Fagron | Fluocinolone acetonide | 18/19-B05-365691 | 1 |
| Fagron | Fluocinolone acetonide | 18/19-B05-370559 | 1 |
| Fagron | Fluocinolone acetonide | 18I19B05-358085 | 1 |
| Fagron | Fluocinolone acetonide | 18I19-B05-358085 | 2 |
| Fagron | Fluocinolone acetonide | 18I19-B05-363303 | 2 |
| Fagron | Fluocinolone acetonide | 18I19-B05-365691 | 2 |
| Fagron | Fluocinolone acetonide | 18I19-B05-370559 | 3 |
| Fagron | Fluocinolone acetonide | 2151nm1b0091723 | 1 |
| Fagron | Fluocinolone acetonide | 2151NM1B0091723 | 2 |
| Fagron | Fluocinolone acetonide | 21H13-B18-213858 | 4 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Fluocinolone acetonide | 21K03-B06 | 2 |
| Fagron | Fluocinolone acetonide | 22D11-B02-221848 | 2 |
| Fagron | Fluocinolone acetonide | B05-3590301 | 1 |
| Fagron | Fluocinolone acetonide | B05-3633003 | 1 |
| Fagron | Fluocinolone acetonide | B05-3705509 | 1 |
| Fargon/Kehr | Fluocinolone acetonide | 14L-19-B04 | 1 |
| Fargon/Noweda | Fluocinolone acetonide | 13L13-B35 | 1 |
| Farmabios s.p.A | Fluocinolone acetonide | C24H30F206 | 1 |
| Gehe | Fluocinolone acetonide | 18/19-B05 | 1 |
| Ichthyol Gesellschaf... | Fluocinolone acetonide | 14L19-B04-321003 | 1 |
| Kehr | Fluocinolone acetonide | 17F14-B08-346965 | 1 |
| Noweda | Fluocinolone acetonide | 23D01-B03-231001 | 1 |

- 256 809 spectra from 1666 *Apo-Ident* customers from a total of 52 103 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Fluocinolone acetonide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Fluocinolone acetonide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 668 | 0 | 157 658 |
| **Type B** | 0 | 378 | 0 | 212 562 |
| **Type C** | 0 | 77 | 0 | 256 809 |

The substance/substance group *Fluocinolone acetonide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1018 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4127 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.2078 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21031 | 21031 | 0.00 | 62.95 |
| 21077 | 21031 | 4.42 | 63.88 |
| 21756 | 21031 | 22.48 | 62.91 |
| 21822 | 21031 | 19.46 | 64.59 |
| 22267 | 21031 | 17.73 | 62.82 |
| 22637 | 22637 | 0.00 | 118.94 |
| 23080 | 21031 | 20.30 | 59.76 |
| 24700 | 21031 | 11.25 | 60.28 |
| 25750 | 25750 | 0.00 | 113.58 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Folic acid hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20370-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Folic acid hydrate; Acidum folicum hydricum

### Special notes

When selecting the *Folic acid hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Folic acid hydrate | 7 | 6 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Folic acid hydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Folic acid hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 93.20 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Folic acid hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Folic acid hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Folic acid hydrate | 1401005-01 | 21288 | 40 | 20140131 |
| Euro OTC | Folic acid hydrate | 1508024 | 21891 | 60 | 20150902* |
| Euro OTC | Folic acid hydrate | 1604036 | 22554 | 40 | 20160429* |
| Euro OTC | Folic acid hydrate | 1611009 | 22868 | 40 | 20161201* |
| Euro OTC | Folic acid hydrate | 1911019 | 25072 | 40 | 20191216* |
| Fagron | Folic acid hydrate | 12G17-N05 | 20767 | 40 | 20120727 |
| Fagron | Folic acid hydrate | 16C03-B06-322513 | 23081 | 40 | 20160411 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 7 reference samples from the substance/substance group *Folic acid hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 026 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 290 spectra of 9 reference samples from the substance/substance group *Folic acid hydrate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Folic acid hydrate | 1608030 | 22818 | 40 |
| Euro OTC | Folic acid hydrate | 1903033 | 24608 | 40 |
| Euro OTC | Folic acid hydrate | 2006021 | 25272 | 40 |
| Euro OTC | Folic acid hydrate | 2201042 | 25964 | 40 |
| Euro OTC | Folic acid hydrate | 2312005 | 27196 | 40 |
| Euro OTC | Folic acid hydrate | 2407015 | 27361 | 40 |
| Euro OTC | Folic acid hydrate | 2201042 | 25964SI | 10 |
| Euro OTC | Folic acid hydrate | 2312005 | 27196SI | 20 |
| Euro OTC | Folic acid hydrate | 2407015 | 27361SI | 20 |

- 212 650 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 27 spectra from 20 *Apo-Ident* customers from 17 batches from the substance/substance group *Folic acid hydrate*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Folic acid hydrate | 1911019-01 | 1 |
| Euro OTC | Folic acid hydrate | 1307041-01 | 1 |
| Euro OTC | Folic acid hydrate | 1401005-01 | 1 |
| Euro OTC | Folic acid hydrate | 1604036-01 | 1 |
| Euro OTC | Folic acid hydrate | 1608030-01 | 1 |
| Euro OTC | Folic acid hydrate | 1611009-01 | 5 |
| Euro OTC | Folic acid hydrate | 1611009-02 | 1 |
| Euro OTC | Folic acid hydrate | 1611009-04 | 1 |
| Euro OTC | Folic acid hydrate | 1903033-01 | 2 |
| Euro OTC | Folic acid hydrate | 1911019-01 | 2 |
| Euro OTC | Folic acid hydrate | 2006021-01 | 1 |
| Euro OTC | Folic acid hydrate | 2201042-01 | 1 |
| Fagron | Folic acid hydrate | 13A11-N01 | 1 |
| Fagron | Folic acid hydrate | 13G16-N02 | 4 |
| Fagron | Folic acid hydrate | 14H05-B03 | 1 |
| Fagron | Folic acid hydrate | 16C03-B06 | 1 |
| Fagron | Folic acid hydrate | UT11110182 | 1 |
| Farmalabor | Folic acid hydrate | P1701610 | 1 |

- 256 859 spectra from 1666 *Apo-Ident* customers from a total of 52 136 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Folic acid hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Folic acid hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 290 | 0 | 212 650 |
| **Type C** | 0 | 27 | 0 | 256 859 |

The substance/substance group *Folic acid hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.9310 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 77.7778 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20767 | 22554 | 4.68 | 119.30 |
| 21288 | 22554 | 4.55 | 118.48 |
| 21891 | 21891 | 0.00 | 116.19 |
| 22554 | 22554 | 0.00 | 116.17 |
| 22868 | 22868 | 0.00 | 115.72 |
| 23081 | 22554 | 4.48 | 113.51 |
| 25072 | 25072 | 0.00 | 118.57 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Fructose** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20074-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Fructose; Fructosum

### Special notes

When selecting the *Fructose* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Fructose | 7 | 22 | 307 |

### Second-stage model

For differentiation of the substance/substance group *Fructose* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Fructose* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 41.31 | – |
| Cannabis flower, CBD-dominant type | 41.63 | – |
| Polymyxin B sulfate | 62.11 | 41.59 |
| ⋮ | ⋮ | ⋮ |
| Calcium glycerophosphate | >50 | 37.25 |
| Colistin sulfate | >50 | 41.50 |
| Riboflavin | >50 | 41.90 |
| Bacitracin | >50 | 57.80 |
| Tosylchloramide sodium | >50 | 58.23 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 59.48 |
| Wheat starch | >50 | 62.15 |
| Rice starch | >50 | 63.91 |
| Calcium pantothenate | >50 | 65.68 |
| SyrSpend® SF Alka | >50 | 66.42 |
| Potato starch | >50 | 70.39 |
| SyrSpend® SF pH4 | >50 | 76.58 |
| Nystatin | >50 | 76.85 |
| Carmellose sodium | >50 | 83.12 |
| Amphotericin B | >50 | 84.11 |
| Gelatine, white | >50 | 85.47 |
| Acacia, dried dispersion | >50 | 86.14 |
| Maltodextrin | >50 | 87.03 |
| Corn starch | >50 | 95.52 |
| Triamcinolone | >50 | 99.72 |
| Hyoscine hydrobromide | >50 | 106.28 |
| Cyanocobalamin | >50 | 109.44 |
| Estradiol hemihydrate | >50 | 113.69 |
| Oxalic acid | >50 | 115.71 |
| alpha-tocopheryl acetate dry concentrate | >50 | 164.28 |
| Methylcobalamin | >50 | 164.41 |
| Estriol | >50 | 168.02 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Fructose* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Fructose*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Fructose | 160667 | 22481 | 60 | 20160425* |
| Caelo | Fructose | 15084311 | 22490 | 40 | 20150316 |
| Euro OTC | Fructose | 1212015-01 | 21281 | 40 | 20130111 |
| Euro OTC | Fructose | 1509037 | 21934 | 60 | 20151027* |
| Euro OTC | Fructose | 1512009 | 22292 | 60 | 20160113* |
| Euro OTC | Fructose | 1701049 | 22986 | 40 | 20170213* |
| Fagron | Fructose | 16H05-B01-326259 | 23018 | 40 | 20160926 |
| Fagron | Fructose | 16H05-B01-326259 | 23082 | 40 | 20160926 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 380 spectra of 8 reference samples from the substance/substance group *Fructose*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.
- 157 946 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 961 spectra of 26 reference samples from the substance/substance group *Fructose*.
- Among them are spectra of independent samples from 22 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Fructose | 15271213 | 22583 | 40 |
| Caelo | Fructose | 171439 | 23422 | 40 |
| Caelo | Fructose | 182916 | 24364 | 40 |
| Caelo | Fructose | 191699 | 24739 | 40 |
| Caelo | Fructose | 21000686007 | 25931 | 40 |
| Caelo | Fructose | 23002084 | 27334 | 40 |
| Caelo | Fructose | 24002305002 | 27584 | 40 |
| Euro OTC | Fructose | 1604024 | 22547 | 41 |
| Euro OTC | Fructose | 1607030 | 22693 | 40 |
| Euro OTC | Fructose | 1705002 | 23391 | 40 |
| Euro OTC | Fructose | 1710034 | 23901 | 40 |
| Euro OTC | Fructose | 1803040 | 24087 | 40 |
| Euro OTC | Fructose | 1811018 | 24486 | 40 |
| Euro OTC | Fructose | 1906017 | 24792 | 40 |
| Euro OTC | Fructose | 1910020 | 24978 | 40 |
| Euro OTC | Fructose | 2006019 | 25298 | 40 |
| Euro OTC | Fructose | 2102008 | 25602 | 40 |
| Euro OTC | Fructose | 2203030 | 26037 | 40 |
| Euro OTC | Fructose | 2212011 | 26516 | 40 |
| Euro OTC | Fructose | 2309017 | 26996 | 40 |
| Euro OTC | Fructose | 2405018 | 27281 | 40 |
| Fagron | Fructose | 19C19-B02-361846 | 25057 | 40 |
| Caelo | Fructose | 171439 | 23673 | 40 |
| Caelo | Fructose | 21000686007 | 25931SI | 10 |
| Euro OTC | Fructose | 2203030 | 26037SI | 10 |
| Euro OTC | Fructose | 2212011 | 26516SI | 20 |

- 211 979 spectra from a total of 4265 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1418 spectra from 352 *Apo-Ident* customers from 310 batches from the substance/substance group *Fructose*.

- Among them are spectra of independent samples from 307 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Fructose | 1803040-01 | 2 |
| | Fructose | 2006019-02 | 2 |
| | Fructose | 2100068018 | 1 |
| | Fructose | 2100068601563/23P | 1 |
| | Fructose | 21000686016 | 1 |
| | Fructose | 21000686022 | 3 |
| | Fructose | 21000686024 | 1 |
| | Fructose | 21000686027 | 1 |
| | Fructose | 22003150002 | 2 |
| | Fructose | 22003150003 | 9 |
| | Fructose | 22003150007 | 2 |
| | Fructose | 22003150009 | 6 |
| | Fructose | 22003150013 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Fructose | 22003150015 | 9 |
| | Fructose | 22003150016 | 2 |
| | Fructose | 22003150021 | 4 |
| | Fructose | 2200315003 | 1 |
| | Fructose | 2203030-01 | 2 |
| | Fructose | 2203030-02 | 1 |
| | Fructose | 2212011-01 | 11 |
| | Fructose | 2212011-02 | 8 |
| | Fructose | 23003367001 | 5 |
| | Fructose | 23003368001 | 9 |
| | Fructose | 23003368002 | 12 |
| | Fructose | 2309017-01 | 10 |
| | Fructose | 240001472001 | 1 |
| | Fructose | 24001472001 | 3 |
| | Fructose | 24001472004 | 1 |
| | Fructose | 24002305001 | 15 |
| | Fructose | 24002305002 | 4 |
| | Fructose | 24002305003 | 2 |
| | Fructose | 2405018-01 | 3 |
| | Fructose | 2520-424 | 1 |
| | Fructose | 252201-0209 | 1 |
| | Fructose | 52305-19000 | 1 |
| | Fructose | FS2P00251808-S02 | 1 |
| AHD | Fructose | FS2P00252305-190 | 1 |
| Alliance Health 13.0… | Fructose | 13C25-N03 | 1 |
| Alliance | Fructose | 22003150002 | 2 |
| Alliance | Fructose | 2212011-01 | 1 |
| Anzag | Fructose | 18291602 | 1 |
| apo-ident | Fructose | 1607030-01 | 2 |
| Audor Pharma | Fructose | AP211029-01 | 1 |
| Beiersdorf | Fructose | 14096208 | 1 |
| Bombastus | Fructose | 1710034-01 | 1 |
| Caelo | Fructose | 10051401 | 1 |
| Caelo | Fructose | 10071201 | 1 |
| Caelo | Fructose | 10087516 | 1 |
| Caelo | Fructose | 10381011 | 1 |
| Caelo | Fructose | 104H20 | 1 |
| Caelo | Fructose | 1081501 | 1 |
| Caelo | Fructose | 11071201 | 1 |
| Caelo | Fructose | 1114A03394 | 1 |
| Caelo | Fructose | 11258611 | 1 |
| Caelo | Fructose | 11258614 | 1 |
| Caelo | Fructose | 11258627 | 3 |
| Caelo | Fructose | 11258628 | 2 |
| Caelo | Fructose | 11I07-N06 | 1 |
| Caelo | Fructose | 12132301 | 2 |
| Caelo | Fructose | 12132305 | 5 |
| Caelo | Fructose | 12132309 | 2 |
| Caelo | Fructose | 12132310 | 1 |
| Caelo | Fructose | 12132313 | 5 |
| Caelo | Fructose | 12132314 | 5 |
| Caelo | Fructose | 12132317 | 2 |
| Caelo | Fructose | 12132320 | 1 |
| Caelo | Fructose | 12132322 | 2 |
| Caelo | Fructose | 12132325 | 3 |
| Caelo | Fructose | 121e29-n08 | 1 |
| Caelo | Fructose | 123456 | 1 |
| Caelo | Fructose | 1234567 | 1 |
| Caelo | Fructose | 12H01-N03 | 1 |
| Caelo | Fructose | 13041802 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Fructose | 1309213394 | 1 |
| Caelo | Fructose | 13098902 | 3 |
| Caelo | Fructose | 13098904 | 1 |
| Caelo | Fructose | 13098906 | 4 |
| Caelo | Fructose | 13098909 | 1 |
| Caelo | Fructose | 13098911 | 1 |
| Caelo | Fructose | 13098913 | 4 |
| Caelo | Fructose | 13098914 | 2 |
| Caelo | Fructose | 13098915 | 1 |
| Caelo | Fructose | 13098917 | 3 |
| Caelo | Fructose | 13098918 | 1 |
| Caelo | Fructose | 13098922 | 1 |
| Caelo | Fructose | 130998922 | 1 |
| Caelo | Fructose | 13111705 | 1 |
| Caelo | Fructose | 13A28-N01 | 1 |
| Caelo | Fructose | 13E27-N07 | 1 |
| Caelo | Fructose | 14096201 | 2 |
| Caelo | Fructose | 14096202 | 1 |
| Caelo | Fructose | 14096203 | 1 |
| Caelo | Fructose | 14096205 | 3 |
| Caelo | Fructose | 14096207 | 1 |
| Caelo | Fructose | 14096208 | 2 |
| Caelo | Fructose | 14096210 | 1 |
| Caelo | Fructose | 14096211 | 1 |
| Caelo | Fructose | 14096219 | 4 |
| Caelo | Fructose | 14096223 | 5 |
| Caelo | Fructose | 14096224 | 2 |
| Caelo | Fructose | 14305201 | 1 |
| Caelo | Fructose | 14305203 | 2 |
| Caelo | Fructose | 14305204 | 1 |
| Caelo | Fructose | 14305206 | 1 |
| Caelo | Fructose | 14E01-B04-297098 | 1 |
| Caelo | Fructose | 1503045-01 | 2 |
| Caelo | Fructose | 15049703 | 1 |
| Caelo | Fructose | 15084301 | 3 |
| Caelo | Fructose | 15084305 | 3 |
| Caelo | Fructose | 15084308 | 2 |
| Caelo | Fructose | 15084311 | 2 |
| Caelo | Fructose | 15084312 | 2 |
| Caelo | Fructose | 152711201 | 1 |
| Caelo | Fructose | 15271201 | 3 |
| Caelo | Fructose | 15271205 | 7 |
| Caelo | Fructose | 15271208 | 2 |
| Caelo | Fructose | 15271209 | 4 |
| Caelo | Fructose | 15271213 | 6 |
| Caelo | Fructose | 15271214 | 2 |
| Caelo | Fructose | 15271215 | 3 |
| Caelo | Fructose | 15A16-B07 | 1 |
| Caelo | Fructose | 15A16-B07-305241 | 1 |
| Caelo | Fructose | 1604024-01 | 1 |
| Caelo | Fructose | 16066101 | 2 |
| Caelo | Fructose | 16066103 | 6 |
| Caelo | Fructose | 16066106 | 20 |
| Caelo | Fructose | 16066107 | 9 |
| Caelo | Fructose | 1607030-01 | 1 |
| Caelo | Fructose | 1610033-01 | 4 |
| Caelo | Fructose | 16283910 | 7 |
| Caelo | Fructose | 17007701 | 5 |
| Caelo | Fructose | 17007702 | 1 |
| Caelo | Fructose | 17007706 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Fructose | 17007707 | 2 |
| Caelo | Fructose | 17007708 | 1 |
| Caelo | Fructose | 1701034-01 | 1 |
| Caelo | Fructose | 170104901 | 1 |
| Caelo | Fructose | 1705002-01 | 1 |
| Caelo | Fructose | 1710034-01 | 3 |
| Caelo | Fructose | 17143902 | 12 |
| Caelo | Fructose | 1714390210087516 | 1 |
| Caelo | Fructose | 17143903 | 2 |
| Caelo | Fructose | 17143904 | 10 |
| Caelo | Fructose | 17346404 | 29 |
| Caelo | Fructose | 17346405 | 1 |
| Caelo | Fructose | 17346405P-180831-1 | 1 |
| Caelo | Fructose | 17346405P-190325-2 | 1 |
| Caelo | Fructose | 17346405P-190718-1 | 1 |
| Caelo | Fructose | 17346406 | 1 |
| Caelo | Fructose | 17346411 | 2 |
| Caelo | Fructose | 18021501 | 1 |
| Caelo | Fructose | 1803040-01 | 1 |
| Caelo | Fructose | 18061801 | 1 |
| Caelo | Fructose | 18062005 | 1 |
| Caelo | Fructose | 18082002 | 6 |
| Caelo | Fructose | 18082005 | 38 |
| Caelo | Fructose | 18082006 | 1 |
| Caelo | Fructose | 18082011 | 4 |
| Caelo | Fructose | 18082012 | 4 |
| Caelo | Fructose | 1811018-01 | 1 |
| Caelo | Fructose | 1829102 | 1 |
| Caelo | Fructose | 18291602 | 43 |
| Caelo | Fructose | 18291603 | 1 |
| Caelo | Fructose | 18291603P-191223-2 | 1 |
| Caelo | Fructose | 18291605 | 2 |
| Caelo | Fructose | 18291609 | 7 |
| Caelo | Fructose | 18291611P-200319-9 | 1 |
| Caelo | Fructose | 18291612 | 2 |
| Caelo | Fructose | 18291613 | 5 |
| Caelo | Fructose | 18291614 | 1 |
| Caelo | Fructose | 18291620 | 2 |
| Caelo | Fructose | 1906017-01 | 5 |
| Caelo | Fructose | 1910020-01 | 2 |
| Caelo | Fructose | 191699005 | 1 |
| Caelo | Fructose | 19169903 | 15 |
| Caelo | Fructose | 19169904 | 8 |
| Caelo | Fructose | 19169905 | 1 |
| Caelo | Fructose | 192965002 | 7 |
| Caelo | Fructose | 192965008 | 17 |
| Caelo | Fructose | 192965009 | 1 |
| Caelo | Fructose | 20003599001 | 2 |
| Caelo | Fructose | 20003599011 | 5 |
| Caelo | Fructose | 20003599012 | 6 |
| Caelo | Fructose | 20081402 | 1 |
| Caelo | Fructose | 2100066022 | 1 |
| Caelo | Fructose | 21000686003 | 1 |
| Caelo | Fructose | 21000686007 | 6 |
| Caelo | Fructose | 21000686009 | 2 |
| Caelo | Fructose | 21000686015 | 6 |
| Caelo | Fructose | 21000686015/95/22P | 1 |
| Caelo | Fructose | 21000686016 | 1 |
| Caelo | Fructose | 21000686018 | 4 |
| Caelo | Fructose | 21000686020 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Fructose | 21000686022 | 8 |
| Caelo | Fructose | 21000686024 | 8 |
| Caelo | Fructose | 21051303 | 1 |
| Caelo | Fructose | 2117E-03394 | 1 |
| Caelo | Fructose | 22003150002 | 4 |
| Caelo | Fructose | 22003150003 | 1 |
| Caelo | Fructose | 22003150007 | 4 |
| Caelo | Fructose | 220425C | 1 |
| Caelo | Fructose | 23021708 | 1 |
| Caelo | Fructose | 31031401 | 1 |
| Caelo | Fructose | 31101810 | 1 |
| Caelo | Fructose | 3313U-03394 | 1 |
| Caelo | Fructose | 5061503 | 1 |
| Caelo | Fructose | 5081701 | 1 |
| Caelo | Fructose | 7051304 | 1 |
| Caelo | Fructose | 7111401 | 1 |
| Caelo | Fructose | 716090F | 1 |
| Caelo | Fructose | 9031504 | 1 |
| Caelo | Fructose | 9061804 | 1 |
| Caelo | Fructose | 92965008 | 1 |
| Caesar & Loretz / Gehe | Fructose | 18082012 | 1 |
| Caesar & Loretz GmbH... | Fructose | 19169904 | 1 |
| Caesar & Loretz GmbH... | Fructose | 18291605 | 2 |
| Caesar & Loretz GmbH... | Fructose | 18291613 | 2 |
| Caesar & Loretz GmbH... | Fructose | 20003599012 | 1 |
| Caesar & Loretz GmbH... | Fructose | 18291602 | 1 |
| Caesar & Loretz GmbH... | Fructose | 18291609 | 1 |
| Caesar & Loretz GmbH... | Fructose | 21000686015 | 1 |
| Caesar & Loretz GmbH... | Fructose | 21000686015 | 1 |
| Caesar & Loretz GmbH/AHD | Fructose | 18291602 | 1 |
| Caesar & Loretz GmbH... | Fructose | 21000686027 | 1 |
| Caesar & Loretz GmbH/Gehe | Fructose | 20003599011 | 1 |
| Caesar & Loretz GmbH/Gehe | Fructose | 21000686022 | 1 |
| Caesar & Loretz GmbH... | Fructose | 18082012 | 1 |
| Caesar & Loretz GmbH... | Fructose | 20003599001 | 1 |
| Caesar & Loretz GmbH... | Fructose | 20003599011 | 1 |
| Caesar & Loretz GmbH... | Fructose | 21000686027 | 6 |
| Caesar & Loretz GmbH... | Fructose | 18291602 | 1 |
| Caesar & Loretz GmbH... | Fructose | 19169904 | 4 |
| Caesar & Loretz GmbH | Fructose | 16283910 | 1 |
| Caesar & Loretz GmbH | Fructose | 18082005 | 4 |
| Caesar & Loretz GmbH | Fructose | 18082011 | 1 |
| Caesar & Loretz GmbH | Fructose | 18291602 | 21 |
| Caesar & Loretz GmbH | Fructose | 18291609 | 2 |
| Caesar & Loretz GmbH | Fructose | 18291613 | 1 |
| Caesar & Loretz GmbH | Fructose | 18307407 | 1 |
| Caesar & Loretz GmbH | Fructose | 191699008 | 1 |
| Caesar & Loretz GmbH | Fructose | 19169903 | 7 |
| Caesar & Loretz GmbH | Fructose | 19169904 | 1 |
| Caesar & Loretz GmbH | Fructose | 19169905 | 1 |
| Caesar & Loretz GmbH | Fructose | 192965002 | 8 |
| Caesar & Loretz GmbH | Fructose | 192965008 | 4 |
| Caesar & Loretz GmbH | Fructose | 20003599001 | 1 |
| Caesar & Loretz GmbH | Fructose | 20003599011 | 4 |
| Caesar & Loretz GmbH | Fructose | 20003599012 | 1 |
| Caesar & Loretz GmbH | Fructose | 21000686007 | 6 |
| Caesar & Loretz GmbH | Fructose | 21000686009 | 2 |
| Caesar & Loretz GmbH | Fructose | 21000686015 | 1 |
| Caesar & Loretz GmbH | Fructose | 21000686016 | 1 |
| Caesar & Loretz GmbH | Fructose | 21000686020 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Fructose | 21000686022 | 3 |
| Caesar & Loretz GmbH | Fructose | 21000686024 | 1 |
| Caesar & Loretz GmbH | Fructose | 22003150003 | 1 |
| Caesar & Loretz GmbH | Fructose | 22003150007 | 1 |
| Caesar & Loretz/Geil... | Fructose | 18291602 | 1 |
| Caesar u. Loretz GmbH | Fructose | 18082002 | 1 |
| Caesar u. Loretz GmbH | Fructose | 19169904 | 1 |
| Caesar&Loretz/Noweda | Fructose | 18082005 | 1 |
| Ebert & Jacobi 08.08.16 | Fructose | 1604024-01 | 1 |
| Eigen | Fructose | 122F21 | 1 |
| Eigen | Fructose | 127D21 | 1 |
| Eigen | Fructose | 128I20 | 1 |
| Eigenherstellung Defektur | Fructose | 5082101 | 1 |
| Eigenherstellung | Fructose | 112K21 | 1 |
| EuRho / Fiebig | Fructose | 1910020-01 | 1 |
| EuRho/Alliance | Fructose | 2006019-01 | 2 |
| Eurho/Gehe | Fructose | 190601701 | 1 |
| EuRho/Gehe | Fructose | 1906017-01 | 2 |
| EuRho/Noweda | Fructose | 1604024-01 | 1 |
| EuRho | Fructose | 1503045-01 | 1 |
| EuRho | Fructose | 1509037-01 | 4 |
| EuRho | Fructose | 1705002-01 | 2 |
| EuRho | Fructose | 171003401 | 2 |
| EuRho | Fructose | 1710034-01 | 3 |
| EuRho | Fructose | 1803040-01 | 1 |
| EuRho | Fructose | 1803040-02 | 2 |
| EuRho | Fructose | 2006019-19 | 1 |
| Euro OTC | Fructose | 1201017-01 | 2 |
| Euro OTC | Fructose | 1205022-01 | 1 |
| Euro OTC | Fructose | 1209010-01 | 1 |
| Euro OTC | Fructose | 121201-01pzn | 1 |
| Euro OTC | Fructose | 1212015-01 | 2 |
| Euro OTC | Fructose | 12E29-N08 | 1 |
| Euro OTC | Fructose | 1307022-01 | 4 |
| Euro OTC | Fructose | 140100401 | 1 |
| Euro OTC | Fructose | 1401004-01 | 4 |
| Euro OTC | Fructose | 141000901 | 2 |
| Euro OTC | Fructose | 1410009-01 | 6 |
| Euro OTC | Fructose | 148890 | 1 |
| Euro OTC | Fructose | 1503045-01 | 7 |
| Euro OTC | Fructose | 1509037-01 | 9 |
| Euro OTC | Fructose | 1512009-01 | 9 |
| Euro OTC | Fructose | 1604024-01 | 4 |
| Euro OTC | Fructose | 1607030-01 | 16 |
| Euro OTC | Fructose | 1610033 | 1 |
| Euro OTC | Fructose | 1610033-01 | 12 |
| Euro OTC | Fructose | 1701049-01 | 15 |
| Euro OTC | Fructose | 170500201 | 1 |
| Euro OTC | Fructose | 1705002-01 | 10 |
| Euro OTC | Fructose | 171003401 | 1 |
| Euro OTC | Fructose | 1710034-01 | 32 |
| Euro OTC | Fructose | 180304001 | 1 |
| Euro OTC | Fructose | 1803040-01 | 36 |
| Euro OTC | Fructose | 1803040-012 | 1 |
| Euro OTC | Fructose | 1803040-02 | 1 |
| Euro OTC | Fructose | 1803040-03 | 1 |
| Euro OTC | Fructose | 1803040-1 | 1 |
| Euro OTC | Fructose | 18082002 | 1 |
| Euro OTC | Fructose | 181018-01 | 1 |
| Euro OTC | Fructose | 1811018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Fructose | 1811018-01 | 39 |
| Euro OTC | Fructose | 19006017-01 | 1 |
| Euro OTC | Fructose | 1906017-01 | 30 |
| Euro OTC | Fructose | 1910020-01 | 22 |
| Euro OTC | Fructose | 2006019-01 | 19 |
| Euro OTC | Fructose | 2006019-02 | 1 |
| Euro OTC | Fructose | 2102008-002 | 1 |
| Euro OTC | Fructose | 2102008-01 | 16 |
| Euro OTC | Fructose | 2102008-02 | 10 |
| Euro OTC | Fructose | 2203030_01 | 1 |
| Euro OTC | Fructose | 220303001 | 3 |
| Euro OTC | Fructose | 2203030-01 | 20 |
| Euro OTC | Fructose | 2203030-02 | 2 |
| Euro OTC | Fructose | 2212011-02 | 2 |
| Euro OTC | Fructose | 252004-1902 | 1 |
| Euro OTC | Fructose | 252201-0209 | 1 |
| Euro OTC | Fructose | 252207-4204 | 1 |
| Euro OTC | Fructose | 2731 | 1 |
| Euro OTC | Fructose | AD15190330 | 1 |
| Euro OTC | Fructose | AD16C91215 | 1 |
| Euro OTC | Fructose | FS2P00251707-304 | 1 |
| Euro OTC | Fructose | FS2P00251802-122 | 1 |
| Euro/ Jenne | Fructose | 1604024-01 | 1 |
| euro//Noweda | Fructose | 1509037-01 | 1 |
| euro//Noweda | Fructose | 1710034-01 | 1 |
| Euro/Gehe | Fructose | 1604024-01 | 1 |
| Euro/Gehe | Fructose | 1607030-01 | 1 |
| Euro/Noweda | Fructose | 1610033-01 | 2 |
| Euro/Phönix | Fructose | 1906017-01 | 2 |
| Euro/Sanacorp | Fructose | 1509037-01 | 1 |
| euroct/gehe | Fructose | 1212015-01 | 1 |
| Europh/Ph | Fructose | 1906017-01 | 1 |
| Europh/Ph | Fructose | 1910020-01 | 2 |
| Fagron | Fructose | 1107-N06 | 1 |
| Fagron | Fructose | 1170 | 1 |
| Fagron | Fructose | 12A26-N04 | 1 |
| Fagron | Fructose | 12E29-N08 | 3 |
| Fagron | Fructose | 12H01-N03 | 1 |
| Fagron | Fructose | 12Ho1-N03 | 1 |
| Fagron | Fructose | 12K28-N06 | 2 |
| Fagron | Fructose | 13098906 | 1 |
| Fagron | Fructose | 1312A-03394 | 1 |
| Fagron | Fructose | 13A28-N01 | 10 |
| Fagron | Fructose | 13C25-N03 | 3 |
| Fagron | Fructose | 13E27-n07 | 1 |
| Fagron | Fructose | 13E27-N07 | 2 |
| Fagron | Fructose | 13J18-B06 | 2 |
| Fagron | Fructose | 13J18-B06-286894 | 1 |
| Fagron | Fructose | 13J18B06286896 | 1 |
| Fagron | Fructose | 13J18-B06-286899 | 1 |
| Fagron | Fructose | 13J18-B06-292061 | 1 |
| Fagron | Fructose | 14E01-B04 | 3 |
| Fagron | Fructose | 14E01-B04-29350 | 1 |
| Fagron | Fructose | 14E01-B04-293505 | 6 |
| Fagron | Fructose | 14E01B04293506 | 1 |
| Fagron | Fructose | 14E01-B04-293506 | 2 |
| Fagron | Fructose | 14E01-B04-297098 | 2 |
| Fagron | Fructose | 14E1-B04-293506 | 1 |
| Fagron | Fructose | 14k17-B99 | 2 |
| Fagron | Fructose | 14K17-B99 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Fructose | 14K17-B99-300913 | 1 |
| Fagron | Fructose | 15/21-B01 | 1 |
| Fagron | Fructose | 15/21-B01-312700 | 1 |
| Fagron | Fructose | 15/21-B01-323021 | 1 |
| Fagron | Fructose | 1521-B01-323021 | 1 |
| Fagron | Fructose | 15A16-B07 | 1 |
| Fagron | Fructose | 15A16-B07-303124 | 2 |
| Fagron | Fructose | 15A16-B07-305241 | 1 |
| Fagron | Fructose | 15A16-B07-308950 | 3 |
| Fagron | Fructose | 15I21-B01 | 1 |
| Fagron | Fructose | 15I21-B01-323020 | 1 |
| Fagron | Fructose | 15I21-B01-323021 | 5 |
| Fagron | Fructose | 15l21-B01-312701 | 2 |
| Fagron | Fructose | 15l21-B01-323021 | 1 |
| Fagron | Fructose | 16H05-B01 | 2 |
| Fagron | Fructose | 16H05-B01-326259 | 1 |
| Fagron | Fructose | 16H05-B01-330164 | 3 |
| Fagron | Fructose | 17007701 | 1 |
| Fagron | Fructose | 1705002-01 | 1 |
| Fagron | Fructose | 18082005 | 1 |
| Fagron | Fructose | 181018-01 | 1 |
| Fagron | Fructose | 1910020-01 | 1 |
| Fagron | Fructose | 19C19-B02-361846 | 1 |
| Fagron | Fructose | 3014Q-03394 | 1 |
| Fagron | Fructose | 326259 | 1 |
| Fagron | Fructose | 508Q-03394 | 1 |
| Fagron | Fructose | 516Q-03394 | 1 |
| Fagron | Fructose | 5217M-03394 | 1 |
| Fagron | Fructose | 7K21-N12 | 1 |
| Fagron | Fructose | FR1413072 | 1 |
| Fagron | Fructose | FR1443072 | 8 |
| Fagron | Fructose | FR1713142 | 2 |
| Fagron | Fructose | K43537721 | 2 |
| Fargon | Fructose | 15I21-B01-312701 | 1 |
| Fiebig | Fructose | 19169903 | 1 |
| Finteler Apotheke | Fructose | 16283910 | 1 |
| fragon | Fructose | FR1413072 | 1 |
| Gatt Koller | Fructose | 1544/05141914 | 1 |
| Gatt-Koller / Phoenix | Fructose | 3156/0813 | 1 |
| GEHE 17.06.2014 | Fructose | 13098913 | 1 |
| Gehe/EuRo | Fructose | 1607030-01 | 3 |
| Gehe | Fructose | 1607030-01 | 2 |
| Gehe | Fructose | 17346404 | 1 |
| GEHE | Fructose | 1803040-01 | 2 |
| Gehe | Fructose | 18082005 | 1 |
| GEHE | Fructose | 1811018-01 | 2 |
| Gehe | Fructose | 1906017-01 | 1 |
| Gehe | Fructose | 2006019-01 | 1 |
| gehe | Fructose | 210200802 | 1 |
| Gehe | Fructose | 22003150021 | 2 |
| Gehe | Fructose | 2203030-01 | 2 |
| Gehe | Fructose | 23003367001 | 1 |
| Geilenkirchen | Fructose | 17007707 | 1 |
| Geilenkirchen | Fructose | 17143904 | 1 |
| Geilenkirchen | Fructose | 18082012 | 1 |
| Geilenkirchen | Fructose | 180822 | 1 |
| Geilenkirchen | Fructose | 18291613 | 7 |
| Geilenkirchen | Fructose | 19169904 | 2 |
| Jenne | Fructose | 14A16-B07 | 1 |
| Jenne | Fructose | 15A16-B07 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Jenne | Fructose | 22003150003 | 2 |
| Kehr | Fructose | 23003367001 | 1 |
| Lihn/Reformhaus | Fructose | 713E-03394 | 2 |
| Max Jenne | Fructose | 221201101 | 1 |
| Nachprüfung | Fructose | 1906017-01 | 1 |
| Noweda/Caesar & Lore… | Fructose | 18082002 | 3 |
| Noweda | Fructose | 1205022-01 | 1 |
| Noweda | Fructose | 16283910 | 1 |
| Noweda | Fructose | 1710034-01 | 4 |
| Noweda | Fructose | 17143902 | 1 |
| Noweda | Fructose | 1906017-01 | 2 |
| Noweda | Fructose | 1910020-01 | 2 |
| Noweda | Fructose | 19169903 | 1 |
| Noweda | Fructose | 20003599001 | 1 |
| Noweda | Fructose | 2003150015 | 1 |
| Noweda | Fructose | 2203030-02 | 1 |
| Noweda | Fructose | 23003367001 | 2 |
| Noweda | Fructose | 2309017-01 | 3 |
| noweda | Fructose | 24002305001 | 1 |
| Noweda | Fructose | 2405018-01 | 1 |
| Noweda | Fructose | FS2P00251808-502 | 1 |
| Phoenix 05.08.2014 | Fructose | FR1336122 | 3 |
| Phoenix 11.12.2018 | Fructose | 1803040-01 | 1 |
| Phoenix 17.11.19 | Fructose | 1803044-01 | 1 |
| Phoenix 22.12.14 | Fructose | 1307022-01 | 1 |
| Phoenix 22.12.14 | Fructose | 1401004-01 | 1 |
| Phoenix Goettin | Fructose | 14E01-B04-293505 | 2 |
| Phoenix | Fructose | 15I21-B01 | 1 |
| phoenix | Fructose | 1906017-01 | 1 |
| Phoenix | Fructose | 1906017-01 | 1 |
| Phoenix | Fructose | 21000686015 | 1 |
| Phönisx | Fructose | 18291602 | 1 |
| Phönix 17.05.2019 | Fructose | 1811018-01 | 2 |
| Phönix Euro | Fructose | FS2P00251707-304 | 1 |
| Phönix | Fructose | 12K28-N06 | 1 |
| Phönix | Fructose | 14K17-B99-300913 | 3 |
| PHÖNIX | Fructose | 1710034-01 | 1 |
| PHÖNIX | Fructose | 17L22-B02 | 2 |
| PHÖNIX | Fructose | 17L22-B02-346104 | 1 |
| Phönix | Fructose | 22003150003 | 2 |
| Sanacorp | Fructose | 17346404 | 1 |
| Sanacorp | Fructose | 22003150002 | 1 |
| Sanacorp | Fructose | 22003150003 | 4 |
| Sanacorp | Fructose | 2212011-01 | 1 |
| Sanacorp | Fructose | K43537721 | 1 |
| Synopharm | Fructose | 202A052 | 1 |

- 255 468 spectra from 1666 *Apo-Ident* customers from a total of 51 849 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Fructose* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Fructose* and it was evaluated how


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many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 961 | 0 | 211 979 |
| **Type C** | 0 | 1417 | 1 | 255 468 |

The substance/substance group *Fructose* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3757 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.9295 % (> 99.7179 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21281 | 22481 | 11.39 | 96.69 |
| 21934 | 21934 | 0.00 | 92.89 |
| 22292 | 22292 | 0.00 | 92.92 |
| 22481 | 22481 | 0.00 | 94.17 |
| 22490 | 22292 | 5.32 | 94.03 |
| 22986 | 22986 | 0.00 | 92.22 |
| 23018 | 22292 | 5.78 | 93.59 |
| 23082 | 22481 | 7.10 | 94.05 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Furosemide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20944-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Furosemide; Furosemidum

### Special notes

When selecting the *Furosemide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Furosemide | 6 | 3 | 31 |

### Second-stage model

For differentiation of the substance/substance group *Furosemide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Furosemide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 158.06 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Furosemide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Furosemide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Furosemide | 13A22-N08 | 20944 | 40 | 1401379 |
| Fagron | Furosemide | 14K10-B02-301746 | 21819 | 60 | 20141215 |
| Fagron | Furosemide | 17D06-B01-338982 | 23940 | 40 | 20170626 |
| Fagron | Furosemide | 19I27-F04-366906 | 25044 | 40 | 20191218 |
| Fagron | Furosemide | 22L05-B06-225369 | 26607 | 40 | 20230104 |
| Fagron | Furosemide | 22L05-B06-225369 | 26607SI | 20 | 20230104 |
| Fagron | Furosemide | 23G05-B14-230372 | 26977 | 40 | 20230830 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 280 spectra of 7 reference samples from the substance/substance group *Furosemide*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 6 reference samples from the substance/substance group *Furosemide*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Furosemide | 16B15-B06-322860 | 23083 | 40 |
| Fagron | Furosemide | 20G10-F10-373076 | 25442 | 40 |
| Fagron | Furosemide | 21K30-B02-221074 | 26168 | 40 |
| Fagron | Furosemide | 16B15-B06-322860 | 23084 | 40 |
| Fagron | Furosemide | 21K30-B02-221074 | 26168SI | 20 |
| Fagron | Furosemide | 23G05-B14-230372 | 26977SI† | 20 |

- 212 740 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 79 spectra from 59 *Apo-Ident* customers from 37 batches from the substance/substance group *Furosemide*.
- Among them are spectra of independent samples from 31 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Furosemide | 20G10-F10-373076 | 1 |
| | Furosemide | 20G10-F10-374131 | 4 |
| | Furosemide | -23201008 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Furosemide | 23G05-B14230372 | 1 |
| | Furosemide | 23G05-B14-230372 | 1 |
| | Furosemide | 23G05-B14-234627 | 1 |
| AHC | Furosemide | 23G05-B14-230372 | 1 |
| Alliance Healthcare/... | Furosemide | 12/13-N06 | 1 |
| Caelo | Furosemide | 16B15-B06 | 1 |
| Caelo | Furosemide | 20G10-F10-374131 | 1 |
| Fagron | Furosemide | 1095H2RI | 1 |
| Fagron | Furosemide | 11K21-N26 | 1 |
| Fagron | Furosemide | 12A18-N03 | 1 |
| Fagron | Furosemide | 12I13-No6 | 1 |
| Fagron | Furosemide | 13A22-N08 | 4 |
| Fagron | Furosemide | 13E28-B40 | 2 |
| Fagron | Furosemide | 13E28-B40-289433 | 1 |
| Fagron | Furosemide | 13E28-B40-295538 | 1 |
| Fagron | Furosemide | 14K10-B02-301746 | 1 |
| Fagron | Furosemide | 15L10B02316506 | 1 |
| Fagron | Furosemide | 15L10-B02-316506 | 2 |
| Fagron | Furosemide | 16/26-B04-329253 | 2 |
| Fagron | Furosemide | 17d06-b01-335672 | 1 |
| Fagron | Furosemide | 17D06-B01-335672 | 2 |
| Fagron | Furosemide | 17D06-B01-338982 | 1 |
| Fagron | Furosemide | 18C27-B02 | 1 |
| Fagron | Furosemide | 18C27-B02-348148 | 2 |
| Fagron | Furosemide | 18C27-B02-351260 | 1 |
| Fagron | Furosemide | 19I27-F04-366906 | 2 |
| Fagron | Furosemide | -20200004 | 1 |
| Fagron | Furosemide | 20G10-F10 | 5 |
| Fagron | Furosemide | 20G10-F10-3730706 | 2 |
| Fagron | Furosemide | 20G10-F10373076 | 1 |
| Fagron | Furosemide | 20G10-F10-373076 | 16 |
| Fagron | Furosemide | 20G10-F10-373079 | 1 |
| Fagron | Furosemide | 20G10-F10-374131 | 3 |
| Fagron | Furosemide | AM20216066 | 1 |
| Fagron | Furosemide | F10-3730706 | 1 |
| Fagron | Furosemide | FRD-2B-202004 | 2 |
| Fagron | Furosemide | FUR-1A-192016 | 1 |
| IPCA/Noweda | Furosemide | 11D29-N08 | 1 |
| Noweda | Furosemide | 23G05-B14-230372 | 1 |
| Phoenix | Furosemide | 17D06-B01-338982 | 1 |
| Sanacorp | Furosemide | FUR-1A-192016 | 1 |

- 256 807 spectra from 1666 *Apo-Ident* customers from a total of 52 117 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Furosemide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Furosemide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 79 | 0 | 256 807 |

The substance/substance group *Furosemide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.4051 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20944 | 20944 | 0.00 | 378.08 |
| 21819 | 20944 | 11.27 | 374.40 |
| 23940 | 20944 | 10.05 | 376.56 |
| 25044 | 20944 | 4.37 | 382.51 |
| 26607 | 20944 | 7.99 | 385.58 |
| 26977 | 20944 | 8.55 | 387.99 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Fusidic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20780-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Fusidic acid; Acidum fusidicum

### Special notes

When selecting the *Fusidic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Fusidic acid | 6 | 3 | 37 |

### Second-stage model

For differentiation of the substance/substance group *Fusidic acid* the following second-stage model is used:

- Submodel 05

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Fusidic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 74.52 | – |
| ⋮ | ⋮ | ⋮ |
| Povidone | >50 | 80.20 |
| Povidone iodine | >50 | 91.01 |
| Progesterone | >50 | 116.26 |
| Spironolactone | >50 | 122.22 |
| Testosterone propionate | >50 | 177.14 |
| Ubidecarenone | >50 | 223.43 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Fusidic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Fusidic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Fusidic acid | 12G04-N01 | 20780 | 40 | 1401162 |
| Fagron | Fusidic acid | 13L13-B01-289513 | 21733 | 60 | 20140113 |
| Fagron | Fusidic acid | 14E01-B08-299791 | 21897 | 60 | 20140605 |
| Fagron | Fusidic acid | 20J21-F02-375395 | 25493 | 40 | 2104173 |
| Fagron | Fusidic acid | 23K21-B01-233624 | 27045 | 40 | 20231206 |
| Fagron | Fusidic acid | 24D18-B07-008392 | 27603 | 40 | 20250127 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:


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**Type A** All calibration spectra.

- 280 spectra of 6 reference samples from the substance/substance group *Fusidic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 6 reference samples from the substance/substance group *Fusidic acid*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Fusidic acid | 15I10-B02-322112 | 23069 | 40 |
| Fagron | Fusidic acid | 17J06-B02-343675 | 23943 | 40 |
| Fagron | Fusidic acid | 22E23-B03-220268 | 26296 | 40 |
| Fagron | Fusidic acid | 22E23-B03-220268 | 26296SI | 20 |
| Fagron | Fusidic acid | 23K21-B01-233624 | 27045SI† | 20 |
| Fagron | Fusidic acid | 24D18-B07-008392 | 27603SI† | 20 |

- 212 760 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 55 spectra from 25 *Apo-Ident* customers from 40 batches from the substance/substance group *Fusidic acid*.

- Among them are spectra of independent samples from 37 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Fusidic acid | 21H13-B05-213845 | 3 |
| | Fusidic acid | 21K17-B02-216070 | 1 |
| | Fusidic acid | 22E23-B03-220268 | 1 |
| Caelo | Fusidic acid | 21E12-F08-378510 | 1 |
| Ebert 24.08.16 | Fusidic acid | 1510-B02_319452 | 1 |
| Fagron | Fusidic acid | 1119I-03682 | 1 |
| Fagron | Fusidic acid | 116E-03682 | 1 |
| Fagron | Fusidic acid | 12B23-N03 | 1 |
| Fagron | Fusidic acid | 12G04-No1 | 1 |
| Fagron | Fusidic acid | 13A07-N10 | 2 |
| Fagron | Fusidic acid | 13H19-N05 | 1 |
| Fagron | Fusidic acid | 13L13-B01 | 1 |
| Fagron | Fusidic acid | 13L13-B01-289513 | 3 |
| Fagron | Fusidic acid | 13L13-B01-289514 | 1 |
| Fagron | Fusidic acid | 14E01-B08-299791 | 3 |
| Fagron | Fusidic acid | 15/10-b02 | 2 |
| Fagron | Fusidic acid | 15/10-B02-314192 | 1 |
| Fagron | Fusidic acid | 15/10-B02-319452 | 1 |
| Fagron | Fusidic acid | 1510-B02_319231 | 1 |
| Fagron | Fusidic acid | 15I10-B02 | 1 |
| Fagron | Fusidic acid | 15I10B02-319231 | 1 |
| Fagron | Fusidic acid | 15I10-B02-326182 | 1 |
| Fagron | Fusidic acid | 17G06-B99-337953 | 1 |
| Fagron | Fusidic acid | 17J06-B02-343677 | 1 |
| Fagron | Fusidic acid | 17J06-B02-345542 | 1 |
| Fagron | Fusidic acid | 17J06-B02-345885 | 1 |
| Fagron | Fusidic acid | 17J06-B02-355108 | 1 |
| Fagron | Fusidic acid | 20J21-F01-375395 | 1 |
| Fagron | Fusidic acid | 20J21-F02-375395 | 1 |
| Fagron | Fusidic acid | 20J21-F02-375397 | 2 |
| Fagron | Fusidic acid | 21D12-B08-213764 | 2 |
| Fagron | Fusidic acid | 21E12-F08 | 1 |
| Fagron | Fusidic acid | 21E12-F08-378510 | 2 |
| Fagron | Fusidic acid | 21H13-BO5-213845 | 1 |
| Fagron | Fusidic acid | 21K17-B02-216069 | 3 |
| Fagron | Fusidic acid | 318A-03682 | 1 |
| Fagron | Fusidic acid | 4113U-07034 | 1 |
| Fagron | Fusidic acid | FS655 | 1 |
| Noweda | Fusidic acid | 17J06-B02-349947 | 1 |
| Phoenix/Cealo | Fusidic acid | 701714-0003/0918A-07 | 1 |
| Phönix | Fusidic acid | F03-3691901 | 1 |
| Tagron | Fusidic acid | 17J06-B02-355108 | 1 |

- 256 831 spectra from 1666 *Apo-Ident* customers from a total of 52 113 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Fusidic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Fusidic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 55 | 0 | 256 831 |

The substance/substance group *Fusidic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 89.0909 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20780 | 20780 | 0.00 | 120.76 |
| 21733 | 20780 | 7.06 | 122.67 |
| 21897 | 20780 | 31.49 | 120.81 |
| 25493 | 25493 | 0.00 | 125.99 |
| 27045 | 20780 | 32.72 | 133.43 |
| 27603 | 20780 | 18.77 | 118.45 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Gabapentin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005490-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Gabapentin; Gabapentinum

### Special notes

When selecting the *Gabapentin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Gabapentin | 3 | 2 | 4 |

### Second-stage model

For differentiation of the substance/substance group *Gabapentin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Gabapentin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Tranexamic acid | 75.90 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Gabapentin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Gabapentin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Gabapentin | 21G13-B17-215252 | 26079 | 40 | 20220329 |
| Hikal Ltd. | Gabapentin | G71010620/077 | 25833 | 50 | 2203054 |
| Hikal Ltd. | Gabapentin | B71010621/105 | 25898 | 50 | 20211111 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 140 spectra of 3 reference samples from the substance/substance group *Gabapentin*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.
- 158 186 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 7 reference samples from the substance/substance group *Gabapentin*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Gabapentin | 22H02-B04-228420 | 26614 | 40 |
| MEDICHEM S.A. | Gabapentin | A-180101 | 25837 | 50 |
| Fagron | Gabapentin | 21G13-B17-215252 | 26079SI† | 40 |
| Fagron | Gabapentin | 22H02-B04-228420 | 26614SI | 20 |
| Hikal Ltd. | Gabapentin | G71010620/077 | 25833SI† | 10 |
| Hikal Ltd. | Gabapentin | B71010621/105 | 25898SI† | 10 |
| MEDICHEM S.A. | Gabapentin | A-180101 | 25837SI | 10 |

- 212 760 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 9 spectra from 3 *Apo-Ident* customers from 4 batches from the substance/substance group *Gabapentin*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Gabapentin | 22H02-B04-228420 | 3 |
| | Gabapentin | B04-2284200 | 4 |
| Fagron | Gabapentin | 21G13-B17-2152502 | 1 |
| INRESA/INRESA | Gabapentin | B71010621/409 | 1 |

- 256 877 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Gabapentin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Gabapentin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 140 | 0 | 158 186 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 9 | 0 | 256 877 |

The substance/substance group *Gabapentin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.7143 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25833 | 25833 | 0.00 | 142.45 |
| 25898 | 25833 | 16.50 | 149.80 |
| 26079 | 25833 | 17.53 | 149.37 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Galactose** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20326-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Galactose; Galactosum

### Special notes

When selecting the *Galactose* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Galactose | 4 | 3 | 27 |

### Second-stage model

For differentiation of the substance/substance group *Galactose* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Galactose* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 68.73 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Galactose* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Galactose*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Galactose | 13I13-B40-287993 | 21762 | 60 | AR-15-FG-008936-01 |
| Fagron | Galactose | 14H05-B09-310972 | 22259 | 60 | 20140818 |
| Fagron | Galactose | 18F14-B02-355816 | 25179 | 40 | 20181212 |
| Fagron | Galactose | 23H08-F01-385354 | 27032 | 40 | 20231009 |
| Fagron | Galactose | 23H08-F01-385354 | 27032SI | 20 | 20231009 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 220 spectra of 5 reference samples from the substance/substance group *Galactose*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 106 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 5 reference samples from the substance/substance group *Galactose*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Galactose | 15G13-B04-320810 | 23106 | 40 |
| Fagron | Galactose | 19G12-F50-373175 | 25443 | 40 |
| Fagron | Galactose | 24H01-B08-001699 | 27422 | 40 |
| Fagron | Galactose | 15G13-B04-320810 | 23595 | 40 |
| Fagron | Galactose | 24H01-B08-001699 | 27422SI | 20 |

- 212 760 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 39 spectra from 5 *Apo-Ident* customers from 28 batches from the substance/substance group *Galactose*.
- Among them are spectra of independent samples from 27 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Applichem | Galactose | 2L009814 | 1 |
| Fagron | Galactose | 16G22-B01-329906 | 1 |
| Falcento | Galactose | 10440003 | 1 |
| Falcento | Galactose | 1223PF4 | 3 |
| Falcento | Galactose | 122PF4 | 1 |
| Falcento | Galactose | 13223PF4 | 1 |
| Falcento | Galactose | 2014 | 1 |
| Falcento | Galactose | 2223PF4 | 3 |
| Falcento | Galactose | 222PF4 | 1 |
| Falcento | Galactose | 233619PF5 | 1 |
| falcento | Galactose | 322619PF5 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Falcento | Galactose | 48223PF2 | 1 |
| Falcento | Galactose | 5223PF4 | 3 |
| Falcento | Galactose | 72619PF7 | 1 |
| Falcento | Galactose | 82619PF64743/16 | 1 |
| Falcento | Galactose | 82619PF7 | 1 |
| Falcento | Galactose | 92619PF64744/16 | 1 |
| inalco | Galactose | 212619PF5 | 1 |
| inalco | Galactose | 32619PF8 | 1 |
| inalco | Galactose | 42619PF4 | 1 |
| Phönix 04.03.2014 | Galactose | | 1 |
| Phönix | Galactose | 12223PF4 | 2 |
| Phönix | Galactose | 39223PF3 | 1 |
| Unisan | Galactose | 382619PF5 | 1 |
| Unisan | Galactose | 432619PF5 | 1 |
| Unisan | Galactose | 442619PF5 | 1 |
| vwr chemicals | Galactose | 1F012304 | 1 |
| VWR | Galactose | 9Y013597 | 5 |

- 256 847 spectra from 1666 *Apo-Ident* customers from a total of 52 125 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Galactose* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Galactose* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 220 | 0 | 158 106 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 39 | 0 | 256 847 |

The substance/substance group *Galactose* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.2727 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 84.6154 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21762 | 21762 | 0.00 | 191.27 |
| 22259 | 21762 | 18.49 | 180.34 |
| 25179 | 21762 | 15.21 | 188.14 |
| 27032 | 21762 | 19.11 | 191.24 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Gelatine, white** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20206-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Gelatine, white; Gelatina alba

### Special notes

When selecting the *Gelatine, white* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Gelatine, white | 3 | 3 | 34 |

### Second-stage model

For differentiation of the substance/substance group *Gelatine, white* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Gelatine, white* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 42.13 | 32.51 |
| Cannabis flower, THC-dominant type | 55.59 | – |
| ⋮ | ⋮ | ⋮ |
| Colistin sulfate | >50 | 23.41 |
| Bacitracin | >50 | 24.30 |
| Cyanocobalamin | >50 | 38.60 |
| Amphotericin B | >50 | 56.71 |
| Nystatin | >50 | 56.89 |
| Calcium pantothenate | >50 | 58.89 |
| Methylcobalamin | >50 | 71.44 |
| Riboflavin | >50 | 73.80 |
| alpha-tocopheryl acetate dry concentrate | >50 | 79.57 |
| Triamcinolone | >50 | 94.35 |
| Calcium glycerophosphate | >50 | 101.75 |
| Carmellose sodium | >50 | 102.11 |
| Hyoscine hydrobromide | >50 | 113.10 |
| Estradiol hemihydrate | >50 | 126.47 |
| Tosylchloramide sodium | >50 | 134.48 |
| Estriol | >50 | 141.46 |
| SyrSpend® SF Alka | >50 | 149.74 |
| Rice starch | >50 | 161.49 |
| Oxalic acid | >50 | 169.12 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 180.56 |
| SyrSpend® SF pH4 | >50 | 195.11 |
| Corn starch | >50 | 235.33 |
| Acacia, dried dispersion | >50 | 237.43 |
| Potato starch | >50 | 288.68 |
| Wheat starch | >50 | 304.94 |
| Maltodextrin | >50 | 319.34 |
| Fructose | >50 | 322.29 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Gelatine, white* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Gelatine, white*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Gelatine, white | 11334025 | 20898 | 40 | 20111214 |
| Caelo | Gelatine, white | 15320504 | 22499 | 40 | AR-16-FG-014461-01 |
| Caelo | Gelatine, white | 15320504 | 22582 | 45 | AR-16-FG-011564-01 |
| Caelo | Gelatine, white | 20000813 | 25289 | 40 | 20200417* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 165 spectra of 4 reference samples from the substance/substance group *Gelatine, white*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.
- 158 161 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Gelatine, white*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Gelatine, white | 172772 | 23792 | 40 |
| Caelo | Gelatine, white | 154419 | 23793 | 40 |
| Caelo | Gelatine, white | 23002360 | 26943 | 40 |
| Caelo | Gelatine, white | 23002360 | 26943SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 49 spectra from 32 *Apo-Ident* customers from 35 batches from the substance/substance group *Gelatine, white*.

- Among them are spectra of independent samples from 34 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Gelatine, white | 2003763018 | 1 |
| Caealo/Phoenix | Gelatine, white | 20003763003 | 2 |
| Caelo | Gelatine, white | 11019308 | 1 |
| Caelo | Gelatine, white | 11334020 | 1 |
| Caelo | Gelatine, white | 11334025 | 4 |
| Caelo | Gelatine, white | 12354401 | 1 |
| Caelo | Gelatine, white | 12354507 | 3 |
| Caelo | Gelatine, white | 14130901 | 2 |
| Caelo | Gelatine, white | 14130912 | 1 |
| Caelo | Gelatine, white | 15084801 | 1 |
| Caelo | Gelatine, white | 15084806 | 1 |
| Caelo | Gelatine, white | 15320502 | 2 |
| Caelo | Gelatine, white | 15441902 | 1 |
| Caelo | Gelatine, white | 1544191916 | 1 |
| Caelo | Gelatine, white | 15441922 | 1 |
| Caelo | Gelatine, white | 17277207 | 1 |
| Caelo | Gelatine, white | 17277210 | 1 |
| Caelo | Gelatine, white | 190907004 | 1 |
| Caelo | Gelatine, white | 19090702 | 1 |
| Caelo | Gelatine, white | 19090706 | 1 |
| Caelo | Gelatine, white | 20003763001 | 1 |
| Caelo | Gelatine, white | 20003763004 | 1 |
| Caelo | Gelatine, white | 20003763006 | 1 |
| Caelo | Gelatine, white | 20003763009 | 2 |
| Caelo | Gelatine, white | 4110I-01578 | 1 |
| Caelo | Gelatine, white | 8031701 | 1 |
| Caelo | Gelatine, white | 8051811 | 1 |
| Caesar & Loretz GmbH... | Gelatine, white | 20003763002 | 1 |
| Caesar & Loretz GmbH... | Gelatine, white | 190907004 | 1 |
| Caesar & Loretz GmbH | Gelatine, white | 17277208 | 1 |
| Caesar & Loretz GmbH | Gelatine, white | 17277213 | 1 |
| Caesar & Loretz GmbH | Gelatine, white | 190907001 | 1 |
| Caesar & Loretz GmbH | Gelatine, white | 190907002 | 3 |
| canea Pharma/noweda | Gelatine, white | GR1617 | 1 |
| EuRho / 20 | Gelatine, white | 1106021-01 | 1 |
| Euro OTC | Gelatine, white | 1106021-01 | 2 |
| ROHA | Gelatine, white | 140110 | 1 |

- 256 837 spectra from 1666 *Apo-Ident* customers from a total of 52 119 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are docu-


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mented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Gelatine, white* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Gelatine, white* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 165 | 0 | 158 161 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 49 | 0 | 256 837 |

The substance/substance group *Gelatine, white* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.3636 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 87.7551 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20898 | 22582 | 9.17 | 96.63 |
| 22499 | 22499 | 0.00 | 95.74 |
| 22582 | 22582 | 0.00 | 92.39 |
| 25289 | 25289 | 0.00 | 99.16 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Gentamicin sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20640-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Gentamicin sulfate; Gentamicin sulphate; Gentamicini sulfas

### Special notes

When selecting the *Gentamicin sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Gentamicin sulfate | 18 | 10 | 379 |

### Second-stage model

For differentiation of the substance/substance group *Gentamicin sulfate* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Gentamicin sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 46.62 | – |
| Polymyxin B sulfate | 48.91 | – |
| Riboflavin sodium phosphate hydrate | 52.11 | 32.47 |
| ⋮ | ⋮ | ⋮ |
| Mg-Ca-K colamine phosphate | >50 | 38.95 |
| Magnesium citrate | >50 | 63.02 |
| Neomycin sulfate | >50 | 72.47 |
| Carbomers | >50 | 78.01 |
| Zinc gluconate | >50 | 102.17 |
| Tobramycin sulfate | >50 | 126.02 |
| Sodium tetraborate | >50 | 261.00 |
| Finasteride | >50 | 960.82 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Gentamicin sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Gentamicin sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Gentamicin sulfate | 13205003 | 21580 | 60 | 20130723 |
| Caelo | Gentamicin sulfate | 14353504 | 22604 | 40 | 20150119 |
| Caelo | Gentamicin sulfate | 192564 | 25201 | 40 | 20191218* |
| Caelo | Gentamicin sulfate | 192564 | 25201SI | 40 | 20191218* |
| Caelo | Gentamicin sulfate | 20003226 | 25638 | 40 | 20201029* |
| Caelo | Gentamicin sulfate | 20003226 | 25638SI | 40 | 20201029* |
| Euro OTC | Gentamicin sulfate | 1305047-01 | 21081 | 30 | 20130919 |
| Euro OTC | Gentamicin sulfate | 1305047-03 | 21582 | 60 | 1411076 |
| Euro OTC | Gentamicin sulfate | 1305047-03 | 21697 | 45 | AR-15-FG-012403-01 |
| Euro OTC | Gentamicin sulfate | 1506016 | 21837 | 60 | 0000010321 |

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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Gentamicin sulfate | 1610036 | 22857 | 40 | 20161124* |
| Euro OTC | Gentamicin sulfate | 1610036-01 | 23782 | 40 | 1804343 |
| Euro OTC | Gentamicin sulfate | 1711025 | 23882 | 40 | 20171206* |
| Euro OTC | Gentamicin sulfate | 1711025 | 23882SI | 40 | 20171206* |
| Euro OTC | Gentamicin sulfate | 1907036 | 24866 | 40 | 20190823* |
| Euro OTC | Gentamicin sulfate | 2003058 | 25252 | 40 | 20200603* |
| Euro OTC | Gentamicin sulfate | 2003058 | 25252SI | 40 | 20200603* |
| Euro OTC | Gentamicin sulfate | 2412004 | 27494 | 40 | 20250303* |
| Euro OTC | Gentamicin sulfate | 2412004 | 27494SI | 40 | 20250303* |
| Fagron | Gentamicin sulfate | 12B21-N02 | 20661 | 40 | 1411075 |
| Fagron | Gentamicin sulfate | 13I19-B05-286565 | 21578 | 60 | 20121214 |
| Fagron | Gentamicin sulfate | 14E08-B03-294848 | 21684 | 60 | 20140616 |
| Fagron | Gentamicin sulfate | 16B29-B01-328731 | 23210 | 40 | 20160411 |
| Fagron | Gentamicin sulfate | 19G17-B05-193462 | 25180 | 40 | 20190805 |
| Fagron | Gentamicin sulfate | 19G17-B05-193462 | 25180SI | 40 | 20190805 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 1095 spectra of 25 reference samples from the substance/substance group *Gentamicin sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 18 different batches.

- 157 231 spectra from a total of 2939 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1030 spectra of 23 reference samples from the substance/substance group *Gentamicin sulfate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Gentamicin sulfate | 170996 | 23335 | 40 |
| Caelo | Gentamicin sulfate | 183001 | 24357 | 40 |
| Caelo | Gentamicin sulfate | 23001024 | 27128 | 40 |
| Euro OTC | Gentamicin sulfate | 1604054 | 22568 | 40 |
| Euro OTC | Gentamicin sulfate | 1808013 | 24300 | 40 |
| Euro OTC | Gentamicin sulfate | 2107013 | 25825 | 50 |
| Euro OTC | Gentamicin sulfate | 2203032 | 26083 | 40 |
| Euro OTC | Gentamicin sulfate | 2210010 | 26434 | 40 |
| Fagron | Gentamicin sulfate | 22C17-B10-218675 | 26181 | 40 |
| Fagron | Gentamicin sulfate | 23G05-B07-232365 | 27612 | 40 |
| Caelo | Gentamicin sulfate | 13205003 | 21580SI† | 60 |
| Caelo | Gentamicin sulfate | 183001 | 24357SI | 40 |
| Caelo | Gentamicin sulfate | 23001024 | 27128SI | 40 |
| Euro OTC | Gentamicin sulfate | 1506016 | 21837SI† | 60 |
| Euro OTC | Gentamicin sulfate | 1808013 | 24300SI | 40 |
| Euro OTC | Gentamicin sulfate | 1907036 | 24866SI† | 40 |
| Euro OTC | Gentamicin sulfate | 2107013 | 25825SI | 50 |
| Euro OTC | Gentamicin sulfate | 2203032 | 26083SI | 50 |
| Euro OTC | Gentamicin sulfate | 2210010 | 26434SI | 40 |
| Fagron | Gentamicin sulfate | 13I19-B05-286565 | 21578SI† | 60 |
| Fagron | Gentamicin sulfate | 14E08-B03-294848 | 21684SI† | 60 |
| Fagron | Gentamicin sulfate | 22C17-B10-218675 | 26181SI | 40 |
| Fagron | Gentamicin sulfate | 23G05-B07-232365 | 27612SI | 40 |

- 211 910 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2800 spectra from 1052 *Apo-Ident* customers from 406 batches from the substance/substance group *Gentamicin sulfate*.

- Among them are spectra of independent samples from 376 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Gentamicin sulfate | | 1 |
| | Gentamicin sulfate | 1610038-01 | 1 |
| | Gentamicin sulfate | 20004483009 | 1 |
| | Gentamicin sulfate | 20004483012 | 1 |
| | Gentamicin sulfate | 2107013-01 | 3 |
| | Gentamicin sulfate | 2107013-02 | 2 |
| | Gentamicin sulfate | 210920013 | 3 |
| | Gentamicin sulfate | 2200075012 | 1 |
| | Gentamicin sulfate | 22000754001 | 4 |
| | Gentamicin sulfate | 22000754003 | 9 |
| | Gentamicin sulfate | 22000754006 | 8 |
| | Gentamicin sulfate | 22000754011 | 3 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Gentamicin sulfate | 22000754012 | 10 |
| | Gentamicin sulfate | 22000754013 | 7 |
| | Gentamicin sulfate | 2203032-01 | 10 |
| | Gentamicin sulfate | 2210010-01 | 5 |
| | Gentamicin sulfate | 2210010-02 | 12 |
| | Gentamicin sulfate | 2210010-03 | 18 |
| | Gentamicin sulfate | 22114-B01-227901 | 1 |
| | Gentamicin sulfate | 22C17-B010-223074 | 1 |
| | Gentamicin sulfate | 22C17-B10 | 2 |
| | Gentamicin sulfate | 22C17-B10_223074 | 1 |
| | Gentamicin sulfate | 22c17-b10-223074 | 1 |
| | Gentamicin sulfate | 22C17-B10-223074 | 6 |
| | Gentamicin sulfate | 22F28-B02-223061 | 1 |
| | Gentamicin sulfate | 22F28-B02-233049 | 3 |
| | Gentamicin sulfate | 22I14-B01-227901 | 5 |
| | Gentamicin sulfate | 22l14-B01-227901 | 1 |
| | Gentamicin sulfate | 23001024001 | 10 |
| | Gentamicin sulfate | 23001024004 | 29 |
| | Gentamicin sulfate | 2300102400418/24P | 1 |
| | Gentamicin sulfate | 23001024005 | 9 |
| | Gentamicin sulfate | 23G05-B07-236824 | 1 |
| | Gentamicin sulfate | 23H21-B03-002464 | 1 |
| | Gentamicin sulfate | 240000133004 | 1 |
| | Gentamicin sulfate | 240000133005 | 1 |
| | Gentamicin sulfate | 24000133004 | 15 |
| | Gentamicin sulfate | 2400013300445/24P | 1 |
| | Gentamicin sulfate | 24000133005 | 1 |
| | Gentamicin sulfate | 2400133005 | 1 |
| AHD /Pharmachem Pößneck | Gentamicin sulfate | 1506016-02 | 1 |
| AHD 14.07.2020 | Gentamicin sulfate | 1907036-01 | 2 |
| AHD 29.10.14 EK6,12 | Gentamicin sulfate | 13205004 | 1 |
| AHD Lamotte GmbH | Gentamicin sulfate | 1604054-02 | 1 |
| AHD | Gentamicin sulfate | 22000754003 | 1 |
| AHD | Gentamicin sulfate | 22000754006 | 1 |
| AHD | Gentamicin sulfate | 22000754012 | 1 |
| AHD | Gentamicin sulfate | 22000754013 | 1 |
| AHD | Gentamicin sulfate | 23001024001 | 1 |
| ALH | Gentamicin sulfate | 15258813 | 1 |
| ALH | Gentamicin sulfate | 15258816 | 1 |
| Alliance healfcare | Gentamicin sulfate | 17358616 | 1 |
| Alliance healfcare | Gentamicin sulfate | 17358618 | 1 |
| Alliance Healthcare | Gentamicin sulfate | 12G04-N16 | 1 |
| Alliance | Gentamicin sulfate | 23001024004 | 1 |
| Anzag | Gentamicin sulfate | 12146602 | 1 |
| Anzag | Gentamicin sulfate | 1305047-03 | 1 |
| Anzag | Gentamicin sulfate | 1407024-01 | 1 |
| Anzag | Gentamicin sulfate | 17K16-B09-343323 | 1 |
| Anzag | Gentamicin sulfate | 2210010-03 | 1 |
| Anzag | Gentamicin sulfate | 230713 | 1 |
| Anzag | Gentamicin sulfate | 241227(03110806) | 1 |
| Anzag | Gentamicin sulfate | 250130(2300024001) | 1 |
| Anzag | Gentamicin sulfate | 250325(23001024001) | 1 |
| Apo Ident/ Noweda | Gentamicin sulfate | 1711025 | 1 |
| Apotheke | Gentamicin sulfate | 2003058-02 | 2 |
| Audor Pharma | Gentamicin sulfate | 1604054-01 | 1 |
| Bombastus | Gentamicin sulfate | 1205021-01 | 1 |
| Bombastus | Gentamicin sulfate | 13024-N05 | 1 |
| Bombastus | Gentamicin sulfate | 17358616 | 1 |
| Bombastus | Gentamicin sulfate | 700175 | 1 |
| Caelo | Gentamicin sulfate | | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Gentamicin sulfate | 10(18300112) | 1 |
| Caelo | Gentamicin sulfate | 100017814 | 1 |
| Caelo | Gentamicin sulfate | 1106016-01 | 1 |
| Caelo | Gentamicin sulfate | 1106016-03 | 1 |
| Caelo | Gentamicin sulfate | 11113303 | 2 |
| Caelo | Gentamicin sulfate | 11113304 | 1 |
| Caelo | Gentamicin sulfate | 11113308 | 4 |
| Caelo | Gentamicin sulfate | 115258818 | 1 |
| Caelo | Gentamicin sulfate | 12011801 | 1 |
| Caelo | Gentamicin sulfate | 1205021-01 | 1 |
| Caelo | Gentamicin sulfate | 1205021-02 | 2 |
| Caelo | Gentamicin sulfate | 12146602 | 8 |
| Caelo | Gentamicin sulfate | 12146604 | 6 |
| Caelo | Gentamicin sulfate | 12146605 | 4 |
| Caelo | Gentamicin sulfate | 12146611 | 11 |
| Caelo | Gentamicin sulfate | 12146612 | 2 |
| Caelo | Gentamicin sulfate | 12163204 | 4 |
| Caelo | Gentamicin sulfate | 12163206 | 1 |
| Caelo | Gentamicin sulfate | 12163207 | 3 |
| Caelo | Gentamicin sulfate | 12163209 | 1 |
| Caelo | Gentamicin sulfate | 12258813 | 1 |
| Caelo | Gentamicin sulfate | 1260417 | 1 |
| Caelo | Gentamicin sulfate | 12G04-N16 | 2 |
| Caelo | Gentamicin sulfate | 130205005 | 1 |
| Caelo | Gentamicin sulfate | 1305047-03 | 3 |
| Caelo | Gentamicin sulfate | 1305047-03(2mal) | 1 |
| Caelo | Gentamicin sulfate | 13091207 | 1 |
| Caelo | Gentamicin sulfate | 13189602 | 5 |
| Caelo | Gentamicin sulfate | 13189603 | 3 |
| Caelo | Gentamicin sulfate | 13189606 | 6 |
| Caelo | Gentamicin sulfate | 13189607 | 11 |
| Caelo | Gentamicin sulfate | 13189608 | 2 |
| Caelo | Gentamicin sulfate | 13189611 | 10 |
| Caelo | Gentamicin sulfate | 13189612 | 13 |
| Caelo | Gentamicin sulfate | 13189613 | 1 |
| Caelo | Gentamicin sulfate | 13189614 | 2 |
| Caelo | Gentamicin sulfate | 13205003 | 10 |
| Caelo | Gentamicin sulfate | 13205004 | 2 |
| Caelo | Gentamicin sulfate | 13205005 | 19 |
| Caelo | Gentamicin sulfate | 13205006 | 6 |
| Caelo | Gentamicin sulfate | 13205007 | 2 |
| Caelo | Gentamicin sulfate | 13D24-N05 | 1 |
| Caelo | Gentamicin sulfate | 13I19-B05-286565 | 1 |
| Caelo | Gentamicin sulfate | 14081307 | 1 |
| Caelo | Gentamicin sulfate | 1435303 | 2 |
| Caelo | Gentamicin sulfate | 143533504 | 1 |
| Caelo | Gentamicin sulfate | 143535 | 1 |
| Caelo | Gentamicin sulfate | 14353502 | 3 |
| Caelo | Gentamicin sulfate | 14353503 | 14 |
| Caelo | Gentamicin sulfate | 14353504 | 12 |
| Caelo | Gentamicin sulfate | 14353505 | 3 |
| Caelo | Gentamicin sulfate | 14E08-B03-294841 | 1 |
| Caelo | Gentamicin sulfate | 14K28-B06-303636 | 1 |
| Caelo | Gentamicin sulfate | 14K28-B06-303646 | 3 |
| Caelo | Gentamicin sulfate | 150320G | 1 |
| Caelo | Gentamicin sulfate | 1506016-01 | 2 |
| Caelo | Gentamicin sulfate | 1506016-02 | 2 |
| Caelo | Gentamicin sulfate | 15128818 | 1 |
| Caelo | Gentamicin sulfate | 15226501 | 20 |
| Caelo | Gentamicin sulfate | 15226502 | 15 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Gentamicin sulfate | 1522650217099604 | 1 |
| Caelo | Gentamicin sulfate | 15226508 | 2 |
| Caelo | Gentamicin sulfate | 15226513 | 1 |
| Caelo | Gentamicin sulfate | 15226514 | 5 |
| Caelo | Gentamicin sulfate | 15226517 | 1 |
| Caelo | Gentamicin sulfate | 15226518 | 9 |
| Caelo | Gentamicin sulfate | 15258802 | 15 |
| Caelo | Gentamicin sulfate | 15258803 | 19 |
| Caelo | Gentamicin sulfate | 15258805 | 2 |
| Caelo | Gentamicin sulfate | 15258808 | 10 |
| Caelo | Gentamicin sulfate | 15258809 | 1 |
| Caelo | Gentamicin sulfate | 15258810 | 18 |
| Caelo | Gentamicin sulfate | 15258813 | 14 |
| Caelo | Gentamicin sulfate | 15258815 | 3 |
| Caelo | Gentamicin sulfate | 15258816 | 16 |
| Caelo | Gentamicin sulfate | 15258818 | 33 |
| Caelo | Gentamicin sulfate | 15258819 | 6 |
| Caelo | Gentamicin sulfate | 15258825 | 2 |
| Caelo | Gentamicin sulfate | 1528802 | 1 |
| Caelo | Gentamicin sulfate | 1528818 | 1 |
| Caelo | Gentamicin sulfate | 15B03-B07-309482 | 1 |
| Caelo | Gentamicin sulfate | 1604054-01 | 3 |
| Caelo | Gentamicin sulfate | 1604054-02 | 1 |
| Caelo | Gentamicin sulfate | 1604054-03 | 1 |
| Caelo | Gentamicin sulfate | 1610036-01 | 6 |
| Caelo | Gentamicin sulfate | 161003602 | 1 |
| Caelo | Gentamicin sulfate | 1610036-02 | 2 |
| Caelo | Gentamicin sulfate | 16119302 | 1 |
| Caelo | Gentamicin sulfate | 16b29-b01-328731 | 1 |
| Caelo | Gentamicin sulfate | 16B29-B01-328731 | 1 |
| Caelo | Gentamicin sulfate | 17081502 | 1 |
| Caelo | Gentamicin sulfate | 1709601 | 1 |
| Caelo | Gentamicin sulfate | 17099601 | 3 |
| Caelo | Gentamicin sulfate | 17099603 | 28 |
| Caelo | Gentamicin sulfate | 17099604 | 19 |
| Caelo | Gentamicin sulfate | 17099606 | 20 |
| Caelo | Gentamicin sulfate | 17099606-20180404Ma1 | 1 |
| Caelo | Gentamicin sulfate | 17099608 | 24 |
| Caelo | Gentamicin sulfate | 1710I-01582 | 1 |
| Caelo | Gentamicin sulfate | 1711025 | 1 |
| Caelo | Gentamicin sulfate | 1711025-01 | 2 |
| Caelo | Gentamicin sulfate | 1711025-02 | 4 |
| Caelo | Gentamicin sulfate | 17332419 | 1 |
| Caelo | Gentamicin sulfate | 17358603 | 35 |
| Caelo | Gentamicin sulfate | 17358604 | 14 |
| Caelo | Gentamicin sulfate | 17358607 | 2 |
| Caelo | Gentamicin sulfate | 17358609 | 39 |
| Caelo | Gentamicin sulfate | 17358609P-180201-2 | 1 |
| Caelo | Gentamicin sulfate | 17358610 | 11 |
| Caelo | Gentamicin sulfate | 17358616 | 38 |
| Caelo | Gentamicin sulfate | 17358618 | 14 |
| Caelo | Gentamicin sulfate | 17358619 | 1 |
| Caelo | Gentamicin sulfate | 17358623 | 1 |
| Caelo | Gentamicin sulfate | 17358909 | 1 |
| Caelo | Gentamicin sulfate | 1800104 | 1 |
| Caelo | Gentamicin sulfate | 18041804 | 1 |
| Caelo | Gentamicin sulfate | 180801301 | 2 |
| Caelo | Gentamicin sulfate | 1808013-01 | 2 |
| Caelo | Gentamicin sulfate | 183001001 | 1 |
| Caelo | Gentamicin sulfate | 183001002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Gentamicin sulfate | 183001004 | 20 |
| Caelo | Gentamicin sulfate | 18300103 | 7 |
| Caelo | Gentamicin sulfate | 18300104 | 26 |
| Caelo | Gentamicin sulfate | 18300108 | 12 |
| Caelo | Gentamicin sulfate | 18300109 | 41 |
| Caelo | Gentamicin sulfate | 183001112 | 1 |
| Caelo | Gentamicin sulfate | 18300112 | 28 |
| Caelo | Gentamicin sulfate | 18300113 | 27 |
| Caelo | Gentamicin sulfate | 18300114 | 9 |
| Caelo | Gentamicin sulfate | 18399104 | 1 |
| Caelo | Gentamicin sulfate | 18C12-B02-349026 | 1 |
| Caelo | Gentamicin sulfate | 18G06-B09-354797 | 1 |
| Caelo | Gentamicin sulfate | 18Go6-351916 | 1 |
| Caelo | Gentamicin sulfate | 190703601 | 1 |
| Caelo | Gentamicin sulfate | 1907036-01 | 1 |
| Caelo | Gentamicin sulfate | 192564002 | 31 |
| Caelo | Gentamicin sulfate | 192564003 | 19 |
| Caelo | Gentamicin sulfate | 192564004 | 2 |
| Caelo | Gentamicin sulfate | 192564008 | 1 |
| Caelo | Gentamicin sulfate | 192564009 | 9 |
| Caelo | Gentamicin sulfate | 192564010 | 22 |
| Caelo | Gentamicin sulfate | 19256402 | 1 |
| Caelo | Gentamicin sulfate | 19300109 | 1 |
| Caelo | Gentamicin sulfate | 19300113 | 1 |
| Caelo | Gentamicin sulfate | 200004483010 | 1 |
| Caelo | Gentamicin sulfate | 20004482002 | 21 |
| Caelo | Gentamicin sulfate | 20004482004 | 7 |
| Caelo | Gentamicin sulfate | 20004483 | 1 |
| Caelo | Gentamicin sulfate | 20004483001 | 36 |
| Caelo | Gentamicin sulfate | 200044830014 | 1 |
| Caelo | Gentamicin sulfate | 20004483005 | 12 |
| Caelo | Gentamicin sulfate | 20004483006 | 2 |
| Caelo | Gentamicin sulfate | 20004483007 | 17 |
| Caelo | Gentamicin sulfate | 20004483008 | 1 |
| Caelo | Gentamicin sulfate | 20004483009 | 8 |
| Caelo | Gentamicin sulfate | 20004483010 | 29 |
| Caelo | Gentamicin sulfate | 20004483011 | 1 |
| Caelo | Gentamicin sulfate | 20004483012 | 1 |
| Caelo | Gentamicin sulfate | 20004483013 | 4 |
| Caelo | Gentamicin sulfate | 20004483014 | 29 |
| Caelo | Gentamicin sulfate | 2000448310 | 1 |
| Caelo | Gentamicin sulfate | 2003058-02 | 1 |
| Caelo | Gentamicin sulfate | 2004483009 | 1 |
| Caelo | Gentamicin sulfate | 2004483014 | 2 |
| Caelo | Gentamicin sulfate | 20161102-4 | 1 |
| Caelo | Gentamicin sulfate | 20170829/1 | 1 |
| Caelo | Gentamicin sulfate | 2200075400 | 1 |
| Caelo | Gentamicin sulfate | 22000754001 | 17 |
| Caelo | Gentamicin sulfate | 22000754003 | 13 |
| Caelo | Gentamicin sulfate | 22000754006 | 14 |
| Caelo | Gentamicin sulfate | 22000754012 | 1 |
| Caelo | Gentamicin sulfate | 2200754001 | 1 |
| Caelo | Gentamicin sulfate | 23012015E | 1 |
| Caelo | Gentamicin sulfate | 2794 | 1 |
| Caelo | Gentamicin sulfate | 31032014E | 1 |
| Caelo | Gentamicin sulfate | 3110806 | 1 |
| Caelo | Gentamicin sulfate | 312012 | 1 |
| Caelo | Gentamicin sulfate | 3265 | 1 |
| Caelo | Gentamicin sulfate | 3714I-01582 | 1 |
| Caelo | Gentamicin sulfate | 4563125 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Gentamicin sulfate | 6082013C | 1 |
| Caelo | Gentamicin sulfate | 7011505 | 1 |
| Caelo | Gentamicin sulfate | 73402189 | 1 |
| Caelo | Gentamicin sulfate | 8702 | 1 |
| Caelo | Gentamicin sulfate | B18-1955204 | 1 |
| Caelo | Gentamicin sulfate | FG1503073 | 1 |
| Caelo | Gentamicin sulfate | FG1603072 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300113 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004482002 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483007 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 192564010 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 17358603 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 183001004 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 17358609 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483005 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300109 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004482002 | 1 |
| Caesar & Loretz GmbH/AEP | Gentamicin sulfate | 20004483010 | 1 |
| Caesar & Loretz GmbH/AHD | Gentamicin sulfate | 20004483007 | 1 |
| Caesar & Loretz GmbH/Gehe | Gentamicin sulfate | 20004483014 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483010 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300114 | 2 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004482004 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483009 | 1 |
| Caesar & Loretz GmbH/Kehr | Gentamicin sulfate | 18300112 | 1 |
| Caesar & Loretz GmbH/Kehr | Gentamicin sulfate | 192564010 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 192564010 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300104 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300113 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300104 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300114 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 192564002 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 192564008 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483005 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483013 | 1 |
| Caesar & Loretz GmbH/Otto | Gentamicin sulfate | 192564003 | 1 |
| Caesar & Loretz GmbH/Ph | Gentamicin sulfate | 183001004 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 192564010 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300112 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300113 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483001 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483007 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 22000754003 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 18300108 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 192564002 | 2 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 22000754003 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 183001004 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 192564010 | 2 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004482002 | 3 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483001 | 3 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483005 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483010 | 1 |
| Caesar & Loretz GmbH... | Gentamicin sulfate | 20004483014 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 14353503 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 17099604 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 17358607 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 17358609 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 17358610 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 17358616 | 5 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 17358618 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Gentamicin sulfate | 17358619 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 183001002 | 4 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 183001004 | 14 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300103 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300104 | 11 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300108 | 3 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300109 | 6 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300110 | 2 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300112 | 10 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300113 | 7 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 18300114 | 3 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 192564002 | 6 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 192564003 | 3 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 192564006 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 192564008 | 2 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 192564009 | 4 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 192564010 | 10 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 19256410 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004482002 | 6 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004482004 | 5 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483001 | 15 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483002 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483005 | 3 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483007 | 5 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483009 | 5 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483010 | 11 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483012 | 3 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483013 | 7 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004483014 | 6 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 20004486010 | 1 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 22000754001 | 3 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 22000754003 | 7 |
| Caesar & Loretz GmbH | Gentamicin sulfate | 22000754006 | 7 |
| Caesar & Loretz | Gentamicin sulfate | 17358603 | 1 |
| Caesar & Loretz | Gentamicin sulfate | 20004483007 | 1 |
| Caesar / Ebert | Gentamicin sulfate | 15258818 | 1 |
| Caesar&Loretz GmbH,2... | Gentamicin sulfate | 15258802 | 1 |
| Caesar&Loretz GmbH | Gentamicin sulfate | 15226501 | 1 |
| Caesar&Loretz GmbH | Gentamicin sulfate | 1907036-01 | 1 |
| Caleo/ Noweda | Gentamicin sulfate | 17099606 | 1 |
| Cealo / Anzag | Gentamicin sulfate | 211108(20004483007) | 1 |
| Cealo | Gentamicin sulfate | | 1 |
| Celo/Jenne | Gentamicin sulfate | 17099603 | 1 |
| CL/Gehe | Gentamicin sulfate | 17358616 | 1 |
| Ebert & Jacobi | Gentamicin sulfate | 1506016-01 | 1 |
| EuRho / Phönix | Gentamicin sulfate | 1610036-02 | 1 |
| Eurho AHD 20.11.19 E... | Gentamicin sulfate | 1808013-02 | 1 |
| Eurho Phönix | Gentamicin sulfate | 2107013-2 | 1 |
| EuRho/Gehe | Gentamicin sulfate | 2003058-01 | 1 |
| EuRho/Gehe | Gentamicin sulfate | 2003058-02 | 2 |
| EuRho/Krieger | Gentamicin sulfate | 1711025-02 | 1 |
| Eurho/Noweda | Gentamicin sulfate | 1604054-02 | 1 |
| EuRho/Noweda | Gentamicin sulfate | 1907036-01 | 2 |
| EuRho/Phoenix | Gentamicin sulfate | 1808013-02 | 1 |
| Eurho/Phönix | Gentamicin sulfate | 200305802 | 1 |
| EuRho/Phönix | Gentamicin sulfate | 2003058-02 | 1 |
| EuRho | Gentamicin sulfate | 1106016-03 | 1 |
| EuRho | Gentamicin sulfate | 1305047-01 | 1 |
| eurho | Gentamicin sulfate | 1711025-01 | 1 |
| EuRho | Gentamicin sulfate | 1711025-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Gentamicin sulfate | 1808013-01 | 8 |
| EuRho | Gentamicin sulfate | 190703601 | 1 |
| EuRho | Gentamicin sulfate | 1907036-01 | 2 |
| euRho | Gentamicin sulfate | 2003058-01 | 1 |
| EuRho | Gentamicin sulfate | 2203032-01 | 1 |
| EuRho | Gentamicin sulfate | FG1112482 | 1 |
| Eurimpharm1 | Gentamicin sulfate | 1604054-01 | 1 |
| euro AHD | Gentamicin sulfate | 1711025-015586 | 1 |
| Euro Gehe | Gentamicin sulfate | 1907036-01 | 1 |
| Euro Noweda | Gentamicin sulfate | FG1802035 | 1 |
| Euro OTC | Gentamicin sulfate | | 1 |
| Euro OTC | Gentamicin sulfate | 1106016-01 | 3 |
| Euro OTC | Gentamicin sulfate | 1106016-02 | 3 |
| Euro OTC | Gentamicin sulfate | 1106016-03 | 5 |
| Euro OTC | Gentamicin sulfate | 1205021-01 | 12 |
| Euro OTC | Gentamicin sulfate | 1205021-02 | 18 |
| Euro OTC | Gentamicin sulfate | 1305047 | 1 |
| Euro OTC | Gentamicin sulfate | 130504701 | 1 |
| Euro OTC | Gentamicin sulfate | 1305047-01 | 10 |
| Euro OTC | Gentamicin sulfate | 130504703 | 2 |
| Euro OTC | Gentamicin sulfate | 1305047-03 | 12 |
| Euro OTC | Gentamicin sulfate | 13189607 | 1 |
| Euro OTC | Gentamicin sulfate | 1407024 | 1 |
| Euro OTC | Gentamicin sulfate | 1407024-01 | 6 |
| Euro OTC | Gentamicin sulfate | 1407024-02 | 1 |
| Euro OTC | Gentamicin sulfate | 140702403 | 1 |
| Euro OTC | Gentamicin sulfate | 1407024-03 | 2 |
| Euro OTC | Gentamicin sulfate | 140702404 | 3 |
| Euro OTC | Gentamicin sulfate | 1407024-04 | 5 |
| Euro OTC | Gentamicin sulfate | 150601601 | 1 |
| Euro OTC | Gentamicin sulfate | 1506016-01 | 18 |
| Euro OTC | Gentamicin sulfate | 150601602 | 2 |
| Euro OTC | Gentamicin sulfate | 1506016-02 | 30 |
| Euro OTC | Gentamicin sulfate | 15258816 | 2 |
| Euro OTC | Gentamicin sulfate | 160405-03 | 1 |
| Euro OTC | Gentamicin sulfate | 160405401 | 1 |
| Euro OTC | Gentamicin sulfate | 1604054-01 | 23 |
| Euro OTC | Gentamicin sulfate | 1604054-02 | 14 |
| Euro OTC | Gentamicin sulfate | 1604054-03 | 4 |
| Euro OTC | Gentamicin sulfate | 1604054-3 | 1 |
| Euro OTC | Gentamicin sulfate | 161003601 | 3 |
| Euro OTC | Gentamicin sulfate | 1610036-01 | 21 |
| Euro OTC | Gentamicin sulfate | 1610036-015339 | 1 |
| Euro OTC | Gentamicin sulfate | 161003602 | 1 |
| Euro OTC | Gentamicin sulfate | 1610036-02 | 15 |
| Euro OTC | Gentamicin sulfate | 171025-02 | 1 |
| Euro OTC | Gentamicin sulfate | 1711025-01 | 37 |
| Euro OTC | Gentamicin sulfate | 171102502 | 1 |
| Euro OTC | Gentamicin sulfate | 1711025-02 | 17 |
| Euro OTC | Gentamicin sulfate | 17358609 | 2 |
| Euro OTC | Gentamicin sulfate | 1801813-02 | 1 |
| Euro OTC | Gentamicin sulfate | 180208G/1711025-01 | 1 |
| Euro OTC | Gentamicin sulfate | 1808013-01 | 23 |
| Euro OTC | Gentamicin sulfate | 180801302 | 2 |
| Euro OTC | Gentamicin sulfate | 1808013-02 | 35 |
| Euro OTC | Gentamicin sulfate | 180813-02 | 1 |
| Euro OTC | Gentamicin sulfate | 18C12-B02-349519 | 1 |
| Euro OTC | Gentamicin sulfate | 18G06-B09 | 1 |
| Euro OTC | Gentamicin sulfate | 1907035-01 | 1 |
| Euro OTC | Gentamicin sulfate | 1907036 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Gentamicin sulfate | 190703601 | 6 |
| Euro OTC | Gentamicin sulfate | 1907036-01 | 53 |
| Euro OTC | Gentamicin sulfate | 1907038-01 | 1 |
| Euro OTC | Gentamicin sulfate | 20003058-01 | 1 |
| Euro OTC | Gentamicin sulfate | 2003052-01 | 1 |
| Euro OTC | Gentamicin sulfate | 20030528-02 | 1 |
| Euro OTC | Gentamicin sulfate | 2003053-01 | 1 |
| Euro OTC | Gentamicin sulfate | 2003058 | 3 |
| Euro OTC | Gentamicin sulfate | 2003058-01 | 52 |
| Euro OTC | Gentamicin sulfate | 200305802 | 2 |
| Euro OTC | Gentamicin sulfate | 2003058-02 | 63 |
| Euro OTC | Gentamicin sulfate | 2003058-42 | 1 |
| Euro OTC | Gentamicin sulfate | 2107013 | 1 |
| Euro OTC | Gentamicin sulfate | 2107013-01 | 4 |
| Euro OTC | Gentamicin sulfate | 2107013-02 | 23 |
| Euro OTC | Gentamicin sulfate | 22000754003 | 1 |
| Euro OTC | Gentamicin sulfate | 2203032-01 | 7 |
| Euro OTC | Gentamicin sulfate | 2210010-02 | 1 |
| Euro OTC | Gentamicin sulfate | 2911034-02 | 1 |
| Euro OTC | Gentamicin sulfate | 4318A-01582 | 1 |
| Euro OTC | Gentamicin sulfate | 4988304 | 1 |
| Euro OTC | Gentamicin sulfate | 700175 | 1 |
| Euro OTC | Gentamicin sulfate | 80616-2 | 1 |
| Euro OTC | Gentamicin sulfate | FG11112482 | 1 |
| Euro OTC | Gentamicin sulfate | FG1501009 | 1 |
| Euro OTC | Gentamicin sulfate | FG1706157 | 1 |
| Euro OTC | Gentamicin sulfate | FG1709241 | 2 |
| Euro OTC | Gentamicin sulfate | FG1802035 | 3 |
| Euro OTC | Gentamicin sulfate | FG1908220 | 1 |
| Euro/Krieger | Gentamicin sulfate | 1711025-02 | 1 |
| Euro/Noweda | Gentamicin sulfate | 1610036-01 | 2 |
| Euro/Phönix | Gentamicin sulfate | 1808013-01 | 1 |
| Euro/Phönix | Gentamicin sulfate | 1907036-01 | 1 |
| Euro/Phönix | Gentamicin sulfate | 2003058-0208 | 1 |
| Euro/Sana | Gentamicin sulfate | 1808013-01 | 2 |
| EuRoh/ Gehe | Gentamicin sulfate | 17358616 | 1 |
| EuRoh/ Gehe | Gentamicin sulfate | 190703601 | 1 |
| Euroo/Noweda | Gentamicin sulfate | 2003058-02 | 1 |
| Euroo/Phoenix | Gentamicin sulfate | 1305047-03 | 1 |
| Fa.Phönix | Gentamicin sulfate | 20004483001 | 2 |
| Fagron | Gentamicin sulfate | | 1 |
| Fagron | Gentamicin sulfate | 10A29-N06 | 1 |
| Fagron | Gentamicin sulfate | 10C22N02 | 1 |
| Fagron | Gentamicin sulfate | 11/09-N10 | 1 |
| Fagron | Gentamicin sulfate | 1106016-01 | 1 |
| Fagron | Gentamicin sulfate | 11604054-01 | 1 |
| Fagron | Gentamicin sulfate | 11k21-n17 | 1 |
| Fagron | Gentamicin sulfate | 11K21-N17 | 2 |
| Fagron | Gentamicin sulfate | 1205021-02 | 1 |
| Fagron | Gentamicin sulfate | 1221-n02 | 1 |
| Fagron | Gentamicin sulfate | 12B21-N02 | 2 |
| Fagron | Gentamicin sulfate | 12D26-N05 | 7 |
| Fagron | Gentamicin sulfate | 12D6-N05 | 1 |
| Fagron | Gentamicin sulfate | 12G04-N16 | 2 |
| Fagron | Gentamicin sulfate | 12l17-no2 | 1 |
| Fagron | Gentamicin sulfate | 13/19-B05 | 1 |
| Fagron | Gentamicin sulfate | 13/19-B05-286568 | 1 |
| Fagron | Gentamicin sulfate | 13189607 | 1 |
| Fagron | Gentamicin sulfate | 1319-B05-286565 | 1 |
| Fagron | Gentamicin sulfate | 13D24-N05 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Gentamicin sulfate | 13F13-N01 | 1 |
| Fagron | Gentamicin sulfate | 13I19-B05 | 1 |
| Fagron | Gentamicin sulfate | 13I19-B05-286568 | 1 |
| Fagron | Gentamicin sulfate | 14081307 | 2 |
| Fagron | Gentamicin sulfate | 14A30-B04 | 3 |
| Fagron | Gentamicin sulfate | 14a30-b04-290858 | 1 |
| Fagron | Gentamicin sulfate | 14A30-B04-290858 | 1 |
| Fagron | Gentamicin sulfate | 14A30-B04-290861 | 2 |
| Fagron | Gentamicin sulfate | 14E08-B03 | 2 |
| Fagron | Gentamicin sulfate | 14E08-B03-294835 | 2 |
| Fagron | Gentamicin sulfate | 14E08-B03-294841 | 1 |
| Fagron | Gentamicin sulfate | 14E08-B03-294848 | 5 |
| Fagron | Gentamicin sulfate | 14e08b03300619 | 1 |
| Fagron | Gentamicin sulfate | 14E08-B03-300619 | 1 |
| Fagron | Gentamicin sulfate | 14K28-B06 | 3 |
| Fagron | Gentamicin sulfate | 14K28-B06_303646 | 1 |
| Fagron | Gentamicin sulfate | 14K28-B06-301951 | 1 |
| Fagron | Gentamicin sulfate | 14k28-b06-303640 | 2 |
| Fagron | Gentamicin sulfate | 14k28-B06-303640 | 1 |
| Fagron | Gentamicin sulfate | 14K28-B06-303640 | 4 |
| Fagron | Gentamicin sulfate | 14K28B06303646 | 2 |
| Fagron | Gentamicin sulfate | 14K28-B06-303646 | 5 |
| Fagron | Gentamicin sulfate | 15121722 | 2 |
| Fagron | Gentamicin sulfate | 15258802 | 1 |
| Fagron | Gentamicin sulfate | 15258816 | 2 |
| Fagron | Gentamicin sulfate | 15803-B07-309482 | 1 |
| Fagron | Gentamicin sulfate | 15B03-B07 | 1 |
| Fagron | Gentamicin sulfate | 15b03-b07-309482 | 1 |
| Fagron | Gentamicin sulfate | 15B03-B07-309482 | 2 |
| Fagron | Gentamicin sulfate | 15E04-B05-316255 | 2 |
| Fagron | Gentamicin sulfate | 15E04-B05-319740 | 1 |
| Fagron | Gentamicin sulfate | 15G29-B09-320305 | 3 |
| Fagron | Gentamicin sulfate | 15G29-B09-322928 | 1 |
| Fagron | Gentamicin sulfate | 15G29B09322936 | 1 |
| Fagron | Gentamicin sulfate | 15G29-B09-322936 | 2 |
| Fagron | Gentamicin sulfate | 15G29-B09-322945 | 2 |
| Fagron | Gentamicin sulfate | 15G29B0932632 | 1 |
| Fagron | Gentamicin sulfate | 15G29-B09-326632 | 4 |
| Fagron | Gentamicin sulfate | 15G29-B09-326635 | 2 |
| Fagron | Gentamicin sulfate | 1604054-01 | 2 |
| Fagron | Gentamicin sulfate | 16829-B01-328731 | 1 |
| Fagron | Gentamicin sulfate | 16B29-B01 | 1 |
| Fagron | Gentamicin sulfate | 16B29-B01-328731 | 4 |
| Fagron | Gentamicin sulfate | 16-B-29-B01-328731 | 1 |
| Fagron | Gentamicin sulfate | 16b29-b01-328915 | 1 |
| Fagron | Gentamicin sulfate | 16B29-B01-328915 | 2 |
| Fagron | Gentamicin sulfate | 17099606 | 1 |
| Fagron | Gentamicin sulfate | 17099608 | 1 |
| Fagron | Gentamicin sulfate | 1711025-01 | 1 |
| Fagron | Gentamicin sulfate | 17G27-B05 | 1 |
| Fagron | Gentamicin sulfate | 17G27-B05-340121 | 2 |
| Fagron | Gentamicin sulfate | 17k16-B09-343323 | 1 |
| Fagron | Gentamicin sulfate | 17K16-B09-343323 | 1 |
| Fagron | Gentamicin sulfate | 17K-16-B09-343323 | 1 |
| Fagron | Gentamicin sulfate | 180810051 | 1 |
| Fagron | Gentamicin sulfate | 18C12-B02 | 3 |
| Fagron | Gentamicin sulfate | 18C12-B02-349025 | 7 |
| Fagron | Gentamicin sulfate | 18C12-B02-349026 | 2 |
| Fagron | Gentamicin sulfate | 18C12-B02-349519 | 1 |
| Fagron | Gentamicin sulfate | 18C12-B02-350 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Gentamicin sulfate | 18C12B02350204 | 1 |
| Fagron | Gentamicin sulfate | 18C12-B02-350204 | 4 |
| Fagron | Gentamicin sulfate | 18G06-B09 | 2 |
| Fagron | Gentamicin sulfate | 18G06-B09-351916 | 6 |
| Fagron | Gentamicin sulfate | 18G06-B09-354797 | 9 |
| Fagron | Gentamicin sulfate | 1914Q-01582 | 1 |
| Fagron | Gentamicin sulfate | 19A22-B05-191434 | 18 |
| Fagron | Gentamicin sulfate | 19-B05-286568 | 1 |
| Fagron | Gentamicin sulfate | 19G17-805-193462 | 1 |
| Fagron | Gentamicin sulfate | 19G17-B05-193462 | 7 |
| Fagron | Gentamicin sulfate | 19G17-BO5-193462 | 2 |
| Fagron | Gentamicin sulfate | 19J15-B18-195524 | 2 |
| Fagron | Gentamicin sulfate | 2003058-02 | 1 |
| Fagron | Gentamicin sulfate | 20820-801-197708 | 1 |
| Fagron | Gentamicin sulfate | 20B20-B01 | 1 |
| Fagron | Gentamicin sulfate | 20B20-B01-1977008 | 1 |
| Fagron | Gentamicin sulfate | 20B20-B01-197708 | 12 |
| Fagron | Gentamicin sulfate | 20B20-B01-200399 | 1 |
| Fagron | Gentamicin sulfate | 20B20-B1-197708 | 1 |
| Fagron | Gentamicin sulfate | 20G27-802-202130 | 1 |
| Fagron | Gentamicin sulfate | 20G27-B02-201922 | 3 |
| Fagron | Gentamicin sulfate | 20G27-B02-202130 | 1 |
| Fagron | Gentamicin sulfate | 2107013-02 | 1 |
| Fagron | Gentamicin sulfate | 210920013 | 1 |
| Fagron | Gentamicin sulfate | 21D23-B07-213630 | 7 |
| Fagron | Gentamicin sulfate | 21D23-B07-215441 | 1 |
| Fagron | Gentamicin sulfate | 21I20-B09 | 1 |
| Fagron | Gentamicin sulfate | 21I20-B09-213601 | 2 |
| Fagron | Gentamicin sulfate | 22C17-B10 | 1 |
| Fagron | Gentamicin sulfate | 22C17-B10-218675 | 2 |
| Fagron | Gentamicin sulfate | 22C17-B10-223074 | 2 |
| Fagron | Gentamicin sulfate | 22F28-B02-223061 | 3 |
| Fagron | Gentamicin sulfate | 5214A-01582 | 1 |
| Fagron | Gentamicin sulfate | B01-1977008 | 2 |
| Fagron | Gentamicin sulfate | B02-2019202 | 2 |
| Fagron | Gentamicin sulfate | B02-3502004 | 2 |
| Fagron | Gentamicin sulfate | B05-1934602 | 3 |
| Fagron | Gentamicin sulfate | B09-3547907 | 1 |
| Fagron | Gentamicin sulfate | FG1212646 | 1 |
| Fagron | Gentamicin sulfate | FG1305122 | 1 |
| Fagron | Gentamicin sulfate | FG1709255 | 1 |
| Fagron | Gentamicin sulfate | FG1711309 | 2 |
| Fargon | Gentamicin sulfate | 13D24-N05 | 1 |
| Fargon | Gentamicin sulfate | 16b29-b01-328915 | 1 |
| Fargon | Gentamicin sulfate | 190110014 | 1 |
| Fargron/AHD | Gentamicin sulfate | 12G04-N16 | 1 |
| Fiebig | Gentamicin sulfate | 23001024001 | 1 |
| Fuijan/Noweda | Gentamicin sulfate | 18300108 | 1 |
| Fuijan/Noweda | Gentamicin sulfate | 192564009 | 1 |
| Fuijan/Phoenix | Gentamicin sulfate | FG1709243 | 3 |
| Fujan | Gentamicin sulfate | 2003058-02 | 1 |
| Fujian FP / Gehe | Gentamicin sulfate | 192564002 | 1 |
| Fujian Fukang Noweda | Gentamicin sulfate | 2210010-01 | 1 |
| Fujian Fukang Pharm... | Gentamicin sulfate | 17358603 | 1 |
| Fujian Fukang Pharma... | Gentamicin sulfate | 12D26-N05 | 2 |
| Fujian Fukang Pharma... | Gentamicin sulfate | 14A30-B04-290861 | 1 |
| Fujian Fukang Pharma... | Gentamicin sulfate | 14E08-B03-300619 | 1 |
| Fujian Fukang Pharma... | Gentamicin sulfate | 2003058-02 | 3 |
| Fujian Fukang Pharma... | Gentamicin sulfate | 12G04-N16 | 2 |
| Fujian Fukang Pharma... | Gentamicin sulfate | 14E08-B03-294848 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fujian/Noweda | Gentamicin sulfate | FG1802035 | 2 |
| Fujian | Gentamicin sulfate | FG1706157 | 1 |
| Gehe am 24.2.14 | Gentamicin sulfate | 1305047-01 | 1 |
| Gehe amax | Gentamicin sulfate | 1711025-01 | 1 |
| Gehe amax | Gentamicin sulfate | 2003058-01 | 1 |
| Gehe/EuRho | Gentamicin sulfate | 2203032-01 | 1 |
| Gehe/Euro | Gentamicin sulfate | 1610036-02 | 1 |
| Gehe | Gentamicin sulfate | | 1 |
| Gehe | Gentamicin sulfate | 12146604 | 1 |
| Gehe | Gentamicin sulfate | 13205007 | 1 |
| Gehe | Gentamicin sulfate | 14353505 | 1 |
| Gehe | Gentamicin sulfate | 15226517 | 1 |
| GEHE | Gentamicin sulfate | 15258808 | 1 |
| GEHE | Gentamicin sulfate | 15258815 | 1 |
| Gehe | Gentamicin sulfate | 15258818 | 1 |
| Gehe | Gentamicin sulfate | 15E04-B05-319740 | 1 |
| Gehe | Gentamicin sulfate | 1610036-01 | 1 |
| Gehe | Gentamicin sulfate | 17099606 | 1 |
| Gehe | Gentamicin sulfate | 1711025-01 | 1 |
| GEHE | Gentamicin sulfate | 17358603 | 2 |
| Gehe | Gentamicin sulfate | 17358609 | 1 |
| GEHE | Gentamicin sulfate | 17358609 | 1 |
| Gehe | Gentamicin sulfate | 1808013-01 | 1 |
| Gehe | Gentamicin sulfate | 1808013-02 | 1 |
| Gehe | Gentamicin sulfate | 18300103 | 1 |
| Gehe | Gentamicin sulfate | 18300108 | 1 |
| Gehe | Gentamicin sulfate | 18300109 | 2 |
| GEHE | Gentamicin sulfate | 18300109 | 1 |
| Gehe | Gentamicin sulfate | 1907036-01 | 1 |
| Gehe | Gentamicin sulfate | 19A22-B05-191434 | 1 |
| Gehe | Gentamicin sulfate | 19G17-B05-193462 | 1 |
| Gehe | Gentamicin sulfate | 20004482004 | 1 |
| Gehe | Gentamicin sulfate | 2002058-01 | 1 |
| Gehe | Gentamicin sulfate | 2003058-02 | 2 |
| Gehe | Gentamicin sulfate | 22000754003 | 1 |
| GEHE | Gentamicin sulfate | 22000754003 | 1 |
| Gehe | Gentamicin sulfate | 22000754013 | 2 |
| Gehe | Gentamicin sulfate | 2210010-01 | 1 |
| Gehe | Gentamicin sulfate | 22C17-B10-223074 | 2 |
| Gehe | Gentamicin sulfate | 22I14-B01-227901 | 1 |
| Gehe | Gentamicin sulfate | 23001024001 | 2 |
| Gehe | Gentamicin sulfate | 23001024004 | 1 |
| Gehe | Gentamicin sulfate | FG1307194 | 1 |
| Geilenkirchen | Gentamicin sulfate | 15258816 | 1 |
| Geilenkirchen | Gentamicin sulfate | 18300104 | 1 |
| Hedinger/Sanacorp | Gentamicin sulfate | 1711025-01 | 2 |
| Hedinger | Gentamicin sulfate | 1711025-01 | 1 |
| Ichthyol/ALH | Gentamicin sulfate | 15258810 | 1 |
| Jenne | Gentamicin sulfate | 20004482002 | 1 |
| Jenne | Gentamicin sulfate | 20004483014 | 1 |
| Jenne | Gentamicin sulfate | 22000754013 | 1 |
| Jenne | Gentamicin sulfate | 23001024004 | 1 |
| Jenne | Gentamicin sulfate | 250210(24000133004) | 1 |
| jujian | Gentamicin sulfate | 2003058-02 | 2 |
| Kehr | Gentamicin sulfate | 110036-02 | 1 |
| Kehr | Gentamicin sulfate | 22000754003 | 1 |
| kehr | Gentamicin sulfate | 22000754012 | 1 |
| Kehr | Gentamicin sulfate | 23001024004 | 2 |
| Kehr | Gentamicin sulfate | 24000133004 | 3 |
| Klosterring | Gentamicin sulfate | 15G29-B09 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Max Jenne | Gentamicin sulfate | 23001024001 | 1 |
| Mömerzheim | Gentamicin sulfate | 1711025-01 | 1 |
| Nachprüfung | Gentamicin sulfate | 123456 | 1 |
| Noweda Taucha | Gentamicin sulfate | 20004483014 | 1 |
| Noweda Taucha | Gentamicin sulfate | 2003058-02 | 1 |
| Noweda/ Caesar&Loren… | Gentamicin sulfate | 192564002 | 1 |
| Noweda | Gentamicin sulfate | 12146602 | 1 |
| Noweda | Gentamicin sulfate | 1305005 | 1 |
| Noweda | Gentamicin sulfate | 13189607 | 1 |
| Noweda | Gentamicin sulfate | 13189611 | 1 |
| Noweda | Gentamicin sulfate | 13189612 | 1 |
| Noweda | Gentamicin sulfate | 140702404 | 1 |
| Noweda | Gentamicin sulfate | 14353504 | 1 |
| Noweda | Gentamicin sulfate | 15226514 | 1 |
| Noweda | Gentamicin sulfate | 15258818 | 1 |
| Noweda | Gentamicin sulfate | 1711025-02 | 1 |
| Noweda | Gentamicin sulfate | 17358616 | 2 |
| Noweda | Gentamicin sulfate | 17358623 | 1 |
| Noweda | Gentamicin sulfate | 18300108 | 2 |
| Noweda | Gentamicin sulfate | 1907036-01 | 2 |
| noweda | Gentamicin sulfate | 192564003 | 1 |
| Noweda | Gentamicin sulfate | 192564003 | 1 |
| Noweda | Gentamicin sulfate | 20004483013 | 1 |
| Noweda | Gentamicin sulfate | 210920013 | 1 |
| Noweda | Gentamicin sulfate | 22000754003 | 1 |
| Noweda | Gentamicin sulfate | 22000754006 | 4 |
| Noweda | Gentamicin sulfate | 22000754012 | 2 |
| Noweda | Gentamicin sulfate | 2210010-03 | 1 |
| Noweda | Gentamicin sulfate | 23001024001 | 3 |
| Noweda | Gentamicin sulfate | 23001024004 | 1 |
| Noweda | Gentamicin sulfate | 23001024005 | 1 |
| Noweda | Gentamicin sulfate | 23G05-B07-236824 | 1 |
| Noweda | Gentamicin sulfate | 24000133004 | 1 |
| Noweda | Gentamicin sulfate | 24000133005 | 1 |
| Noweda | Gentamicin sulfate | B02-2019202 | 1 |
| ph euro | Gentamicin sulfate | 2003058-01 | 1 |
| PHOENIX 10.03.2014 | Gentamicin sulfate | 1305047 | 1 |
| Phoenix | Gentamicin sulfate | 12D26-N05 | 1 |
| Phoenix | Gentamicin sulfate | 1305047-03 | 1 |
| Phoenix | Gentamicin sulfate | 15226501 | 1 |
| Phoenix | Gentamicin sulfate | 15226502 | 1 |
| Phoenix | Gentamicin sulfate | 15258816 | 1 |
| Phoenix | Gentamicin sulfate | 1604054-02 | 1 |
| Phoenix | Gentamicin sulfate | 16b29-b01-328731 | 1 |
| Phoenix | Gentamicin sulfate | 17099603 | 1 |
| Phoenix | Gentamicin sulfate | 1711025-02 | 2 |
| phoenix | Gentamicin sulfate | 17358603 | 1 |
| Phoenix | Gentamicin sulfate | 17358603 | 1 |
| Phoenix | Gentamicin sulfate | 17G27-B05-340121 | 1 |
| Phoenix | Gentamicin sulfate | 18300108 | 1 |
| Phoenix | Gentamicin sulfate | 18300113 | 1 |
| Phoenix | Gentamicin sulfate | 2003058-01 | 1 |
| Phoenix | Gentamicin sulfate | 2107013-02 | 1 |
| Phoenix | Gentamicin sulfate | 22000754003 | 1 |
| Phoenix | Gentamicin sulfate | 23001024001 | 1 |
| Phoenix | Gentamicin sulfate | 23001024005 | 1 |
| Phoenix | Gentamicin sulfate | 3404 | 1 |
| phoenix | Gentamicin sulfate | FG2202039 | 1 |
| Phönix Gotha | Gentamicin sulfate | 13189611 | 1 |
| Phönix | Gentamicin sulfate | 11113309 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| phönix | Gentamicin sulfate | 1214605 | 1 |
| Phönix | Gentamicin sulfate | 12146602 | 1 |
| Phönix | Gentamicin sulfate | 13189611 | 1 |
| Phönix | Gentamicin sulfate | 14353502 | 1 |
| PHÖNIX | Gentamicin sulfate | 15226514 | 1 |
| Phönix | Gentamicin sulfate | 15258818 | 1 |
| Phönix | Gentamicin sulfate | 17099603 | 1 |
| Phönix | Gentamicin sulfate | 17099604 | 1 |
| phönix | Gentamicin sulfate | 18300103 | 1 |
| Phönix | Gentamicin sulfate | 18300109 | 2 |
| Phönix | Gentamicin sulfate | 192564009 | 1 |
| PHÖNIX | Gentamicin sulfate | 20004483001 | 1 |
| Phönix | Gentamicin sulfate | 2003058-01 | 2 |
| Phönix | Gentamicin sulfate | 22000754003 | 3 |
| phönix | Gentamicin sulfate | 22000754006 | 1 |
| Phönix | Gentamicin sulfate | 22000754013 | 2 |
| Phönix | Gentamicin sulfate | 23001024004 | 2 |
| Phönix | Gentamicin sulfate | 240001330004 | 1 |
| Phönix | Gentamicin sulfate | 24000133004 | 2 |
| Phönix | Gentamicin sulfate | 3141 | 1 |
| Sanacorp 06.01.15 EK 6,20 | Gentamicin sulfate | 1305047-03 | 1 |
| Sanacorp WE: 28.09.1… | Gentamicin sulfate | 15258825 | 1 |
| Sanacorp | Gentamicin sulfate | 1305047-03 | 1 |
| Sanacorp | Gentamicin sulfate | 13189607 | 1 |
| Sanacorp | Gentamicin sulfate | 13189608 | 1 |
| Sanacorp | Gentamicin sulfate | 161003601 | 1 |
| Sanacorp | Gentamicin sulfate | 1610036-01 | 2 |
| Sanacorp | Gentamicin sulfate | 1610036-02 | 1 |
| Sanacorp | Gentamicin sulfate | 161036-02 | 1 |
| Sanacorp | Gentamicin sulfate | 1711025-02 | 1 |
| Sanacorp | Gentamicin sulfate | 17358603 | 1 |
| Sanacorp | Gentamicin sulfate | 17358604 | 1 |
| Sanacorp | Gentamicin sulfate | 17358618 | 1 |
| Sanacorp | Gentamicin sulfate | 18300104 | 1 |
| Sanacorp | Gentamicin sulfate | 18300109 | 1 |
| Sanacorp | Gentamicin sulfate | 18300112 | 1 |
| sanacorp | Gentamicin sulfate | 18300113 | 1 |
| Sanacorp | Gentamicin sulfate | 18300113 | 1 |
| Sanacorp | Gentamicin sulfate | 18C12-B02-349026 | 1 |
| Sanacorp | Gentamicin sulfate | 19G17-B05-193462 | 1 |
| Sanacorp | Gentamicin sulfate | 2003058-02 | 3 |
| Sanacorp | Gentamicin sulfate | 2203032-01 | 2 |
| Sanacorp | Gentamicin sulfate | 23001024004 | 1 |
| Sanacorp | Gentamicin sulfate | 23001024005 | 1 |
| Sanacorp | Gentamicin sulfate | 24000133004 | 1 |
| Sanacorp | Gentamicin sulfate | FG1711309 | 1 |
| Sanarcorp | Gentamicin sulfate | 17099608 | 1 |
| vdl | Gentamicin sulfate | 12146602 | 1 |
| Yantai Justaware Ph.… | Gentamicin sulfate | 14081307 | 1 |
| Yantai Justaware Ph.… | Gentamicin sulfate | 14K28-B06_303646 | 1 |
| Yantai Justaware Pha… | Gentamicin sulfate | 14K28-B06 | 1 |

- 254 086 spectra from 1666 *Apo-Ident* customers from a total of 51 754 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Gentamicin sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Gentamicin sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 1095 | 0 | 157 231 |
| **Type B** | 0 | 1029 | 1 | 211 910 |
| **Type C** | 0 | 2723 | 77 | 254 086 |

The substance/substance group *Gentamicin sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.4521 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 99.9029 % (> 99.6117 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.2500 % (> 97.1429 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20661 | 20661 | 0.00 | 117.85 |
| 21081 | 21837 | 4.28 | 118.56 |
| 21578 | 25201 | 42.98 | 86.54 |
| 21580 | 21837 | 7.17 | 116.40 |
| 21582 | 21582 | 0.00 | 114.27 |
| 21684 | 21582 | 5.22 | 113.66 |
| 21697 | 21697 | 0.00 | 112.60 |
| 21837 | 21837 | 0.00 | 114.67 |
| 22604 | 21837 | 3.63 | 118.10 |
| 22857 | 22857 | 0.00 | 129.56 |
| 23210 | 27494 | 6.49 | 115.83 |
| 23782 | 23782 | 0.00 | 116.70 |
| 23882 | 23882 | 0.00 | 115.14 |
| 24866 | 24866 | 0.00 | 114.68 |
| 25180 | 22857 | 21.59 | 123.39 |
| 25201 | 25201 | 0.00 | 101.23 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25252 | 25252 | 0.00 | 118.60 |
| 25638 | 25638 | 0.00 | 97.81 |
| 27494 | 27494 | 0.00 | 116.90 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Glucose** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20982-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Glucose; Glucosum

### Special notes

When selecting the *Glucose* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Glucose | 6 | 3 | 259 |

### Second-stage model

For differentiation of the substance/substance group *Glucose* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Glucose* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 68.02 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Glucose* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Glucose*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Glucose | 12294514 | 20982 | 40 | 1402475 |
| Caelo | Glucose | 14033901 | 21363 | 40 | 20140214 |
| Caelo | Glucose | 14142310 | 21703 | 45 | 20140523 |
| Caelo | Glucose | 16050501 | 22586 | 40 | 20160317 |
| Caelo | Glucose | 190380 | 24511 | 40 | 20190411* |
| Caelo | Glucose | 22002306 | 26366 | 40 | 20220909* |
| Caelo | Glucose | 22002306 | 26366SI | 20 | 20220909* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 265 spectra of 7 reference samples from the substance/substance group *Glucose*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 061 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Glucose*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Glucose | 16157401 | 23583 | 40 |
| Caelo | Glucose | 180129 | 23820 | 40 |
| Caelo | Glucose | 24002221 | 27555 | 40 |
| Caelo | Glucose | 24002221 | 27555SI | 20 |

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1589 spectra from 332 *Apo-Ident* customers from 266 batches from the substance/substance group *Glucose*.

- Among them are spectra of independent samples from 258 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Glucose | | 1 |
| | Glucose | 21002549007 | 3 |
| | Glucose | 21002549009 | 1 |
| | Glucose | 21002549010 | 1 |
| | Glucose | 21002549012 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Glucose | 21002549013 | 1 |
| | Glucose | 21002549014 | 1 |
| | Glucose | 22002306002 | 1 |
| | Glucose | 22002306003 | 2 |
| | Glucose | 22002306004 | 2 |
| | Glucose | 22002306006 | 11 |
| | Glucose | 22002306008 | 1 |
| | Glucose | 22002306010 | 2 |
| | Glucose | 22003206006 | 1 |
| | Glucose | 23002088001 | 2 |
| | Glucose | 24000072002 | 1 |
| 21.03.2017 | Glucose | 6910499 | 1 |
| AHD | Glucose | 14033908 | 1 |
| AHD | Glucose | 21002549004 | 1 |
| AHD | Glucose | 21002549012 | 3 |
| AHD | Glucose | 21002549014 | 1 |
| AHD | Glucose | 22002306006 | 4 |
| AHD | Glucose | 22002306010 | 1 |
| Aliance Healthcare | Glucose | 21002549012 | 2 |
| Allianc. Healthc. /c | Glucose | 16050510 | 1 |
| Alliance Healthcare | Glucose | 22002306008 | 1 |
| Alliance | Glucose | 20004066006 | 1 |
| Alliance | Glucose | 22002306008 | 1 |
| Anzag | Glucose | 13329505 | 1 |
| Anzag | Glucose | 240118(21002549014) | 1 |
| Anzag | Glucose | 240709(22002306004) | 1 |
| apomix | Glucose | 13329509 | 2 |
| apomix | Glucose | 14033906 | 1 |
| Apotheke/Defektur Mi... | Glucose | | 1 |
| Apotheke-SiO2-Mischung | Glucose | 18/15 | 1 |
| Audor Pharma | Glucose | 16157402 | 3 |
| Bombastus | Glucose | 13178707 | 2 |
| Bombastus | Glucose | 160505202 | 1 |
| Caelo | Glucose | 1001313393 | 1 |
| Caelo | Glucose | 10091503 | 1 |
| Caelo | Glucose | 1061703 | 1 |
| Caelo | Glucose | 106213393 | 1 |
| Caelo | Glucose | 1114A03393 | 1 |
| Caelo | Glucose | 11358823 | 1 |
| Caelo | Glucose | 12041801 | 1 |
| Caelo | Glucose | 120718A | 1 |
| Caelo | Glucose | 12141705 | 1 |
| Caelo | Glucose | 12141706 | 3 |
| Caelo | Glucose | 12141711 | 1 |
| Caelo | Glucose | 12141714 | 2 |
| Caelo | Glucose | 12141715 | 1 |
| Caelo | Glucose | 12141717 | 1 |
| Caelo | Glucose | 12141718 | 3 |
| Caelo | Glucose | 12294505 | 3 |
| Caelo | Glucose | 12294509 | 2 |
| Caelo | Glucose | 12294509-3425311150 | 1 |
| Caelo | Glucose | 12294510 | 4 |
| Caelo | Glucose | 12294511 | 1 |
| Caelo | Glucose | 12294514 | 2 |
| Caelo | Glucose | 12294515 | 3 |
| Caelo | Glucose | 12294517 | 1 |
| Caelo | Glucose | 12294519 | 1 |
| Caelo | Glucose | 13041501 | 1 |
| Caelo | Glucose | 1317815 | 1 |
| Caelo | Glucose | 13178701 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose | 13178702 | 1 |
| Caelo | Glucose | 13178704 | 3 |
| Caelo | Glucose | 13178711 | 3 |
| Caelo | Glucose | 13178712 | 1 |
| Caelo | Glucose | 13178715 | 4 |
| Caelo | Glucose | 13178716 | 1 |
| Caelo | Glucose | 13178718 | 1 |
| Caelo | Glucose | 13329501 | 4 |
| Caelo | Glucose | 13329503 | 3 |
| Caelo | Glucose | 13329504 | 2 |
| Caelo | Glucose | 13329507 | 1 |
| Caelo | Glucose | 13329512 | 7 |
| Caelo | Glucose | 14033901 | 2 |
| Caelo | Glucose | 14033902 | 4 |
| Caelo | Glucose | 14033906 | 5 |
| Caelo | Glucose | 14033907 | 5 |
| Caelo | Glucose | 14033908 | 2 |
| Caelo | Glucose | 14051401 | 1 |
| Caelo | Glucose | 14051802 | 1 |
| Caelo | Glucose | 14142301 | 1 |
| Caelo | Glucose | 14142303 | 3 |
| Caelo | Glucose | 14142304 | 1 |
| Caelo | Glucose | 14142308 | 1 |
| Caelo | Glucose | 14142310 | 5 |
| Caelo | Glucose | 14142313 | 2 |
| Caelo | Glucose | 14142314 | 3 |
| Caelo | Glucose | 1415U-03393 | 1 |
| Caelo | Glucose | 14319302 | 1 |
| Caelo | Glucose | 14319304 | 6 |
| Caelo | Glucose | 14319308 | 1 |
| Caelo | Glucose | 14319309 | 3 |
| Caelo | Glucose | 14319310 | 2 |
| Caelo | Glucose | 1439304 | 1 |
| Caelo | Glucose | 15021801 | 1 |
| Caelo | Glucose | 15051301 | 1 |
| Caelo | Glucose | 15081831 | 1 |
| Caelo | Glucose | 1509500 | 3 |
| Caelo | Glucose | 15095001 | 8 |
| Caelo | Glucose | 15095003 | 4 |
| Caelo | Glucose | 15095004 | 3 |
| Caelo | Glucose | 15095005 | 2 |
| Caelo | Glucose | 15148801 | 4 |
| Caelo | Glucose | 15148802 | 6 |
| Caelo | Glucose | 15148803 | 1 |
| Caelo | Glucose | 15148807 | 4 |
| Caelo | Glucose | 15148808 | 4 |
| Caelo | Glucose | 15148809 | 1 |
| Caelo | Glucose | 15148810 | 4 |
| Caelo | Glucose | 15148813 | 1 |
| Caelo | Glucose | 15329001 | 6 |
| Caelo | Glucose | 15329002 | 3 |
| Caelo | Glucose | 15329004 | 4 |
| Caelo | Glucose | 15329005 | 6 |
| Caelo | Glucose | 15329006 | 11 |
| Caelo | Glucose | 15329008 | 2 |
| Caelo | Glucose | 15329010 | 2 |
| Caelo | Glucose | 160308G | 1 |
| Caelo | Glucose | 16050501 | 19 |
| Caelo | Glucose | 16050502 | 12 |
| Caelo | Glucose | 16050503 | 23 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose | 16050504 | 1 |
| Caelo | Glucose | 16050507 | 3 |
| Caelo | Glucose | 16050508 | 3 |
| Caelo | Glucose | 16050510 | 3 |
| Caelo | Glucose | 16101204 | 1 |
| Caelo | Glucose | 16101205 | 1 |
| Caelo | Glucose | 1614U3393 | 1 |
| Caelo | Glucose | 16157402 | 5 |
| Caelo | Glucose | 16157403 | 28 |
| Caelo | Glucose | 16157403160117/1 | 1 |
| Caelo | Glucose | 16157406 | 24 |
| Caelo | Glucose | 16157406160117/2 | 1 |
| Caelo | Glucose | 16157411 | 10 |
| Caelo | Glucose | 16328801 | 13 |
| Caelo | Glucose | 16328803 | 12 |
| Caelo | Glucose | 16328805 | 21 |
| Caelo | Glucose | 16328807 | 4 |
| Caelo | Glucose | 16328811 | 9 |
| Caelo | Glucose | 16328812 | 16 |
| Caelo | Glucose | 16328813 | 1 |
| Caelo | Glucose | 1638803 | 1 |
| Caelo | Glucose | 1650502 | 1 |
| Caelo | Glucose | 17041701 | 1 |
| Caelo | Glucose | 17111803 | 1 |
| Caelo | Glucose | 18012902 | 31 |
| Caelo | Glucose | 1801290246/18 | 1 |
| Caelo | Glucose | 18012903 | 3 |
| Caelo | Glucose | 18012905 | 16 |
| Caelo | Glucose | 18012907 | 39 |
| Caelo | Glucose | 18012909 | 14 |
| Caelo | Glucose | 18012910 | 2 |
| Caelo | Glucose | 18012911 | 6 |
| Caelo | Glucose | 18012912 | 29 |
| Caelo | Glucose | 18012913 | 8 |
| Caelo | Glucose | 18012914 | 17 |
| Caelo | Glucose | 18012915 | 26 |
| Caelo | Glucose | 18012916 | 1 |
| Caelo | Glucose | 18012917 | 10 |
| Caelo | Glucose | 18012920 | 4 |
| Caelo | Glucose | 18012921 | 38 |
| Caelo | Glucose | 18012922 | 7 |
| Caelo | Glucose | 18012923 | 3 |
| Caelo | Glucose | 18012926 | 3 |
| Caelo | Glucose | 18111702 | 1 |
| Caelo | Glucose | 1812913 | 1 |
| Caelo | Glucose | 19028005 | 1 |
| Caelo | Glucose | 190320011 | 1 |
| Caelo | Glucose | 190380002 | 5 |
| Caelo | Glucose | 190380003 | 38 |
| Caelo | Glucose | 190380006 | 8 |
| Caelo | Glucose | 190380007 | 1 |
| Caelo | Glucose | 190380009 | 32 |
| Caelo | Glucose | 19038001 | 7 |
| Caelo | Glucose | 190380011 | 2 |
| Caelo | Glucose | 19038002 | 46 |
| Caelo | Glucose | 19038003 | 6 |
| Caelo | Glucose | 19038005 | 12 |
| Caelo | Glucose | 19038006 | 14 |
| Caelo | Glucose | 19038007 | 41 |
| Caelo | Glucose | 19080009 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose | 1914I03393 | 1 |
| Caelo | Glucose | 20001066020 | 2 |
| Caelo | Glucose | 20004066 | 1 |
| Caelo | Glucose | 20004066001 | 5 |
| Caelo | Glucose | 20004066002 | 3 |
| Caelo | Glucose | 20004066003 | 1 |
| Caelo | Glucose | 20004066004 | 31 |
| Caelo | Glucose | 200040660042x | 1 |
| Caelo | Glucose | 20004066005 | 4 |
| Caelo | Glucose | 200040660058 | 1 |
| Caelo | Glucose | 20004066006 | 6 |
| Caelo | Glucose | 20004066008 | 49 |
| Caelo | Glucose | 20004066010 | 8 |
| Caelo | Glucose | 20004066011 | 5 |
| Caelo | Glucose | 20004066013 | 1 |
| Caelo | Glucose | 20004066014 | 1 |
| Caelo | Glucose | 20004066015 | 6 |
| Caelo | Glucose | 20004066017 | 8 |
| Caelo | Glucose | 20004066018 | 20 |
| Caelo | Glucose | 20004066019 | 2 |
| Caelo | Glucose | 20004066020 | 4 |
| Caelo | Glucose | 20004066021 | 7 |
| Caelo | Glucose | 20004066023 | 13 |
| Caelo | Glucose | 2000406608 | 1 |
| Caelo | Glucose | 2000406611 | 1 |
| Caelo | Glucose | 2004066008 | 1 |
| Caelo | Glucose | 2004066014 | 1 |
| Caelo | Glucose | 2004066021 | 1 |
| Caelo | Glucose | 2004066023 | 1 |
| Caelo | Glucose | 200406604 | 1 |
| Caelo | Glucose | 2013Q-03393 | 1 |
| Caelo | Glucose | 2021902 | 1 |
| Caelo | Glucose | 2051701 | 1 |
| Caelo | Glucose | 208223393 | 1 |
| Caelo | Glucose | 210002549007 | 1 |
| Caelo | Glucose | 210002549012 | 1 |
| Caelo | Glucose | 2100254009 | 1 |
| Caelo | Glucose | 21002549 | 1 |
| Caelo | Glucose | 21002549001 | 1 |
| Caelo | Glucose | 21002549002 | 2 |
| Caelo | Glucose | 21002549003 | 32 |
| Caelo | Glucose | 21002549004 | 7 |
| Caelo | Glucose | 21002549007 | 22 |
| Caelo | Glucose | 21002549008 | 2 |
| Caelo | Glucose | 21002549009 | 10 |
| Caelo | Glucose | 21002549011 | 1 |
| Caelo | Glucose | 21002549012 | 12 |
| Caelo | Glucose | 21002549013 | 4 |
| Caelo | Glucose | 21002549014 | 1 |
| Caelo | Glucose | 2102201301 | 1 |
| Caelo | Glucose | 214U-03393 | 1 |
| Caelo | Glucose | 220002306003 | 1 |
| Caelo | Glucose | 22002306003 | 1 |
| Caelo | Glucose | 23091401 | 1 |
| Caelo | Glucose | 250004066021 | 1 |
| Caelo | Glucose | 25061204 | 1 |
| Caelo | Glucose | 2513M03393 | 1 |
| Caelo | Glucose | 26041303 | 1 |
| Caelo | Glucose | 28111714 | 1 |
| Caelo | Glucose | 2x18012915 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose | 3121402 | 1 |
| Caelo | Glucose | 3214M-03393 | 1 |
| Caelo | Glucose | 3513I-03393 | 1 |
| Caelo | Glucose | 3918M-03393 | 1 |
| Caelo | Glucose | 402313393 | 2 |
| Caelo | Glucose | 4071505 | 1 |
| Caelo | Glucose | 4117I-03393 | 1 |
| Caelo | Glucose | 4313Q3393 | 1 |
| Caelo | Glucose | 4616I-03393 | 1 |
| Caelo | Glucose | 47131-03393 | 1 |
| Caelo | Glucose | 5013I3393 | 1 |
| Caelo | Glucose | 5081401 | 1 |
| Caelo | Glucose | 551616157406 | 1 |
| Caelo | Glucose | 6031505 | 1 |
| Caelo | Glucose | 6071717 | 1 |
| Caelo | Glucose | 69010513 | 1 |
| Caelo | Glucose | 7091705 | 1 |
| Caelo | Glucose | 712213393 | 1 |
| Caelo | Glucose | 8031703 | 1 |
| Caelo | Glucose | 8091810 | 1 |
| Caelo | Glucose | 85(06910499) | 1 |
| Caelo | Glucose | AKD14 | 1 |
| Caelo | Glucose | I-180716-1605010 | 1 |
| Caesar & Loretz GmbH... | Glucose | 21002549005 | 1 |
| Caesar & Loretz GmbH... | Glucose | 20004066018 | 2 |
| Caesar & Loretz GmbH... | Glucose | 21002549009 | 1 |
| Caesar & Loretz GmbH/AHD | Glucose | 190380003 | 3 |
| Caesar & Loretz GmbH... | Glucose | 18012921 | 3 |
| Caesar & Loretz GmbH... | Glucose | 20004066006 | 3 |
| Caesar & Loretz GmbH/Gehe | Glucose | 190380003 | 3 |
| Caesar & Loretz GmbH/Gehe | Glucose | 20004066011 | 1 |
| Caesar & Loretz GmbH/Gehe | Glucose | 21002549003 | 4 |
| Caesar & Loretz GmbH/Gehe | Glucose | 21002549007 | 1 |
| Caesar & Loretz GmbH... | Glucose | 19038002 | 2 |
| Caesar & Loretz GmbH... | Glucose | 21002549003 | 1 |
| Caesar & Loretz GmbH... | Glucose | 190380009 | 1 |
| Caesar & Loretz GmbH... | Glucose | 20004066013 | 1 |
| Caesar & Loretz GmbH/Phoe | Glucose | 20004066008 | 2 |
| Caesar & Loretz GmbH... | Glucose | 20004066017 | 1 |
| Caesar & Loretz GmbH... | Glucose | 19038002 | 1 |
| Caesar & Loretz GmbH... | Glucose | 21002549003 | 1 |
| Caesar & Loretz GmbH | Glucose | 16157403 | 1 |
| Caesar & Loretz GmbH | Glucose | 18012909 | 1 |
| Caesar & Loretz GmbH | Glucose | 18012912 | 1 |
| Caesar & Loretz GmbH | Glucose | 18012915 | 6 |
| Caesar & Loretz GmbH | Glucose | 18012921 | 7 |
| Caesar & Loretz GmbH | Glucose | 18012922 | 2 |
| Caesar & Loretz GmbH | Glucose | 18012926 | 1 |
| Caesar & Loretz GmbH | Glucose | 190380002 | 4 |
| Caesar & Loretz GmbH | Glucose | 190380003 | 10 |
| Caesar & Loretz GmbH | Glucose | 190380005 | 1 |
| Caesar & Loretz GmbH | Glucose | 190380009 | 5 |
| Caesar & Loretz GmbH | Glucose | 19038001 | 3 |
| Caesar & Loretz GmbH | Glucose | 190380010 | 2 |
| Caesar & Loretz GmbH | Glucose | 19038002 | 1 |
| Caesar & Loretz GmbH | Glucose | 19038005 | 2 |
| Caesar & Loretz GmbH | Glucose | 19038006 | 4 |
| Caesar & Loretz GmbH | Glucose | 19038007 | 9 |
| Caesar & Loretz GmbH | Glucose | 20004066002 | 3 |
| Caesar & Loretz GmbH | Glucose | 20004066004 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Glucose | 20004066005 | 2 |
| Caesar & Loretz GmbH | Glucose | 20004066007 | 1 |
| Caesar & Loretz GmbH | Glucose | 20004066008 | 2 |
| Caesar & Loretz GmbH | Glucose | 20004066010 | 1 |
| Caesar & Loretz GmbH | Glucose | 20004066011 | 1 |
| Caesar & Loretz GmbH | Glucose | 20004066017 | 1 |
| Caesar & Loretz GmbH | Glucose | 20004066018 | 1 |
| Caesar & Loretz GmbH | Glucose | 20004066020 | 2 |
| Caesar & Loretz GmbH | Glucose | 20004066022 | 1 |
| Caesar & Loretz GmbH | Glucose | 20004066023 | 2 |
| Caesar & Loretz GmbH | Glucose | 21002549002 | 3 |
| Caesar & Loretz GmbH | Glucose | 21002549003 | 4 |
| Caesar & Loretz GmbH | Glucose | 21002549004 | 2 |
| Caesar & Loretz GmbH | Glucose | 21002549007 | 4 |
| Caesar & Loretz GmbH | Glucose | 21002549008 | 2 |
| Caesar & Loretz GmbH | Glucose | 21002549009 | 1 |
| Caesar & Loretz GmbH | Glucose | 21002549012 | 2 |
| Caesar & Loretz GmbH | Glucose | 21002549013 | 1 |
| Caesar & Loretz GmbH | Glucose | 21002549014 | 1 |
| Caesar & Loretz GmbH | Glucose | 210025949007 | 1 |
| Caesar & Loretz GmbH | Glucose | 22002306002 | 1 |
| Caesar & Loretz Hild… | Glucose | 18012921 | 1 |
| Caesar & Loretz Hild… | Glucose | 190380003 | 2 |
| Caesar & Loretz Hild… | Glucose | 190380003190380009 | 1 |
| Caesar & Loretz Hild… | Glucose | 19038007 | 1 |
| Caesar & Loretz Hilden | Glucose | 18012914 | 2 |
| Caesar & Loretz Hilden | Glucose | 18012915 | 1 |
| Caesar & Loretz Hilden | Glucose | 19038002 | 3 |
| Caesar & Loretz Hilden | Glucose | 20004066004 | 1 |
| Caesar & Loretz | Glucose | 16157402 | 1 |
| Caesar & Loretz | Glucose | 18012923 | 1 |
| Caesar u. Loretz GmbH | Glucose | 190380003 | 2 |
| Caesar u. Loretz GmbH | Glucose | 190380009 | 1 |
| Caesar u. Loretz GmbH | Glucose | 20004066008 | 2 |
| Caesar&loretz,Anzag | Glucose | 12294509 | 1 |
| Caesar&Loretz | Glucose | 15148808 | 1 |
| Euro OTC | Glucose | | 1 |
| Euro OTC | Glucose | 15148808 | 1 |
| Euro OTC | Glucose | 16050501 | 1 |
| Euro OTC | Glucose | 16050502 | 2 |
| Euro OTC | Glucose | 16328801 | 3 |
| Euro OTC | Glucose | 16328803 | 2 |
| Euro OTC | Glucose | 18012922 | 1 |
| Fagron | Glucose | 13178716 | 1 |
| Fagron | Glucose | 14142303 | 1 |
| Fiebig 02.05.2019 | Glucose | 18012915 | 1 |
| Fiebig | Glucose | 18012907 | 1 |
| GEHE 17.07.2014 | Glucose | 14033907 | 1 |
| Gehe 27.11.14 | Glucose | 14142309 | 1 |
| Gehe Kassel | Glucose | 14142313 | 1 |
| GEHE | Glucose | 13178715 | 1 |
| Gehe | Glucose | 16157403 | 2 |
| GEHE | Glucose | 16157406 | 1 |
| GEHE | Glucose | 16328801 | 1 |
| Gehe | Glucose | 16328803 | 1 |
| Gehe | Glucose | 16328805 | 2 |
| GEHE | Glucose | 16328805 | 1 |
| Gehe | Glucose | 163288205 | 1 |
| Gehe | Glucose | 18012902 | 1 |
| GEHE | Glucose | 18012902 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Glucose | 18012907 | 4 |
| GEHE | Glucose | 18012907 | 4 |
| Gehe | Glucose | 18012912 | 1 |
| GEHE | Glucose | 18012912 | 2 |
| Gehe | Glucose | 18012914 | 1 |
| Gehe | Glucose | 18012915 | 2 |
| Gehe | Glucose | 18012921 | 2 |
| Gehe | Glucose | 190380003 | 7 |
| Gehe | Glucose | 19038002 | 3 |
| GEHE | Glucose | 19038002 | 2 |
| Gehe | Glucose | 19038003 | 1 |
| Gehe | Glucose | 19038007 | 1 |
| Gehe | Glucose | 20004066004 | 2 |
| Gehe | Glucose | 21002549007 | 3 |
| Gehe | Glucose | 21002549013 | 1 |
| gehe | Glucose | 22002306003 | 1 |
| Geibo/Noweda | Glucose | 18012907 | 1 |
| Geibo | Glucose | 18012921 | 3 |
| Geibo | Glucose | 190380003 | 1 |
| Geibo | Glucose | 19038007 | 2 |
| Geilenkirchen | Glucose | 18012902 | 1 |
| Geilenkirchen | Glucose | 190380009 | 1 |
| Geilenkirchen | Glucose | 20004066023 | 1 |
| Ichtyol-Ges HH/Sanacorp | Glucose | 18012909 | 1 |
| Jenne | Glucose | 12141705 | 1 |
| Klenk | Glucose | 16050502 | 1 |
| Max Jenne | Glucose | 23002088001 | 1 |
| Nachprüfung | Glucose | | 3 |
| Nachprüfung | Glucose | 16328807 | 2 |
| Noweda | Glucose | 18012922 | 1 |
| Noweda | Glucose | 20004066004 | 1 |
| Noweda | Glucose | 20004066014 | 1 |
| Noweda | Glucose | 21002549007 | 4 |
| Noweda | Glucose | 21002549008 | 1 |
| Noweda | Glucose | 22002306002 | 1 |
| PHOENIX 30.05.2014 | Glucose | 13329514 | 1 |
| PHOENIX 30.05.2014 | Glucose | 14033902 | 1 |
| Phoenix | Glucose | 14142310 | 1 |
| Phoenix | Glucose | 15148801 | 1 |
| Phoenix | Glucose | 15329010 | 2 |
| Phoenix | Glucose | 16050501 | 1 |
| Phoenix | Glucose | 16050503 | 4 |
| Phoenix | Glucose | 16328812 | 3 |
| Phoenix | Glucose | 190380009 | 1 |
| Phoenix | Glucose | 191250611 | 1 |
| Phönix/Fagon | Glucose | 16328807 | 1 |
| Phönix | Glucose | 13178701 | 1 |
| PHÖNIX | Glucose | 16328805 | 2 |
| PHÖNIX | Glucose | 18012902 | 1 |
| Rondell Apotheke | Glucose | 15329003 | 1 |
| Sanacorp | Glucose | 12294509 | 1 |
| Sanacorp | Glucose | 16328805 | 1 |
| Sanacorp | Glucose | 18012909 | 1 |
| Sanacorp | Glucose | 190380009 | 2 |
| Sanacorp | Glucose | 20004066023 | 1 |
| Sanacorp | Glucose | 2004066023 | 1 |
| Sanacorp | Glucose | 21002549004 | 2 |
| Sanacorp | Glucose | 21002549008 | 1 |
| sanacorp | Glucose | 22002306003 | 1 |
| Sanacorp | Glucose | 22002306003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Glucose | 23002088001 | 1 |
| Sonnen-Apotheke Wefe… | Glucose | 17/16 | 1 |
| Sonnen-Apotheke Wefe… | Glucose | 21/17Glucose-SiO2-M | 1 |
| Sonnen-Apotheke Wefe… | Glucose | 34/16 | 1 |

- 255 297 spectra from 1666 *Apo-Ident* customers from a total of 51 889 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Glucose* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Glucose* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 265 | 0 | 158 061 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 1586 | 3 | 255 297 |

The substance/substance group *Glucose* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7358 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8112 % (> 99.6224 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20982 | 20982 | 0.00 | 218.68 |
| 21363 | 26366 | 11.02 | 228.29 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21703 | 20982 | 6.22 | 223.29 |
| 22586 | 20982 | 4.14 | 223.01 |
| 24511 | 24511 | 0.00 | 239.43 |
| 26366 | 26366 | 0.00 | 245.01 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Glucose monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20031-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Glucose monohydrate; Glucosum monohydricum

### Special notes

When selecting the *Glucose monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Glucose monohydrate | 12 | 24 | 607 |

### Second-stage model

For differentiation of the substance/substance group *Glucose monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Glucose monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 56.15 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Glucose monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Glucose monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Glucose monohydrate | 171368 | 23304 | 40 | 20170601* |
| Caelo | Glucose monohydrate | 173050 | 23802 | 40 | 20171110* |
| Caelo | Glucose monohydrate | 20003964 | 25627 | 40 | 20210115* |
| Caelo | Glucose monohydrate | 20003963 | 25637 | 40 | 20210115* |
| Caelo | Glucose monohydrate | 20002144 | 25653 | 40 | 20200813* |
| Euro OTC | Glucose monohydrate | 1509006 | 21905 | 60 | 20150914* |
| Euro OTC | Glucose monohydrate | 1601016 | 22308 | 60 | 20160129* |
| Euro OTC | Glucose monohydrate | 1604006 | 22538 | 40 | 20160511* |
| Euro OTC | Glucose monohydrate | 1701002 | 23006 | 40 | 20170213* |
| Euro OTC | Glucose monohydrate | 1807005 | 24162 | 40 | 20180718* |
| Fagron | Glucose monohydrate | 11L19-N13 | 20799 | 40 | 20120105 |
| Fagron | Glucose monohydrate | 14B04-B01 | 21274 | 40 | 20140304 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 520 spectra of 12 reference samples from the substance/substance group *Glucose monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.

- 157 806 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1010 spectra of 27 reference samples from the substance/substance group *Glucose monohydrate*.

- Among them are spectra of independent samples from 24 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Glucose monohydrate | 16184807 | 23025 | 40 |
| Caelo | Glucose monohydrate | 190733 | 24506 | 40 |
| Caelo | Glucose monohydrate | 182174 | 24906 | 40 |
| Caelo | Glucose monohydrate | 22001899 | 26364 | 30 |
| Caelo | Glucose monohydrate | 24002353 | 27438 | 40 |
| Euro OTC | Glucose monohydrate | 1210034-02 | 21285 | 40 |
| Euro OTC | Glucose monohydrate | 1607024 | 22692 | 40 |
| Euro OTC | Glucose monohydrate | 1707004 | 23545 | 40 |
| Euro OTC | Glucose monohydrate | 1801009 | 23897 | 40 |
| Euro OTC | Glucose monohydrate | 1811020 | 24418 | 40 |
| Euro OTC | Glucose monohydrate | 1904029 | 24640 | 40 |
| Euro OTC | Glucose monohydrate | 1908012 | 24860 | 40 |
| Euro OTC | Glucose monohydrate | 2001006 | 25083 | 40 |
| Euro OTC | Glucose monohydrate | 2006007 | 25310 | 40 |
| Euro OTC | Glucose monohydrate | 2009024 | 25461 | 40 |
| Euro OTC | Glucose monohydrate | 2103027 | 25671 | 40 |
| Euro OTC | Glucose monohydrate | 2107024 | 25772 | 50 |
| Euro OTC | Glucose monohydrate | 2109008 | 25824 | 50 |
| Euro OTC | Glucose monohydrate | 2202015 | 26040 | 40 |
| Euro OTC | Glucose monohydrate | 2206018 | 26209 | 40 |
| Euro OTC | Glucose monohydrate | 2210005 | 26418 | 30 |
| Euro OTC | Glucose monohydrate | 2302007 | 26591 | 40 |
| Euro OTC | Glucose monohydrate | 2310008 | 26997 | 40 |
| Euro OTC | Glucose monohydrate | 2501016 | 27500 | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Glucose monohydrate | 22001899 | 26364SI | 20 |
| Euro OTC | Glucose monohydrate | 2202015 | 26040SI | 10 |
| Euro OTC | Glucose monohydrate | 2206018 | 26209SI | 20 |

- 211 930 spectra from a total of 4263 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 5001 spectra from 1001 *Apo-Ident* customers from 617 batches from the substance/substance group *Glucose monohydrate*.

- Among them are spectra of independent samples from 607 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Glucose monohydrate | | 2 |
| | Glucose monohydrate | 21001886009 | 1 |
| | Glucose monohydrate | 21004018009 | 1 |
| | Glucose monohydrate | 2109008-01 | 1 |
| | Glucose monohydrate | 2109008-02 | 1 |
| | Glucose monohydrate | 22000756006 | 8 |
| | Glucose monohydrate | 22000756007 | 4 |
| | Glucose monohydrate | 22000756015 | 12 |
| | Glucose monohydrate | 22000756019 | 14 |
| | Glucose monohydrate | 22000756021 | 3 |
| | Glucose monohydrate | 22001899001 | 1 |
| | Glucose monohydrate | 22001899002 | 16 |
| | Glucose monohydrate | 22001899003 | 4 |
| | Glucose monohydrate | 22001899005 | 8 |
| | Glucose monohydrate | 22001899010 | 5 |
| | Glucose monohydrate | 22001899011 | 18 |
| | Glucose monohydrate | 22001899012 | 2 |
| | Glucose monohydrate | 2200756015 | 1 |
| | Glucose monohydrate | 2202015-03 | 1 |
| | Glucose monohydrate | 22021899011 | 1 |
| | Glucose monohydrate | 2206018-01 | 9 |
| | Glucose monohydrate | 2206018-02 | 3 |
| | Glucose monohydrate | 2210005 | 1 |
| | Glucose monohydrate | 2210005-01 | 5 |
| | Glucose monohydrate | 221000502 | 1 |
| | Glucose monohydrate | 2210005-02 | 15 |
| | Glucose monohydrate | 2300021006 | 1 |
| | Glucose monohydrate | 23000211001 | 4 |
| | Glucose monohydrate | 23000211002 | 7 |
| | Glucose monohydrate | 23000211004 | 2 |
| | Glucose monohydrate | 23000211005 | 27 |
| | Glucose monohydrate | 23000211006 | 8 |
| | Glucose monohydrate | 23000211008 | 5 |
| | Glucose monohydrate | 23000211010 | 9 |
| | Glucose monohydrate | 230008-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Glucose monohydrate | 23003430001 | 5 |
| | Glucose monohydrate | 23003430002 | 8 |
| | Glucose monohydrate | 23003430003 | 2 |
| | Glucose monohydrate | 23003430006 | 5 |
| | Glucose monohydrate | 2302007-01 | 24 |
| | Glucose monohydrate | 2302007-02 | 6 |
| | Glucose monohydrate | 23100008-02 | 1 |
| | Glucose monohydrate | 2310008-01 | 10 |
| | Glucose monohydrate | 2310008-02 | 1 |
| | Glucose monohydrate | 232007-1 | 2 |
| | Glucose monohydrate | 24000422002 | 3 |
| | Glucose monohydrate | 24000422003 | 1 |
| | Glucose monohydrate | 24000422004 | 7 |
| | Glucose monohydrate | 24000422005 | 5 |
| | Glucose monohydrate | 24000422006 | 2 |
| | Glucose monohydrate | 2400042200617/25P | 1 |
| | Glucose monohydrate | 24000422007 | 9 |
| | Glucose monohydrate | 24000422009 | 4 |
| | Glucose monohydrate | 24000422010 | 6 |
| | Glucose monohydrate | 24000422011 | 4 |
| | Glucose monohydrate | 24002353001 | 3 |
| | Glucose monohydrate | 24002353002 | 6 |
| | Glucose monohydrate | 24002353005 | 1 |
| | Glucose monohydrate | 24002353006 | 2 |
| | Glucose monohydrate | 24002353007 | 5 |
| | Glucose monohydrate | 24002353008 | 2 |
| | Glucose monohydrate | 24002353010 | 2 |
| | Glucose monohydrate | 24002353011 | 5 |
| | Glucose monohydrate | 2400253002 | 1 |
| | Glucose monohydrate | 2402553002 | 1 |
| | Glucose monohydrate | 2501016-01 | 3 |
| | Glucose monohydrate | 557473 | 1 |
| 73098/Gehe | Glucose monohydrate | E388S | 1 |
| ACM | Glucose monohydrate | KNC1164J15 | 1 |
| ACM | Glucose monohydrate | KNC1282J14 | 1 |
| AHD | Glucose monohydrate | 14102407 | 1 |
| AHD | Glucose monohydrate | 21001886013 | 1 |
| AHD | Glucose monohydrate | 2202015-02 | 1 |
| AHD | Glucose monohydrate | 2210005-01 | 2 |
| AHD | Glucose monohydrate | 2302007-01 | 5 |
| AHD | Glucose monohydrate | 2310008-01 | 2 |
| AHD | Glucose monohydrate | 24000422004 | 1 |
| Alliance/EurRho | Glucose monohydrate | 2103027-01 | 1 |
| Alliance | Glucose monohydrate | 16049101 | 1 |
| Alliance | Glucose monohydrate | 22000756011 | 1 |
| Alliance | Glucose monohydrate | 22001899005 | 1 |
| Alliance | Glucose monohydrate | 2202015-01 | 2 |
| Alliance | Glucose monohydrate | 2202015-02 | 1 |
| Allianz Healthcare | Glucose monohydrate | 19073305 | 1 |
| allianz | Glucose monohydrate | 1543409 | 1 |
| Anzag | Glucose monohydrate | 14334810 | 1 |
| anzag | Glucose monohydrate | 15095601 | 2 |
| Anzag | Glucose monohydrate | 16184808 | 1 |
| Anzag | Glucose monohydrate | 17005804 | 1 |
| Anzag | Glucose monohydrate | 17136805 | 1 |
| Anzag | Glucose monohydrate | 2301007-01 | 1 |
| Anzag | Glucose monohydrate | 2302007-01 | 1 |
| Anzag | Glucose monohydrate | 240822(22000756019) | 1 |
| api-ident / AHD | Glucose monohydrate | 2009024-01 | 1 |
| apo ident/Noweda | Glucose monohydrate | 2103027-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| apo ident | Glucose monohydrate | 202015-02 | 1 |
| apo-ident Phonix | Glucose monohydrate | 2210005-01 | 1 |
| Apoident/ Phoenix | Glucose monohydrate | 2009024-01 | 1 |
| Apo-Ident/Phoenix | Glucose monohydrate | 1701002-01 | 1 |
| apo-ident | Glucose monohydrate | 1604006-02 | 1 |
| ApoIdent | Glucose monohydrate | 2107024-02 | 1 |
| ApoIdent | Glucose monohydrate | 2206018-01 | 1 |
| Apotheke im Forum | Glucose monohydrate | 17010002-01 | 1 |
| Audor Pharma | Glucose monohydrate | 16184810 | 3 |
| Audor Pharma | Glucose monohydrate | 2202015-03 | 1 |
| Audor Pharma | Glucose monohydrate | 2206018-01 | 2 |
| Audor Pharma | Glucose monohydrate | E732N | 1 |
| Beiersdorf/Phönix | Glucose monohydrate | L6209 | 1 |
| Bombastus | Glucose monohydrate | 14334802 | 2 |
| Bombastus | Glucose monohydrate | 15413410 | 1 |
| Bombastus | Glucose monohydrate | 16184810 | 2 |
| Bombastus | Glucose monohydrate | 1807005-01 | 1 |
| Bombastus | Glucose monohydrate | 18101901 | 2 |
| Caele | Glucose monohydrate | 15413304 | 3 |
| Caelo | Glucose monohydrate | | 3 |
| Caelo | Glucose monohydrate | 10159501 | 1 |
| Caelo | Glucose monohydrate | 1073303 | 1 |
| Caelo | Glucose monohydrate | 11021509 | 1 |
| Caelo | Glucose monohydrate | 11082014 | 1 |
| Caelo | Glucose monohydrate | 11082020 | 1 |
| Caelo | Glucose monohydrate | 111111111 | 1 |
| Caelo | Glucose monohydrate | 11314516 | 3 |
| Caelo | Glucose monohydrate | 11314519 | 1 |
| Caelo | Glucose monohydrate | 11314526 | 1 |
| Caelo | Glucose monohydrate | 11314528 | 8 |
| Caelo | Glucose monohydrate | 1134506 | 1 |
| Caelo | Glucose monohydrate | 11L19-N13 | 3 |
| Caelo | Glucose monohydrate | 1204044-01 | 2 |
| Caelo | Glucose monohydrate | 12284202 | 6 |
| Caelo | Glucose monohydrate | 12284204 | 2 |
| Caelo | Glucose monohydrate | 12284206 | 6 |
| Caelo | Glucose monohydrate | 12284219 | 8 |
| Caelo | Glucose monohydrate | 12284222 | 3 |
| Caelo | Glucose monohydrate | 12284229 | 3 |
| Caelo | Glucose monohydrate | 12284230 | 3 |
| Caelo | Glucose monohydrate | 12284231 | 1 |
| Caelo | Glucose monohydrate | 12345 | 1 |
| Caelo | Glucose monohydrate | 123456 | 2 |
| Caelo | Glucose monohydrate | 12435 | 1 |
| Caelo | Glucose monohydrate | 12G30-N01 | 1 |
| Caelo | Glucose monohydrate | 12G30-NO01 | 1 |
| Caelo | Glucose monohydrate | 1305030-02 | 1 |
| Caelo | Glucose monohydrate | 13157002 | 2 |
| Caelo | Glucose monohydrate | 13157004 | 1 |
| Caelo | Glucose monohydrate | 13157005 | 12 |
| Caelo | Glucose monohydrate | 13157007 | 6 |
| Caelo | Glucose monohydrate | 13157008 | 1 |
| Caelo | Glucose monohydrate | 13157011 | 9 |
| Caelo | Glucose monohydrate | 13157012 | 1 |
| Caelo | Glucose monohydrate | 13157013 | 1 |
| Caelo | Glucose monohydrate | 13157017 | 1 |
| Caelo | Glucose monohydrate | 13157019 | 10 |
| Caelo | Glucose monohydrate | 13157022 | 1 |
| Caelo | Glucose monohydrate | 13157026 | 3 |
| Caelo | Glucose monohydrate | 13A25-N01 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose monohydrate | 13H06-N08 | 2 |
| Caelo | Glucose monohydrate | 1401019-01 | 5 |
| Caelo | Glucose monohydrate | 1410019-02 | 1 |
| Caelo | Glucose monohydrate | 14102401 | 4 |
| Caelo | Glucose monohydrate | 14102407 | 2 |
| Caelo | Glucose monohydrate | 14102411 | 4 |
| Caelo | Glucose monohydrate | 14102412 | 9 |
| Caelo | Glucose monohydrate | 14102415 | 2 |
| Caelo | Glucose monohydrate | 14102416 | 5 |
| Caelo | Glucose monohydrate | 14102418 | 10 |
| Caelo | Glucose monohydrate | 14102420 | 6 |
| Caelo | Glucose monohydrate | 14102421 | 4 |
| Caelo | Glucose monohydrate | 14102424 | 1 |
| Caelo | Glucose monohydrate | 14102427 | 1 |
| Caelo | Glucose monohydrate | 14102430 | 3 |
| Caelo | Glucose monohydrate | 14334802 | 11 |
| Caelo | Glucose monohydrate | 14334805 | 2 |
| Caelo | Glucose monohydrate | 14334806 | 3 |
| Caelo | Glucose monohydrate | 14334807 | 4 |
| Caelo | Glucose monohydrate | 14334808 | 2 |
| Caelo | Glucose monohydrate | 14334809 | 1 |
| Caelo | Glucose monohydrate | 14334810 | 8 |
| Caelo | Glucose monohydrate | 14334811 | 2 |
| Caelo | Glucose monohydrate | 14B04-B01-291137 | 1 |
| Caelo | Glucose monohydrate | 14B28-B02-291354 | 1 |
| Caelo | Glucose monohydrate | 14I04-B08 | 4 |
| Caelo | Glucose monohydrate | 150302G | 1 |
| Caelo | Glucose monohydrate | 15095601 | 12 |
| Caelo | Glucose monohydrate | 15095602 | 1 |
| Caelo | Glucose monohydrate | 15095603 | 1 |
| Caelo | Glucose monohydrate | 15095605 | 3 |
| Caelo | Glucose monohydrate | 15095606 | 1 |
| Caelo | Glucose monohydrate | 15095611 | 3 |
| Caelo | Glucose monohydrate | 15095612 | 13 |
| Caelo | Glucose monohydrate | 15180001 | 12 |
| Caelo | Glucose monohydrate | 15180002 | 17 |
| Caelo | Glucose monohydrate | 15180003 | 3 |
| Caelo | Glucose monohydrate | 15180005 | 3 |
| Caelo | Glucose monohydrate | 15180009 | 1 |
| Caelo | Glucose monohydrate | 15180010 | 8 |
| Caelo | Glucose monohydrate | 15180012 | 18 |
| Caelo | Glucose monohydrate | 15180013 | 2 |
| Caelo | Glucose monohydrate | 15180015 | 8 |
| Caelo | Glucose monohydrate | 15180016 | 2 |
| Caelo | Glucose monohydrate | 1518002 | 1 |
| Caelo | Glucose monohydrate | 15413301 | 1 |
| Caelo | Glucose monohydrate | 15413302 | 3 |
| Caelo | Glucose monohydrate | 15413303 | 1 |
| Caelo | Glucose monohydrate | 15413304 | 26 |
| Caelo | Glucose monohydrate | 15413304/20160309/6 | 1 |
| Caelo | Glucose monohydrate | 15413401 | 6 |
| Caelo | Glucose monohydrate | 15413402 | 6 |
| Caelo | Glucose monohydrate | 15413405 | 6 |
| Caelo | Glucose monohydrate | 15413409 | 25 |
| Caelo | Glucose monohydrate | 15413410 | 4 |
| Caelo | Glucose monohydrate | 15413412 | 3 |
| Caelo | Glucose monohydrate | 15413413 | 1 |
| Caelo | Glucose monohydrate | 154134o2 | 1 |
| Caelo | Glucose monohydrate | 160101 | 1 |
| Caelo | Glucose monohydrate | 160400601 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose monohydrate | 1604006-01 | 1 |
| Caelo | Glucose monohydrate | 1604104 | 1 |
| Caelo | Glucose monohydrate | 16049101 | 16 |
| Caelo | Glucose monohydrate | 16049102 | 9 |
| Caelo | Glucose monohydrate | 16049103 | 6 |
| Caelo | Glucose monohydrate | 16049104 | 22 |
| Caelo | Glucose monohydrate | 16049105 | 10 |
| Caelo | Glucose monohydrate | 16049107 | 6 |
| Caelo | Glucose monohydrate | 16049108 | 4 |
| Caelo | Glucose monohydrate | 1607024-01 | 1 |
| Caelo | Glucose monohydrate | 1618401 | 2 |
| Caelo | Glucose monohydrate | 16184616 | 1 |
| Caelo | Glucose monohydrate | 16184801 | 20 |
| Caelo | Glucose monohydrate | 16184802 | 2 |
| Caelo | Glucose monohydrate | 16184807 | 12 |
| Caelo | Glucose monohydrate | 16184808 | 7 |
| Caelo | Glucose monohydrate | 16184810 | 23 |
| Caelo | Glucose monohydrate | 16184816 | 3 |
| Caelo | Glucose monohydrate | 17005801 | 3 |
| Caelo | Glucose monohydrate | 17005802 | 12 |
| Caelo | Glucose monohydrate | 170058025312 | 1 |
| Caelo | Glucose monohydrate | 170058025458 | 1 |
| Caelo | Glucose monohydrate | 170058025517 | 1 |
| Caelo | Glucose monohydrate | 170058025621 | 1 |
| Caelo | Glucose monohydrate | 17005803 | 34 |
| Caelo | Glucose monohydrate | 17005804 | 10 |
| Caelo | Glucose monohydrate | 17005805 | 2 |
| Caelo | Glucose monohydrate | 17005811 | 2 |
| Caelo | Glucose monohydrate | 17005812 | 13 |
| Caelo | Glucose monohydrate | 17005813 | 9 |
| Caelo | Glucose monohydrate | 1701002-01 | 3 |
| Caelo | Glucose monohydrate | 170100401 | 1 |
| Caelo | Glucose monohydrate | 170323183 | 1 |
| Caelo | Glucose monohydrate | 1707004-001 | 1 |
| Caelo | Glucose monohydrate | 1707004-01 | 5 |
| Caelo | Glucose monohydrate | 17136801 | 29 |
| Caelo | Glucose monohydrate | 17136801/P-11101722 | 1 |
| Caelo | Glucose monohydrate | 17136802 | 17 |
| Caelo | Glucose monohydrate | 17136804 | 20 |
| Caelo | Glucose monohydrate | 17136804x2 | 1 |
| Caelo | Glucose monohydrate | 17136805 | 14 |
| Caelo | Glucose monohydrate | 17305003 | 47 |
| Caelo | Glucose monohydrate | 17305004 | 13 |
| Caelo | Glucose monohydrate | 1801009 | 1 |
| Caelo | Glucose monohydrate | 1801009-01 | 8 |
| Caelo | Glucose monohydrate | 180101901 | 1 |
| Caelo | Glucose monohydrate | 180101907 | 1 |
| Caelo | Glucose monohydrate | 180300004 | 1 |
| Caelo | Glucose monohydrate | 18030003 | 15 |
| Caelo | Glucose monohydrate | 18030004 | 7 |
| Caelo | Glucose monohydrate | 18030005 | 7 |
| Caelo | Glucose monohydrate | 18030006 | 1 |
| Caelo | Glucose monohydrate | 1803006 | 1 |
| Caelo | Glucose monohydrate | 18064912 | 1 |
| Caelo | Glucose monohydrate | 180700501 | 1 |
| Caelo | Glucose monohydrate | 1807005-01 | 2 |
| Caelo | Glucose monohydrate | 1807005-02 | 1 |
| Caelo | Glucose monohydrate | 18071402 | 1 |
| Caelo | Glucose monohydrate | 18101901 | 70 |
| Caelo | Glucose monohydrate | 18101902 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose monohydrate | 18101903 | 26 |
| Caelo | Glucose monohydrate | 181019030 | 1 |
| Caelo | Glucose monohydrate | 18101907 | 34 |
| Caelo | Glucose monohydrate | 18101909 | 1 |
| Caelo | Glucose monohydrate | 18107907 | 1 |
| Caelo | Glucose monohydrate | 1810901 | 1 |
| Caelo | Glucose monohydrate | 1810907 | 1 |
| Caelo | Glucose monohydrate | 1811020-01 | 5 |
| Caelo | Glucose monohydrate | 181197 | 1 |
| Caelo | Glucose monohydrate | 181401903 | 1 |
| Caelo | Glucose monohydrate | 18214701 | 20 |
| Caelo | Glucose monohydrate | 18214702 | 1 |
| Caelo | Glucose monohydrate | 18214703 | 56 |
| Caelo | Glucose monohydrate | 18214704 | 20 |
| Caelo | Glucose monohydrate | 18214708 | 32 |
| Caelo | Glucose monohydrate | 18214709 | 6 |
| Caelo | Glucose monohydrate | 18214710 | 8 |
| Caelo | Glucose monohydrate | 18214712 | 1 |
| Caelo | Glucose monohydrate | 182414703 | 1 |
| Caelo | Glucose monohydrate | 1891009-01 | 1 |
| Caelo | Glucose monohydrate | 190073303 | 1 |
| Caelo | Glucose monohydrate | 190402901 | 1 |
| Caelo | Glucose monohydrate | 19073033 | 1 |
| Caelo | Glucose monohydrate | 19073301 | 12 |
| Caelo | Glucose monohydrate | 19073302 | 12 |
| Caelo | Glucose monohydrate | 190733023 | 1 |
| Caelo | Glucose monohydrate | 19073303 | 49 |
| Caelo | Glucose monohydrate | 19073304 | 16 |
| Caelo | Glucose monohydrate | 19073305 | 8 |
| Caelo | Glucose monohydrate | 19073309 | 30 |
| Caelo | Glucose monohydrate | 19073310 | 8 |
| Caelo | Glucose monohydrate | 191486003 | 1 |
| Caelo | Glucose monohydrate | 19246002 | 1 |
| Caelo | Glucose monohydrate | 19248600 | 1 |
| Caelo | Glucose monohydrate | 1924860002 | 1 |
| Caelo | Glucose monohydrate | 192486002 | 15 |
| Caelo | Glucose monohydrate | 192486003 | 62 |
| Caelo | Glucose monohydrate | 192486004 | 25 |
| Caelo | Glucose monohydrate | 192486006 | 11 |
| Caelo | Glucose monohydrate | 192486007 | 9 |
| Caelo | Glucose monohydrate | 1973303 | 1 |
| Caelo | Glucose monohydrate | 200002144002 | 2 |
| Caelo | Glucose monohydrate | 200003964015 | 1 |
| Caelo | Glucose monohydrate | 2000214006 | 1 |
| Caelo | Glucose monohydrate | 20002144002 | 62 |
| Caelo | Glucose monohydrate | 20002144005 | 6 |
| Caelo | Glucose monohydrate | 20002144006 | 6 |
| Caelo | Glucose monohydrate | 20002144007 | 7 |
| Caelo | Glucose monohydrate | 20002144022 | 1 |
| Caelo | Glucose monohydrate | 200021444005 | 1 |
| Caelo | Glucose monohydrate | 20003963001 | 2 |
| Caelo | Glucose monohydrate | 20003964001 | 9 |
| Caelo | Glucose monohydrate | 20003964002 | 57 |
| Caelo | Glucose monohydrate | 20003964004 | 20 |
| Caelo | Glucose monohydrate | 20003964005 | 3 |
| Caelo | Glucose monohydrate | 20003964008 | 4 |
| Caelo | Glucose monohydrate | 20003964009 | 21 |
| Caelo | Glucose monohydrate | 20003964012 | 1 |
| Caelo | Glucose monohydrate | 20003964013 | 8 |
| Caelo | Glucose monohydrate | 20003964015 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose monohydrate | 20003964016 | 2 |
| Caelo | Glucose monohydrate | 20004180002 | 1 |
| Caelo | Glucose monohydrate | 2000418009 | 1 |
| Caelo | Glucose monohydrate | 200041820009 | 3 |
| Caelo | Glucose monohydrate | 20004182001 | 4 |
| Caelo | Glucose monohydrate | 20004182002 | 11 |
| Caelo | Glucose monohydrate | 20004182003 | 23 |
| Caelo | Glucose monohydrate | 20004182004 | 2 |
| Caelo | Glucose monohydrate | 20004182006 | 1 |
| Caelo | Glucose monohydrate | 20004182007 | 4 |
| Caelo | Glucose monohydrate | 20004182008 | 16 |
| Caelo | Glucose monohydrate | 20004182009 | 29 |
| Caelo | Glucose monohydrate | 20004182010 | 3 |
| Caelo | Glucose monohydrate | 2000418209 | 2 |
| Caelo | Glucose monohydrate | 2002144002 | 2 |
| Caelo | Glucose monohydrate | 2002144006 | 1 |
| Caelo | Glucose monohydrate | 200415PJK01 | 1 |
| Caelo | Glucose monohydrate | 2004182006 | 1 |
| Caelo | Glucose monohydrate | 2004182009 | 1 |
| Caelo | Glucose monohydrate | 2006007-01 | 2 |
| Caelo | Glucose monohydrate | 2009024-01 | 1 |
| Caelo | Glucose monohydrate | 2017Q-02209 | 1 |
| Caelo | Glucose monohydrate | 210018586004 | 1 |
| Caelo | Glucose monohydrate | 210018860008 | 3 |
| Caelo | Glucose monohydrate | 21001886003 | 10 |
| Caelo | Glucose monohydrate | 21001886004 | 25 |
| Caelo | Glucose monohydrate | 21001886005 | 22 |
| Caelo | Glucose monohydrate | 21001886008 | 5 |
| Caelo | Glucose monohydrate | 21001886009 | 13 |
| Caelo | Glucose monohydrate | 21001886011 | 7 |
| Caelo | Glucose monohydrate | 21001886013 | 2 |
| Caelo | Glucose monohydrate | 21002018013 | 1 |
| Caelo | Glucose monohydrate | 21004018003 | 6 |
| Caelo | Glucose monohydrate | 21004018006 | 5 |
| Caelo | Glucose monohydrate | 21004018007 | 16 |
| Caelo | Glucose monohydrate | 21004018009 | 11 |
| Caelo | Glucose monohydrate | 21004018011 | 3 |
| Caelo | Glucose monohydrate | 21004018013 | 6 |
| Caelo | Glucose monohydrate | 21004018014 | 22 |
| Caelo | Glucose monohydrate | 21004018015 | 20 |
| Caelo | Glucose monohydrate | 21004018016 | 5 |
| Caelo | Glucose monohydrate | 21004018017 | 3 |
| Caelo | Glucose monohydrate | 21004018018 | 1 |
| Caelo | Glucose monohydrate | 2100886013 | 1 |
| Caelo | Glucose monohydrate | 2101402 | 1 |
| Caelo | Glucose monohydrate | 2103027-01 | 3 |
| Caelo | Glucose monohydrate | 2104018009 | 2 |
| Caelo | Glucose monohydrate | 219317005803 | 1 |
| Caelo | Glucose monohydrate | 22000456006 | 1 |
| Caelo | Glucose monohydrate | 220007560009 | 1 |
| Caelo | Glucose monohydrate | 22000756003 | 3 |
| Caelo | Glucose monohydrate | 22000756004 | 2 |
| Caelo | Glucose monohydrate | 22000756005 | 4 |
| Caelo | Glucose monohydrate | 22000756006 | 24 |
| Caelo | Glucose monohydrate | 22000756007 | 5 |
| Caelo | Glucose monohydrate | 22000756009 | 1 |
| Caelo | Glucose monohydrate | 22000756010 | 4 |
| Caelo | Glucose monohydrate | 22000756011 | 4 |
| Caelo | Glucose monohydrate | 22000756014 | 5 |
| Caelo | Glucose monohydrate | 22000756015 | 24 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glucose monohydrate | 22000756017 | 1 |
| Caelo | Glucose monohydrate | 22000756018 | 1 |
| Caelo | Glucose monohydrate | 22000756019 | 1 |
| Caelo | Glucose monohydrate | 22000756020 | 4 |
| Caelo | Glucose monohydrate | 22000756021 | 2 |
| Caelo | Glucose monohydrate | 22000756022 | 6 |
| Caelo | Glucose monohydrate | 220007567 | 1 |
| Caelo | Glucose monohydrate | 22001899001 | 2 |
| Caelo | Glucose monohydrate | 22001899002 | 3 |
| Caelo | Glucose monohydrate | 22001899003 | 1 |
| Caelo | Glucose monohydrate | 22001899005 | 2 |
| Caelo | Glucose monohydrate | 22001899005c | 1 |
| Caelo | Glucose monohydrate | 2200189901 | 1 |
| Caelo | Glucose monohydrate | 2202015-02 | 4 |
| Caelo | Glucose monohydrate | 2206018-01 | 1 |
| Caelo | Glucose monohydrate | 220616(21004018009) | 1 |
| Caelo | Glucose monohydrate | 220756015 | 1 |
| Caelo | Glucose monohydrate | 2222222222 | 1 |
| Caelo | Glucose monohydrate | 23000211001 | 1 |
| Caelo | Glucose monohydrate | 23000211002 | 2 |
| Caelo | Glucose monohydrate | 23000211004 | 3 |
| Caelo | Glucose monohydrate | 23000211006 | 1 |
| Caelo | Glucose monohydrate | 23000211008 | 1 |
| Caelo | Glucose monohydrate | 2300021104 | 1 |
| Caelo | Glucose monohydrate | 23003217004 | 2 |
| Caelo | Glucose monohydrate | 23051801 | 1 |
| Caelo | Glucose monohydrate | 2315Q-02209NP | 1 |
| Caelo | Glucose monohydrate | 2316E-02209 | 1 |
| Caelo | Glucose monohydrate | 24081801 | 1 |
| Caelo | Glucose monohydrate | 26061802 | 1 |
| Caelo | Glucose monohydrate | 27081801 | 1 |
| Caelo | Glucose monohydrate | 2743 | 1 |
| Caelo | Glucose monohydrate | 2745 | 1 |
| Caelo | Glucose monohydrate | 2795 | 1 |
| Caelo | Glucose monohydrate | 28051507 | 1 |
| Caelo | Glucose monohydrate | 3612J-02209 | 1 |
| Caelo | Glucose monohydrate | 4616M-02209 | 1 |
| Caelo | Glucose monohydrate | 5051401 | 1 |
| Caelo | Glucose monohydrate | 5092 | 1 |
| Caelo | Glucose monohydrate | 613011-3p | 1 |
| Caelo | Glucose monohydrate | 716I-02209 | 1 |
| Caelo | Glucose monohydrate | 718A-02209 | 1 |
| Caelo | Glucose monohydrate | 719092G | 1 |
| Caelo | Glucose monohydrate | 72714068 | 1 |
| Caelo | Glucose monohydrate | 8697 | 1 |
| Caelo | Glucose monohydrate | E144C | 1 |
| Caelo | Glucose monohydrate | E388S | 1 |
| Caelo | Glucose monohydrate | Test | 1 |
| Caelo | Glucose monohydrate | UIUJHJH | 1 |
| Caeo | Glucose monohydrate | 1049103 | 1 |
| Caeolo / noweda | Glucose monohydrate | | 1 |
| Caeolo/Noweda | Glucose monohydrate | 15413301 | 1 |
| Caeolo/Phönix | Glucose monohydrate | 16184810 | 2 |
| Caeöo Gehe | Glucose monohydrate | 19073304 | 2 |
| Caesa/Phoenix | Glucose monohydrate | 15413304 | 1 |
| Caesar & Lorenz | Glucose monohydrate | 13157007 | 1 |
| Caesar & Loretz GmbH… | Glucose monohydrate | 19073305 | 1 |
| Caesar & Loretz GmbH… | Glucose monohydrate | 19073310 | 1 |
| Caesar & Loretz GmbH… | Glucose monohydrate | 19073303 | 2 |
| Caesar & Loretz GmbH… | Glucose monohydrate | 19073309 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Glucose monohydrate | 21001886009 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964002 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486006 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964001 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182001 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21001886011 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018006 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018017 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 22000756012 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486007 | 3 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964008 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182006 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21001886003 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018014 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018007 | 1 |
| Caesar & Loretz GmbH L 50 | Glucose monohydrate | 22000756006 | 2 |
| Caesar & Loretz GmbH Phx | Glucose monohydrate | 21004018014 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21001886008 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486003 | 7 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018009 | 1 |
| Caesar & Loretz GmbH/AEP | Glucose monohydrate | 18214703 | 1 |
| Caesar & Loretz GmbH/AHD | Glucose monohydrate | 20004182009 | 1 |
| Caesar & Loretz GmbH/AHD | Glucose monohydrate | 22000756004 | 1 |
| Caesar & Loretz GmbH/AHD | Glucose monohydrate | 22000756022 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486002 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 19073310 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486002 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486007 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486003 | 3 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20002144002 | 1 |
| Caesar & Loretz GmbH/G | Glucose monohydrate | 20003964002 | 1 |
| Caesar & Loretz GmbH/Gehe | Glucose monohydrate | 18214703 | 3 |
| Caesar & Loretz GmbH/Gehe | Glucose monohydrate | 19073305 | 2 |
| Caesar & Loretz GmbH/Gehe | Glucose monohydrate | 192486003 | 1 |
| Caesar & Loretz GmbH/Gehe | Glucose monohydrate | 20002144002 | 1 |
| Caesar & Loretz GmbH/Gehe | Glucose monohydrate | 20004182008 | 1 |
| Caesar & Loretz GmbH/Gehe | Glucose monohydrate | 21004018006 | 1 |
| Caesar & Loretz GmbH/Gehe | Glucose monohydrate | 22000756015 | 3 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20002144005 | 1 |
| Caesar & Loretz GmbH/Gö | Glucose monohydrate | 20002144002 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20002144002 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 2009024-01 | 1 |
| Caesar & Loretz GmbH/K | Glucose monohydrate | 21004018014 | 1 |
| Caesar & Loretz GmbH/Kehr | Glucose monohydrate | 18214704 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 18214703 | 11 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 19073303 | 20 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20002144002 | 4 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964015 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182009 | 4 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21001886005 | 2 |
| Caesar & Loretz GmbH/L10 | Glucose monohydrate | 21004018015 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 19073303 | 3 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182008 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182003 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182006 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21001886008 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018009 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 22001899001 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 19073303 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 19073309 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Glucose monohydrate | 192486003 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964002 | 5 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964009 | 3 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182009 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018007 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21004018015 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 22000756006 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 22000756006 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 22000756011 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 22001899005 | 2 |
| Caesar & Loretz GmbH/Sana | Glucose monohydrate | 21004018007 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 19073303 | 5 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20002144002 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964002 | 2 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20003964004 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 20004182003 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 21001886004 | 1 |
| Caesar & Loretz GmbH... | Glucose monohydrate | 22000756015 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 128214703 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 15180010 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 15180013 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 15413402 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 17005802 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18101901 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18101907 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18179716 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18214701 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18214703 | 13 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18214704 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18214708 | 5 |
| Caesar & Loretz GmbH | Glucose monohydrate | 18214710 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 19073301 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 19073302 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 19073303 | 28 |
| Caesar & Loretz GmbH | Glucose monohydrate | 19073304 | 10 |
| Caesar & Loretz GmbH | Glucose monohydrate | 19073305 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 19073309 | 8 |
| Caesar & Loretz GmbH | Glucose monohydrate | 19073310 | 7 |
| Caesar & Loretz GmbH | Glucose monohydrate | 192486002 | 5 |
| Caesar & Loretz GmbH | Glucose monohydrate | 192486003 | 15 |
| Caesar & Loretz GmbH | Glucose monohydrate | 192486004 | 10 |
| Caesar & Loretz GmbH | Glucose monohydrate | 192486006 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 192486007 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20000461007 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20002144002 | 16 |
| CAESAR & LORETZ GMBH | Glucose monohydrate | 20002144002 | 4 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20002144005 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20002144006 | 7 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20002144007 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003963001 | 4 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964001 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964002 | 14 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964004 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964005 | 5 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964008 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964009 | 11 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964012 | 6 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964013 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964015 | 4 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20003964016 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182001 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182002 | 8 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182003 | 11 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182004 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182006 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182007 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182008 | 11 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182009 | 16 |
| Caesar & Loretz GmbH | Glucose monohydrate | 20004182010 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 2004182010 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21001886003 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21001886004 | 5 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21001886005 | 17 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21001886008 | 9 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21001886009 | 5 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21001886011 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018003 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018006 | 4 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018007 | 6 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018009 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018011 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018013 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018014 | 6 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018015 | 10 |
| Caesar & Loretz GmbH | Glucose monohydrate | 21004018018 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 2102027-1 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756003 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756004 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756006 | 11 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756007 | 8 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756009 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756010 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756011 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756012 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756013 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756014 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756015 | 18 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756017 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756018 | 3 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756020 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756021 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22000756022 | 6 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22001899001 | 4 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22001899002 | 5 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22001899010 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 22001899012 | 2 |
| Caesar & Loretz GmbH | Glucose monohydrate | 2200756015 | 1 |
| Caesar & Loretz GmbH | Glucose monohydrate | 23000211001 | 1 |
| Caesar & Loretz GmbHKehr | Glucose monohydrate | 192486002 | 1 |
| Caesar & Loretz/ Cae... | Glucose monohydrate | 18030004 | 1 |
| Caesar & Loretz/Noweda | Glucose monohydrate | 16049102 | 1 |
| Caesar & Loretz/Phönix | Glucose monohydrate | 18101907 | 1 |
| Caesar & Loretz | Glucose monohydrate | 21001886008 | 1 |
| Caesar & Loretz | Glucose monohydrate | 22000756004 | 1 |
| Caesar & Loretz | Glucose monohydrate | 22000756010 | 1 |
| Caesar / Gehe | Glucose monohydrate | 17005802 | 1 |
| Caesar und Loretz GmbH | Glucose monohydrate | 16184807 | 1 |
| Caesar&Loretz GmbH | Glucose monohydrate | 22000756005 | 1 |
| Caesar&Loretz GmbH | Glucose monohydrate | 22000756009 | 1 |
| Calo | Glucose monohydrate | 15180010 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Cealo/ Noweda | Glucose monohydrate | 15413412 | 1 |
| Cealo/Noweda | Glucose monohydrate | 20003964012 | 2 |
| Cealo/Sanacorp | Glucose monohydrate | 22000756015 | 1 |
| Cealo | Glucose monohydrate | 13157017 | 1 |
| Cealo | Glucose monohydrate | 14102430 | 1 |
| Cealo | Glucose monohydrate | 16049101 | 3 |
| Celo/Jenne | Glucose monohydrate | 20003964009 | 1 |
| Dermapharm | Glucose monohydrate | 1601016-02 | 1 |
| dextro energy / Noweda | Glucose monohydrate | L1299 | 1 |
| Dextro Energy GmbH/Gehe | Glucose monohydrate | L2284 | 1 |
| Dextro Energy GmbH/Gehe | Glucose monohydrate | L4163 | 2 |
| Dextro Energy GmbH/Gehe | Glucose monohydrate | L4164 | 1 |
| Dextro Energy GmbH/Gehe | Glucose monohydrate | L4274 | 1 |
| Dextro Energy GmbH/S... | Glucose monohydrate | L1299 | 1 |
| Dextro Energy GmbH | Glucose monohydrate | 5/2018L6315 | 1 |
| Dextro energy/ Fiebig | Glucose monohydrate | L1147 | 1 |
| Dextro Energy/Gehe | Glucose monohydrate | L1147 | 1 |
| Dextro energy | Glucose monohydrate | L0086 | 1 |
| Dextro energy | Glucose monohydrate | L0097 | 1 |
| Dextro Energy | Glucose monohydrate | 13171 | 1 |
| dextro energy | Glucose monohydrate | 19016127 | 1 |
| dextro energy | Glucose monohydrate | 19050634 | 1 |
| Dextro EnergyGmbH | Glucose monohydrate | L4036 | 1 |
| Dextro EnergyGmbH | Glucose monohydrate | L4273 | 1 |
| Dextro ernergy Gmbh | Glucose monohydrate | L6043 | 1 |
| Dextro GmbH/Noweda | Glucose monohydrate | L5301 | 1 |
| Dextro/Krieger/15.05.13 | Glucose monohydrate | 13092 | 1 |
| DextroEnergy/Noweda | Glucose monohydrate | L2283 | 1 |
| dextroenergy | Glucose monohydrate | 190161027 | 1 |
| Dr. Aug. Wolff GmbH ... | Glucose monohydrate | 21001886011 | 1 |
| Eigenherstellung | Glucose monohydrate | 110912HML01 | 1 |
| Eigenherstellung | Glucose monohydrate | 110913HJK02 | 1 |
| Eigenherstellung | Glucose monohydrate | 120912HML02 | 1 |
| Eigenherstellung | Glucose monohydrate | 160915HML01 | 1 |
| Eigenherstellung | Glucose monohydrate | 180213HJK01 | 1 |
| Eigenherstellung | Glucose monohydrate | 30912HML01 | 1 |
| Eigenherstellung | Glucose monohydrate | 40615HJK01 | 1 |
| Eurho / Alliance | Glucose monohydrate | 2001006-01 | 2 |
| EuRho / Alliance | Glucose monohydrate | 2103027-01 | 1 |
| EuRho Noweda | Glucose monohydrate | 2006007-01 | 1 |
| EuRho/ Kehr | Glucose monohydrate | 220201501 | 1 |
| EuRho/Gehe 09.07.2022 | Glucose monohydrate | 2202015-01 | 1 |
| EuRho/GEHE | Glucose monohydrate | 1410019-01 | 1 |
| EuRho/GEHE | Glucose monohydrate | 1904029-01 | 2 |
| EuRho/Noweda | Glucose monohydrate | 2009024-01 | 3 |
| EuRho/Noweda | Glucose monohydrate | 2103027-01 | 7 |
| EuRho/Noweda | Glucose monohydrate | 2202015-02 | 1 |
| euRho/Noweda | Glucose monohydrate | 2206018-01 | 1 |
| EuRho/Phoenix | Glucose monohydrate | 140500401 | 1 |
| EuRho/Phoenix | Glucose monohydrate | 1604006-01 | 1 |
| EuRho/Phoenix | Glucose monohydrate | 221005-02 | 1 |
| Eurho/Sanacorp | Glucose monohydrate | 1108061-01 | 2 |
| EuRho | Glucose monohydrate | 1108061-01 | 2 |
| EuRho | Glucose monohydrate | 1108061-02 | 1 |
| EuRho | Glucose monohydrate | 1204044-01 | 2 |
| EuRho | Glucose monohydrate | 151780 | 1 |
| EuRho | Glucose monohydrate | 1604006-0104932048 | 1 |
| EuRho | Glucose monohydrate | 1701002-01 | 1 |
| EuRho | Glucose monohydrate | 1707004-01 | 2 |
| EuRho | Glucose monohydrate | 2006007-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Glucose monohydrate | 2103027-01 | 1 |
| EuRho | Glucose monohydrate | 2107024-02 | 2 |
| euRho | Glucose monohydrate | 220215-02 | 1 |
| EuRho | Glucose monohydrate | 2710Q-02209 | 1 |
| EuRho | Glucose monohydrate | E882R | 1 |
| Euro OT>C | Glucose monohydrate | 2006007-01 | 2 |
| Euro OTC | Glucose monohydrate | | 1 |
| Euro OTC | Glucose monohydrate | 103027-012 | 3 |
| Euro OTC | Glucose monohydrate | 1103027-01 | 1 |
| Euro OTC | Glucose monohydrate | 1108061-01 | 2 |
| Euro OTC | Glucose monohydrate | 1114U2209 | 1 |
| Euro OTC | Glucose monohydrate | 1204044-01 | 1 |
| Euro OTC | Glucose monohydrate | 1204044-02 | 4 |
| Euro OTC | Glucose monohydrate | 1210034-01 | 9 |
| Euro OTC | Glucose monohydrate | 1210034-02 | 10 |
| Euro OTC | Glucose monohydrate | 1210034-03 | 1 |
| Euro OTC | Glucose monohydrate | 130503001 | 1 |
| Euro OTC | Glucose monohydrate | 1305030-01 | 6 |
| Euro OTC | Glucose monohydrate | 1305030-02 | 6 |
| Euro OTC | Glucose monohydrate | 1305030-02 | 1 |
| Euro OTC | Glucose monohydrate | 140004-01 | 1 |
| Euro OTC | Glucose monohydrate | 14005004-02 | 1 |
| Euro OTC | Glucose monohydrate | 140101901 | 1 |
| Euro OTC | Glucose monohydrate | 1401019-01 | 10 |
| Euro OTC | Glucose monohydrate | 140101902 | 2 |
| Euro OTC | Glucose monohydrate | 140500401 | 1 |
| Euro OTC | Glucose monohydrate | 1405004-01 | 16 |
| Euro OTC | Glucose monohydrate | 140500402 | 1 |
| Euro OTC | Glucose monohydrate | 1405004-02 | 4 |
| Euro OTC | Glucose monohydrate | 1406212209 | 1 |
| Euro OTC | Glucose monohydrate | 141001901 | 1 |
| Euro OTC | Glucose monohydrate | 1410019-01 | 7 |
| Euro OTC | Glucose monohydrate | 1410019-02 | 4 |
| Euro OTC | Glucose monohydrate | 150402801 | 1 |
| Euro OTC | Glucose monohydrate | 1504028-01 | 14 |
| Euro OTC | Glucose monohydrate | 1504028-02 | 10 |
| Euro OTC | Glucose monohydrate | 15040281 | 1 |
| Euro OTC | Glucose monohydrate | 150900601 | 1 |
| Euro OTC | Glucose monohydrate | 1509006-01 | 19 |
| Euro OTC | Glucose monohydrate | 1509006-02 | 5 |
| Euro OTC | Glucose monohydrate | 1509006-1 | 1 |
| Euro OTC | Glucose monohydrate | 15095601 | 1 |
| Euro OTC | Glucose monohydrate | 151780 | 1 |
| Euro OTC | Glucose monohydrate | 15180010 | 1 |
| Euro OTC | Glucose monohydrate | 160101601 | 2 |
| Euro OTC | Glucose monohydrate | 1601016-01 | 23 |
| Euro OTC | Glucose monohydrate | 1601016-02 | 5 |
| Euro OTC | Glucose monohydrate | 16040060-01 | 1 |
| Euro OTC | Glucose monohydrate | 1604006-01 | 33 |
| Euro OTC | Glucose monohydrate | 160400602 | 2 |
| Euro OTC | Glucose monohydrate | 1604006-02 | 31 |
| Euro OTC | Glucose monohydrate | 1607024 | 1 |
| Euro OTC | Glucose monohydrate | 1607024-01 | 19 |
| Euro OTC | Glucose monohydrate | 1607024-02 | 31 |
| Euro OTC | Glucose monohydrate | 160704-01 | 1 |
| Euro OTC | Glucose monohydrate | 16184807 | 1 |
| Euro OTC | Glucose monohydrate | 1701002_01 | 1 |
| Euro OTC | Glucose monohydrate | 1701002-01 | 28 |
| Euro OTC | Glucose monohydrate | 170100202 | 1 |
| Euro OTC | Glucose monohydrate | 1701002-02 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Glucose monohydrate | 1707004 | 1 |
| Euro OTC | Glucose monohydrate | 1707004-001 | 1 |
| Euro OTC | Glucose monohydrate | 170700401 | 2 |
| Euro OTC | Glucose monohydrate | 1707004-01 | 72 |
| Euro OTC | Glucose monohydrate | 170704401 | 1 |
| Euro OTC | Glucose monohydrate | 17136801 | 1 |
| Euro OTC | Glucose monohydrate | 17136804 | 1 |
| Euro OTC | Glucose monohydrate | 180100-01 | 1 |
| Euro OTC | Glucose monohydrate | 1801009_01 | 1 |
| Euro OTC | Glucose monohydrate | 180100901 | 2 |
| Euro OTC | Glucose monohydrate | 1801009-01 | 71 |
| Euro OTC | Glucose monohydrate | 180100941 | 1 |
| Euro OTC | Glucose monohydrate | 18070005-001 | 1 |
| Euro OTC | Glucose monohydrate | 180700501 | 2 |
| Euro OTC | Glucose monohydrate | 1807005-01 | 45 |
| Euro OTC | Glucose monohydrate | 1807005-02 | 4 |
| Euro OTC | Glucose monohydrate | 18070501 | 1 |
| Euro OTC | Glucose monohydrate | 18070521 | 1 |
| Euro OTC | Glucose monohydrate | 18101901 | 2 |
| Euro OTC | Glucose monohydrate | 18101907 | 1 |
| Euro OTC | Glucose monohydrate | 181101001 | 1 |
| Euro OTC | Glucose monohydrate | 1811020 | 1 |
| Euro OTC | Glucose monohydrate | 181102001 | 2 |
| Euro OTC | Glucose monohydrate | 1811020-01 | 42 |
| Euro OTC | Glucose monohydrate | 1811020-02 | 8 |
| Euro OTC | Glucose monohydrate | 181102003 | 1 |
| Euro OTC | Glucose monohydrate | 1811020-1 | 1 |
| Euro OTC | Glucose monohydrate | 18110201-02 | 1 |
| Euro OTC | Glucose monohydrate | 18111020-01 | 1 |
| Euro OTC | Glucose monohydrate | 18214704 | 1 |
| Euro OTC | Glucose monohydrate | 187005-001 | 1 |
| Euro OTC | Glucose monohydrate | 1900402901 | 1 |
| Euro OTC | Glucose monohydrate | 1904029 | 1 |
| Euro OTC | Glucose monohydrate | 1904029/01 | 1 |
| Euro OTC | Glucose monohydrate | 190402901 | 5 |
| Euro OTC | Glucose monohydrate | 1904029-01 | 55 |
| Euro OTC | Glucose monohydrate | 190429-01 | 1 |
| Euro OTC | Glucose monohydrate | 1907012-01 | 1 |
| Euro OTC | Glucose monohydrate | 1908010-01 | 1 |
| Euro OTC | Glucose monohydrate | 190801201 | 2 |
| Euro OTC | Glucose monohydrate | 1908012-01 | 59 |
| Euro OTC | Glucose monohydrate | 19080122-01 | 1 |
| Euro OTC | Glucose monohydrate | 190801241 | 1 |
| Euro OTC | Glucose monohydrate | 192486006 | 2 |
| Euro OTC | Glucose monohydrate | 200007-01 | 1 |
| Euro OTC | Glucose monohydrate | 20009024-01 | 1 |
| Euro OTC | Glucose monohydrate | 2001006-001 | 1 |
| Euro OTC | Glucose monohydrate | 200100601 | 6 |
| Euro OTC | Glucose monohydrate | 2001006-01 | 67 |
| Euro OTC | Glucose monohydrate | 200600-01 | 1 |
| Euro OTC | Glucose monohydrate | 200600701 | 4 |
| Euro OTC | Glucose monohydrate | 2006007-01 | 48 |
| Euro OTC | Glucose monohydrate | 200902401 | 3 |
| Euro OTC | Glucose monohydrate | 2009024-01 | 102 |
| Euro OTC | Glucose monohydrate | 200902-41 | 1 |
| Euro OTC | Glucose monohydrate | 2013U-02209 | 1 |
| Euro OTC | Glucose monohydrate | 20160405-04 | 1 |
| Euro OTC | Glucose monohydrate | 2023012-1 | 1 |
| Euro OTC | Glucose monohydrate | 210005-01 | 1 |
| Euro OTC | Glucose monohydrate | 2103027 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Glucose monohydrate | 210302701 | 2 |
| Euro OTC | Glucose monohydrate | 2103027-01 | 105 |
| Euro OTC | Glucose monohydrate | 210307-01 | 1 |
| Euro OTC | Glucose monohydrate | 2103207-01 | 1 |
| Euro OTC | Glucose monohydrate | 210327 | 1 |
| Euro OTC | Glucose monohydrate | 2107024_02 | 2 |
| Euro OTC | Glucose monohydrate | 2107024-01 | 31 |
| Euro OTC | Glucose monohydrate | 2107024-02 | 54 |
| Euro OTC | Glucose monohydrate | 2107042-02 | 1 |
| Euro OTC | Glucose monohydrate | 210724-02 | 1 |
| Euro OTC | Glucose monohydrate | 2109008 | 1 |
| Euro OTC | Glucose monohydrate | 210900801 | 1 |
| Euro OTC | Glucose monohydrate | 2109008-01 | 33 |
| Euro OTC | Glucose monohydrate | 2109008-02 | 16 |
| Euro OTC | Glucose monohydrate | 219008-01 | 1 |
| Euro OTC | Glucose monohydrate | 2202015/01 | 1 |
| Euro OTC | Glucose monohydrate | 2202015-01 | 28 |
| Euro OTC | Glucose monohydrate | 2202015-02 | 30 |
| Euro OTC | Glucose monohydrate | 2202015-03 | 6 |
| Euro OTC | Glucose monohydrate | 220215-03 | 1 |
| Euro OTC | Glucose monohydrate | 22022015-01 | 1 |
| Euro OTC | Glucose monohydrate | 2205004-01 | 1 |
| Euro OTC | Glucose monohydrate | 220601801 | 1 |
| Euro OTC | Glucose monohydrate | 2206018-01 | 48 |
| Euro OTC | Glucose monohydrate | 2206018-02 | 8 |
| Euro OTC | Glucose monohydrate | 2210005-01 | 5 |
| Euro OTC | Glucose monohydrate | 2210005-02 | 15 |
| Euro OTC | Glucose monohydrate | 226018-01 | 1 |
| Euro OTC | Glucose monohydrate | 2302007-01 | 4 |
| Euro OTC | Glucose monohydrate | 23051802 | 1 |
| Euro OTC | Glucose monohydrate | 2313E-02209 | 1 |
| Euro OTC | Glucose monohydrate | 31102013B | 1 |
| Euro OTC | Glucose monohydrate | 557473 | 1 |
| Euro OTC | Glucose monohydrate | 8638943 | 1 |
| Euro OTC | Glucose monohydrate | 96-01 | 1 |
| Euro OTC | Glucose monohydrate | E024R | 1 |
| Euro OTC | Glucose monohydrate | E042R/2009024-01 | 1 |
| Euro OTC | Glucose monohydrate | E108T | 3 |
| Euro OTC | Glucose monohydrate | E255L | 1 |
| Euro OTC | Glucose monohydrate | E267X | 1 |
| Euro OTC | Glucose monohydrate | E388S | 2 |
| Euro OTC | Glucose monohydrate | E470S | 2 |
| Euro OTC | Glucose monohydrate | E617K | 1 |
| Euro OTC | Glucose monohydrate | E643N | 1 |
| Euro OTC | Glucose monohydrate | E732N | 2 |
| Euro OTC | Glucose monohydrate | E777P | 2 |
| Euro OTC | Glucose monohydrate | E882R | 1 |
| Euro OTC | Glucose monohydrate | E961M | 1 |
| Euro OTG/ AHD | Glucose monohydrate | 1701002-01 | 1 |
| Euro OTG/ AHD | Glucose monohydrate | 1801009-01 | 1 |
| Euro Pharma/Phönix | Glucose monohydrate | 2103027-01 | 3 |
| EuRo/ Noweda | Glucose monohydrate | 1904029-01 | 1 |
| Euro/ Sanacorp | Glucose monohydrate | 1504028-01 | 1 |
| Euro/Alliance Healthcare | Glucose monohydrate | 1604006-01 | 1 |
| Euro/Krieger | Glucose monohydrate | 1807005-01 | 1 |
| Euro/Noweda | Glucose monohydrate | 1604006-02 | 2 |
| Euro/Phoenix | Glucose monohydrate | 210724-01 | 1 |
| Euro/Phönix | Glucose monohydrate | 1707004-01 | 1 |
| Euro/Phönix | Glucose monohydrate | 1811020-01 | 1 |
| Euro/Phönix | Glucose monohydrate | 1811020-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro/Phönix | Glucose monohydrate | 2210005-01 | 1 |
| Euroo | Glucose monohydrate | 1604006-01 | 1 |
| Fa.Phönix | Glucose monohydrate | 192486003 | 2 |
| Fa.Phönix | Glucose monohydrate | 20002144005 | 1 |
| Fa.Phönix | Glucose monohydrate | 20003964008 | 1 |
| Fa.Phönix | Glucose monohydrate | 22000756010 | 1 |
| Fa.Phönix | Glucose monohydrate | 22000756022 | 1 |
| Fagron | Glucose monohydrate | | 1 |
| Fagron | Glucose monohydrate | 11L19-N13 | 1 |
| Fagron | Glucose monohydrate | 12B09-N05 | 1 |
| Fagron | Glucose monohydrate | 12G30-N01 | 12 |
| Fagron | Glucose monohydrate | 12G30-NO1 | 2 |
| Fagron | Glucose monohydrate | 13A_N01 | 1 |
| Fagron | Glucose monohydrate | 13A25-n01 | 1 |
| Fagron | Glucose monohydrate | 13A25-N01 | 6 |
| Fagron | Glucose monohydrate | 13A25-No1 | 1 |
| Fagron | Glucose monohydrate | 13A25-NO1 | 2 |
| Fagron | Glucose monohydrate | 13B01-N03 | 5 |
| Fagron | Glucose monohydrate | 13C25N09 | 2 |
| Fagron | Glucose monohydrate | 13C25-N09 | 8 |
| Fagron | Glucose monohydrate | 13h06-n08 | 1 |
| Fagron | Glucose monohydrate | 13H06-N08 | 15 |
| Fagron | Glucose monohydrate | 13H14-B06-289483 | 1 |
| Fagron | Glucose monohydrate | 1401019-01 | 1 |
| Fagron | Glucose monohydrate | 1404-B08-298601 | 2 |
| Fagron | Glucose monohydrate | 1404-B08-298604 | 1 |
| Fagron | Glucose monohydrate | 1407-808-307707 | 1 |
| Fagron | Glucose monohydrate | 14102420 | 1 |
| Fagron | Glucose monohydrate | 14104-B08-302707 | 1 |
| Fagron | Glucose monohydrate | 14B04-B01 | 3 |
| Fagron | Glucose monohydrate | 14B04-B01-291137 | 7 |
| Fagron | Glucose monohydrate | 14B04-B01-291138 | 3 |
| Fagron | Glucose monohydrate | 14B04-B01-291143 | 2 |
| Fagron | Glucose monohydrate | 14B28-B02 | 2 |
| Fagron | Glucose monohydrate | 14b28-b02-291353 | 1 |
| Fagron | Glucose monohydrate | 14B28-B02-291353 | 11 |
| Fagron | Glucose monohydrate | 14B28-B02-291354 | 3 |
| Fagron | Glucose monohydrate | 14D30-B06-294678 | 1 |
| Fagron | Glucose monohydrate | 14D30-bo6-294678 | 1 |
| Fagron | Glucose monohydrate | 14I04-808 | 1 |
| Fagron | Glucose monohydrate | 14I04-B08 | 1 |
| Fagron | Glucose monohydrate | 14I04-B08-298601 | 1 |
| Fagron | Glucose monohydrate | 14I04-B08-298602 | 3 |
| Fagron | Glucose monohydrate | 14I04B8298602 | 1 |
| Fagron | Glucose monohydrate | 1509006-01 | 1 |
| Fagron | Glucose monohydrate | 151780-0004 | 1 |
| Fagron | Glucose monohydrate | 1521-B06-309508 | 1 |
| Fagron | Glucose monohydrate | 15A21-B06-309508 | 3 |
| Fagron | Glucose monohydrate | 15B01291137 | 1 |
| Fagron | Glucose monohydrate | 1707004-01 | 3 |
| Fagron | Glucose monohydrate | 17136805 | 1 |
| Fagron | Glucose monohydrate | 18214701 | 2 |
| Fagron | Glucose monohydrate | 270313PML01 | 1 |
| Fagron | Glucose monohydrate | 3413E-02209 | 1 |
| Fagron | Glucose monohydrate | 4213Q-02209 | 1 |
| Fagron | Glucose monohydrate | 4562135 | 1 |
| Fagron | Glucose monohydrate | 8G31-N09 | 1 |
| Fagron | Glucose monohydrate | E0AJ5 | 1 |
| Fagron | Glucose monohydrate | E144C | 1 |
| Fagron | Glucose monohydrate | E524W | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Glucose monohydrate | E571X | 1 |
| Fargon | Glucose monohydrate | 13C25-N09 | 1 |
| Fargron | Glucose monohydrate | 13A25-N01 | 1 |
| Fargron | Glucose monohydrate | 13H06-N08 | 2 |
| Fiebig/ Dextropur | Glucose monohydrate | L7045 | 1 |
| Fiebig | Glucose monohydrate | 18101907 | 1 |
| Fragon | Glucose monohydrate | 13H06-N08 | 1 |
| Frey+Lau GmbH | Glucose monohydrate | 1601016-01 | 1 |
| GATT-KOLLER/PHOENIX | Glucose monohydrate | 243/02141714 | 1 |
| GATT-KOLLER/PHOENIX | Glucose monohydrate | 243/02142614 | 1 |
| Gehe | Glucose monohydrate | 13157026 | 2 |
| GEHE | Glucose monohydrate | 17005803 | 1 |
| Gehe | Glucose monohydrate | 1707004-01 | 1 |
| GEHE | Glucose monohydrate | 1707004-01 | 1 |
| Gehe | Glucose monohydrate | 17305003 | 1 |
| GEHE | Glucose monohydrate | 18030003 | 2 |
| Gehe | Glucose monohydrate | 18101907 | 1 |
| Gehe | Glucose monohydrate | 18214703 | 1 |
| Gehe | Glucose monohydrate | 22001899011 | 4 |
| Gehe | Glucose monohydrate | 2210005-01 | 1 |
| Gehe | Glucose monohydrate | 23000211001 | 1 |
| Gehe | Glucose monohydrate | 2302007-01 | 2 |
| Gehe | Glucose monohydrate | 24000422006 | 1 |
| Gehe | Glucose monohydrate | E316T | 1 |
| geibo | Glucose monohydrate | 220601801 | 1 |
| Gutenberg-Apotheke | Glucose monohydrate | 14B04-B01 | 1 |
| Holdermann | Glucose monohydrate | 22000756019 | 1 |
| Holdermann | Glucose monohydrate | 2206018-01 | 1 |
| hzdjfdj | Glucose monohydrate | jdhdfhhf | 1 |
| Ichthyol/Noweda | Glucose monohydrate | 17305003 | 3 |
| Jenne | Glucose monohydrate | 20004182002 | 3 |
| Jenne | Glucose monohydrate | 2009024-01 | 1 |
| Jenne | Glucose monohydrate | 22001899002 | 1 |
| Jenne | Glucose monohydrate | 2210005-02 | 2 |
| Kehr | Glucose monohydrate | 18101907 | 1 |
| Kehr | Glucose monohydrate | 22000756019 | 1 |
| Kehr | Glucose monohydrate | 23000211010 | 1 |
| Klenk | Glucose monohydrate | 112233 | 1 |
| Klosterring | Glucose monohydrate | 17136802 | 1 |
| Kyberg Experts | Glucose monohydrate | L9009 | 1 |
| Nowed17.04.2015 | Glucose monohydrate | 14334802 | 3 |
| Noweda 30.07.2015 | Glucose monohydrate | 15095612 | 1 |
| Noweda/apo-ident | Glucose monohydrate | 210702402 | 1 |
| Noweda/EuRho 01.02.2... | Glucose monohydrate | 2009024-01 | 1 |
| Noweda | Glucose monohydrate | 1204044-01 | 2 |
| Noweda | Glucose monohydrate | 1210034 | 1 |
| Noweda | Glucose monohydrate | 151780 | 1 |
| Noweda | Glucose monohydrate | 1601016-01 | 1 |
| Noweda | Glucose monohydrate | 1607024-02 | 1 |
| Noweda | Glucose monohydrate | 17005801 | 1 |
| Noweda | Glucose monohydrate | 1701002-01 | 2 |
| Noweda | Glucose monohydrate | 17136801 | 4 |
| Noweda | Glucose monohydrate | 1807005-01 | 1 |
| Noweda | Glucose monohydrate | 18101909 | 1 |
| Noweda | Glucose monohydrate | 1811020-02 | 1 |
| Noweda | Glucose monohydrate | 18214703 | 2 |
| Noweda | Glucose monohydrate | 1904029-01 | 3 |
| Noweda | Glucose monohydrate | 1908012-01 | 2 |
| Noweda | Glucose monohydrate | 2006007-01E777P | 1 |
| Noweda | Glucose monohydrate | 200902401 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Glucose monohydrate | 2009024-01 | 1 |
| Noweda | Glucose monohydrate | 2107024-02 | 1 |
| Noweda | Glucose monohydrate | 22000756007 | 8 |
| Noweda | Glucose monohydrate | 22001899010 | 1 |
| Noweda | Glucose monohydrate | 22001899011 | 1 |
| Noweda | Glucose monohydrate | 2200199011 | 1 |
| NOWEDA | Glucose monohydrate | 2206018-01 | 1 |
| Noweda | Glucose monohydrate | 2210005-02 | 4 |
| Noweda | Glucose monohydrate | 2230756007 | 1 |
| Noweda | Glucose monohydrate | 23000211005 | 1 |
| Noweda | Glucose monohydrate | 23000211008 | 1 |
| Noweda | Glucose monohydrate | 2302007-01 | 1 |
| noweda | Glucose monohydrate | 2310008-01 | 1 |
| Noweda | Glucose monohydrate | 24000422004 | 1 |
| Noweda | Glucose monohydrate | 24000422009 | 1 |
| Noweda | Glucose monohydrate | 24002353001 | 1 |
| Noweda | Glucose monohydrate | A000018 | 1 |
| Noweda | Glucose monohydrate | E882R | 2 |
| Pala | Glucose monohydrate | 18214704 | 1 |
| Pala | Glucose monohydrate | 192486002 | 1 |
| Ph.Eur.8.0 | Glucose monohydrate | 1401019-02 | 1 |
| ph.Eur | Glucose monohydrate | 2206018-01 | 1 |
| pharma gmbh | Glucose monohydrate | 1401019-01 | 1 |
| Phoenix/Cealo | Glucose monohydrate | 17305004 | 1 |
| Phoenix | Glucose monohydrate | 1707004-01 | 1 |
| Phoenix | Glucose monohydrate | 18101901 | 1 |
| Phoenix | Glucose monohydrate | 18214710 | 1 |
| Phoenix | Glucose monohydrate | 192486002 | 1 |
| Phoenix | Glucose monohydrate | 192486003 | 5 |
| Phoenix | Glucose monohydrate | 192486007 | 1 |
| Phoenix | Glucose monohydrate | 20003963001 | 1 |
| Phoenix | Glucose monohydrate | 2100186003 | 1 |
| Phoenix | Glucose monohydrate | 210702402 | 1 |
| Phoenix | Glucose monohydrate | 210800_01 | 1 |
| Phoenix | Glucose monohydrate | 22000756006 | 1 |
| Phoenix | Glucose monohydrate | 22000756019 | 2 |
| Phoenix | Glucose monohydrate | 22001899011 | 1 |
| Phoenix | Glucose monohydrate | 2210005-02 | 1 |
| Phoenix | Glucose monohydrate | 2302007-01 | 2 |
| Phoenix | Glucose monohydrate | 24002353002 | 1 |
| Phoenix | Glucose monohydrate | 24002353006 | 2 |
| Phoenix | Glucose monohydrate | 24002353012 | 1 |
| Phoenix | Glucose monohydrate | 3242 | 1 |
| Phoenix | Glucose monohydrate | 3385 | 1 |
| Phönix Gotha | Glucose monohydrate | 1401019-01 | 1 |
| Phönix Gotha | Glucose monohydrate | 1405004-02 | 1 |
| Phönix Gotha | Glucose monohydrate | 17136801 | 1 |
| Phönix Gotha | Glucose monohydrate | 17305003 | 1 |
| Phönix Gotha | Glucose monohydrate | 18101901 | 1 |
| Phönix Gotha | Glucose monohydrate | 18214703 | 3 |
| Phönix Gotha | Glucose monohydrate | 19073303 | 2 |
| Phönix Gotha | Glucose monohydrate | 192486003 | 1 |
| Phönix | Glucose monohydrate | 1210334-02 | 1 |
| Phönix | Glucose monohydrate | 1401019-01 | 1 |
| phönix | Glucose monohydrate | 16049101 | 1 |
| phönix | Glucose monohydrate | 16049104 | 1 |
| phönix | Glucose monohydrate | 16184816 | 1 |
| Phönix | Glucose monohydrate | 1801009-01 | 1 |
| Phönix | Glucose monohydrate | 18030005 | 1 |
| Phönix | Glucose monohydrate | 1807005-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Glucose monohydrate | 18101907 | 1 |
| Phönix | Glucose monohydrate | 18214703 | 1 |
| Phönix | Glucose monohydrate | 1904029-01 | 1 |
| Phönix | Glucose monohydrate | 19073304 | 1 |
| Phönix | Glucose monohydrate | 192486003 | 1 |
| Phönix | Glucose monohydrate | 200002144002 | 1 |
| Phönix | Glucose monohydrate | 20003963001 | 1 |
| Phönix | Glucose monohydrate | 20003964009 | 1 |
| Phönix | Glucose monohydrate | 20004182009 | 1 |
| Phönix | Glucose monohydrate | 200100601 | 1 |
| Phönix | Glucose monohydrate | 2006007-01 | 1 |
| Phönix | Glucose monohydrate | 21004018006 | 1 |
| Phönix | Glucose monohydrate | 21004018014 | 1 |
| Phönix | Glucose monohydrate | 22001899010 | 1 |
| phönix | Glucose monohydrate | 2202015-03 | 1 |
| phönix | Glucose monohydrate | 2206018-01 | 1 |
| Phönix | Glucose monohydrate | 2240004422004 | 1 |
| Phönix | Glucose monohydrate | 23000211002 | 1 |
| Phönix | Glucose monohydrate | 23000211005 | 1 |
| Phönix | Glucose monohydrate | 23000211006 | 3 |
| Phönix | Glucose monohydrate | 23003430001 | 1 |
| Phönix | Glucose monohydrate | 24002353007 | 1 |
| Phönix | Glucose monohydrate | 24002353010 | 1 |
| QUALI | Glucose monohydrate | | 1 |
| Roquette Freres/AHD | Glucose monohydrate | 12G30-N01 | 1 |
| Roquette Lestrem FR/... | Glucose monohydrate | 1210034-02 | 1 |
| Roquette Lestrem | Glucose monohydrate | 160702402 | 1 |
| Roquette Lestrem | Glucose monohydrate | 1904029-01 | 8 |
| roquette lestrem | Glucose monohydrate | 2009024-01 | 2 |
| Roquette/Phoenix | Glucose monohydrate | E732N | 1 |
| Sanacop | Glucose monohydrate | | 1 |
| Sanacorp,30.03.17, 7,12EUR | Glucose monohydrate | 16184810 | 1 |
| Sanacorp | Glucose monohydrate | 12284230 | 1 |
| sanacorp | Glucose monohydrate | 13157026 | 1 |
| Sanacorp | Glucose monohydrate | 14102430 | 1 |
| Sanacorp | Glucose monohydrate | 1607024-01 | 1 |
| Sanacorp | Glucose monohydrate | 16184810 | 1 |
| Sanacorp | Glucose monohydrate | 17136804 | 1 |
| Sanacorp | Glucose monohydrate | 1807005-02 | 1 |
| Sanacorp | Glucose monohydrate | 18101903 | 2 |
| Sanacorp | Glucose monohydrate | 18101907 | 1 |
| Sanacorp | Glucose monohydrate | 1811020 | 1 |
| Sanacorp | Glucose monohydrate | 18214703 | 1 |
| Sanacorp | Glucose monohydrate | 18214704 | 1 |
| Sanacorp | Glucose monohydrate | 19073301 | 1 |
| Sanacorp | Glucose monohydrate | 19073303 | 1 |
| sanacorp | Glucose monohydrate | 19073304 | 1 |
| Sanacorp | Glucose monohydrate | 192486002 | 1 |
| Sanacorp | Glucose monohydrate | 20004182008 | 1 |
| Sanacorp | Glucose monohydrate | 2001006-01 | 1 |
| Sanacorp | Glucose monohydrate | 21001886009 | 1 |
| sanacorp | Glucose monohydrate | 2103027-01 | 1 |
| Sanacorp | Glucose monohydrate | 2107024-02 | 2 |
| Sanacorp | Glucose monohydrate | 22000756007 | 1 |
| Sanacorp | Glucose monohydrate | 22000756017 | 1 |
| Sanacorp | Glucose monohydrate | 2202015-01 | 2 |
| Sanacorp | Glucose monohydrate | 2206018-01 | 2 |
| Sanacorp | Glucose monohydrate | 23000211001 | 1 |
| Sanacorp | Glucose monohydrate | 23000211005 | 2 |
| Sanacorp | Glucose monohydrate | 23003430002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Glucose monohydrate | 2302007-01 | 1 |
| Sanacorp | Glucose monohydrate | 2310008-01 | 1 |
| Sanacorp | Glucose monohydrate | 24002353013 | 1 |
| Sanacorp | Glucose monohydrate | 3/AKD100 | 1 |
| Sanacorp | Glucose monohydrate | E316T | 1 |
| Sanacorp | Glucose monohydrate | E388S | 2 |
| sittig | Glucose monohydrate | 17005805 | 1 |
| Sonnenberg-Apotheke | Glucose monohydrate | 140500401 | 1 |

- 251 885 spectra from 1666 *Apo-Ident* customers from a total of 51 550 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Glucose monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Glucose monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 520 | 0 | 157 806 |
| **Type B** | 0 | 1010 | 0 | 211 930 |
| **Type C** | 0 | 4989 | 12 | 251 885 |

The substance/substance group *Glucose monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8462 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4059 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7600 % (> 99.7001 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20799 | 22538 | 6.14 | 166.60 |
| 21274 | 21905 | 6.39 | 170.53 |
| 21905 | 21905 | 0.00 | 164.76 |
| 22308 | 22308 | 0.00 | 168.72 |
| 22538 | 22538 | 0.00 | 167.35 |
| 23006 | 23006 | 0.00 | 166.77 |
| 23304 | 23304 | 0.00 | 167.78 |
| 23802 | 23802 | 0.00 | 169.87 |
| 24162 | 24162 | 0.00 | 172.20 |
| 25627 | 25627 | 0.00 | 169.90 |
| 25637 | 25637 | 0.00 | 169.09 |
| 25653 | 25653 | 0.00 | 169.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Glutamic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20436-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Glutamic acid; Acidum glutaminicum

### Special notes

When selecting the *Glutamic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Glutamic acid | 6 | 3 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Glutamic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Glutamic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycine | 89.27 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Glutamic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Glutamic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Glutamic acid | 1604056 | 22562 | 40 | 20160523* |
| Euro OTC | Glutamic acid | 1604056 | 24124 | 40 | 20180613* |
| Euro OTC | Glutamic acid | 2002044 | 25158 | 40 | 20200513* |
| Euro OTC | Glutamic acid | 2305025 | 26753 | 40 | 20230705* |
| Fagron | Glutamic acid | 11I30-N02 | 20840 | 40 | AR-15-FG-010446-02 |
| Fagron | Glutamic acid | 15G31-B08-311884 | 23599 | 40 | 20150817 |
| Fagron | Glutamic acid | 23B20-B04-008732 | 27649 | 40 | 20230321 |
| Fagron | Glutamic acid | 23B20-B04-008732 | 27649SI | 20 | 20230321 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 8 reference samples from the substance/substance group *Glutamic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 026 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 5 reference samples from the substance/substance group *Glutamic acid*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Glutamic acid | 1907031 | 24788 | 40 |
| Euro OTC | Glutamic acid | 2008026 | 25405 | 40 |
| Euro OTC | Glutamic acid | 2501031 | 27623 | 40 |
| Euro OTC | Glutamic acid | 2305025 | 26753SI† | 20 |
| Euro OTC | Glutamic acid | 2501031 | 27623SI | 20 |

- 212 780 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3 spectra from 2 *Apo-Ident* customers from 3 batches from the substance/substance group *Glutamic acid*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Glutamic acid | 2008026-01 | 1 |
| Euro OTC | Glutamic acid | 28071505 | 1 |
| Fagron | Glutamic acid | 3031502 | 1 |

- 256 883 spectra from 1666 *Apo-Ident* customers from a total of 52 150 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Glutamic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Glutamic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 3 | 0 | 256 883 |

The substance/substance group *Glutamic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9030 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20840 | 20840 | 0.00 | 164.04 |
| 22562 | 22562 | 0.00 | 164.79 |
| 23599 | 22562 | 7.78 | 129.81 |
| 24124 | 24124 | 0.00 | 156.11 |

*continued on the next page*


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*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25158 | 25158 | 0.00 | 155.05 |
| 26753 | 26753 | 0.00 | 159.49 |
| 27649 | 24124 | 8.94 | 169.03 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Glutamine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 23150-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Glutamine; Glutaminum; L-glutamine

### Special notes

When selecting the *Glutamine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Glutamine | 6 | 7 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Glutamine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Glutamine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 113.77 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Glutamine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Glutamine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Glutamine | 1702007 | 23150 | 40 | 20170322* |
| Euro OTC | Glutamine | 1706010 | 23543 | 40 | 20170802* |
| Euro OTC | Glutamine | 2003034 | 25238 | 40 | 20200619* |
| Euro OTC | Glutamine | 2006029 | 25347 | 40 | 20200813* |
| Euro OTC | Glutamine | 2011010 | 25458 | 40 | 20201208* |
| Fagron | Glutamine | 17E05-B06-334869 | 23415 | 40 | 20170601 |
| Fagron | Glutamine | 17E05-B06-334869 | 23416 | 40 | AR-17-FG-016178-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 280 spectra of 7 reference samples from the substance/substance group *Glutamine*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 330 spectra of 9 reference samples from the substance/substance group *Glutamine*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Glutamine | 1802010 | 23950 | 40 |
| Euro OTC | Glutamine | 1806001 | 24121 | 40 |
| Euro OTC | Glutamine | 1901009 | 24483 | 40 |
| Euro OTC | Glutamine | 2101010 | 25576 | 40 |
| Euro OTC | Glutamine | 2108006 | 25773 | 50 |
| Euro OTC | Glutamine | 2205028 | 26224 | 40 |
| Euro OTC | Glutamine | 2301005 | 26519 | 40 |
| Euro OTC | Glutamine | 2205028 | 26224SI | 20 |
| Euro OTC | Glutamine | 2301005 | 26519SI | 20 |

- 212 610 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2 spectra from 2 *Apo-Ident* customers from 2 batches from the substance/substance group *Glutamine*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Glutamine | | 1 |
| Euro OTC | Glutamine | 1706010-01 | 1 |

- 256 884 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Glutamine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Glutamine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 330 | 0 | 212 610 |
| **Type C** | 0 | 2 | 0 | 256 884 |

The substance/substance group *Glutamine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.1818 %) |
| **Type C** | 100.0000 % (> 99.9032 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23150 | 23150 | 0.00 | 205.19 |
| 23415 | 23416 | 1.75 | 211.57 |
| 23416 | 23416 | 0.00 | 211.28 |
| 23543 | 23543 | 0.00 | 204.79 |
| 25238 | 25238 | 0.00 | 205.74 |
| 25347 | 25347 | 0.00 | 208.44 |
| 25458 | 25458 | 0.00 | 210.83 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Glutathione** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20366-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Glutathione; Glutathionum

### Special notes

When selecting the *Glutathione* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Glutathione | 7 | 8 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Glutathione* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Glutathione* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 80.67 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Glutathione* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Glutathione*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Glutathione | 1102019-02 | 21788 | 60 | AR-15-FG-008218-01 |
| Euro OTC | Glutathione | 1703008 | 23143 | 40 | 20170327* |
| Euro OTC | Glutathione | 1808036 | 24314 | 40 | 20180919* |
| Euro OTC | Glutathione | 2002042 | 25250 | 40 | 20200622* |
| Euro OTC | Glutathione | 2007021 | 25337 | 40 | 20200810* |
| Euro OTC | Glutathione | 2306012 | 27069 | 40 | 20240208* |
| Euro OTC | Glutathione | 2306012 | 27069SI | 20 | 20240208* |
| Fagron | Glutathione | 18C01-B08-347604 | 24059 | 40 | 20180416 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 8 reference samples from the substance/substance group *Glutathione*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 006 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 360 spectra of 10 reference samples from the substance/substance group *Glutathione*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Glutathione | 1711009 | 23729 | 40 |
| Euro OTC | Glutathione | 1901052 | 24491 | 40 |
| Euro OTC | Glutathione | 1905011 | 24675 | 40 |
| Euro OTC | Glutathione | 2105017 | 25680 | 40 |
| Euro OTC | Glutathione | 2205027 | 26436 | 40 |
| Fagron | Glutathione | 19B04-B04-365527 | 25439 | 40 |
| Fagron | Glutathione | 22K21-B03-230393 | 26978 | 40 |
| Fagron | Glutathione | 24B02-B06-234647 | 27565 | 40 |
| Fagron | Glutathione | 22K21-B03-230393 | 26978SI | 20 |
| Fagron | Glutathione | 24B02-B06-234647 | 27565SI | 20 |

- 212 580 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 25 spectra from 5 *Apo-Ident* customers from 12 batches from the substance/substance group *Glutathione*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Changsha Huir | Glutathione | 2201190 | 1 |
| Euro OTC | Glutathione | 1905011-01 | 1 |
| Euro OTC | Glutathione | 2002042-01 | 13 |
| Fagron | Glutathione | 14H21-B02 | 1 |
| Farmalabor | Glutathione | P1700811 | 1 |
| Shangei tengben Biot… | Glutathione | B210411 | 1 |
| Vivatis Pharma | Glutathione | B200617 | 1 |
| Vivatis Pharma | Glutathione | B210107 | 1 |
| Vivatis Pharma | Glutathione | B210115 | 1 |
| Vivatis Pharma | Glutathione | B210413 | 2 |
| Vivatis Pharma | Glutathione | B210530 | 1 |
| Vivatis Pharma | Glutathione | B220117 | 1 |

- 256 861 spectra from 1666 *Apo-Ident* customers from a total of 52 141 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Glutathione* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Glutathione* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 360 | 0 | 212 580 |
| **Type C** | 0 | 25 | 0 | 256 861 |

The substance/substance group *Glutathione* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.3333 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 76.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21788 | 21788 | 0.00 | 169.58 |
| 23143 | 23143 | 0.00 | 174.44 |
| 24059 | 27069 | 8.42 | 178.67 |
| 24314 | 24314 | 0.00 | 151.22 |
| 25250 | 25250 | 0.00 | 163.96 |
| 25337 | 25337 | 0.00 | 166.85 |
| 27069 | 27069 | 0.00 | 170.80 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Glycine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20823-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Glycine; Glycinum

### Special notes

When selecting the *Glycine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Glycine | 11 | 17 | 18 |

### Second-stage model

For differentiation of the substance/substance group *Glycine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Glycine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| L-alanine | 100.33 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Glycine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Glycine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Glycine | 13157303 | 21687 | 60 | 20130625 |
| Caelo | Glycine | 14147006 | 21818 | 60 | AR-16-FG-012263-01 |
| Caelo | Glycine | 15262518 | 23124 | 40 | 20150910 |
| Caelo | Glycine | 170265 | 23295 | 40 | 20170315* |
| Caelo | Glycine | 173493 | 23834 | 40 | 20180117* |
| Caelo | Glycine | 20001656 | 25218 | 40 | 20200703* |
| Caelo | Glycine | 22002518 | 26368 | 40 | 20220926* |
| Caelo | Glycine | 22002518 | 26368SI | 20 | 20220926* |
| Euro OTC | Glycine | 1402022-01 | 21284 | 40 | 20140328 |
| Euro OTC | Glycine | 1402022-01 | 21534 | 60 | AR-15-FG-005430-01 |
| Euro OTC | Glycine | 1801005 | 23912 | 40 | 20180125* |
| Fagron | Glycine | 12G13-N04 | 20823 | 40 | 1401163 |
| Fagron | Glycine | 13G09-N03 | 21276 | 40 | 20120711 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 560 spectra of 13 reference samples from the substance/substance group *Glycine*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 766 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 770 spectra of 22 reference samples from the substance/substance group *Glycine*.

- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Glycine | 191009 | 24507 | 40 |
| Caelo | Glycine | 23002306 | 26957 | 40 |
| Caelo | Glycine | 24001068 | 27319 | 40 |
| Euro OTC | Glycine | 1605035 | 22683 | 40 |
| Euro OTC | Glycine | 1704015 | 23387 | 40 |
| Euro OTC | Glycine | 1906006 | 24793 | 40 |
| Euro OTC | Glycine | 1911011 | 25103 | 40 |
| Euro OTC | Glycine | 2005028 | 25291 | 40 |
| Euro OTC | Glycine | 2009013 | 25424 | 40 |
| Euro OTC | Glycine | 2101030 | 25529 | 40 |
| Euro OTC | Glycine | 2203024 | 26038 | 40 |
| Euro OTC | Glycine | 2301025 | 26647 | 40 |
| Euro OTC | Glycine | 2307011 | 26890 | 40 |
| Euro OTC | Glycine | 2307010 | 26891 | 40 |
| Euro OTC | Glycine | 2404013 | 27364 | 40 |
| Euro OTC | Glycine | 2501029 | 27491 | 40 |
| Fagron | Glycine | 23G05-B12-230974 | 26987 | 40 |
| Caelo | Glycine | 24001068 | 27319SI | 20 |
| Euro OTC | Glycine | 2203024 | 26038SI | 10 |
| Euro OTC | Glycine | 2301025 | 26647SI | 20 |
| Euro OTC | Glycine | 2404013 | 27364SI | 20 |
| Euro OTC | Glycine | 2501029 | 27491SI | 20 |

- 212 170 spectra from a total of 4270 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 35 spectra from 14 *Apo-Ident* customers from 19 batches from the substance/substance group *Glycine*.
- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Glycine | 23002306001 | 1 |
| | Glycine | 2307010-01 | 2 |
| | Glycine | 2404013-01 | 1 |
| Caelo | Glycine | 14147005 | 1 |
| Caelo | Glycine | 15262502 | 2 |
| Caelo | Glycine | 15262503 | 1 |
| Caelo | Glycine | 15262504 | 1 |
| Caelo | Glycine | 15262518 | 1 |
| Caelo | Glycine | 17026502 | 1 |
| Caelo | Glycine | 19100902 | 3 |
| Caesar & Loretz GmbH | Glycine | 17349306 | 1 |
| Caesar & Loretz GmbH | Glycine | 19100902 | 2 |
| Caesar & Loretz GmbH | Glycine | 19100903 | 2 |
| Euro OTC | Glycine | 1801005-01 | 1 |
| Euro OTC | Glycine | 1906006-01 | 1 |
| Euro OTC | Glycine | 2101030-01 | 4 |
| Euro OTC | Glycine | 2203024-01 | 3 |
| Fagron | Glycine | 19E29-B04-366853 | 1 |
| Fagron | Glycine | 20J13-F06-374988 | 1 |
| Fagron | Glycine | 20J13-F06-376061 | 4 |
| Sanacorp | Glycine | 17349306 | 1 |

- 256 851 spectra from 1666 *Apo-Ident* customers from a total of 52 134 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Glycine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Glycine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 560 | 0 | 157 766 |
| **Type B** | 0 | 770 | 0 | 212 170 |
| **Type C** | 0 | 35 | 0 | 256 851 |

The substance/substance group *Glycine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9286 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2208 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 82.8571 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20823 | 20823 | 0.00 | 197.11 |
| 21276 | 20823 | 13.52 | 199.10 |
| 21284 | 21534 | 13.32 | 183.28 |
| 21534 | 21534 | 0.00 | 180.14 |
| 21687 | 21534 | 15.60 | 185.13 |
| 21818 | 21818 | 0.00 | 213.44 |
| 23124 | 20823 | 31.42 | 193.93 |
| 23295 | 23295 | 0.00 | 211.09 |
| 23834 | 23834 | 0.00 | 184.32 |
| 23912 | 23912 | 0.00 | 181.54 |
| 25218 | 25218 | 0.00 | 206.33 |
| 26368 | 26368 | 0.00 | 183.96 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Glycopyrronium bromide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 23076-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Glycopyrronium bromide; Glycopyrronii bromidum

### Special notes

When selecting the *Glycopyrronium bromide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Glycopyrronium bromide | 6 | 3 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Glycopyrronium bromide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Glycopyrronium bromide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Clobetasol propionate | 111.29 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Glycopyrronium bromide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Glycopyrronium bromide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Glycopyrronium bromide | 16E09-B08-331027 | 23076 | 40 | 1707615 |
| Fagron | Glycopyrronium bromide | 16E09-B08-331027 | 23077 | 40 | 20160530 |
| Fagron | Glycopyrronium bromide | 18C30-B07-350744 | 24183 | 40 | 20180502 |
| Fagron | Glycopyrronium bromide | 18G25-B01-356318 | 24575 | 40 | 20180907 |
| Fagron | Glycopyrronium bromide | 20B03-F12-368270 | 25440 | 40 | 20200228 |
| Fagron | Glycopyrronium bromide | 22B10-B05-219477 | 26285 | 40 | 20220624 |
| Fagron | Glycopyrronium bromide | 23C02-B07-228663 | 26669 | 40 | 20230321 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 280 spectra of 7 reference samples from the substance/substance group *Glycopyrronium bromide*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 6 reference samples from the substance/substance group *Glycopyrronium bromide*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Glycopyrronium bromide | 17D28-B04-341606 | 23939 | 40 |
| Fagron | Glycopyrronium bromide | 21A08-F03-376481 | 25742 | 50 |
| Fagron | Glycopyrronium bromide | 21H13-B22-215731 | 25906 | 40 |
| Fagron | Glycopyrronium bromide | 21H13-B22-215731 | 25906SI | 10 |
| Fagron | Glycopyrronium bromide | 22B10-B05-219477 | 26285SI† | 20 |
| Fagron | Glycopyrronium bromide | 23C02-B07-228663 | 26669SI† | 20 |

- 212 760 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 7 spectra from 6 *Apo-Ident* customers from 4 batches from the substance/substance group *Glycopyrronium bromide*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Glycopyrronium bromide | 18C30-B07-350744 | 3 |
| Fagron | Glycopyrronium bromide | 21A08-F03-376481 | 2 |
| Fagron | Glycopyrronium bromide | 21H13-B22-215731 | 1 |
| Fagron | Glycopyrronium bromide | 21H13-B22-217575 | 1 |

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 256 879 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Glycopyrronium bromide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Glycopyrronium bromide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 7 | 0 | 256 879 |

The substance/substance group *Glycopyrronium bromide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23076 | 23076 | 0.00 | 131.07 |
| 23077 | 23076 | 2.68 | 130.70 |
| 24183 | 23076 | 6.28 | 129.69 |
| 24575 | 23076 | 10.02 | 129.43 |
| 25440 | 23076 | 12.26 | 129.00 |
| 26285 | 23076 | 13.30 | 127.87 |
| 26669 | 23076 | 14.05 | 128.26 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Gramicidin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20203-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Gramicidin; Gramicidinum

### Special notes

When selecting the *Gramicidin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Gramicidin | 6 | 3 | 9 |

### Second-stage model

For differentiation of the substance/substance group *Gramicidin* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Gramicidin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 65.70 | – |
| ⋮ | ⋮ | ⋮ |
| Tyrothricin | >50 | 52.43 |
| Fluocinolone acetonide | >50 | 99.37 |
| Methylprednisolone | >50 | 99.68 |
| Triamcinolone acetonide | >50 | 104.32 |
| Prednisolone | >50 | 125.28 |
| Betamethasone | >50 | 165.20 |
| Dexamethasone | >50 | 169.13 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Gramicidin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Gramicidin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Gramicidin | 13J15-N02 | 21253 | 40 | AR-15-FG-000813-01 |
| Fagron | Gramicidin | 17E09-B02-341211 | 23744 | 40 | AR-18-FG-008970-02 |
| Fagron | Gramicidin | 18A19-B14-350428 | 24171 | 40 | 20180704 |
| Fagron | Gramicidin | 18L20-B01-358528 | 24571 | 40 | 20190320 |
| Fagron | Gramicidin | 19D30-B01-195185 | 25181 | 40 | 20190619 |
| Fagron | Gramicidin | 21G10-B12-213720 | 26326 | 40 | 20210928 |
| Fagron | Gramicidin | 21G10-B12-213720 | 26326SI | 20 | 20210928 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 7 reference samples from the substance/substance group *Gramicidin*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 3 reference samples from the substance/substance group *Gramicidin*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Gramicidin | 14C07-B06-292886 | 21544 | 40 |
| Fagron | Gramicidin | 15H18-B01-316269 | 22748 | 40 |
| Fagron | Gramicidin | 20I29-B07-200272 | 25587 | 40 |

- 212 820 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 12 spectra from 7 *Apo-Ident* customers from 11 batches from the substance/substance group *Gramicidin*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Gramicidin | | 1 |
| Fagron | Gramicidin | 11F-24-N03 | 1 |
| Fagron | Gramicidin | 12K22-N12 | 1 |
| Fagron | Gramicidin | 14H06-B03-297614 | 2 |
| Fagron | Gramicidin | 15C11-B04-306766 | 1 |
| Fagron | Gramicidin | 15H18B01316269 | 1 |
| Fagron | Gramicidin | 17E09-B02-341211 | 1 |
| Fagron | Gramicidin | 20129-B07-200272 | 1 |
| Fagron | Gramicidin | 20I29B07200272 | 1 |
| Fagron | Gramicidin | 21G10B12213720 | 1 |
| Fagron | Gramicidin | B3200266 | 1 |

- 256 874 spectra from 1666 *Apo-Ident* customers from a total of 52 142 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Gramicidin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Gramicidin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 12 | 0 | 256 874 |

The substance/substance group *Gramicidin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21253 | 21253 | 0.00 | 119.06 |
| 23744 | 23744 | 0.00 | 122.27 |
| 24171 | 23744 | 4.72 | 122.17 |
| 24571 | 21253 | 9.07 | 131.90 |
| 25181 | 23744 | 4.96 | 129.12 |
| 26326 | 23744 | 6.25 | 130.02 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Griseofulvin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20939-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Griseofulvin; Griseofulvinum

### Special notes

When selecting the *Griseofulvin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Griseofulvin | 4 | 2 | 63 |

### Second-stage model

For differentiation of the substance/substance group *Griseofulvin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Griseofulvin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Neostigmine bromide | 100.54 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Griseofulvin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Griseofulvin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Griseofulvin | 13D19-N03 | 20939 | 40 | 1401419 |
| Fagron | Griseofulvin | 14E16-B01-296834 | 21725 | 60 | 20140526 |
| Fagron | Griseofulvin | 16F13-B06-330832 | 23594 | 40 | 20160713 |
| Fagron | Griseofulvin | 22K14-B07-213300 | 26459 | 40 | 20221123 |
| Fagron | Griseofulvin | 22K14-B07-213300 | 26459SI | 20 | 20221123 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 5 reference samples from the substance/substance group *Griseofulvin*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 126 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 2 reference samples from the substance/substance group *Griseofulvin*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Griseofulvin | 17L05-B05-345995 | 23996 | 40 |
| Fagron | Griseofulvin | 18L04_B01-357660 | 24440 | 40 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 139 spectra from 55 *Apo-Ident* customers from 70 batches from the substance/substance group *Griseofulvin*.
- Among them are spectra of independent samples from 63 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Griseofulvin | 22K14-B07-213300 | 1 |
| AHD | Griseofulvin | 17L05-B05-349129 | 1 |
| AHD | Griseofulvin | 18L04-B01-357660 | 1 |
| AHD | Griseofulvin | 18L04-B01-361614 | 1 |
| AHD | Griseofulvin | 18Lo4-B01-357660 | 1 |
| AHD | Griseofulvin | B01-3616104 | 1 |
| Alliance Healthcare | Griseofulvin | 18L04-B01-363841 | 1 |
| Bombastus | Griseofulvin | 15L03-HH150640 | 1 |
| Bombastus | Griseofulvin | 16F13-B06-323068 | 2 |
| Bombastus | Griseofulvin | 16F13-B06-326073 | 1 |
| Bombastus | Griseofulvin | 17L05-B05-345996 | 1 |
| Caelo | Griseofulvin | 100910 | 1 |
| Caelo | Griseofulvin | 16F13-B06-323068 | 1 |
| Caelo | Griseofulvin | 16F13-B06-326074 | 1 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Griseofulvin | 16F13-B06-330833 | 1 |
| Euro OTC | Griseofulvin | | 1 |
| Euro OTC | Griseofulvin | 14E16-B01-300367 | 1 |
| Fagron | Griseofulvin | 10F03-N12 | 1 |
| Fagron | Griseofulvin | 11J11-N13 | 1 |
| Fagron | Griseofulvin | 12D04-N12 | 1 |
| Fagron | Griseofulvin | 12F18-N04 | 1 |
| Fagron | Griseofulvin | 130922 | 2 |
| Fagron | Griseofulvin | 13D19-N03 | 1 |
| Fagron | Griseofulvin | 13F12-N22 | 1 |
| Fagron | Griseofulvin | 13L13-B08 | 1 |
| Fagron | Griseofulvin | 13L-13B08 | 1 |
| Fagron | Griseofulvin | 13L13-B08-290316 | 4 |
| Fagron | Griseofulvin | 13L13-B08-290317 | 1 |
| Fagron | Griseofulvin | 140410 | 2 |
| Fagron | Griseofulvin | 14E16-B01-300366 | 3 |
| Fagron | Griseofulvin | 14E16-B01-300367 | 1 |
| Fagron | Griseofulvin | 15062015A | 1 |
| Fagron | Griseofulvin | 15810-B06 | 1 |
| Fagron | Griseofulvin | 15B10-B06 | 1 |
| Fagron | Griseofulvin | 15B10-B06-306547 | 9 |
| Fagron | Griseofulvin | 15B10-B06-306663 | 1 |
| Fagron | Griseofulvin | 15B10-B06-396547 | 1 |
| Fagron | Griseofulvin | 15l03-b04-315624 | 1 |
| Fagron | Griseofulvin | 15L03-B04-315624 | 3 |
| Fagron | Griseofulvin | 15L03-B315624 | 1 |
| Fagron | Griseofulvin | 16F13-B06 | 1 |
| Fagron | Griseofulvin | 16F13-B06-323067 | 3 |
| Fagron | Griseofulvin | 16F13-B06-326073 | 1 |
| Fagron | Griseofulvin | 16f13-b06-326074 | 1 |
| Fagron | Griseofulvin | 16F13-B06-330832 | 5 |
| Fagron | Griseofulvin | 16f13-b06-330833 | 1 |
| Fagron | Griseofulvin | 16F13B06330833 | 1 |
| Fagron | Griseofulvin | 16F13-B06-330833 | 5 |
| Fagron | Griseofulvin | 17-L05-352461 | 1 |
| Fagron | Griseofulvin | 17L05-B05 | 5 |
| Fagron | Griseofulvin | 17L05-B05-345995 | 3 |
| Fagron | Griseofulvin | 17L05-B05-34999 | 1 |
| Fagron | Griseofulvin | 17L05-B05-351232 | 4 |
| Fagron | Griseofulvin | 17L05B05352461 | 2 |
| Fagron | Griseofulvin | 17L05-B05-352461 | 3 |
| Fagron | Griseofulvin | 17L05-B05-355075 | 1 |
| Fagron | Griseofulvin | 17LO05-B05-352461 | 1 |
| Fagron | Griseofulvin | 17LO5-BO5 | 1 |
| Fagron | Griseofulvin | 17LO5-BO5-352461 | 1 |
| Fagron | Griseofulvin | 17LOS-B05-351232 | 1 |
| Fagron | Griseofulvin | 18L04-B01 | 3 |
| Fagron | Griseofulvin | 18L04-B01-357660 | 3 |
| Fagron | Griseofulvin | 18L04-B01-357661 | 1 |
| Fagron | Griseofulvin | 18L04-B01-359072 | 2 |
| Fagron | Griseofulvin | 18L04-B01-359073 | 2 |
| Fagron | Griseofulvin | 18L04-B01-361614 | 4 |
| Fagron | Griseofulvin | 18L04-B01-361615 | 3 |
| Fagron | Griseofulvin | 18L04-B01-3670033 | 1 |
| Fagron | Griseofulvin | 18LO4-BO1-357660 | 1 |
| Fagron | Griseofulvin | 700771-0001 | 1 |
| Fagron | Griseofulvin | B01-3670303 | 1 |
| Fagron | Griseofulvin | HH160510 | 1 |
| Fagron | Griseofulvin | HH171022 | 1 |
| Fargon GmbH & Co.KG | Griseofulvin | 16F13-B06-323067 | 1 |

*continued on the next page*



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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fargon/Sanacorp | Griseofulvin | 17L05-B05-351231 | 1 |
| Gehe amax | Griseofulvin | 15B10-B06-306547 | 2 |
| LAP | Griseofulvin | 15L03-B04-315624 | 1 |
| Noweda | Griseofulvin | 16F13-B06-330833 | 1 |
| Noweda | Griseofulvin | 17L05-B05-345995 | 2 |
| Phönix Gotha | Griseofulvin | 140410 | 1 |
| Sanacorp Stralsund | Griseofulvin | 18L04-B01-359073 | 2 |
| Sanacorp/ F | Griseofulvin | 12B06-N07 | 1 |
| Sanacorp | Griseofulvin | 17L05-B05-345995 | 1 |
| Sanacorp | Griseofulvin | 22K14-B07-213300 | 1 |
| Sanacorp | Griseofulvin | 22K14-B07-213301 | 1 |

- 256 747 spectra from 1666 *Apo-Ident* customers from a total of 52 084 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Griseofulvin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Griseofulvin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 125 | 14 | 256 747 |

The substance/substance group *Griseofulvin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 89.9281 % (> 87.7698 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20939 | 20939 | 0.00 | 122.05 |
| 21725 | 20939 | 14.20 | 123.89 |
| 23594 | 20939 | 7.91 | 131.33 |
| 26459 | 20939 | 10.81 | 131.49 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Guaifenesin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20551-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Guaifenesin; Guaifenesinum

### Special notes

When selecting the *Guaifenesin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Guaifenesin | 8 | 14 | 21 |

### Second-stage model

For differentiation of the substance/substance group *Guaifenesin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Guaifenesin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 75.55 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Guaifenesin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Guaifenesin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Guaifenesin | 163333 | 23051 | 40 | 20161221* |
| Caelo | Guaifenesin | 172496 | 23644 | 40 | 20171005* |
| Euro OTC | Guaifenesin | 1212002-01 | 21287 | 40 | 20121214 |
| Euro OTC | Guaifenesin | 1506044 | 21864 | 60 | 20150708* |
| Euro OTC | Guaifenesin | 1605005 | 22555 | 40 | 20160525* |
| Euro OTC | Guaifenesin | 1910023 | 24941 | 40 | 20191114* |
| Euro OTC | Guaifenesin | 2206012 | 26219 | 40 | 20220715* |
| Euro OTC | Guaifenesin | 2206012 | 26219SI | 20 | 20220715* |
| Fagron | Guaifenesin | 22H03-B01-227258 | 26549 | 40 | 20220823 |
| Fagron | Guaifenesin | 22H03-B01-227258 | 26549SI | 20 | 20220823 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 380 spectra of 10 reference samples from the substance/substance group *Guaifenesin*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 946 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 580 spectra of 15 reference samples from the substance/substance group *Guaifenesin*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Guaifenesin | 190134 | 24518 | 40 |
| Euro OTC | Guaifenesin | 1701011 | 22993 | 40 |
| Euro OTC | Guaifenesin | 1706006 | 23551 | 40 |
| Euro OTC | Guaifenesin | 1710033 | 23741 | 40 |
| Euro OTC | Guaifenesin | 1802001 | 23949 | 40 |
| Euro OTC | Guaifenesin | 1804004 | 24076 | 40 |
| Euro OTC | Guaifenesin | 1809011 | 24316 | 40 |
| Euro OTC | Guaifenesin | 1901047 | 24474 | 40 |
| Euro OTC | Guaifenesin | 1906008 | 24801 | 40 |
| Euro OTC | Guaifenesin | 2007006 | 25245 | 40 |
| Euro OTC | Guaifenesin | 2002034 | 25292 | 40 |
| Euro OTC | Guaifenesin | 2102012 | 25601 | 40 |
| Euro OTC | Guaifenesin | 2306003 | 26770 | 40 |
| Euro OTC | Guaifenesin | 2406001 | 27280 | 40 |
| Euro OTC | Guaifenesin | 2306003 | 26770SI | 20 |

- 212 360 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 31 spectra from 10 *Apo-Ident* customers from 22 batches from the substance/substance group *Guaifenesin*.

- Among them are spectra of independent samples from 21 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Guaifenesin | 2306003-01 | 1 |
| | Guaifenesin | 2306003-02 | 1 |
| Caelo | Guaifenesin | 1212002-01 | 1 |
| Caelo | Guaifenesin | 12277307 | 1 |
| Caelo | Guaifenesin | 12277311 | 1 |
| Caelo | Guaifenesin | 15302502 | 1 |
| Caelo | Guaifenesin | 15F30-b06-317816 | 1 |
| Caelo | Guaifenesin | 16135507 | 1 |
| Caelo | Guaifenesin | 1706006 | 1 |
| Caelo | Guaifenesin | 18018302 | 1 |
| Euro OTC | Guaifenesin | 1701011-01 | 1 |
| Euro OTC | Guaifenesin | 1706006-01 | 3 |
| Euro OTC | Guaifenesin | 1804004-01 | 1 |
| Euro OTC | Guaifenesin | 1809011-01 | 2 |
| Euro OTC | Guaifenesin | 18GF06347 | 1 |
| Euro OTC | Guaifenesin | 1906008-01 | 4 |
| Euro OTC | Guaifenesin | 1910023-01 | 1 |
| Euro OTC | Guaifenesin | 2002034-01 | 1 |
| Euro OTC | Guaifenesin | 2007006-01 | 3 |
| Euro OTC | Guaifenesin | 2102012-01 | 1 |
| Euro OTC | Guaifenesin | 2206012-01 | 1 |
| Phoenix 05.07.2014 | Guaifenesin | 1402023-01 | 2 |

- 256 855 spectra from 1666 *Apo-Ident* customers from a total of 52 131 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Guaifenesin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Guaifenesin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 580 | 0 | 212 360 |
| **Type C** | 0 | 31 | 0 | 256 855 |

The substance/substance group *Guaifenesin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.9655 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 80.6452 %) |


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In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21287 | 21864 | 16.42 | 241.77 |
| 21864 | 21864 | 0.00 | 240.85 |
| 22555 | 22555 | 0.00 | 236.57 |
| 23051 | 23051 | 0.00 | 242.34 |
| 23644 | 23644 | 0.00 | 241.93 |
| 24941 | 24941 | 0.00 | 242.01 |
| 26219 | 26219 | 0.00 | 239.97 |
| 26549 | 23051 | 5.61 | 242.58 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Heparin sodium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20638-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Heparin sodium; Heparinum natricum

### Special notes

When selecting the *Heparin sodium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Heparin sodium | 7 | 16 | 30 |

### Second-stage model

For differentiation of the substance/substance group *Heparin sodium* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Heparin sodium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 40.52 | – |
| Sodium cromoglicate | 71.60 | – |
| ⋮ | ⋮ | ⋮ |
| Sodium citrate | >50 | 135.19 |
| Capsaicin | >50 | 284.49 |
| Sucrose | >50 | 365.45 |
| Oxybutynin hydrochloride | >50 | 468.26 |
| Prednicarbate | >50 | 477.84 |
| Quinine hydrochloride dihydrate | >50 | 558.21 |
| Levocarnitine | >50 | 582.01 |
| Pyridoxal-5-phosphate hydrate | >50 | 737.58 |
| Ciprofloxacin hydrochloride | >50 | 851.62 |
| Amifampridine | >50 | 862.59 |
| Tetracaine | >50 | 928.33 |
| Methoxsalen | >50 | 1030.88 |
| Alfatradiol | >50 | 1038.96 |
| Norethisterone acetate | >50 | 1227.90 |
| Cyproterone acetate | >50 | 1353.97 |
| Triclosan | >50 | 1679.81 |
| Amitriptyline hydrochloride | >50 | 2490.42 |
| Valine | >50 | 3504.85 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Heparin sodium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Heparin sodium*:


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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Heparin sodium | 12050009-03 | 21294 | 40 | AR-15-FG-007427-02 |
| Euro OTC | Heparin sodium | 1605022-01 | 22804 | 40 | 9699 |
| Fagron | Heparin sodium | 12H30-N07 | 20798 | 40 | 1404230 |
| Fagron | Heparin sodium | 12L20-B01-317990 | 22824 | 40 | 20130312 |
| Yino Pharma | Heparin sodium | YN01011170904 | 23978 | 40 | 20180411* |
| Yino Pharma | Heparin sodium | YN01011170904 | 23979 | 40 | 20180411* |
| Yino Pharma | Heparin sodium | YN01011170502 | 23980 | 40 | 20180411* |
| Yino Pharma | Heparin sodium | YN01011170502 | 23981 | 40 | 20180411* |
| Yino Pharma | Heparin sodium | YN01011170904 | 24195 | 40 | 20180531* |
| Yino Pharma | Heparin sodium | YN010182005002 | 25757 | 50 | 20200528* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 410 spectra of 10 reference samples from the substance/substance group *Heparin sodium*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 916 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 810 spectra of 21 reference samples from the substance/substance group *Heparin sodium*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Heparin sodium | 1908030-01 | 25783 | 50 |
| Fagron | Heparin sodium | 16I26-B02-332108 | 23591 | 40 |
| Fagron | Heparin sodium | 21E10-B02-220313 | 26391 | 40 |
| Fagron | Heparin sodium | 22K21-B06-224495 | 26665 | 40 |
| Fagron | Heparin sodium | 24K06-B11-009373 | 27634 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Yino Pharma | Heparin sodium | YN01011R1170803 | 23976 | 40 |
| Yino Pharma | Heparin sodium | YN010111805002 | 24196 | 40 |
| Yino Pharma | Heparin sodium | YN010121805010 | 24197 | 40 |
| Yino Pharma | Heparin sodium | YN01011R11901002 | 24907 | 40 |
| Yino Pharma | Heparin sodium | YN010111906005 | 24908 | 40 |
| Yino Pharma | Heparin sodium | YN010111906006 | 24909 | 40 |
| Yino Pharma | Heparin sodium | YN010111907007 | 24910 | 40 |
| Yino Pharma | Heparin sodium | YN010111908008 | 24911 | 40 |
| Yino Pharma | Heparin sodium | YN010121810018 | 24912 | 40 |
| Yino Pharma | Heparin sodium | YN010111910009 | 24984 | 40 |
| Yino Pharma | Heparin sodium | YN010112107004 | 25758 | 50 |
| Fagron | Heparin sodium | 21E10-B02-220313 | 26391SI | 20 |
| Fagron | Heparin sodium | 22K21-B06-224495 | 26665SI | 20 |
| Fagron | Heparin sodium | 24K06-B11-009373 | 27634SI | 20 |
| Yino Pharma | Heparin sodium | YN01011R1170803 | 23977 | 40 |
| Yino Pharma | Heparin sodium | YN01011R11901002 | 25756 | 50 |

- 212 130 spectra from a total of 4271 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 45 spectra from 24 *Apo-Ident* customers from 31 batches from the substance/substance group *Heparin sodium*.

- Among them are spectra of independent samples from 30 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Heparin sodium | 20K06-B02-200814 | 1 |
| | Heparin sodium | 21E10-B02-220313 | 4 |
| Caelo | Heparin sodium | 16I26-B02-327885 | 1 |
| Changzhou Qianhong B... | Heparin sodium | 20K06-B02-200814 | 1 |
| Euro OTC | Heparin sodium | 1605022-02 | 2 |
| Fagron | Heparin sodium | 11190188SH | 2 |
| Fagron | Heparin sodium | 12190453CQ | 1 |
| Fagron | Heparin sodium | 12G19-B02-313422 | 1 |
| Fagron | Heparin sodium | 12H30-N07 | 2 |
| Fagron | Heparin sodium | 12120-B01-323107 | 1 |
| Fagron | Heparin sodium | 13G03-N13 | 3 |
| Fagron | Heparin sodium | 14D09-B08-293944 | 2 |
| Fagron | Heparin sodium | 14D09-B08-307077 | 1 |
| Fagron | Heparin sodium | 15A20-B02-307307 | 1 |
| Fagron | Heparin sodium | 16I26-B02 | 1 |
| Fagron | Heparin sodium | 16I26-B02-327885 | 1 |
| Fagron | Heparin sodium | 16I26-B02-332108 | 1 |
| Fagron | Heparin sodium | 16I26-B02-342640 | 1 |
| Fagron | Heparin sodium | 17L06-B01 | 1 |
| Fagron | Heparin sodium | 17L06-B01-354811 | 1 |
| Fagron | Heparin sodium | 18C21-B03-349501 | 1 |
| Fagron | Heparin sodium | 19J11B02195123 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Heparin sodium | 20D28-B01 | 2 |
| Fagron | Heparin sodium | 20D28-B01-201583 | 2 |
| Fagron | Heparin sodium | 20K06-B02-200814 | 1 |
| Fagron | Heparin sodium | 21E10-B02-213670 | 2 |
| Fagron | Heparin sodium | B01-2015803 | 1 |
| Fagron | Heparin sodium | B02-1951203 | 1 |
| Faron/Kehr /07.07.2020 | Heparin sodium | 19J11-B02-195122 | 1 |
| Fiebig | Heparin sodium | 16190116C0 | 1 |
| Gatt-Koller | Heparin sodium | 1901027 | 1 |
| L31 | Heparin sodium | 16I26-B02-337593 | 1 |
| Phoenix | Heparin sodium | 5920101900 | 1 |

- 256 841 spectra from 1666 *Apo-Ident* customers from a total of 52 122 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Heparin sodium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Heparin sodium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 410 | 0 | 157 916 |
| **Type B** | 0 | 810 | 0 | 212 130 |
| **Type C** | 0 | 41 | 4 | 256 841 |

The substance/substance group *Heparin sodium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5366 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2593 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 91.1111 % (> 84.4444 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20798 | 20798 | 0.00 | 116.52 |
| 21294 | 21294 | 0.00 | 74.41 |
| 22804 | 22804 | 0.00 | 68.60 |
| 22824 | 21294 | 19.41 | 102.78 |
| 23978 | 23978 | 0.00 | 49.51 |
| 23979 | 23979 | 0.00 | 50.66 |
| 23980 | 23980 | 0.00 | 63.19 |
| 23981 | 23981 | 0.00 | 75.01 |
| 24195 | 24195 | 0.00 | 87.31 |
| 25757 | 25757 | 0.00 | 94.47 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Histamine dihydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20963-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Histamine dihydrochloride; Histamini dihydrochloridum

### Special notes

When selecting the *Histamine dihydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Histamine dihydrochloride | 6 | 6 | 31 |

### Second-stage model

For differentiation of the substance/substance group *Histamine dihydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Histamine dihydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycine | 89.51 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Histamine dihydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Histamine dihydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Histamine dihydrochloride | 1111004-02 | 20963 | 40 | 1403674 |
| Euro OTC | Histamine dihydrochloride | 1506030 | 21863 | 60 | 20150706* |
| Euro OTC | Histamine dihydrochloride | 2004012 | 25166 | 40 | 20200525* |
| Euro OTC | Histamine dihydrochloride | 2009009 | 25413 | 40 | 20201005* |
| Fagron | Histamine dihydrochloride | 14G16-B02-299175 | 21668 | 100 | 20140729 |
| Fagron | Histamine dihydrochloride | 19D19-B02-361228 | 24589 | 40 | 20190516 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 6 reference samples from the substance/substance group *Histamine dihydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 340 spectra of 10 reference samples from the substance/substance group *Histamine dihydrochloride*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Histamine dihydrochloride | 1812018 | 24541 | 40 |
| Euro OTC | Histamine dihydrochloride | 1905003 | 24616 | 40 |
| Euro OTC | Histamine dihydrochloride | 2301007 | 26526 | 40 |
| Euro OTC | Histamine dihydrochloride | 2409007 | 27453 | 40 |
| Fagron | Histamine dihydrochloride | 15C25-B50-331242 | 23196 | 40 |
| Fagron | Histamine dihydrochloride | 22H25-B01-222394 | 26389 | 40 |
| Euro OTC | Histamine dihydrochloride | 2301007 | 26526SI | 20 |
| Euro OTC | Histamine dihydrochloride | 2409007 | 27453SI | 20 |
| Fagron | Histamine dihydrochloride | 15C25-B50-331242 | 23197 | 40 |
| Fagron | Histamine dihydrochloride | 22H25-B01-222394 | 26389SI | 20 |

- 212 600 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 61 spectra from 32 *Apo-Ident* customers from 34 batches from the substance/substance group *Histamine dihydrochloride*.

- Among them are spectra of independent samples from 31 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Histamine dihydrochloride | 1111004-02 | 1 |
| Caelo | Histamine dihydrochloride | 130500601 | 1 |
| Euro OTC | Histamine dihydrochloride | 1104004-03 | 1 |
| Euro OTC | Histamine dihydrochloride | 111004-02 | 1 |
| Euro OTC | Histamine dihydrochloride | 1111004-01 | 5 |
| Euro OTC | Histamine dihydrochloride | 1111004-02 | 1 |
| Euro OTC | Histamine dihydrochloride | 1305006-01 | 1 |
| Euro OTC | Histamine dihydrochloride | 1411012-02 | 4 |
| Euro OTC | Histamine dihydrochloride | 1411012-03 | 1 |
| Euro OTC | Histamine dihydrochloride | 1506030-01 | 3 |
| Euro OTC | Histamine dihydrochloride | 1811014-01 | 1 |
| Euro OTC | Histamine dihydrochloride | 1812018-01 | 1 |
| Euro OTC | Histamine dihydrochloride | 1905003-01 | 2 |
| Euro OTC | Histamine dihydrochloride | 1905003-02 | 3 |
| Euro OTC | Histamine dihydrochloride | 20021412 | 1 |
| Euro OTC | Histamine dihydrochloride | 2004012-01 | 1 |
| Euro OTC | Histamine dihydrochloride | 3031503 | 1 |
| Fa Roth | Histamine dihydrochloride | 47252901 | 1 |
| Fagron | Histamine dihydrochloride | 11E25-N07 | 2 |
| Fagron | Histamine dihydrochloride | 12D02-N16 | 1 |
| Fagron | Histamine dihydrochloride | 12E29-N09 | 3 |
| Fagron | Histamine dihydrochloride | 12K06-N08 | 7 |
| Fagron | Histamine dihydrochloride | 1305006-01 | 1 |
| Fagron | Histamine dihydrochloride | 14J06B01299179 | 1 |
| Fagron | Histamine dihydrochloride | 15E08-B06-313037 | 3 |
| Fagron | Histamine dihydrochloride | 17D11-B001-339451 | 1 |
| Fagron | Histamine dihydrochloride | 19D19-B02-361228 | 1 |
| Fagron | Histamine dihydrochloride | 28051305 | 1 |
| Fagron | Histamine dihydrochloride | 454545 | 1 |
| Fagron | Histamine dihydrochloride | L17100130-OF-222030 | 1 |
| Fargon/Fargon | Histamine dihydrochloride | 19019-B02 | 1 |
| Fargon/Fargon | Histamine dihydrochloride | 19D19-B02 | 1 |
| Fargon/Fargon | Histamine dihydrochloride | 19H23-F04-364053 | 3 |
| Merck | Histamine dihydrochloride | Wxbc3407V | 1 |
| Merck | Histamine dihydrochloride | WXBC3407V | 1 |
| Sanacop | Histamine dihydrochloride | 15C25-B01-306047 | 1 |

- 256 825 spectra from 1666 *Apo-Ident* customers from a total of 52 120 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Histamine dihydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Histamine dihydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 340 | 0 | 212 600 |
| **Type C** | 0 | 61 | 0 | 256 825 |

The substance/substance group *Histamine dihydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.2353 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 90.1639 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20963 | 20963 | 0.00 | 155.03 |
| 21668 | 21863 | 12.19 | 158.93 |
| 21863 | 21863 | 0.00 | 155.65 |
| 24589 | 25166 | 6.81 | 154.66 |
| 25166 | 25166 | 0.00 | 154.76 |
| 25413 | 25413 | 0.00 | 152.87 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Histidine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 23135-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Histidine; Histidinum; L-histidine

### Special notes

When selecting the *Histidine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Histidine | 6 | 6 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Histidine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Histidine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycine | 116.01 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Histidine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Histidine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Histidine | 1703022 | 23135 | 40 | 20170405* |
| Euro OTC | Histidine | 2004038 | 25163 | 40 | 20200528* |
| Euro OTC | Histidine | 2101009 | 25577 | 40 | 20210121* |
| Euro OTC | Histidine | 2301009 | 26520 | 40 | 20230201* |
| Euro OTC | Histidine | 2301009 | 26520SI | 20 | 20230201* |
| Fagron | Histidine | 15I01-B12-329082 | 23590 | 40 | 20150921 |
| Fagron | Histidine | 18J03-B02-355093 | 24701 | 40 | 20181123 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 260 spectra of 7 reference samples from the substance/substance group *Histidine*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 270 spectra of 8 reference samples from the substance/substance group *Histidine*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Histidine | 2201021 | 25953 | 40 |
| Euro OTC | Histidine | 2501030 | 27622 | 40 |
| Fagron | Histidine | 17F15-B04-343276 | 23935 | 40 |
| Fagron | Histidine | 20J15-B01-202794 | 25487 | 40 |
| Fagron | Histidine | 23C07-B06-229457 | 26684 | 40 |
| Fagron | Histidine | 24A24-B08-006359 | 27595 | 40 |
| Euro OTC | Histidine | 2201021 | 25953SI | 10 |
| Fagron | Histidine | 23C07-B06-229457 | 26684SI | 20 |

- 212 670 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Histidine*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Histidine | 2004038-01 | 1 |

- 256 885 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Histidine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Histidine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 270 | 0 | 212 670 |
| **Type C** | 0 | 1 | 0 | 256 885 |

The substance/substance group *Histidine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.7778 %) |
| **Type C** | 100.0000 % (> 99.9038 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23135 | 23135 | 0.00 | 186.91 |
| 23590 | 25577 | 5.40 | 187.85 |
| 24701 | 25577 | 4.66 | 187.90 |
| 25163 | 25163 | 0.00 | 186.82 |
| 25577 | 25577 | 0.00 | 187.01 |
| 26520 | 26520 | 0.00 | 188.24 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Homatropine hydrobromide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24442-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Homatropine hydrobromide; Homatropini hydrobromidum

### Special notes

When selecting the *Homatropine hydrobromide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Homatropine hydrobromide | 2 | 2 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Homatropine hydrobromide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Homatropine hydrobromide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 119.68 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Homatropine hydrobromide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Homatropine hydrobromide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Homatropine hydrobromide | 18L11-B03-356938 | 24442 | 40 | 1905511 |
| Fagron | Homatropine hydrobromide | 23G12-B16-233048 | 27020 | 40 | 20230726 |
| Fagron | Homatropine hydrobromide | 23G12-B16-233048 | 27020SI | 20 | 20230726 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 100 spectra of 3 reference samples from the substance/substance group *Homatropine hydrobromide*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.
- 158 226 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 4 reference samples from the substance/substance group *Homatropine hydrobromide*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Homatropine hydrobromide | 21J07-B04-213599 | 26056 | 40 |
| Fagron | Homatropine hydrobromide | 24D24-B09-000930 | 27375 | 40 |
| Fagron | Homatropine hydrobromide | 21J07-B04-213599 | 26056SI | 20 |
| Fagron | Homatropine hydrobromide | 24D24-B09-000930 | 27375SI | 20 |

- 212 820 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Homatropine hydrobromide*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Homatropine hydrobromide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Homatropine hydrobromide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 100 | 0 | 158 226 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Homatropine hydrobromide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 94.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24442 | 24442 | 0.00 | 182.09 |
| 27020 | 24442 | 7.73 | 179.31 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hydrochlorothiazide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20323-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hydrochlorothiazide; Hydrochlorothiazidum

### Special notes

When selecting the *Hydrochlorothiazide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hydrochlorothiazide | 6 | 4 | 119 |

### Second-stage model

For differentiation of the substance/substance group *Hydrochlorothiazide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hydrochlorothiazide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 113.38 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hydrochlorothiazide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hydrochlorothiazide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Hydrochlorothiazide | 13008505 | 21589 | 60 | AR-15-FG-014461-01 |
| Caelo | Hydrochlorothiazide | 182649 | 24362 | 40 | 20181127* |
| Fagron | Hydrochlorothiazide | 11L01-N02 | 20888 | 40 | 20111209 |
| Fagron | Hydrochlorothiazide | 17L20-B02-345079 | 23989 | 40 | 20180125 |
| Fagron | Hydrochlorothiazide | 20E27-F01-371506 | 25590 | 40 | 20200630 |
| Fagron | Hydrochlorothiazide | 21H27-B04-220130 | 26172 | 40 | 20220202 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 6 reference samples from the substance/substance group *Hydrochlorothiazide*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 6 reference samples from the substance/substance group *Hydrochlorothiazide*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hydrochlorothiazide | 14009701 | 23116 | 40 |
| Caelo | Hydrochlorothiazide | 192328 | 24888 | 40 |
| Caelo | Hydrochlorothiazide | 23002418 | 27125 | 40 |
| Fagron | Hydrochlorothiazide | 16F17-B07-327489 | 23600 | 40 |
| Caelo | Hydrochlorothiazide | 23002418 | 27125SI | 20 |
| Fagron | Hydrochlorothiazide | 21H27-B04-220130 | 26172SI† | 20 |

- 212 740 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 466 spectra from 286 *Apo-Ident* customers from 127 batches from the substance/substance group *Hydrochlorothiazide*.
- Among them are spectra of independent samples from 118 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hydrochlorothiazide | 18017305 | 1 |
| | Hydrochlorothiazide | 192328002 | 1 |
| | Hydrochlorothiazide | 20004000011 | 1 |
| | Hydrochlorothiazide | 20004000014 | 1 |
| | Hydrochlorothiazide | 20E27-F01-373727 | 1 |
| | Hydrochlorothiazide | 21H27-B04-216272 | 1 |
| | Hydrochlorothiazide | 22044HC10RII | 1 |
| | Hydrochlorothiazide | 22K29-B01-224324 | 5 |
| | Hydrochlorothiazide | 23002418002 | 2 |
| | Hydrochlorothiazide | 23A04-B06-22044HC10RII | 1 |
| | Hydrochlorothiazide | 23A04-B06-229298 | 4 |
| | Hydrochlorothiazide | 23A04-B06-233623 | 1 |
| | Hydrochlorothiazide | 23A18-F02-386051 | 1 |
| | Hydrochlorothiazide | 23L28-B02-237422 | 4 |
| | Hydrochlorothiazide | 24000132002 | 1 |
| | Hydrochlorothiazide | B06-0292908 | 1 |
| | Hydrochlorothiazide | B06-2336203 | 1 |
| | Hydrochlorothiazide | BO6-2336203 | 1 |
| AHD | Hydrochlorothiazide | 17H28-B01-340561 | 1 |
| Caelo | Hydrochlorothiazide | 11l01n02 | 1 |
| Caelo | Hydrochlorothiazide | 13008507 | 2 |
| Caelo | Hydrochlorothiazide | 13008509 | 5 |
| Caelo | Hydrochlorothiazide | 14009701 | 25 |
| Caelo | Hydrochlorothiazide | 140097012 | 1 |
| Caelo | Hydrochlorothiazide | 14B10-B01-305043 | 2 |
| Caelo | Hydrochlorothiazide | 15231002 | 3 |
| Caelo | Hydrochlorothiazide | 15231003 | 5 |
| Caelo | Hydrochlorothiazide | 15231005 | 1 |
| Caelo | Hydrochlorothiazide | 15231008 | 2 |
| Caelo | Hydrochlorothiazide | 15231009 | 3 |
| Caelo | Hydrochlorothiazide | 15231011 | 1 |
| Caelo | Hydrochlorothiazide | 16269301 | 4 |
| Caelo | Hydrochlorothiazide | 16269304 | 2 |
| Caelo | Hydrochlorothiazide | 16269306 | 1 |
| Caelo | Hydrochlorothiazide | 16269307 | 3 |
| Caelo | Hydrochlorothiazide | 16269309 | 6 |
| Caelo | Hydrochlorothiazide | 16269311 | 3 |
| Caelo | Hydrochlorothiazide | 16269312 | 2 |
| Caelo | Hydrochlorothiazide | 16269313 | 4 |
| Caelo | Hydrochlorothiazide | 16F17-B07-324062 | 1 |
| Caelo | Hydrochlorothiazide | 16F17B07327489 | 1 |
| Caelo | Hydrochlorothiazide | 16F17-B07-327489 | 1 |
| Caelo | Hydrochlorothiazide | 17H28-B01-340561 | 1 |
| Caelo | Hydrochlorothiazide | 17L20-B02-345079 | 1 |
| Caelo | Hydrochlorothiazide | 18017301 | 2 |
| Caelo | Hydrochlorothiazide | 18017302 | 5 |
| Caelo | Hydrochlorothiazide | 18017303 | 1 |
| Caelo | Hydrochlorothiazide | 18017304 | 6 |
| Caelo | Hydrochlorothiazide | 18017305 | 10 |
| Caelo | Hydrochlorothiazide | 18017307 | 1 |
| Caelo | Hydrochlorothiazide | 18108HCRII | 1 |
| Caelo | Hydrochlorothiazide | 182649005 | 1 |
| Caelo | Hydrochlorothiazide | 18264901 | 7 |
| Caelo | Hydrochlorothiazide | 18264904 | 7 |
| Caelo | Hydrochlorothiazide | 18264907 | 6 |
| Caelo | Hydrochlorothiazide | 1923280002 | 1 |
| Caelo | Hydrochlorothiazide | 192328002 | 14 |
| Caelo | Hydrochlorothiazide | 20004000002 | 9 |
| Caelo | Hydrochlorothiazide | 20004000004 | 4 |
| Caelo | Hydrochlorothiazide | 20004000007 | 2 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrochlorothiazide | 20004000010 | 5 |
| Caelo | Hydrochlorothiazide | 20004000011 | 3 |
| Caelo | Hydrochlorothiazide | 2000400002 | 1 |
| Caelo | Hydrochlorothiazide | 2000400004 | 1 |
| Caelo | Hydrochlorothiazide | 2004000002 | 1 |
| Caelo | Hydrochlorothiazide | 20E27-F01-371506 | 1 |
| Caelo | Hydrochlorothiazide | F01-3715006 | 1 |
| Caeol/Noweda | Hydrochlorothiazide | 15231009 | 2 |
| Caeol/Noweda | Hydrochlorothiazide | 18017307 | 2 |
| Caesar & Loretz GmbH... | Hydrochlorothiazide | 18264907 | 2 |
| Caesar & Loretz GmbH... | Hydrochlorothiazide | 192328002 | 1 |
| Caesar & Loretz GmbH... | Hydrochlorothiazide | 20004000007 | 1 |
| Caesar & Loretz GmbH... | Hydrochlorothiazide | 20004000004 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrochlorothiazide | 18017304 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrochlorothiazide | 18264904 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrochlorothiazide | 18264906 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrochlorothiazide | 18264907 | 1 |
| Caesar & Loretz GmbH... | Hydrochlorothiazide | 18017307 | 1 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 18017305 | 3 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 18017307 | 1 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 18264901 | 1 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 18264904 | 4 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 18264907 | 1 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 192328002 | 14 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 20004000002 | 5 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 20004000003 | 1 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 20004000004 | 1 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 20004000007 | 4 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 20004000010 | 1 |
| Caesar & Loretz GmbH | Hydrochlorothiazide | 20004000011 | 1 |
| Caesar & Loretz | Hydrochlorothiazide | 18017302 | 1 |
| Fagon/Gehe | Hydrochlorothiazide | 22K29-B01-224324 | 1 |
| Fagron | Hydrochlorothiazide | | 1 |
| Fagron | Hydrochlorothiazide | 11E04-N10 | 1 |
| Fagron | Hydrochlorothiazide | 11G12-N12 | 1 |
| Fagron | Hydrochlorothiazide | 11l01-n02 | 2 |
| Fagron | Hydrochlorothiazide | 11L01-N02 | 2 |
| Fagron | Hydrochlorothiazide | 11L01-No2 | 1 |
| Fagron | Hydrochlorothiazide | 11Lo1-No2 | 1 |
| Fagron | Hydrochlorothiazide | 12A03-B40 | 3 |
| Fagron | Hydrochlorothiazide | 12A03-B40-286110 | 1 |
| Fagron | Hydrochlorothiazide | 12A03-B40-286111 | 3 |
| Fagron | Hydrochlorothiazide | 12E04-N02 | 1 |
| Fagron | Hydrochlorothiazide | 12L14-N11 | 4 |
| Fagron | Hydrochlorothiazide | 13008504 | 1 |
| Fagron | Hydrochlorothiazide | 13C25-N08 | 6 |
| Fagron | Hydrochlorothiazide | 14B10B01 | 1 |
| Fagron | Hydrochlorothiazide | 14B10-B01 | 2 |
| Fagron | Hydrochlorothiazide | 14b10-b01-294558 | 1 |
| Fagron | Hydrochlorothiazide | 14B10-B01-294558 | 6 |
| Fagron | Hydrochlorothiazide | 14B10-B01-300822 | 2 |
| Fagron | Hydrochlorothiazide | 14B10-B01-305043 | 3 |
| Fagron | Hydrochlorothiazide | 15E04-B03 | 1 |
| Fagron | Hydrochlorothiazide | 15E04-B03-309670 | 5 |
| Fagron | Hydrochlorothiazide | 15K16 | 1 |
| Fagron | Hydrochlorothiazide | 15K16-B01 | 4 |
| Fagron | Hydrochlorothiazide | 15K16-B01-315836 | 3 |
| Fagron | Hydrochlorothiazide | 15K16-B01-319833 | 9 |
| Fagron | Hydrochlorothiazide | 16F17-B07 | 2 |
| Fagron | Hydrochlorothiazide | 16F17-B07-322773 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hydrochlorothiazide | 16F17-B07-324062 | 5 |
| Fagron | Hydrochlorothiazide | 16F17-B07-327489 | 5 |
| Fagron | Hydrochlorothiazide | 17038HCRII | 1 |
| Fagron | Hydrochlorothiazide | 17H28-B01340561 | 1 |
| Fagron | Hydrochlorothiazide | 17H28-B01-340561 | 4 |
| Fagron | Hydrochlorothiazide | 17L20-B02 | 1 |
| Fagron | Hydrochlorothiazide | 17L20-B02-345079 | 5 |
| Fagron | Hydrochlorothiazide | 17L20-B02-347789 | 6 |
| Fagron | Hydrochlorothiazide | 17L20-B02-349593 | 6 |
| Fagron | Hydrochlorothiazide | 17L20-B02-353429 | 4 |
| Fagron | Hydrochlorothiazide | 17L20B02355636 | 1 |
| Fagron | Hydrochlorothiazide | 17L20-B02-355636 | 6 |
| Fagron | Hydrochlorothiazide | 17L20B05 | 1 |
| Fagron | Hydrochlorothiazide | 19100HCRII | 1 |
| Fagron | Hydrochlorothiazide | 19A04-B01 | 4 |
| Fagron | Hydrochlorothiazide | 19A04-B01-359105 | 5 |
| Fagron | Hydrochlorothiazide | 19a04-b01-363321 | 1 |
| Fagron | Hydrochlorothiazide | 19A04-B01-363321 | 7 |
| Fagron | Hydrochlorothiazide | 2002311234 | 1 |
| Fagron | Hydrochlorothiazide | 20E27-F01 | 4 |
| Fagron | Hydrochlorothiazide | 20E27-F01-371506 | 10 |
| Fagron | Hydrochlorothiazide | 20E27-F01-373727 | 4 |
| Fagron | Hydrochlorothiazide | 21H27-B04-216272 | 5 |
| Fagron | Hydrochlorothiazide | 21H27-B04-220130 | 4 |
| Fagron | Hydrochlorothiazide | 22K29-B01-224324 | 3 |
| Fagron | Hydrochlorothiazide | 27101804 | 1 |
| Fagron | Hydrochlorothiazide | 5013Q-03660 | 1 |
| Fagron | Hydrochlorothiazide | B01-3591005 | 1 |
| Fagron | Hydrochlorothiazide | B04-2162702 | 1 |
| Fagron | Hydrochlorothiazide | C01-20150412 | 1 |
| Fagron | Hydrochlorothiazide | c01-20160510 | 1 |
| Fagron | Hydrochlorothiazide | C01-20160510 | 1 |
| Fagron | Hydrochlorothiazide | Co1-20150412 | 1 |
| Fagron | Hydrochlorothiazide | CQ1108 | 1 |
| Fagron | Hydrochlorothiazide | CR0601 | 1 |
| Fagron | Hydrochlorothiazide | F01-3737207 | 1 |
| Fargon - Alliance He... | Hydrochlorothiazide | 17L20-B02-353429 | 1 |
| Fargon/Phönix | Hydrochlorothiazide | 16F17-B07-327489 | 1 |
| Fiebig | Hydrochlorothiazide | 115231003 | 1 |
| Fiebig | Hydrochlorothiazide | 19100hcrII | 1 |
| Fiebig | Hydrochlorothiazide | B01-3633201 | 1 |
| Gehe | Hydrochlorothiazide | 12E04-N02 | 1 |
| Gehe | Hydrochlorothiazide | 17L20-B02-353429 | 1 |
| Gehe | Hydrochlorothiazide | 17L20-B02-355636 | 1 |
| Gehe | Hydrochlorothiazide | 18017302 | 2 |
| GEHE | Hydrochlorothiazide | 18017302 | 1 |
| Gehe | Hydrochlorothiazide | 18017304 | 1 |
| Gehe | Hydrochlorothiazide | 20004000011 | 1 |
| Gehe | Hydrochlorothiazide | 23002418002 | 1 |
| Kehr | Hydrochlorothiazide | 20004000011 | 1 |
| Kehr | Hydrochlorothiazide | 23A04-B06-229298 | 1 |
| Neweda | Hydrochlorothiazide | 23L28-B02-237422 | 1 |
| noweda | Hydrochlorothiazide | 15231009 | 1 |
| Noweda | Hydrochlorothiazide | 16269307 | 1 |
| noweda | Hydrochlorothiazide | 23A04-B06-229298 | 1 |
| Noweda | Hydrochlorothiazide | 23A04-B06-229298 | 2 |
| Phoenix | Hydrochlorothiazide | 15231003 | 1 |
| Phoenix | Hydrochlorothiazide | 17L20-B02-347789 | 1 |
| Phoenix | Hydrochlorothiazide | 18264901 | 1 |
| Phoenix | Hydrochlorothiazide | 18264904 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Hydrochlorothiazide | 192328002 | 1 |
| Sanacorp | Hydrochlorothiazide | 12A03-B40-26111 | 1 |
| Sanacorp | Hydrochlorothiazide | 15231008 | 1 |
| Sanacorp | Hydrochlorothiazide | 16269302 | 1 |
| Sanacorp | Hydrochlorothiazide | 18017302 | 1 |
| Sanacorp | Hydrochlorothiazide | 19A04-B01 | 2 |
| Sanacorp | Hydrochlorothiazide | 22K29-B01-224324 | 1 |
| Sanacorp | Hydrochlorothiazide | 23A04-B06-233623 | 1 |
| Sanacorp | Hydrochlorothiazide | 23A04-B06-233623 | 1 |

- 256 420 spectra from 1666 *Apo-Ident* customers from a total of 52 026 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hydrochlorothiazide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hydrochlorothiazide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 456 | 10 | 256 420 |

The substance/substance group *Hydrochlorothiazide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.8541 % (> 97.2103 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20888 | 21589 | 16.58 | 314.32 |
| 21589 | 21589 | 0.00 | 319.73 |
| 23989 | 24362 | 5.97 | 324.65 |
| 24362 | 24362 | 0.00 | 325.77 |
| 25590 | 24362 | 5.38 | 323.82 |
| 26172 | 21589 | 9.54 | 323.88 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hydrocortisone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20006-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hydrocortisone; Hydrocortisonum

### Special notes

When selecting the *Hydrocortisone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hydrocortisone | 9 | 11 | 631 |

### Second-stage model

For differentiation of the substance/substance group *Hydrocortisone* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hydrocortisone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 82.69 | – |
| ⋮ | ⋮ | ⋮ |
| Mometasone furoate | >50 | 118.46 |
| Potassium sorbate | >50 | 179.96 |
| Magnesium hydrogen citrate | >50 | 180.65 |
| Atropine sulfate | >50 | 221.29 |
| Quinoline yellow | >50 | 374.97 |
| Calcium orotate dihydrate | >50 | 486.62 |
| Saccharin sodium | >50 | 589.94 |
| Propranolol hydrochloride | >50 | 609.08 |
| Phenytoin | >50 | 879.93 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hydrocortisone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hydrocortisone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Hydrocortisone | 13341502 | 21461 | 60 | 20131203 |
| Caelo | Hydrocortisone | 13341502 | 21463 | 60 | 20131203 |
| Caelo | Hydrocortisone | 180915 | 24020 | 40 | 20180412* |
| Euro OTC | Hydrocortisone | 1206018-01 | 21293 | 40 | 20130727 |
| Euro OTC | Hydrocortisone | 1509029 | 21899 | 60 | 20151014* |
| Euro OTC | Hydrocortisone | 1509029 | 21899SI | 51 | 20151014* |
| Euro OTC | Hydrocortisone | 1611016 | 22910 | 40 | 20161220* |
| Euro OTC | Hydrocortisone | 2101003 | 25571 | 40 | 20210128* |
| Euro OTC | Hydrocortisone | 2101003 | 25571SI | 40 | 20210128* |
| Fagron | Hydrocortisone | 16A19-B06-320970 | 22829 | 40 | 20160204 |
| Fagron | Hydrocortisone | 16A19-B06-320970 | 22829SI | 30 | 20160204 |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Hydrocortisone | 16A19-B06-321981 | 22837 | 40 | 20160204 |
| Fagron | Hydrocortisone | 16A19-B06-321981 | 22838 | 40 | 1702302 |
| Fagron | Hydrocortisone | 16H01-B01-326071 | 22928 | 40 | 20160907 |
| Fagron | Hydrocortisone | 16H01-B01-326071 | 22928SI | 40 | 20160907 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 661 spectra of 15 reference samples from the substance/substance group *Hydrocortisone*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.
- 157 665 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1119 spectra of 29 reference samples from the substance/substance group *Hydrocortisone*.
- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hydrocortisone | 160952 | 22778 | 40 |
| Caelo | Hydrocortisone | 171194 | 23340 | 20 |
| Caelo | Hydrocortisone | 172566 | 23840 | 40 |
| Caelo | Hydrocortisone | 183243 | 24521 | 40 |
| Caelo | Hydrocortisone | 21001215005 | 25926 | 40 |
| Caelo | Hydrocortisone | 22003779 | 27250 | 40 |
| Euro OTC | Hydrocortisone | 1802009 | 23945 | 40 |
| Euro OTC | Hydrocortisone | 1906033 | 24771 | 40 |
| Euro OTC | Hydrocortisone | 2205003 | 26213 | 40 |
| Euro OTC | Hydrocortisone | 2401017 | 27152 | 40 |
| Fagron | Hydrocortisone | 22E09-B02-220942 | 26395 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hydrocortisone | 13341502 | 21463SI† | 60 |
| Caelo | Hydrocortisone | 160952 | 22778SI | 40 |
| Caelo | Hydrocortisone | 171194 | 23340SI | 28 |
| Caelo | Hydrocortisone | 171194 | 23659 | 40 |
| Caelo | Hydrocortisone | 171194 | 23659SI | 30 |
| Caelo | Hydrocortisone | 172566 | 23840SI | 40 |
| Caelo | Hydrocortisone | 180915 | 24020SI† | 40 |
| Caelo | Hydrocortisone | 183243 | 24521SI | 40 |
| Caelo | Hydrocortisone | 21001215005 | 25926SI | 40 |
| Caelo | Hydrocortisone | 22003779 | 27250SI | 40 |
| Euro OTC | Hydrocortisone | 1611016 | 22910SI† | 40 |
| Euro OTC | Hydrocortisone | 1802009 | 23945SI | 40 |
| Euro OTC | Hydrocortisone | 1906033 | 24771SI | 40 |
| Euro OTC | Hydrocortisone | 2205003 | 26213SI | 40 |
| Euro OTC | Hydrocortisone | 2401017 | 27152SI | 40 |
| Fagron | Hydrocortisone | 16A19-B06-321981 | 22837SI† | 30 |
| Fagron | Hydrocortisone | 16A19-B06-321981 | 22838SI† | 31 |
| Fagron | Hydrocortisone | 22E09-B02-220942 | 26395SI | 40 |

- 211 821 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4946 spectra from 1204 *Apo-Ident* customers from 651 batches from the substance/substance group *Hydrocortisone*.
- Among them are spectra of independent samples from 631 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hydrocortisone | 181023/8 | 1 |
| | Hydrocortisone | 2100121029 | 1 |
| | Hydrocortisone | 21001215013 | 1 |
| | Hydrocortisone | 21001215015 | 1 |
| | Hydrocortisone | 21001215017 | 2 |
| | Hydrocortisone | 21001215018 | 7 |
| | Hydrocortisone | 21001215019 | 6 |
| | Hydrocortisone | 21001215023 | 3 |
| | Hydrocortisone | 21001215026 | 3 |
| | Hydrocortisone | 21001215027 | 6 |
| | Hydrocortisone | 21001215028 | 1 |
| | Hydrocortisone | 21001215029 | 13 |
| | Hydrocortisone | 21001215030 | 7 |
| | Hydrocortisone | 21001215032 | 5 |
| | Hydrocortisone | 21001215034 | 13 |
| | Hydrocortisone | 21001215035 | 4 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hydrocortisone | 21001215036 | 4 |
| | Hydrocortisone | 21001250029 | 1 |
| | Hydrocortisone | 2100125032 | 1 |
| | Hydrocortisone | 2101003-003 | 1 |
| | Hydrocortisone | 2101003-01 | 1 |
| | Hydrocortisone | 2101003-03 | 4 |
| | Hydrocortisone | 2200377900 | 1 |
| | Hydrocortisone | 22003779003 | 5 |
| | Hydrocortisone | 22003779004 | 32 |
| | Hydrocortisone | 22003779005 | 19 |
| | Hydrocortisone | 22003779006 | 38 |
| | Hydrocortisone | 22003779008 | 4 |
| | Hydrocortisone | 22003779011 | 16 |
| | Hydrocortisone | 22003779012 | 23 |
| | Hydrocortisone | 220037799011 | 1 |
| | Hydrocortisone | 2203779004 | 1 |
| | Hydrocortisone | 2203779008 | 1 |
| | Hydrocortisone | 2203779011 | 1 |
| | Hydrocortisone | 220500301 | 3 |
| | Hydrocortisone | 2205003-01 | 19 |
| | Hydrocortisone | 22E09-B02-219558 | 1 |
| | Hydrocortisone | 23003407002 | 11 |
| | Hydrocortisone | 23003407005 | 11 |
| | Hydrocortisone | 23003407006 | 5 |
| | Hydrocortisone | 23003407007 | 1 |
| | Hydrocortisone | 2300347002 | 1 |
| | Hydrocortisone | 23D06-B01-232991 | 2 |
| | Hydrocortisone | 23I19-B25-238304 | 2 |
| | Hydrocortisone | 24002019004 | 1 |
| | Hydrocortisone | 24002019005 | 6 |
| | Hydrocortisone | 2401017-01 | 11 |
| | Hydrocortisone | 240909(22003779008) | 1 |
| | Hydrocortisone | 24H12-B01-003889 | 1 |
| | Hydrocortisone | 24H12-B01-005941 | 1 |
| | Hydrocortisone | 250409(22003779008) | 1 |
| | Hydrocortisone | K05M20211103 | 1 |
| / AHD | Hydrocortisone | 16095202 | 1 |
| A.H. 10.06.13 ek: 10,01EUR | Hydrocortisone | 1204037-01 | 1 |
| AEP | Hydrocortisone | 21001215015 | 1 |
| AEP | Hydrocortisone | 21001215032 | 1 |
| AHC 02.09.13 EK9,85 | Hydrocortisone | 1112030-01 | 1 |
| AHC | Hydrocortisone | 22003779006 | 1 |
| ahd,11,95EUR 10.04.14 | Hydrocortisone | 13341504-07R07 | 1 |
| AHD/Euro | Hydrocortisone | 1802009 | 1 |
| AHD/Euro | Hydrocortisone | 1802009-01 | 2 |
| AHD | Hydrocortisone | 13069507 | 1 |
| AHD | Hydrocortisone | 13155601 | 2 |
| AHD | Hydrocortisone | 18091503 | 1 |
| AHD | Hydrocortisone | 18091520 | 1 |
| AHD | Hydrocortisone | 21001215021 | 2 |
| AHD | Hydrocortisone | 21001215032 | 1 |
| AHD | Hydrocortisone | 22003779004 | 1 |
| AHD | Hydrocortisone | 22003779011 | 2 |
| AHD | Hydrocortisone | 2205003-01 | 1 |
| AHD | Hydrocortisone | K05M20211103 | 1 |
| AHD;19.06.15;18,70EUR | Hydrocortisone | 14301306 | 1 |
| AHL | Hydrocortisone | 15125-B01-313084 | 1 |
| Alliance healfcare | Hydrocortisone | 18091506 | 1 |
| Alliance Healtcare | Hydrocortisone | 192241008 | 1 |
| Alliance Healtcare | Hydrocortisone | 21001215018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Health 11.0... | Hydrocortisone | 1315505 | 1 |
| Alliance Health25.04.2014 | Hydrocortisone | 13341503 | 3 |
| Alliance Healthcare | Hydrocortisone | 192241005 | 1 |
| Alliance | Hydrocortisone | 21001215021 | 1 |
| Alliance | Hydrocortisone | 21001215034 | 1 |
| Allianz Healthcare | Hydrocortisone | 1509029-01 | 1 |
| Allianz Healthcare | Hydrocortisone | 1802009-01 | 1 |
| Anzag 14.12.12 ek:10,01 | Hydrocortisone | 1202032-01 | 1 |
| Anzag ek:10.01EUR 18.07.12 | Hydrocortisone | 1107005-03 | 1 |
| Anzag | Hydrocortisone | 1107005-02 | 1 |
| Anzag | Hydrocortisone | 11260305 | 1 |
| Anzag | Hydrocortisone | 1206018-01 | 1 |
| Anzag | Hydrocortisone | 12104307 | 1 |
| Anzag | Hydrocortisone | 14301306 | 1 |
| Anzag | Hydrocortisone | 1501034-01 | 1 |
| Anzag | Hydrocortisone | 1505016-01 | 1 |
| Anzag | Hydrocortisone | 1509229-01 | 1 |
| Anzag | Hydrocortisone | 183243006 | 1 |
| Anzag | Hydrocortisone | 192241007 | 1 |
| Anzag | Hydrocortisone | 19224107 | 1 |
| Anzag | Hydrocortisone | 20004116003 | 2 |
| Anzag | Hydrocortisone | 20004116007 | 1 |
| Anzag | Hydrocortisone | 21001215019 | 1 |
| Anzag | Hydrocortisone | 230424(21001215018) | 1 |
| Anzag | Hydrocortisone | 230509(21001215018) | 1 |
| Anzag | Hydrocortisone | 230810(21001215018) | 1 |
| Anzag | Hydrocortisone | 231004(21001215018) | 1 |
| Anzag | Hydrocortisone | 231025(21001215018) | 1 |
| Anzag | Hydrocortisone | 231128(22003779003) | 1 |
| Anzag | Hydrocortisone | 231204(22003779008) | 1 |
| Anzag | Hydrocortisone | 231213(22003779008) | 1 |
| Anzag | Hydrocortisone | 240103(22003779008) | 1 |
| Anzag | Hydrocortisone | 240116(2203779008) | 1 |
| Anzag | Hydrocortisone | 240223(22003779003) | 1 |
| Anzag | Hydrocortisone | 240308(22003779003) | 1 |
| Anzag | Hydrocortisone | 240809(22003779008) | 1 |
| Anzag | Hydrocortisone | 241030(22003779008) | 1 |
| Anzag | Hydrocortisone | 241101(22003779008) | 1 |
| Anzag | Hydrocortisone | 241120(22003779008) | 1 |
| Anzag | Hydrocortisone | 250313(22003779008) | 1 |
| Anzag | Hydrocortisone | 250325(22003779008) | 1 |
| Anzag | Hydrocortisone | 250512(2300340700) | 1 |
| Beiersdorf/ Vedono | Hydrocortisone | 15181004 | 1 |
| Berkel AHK | Hydrocortisone | 14301305 | 1 |
| Bionorica | Hydrocortisone | 16004604 | 1 |
| Bombastus | Hydrocortisone | 14I05-B02-300227 | 1 |
| cae | Hydrocortisone | 18324307 | 1 |
| Caeelo | Hydrocortisone | 17090005 | 1 |
| cael | Hydrocortisone | 183243002 | 1 |
| Caelo | Hydrocortisone | | 2 |
| Caelo | Hydrocortisone | 10071704 | 1 |
| Caelo | Hydrocortisone | 10282208 | 1 |
| Caelo | Hydrocortisone | 11021302 | 1 |
| Caelo | Hydrocortisone | 1109845 | 1 |
| Caelo | Hydrocortisone | 11260308 | 3 |
| Caelo | Hydrocortisone | 11260309 | 3 |
| Caelo | Hydrocortisone | 11273704 | 1 |
| Caelo | Hydrocortisone | 113I-01719 | 1 |
| Caelo | Hydrocortisone | 1140317 | 1 |
| Caelo | Hydrocortisone | 1190218/17256602 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone | 120403701 | 1 |
| Caelo | Hydrocortisone | 12104301 | 1 |
| Caelo | Hydrocortisone | 12104303 | 5 |
| Caelo | Hydrocortisone | 12104304 | 6 |
| Caelo | Hydrocortisone | 12104305 | 3 |
| Caelo | Hydrocortisone | 12104306 | 9 |
| Caelo | Hydrocortisone | 12104307 | 17 |
| Caelo | Hydrocortisone | 12104308 | 8 |
| Caelo | Hydrocortisone | 12104309 | 2 |
| Caelo | Hydrocortisone | 12119303 | 9 |
| Caelo | Hydrocortisone | 12119304 | 4 |
| Caelo | Hydrocortisone | 12167001 | 7 |
| Caelo | Hydrocortisone | 12167007 | 10 |
| Caelo | Hydrocortisone | 12167010 | 10 |
| Caelo | Hydrocortisone | 12167010-3437311151 | 1 |
| Caelo | Hydrocortisone | 1216707 | 1 |
| Caelo | Hydrocortisone | 12k08-n01 | 1 |
| Caelo | Hydrocortisone | 130617H | 1 |
| Caelo | Hydrocortisone | 13063501 | 1 |
| Caelo | Hydrocortisone | 1306906 | 1 |
| Caelo | Hydrocortisone | 13069501 | 10 |
| Caelo | Hydrocortisone | 13069502 | 5 |
| Caelo | Hydrocortisone | 13069505 | 4 |
| Caelo | Hydrocortisone | 13069506 | 8 |
| Caelo | Hydrocortisone | 13069507 | 4 |
| Caelo | Hydrocortisone | 13069509 | 3 |
| Caelo | Hydrocortisone | 13069510 | 6 |
| Caelo | Hydrocortisone | 13155601 | 7 |
| Caelo | Hydrocortisone | 13155602 | 8 |
| Caelo | Hydrocortisone | 13155603 | 12 |
| Caelo | Hydrocortisone | 13155604 | 8 |
| Caelo | Hydrocortisone | 13155605 | 3 |
| Caelo | Hydrocortisone | 13155611 | 2 |
| Caelo | Hydrocortisone | 13155614 | 3 |
| Caelo | Hydrocortisone | 133341502 | 1 |
| Caelo | Hydrocortisone | 13341501 | 7 |
| Caelo | Hydrocortisone | 13341502 | 11 |
| Caelo | Hydrocortisone | 13341503 | 1 |
| Caelo | Hydrocortisone | 13341504 | 9 |
| Caelo | Hydrocortisone | 13341508 | 4 |
| Caelo | Hydrocortisone | 13341509 | 8 |
| Caelo | Hydrocortisone | 13341510 | 12 |
| Caelo | Hydrocortisone | 13341511 | 5 |
| Caelo | Hydrocortisone | 13342504 | 1 |
| Caelo | Hydrocortisone | 140301305 | 1 |
| Caelo | Hydrocortisone | 14115103 | 2 |
| Caelo | Hydrocortisone | 14115104 | 1 |
| Caelo | Hydrocortisone | 14115105 | 3 |
| Caelo | Hydrocortisone | 14115107 | 11 |
| Caelo | Hydrocortisone | 14115108 | 2 |
| Caelo | Hydrocortisone | 14301304 | 4 |
| Caelo | Hydrocortisone | 14301305 | 5 |
| Caelo | Hydrocortisone | 14301306 | 6 |
| Caelo | Hydrocortisone | 14301307 | 2 |
| Caelo | Hydrocortisone | 14301310 | 14 |
| Caelo | Hydrocortisone | 14301311 | 10 |
| Caelo | Hydrocortisone | 14301312 | 8 |
| Caelo | Hydrocortisone | 14301313 | 6 |
| Caelo | Hydrocortisone | 14b04-B02-293422 | 1 |
| Caelo | Hydrocortisone | 15/25-B01-318486 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone | 1501034-01 | 2 |
| Caelo | Hydrocortisone | 15021104 | 7 |
| Caelo | Hydrocortisone | 15021105 | 7 |
| Caelo | Hydrocortisone | 15021106 | 3 |
| Caelo | Hydrocortisone | 15021107 | 11 |
| Caelo | Hydrocortisone | 1505016-01 | 3 |
| Caelo | Hydrocortisone | 150-5016-01 | 1 |
| Caelo | Hydrocortisone | 1509029-01 | 8 |
| Caelo | Hydrocortisone | 1518012 | 1 |
| Caelo | Hydrocortisone | 1518013 | 1 |
| Caelo | Hydrocortisone | 15181003 | 12 |
| Caelo | Hydrocortisone | 15181004 | 11 |
| Caelo | Hydrocortisone | 15181006 | 20 |
| Caelo | Hydrocortisone | 15181007 | 5 |
| Caelo | Hydrocortisone | 15181008 | 2 |
| Caelo | Hydrocortisone | 15181012 | 16 |
| Caelo | Hydrocortisone | 15181012/20160309/10 | 1 |
| Caelo | Hydrocortisone | 15181013 | 11 |
| Caelo | Hydrocortisone | 15181014 | 6 |
| Caelo | Hydrocortisone | 15216101 | 11 |
| Caelo | Hydrocortisone | 15278702 | 11 |
| Caelo | Hydrocortisone | 15278703 | 9 |
| Caelo | Hydrocortisone | 15278705 | 11 |
| Caelo | Hydrocortisone | 15278706 | 6 |
| Caelo | Hydrocortisone | 16004603 | 14 |
| Caelo | Hydrocortisone | 16004604 | 28 |
| Caelo | Hydrocortisone | 16004605 | 14 |
| Caelo | Hydrocortisone | 16004607 | 16 |
| Caelo | Hydrocortisone | 16004608 | 12 |
| Caelo | Hydrocortisone | 16004611 | 11 |
| Caelo | Hydrocortisone | 16004612 | 16 |
| Caelo | Hydrocortisone | 16004612/2020317 | 1 |
| Caelo | Hydrocortisone | 16041801 | 1 |
| Caelo | Hydrocortisone | 16095201 | 27 |
| Caelo | Hydrocortisone | 16095202 | 12 |
| Caelo | Hydrocortisone | 16095203 | 10 |
| Caelo | Hydrocortisone | 16095207 | 8 |
| Caelo | Hydrocortisone | 16095209 | 7 |
| Caelo | Hydrocortisone | 16095210 | 22 |
| Caelo | Hydrocortisone | 16095212 | 8 |
| Caelo | Hydrocortisone | 16095213 | 13 |
| Caelo | Hydrocortisone | 16095213-20170704Ma7 | 1 |
| Caelo | Hydrocortisone | 16098201 | 2 |
| Caelo | Hydrocortisone | 1611016 | 1 |
| Caelo | Hydrocortisone | 1611016-01 | 5 |
| Caelo | Hydrocortisone | 16255603 | 10 |
| Caelo | Hydrocortisone | 16255604 | 2 |
| Caelo | Hydrocortisone | 16255606 | 1 |
| Caelo | Hydrocortisone | 16255607 | 13 |
| Caelo | Hydrocortisone | 16255608 | 15 |
| Caelo | Hydrocortisone | 16255608NP | 1 |
| Caelo | Hydrocortisone | 16255680 | 1 |
| Caelo | Hydrocortisone | 1626-B04-330340 | 1 |
| Caelo | Hydrocortisone | 16272304 | 13 |
| Caelo | Hydrocortisone | 16272305 | 11 |
| Caelo | Hydrocortisone | 16272306 | 14 |
| Caelo | Hydrocortisone | 16272308 | 5 |
| Caelo | Hydrocortisone | 1627231 | 1 |
| Caelo | Hydrocortisone | 16272311 | 7 |
| Caelo | Hydrocortisone | 1672305 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone | 1672308 | 1 |
| Caelo | Hydrocortisone | 167272306 | 1 |
| Caelo | Hydrocortisone | 17090003 | 4 |
| Caelo | Hydrocortisone | 17090004 | 1 |
| Caelo | Hydrocortisone | 17090005 | 8 |
| Caelo | Hydrocortisone | 170921HA/17090003 | 1 |
| Caelo | Hydrocortisone | 1711940 | 1 |
| Caelo | Hydrocortisone | 17119402 | 21 |
| Caelo | Hydrocortisone | 17119403 | 26 |
| Caelo | Hydrocortisone | 17119404 | 1 |
| Caelo | Hydrocortisone | 17119405 | 36 |
| Caelo | Hydrocortisone | 17119406 | 23 |
| Caelo | Hydrocortisone | 17119407 | 31 |
| Caelo | Hydrocortisone | 17119410 | 7 |
| Caelo | Hydrocortisone | 1719402-20171106Ma2 | 1 |
| Caelo | Hydrocortisone | 1719405 | 1 |
| Caelo | Hydrocortisone | 17229410 | 1 |
| Caelo | Hydrocortisone | 17256602 | 56 |
| Caelo | Hydrocortisone | 17256603 | 10 |
| Caelo | Hydrocortisone | 17256604 | 36 |
| Caelo | Hydrocortisone | 17256605 | 26 |
| Caelo | Hydrocortisone | 17256607 | 15 |
| Caelo | Hydrocortisone | 17256804 | 1 |
| Caelo | Hydrocortisone | 1726602 | 1 |
| Caelo | Hydrocortisone | 1726603 | 1 |
| Caelo | Hydrocortisone | 1731205 | 1 |
| Caelo | Hydrocortisone | 173512 | 1 |
| Caelo | Hydrocortisone | 173512005 | 1 |
| Caelo | Hydrocortisone | 17351202 | 19 |
| Caelo | Hydrocortisone | 17351203 | 38 |
| Caelo | Hydrocortisone | 17351205 | 65 |
| Caelo | Hydrocortisone | 17351206 | 11 |
| Caelo | Hydrocortisone | 17351209 | 11 |
| Caelo | Hydrocortisone | 17351209-20180830Ma3 | 1 |
| Caelo | Hydrocortisone | 17351210 | 2 |
| Caelo | Hydrocortisone | 1735123 | 1 |
| Caelo | Hydrocortisone | 17526602 | 1 |
| Caelo | Hydrocortisone | 1756602 | 1 |
| Caelo | Hydrocortisone | 17E10-B04-334857 | 1 |
| Caelo | Hydrocortisone | 18002009-01 | 1 |
| Caelo | Hydrocortisone | 1802009-01 | 3 |
| Caelo | Hydrocortisone | 18031508 | 1 |
| Caelo | Hydrocortisone | 18042601 | 1 |
| Caelo | Hydrocortisone | 18061802 | 1 |
| Caelo | Hydrocortisone | 18062003 | 1 |
| Caelo | Hydrocortisone | 18091501 | 27 |
| Caelo | Hydrocortisone | 18091501-H20181115Ma | 3 |
| Caelo | Hydrocortisone | 18091502 | 4 |
| Caelo | Hydrocortisone | 18091503 | 36 |
| Caelo | Hydrocortisone | 18091505 | 36 |
| Caelo | Hydrocortisone | 18091506 | 27 |
| Caelo | Hydrocortisone | 18091507 | 33 |
| Caelo | Hydrocortisone | 18091508 | 8 |
| Caelo | Hydrocortisone | 18091519 | 41 |
| Caelo | Hydrocortisone | 18091520 | 38 |
| Caelo | Hydrocortisone | 180915208 | 1 |
| Caelo | Hydrocortisone | 18091521 | 2 |
| Caelo | Hydrocortisone | 18091524 | 22 |
| Caelo | Hydrocortisone | 18091525 | 44 |
| Caelo | Hydrocortisone | 180915252 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone | 18091526 | 6 |
| Caelo | Hydrocortisone | 18091528 | 19 |
| Caelo | Hydrocortisone | 18091530 | 1 |
| Caelo | Hydrocortisone | 18091531 | 18 |
| Caelo | Hydrocortisone | 18091531x2 | 1 |
| Caelo | Hydrocortisone | 180915321 | 1 |
| Caelo | Hydrocortisone | 180921531 | 1 |
| Caelo | Hydrocortisone | 18121713 | 1 |
| Caelo | Hydrocortisone | 1824311 | 1 |
| Caelo | Hydrocortisone | 1832243006 | 1 |
| Caelo | Hydrocortisone | 18323006 | 1 |
| Caelo | Hydrocortisone | 18324207 | 1 |
| Caelo | Hydrocortisone | 183243002 | 51 |
| Caelo | Hydrocortisone | 183243003 | 7 |
| Caelo | Hydrocortisone | 183243004 | 19 |
| Caelo | Hydrocortisone | 183243006 | 56 |
| Caelo | Hydrocortisone | 18324301 | 35 |
| Caelo | Hydrocortisone | 18324302 | 32 |
| Caelo | Hydrocortisone | 18324303 | 6 |
| Caelo | Hydrocortisone | 18324306 | 35 |
| Caelo | Hydrocortisone | 18324307 | 34 |
| Caelo | Hydrocortisone | 18324308 | 21 |
| Caelo | Hydrocortisone | 18324310 | 11 |
| Caelo | Hydrocortisone | 18324311 | 26 |
| Caelo | Hydrocortisone | 18343002 | 1 |
| Caelo | Hydrocortisone | 186324307 | 1 |
| Caelo | Hydrocortisone | 1891528 | 1 |
| Caelo | Hydrocortisone | 1907151621 | 1 |
| Caelo | Hydrocortisone | 19224002 | 1 |
| Caelo | Hydrocortisone | 19224100 | 1 |
| Caelo | Hydrocortisone | 192241002 | 5 |
| Caelo | Hydrocortisone | 192241004 | 15 |
| Caelo | Hydrocortisone | 192241005 | 30 |
| Caelo | Hydrocortisone | 192241007 | 23 |
| Caelo | Hydrocortisone | 192241008 | 69 |
| Caelo | Hydrocortisone | 200004116007 | 2 |
| Caelo | Hydrocortisone | 20004106005 | 1 |
| Caelo | Hydrocortisone | 200041116003 | 1 |
| Caelo | Hydrocortisone | 20004116001 | 34 |
| Caelo | Hydrocortisone | 20004116002 | 11 |
| Caelo | Hydrocortisone | 20004116003 | 31 |
| Caelo | Hydrocortisone | 20004116004 | 32 |
| Caelo | Hydrocortisone | 20004116005 | 21 |
| Caelo | Hydrocortisone | 20004116006 | 24 |
| Caelo | Hydrocortisone | 20004116007 | 16 |
| Caelo | Hydrocortisone | 20004278004 | 1 |
| Caelo | Hydrocortisone | 2004116006 | 1 |
| Caelo | Hydrocortisone | 200411606 | 1 |
| Caelo | Hydrocortisone | 2013U-01719 | 1 |
| Caelo | Hydrocortisone | 2100115007 | 1 |
| Caelo | Hydrocortisone | 21001215003 | 3 |
| Caelo | Hydrocortisone | 21001215004 | 16 |
| Caelo | Hydrocortisone | 21001215005 | 40 |
| Caelo | Hydrocortisone | 21001215006 | 23 |
| Caelo | Hydrocortisone | 21001215007 | 30 |
| Caelo | Hydrocortisone | 21001215009 | 1 |
| Caelo | Hydrocortisone | 21001215010 | 32 |
| Caelo | Hydrocortisone | 21001215011 | 13 |
| Caelo | Hydrocortisone | 21001215013 | 29 |
| Caelo | Hydrocortisone | 21001215014 | 23 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone | 21001215015 | 7 |
| Caelo | Hydrocortisone | 21001215017 | 11 |
| Caelo | Hydrocortisone | 21001215018 | 5 |
| Caelo | Hydrocortisone | 21001215019 | 14 |
| Caelo | Hydrocortisone | 21001215020 | 16 |
| Caelo | Hydrocortisone | 21001215021 | 27 |
| Caelo | Hydrocortisone | 21001215023 | 10 |
| Caelo | Hydrocortisone | 21001215026 | 2 |
| Caelo | Hydrocortisone | 21001215027 | 2 |
| Caelo | Hydrocortisone | 21001215028 | 1 |
| Caelo | Hydrocortisone | 21001215029 | 1 |
| Caelo | Hydrocortisone | 21001215030 | 1 |
| Caelo | Hydrocortisone | 21001215032 | 1 |
| Caelo | Hydrocortisone | 21001215036 | 1 |
| Caelo | Hydrocortisone | 21001250013 | 1 |
| Caelo | Hydrocortisone | 2100125014 | 1 |
| Caelo | Hydrocortisone | 210012515010 | 1 |
| Caelo | Hydrocortisone | 2100215013 | 1 |
| Caelo | Hydrocortisone | 2101003-01 | 2 |
| Caelo | Hydrocortisone | 210922(20004116002) | 1 |
| Caelo | Hydrocortisone | 21101303 | 1 |
| Caelo | Hydrocortisone | 211029(21001215003) | 1 |
| Caelo | Hydrocortisone | 211115(21001215003) | 1 |
| Caelo | Hydrocortisone | 211123(21001215003) | 2 |
| Caelo | Hydrocortisone | 211130(21001215003) | 1 |
| Caelo | Hydrocortisone | 211227(21001215003) | 1 |
| Caelo | Hydrocortisone | 2180917/16255608 | 1 |
| Caelo | Hydrocortisone | 220037789006 | 1 |
| Caelo | Hydrocortisone | 22003779005 | 2 |
| Caelo | Hydrocortisone | 22003779006 | 2 |
| Caelo | Hydrocortisone | 22003779008 | 1 |
| Caelo | Hydrocortisone | 22003779012 | 1 |
| Caelo | Hydrocortisone | 220118(21001215003) | 1 |
| Caelo | Hydrocortisone | 220120 | 1 |
| Caelo | Hydrocortisone | 220127 | 1 |
| Caelo | Hydrocortisone | 220210(21001215003) | 1 |
| Caelo | Hydrocortisone | 220413(21001215003) | 1 |
| Caelo | Hydrocortisone | 2205003-01 | 4 |
| Caelo | Hydrocortisone | 220510(21001215009) | 1 |
| Caelo | Hydrocortisone | 220519(21001215003) | 1 |
| Caelo | Hydrocortisone | 220905(21001215015) | 1 |
| Caelo | Hydrocortisone | 221026(21001215015) | 1 |
| Caelo | Hydrocortisone | 221110(21001215009) | 2 |
| Caelo | Hydrocortisone | 230104(21001215018) | 1 |
| Caelo | Hydrocortisone | 230206(21001215018) | 1 |
| Caelo | Hydrocortisone | 230327(2100121518) | 1 |
| Caelo | Hydrocortisone | 260416v4 | 1 |
| Caelo | Hydrocortisone | 27101801 | 1 |
| Caelo | Hydrocortisone | 2760 | 1 |
| Caelo | Hydrocortisone | 3081604 | 1 |
| Caelo | Hydrocortisone | 31032014D | 1 |
| Caelo | Hydrocortisone | 3110396 | 1 |
| Caelo | Hydrocortisone | 3110456 | 1 |
| Caelo | Hydrocortisone | 39/AKD17 | 1 |
| Caelo | Hydrocortisone | 3912Q-01719 | 1 |
| Caelo | Hydrocortisone | 4817Q-01719 | 1 |
| Caelo | Hydrocortisone | 7082004 | 1 |
| Caelo | Hydrocortisone | 7101301 | 1 |
| Caelo | Hydrocortisone | 8041701 | 1 |
| Caelo | Hydrocortisone | 810911 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone | 8717 | 1 |
| Caelo | Hydrocortisone | 9271205 | 1 |
| Caelo | Hydrocortisone | B02-2005104 | 1 |
| Caelo | Hydrocortisone | caelo | 1 |
| Caelo | Hydrocortisone | Caelo21001215003 | 2 |
| Caelo | Hydrocortisone | K05B20160909 | 1 |
| Caeol/Noweda | Hydrocortisone | 16095212 | 1 |
| Caeolo/Krieger | Hydrocortisone | 17119406 | 1 |
| Caesar & Lorenz GmbH | Hydrocortisone | 15181004 | 1 |
| Caesar & Lorenz | Hydrocortisone | 21001215026 | 1 |
| Caesar & Loretz /Phönix | Hydrocortisone | 21001215003 | 1 |
| Caesar & Loretz /Sanacorp | Hydrocortisone | 21001215011 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215014 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116001 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215021 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324306 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116007 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215021 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116001 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324307 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324308 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116003 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324211 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215023 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324311 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215009 | 1 |
| Caesar & Loretz GmbH/AEP | Hydrocortisone | 18091525 | 1 |
| Caesar & Loretz GmbH/AEP | Hydrocortisone | 21001215011 | 1 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone | 183243003 | 2 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone | 20004116004 | 1 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone | 21001215011 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116001 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215007 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215017 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18091508 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243003 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH/G | Hydrocortisone | 192241007 | 1 |
| Caesar & Loretz GmbH/G | Hydrocortisone | 21001215004 | 1 |
| Caesar & Loretz GmbH/G | Hydrocortisone | 21001215011 | 1 |
| Caesar & Loretz GmbH/GEHE | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone | 20004116005 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone | 21001215023 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215005 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324302 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116006 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215020 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18091524 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Hydrocortisone | 183243004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324306 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215004 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215007 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215010 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215013 | 1 |
| Caesar & Loretz GmbH/Kehr | Hydrocortisone | 183243006 | 1 |
| Caesar & Loretz GmbH/Kehr | Hydrocortisone | 18324301 | 1 |
| Caesar & Loretz GmbH/Kehr | Hydrocortisone | 18324306 | 1 |
| Caesar & Loretz GmbH/Kehr | Hydrocortisone | 18324308 | 1 |
| Caesar & Loretz GmbH/Kehr | Hydrocortisone | 20004116007 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116001 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215010 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243003 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324302 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241005 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116007 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215004 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215010 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215020 | 1 |
| Caesar & Loretz GmbH/Otto | Hydrocortisone | 18324307 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116002 | 2 |
| Caesar & Loretz GmbH/Phoe | Hydrocortisone | 20004116004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324302 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116003 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215004 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215010 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215021 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18091520 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 18324301 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116003 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215003 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215007 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215013 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215014 | 1 |
| Caesar & Loretz GmbH/Sa | Hydrocortisone | 18324302 | 1 |
| Caesar & Loretz GmbH/Sana | Hydrocortisone | 20004116004 | 1 |
| Caesar & Loretz GmbH/Sana | Hydrocortisone | 21001215006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 183243002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241008 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 20004116003 | 3 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215007 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215013 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215014 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 21001215017 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 12167010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Hydrocortisone | 13069506 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 13069507 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 15021107 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 15181012 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 16004612 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 17256605 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 17351205 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 17351210 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091505 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091506 | 7 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091507 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091519 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091520 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091524 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091525 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091526 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091528 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone | 18091531 | 4 |
| Caesar & Loretz GmbH | Hydrocortisone | 183243002 | 13 |
| Caesar & Loretz GmbH | Hydrocortisone | 183243004 | 13 |
| Caesar & Loretz GmbH | Hydrocortisone | 183243006 | 12 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324301 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324302 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324303 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324306 | 13 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324307 | 13 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324308 | 11 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324310 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 18324311 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone | 192241002 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone | 192241003 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 192241004 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 192241005 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone | 192241007 | 12 |
| Caesar & Loretz GmbH | Hydrocortisone | 192241008 | 23 |
| Caesar & Loretz GmbH | Hydrocortisone | 19K05-B02-195614 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 20000978010 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 20004116001 | 18 |
| Caesar & Loretz GmbH | Hydrocortisone | 20004116002 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone | 20004116003 | 15 |
| Caesar & Loretz GmbH | Hydrocortisone | 20004116004 | 12 |
| Caesar & Loretz GmbH | Hydrocortisone | 20004116005 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 20004116006 | 17 |
| Caesar & Loretz GmbH | Hydrocortisone | 20004116007 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone | 20B17-B02-200514 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215003 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215004 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215005 | 7 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215006 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215007 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215009 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215010 | 11 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215011 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215013 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215014 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215015 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215016 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215017 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215018 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215019 | 11 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Hydrocortisone | 21001215020 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215021 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215023 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215028 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215029 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215030 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215032 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 21001215035 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone | 22003779004 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone | 22003779006 | 4 |
| Caesar & Loretz GmbH | Hydrocortisone | B02-1956104 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone | 192241007 | 1 |
| Caesar & Loretz Hild... | Hydrocortisone | 192241004 | 1 |
| Caesar & Loretz Hilden | Hydrocortisone | 18091520 | 1 |
| Caesar & Loretz Hilden | Hydrocortisone | 183243002 | 1 |
| Caesar & Loretz Hilden | Hydrocortisone | 183243006 | 1 |
| Caesar & Loretz Hilden | Hydrocortisone | 18324306 | 1 |
| Caesar & Loretz/ Gei... | Hydrocortisone | 18091520 | 1 |
| Caesar & Loretz/Geil... | Hydrocortisone | 18091528 | 1 |
| Caesar & Loretz/Noweda | Hydrocortisone | 192241005 | 1 |
| Caesar & Loretz/Phoenix | Hydrocortisone | 21001215006 | 1 |
| Caesar & Loretz | Hydrocortisone | 16095201 | 1 |
| Caesar & Loretz | Hydrocortisone | 16255603 | 1 |
| Caesar & Loretz | Hydrocortisone | 17256603 | 2 |
| Caesar & Loretz | Hydrocortisone | 192241008 | 1 |
| Caesar / Phönix 22.0... | Hydrocortisone | 20004116007 | 1 |
| Caesar&Lorenz | Hydrocortisone | 20004116003 | 1 |
| Caesar&Loretz GmbH,A... | Hydrocortisone | 16272305 | 1 |
| Caesar&Loretz GmbH | Hydrocortisone | 12104308 | 1 |
| Caesar&Loretz GmbH | Hydrocortisone | 21001215020 | 1 |
| Caesar&loretz,Phoenix | Hydrocortisone | 15021105 | 1 |
| Caesar&loretz,Phoenix | Hydrocortisone | 15181004 | 1 |
| Caesar/Alliance Heal... | Hydrocortisone | 20004116004 | 1 |
| Cealo / Anzag | Hydrocortisone | 220322(21001215003) | 1 |
| Cealo / Anzag | Hydrocortisone | 220419(21001215003) | 1 |
| Cealo / Anzag | Hydrocortisone | 220531(21001215003) | 1 |
| Cealo / Anzag | Hydrocortisone | 220712(21001215003) | 1 |
| Cealo / Anzag | Hydrocortisone | 230117(21001215018) | 1 |
| Cealo / Anzag | Hydrocortisone | 230208(21001215018) | 1 |
| Cealo, Anzag 26.08.19 | Hydrocortisone | 18091528 | 1 |
| Cealo/ Anzag | Hydrocortisone | 16095210 | 1 |
| Cealo/ Noweda | Hydrocortisone | 17351209 | 1 |
| Cealo/Jenne | Hydrocortisone | 211019(21001215003) | 2 |
| Cealo/Jenne | Hydrocortisone | 211104(20004116005) | 2 |
| Cealo/Sanacorp | Hydrocortisone | 20004116004 | 1 |
| Cealo | Hydrocortisone | 16004612 | 1 |
| Cealo | Hydrocortisone | 17119405 | 1 |
| Cealo | Hydrocortisone | 18091503 | 1 |
| Cealo | Hydrocortisone | 18091505 | 1 |
| Cealo | Hydrocortisone | 18091531 | 1 |
| Cealo | Hydrocortisone | 192241004 | 1 |
| Celo/AHD | Hydrocortisone | 18091506 | 1 |
| Delta | Hydrocortisone | 16H01-B01-326071 | 1 |
| Ebert & Jacobi | Hydrocortisone | 1509029-01 | 1 |
| Eu Rho/gehe | Hydrocortisone | 1611016-01 | 1 |
| EuRho / Noweda | Hydrocortisone | 1906033-01 | 1 |
| EuRho 12.03.2013 Anzag | Hydrocortisone | 1112030-01 | 1 |
| EuRho/ Anzag | Hydrocortisone | 113(1906033-01) | 1 |
| EuRho/ Anzag | Hydrocortisone | 84(1802009-01) | 1 |
| EuRho/ Anzag | Hydrocortisone | 87(1906033-01) | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho/ Anzag | Hydrocortisone | 96(1906033-01) | 1 |
| Eurho/ Phönix | Hydrocortisone | 180200901 | 1 |
| EuRho/AHD | Hydrocortisone | 1802009-01 | 1 |
| EuRho/GEHE | Hydrocortisone | 1611016-01 | 1 |
| EuRho/Jenne | Hydrocortisone | 1906033-01 | 1 |
| EuRho/Noweda | Hydrocortisone | 1611016-01 | 1 |
| Eurho/Phönix | Hydrocortisone | 210100302 | 1 |
| EuRho | Hydrocortisone | 1107005-02 | 1 |
| EuRho | Hydrocortisone | 1202032-01 | 1 |
| EuRho | Hydrocortisone | 1204037-01 | 1 |
| EuRho | Hydrocortisone | 1405001-01 | 3 |
| EuRho | Hydrocortisone | 1509029-01 | 1 |
| EuRho | Hydrocortisone | 1611016-01 | 1 |
| EuRho | Hydrocortisone | 180200-01 | 1 |
| EuRho | Hydrocortisone | 2101003-01 | 1 |
| Euro / AHD | Hydrocortisone | 1906033-01 | 1 |
| EURO / Gehe | Hydrocortisone | 1405001-01 | 1 |
| Euro Gehe | Hydrocortisone | 1611016-01 | 1 |
| Euro Gehe | Hydrocortisone | 1802009-01 | 1 |
| Euro OTC | Hydrocortisone | 100(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 101(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 102(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 103(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 104(1906033) | 1 |
| Euro OTC | Hydrocortisone | 105(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 106(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 107(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 108(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 1082009-01 | 1 |
| Euro OTC | Hydrocortisone | 109(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 1096033-01 | 1 |
| Euro OTC | Hydrocortisone | 110(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 1107005-01 | 1 |
| Euro OTC | Hydrocortisone | 1107005-02 | 3 |
| Euro OTC | Hydrocortisone | 1107005-03 | 8 |
| Euro OTC | Hydrocortisone | 111(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 1112030-01 | 9 |
| Euro OTC | Hydrocortisone | 112(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 11611016-01 | 1 |
| Euro OTC | Hydrocortisone | 119(2101003-01) | 1 |
| Euro OTC | Hydrocortisone | 1202032-01 | 3 |
| Euro OTC | Hydrocortisone | 120403701 | 3 |
| Euro OTC | Hydrocortisone | 1204037-01 | 26 |
| Euro OTC | Hydrocortisone | 1204307-01 | 1 |
| Euro OTC | Hydrocortisone | 12060018-01 | 1 |
| Euro OTC | Hydrocortisone | 1206018-01 | 23 |
| Euro OTC | Hydrocortisone | 120618-01 | 1 |
| Euro OTC | Hydrocortisone | 1405001 | 1 |
| Euro OTC | Hydrocortisone | 1405001-01 | 2 |
| Euro OTC | Hydrocortisone | 1408023-01 | 4 |
| Euro OTC | Hydrocortisone | 1501034 | 1 |
| Euro OTC | Hydrocortisone | 1501034-01 | 10 |
| Euro OTC | Hydrocortisone | 1505010601 | 1 |
| Euro OTC | Hydrocortisone | 150501601 | 1 |
| Euro OTC | Hydrocortisone | 1505016-01 | 30 |
| Euro OTC | Hydrocortisone | 15050-16-01 | 1 |
| Euro OTC | Hydrocortisone | 150516-01 | 1 |
| Euro OTC | Hydrocortisone | 150902 | 1 |
| Euro OTC | Hydrocortisone | 1509029 | 1 |
| Euro OTC | Hydrocortisone | 150902901 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Hydrocortisone | 1509029-01 | 41 |
| Euro OTC | Hydrocortisone | 150929-01 | 1 |
| Euro OTC | Hydrocortisone | 15278703 | 1 |
| Euro OTC | Hydrocortisone | 157015 | 2 |
| Euro OTC | Hydrocortisone | 16004612 | 1 |
| Euro OTC | Hydrocortisone | 161016-01 | 1 |
| Euro OTC | Hydrocortisone | 16110016-01 | 1 |
| Euro OTC | Hydrocortisone | 1611016 | 1 |
| Euro OTC | Hydrocortisone | 161101601 | 3 |
| Euro OTC | Hydrocortisone | 1611016-01 | 83 |
| Euro OTC | Hydrocortisone | 161116-01 | 1 |
| Euro OTC | Hydrocortisone | 16272305 | 1 |
| Euro OTC | Hydrocortisone | 16272311 | 1 |
| Euro OTC | Hydrocortisone | 1708006-01 | 1 |
| Euro OTC | Hydrocortisone | 17119402 | 1 |
| Euro OTC | Hydrocortisone | 17256603 | 1 |
| Euro OTC | Hydrocortisone | 17351202 | 1 |
| Euro OTC | Hydrocortisone | 1801009-01 | 1 |
| Euro OTC | Hydrocortisone | 1802008-01 | 1 |
| Euro OTC | Hydrocortisone | 1802009 | 1 |
| Euro OTC | Hydrocortisone | 180200901 | 4 |
| Euro OTC | Hydrocortisone | 1802009-01 | 84 |
| Euro OTC | Hydrocortisone | 1802009-1 | 2 |
| Euro OTC | Hydrocortisone | 18091501 | 1 |
| Euro OTC | Hydrocortisone | 18091506 | 1 |
| Euro OTC | Hydrocortisone | 181102182 | 1 |
| Euro OTC | Hydrocortisone | 1906033 | 2 |
| Euro OTC | Hydrocortisone | 190603301 | 1 |
| Euro OTC | Hydrocortisone | 1906033-01 | 97 |
| Euro OTC | Hydrocortisone | 190633-01 | 3 |
| Euro OTC | Hydrocortisone | 19069033-01 | 1 |
| Euro OTC | Hydrocortisone | 2019Q-01719 | 1 |
| Euro OTC | Hydrocortisone | 210100-02 | 1 |
| Euro OTC | Hydrocortisone | 2101003-001 | 1 |
| Euro OTC | Hydrocortisone | 210100301 | 1 |
| Euro OTC | Hydrocortisone | 2101003-01 | 47 |
| Euro OTC | Hydrocortisone | 2101003-02 | 9 |
| Euro OTC | Hydrocortisone | 210818A | 1 |
| Euro OTC | Hydrocortisone | 210826 | 1 |
| Euro OTC | Hydrocortisone | 210906(2101003-01) | 1 |
| Euro OTC | Hydrocortisone | 211118(2101003-01) | 1 |
| Euro OTC | Hydrocortisone | 2205003-01 | 5 |
| Euro OTC | Hydrocortisone | 2401017-01 | 1 |
| Euro OTC | Hydrocortisone | 29011504 | 1 |
| Euro OTC | Hydrocortisone | 3817A-01719 | 1 |
| Euro OTC | Hydrocortisone | 4091510 | 1 |
| Euro OTC | Hydrocortisone | 4112A-01719 | 1 |
| Euro OTC | Hydrocortisone | 4616U-01719 | 1 |
| Euro OTC | Hydrocortisone | 6051502 | 1 |
| Euro OTC | Hydrocortisone | 715Q-01719 | 1 |
| Euro OTC | Hydrocortisone | 79(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 80(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 81(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 82(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 83(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 85(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 86(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 8639285 | 1 |
| Euro OTC | Hydrocortisone | 88(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 89(1906033-01) | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Hydrocortisone | 90(1802009-01) | 1 |
| Euro OTC | Hydrocortisone | 906033-01 | 1 |
| Euro OTC | Hydrocortisone | 91(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 92(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 93(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 94(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 95(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 97(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 98(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | 99(1906033-01) | 1 |
| Euro OTC | Hydrocortisone | K05B20160909 | 1 |
| Euro OTC | Hydrocortisone | K05B20180323 | 1 |
| Euro OTC | Hydrocortisone | K05M20170313 | 1 |
| Euro OTC | Hydrocortisone | k05m20201110 | 1 |
| Euro OTC | Hydrocortisone | L03971 | 1 |
| Euro OTC | Hydrocortisone | L39844 | 1 |
| Euro/ Phönix | Hydrocortisone | 1509029-01 | 1 |
| Euro/Jenne | Hydrocortisone | 1501034-01 | 1 |
| Euro/Jenne | Hydrocortisone | 1505016-01 | 1 |
| Euro/Phönix | Hydrocortisone | 210100301 | 1 |
| Fa.Alliance Healtc. | Hydrocortisone | 16095202 | 1 |
| Fa.Phönix | Hydrocortisone | 18324308 | 1 |
| Fa.Phönix | Hydrocortisone | 20004116004 | 1 |
| Fagro/Otto Geilenkirchen | Hydrocortisone | 19k05-b02-195614 | 1 |
| Fagron | Hydrocortisone | | 2 |
| Fagron | Hydrocortisone | 11021403 | 1 |
| Fagron | Hydrocortisone | 114(19K05-B02-195615) | 1 |
| Fagron | Hydrocortisone | 115(19K015-0004) | 1 |
| Fagron | Hydrocortisone | 116(19K05-B02-195615) | 1 |
| Fagron | Hydrocortisone | 117(19K05-B02-195615) | 1 |
| Fagron | Hydrocortisone | 11K18-N01 | 2 |
| Fagron | Hydrocortisone | 12/25-N01 | 1 |
| Fagron | Hydrocortisone | 1204037-01 | 1 |
| Fagron | Hydrocortisone | 120601801 | 1 |
| Fagron | Hydrocortisone | 12091401 | 1 |
| Fagron | Hydrocortisone | 12104304 | 1 |
| Fagron | Hydrocortisone | 12119303 | 1 |
| Fagron | Hydrocortisone | 12G19-N01 | 2 |
| Fagron | Hydrocortisone | 12I25-N01 | 2 |
| Fagron | Hydrocortisone | 13341510 | 1 |
| Fagron | Hydrocortisone | 13H08-B01-285469 | 1 |
| Fagron | Hydrocortisone | 13H08-B01-285472 | 1 |
| Fagron | Hydrocortisone | 13H08B01285473 | 1 |
| Fagron | Hydrocortisone | 13H08-B01-285473 | 1 |
| Fagron | Hydrocortisone | 13H08-B01-28571 | 1 |
| Fagron | Hydrocortisone | 13K22-B01-288282 | 1 |
| Fagron | Hydrocortisone | 13K22-B01-288283 | 1 |
| Fagron | Hydrocortisone | 13K22-B01-288284 | 3 |
| Fagron | Hydrocortisone | 14/05-B02-300227 | 2 |
| Fagron | Hydrocortisone | 14/05-BO2-300227 | 1 |
| Fagron | Hydrocortisone | 14B04-B02 | 2 |
| Fagron | Hydrocortisone | 14B04-B02-293422 | 3 |
| Fagron | Hydrocortisone | 14B04-B02-293423 | 4 |
| Fagron | Hydrocortisone | 14B04-B02-293424 | 6 |
| Fagron | Hydrocortisone | 14I05-B02 | 2 |
| Fagron | Hydrocortisone | 14I05-B02-300227 | 3 |
| Fagron | Hydrocortisone | 14I05-B02-300228 | 1 |
| Fagron | Hydrocortisone | 14I05-B02-300229 | 1 |
| Fagron | Hydrocortisone | 14l05-B02-300227 | 1 |
| Fagron | Hydrocortisone | 14l05-B02-300228 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hydrocortisone | 15/25-B01-313084 | 1 |
| Fagron | Hydrocortisone | 15/25-B01-318727 | 1 |
| Fagron | Hydrocortisone | 15015 | 1 |
| Fagron | Hydrocortisone | 1509029-01 | 1 |
| Fagron | Hydrocortisone | 15D14-B02 | 1 |
| Fagron | Hydrocortisone | 15D14-B02-311696 | 3 |
| Fagron | Hydrocortisone | 15I04-B03-315021 | 1 |
| Fagron | Hydrocortisone | 15I25-B01-318727 | 1 |
| Fagron | Hydrocortisone | 15l25-B01-318486 | 1 |
| Fagron | Hydrocortisone | 16272311 | 1 |
| Fagron | Hydrocortisone | 16A19-B06 | 1 |
| Fagron | Hydrocortisone | 16A19-B06-320970 | 20 |
| Fagron | Hydrocortisone | 16A19-B06-321981 | 4 |
| Fagron | Hydrocortisone | 16A19-B06-321982 | 1 |
| Fagron | Hydrocortisone | 16H01-B01 | 1 |
| Fagron | Hydrocortisone | 16H01-B01-324891 | 1 |
| Fagron | Hydrocortisone | 16H01-B01-324944 | 5 |
| Fagron | Hydrocortisone | 16H01-B01-326071 | 3 |
| Fagron | Hydrocortisone | 16J26-B04 | 1 |
| Fagron | Hydrocortisone | 16J26-B04-328188 | 1 |
| Fagron | Hydrocortisone | 16J26-B04-329419 | 2 |
| Fagron | Hydrocortisone | 16j26-b04-330339 | 1 |
| Fagron | Hydrocortisone | 16J26-B04-330340 | 2 |
| Fagron | Hydrocortisone | 17/12-b05-344220 | 1 |
| Fagron | Hydrocortisone | 17/12-B05-344220 | 2 |
| Fagron | Hydrocortisone | 17/12-B05-345540 | 1 |
| Fagron | Hydrocortisone | 17/12-Bos-344220 | 1 |
| Fagron | Hydrocortisone | 17119405 | 1 |
| Fagron | Hydrocortisone | 17-12B05-342611 | 1 |
| Fagron | Hydrocortisone | 1712-B05-345540 | 2 |
| Fagron | Hydrocortisone | 17256604 | 1 |
| Fagron | Hydrocortisone | 17351205 | 1 |
| Fagron | Hydrocortisone | 17c13-B06 | 1 |
| Fagron | Hydrocortisone | 17C13-B06 | 1 |
| Fagron | Hydrocortisone | 17C13-B06-333045 | 4 |
| Fagron | Hydrocortisone | 17E10-B04 | 2 |
| Fagron | Hydrocortisone | 17E10-B04-334857 | 5 |
| Fagron | Hydrocortisone | 17E-10-B04-334857 | 1 |
| Fagron | Hydrocortisone | 17E10-B04-334858 | 4 |
| Fagron | Hydrocortisone | 17e10-b04-335056 | 1 |
| Fagron | Hydrocortisone | 17E10-B04-335056 | 3 |
| Fagron | Hydrocortisone | 17E10B04335656 | 1 |
| Fagron | Hydrocortisone | 17E10-B04-335656 | 2 |
| Fagron | Hydrocortisone | 17E10-B04-336435 | 8 |
| Fagron | Hydrocortisone | 17E10-B04-336436 | 2 |
| Fagron | Hydrocortisone | 17g25-b02-340864 | 1 |
| Fagron | Hydrocortisone | 17G25-B02-340864 | 2 |
| Fagron | Hydrocortisone | 17G25-B02-340865 | 1 |
| Fagron | Hydrocortisone | 17I12-B05 | 1 |
| Fagron | Hydrocortisone | 17I12-B05-344220 | 2 |
| Fagron | Hydrocortisone | 17I12-B05-34554 | 1 |
| Fagron | Hydrocortisone | 18091501 | 1 |
| Fagron | Hydrocortisone | 183243002 | 3 |
| Fagron | Hydrocortisone | 18B21-B07 | 2 |
| Fagron | Hydrocortisone | 18B21-B07-348430 | 3 |
| Fagron | Hydrocortisone | 18B21-B07-348431 | 4 |
| Fagron | Hydrocortisone | 18B21-B07-348432 | 3 |
| Fagron | Hydrocortisone | 18B21-B07-360920 | 1 |
| Fagron | Hydrocortisone | 19051403 | 1 |
| Fagron | Hydrocortisone | 19K05-802-195615 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hydrocortisone | 19K05-B02-195613 | 3 |
| Fagron | Hydrocortisone | 19K05-B02-195614 | 3 |
| Fagron | Hydrocortisone | 19k05-b02-195615 | 1 |
| Fagron | Hydrocortisone | 19K05-B02-195615 | 6 |
| Fagron | Hydrocortisone | 20B17-802-2000542 | 1 |
| Fagron | Hydrocortisone | 20B17-B02-200514 | 4 |
| Fagron | Hydrocortisone | 20B17-B02-200543 | 4 |
| Fagron | Hydrocortisone | 20B17-B02-200544 | 8 |
| Fagron | Hydrocortisone | 20B17-B02-200571 | 2 |
| Fagron | Hydrocortisone | 21011003-02 | 1 |
| Fagron | Hydrocortisone | -21965000 | 1 |
| Fagron | Hydrocortisone | 22E09-B02-219650 | 1 |
| Fagron | Hydrocortisone | 22E09-B02-220942 | 1 |
| Fagron | Hydrocortisone | 23D06-B02-234497 | 1 |
| Fagron | Hydrocortisone | 2OB17-BO2-200543 | 1 |
| Fagron | Hydrocortisone | 5061304 | 1 |
| Fagron | Hydrocortisone | BO-20051004 | 1 |
| Fagron | Hydrocortisone | BO2-2005104 | 1 |
| Fagron | Hydrocortisone | BO2-2005403 | 3 |
| Fagron | Hydrocortisone | BO2-1956104 | 1 |
| Fagron | Hydrocortisone | K05B20130407M | 1 |
| Fagron | Hydrocortisone | K05B20131101 | 1 |
| Fagron | Hydrocortisone | K05M20170702 | 1 |
| Fagron | Hydrocortisone | PH132 | 1 |
| Fagron | Hydrocortisone | T3319 | 1 |
| Fargo/Anzag | Hydrocortisone | 17E10-B04-335056 | 1 |
| Fargon | Hydrocortisone | 17E10-B04-334858 | 1 |
| fargon | Hydrocortisone | T3325 | 1 |
| fargron | Hydrocortisone | 13K22-B01-288284 | 1 |
| Fiebig | Hydrocortisone | 1509029-01 | 2 |
| Fiebig | Hydrocortisone | 16095207 | 1 |
| Fiebig | Hydrocortisone | 16095210 | 1 |
| Fiebig | Hydrocortisone | 17119402 | 2 |
| Fiebig | Hydrocortisone | 17256602 | 1 |
| Fiebig | Hydrocortisone | 18091520 | 1 |
| Fiebig | Hydrocortisone | 18091525 | 1 |
| Fiebig | Hydrocortisone | 18091528 | 1 |
| Fiebig | Hydrocortisone | 22003779005 | 1 |
| Fiebig | Hydrocortisone | 22003779006 | 1 |
| Fiebig | Hydrocortisone | 23003407006 | 1 |
| Fischar/ Anzag | Hydrocortisone | 118(20B17-B02-200544) | 1 |
| Fragon/Anzag | Hydrocortisone | 19K05-b02-195615 | 1 |
| Fragon/Sanacorp | Hydrocortisone | 17E10-B04-335056 | 1 |
| Gatt-Koller | Hydrocortisone | 1804169 | 1 |
| Gatt-Koller | Hydrocortisone | 20172187 | 1 |
| Gatt-Koller | Hydrocortisone | 22J00274 | 1 |
| GEHE 03.05.2014 | Hydrocortisone | 13155605 | 1 |
| GEHE 14.04.2014 | Hydrocortisone | 13069509 | 1 |
| Gehe,27.0415 | Hydrocortisone | 14301310 | 1 |
| Gehe/EuRho | Hydrocortisone | 19060033-01 | 1 |
| Gehe/Europharm | Hydrocortisone | 1802009-01 | 1 |
| Gehe/Jenne | Hydrocortisone | 20004116001 | 1 |
| Gehe | Hydrocortisone | 1206018-01 | 2 |
| Gehe | Hydrocortisone | 12104304 | 3 |
| Gehe | Hydrocortisone | 13069510 | 1 |
| Gehe | Hydrocortisone | 13341510 | 1 |
| Gehe | Hydrocortisone | 13H08-B01-285469 | 1 |
| Gehe | Hydrocortisone | 13H08-B01-285471 | 1 |
| Gehe | Hydrocortisone | 1405001-01 | 1 |
| Gehe | Hydrocortisone | 1501034-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Hydrocortisone | 1509029-01 | 1 |
| gehe | Hydrocortisone | 1611016-01 | 1 |
| Gehe | Hydrocortisone | 1611016-01 | 1 |
| gehe | Hydrocortisone | 16255607 | 1 |
| Gehe | Hydrocortisone | 16255607 | 1 |
| Gehe | Hydrocortisone | 16255608 | 1 |
| Gehe | Hydrocortisone | 16272306 | 1 |
| GEHE | Hydrocortisone | 16272311 | 1 |
| Gehe | Hydrocortisone | 17256604 | 1 |
| Gehe | Hydrocortisone | 17351203 | 1 |
| Gehe | Hydrocortisone | 17351206 | 1 |
| GEHE | Hydrocortisone | 17351210 | 2 |
| Gehe | Hydrocortisone | 17E10-B04-335656 | 1 |
| Gehe | Hydrocortisone | 1802009-01 | 1 |
| Gehe | Hydrocortisone | 18091521 | 1 |
| Gehe | Hydrocortisone | 18091524 | 3 |
| Gehe | Hydrocortisone | 183243004 | 1 |
| GEHE | Hydrocortisone | 18324301 | 1 |
| Gehe | Hydrocortisone | 18324303 | 1 |
| Gehe | Hydrocortisone | 18324310 | 1 |
| Gehe | Hydrocortisone | 1906033-01 | 1 |
| Gehe | Hydrocortisone | 192241002 | 1 |
| Gehe | Hydrocortisone | 20004116005 | 2 |
| Gehe | Hydrocortisone | 2004116006 | 1 |
| Gehe | Hydrocortisone | 201010(22003779008) | 1 |
| Gehe | Hydrocortisone | 21001215003 | 1 |
| Gehe | Hydrocortisone | 21001215013 | 1 |
| Gehe | Hydrocortisone | 21001215019 | 1 |
| Gehe | Hydrocortisone | 21001215021 | 1 |
| Gehe | Hydrocortisone | 21001215027 | 2 |
| Gehe | Hydrocortisone | 21001215035 | 3 |
| Gehe | Hydrocortisone | 2101003-01 | 3 |
| Gehe | Hydrocortisone | 22003779004 | 1 |
| Gehe | Hydrocortisone | 22003779005 | 1 |
| Gehe | Hydrocortisone | 22003779006 | 2 |
| Gehe | Hydrocortisone | 22003779011 | 1 |
| Gehe | Hydrocortisone | 22003779012 | 1 |
| GEHE | Hydrocortisone | 2205003-01 | 1 |
| Gehe | Hydrocortisone | 2401017-01 | 1 |
| Gehe | Hydrocortisone | 240425(22003779008) | 1 |
| Gehe | Hydrocortisone | 241128(22003779008) | 2 |
| Ge-Hh | Hydrocortisone | 192241002 | 1 |
| Geilenkirchen | Hydrocortisone | 1611016-01 | 1 |
| Geilenkirchen | Hydrocortisone | 20004116007 | 1 |
| Henan Lihua Pharm/AHD | Hydrocortisone | 18B21-B07-348430 | 1 |
| Henan Lihua Pharmace… | Hydrocortisone | 15D14-B02-311696 | 2 |
| Henan Lihua Pharmace… | Hydrocortisone | 1906033-01 | 1 |
| Henan/Noweda | Hydrocortisone | K05M20170408 | 1 |
| Henan/Noweda | Hydrocortisone | K05M20170701 | 1 |
| Holdermann | Hydrocortisone | 2205003-01 | 3 |
| Jenne/Gehe | Hydrocortisone | 240527(22003779008) | 1 |
| Jenne | Hydrocortisone | 18324307 | 2 |
| Jenne | Hydrocortisone | 2101003 | 1 |
| Jenne | Hydrocortisone | 22003779004 | 1 |
| Jenne | Hydrocortisone | 22003779005 | 1 |
| Jenne | Hydrocortisone | 22003779008 | 1 |
| Jenne | Hydrocortisone | 22003779012 | 1 |
| Jenne | Hydrocortisone | 230330(21001215015) | 1 |
| Jenne | Hydrocortisone | 230330(21001215018) | 1 |
| Jenne | Hydrocortisone | 231115(22003779003) | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Jenne | Hydrocortisone | 231117(21001215018) | 1 |
| Jenne | Hydrocortisone | 231211(22003779008) | 1 |
| Jenne | Hydrocortisone | 240408(22003779008) | 1 |
| Jenne | Hydrocortisone | 240416(22003779008) | 1 |
| Jenne | Hydrocortisone | 240521 | 1 |
| Jenne | Hydrocortisone | 240926(22003779008) | 1 |
| Jenne | Hydrocortisone | 240930(22003779008) | 1 |
| Jenne | Hydrocortisone | 241126(22003779008) | 1 |
| Jenne | Hydrocortisone | 250722(23003407008) | 1 |
| Kehr | Hydrocortisone | 16095213 | 1 |
| Kehr | Hydrocortisone | 17119407 | 1 |
| Kehr | Hydrocortisone | 17256602 | 1 |
| Kehr | Hydrocortisone | 21001215026 | 2 |
| Kehr | Hydrocortisone | 21001215027 | 2 |
| Kehr | Hydrocortisone | 21001215029 | 1 |
| Kehr | Hydrocortisone | 22003779004 | 2 |
| Kehr | Hydrocortisone | 22003779006 | 1 |
| Kehr | Hydrocortisone | 22003779011 | 1 |
| Kehr | Hydrocortisone | 2205003-01 | 2 |
| Klenk | Hydrocortisone | 12167007 | 1 |
| Krieger | Hydrocortisone | 22003779011 | 3 |
| L12 | Hydrocortisone | 16H01-B01-326071 | 2 |
| L12 | Hydrocortisone | 1802009-01 | 1 |
| Laborchemie Apolda/Phönix | Hydrocortisone | 15181004 | 1 |
| Midas | Hydrocortisone | 17256602 | 1 |
| Midas | Hydrocortisone | 18091519 | 1 |
| Nachprüfung 2312 | Hydrocortisone | 10282201 | 1 |
| Nachprüfung | Hydrocortisone | 123456 | 1 |
| Nachprüfung | Hydrocortisone | 192241008 | 2 |
| Nachprüfung | Hydrocortisone | 2082019-6 | 1 |
| Noweda 28.10.2019 | Hydrocortisone | 18091531 | 1 |
| Noweda 5,45 06.0... | Hydrocortisone | 18324311 | 1 |
| Noweda 5,45 14.04.2020 | Hydrocortisone | 183243002 | 1 |
| Noweda Herford | Hydrocortisone | 21001215006 | 1 |
| Noweda Taucha | Hydrocortisone | 21001215013 | 2 |
| Noweda/ Caesar&Loren... | Hydrocortisone | 18324303 | 1 |
| Noweda | Hydrocortisone | 12104303 | 1 |
| Noweda | Hydrocortisone | 12167001 | 1 |
| Noweda | Hydrocortisone | 13155605 | 1 |
| Noweda | Hydrocortisone | 16004612 | 1 |
| Noweda | Hydrocortisone | 16095212 | 1 |
| Noweda | Hydrocortisone | 1611016-01 | 1 |
| Noweda | Hydrocortisone | 16255608 | 1 |
| Noweda | Hydrocortisone | 17090005 | 1 |
| Noweda | Hydrocortisone | 17119402 | 1 |
| Noweda | Hydrocortisone | 17256602 | 3 |
| Noweda | Hydrocortisone | 17256605 | 2 |
| Noweda | Hydrocortisone | 17351203 | 1 |
| Noweda | Hydrocortisone | 17351204 | 1 |
| Noweda | Hydrocortisone | 17351210 | 1 |
| noweda | Hydrocortisone | 18091506 | 1 |
| Noweda | Hydrocortisone | 183243002 | 2 |
| Noweda | Hydrocortisone | 18324301 | 1 |
| Noweda | Hydrocortisone | 18324308 | 1 |
| Noweda | Hydrocortisone | 18324311 | 1 |
| Noweda | Hydrocortisone | 192241005 | 1 |
| Noweda | Hydrocortisone | 192241008 | 1 |
| Noweda | Hydrocortisone | 20004116004 | 1 |
| Noweda | Hydrocortisone | 20004116005 | 2 |
| Noweda | Hydrocortisone | 20004116007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Hydrocortisone | 21001215003 | 4 |
| Noweda | Hydrocortisone | 21001215011 | 1 |
| Noweda | Hydrocortisone | 21001215028 | 1 |
| Noweda | Hydrocortisone | 21001215029 | 1 |
| Noweda | Hydrocortisone | 21001215032 | 2 |
| noweda | Hydrocortisone | 21001215034 | 2 |
| Noweda | Hydrocortisone | 2101003-01 | 3 |
| Noweda | Hydrocortisone | 22003779004 | 2 |
| Noweda | Hydrocortisone | 22003779005 | 2 |
| Noweda | Hydrocortisone | 22003779006 | 3 |
| NOWEDA | Hydrocortisone | 22003779006 | 1 |
| Noweda | Hydrocortisone | 22003779008 | 3 |
| Noweda | Hydrocortisone | 22003779012 | 2 |
| Noweda | Hydrocortisone | 2205003-01 | 1 |
| Noweda | Hydrocortisone | 23003407002 | 1 |
| Noweda | Hydrocortisone | 23003407005 | 1 |
| noweda | Hydrocortisone | 23003407006 | 1 |
| Noweda | Hydrocortisone | 23003407006 | 1 |
| Otto Geilenkirchen | Hydrocortisone | 21001215029 | 1 |
| Ph.Eur 8.0 | Hydrocortisone | 16095210 | 2 |
| Pharmachem/ Anzag | Hydrocortisone | 18091520 | 1 |
| Pharmacia&Upjohn/ Phönix | Hydrocortisone | 13155614 | 1 |
| Phoenix | Hydrocortisone | 13341504 | 1 |
| Phoenix | Hydrocortisone | 1509029-01 | 2 |
| Phoenix | Hydrocortisone | 16095207 | 1 |
| Phoenix | Hydrocortisone | 1611016-01 | 1 |
| Phoenix | Hydrocortisone | 17256605 | 1 |
| Phoenix | Hydrocortisone | 1802009-01 | 2 |
| Phoenix | Hydrocortisone | 18091528 | 1 |
| Phoenix | Hydrocortisone | 18091531 | 1 |
| Phoenix | Hydrocortisone | 183243002 | 1 |
| Phoenix | Hydrocortisone | 18324301 | 1 |
| Phoenix | Hydrocortisone | 18324306 | 1 |
| Phoenix | Hydrocortisone | 18324311 | 1 |
| phoenix | Hydrocortisone | 192241008 | 1 |
| Phoenix | Hydrocortisone | 21001215005 | 1 |
| Phoenix | Hydrocortisone | 21001215018 | 3 |
| Phoenix | Hydrocortisone | 21001215020 | 2 |
| Phoenix | Hydrocortisone | 21001215029 | 1 |
| Phoenix | Hydrocortisone | 2101003-01 | 2 |
| Phoenix | Hydrocortisone | 22003779004 | 1 |
| Phoenix | Hydrocortisone | 22003779011 | 1 |
| Phoenix | Hydrocortisone | 22003779012 | 1 |
| Phoenix | Hydrocortisone | 23003407006 | 2 |
| Phoenix | Hydrocortisone | 24002019005 | 2 |
| Phoenix | Hydrocortisone | 3117 | 1 |
| Phoenix | Hydrocortisone | 3370 | 1 |
| Phönix 15.7.2019 | Hydrocortisone | 18091520 | 1 |
| Phönix Caesar u. Loretz | Hydrocortisone | 13225507 | 1 |
| Phönix Gotha | Hydrocortisone | 12104309 | 1 |
| Phönix Gotha | Hydrocortisone | 13341502 | 1 |
| Phönix Gotha | Hydrocortisone | 15021107 | 1 |
| Phönix Gotha | Hydrocortisone | 15181004 | 1 |
| Phönix Gotha | Hydrocortisone | 18324307 | 1 |
| Phönix, Caesar&Loret… | Hydrocortisone | 183243003 | 1 |
| phönix | Hydrocortisone | | 2 |
| Phönix | Hydrocortisone | 11119-N03 | 1 |
| Phönix | Hydrocortisone | 1204037-01 | 1 |
| Phönix | Hydrocortisone | 12167001 | 2 |
| Phönix | Hydrocortisone | 12167010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Hydrocortisone | 13341508 | 1 |
| Phönix | Hydrocortisone | 1408023-01 | 1 |
| phönix | Hydrocortisone | 14301306 | 1 |
| Phönix | Hydrocortisone | 15181005 | 1 |
| phönix | Hydrocortisone | 15181013 | 1 |
| Phönix | Hydrocortisone | 1611016-01 | 2 |
| Phönix | Hydrocortisone | 16110161-01 | 1 |
| Phönix | Hydrocortisone | 16272306 | 1 |
| Phönix | Hydrocortisone | 17119405 | 3 |
| Phönix | Hydrocortisone | 17119406 | 1 |
| PHÖNIX | Hydrocortisone | 17119410 | 1 |
| Phönix | Hydrocortisone | 17256602 | 1 |
| Phönix | Hydrocortisone | 17256603 | 1 |
| Phönix | Hydrocortisone | 17351206 | 2 |
| Phönix | Hydrocortisone | 17E10-B04-334858 | 1 |
| Phönix | Hydrocortisone | 1802009-01 | 3 |
| Phönix | Hydrocortisone | 18081508 | 1 |
| Phönix | Hydrocortisone | 18091505 | 1 |
| Phönix | Hydrocortisone | 1824302 | 1 |
| Phönix | Hydrocortisone | 183243002 | 4 |
| Phönix | Hydrocortisone | 183243006 | 1 |
| Phönix | Hydrocortisone | 18324302 | 1 |
| Phönix | Hydrocortisone | 18B21-B07-360920 | 1 |
| Phönix | Hydrocortisone | 1906033 | 1 |
| PHÖNIX | Hydrocortisone | 192241008 | 1 |
| Phönix | Hydrocortisone | 20004116002 | 1 |
| Phönix | Hydrocortisone | 20004116007 | 1 |
| Phönix | Hydrocortisone | 201073010 | 1 |
| Phönix | Hydrocortisone | 21001215005 | 3 |
| Phönix | Hydrocortisone | 21001215007 | 1 |
| Phönix | Hydrocortisone | 21001215032 | 1 |
| Phönix | Hydrocortisone | 21001215035 | 1 |
| Phönix | Hydrocortisone | 21001215036 | 1 |
| phönix | Hydrocortisone | 22003779004 | 2 |
| Phönix | Hydrocortisone | 22003779004 | 1 |
| Phönix | Hydrocortisone | 22003779006 | 3 |
| Phönix | Hydrocortisone | 22003779011 | 3 |
| Phönix | Hydrocortisone | 22003779012 | 1 |
| phönix | Hydrocortisone | 23003407006 | 1 |
| Phönix | Hydrocortisone | 3181 | 1 |
| Phönix | Hydrocortisone | Hy19 | 1 |
| Röntgen | Hydrocortisone | 17256605 | 1 |
| Röntgen | Hydrocortisone | 1906033-01 | 1 |
| sana corp | Hydrocortisone | 13069507 | 1 |
| Sanacorp/Caesar & Lo… | Hydrocortisone | 18091505 | 2 |
| Sanacorp | Hydrocortisone | 1112030-01 | 1 |
| Sanacorp | Hydrocortisone | 13069509 | 1 |
| Sanacorp | Hydrocortisone | 13341509 | 1 |
| Sanacorp | Hydrocortisone | 14301307 | 1 |
| Sanacorp | Hydrocortisone | 14B04-B02 | 1 |
| Sanacorp | Hydrocortisone | 1509029-01 | 1 |
| sanacorp | Hydrocortisone | 15181012 | 1 |
| sanacorp | Hydrocortisone | 15181013 | 1 |
| Sanacorp | Hydrocortisone | 16004607 | 1 |
| Sanacorp | Hydrocortisone | 17119405 | 1 |
| Sanacorp | Hydrocortisone | 17256604 | 1 |
| Sanacorp | Hydrocortisone | 1802009-01 | 3 |
| Sanacorp | Hydrocortisone | 18091501 | 1 |
| Sanacorp | Hydrocortisone | 18091502 | 2 |
| Sanacorp | Hydrocortisone | 18091507 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Hydrocortisone | 18091520 | 1 |
| Sanacorp | Hydrocortisone | 18091525 | 1 |
| Sanacorp | Hydrocortisone | 183243006 | 1 |
| Sanacorp | Hydrocortisone | 18324311 | 2 |
| Sanacorp | Hydrocortisone | 1906033-01 | 1 |
| sanacorp | Hydrocortisone | 192241008 | 1 |
| Sanacorp | Hydrocortisone | 20b17-b02-200514 | 1 |
| Sanacorp | Hydrocortisone | 21001215014 | 1 |
| Sanacorp | Hydrocortisone | 21001215023 | 2 |
| Sanacorp | Hydrocortisone | 22003779004 | 4 |
| Sanacorp | Hydrocortisone | 22003779006 | 1 |
| Sanacorp | Hydrocortisone | 22003779011 | 2 |
| Sanacorp | Hydrocortisone | 22003779012 | 1 |
| sanacorp | Hydrocortisone | 2205003-01 | 4 |
| Sanacorp | Hydrocortisone | 42/AKD6 | 1 |
| Sanacorp | Hydrocortisone | Fagron | 1 |
| Sanacorp | Hydrocortisone | K05M20221003 | 1 |
| Sanarcorp | Hydrocortisone | 2101003-02 | 1 |
| Spangro 23.1.2014 | Hydrocortisone | 13069510 | 1 |
| Spangro_21.05.2019 | Hydrocortisone | 18091524 | 1 |
| Spangropharm | Hydrocortisone | 13341504 | 2 |
| Tianjin JP / Gehe | Hydrocortisone | 183243004 | 1 |
| Tianjin/Noweda | Hydrocortisone | T3307 | 1 |
| Tianjin/Noweda | Hydrocortisone | TA0075 | 1 |
| Upjohn/Phönix | Hydrocortisone | 1509029-01 | 1 |
| VDL | Hydrocortisone | 18091525 | 1 |
| xxx | Hydrocortisone | 911Q-01719 | 2 |

- 251 940 spectra from 1665 *Apo-Ident* customers from a total of 51 519 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hydrocortisone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hydrocortisone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 661 | 0 | 157 665 |
| **Type B** | 0 | 1119 | 0 | 211 821 |
| **Type C** | 0 | 4934 | 12 | 251 940 |

The substance/substance group *Hydrocortisone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4638 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7574 % (> 99.6967 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21293 | 21899 | 7.22 | 116.35 |
| 21461 | 21899 | 7.99 | 116.89 |
| 21463 | 21899 | 3.35 | 116.80 |
| 21899 | 21899 | 0.00 | 117.04 |
| 22829 | 22838 | 7.65 | 119.16 |
| 22837 | 22838 | 5.21 | 117.08 |
| 22838 | 22838 | 0.00 | 119.16 |
| 22910 | 22910 | 0.00 | 119.78 |
| 22928 | 22910 | 5.73 | 121.67 |
| 24020 | 24020 | 0.00 | 119.24 |
| 25571 | 25571 | 0.00 | 122.18 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hydrocortisone acetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20010-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hydrocortisone acetate; Hydrocortisoni acetas

### Special notes

When selecting the *Hydrocortisone acetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hydrocortisone acetate | 7 | 18 | 636 |

### Second-stage model

For differentiation of the substance/substance group *Hydrocortisone acetate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hydrocortisone acetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 101.53 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hydrocortisone acetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hydrocortisone acetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Hydrocortisone acetate | 13291708 | 21462 | 60 | 20130926 |
| Caelo | Hydrocortisone acetate | 182780 | 24392 | 40 | 20181210* |
| Euro OTC | Hydrocortisone acetate | 1209003-01 | 21295 | 40 | 20121108 |
| Euro OTC | Hydrocortisone acetate | 1209003-01 | 21295SI | 45 | 20121108 |
| Euro OTC | Hydrocortisone acetate | 1508029 | 21889 | 60 | 20150902* |
| Euro OTC | Hydrocortisone acetate | 1508029 | 21889SI | 44 | 20150902* |
| Euro OTC | Hydrocortisone acetate | 1604052 | 22564 | 40 | 20160525* |
| Fagron | Hydrocortisone acetate | 15A30-B09-307090 | 22241 | 60 | 20150226 |
| Fagron | Hydrocortisone acetate | 18H07-B03-356259 | 24590 | 40 | 20180829 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 429 spectra of 9 reference samples from the substance/substance group *Hydrocortisone acetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 897 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1418 spectra of 40 reference samples from the substance/substance group *Hydrocortisone - acetate*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hydrocortisone acetate | 16238706 | 23115 | 40 |
| Caelo | Hydrocortisone acetate | 170862 | 23328 | 40 |
| Caelo | Hydrocortisone acetate | 21002415001 | 25924 | 40 |
| Caelo | Hydrocortisone acetate | 21003553 | 25992 | 40 |
| Caelo | Hydrocortisone acetate | 22002539 | 26363 | 40 |
| Caelo | Hydrocortisone acetate | 23001089 | 26853 | 40 |
| Caelo | Hydrocortisone acetate | 23003142 | 27133 | 40 |
| Caelo | Hydrocortisone acetate | 25000497 | 27666 | 30 |
| Euro OTC | Hydrocortisone acetate | 1706021 | 23559 | 40 |
| Euro OTC | Hydrocortisone acetate | 1805010 | 24130 | 40 |
| Euro OTC | Hydrocortisone acetate | 1907011 | 24789 | 40 |
| Euro OTC | Hydrocortisone acetate | 2004029 | 25331 | 40 |
| Euro OTC | Hydrocortisone acetate | 2205004 | 26212 | 40 |
| Euro OTC | Hydrocortisone acetate | 2306007 | 26883 | 40 |
| Euro OTC | Hydrocortisone acetate | 2406005 | 27349 | 40 |
| Fagron | Hydrocortisone acetate | 22A17-B07-216283 | 26138 | 40 |
| Fagron | Hydrocortisone acetate | 23E18-B03-229951 | 27266 | 40 |
| Fagron | Hydrocortisone acetate | 24A09-B03-005487 | 27608 | 40 |
| Caelo | Hydrocortisone acetate | 16238706 | 23115SI | 20 |
| Caelo | Hydrocortisone acetate | 170862 | 23328SI | 21 |
| Caelo | Hydrocortisone acetate | 182780 | 24392SI† | 32 |
| Caelo | Hydrocortisone acetate | 21002415001 | 25924SI | 40 |
| Caelo | Hydrocortisone acetate | 21003553 | 25992SI | 35 |
| Caelo | Hydrocortisone acetate | 22002539 | 26363SI | 40 |
| Caelo | Hydrocortisone acetate | 23001089 | 26853SI | 40 |
| Caelo | Hydrocortisone acetate | 23003142 | 27133SI | 30 |
| Caelo | Hydrocortisone acetate | 25000497 | 27666SI | 20 |
| Euro OTC | Hydrocortisone acetate | 1604052 | 22564SI† | 30 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Hydrocortisone acetate | 1706021 | 23559SI | 30 |
| Euro OTC | Hydrocortisone acetate | 1805010 | 24130SI | 21 |
| Euro OTC | Hydrocortisone acetate | 1907011 | 24789SI | 40 |
| Euro OTC | Hydrocortisone acetate | 2004029 | 25331SI | 40 |
| Euro OTC | Hydrocortisone acetate | 2205004 | 26212SI | 20 |
| Euro OTC | Hydrocortisone acetate | 2306007 | 26883SI | 40 |
| Euro OTC | Hydrocortisone acetate | 2406005 | 27349SI | 40 |
| Fagron | Hydrocortisone acetate | 15A30-B09-307090 | 22241SI† | 24 |
| Fagron | Hydrocortisone acetate | 18H07-B03-356259 | 24590SI† | 33 |
| Fagron | Hydrocortisone acetate | 22A17-B07-216283 | 26138SI | 40 |
| Fagron | Hydrocortisone acetate | 23E18-B03-229951 | 27266SI | 40 |
| Fagron | Hydrocortisone acetate | 24A09-B03-005487 | 27608SI | 32 |

- 211 522 spectra from a total of 4265 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6227 spectra from 1382 *Apo-Ident* customers from 655 batches from the substance/substance group *Hydrocortisone acetate*.
- Among them are spectra of independent samples from 633 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hydrocortisone acetate | 14043902 | 1 |
| | Hydrocortisone acetate | 2004029-02 | 1 |
| | Hydrocortisone acetate | 21002415001 | 1 |
| | Hydrocortisone acetate | 21002415010 | 1 |
| | Hydrocortisone acetate | 21002415011 | 1 |
| | Hydrocortisone acetate | 21002415013 | 5 |
| | Hydrocortisone acetate | 21002415014 | 1 |
| | Hydrocortisone acetate | 21002415015 | 1 |
| | Hydrocortisone acetate | 21003553006 | 1 |
| | Hydrocortisone acetate | 2100415014 | 1 |
| | Hydrocortisone acetate | 22002539002 | 17 |
| | Hydrocortisone acetate | 22002539003 | 3 |
| | Hydrocortisone acetate | 22002539004 | 11 |
| | Hydrocortisone acetate | 22002539005 | 5 |
| | Hydrocortisone acetate | 22002539008 | 7 |
| | Hydrocortisone acetate | 22002539009 | 14 |
| | Hydrocortisone acetate | 22002539010 | 24 |
| | Hydrocortisone acetate | 220025390115 | 1 |
| | Hydrocortisone acetate | 22002539013 | 25 |
| | Hydrocortisone acetate | 22002539014 | 14 |
| | Hydrocortisone acetate | 22002539015 | 25 |
| | Hydrocortisone acetate | 22002539016 | 1 |
| | Hydrocortisone acetate | 22002539018 | 9 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hydrocortisone acetate | 22002539019 | 14 |
| | Hydrocortisone acetate | 2200253904 | 2 |
| | Hydrocortisone acetate | 2202004-01 | 1 |
| | Hydrocortisone acetate | 2202539004 | 1 |
| | Hydrocortisone acetate | 2202539018 | 1 |
| | Hydrocortisone acetate | 2205004-01 | 10 |
| | Hydrocortisone acetate | 22H11-B01-229287 | 2 |
| | Hydrocortisone acetate | 22K21-B02-225805 | 2 |
| | Hydrocortisone acetate | 230010089008 | 1 |
| | Hydrocortisone acetate | 23001089002 | 2 |
| | Hydrocortisone acetate | 23001089003 | 15 |
| | Hydrocortisone acetate | 23001089004 | 33 |
| | Hydrocortisone acetate | 23001089005 | 63 |
| | Hydrocortisone acetate | 23001089006 | 18 |
| | Hydrocortisone acetate | 23001089008 | 21 |
| | Hydrocortisone acetate | 23001089009 | 33 |
| | Hydrocortisone acetate | 2300108900925/24P | 1 |
| | Hydrocortisone acetate | 2300108900935/24P | 1 |
| | Hydrocortisone acetate | 23003142001 | 20 |
| | Hydrocortisone acetate | 23003142002 | 8 |
| | Hydrocortisone acetate | 23003142003 | 37 |
| | Hydrocortisone acetate | 23003142004 | 4 |
| | Hydrocortisone acetate | 23003142006 | 2 |
| | Hydrocortisone acetate | 23003142007 | 1 |
| | Hydrocortisone acetate | 23003142008 | 4 |
| | Hydrocortisone acetate | 23003142010 | 4 |
| | Hydrocortisone acetate | 23003142011 | 3 |
| | Hydrocortisone acetate | 2303007-01 | 1 |
| | Hydrocortisone acetate | 230403(22002539010) | 1 |
| | Hydrocortisone acetate | 2306006-01 | 1 |
| | Hydrocortisone acetate | 2306007-01 | 24 |
| | Hydrocortisone acetate | 230607-01 | 1 |
| | Hydrocortisone acetate | 23E18-B03-238322 | 1 |
| | Hydrocortisone acetate | 240600501 | 1 |
| | Hydrocortisone acetate | 2406005-01 | 3 |
| | Hydrocortisone acetate | 24A09-B03-005484 | 1 |
| | Hydrocortisone acetate | 333961 | 1 |
| | Hydrocortisone acetate | HD0125 | 1 |
| AEP | Hydrocortisone acetate | 18278005 | 1 |
| AEP | Hydrocortisone acetate | 18278020 | 4 |
| AEP | Hydrocortisone acetate | 23001089005 | 2 |
| AHD 07.03.2017 EK: 5,33 | Hydrocortisone acetate | 16004407 | 1 |
| AHD/Euro | Hydrocortisone acetate | 1706021-01 | 1 |
| AHD/Euro | Hydrocortisone acetate | 1805010-01 | 1 |
| AHD | Hydrocortisone acetate | 1205034-01 | 1 |
| AHD | Hydrocortisone acetate | 13291707 | 1 |
| AHD | Hydrocortisone acetate | 1706021-01 | 1 |
| AHD | Hydrocortisone acetate | 17219704 | 1 |
| AHD | Hydrocortisone acetate | 17219708 | 1 |
| AHD | Hydrocortisone acetate | 21002415004 | 1 |
| AHD | Hydrocortisone acetate | 22002539003 | 1 |
| AHD | Hydrocortisone acetate | 22002539009 | 1 |
| AHD | Hydrocortisone acetate | 22002539013 | 1 |
| AHD | Hydrocortisone acetate | 22002539018 | 1 |
| AHD | Hydrocortisone acetate | 23001089006 | 1 |
| AHD | Hydrocortisone acetate | 23001089009 | 1 |
| AHD;05,02,15; 12.48EUR | Hydrocortisone acetate | 14144805 | 1 |
| Aliance Health Care | Hydrocortisone acetate | 22002539014 | 1 |
| Alli | Hydrocortisone acetate | 23003142002 | 1 |
| Alliance Healthcare | Hydrocortisone acetate | 21002415006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Healthcare | Hydrocortisone acetate | 21002415011 | 1 |
| Alliance Healthcare | Hydrocortisone acetate | 22002539010 | 1 |
| Alliance Healthcare | Hydrocortisone acetate | 23001089008 | 1 |
| Alliance/EurRho | Hydrocortisone acetate | 1907011-02 | 1 |
| Alliance | Hydrocortisone acetate | 1604052-01 | 1 |
| Alliance | Hydrocortisone acetate | 2004029-02 | 1 |
| Alliance | Hydrocortisone acetate | 21002415013 | 1 |
| Alliance | Hydrocortisone acetate | 21002415014 | 1 |
| Alliance | Hydrocortisone acetate | 22002539014 | 1 |
| Allianz Healthcare | Hydrocortisone acetate | 18278005 | 1 |
| Allianz Healthcare | Hydrocortisone acetate | 18278021 | 1 |
| Allianz | Hydrocortisone acetate | 17219705 | 1 |
| AMH Niemann/Sanacorp | Hydrocortisone acetate | 17219705 | 1 |
| Anzag 20.12.17 5.28 | Hydrocortisone acetate | 17219702 | 1 |
| Anzag | Hydrocortisone acetate | 1112031-02 | 1 |
| Anzag | Hydrocortisone acetate | 1209003-01 | 1 |
| Anzag | Hydrocortisone acetate | 16238708 | 1 |
| Anzag | Hydrocortisone acetate | 16238712 | 1 |
| Anzag | Hydrocortisone acetate | 16238713 | 1 |
| Anzag | Hydrocortisone acetate | 17086206 | 2 |
| Anzag | Hydrocortisone acetate | 17219702 | 2 |
| Anzag | Hydrocortisone acetate | 17219703 | 1 |
| Anzag | Hydrocortisone acetate | 20004117001 | 1 |
| Anzag | Hydrocortisone acetate | 22002539010 | 1 |
| Anzag | Hydrocortisone acetate | 22002539013 | 1 |
| Anzag | Hydrocortisone acetate | 2205004-01 | 1 |
| Anzag | Hydrocortisone acetate | 23001089005 | 1 |
| Apo-ident | Hydrocortisone acetate | 1805010-01 | 1 |
| Apo-ident | Hydrocortisone acetate | 1907011-01 | 1 |
| apomix | Hydrocortisone acetate | 1404017-02 | 1 |
| apomix | Hydrocortisone acetate | 16095407 | 1 |
| Bären Apotheke | Hydrocortisone acetate | 16238706 | 2 |
| Bombastus | Hydrocortisone acetate | 123Validierung | 1 |
| Bombastus | Hydrocortisone acetate | 1505008-03 | 1 |
| Bombastus | Hydrocortisone acetate | 15356903 | 1 |
| Bombastus | Hydrocortisone acetate | 1604052-01 | 1 |
| Bombastus | Hydrocortisone acetate | 2712M01718 | 1 |
| Caeelo | Hydrocortisone acetate | 17086204 | 1 |
| Caello/Anzag | Hydrocortisone acetate | 15067003 | 1 |
| Caelo | Hydrocortisone acetate | | 7 |
| Caelo | Hydrocortisone acetate | 10024150042 | 1 |
| Caelo | Hydrocortisone acetate | 10024150112 | 1 |
| Caelo | Hydrocortisone acetate | 10301904 | 1 |
| Caelo | Hydrocortisone acetate | 1061704 | 1 |
| Caelo | Hydrocortisone acetate | 11098604 | 1 |
| Caelo | Hydrocortisone acetate | 11098612 | 1 |
| Caelo | Hydrocortisone acetate | 11098615 | 1 |
| Caelo | Hydrocortisone acetate | 1112031-02 | 1 |
| Caelo | Hydrocortisone acetate | 11263902 | 1 |
| Caelo | Hydrocortisone acetate | 11263905 | 1 |
| Caelo | Hydrocortisone acetate | 11263913 | 1 |
| Caelo | Hydrocortisone acetate | 11263915 | 2 |
| Caelo | Hydrocortisone acetate | 11263916 | 1 |
| Caelo | Hydrocortisone acetate | 11263917 | 3 |
| Caelo | Hydrocortisone acetate | 1130317 | 1 |
| Caelo | Hydrocortisone acetate | 118107-3 | 1 |
| Caelo | Hydrocortisone acetate | 12008303 | 1 |
| Caelo | Hydrocortisone acetate | 12008402 | 2 |
| Caelo | Hydrocortisone acetate | 12008405 | 4 |
| Caelo | Hydrocortisone acetate | 12021502 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone acetate | 1205034-01 | 3 |
| Caelo | Hydrocortisone acetate | 1209003-01 | 3 |
| Caelo | Hydrocortisone acetate | 12121801 | 1 |
| Caelo | Hydrocortisone acetate | 1213M-01718 | 1 |
| Caelo | Hydrocortisone acetate | 12182402 | 10 |
| Caelo | Hydrocortisone acetate | 12182403 | 5 |
| Caelo | Hydrocortisone acetate | 12182404 | 22 |
| Caelo | Hydrocortisone acetate | 12182405 | 17 |
| Caelo | Hydrocortisone acetate | 12182408 | 2 |
| Caelo | Hydrocortisone acetate | 12183403 | 1 |
| Caelo | Hydrocortisone acetate | 12330102 | 8 |
| Caelo | Hydrocortisone acetate | 12330103 | 8 |
| Caelo | Hydrocortisone acetate | 12330104 | 10 |
| Caelo | Hydrocortisone acetate | 12330105 | 3 |
| Caelo | Hydrocortisone acetate | 12330106 | 4 |
| Caelo | Hydrocortisone acetate | 12330107 | 8 |
| Caelo | Hydrocortisone acetate | 12330108 | 13 |
| Caelo | Hydrocortisone acetate | 12330110 | 2 |
| Caelo | Hydrocortisone acetate | 12330111 | 3 |
| Caelo | Hydrocortisone acetate | 12330111-3507411061 | 1 |
| Caelo | Hydrocortisone acetate | 12330112 | 13 |
| Caelo | Hydrocortisone acetate | 12330113 | 1 |
| Caelo | Hydrocortisone acetate | 12330114 | 1 |
| Caelo | Hydrocortisone acetate | 12330116 | 12 |
| Caelo | Hydrocortisone acetate | 13155302 | 8 |
| Caelo | Hydrocortisone acetate | 13155303 | 9 |
| Caelo | Hydrocortisone acetate | 13155304 | 5 |
| Caelo | Hydrocortisone acetate | 13155306 | 5 |
| Caelo | Hydrocortisone acetate | 13155307 | 2 |
| Caelo | Hydrocortisone acetate | 13155308 | 8 |
| Caelo | Hydrocortisone acetate | 131553080 | 1 |
| Caelo | Hydrocortisone acetate | 13291701 | 1 |
| Caelo | Hydrocortisone acetate | 13291704 | 5 |
| Caelo | Hydrocortisone acetate | 13291705 | 4 |
| Caelo | Hydrocortisone acetate | 13291706 | 10 |
| Caelo | Hydrocortisone acetate | 13291707 | 14 |
| Caelo | Hydrocortisone acetate | 13291708 | 7 |
| Caelo | Hydrocortisone acetate | 13291709 | 4 |
| Caelo | Hydrocortisone acetate | 13291711 | 7 |
| Caelo | Hydrocortisone acetate | 1391704 | 1 |
| Caelo | Hydrocortisone acetate | 1391706 | 1 |
| Caelo | Hydrocortisone acetate | 13G09-N08 | 2 |
| Caelo | Hydrocortisone acetate | 1403903 | 1 |
| Caelo | Hydrocortisone acetate | 14043901 | 11 |
| Caelo | Hydrocortisone acetate | 14043902 | 10 |
| Caelo | Hydrocortisone acetate | 14043903 | 13 |
| Caelo | Hydrocortisone acetate | 14043904 | 14 |
| Caelo | Hydrocortisone acetate | 14043905 | 11 |
| Caelo | Hydrocortisone acetate | 14043906 | 9 |
| Caelo | Hydrocortisone acetate | 14043907 | 14 |
| Caelo | Hydrocortisone acetate | 14043908 | 1 |
| Caelo | Hydrocortisone acetate | 1406211718 | 1 |
| Caelo | Hydrocortisone acetate | 14144802 | 1 |
| Caelo | Hydrocortisone acetate | 14144803 | 9 |
| Caelo | Hydrocortisone acetate | 14144804 | 6 |
| Caelo | Hydrocortisone acetate | 14144805 | 21 |
| Caelo | Hydrocortisone acetate | 14144806 | 15 |
| Caelo | Hydrocortisone acetate | 14144807 | 6 |
| Caelo | Hydrocortisone acetate | 1430102 | 1 |
| Caelo | Hydrocortisone acetate | 1430140 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone acetate | 14301401 | 15 |
| Caelo | Hydrocortisone acetate | 14301402 | 8 |
| Caelo | Hydrocortisone acetate | 14301403 | 7 |
| Caelo | Hydrocortisone acetate | 14301404 | 7 |
| Caelo | Hydrocortisone acetate | 14301405 | 26 |
| Caelo | Hydrocortisone acetate | 14301406 | 18 |
| Caelo | Hydrocortisone acetate | 14301407 | 17 |
| Caelo | Hydrocortisone acetate | 14301408 | 8 |
| Caelo | Hydrocortisone acetate | 14I16-B01-300292 | 1 |
| Caelo | Hydrocortisone acetate | 1501035 | 1 |
| Caelo | Hydrocortisone acetate | 1505008-01 | 7 |
| Caelo | Hydrocortisone acetate | 15061006 | 1 |
| Caelo | Hydrocortisone acetate | 15061207 | 1 |
| Caelo | Hydrocortisone acetate | 15067003 | 13 |
| Caelo | Hydrocortisone acetate | 15067004 | 26 |
| Caelo | Hydrocortisone acetate | 15067005 | 18 |
| Caelo | Hydrocortisone acetate | 15067006 | 13 |
| Caelo | Hydrocortisone acetate | 15067010 | 3 |
| Caelo | Hydrocortisone acetate | 15067011 | 8 |
| Caelo | Hydrocortisone acetate | 15067013 | 11 |
| Caelo | Hydrocortisone acetate | 15067017 | 1 |
| Caelo | Hydrocortisone acetate | 1508029-01 | 5 |
| Caelo | Hydrocortisone acetate | 15216204 | 3 |
| Caelo | Hydrocortisone acetate | 15356901 | 17 |
| Caelo | Hydrocortisone acetate | 15356902 | 20 |
| Caelo | Hydrocortisone acetate | 15356903 | 23 |
| Caelo | Hydrocortisone acetate | 15356904 | 8 |
| Caelo | Hydrocortisone acetate | 1536902 | 1 |
| Caelo | Hydrocortisone acetate | 15A07-B03-306545 | 1 |
| Caelo | Hydrocortisone acetate | 15A30-B09-307133 | 2 |
| Caelo | Hydrocortisone acetate | 15H24_B01-316480 | 1 |
| Caelo | Hydrocortisone acetate | 15H24-B01-314236 | 2 |
| Caelo | Hydrocortisone acetate | 1600406 | 1 |
| Caelo | Hydrocortisone acetate | 160044003 | 1 |
| Caelo | Hydrocortisone acetate | 16004402 | 19 |
| Caelo | Hydrocortisone acetate | 16004403 | 9 |
| Caelo | Hydrocortisone acetate | 16004404 | 1 |
| Caelo | Hydrocortisone acetate | 16004405 | 13 |
| Caelo | Hydrocortisone acetate | 16004406 | 28 |
| Caelo | Hydrocortisone acetate | 16004407 | 23 |
| Caelo | Hydrocortisone acetate | 16004408 | 22 |
| Caelo | Hydrocortisone acetate | 160044402 | 1 |
| Caelo | Hydrocortisone acetate | 1604052 | 1 |
| Caelo | Hydrocortisone acetate | 1604052-01 | 2 |
| Caelo | Hydrocortisone acetate | 1605410 | 1 |
| Caelo | Hydrocortisone acetate | 160629HA | 1 |
| Caelo | Hydrocortisone acetate | 16095402 | 1 |
| Caelo | Hydrocortisone acetate | 16095404 | 34 |
| Caelo | Hydrocortisone acetate | 16095405 | 22 |
| Caelo | Hydrocortisone acetate | 16095406 | 26 |
| Caelo | Hydrocortisone acetate | 16095407 | 37 |
| Caelo | Hydrocortisone acetate | 16095408 | 4 |
| Caelo | Hydrocortisone acetate | 16095410 | 7 |
| Caelo | Hydrocortisone acetate | 1623708 | 1 |
| Caelo | Hydrocortisone acetate | 16238704 | 11 |
| Caelo | Hydrocortisone acetate | 16238705 | 3 |
| Caelo | Hydrocortisone acetate | 16238706 | 32 |
| Caelo | Hydrocortisone acetate | 16238706-12517/2 | 1 |
| Caelo | Hydrocortisone acetate | 16238707 | 16 |
| Caelo | Hydrocortisone acetate | 16238708 | 22 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone acetate | 16238708-200417/1 | 1 |
| Caelo | Hydrocortisone acetate | 16238709 | 8 |
| Caelo | Hydrocortisone acetate | 16238710 | 23 |
| Caelo | Hydrocortisone acetate | 16238712 | 25 |
| Caelo | Hydrocortisone acetate | 16238713 | 8 |
| Caelo | Hydrocortisone acetate | 16238713-20170818Ma2 | 1 |
| Caelo | Hydrocortisone acetate | 16238714 | 13 |
| Caelo | Hydrocortisone acetate | 1623888704 | 1 |
| Caelo | Hydrocortisone acetate | 163163055402 | 1 |
| Caelo | Hydrocortisone acetate | 166004407 | 1 |
| Caelo | Hydrocortisone acetate | 16C15-B04-321459 | 1 |
| Caelo | Hydrocortisone acetate | 16J28-B51-333889 | 2 |
| Caelo | Hydrocortisone acetate | 17011402 | 1 |
| Caelo | Hydrocortisone acetate | 17053185 | 1 |
| Caelo | Hydrocortisone acetate | 170602101 | 1 |
| Caelo | Hydrocortisone acetate | 1706021-01 | 7 |
| Caelo | Hydrocortisone acetate | 170804HA/1604052-01 | 1 |
| Caelo | Hydrocortisone acetate | 170856206 | 1 |
| Caelo | Hydrocortisone acetate | 17086202 | 1 |
| Caelo | Hydrocortisone acetate | 170862024 | 1 |
| Caelo | Hydrocortisone acetate | 17086203 | 18 |
| Caelo | Hydrocortisone acetate | 17086204 | 27 |
| Caelo | Hydrocortisone acetate | 17086205 | 28 |
| Caelo | Hydrocortisone acetate | 17086205-20170818Ma3 | 1 |
| Caelo | Hydrocortisone acetate | 17086206 | 11 |
| Caelo | Hydrocortisone acetate | 17086207 | 4 |
| Caelo | Hydrocortisone acetate | 17086209 | 2 |
| Caelo | Hydrocortisone acetate | 17086211 | 12 |
| Caelo | Hydrocortisone acetate | 17086212 | 3 |
| Caelo | Hydrocortisone acetate | 17086221 | 1 |
| Caelo | Hydrocortisone acetate | 171106HA/17086204 | 1 |
| Caelo | Hydrocortisone acetate | 17142802 | 1 |
| Caelo | Hydrocortisone acetate | 1721905 | 1 |
| Caelo | Hydrocortisone acetate | 17219702 | 21 |
| Caelo | Hydrocortisone acetate | 17219703 | 26 |
| Caelo | Hydrocortisone acetate | 17219704 | 26 |
| Caelo | Hydrocortisone acetate | 17219705 | 65 |
| Caelo | Hydrocortisone acetate | 172197050 | 1 |
| Caelo | Hydrocortisone acetate | 172197055662 | 1 |
| Caelo | Hydrocortisone acetate | 17219706 | 31 |
| Caelo | Hydrocortisone acetate | 17219707 | 49 |
| Caelo | Hydrocortisone acetate | 17219708 | 45 |
| Caelo | Hydrocortisone acetate | 172197085556 | 1 |
| Caelo | Hydrocortisone acetate | 17219709 | 8 |
| Caelo | Hydrocortisone acetate | 17219710 | 2 |
| Caelo | Hydrocortisone acetate | 17219713 | 4 |
| Caelo | Hydrocortisone acetate | 17219714 | 1 |
| Caelo | Hydrocortisone acetate | 17358402 | 1 |
| Caelo | Hydrocortisone acetate | 17358403 | 9 |
| Caelo | Hydrocortisone acetate | 17358404 | 1 |
| Caelo | Hydrocortisone acetate | 17C10-B01-333962 | 2 |
| Caelo | Hydrocortisone acetate | 17L19-B04-348983 | 1 |
| Caelo | Hydrocortisone acetate | 18011304 | 1 |
| Caelo | Hydrocortisone acetate | 180219HA/17219707 | 1 |
| Caelo | Hydrocortisone acetate | 1805010-01 | 1 |
| Caelo | Hydrocortisone acetate | 181115181 | 1 |
| Caelo | Hydrocortisone acetate | 18121710 | 1 |
| Caelo | Hydrocortisone acetate | 18142802 | 16 |
| Caelo | Hydrocortisone acetate | 18142803 | 13 |
| Caelo | Hydrocortisone acetate | 18142804 | 39 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone acetate | 18142805 | 45 |
| Caelo | Hydrocortisone acetate | 18142805-H20181115Ma | 1 |
| Caelo | Hydrocortisone acetate | 18142806 | 43 |
| Caelo | Hydrocortisone acetate | 18142807 | 26 |
| Caelo | Hydrocortisone acetate | 18142808 | 21 |
| Caelo | Hydrocortisone acetate | 181428087 | 1 |
| Caelo | Hydrocortisone acetate | 18142809 | 21 |
| Caelo | Hydrocortisone acetate | 18142810 | 2 |
| Caelo | Hydrocortisone acetate | 18142811 | 16 |
| Caelo | Hydrocortisone acetate | 18142812 | 23 |
| Caelo | Hydrocortisone acetate | 18142814 | 1 |
| Caelo | Hydrocortisone acetate | 18142815 | 20 |
| Caelo | Hydrocortisone acetate | 18142904 | 1 |
| Caelo | Hydrocortisone acetate | 181442805 | 1 |
| Caelo | Hydrocortisone acetate | 1827006 | 1 |
| Caelo | Hydrocortisone acetate | 1827015 | 1 |
| Caelo | Hydrocortisone acetate | 18278003 | 20 |
| Caelo | Hydrocortisone acetate | 18278004 | 40 |
| Caelo | Hydrocortisone acetate | 18278005 | 60 |
| Caelo | Hydrocortisone acetate | 18278006 | 29 |
| Caelo | Hydrocortisone acetate | 18278007 | 24 |
| Caelo | Hydrocortisone acetate | 18278008 | 23 |
| Caelo | Hydrocortisone acetate | 18278010 | 33 |
| Caelo | Hydrocortisone acetate | 18278011 | 1 |
| Caelo | Hydrocortisone acetate | 18278014 | 23 |
| Caelo | Hydrocortisone acetate | 18278015 | 33 |
| Caelo | Hydrocortisone acetate | 18278016 | 34 |
| Caelo | Hydrocortisone acetate | 18278017 | 5 |
| Caelo | Hydrocortisone acetate | 18278018 | 20 |
| Caelo | Hydrocortisone acetate | 18278019 | 22 |
| Caelo | Hydrocortisone acetate | 18278020 | 24 |
| Caelo | Hydrocortisone acetate | 18278021 | 23 |
| Caelo | Hydrocortisone acetate | 18278021ma | 1 |
| Caelo | Hydrocortisone acetate | 1828007 | 1 |
| Caelo | Hydrocortisone acetate | 1828014 | 1 |
| Caelo | Hydrocortisone acetate | 187278005 | 1 |
| Caelo | Hydrocortisone acetate | 190372703 | 1 |
| Caelo | Hydrocortisone acetate | 1907011-02 | 1 |
| Caelo | Hydrocortisone acetate | 190910209 | 1 |
| Caelo | Hydrocortisone acetate | 1913807 | 1 |
| Caelo | Hydrocortisone acetate | 191383001 | 10 |
| Caelo | Hydrocortisone acetate | 191383004 | 19 |
| Caelo | Hydrocortisone acetate | 19138301 | 24 |
| Caelo | Hydrocortisone acetate | 19138302 | 18 |
| Caelo | Hydrocortisone acetate | 19138303 | 1 |
| Caelo | Hydrocortisone acetate | 19138304 | 29 |
| Caelo | Hydrocortisone acetate | 19138305 | 30 |
| Caelo | Hydrocortisone acetate | 19138306 | 1 |
| Caelo | Hydrocortisone acetate | 19138307 | 45 |
| Caelo | Hydrocortisone acetate | 19138308 | 8 |
| Caelo | Hydrocortisone acetate | 1918304 | 1 |
| Caelo | Hydrocortisone acetate | 192241005 | 2 |
| Caelo | Hydrocortisone acetate | 192241008 | 1 |
| Caelo | Hydrocortisone acetate | 1938305 | 1 |
| Caelo | Hydrocortisone acetate | 19j10-f04-366276 | 1 |
| Caelo | Hydrocortisone acetate | 19J10-F04-366276 | 1 |
| Caelo | Hydrocortisone acetate | 200000978004 | 1 |
| Caelo | Hydrocortisone acetate | 200000978007 | 1 |
| Caelo | Hydrocortisone acetate | 200004117001 | 1 |
| Caelo | Hydrocortisone acetate | 2000078008 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone acetate | 20000977002 | 14 |
| Caelo | Hydrocortisone acetate | 20000978003 | 1 |
| Caelo | Hydrocortisone acetate | 20000978004 | 36 |
| Caelo | Hydrocortisone acetate | 20000978005 | 28 |
| Caelo | Hydrocortisone acetate | 20000978006 | 31 |
| Caelo | Hydrocortisone acetate | 20000978007 | 23 |
| Caelo | Hydrocortisone acetate | 20000978008 | 22 |
| Caelo | Hydrocortisone acetate | 20000978009 | 10 |
| Caelo | Hydrocortisone acetate | 20000978010 | 9 |
| Caelo | Hydrocortisone acetate | 2000097808 | 1 |
| Caelo | Hydrocortisone acetate | 200009978005 | 1 |
| Caelo | Hydrocortisone acetate | 20001708003 | 1 |
| Caelo | Hydrocortisone acetate | 200041117006 | 1 |
| Caelo | Hydrocortisone acetate | 200041147001 | 1 |
| Caelo | Hydrocortisone acetate | 20004117001 | 67 |
| Caelo | Hydrocortisone acetate | 20004117004 | 17 |
| Caelo | Hydrocortisone acetate | 20004117005 | 4 |
| Caelo | Hydrocortisone acetate | 20004117006 | 18 |
| Caelo | Hydrocortisone acetate | 20004117007 | 3 |
| Caelo | Hydrocortisone acetate | 2000411701 | 1 |
| Caelo | Hydrocortisone acetate | 200041176 | 1 |
| Caelo | Hydrocortisone acetate | 2000417001 | 2 |
| Caelo | Hydrocortisone acetate | 20004278002 | 26 |
| Caelo | Hydrocortisone acetate | 20004278003 | 30 |
| Caelo | Hydrocortisone acetate | 20004278004 | 54 |
| Caelo | Hydrocortisone acetate | 20004278005 | 16 |
| Caelo | Hydrocortisone acetate | 20004278006 | 8 |
| Caelo | Hydrocortisone acetate | 20004278008 | 13 |
| Caelo | Hydrocortisone acetate | 20004278009 | 9 |
| Caelo | Hydrocortisone acetate | 2000427806 | 1 |
| Caelo | Hydrocortisone acetate | 2000977002 | 1 |
| Caelo | Hydrocortisone acetate | 2000978008 | 1 |
| Caelo | Hydrocortisone acetate | 2004029-01 | 2 |
| Caelo | Hydrocortisone acetate | 2004117001 | 2 |
| Caelo | Hydrocortisone acetate | 2004117006 | 1 |
| Caelo | Hydrocortisone acetate | 2004117007 | 2 |
| Caelo | Hydrocortisone acetate | 2004278005 | 1 |
| Caelo | Hydrocortisone acetate | 2004278008 | 1 |
| Caelo | Hydrocortisone acetate | 200660707 | 1 |
| Caelo | Hydrocortisone acetate | 20160727Ma2 | 1 |
| Caelo | Hydrocortisone acetate | 2021803 | 1 |
| Caelo | Hydrocortisone acetate | 2061401 | 1 |
| Caelo | Hydrocortisone acetate | 2100215013 | 1 |
| Caelo | Hydrocortisone acetate | 21002415 | 1 |
| Caelo | Hydrocortisone acetate | 210024150002 | 1 |
| Caelo | Hydrocortisone acetate | 21002415001 | 38 |
| Caelo | Hydrocortisone acetate | 21002415002 | 26 |
| Caelo | Hydrocortisone acetate | 21002415004 | 33 |
| Caelo | Hydrocortisone acetate | 21002415005 | 8 |
| Caelo | Hydrocortisone acetate | 21002415006 | 25 |
| Caelo | Hydrocortisone acetate | 21002415007 | 1 |
| Caelo | Hydrocortisone acetate | 21002415008 | 7 |
| Caelo | Hydrocortisone acetate | 21002415009 | 19 |
| Caelo | Hydrocortisone acetate | 21002415010 | 23 |
| Caelo | Hydrocortisone acetate | 21002415011 | 41 |
| Caelo | Hydrocortisone acetate | 21002415012 | 16 |
| Caelo | Hydrocortisone acetate | 21002415014 | 26 |
| Caelo | Hydrocortisone acetate | 21002415015 | 4 |
| Caelo | Hydrocortisone acetate | 2100245009 | 1 |
| Caelo | Hydrocortisone acetate | 2100245011 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydrocortisone acetate | 21003093011 | 1 |
| Caelo | Hydrocortisone acetate | 2100355 | 1 |
| Caelo | Hydrocortisone acetate | 210035530004 | 1 |
| Caelo | Hydrocortisone acetate | 21003553002 | 1 |
| Caelo | Hydrocortisone acetate | 21003553003 | 5 |
| Caelo | Hydrocortisone acetate | 21003553004 | 17 |
| Caelo | Hydrocortisone acetate | 21003553005 | 17 |
| Caelo | Hydrocortisone acetate | 2100355300573/22P | 1 |
| Caelo | Hydrocortisone acetate | 21003553006 | 14 |
| Caelo | Hydrocortisone acetate | 21003553007 | 16 |
| Caelo | Hydrocortisone acetate | 21003553009 | 6 |
| Caelo | Hydrocortisone acetate | 21003553010 | 8 |
| Caelo | Hydrocortisone acetate | 2100415004 | 1 |
| Caelo | Hydrocortisone acetate | 2100415009 | 1 |
| Caelo | Hydrocortisone acetate | 2200253008 | 1 |
| Caelo | Hydrocortisone acetate | 22002539 | 1 |
| Caelo | Hydrocortisone acetate | 22002539002 | 13 |
| Caelo | Hydrocortisone acetate | 22002539003 | 11 |
| Caelo | Hydrocortisone acetate | 22002539004 | 3 |
| Caelo | Hydrocortisone acetate | 22002539005 | 3 |
| Caelo | Hydrocortisone acetate | 22002539008 | 8 |
| Caelo | Hydrocortisone acetate | 22002539009 | 1 |
| Caelo | Hydrocortisone acetate | 22002539010 | 4 |
| Caelo | Hydrocortisone acetate | 22002539013 | 2 |
| Caelo | Hydrocortisone acetate | 22002539014 | 2 |
| Caelo | Hydrocortisone acetate | 22002539015 | 6 |
| Caelo | Hydrocortisone acetate | 22002539018 | 1 |
| Caelo | Hydrocortisone acetate | 22002539019 | 2 |
| Caelo | Hydrocortisone acetate | 2202539003 | 1 |
| Caelo | Hydrocortisone acetate | 2202539004 | 1 |
| Caelo | Hydrocortisone acetate | 2202539008 | 1 |
| Caelo | Hydrocortisone acetate | 2205004-01 | 2 |
| Caelo | Hydrocortisone acetate | 23001089004 | 2 |
| Caelo | Hydrocortisone acetate | 23001089005 | 3 |
| Caelo | Hydrocortisone acetate | 23003142001 | 2 |
| Caelo | Hydrocortisone acetate | 23003142003 | 1 |
| Caelo | Hydrocortisone acetate | 25(1805010-01) | 1 |
| Caelo | Hydrocortisone acetate | 2510120I | 1 |
| Caelo | Hydrocortisone acetate | 2612M01718 | 1 |
| Caelo | Hydrocortisone acetate | 27091307 | 1 |
| Caelo | Hydrocortisone acetate | 27091403 | 1 |
| Caelo | Hydrocortisone acetate | 2734 | 1 |
| Caelo | Hydrocortisone acetate | 28071508 | 1 |
| Caelo | Hydrocortisone acetate | 301115 | 1 |
| Caelo | Hydrocortisone acetate | 3110491 | 1 |
| Caelo | Hydrocortisone acetate | 3110516 | 1 |
| Caelo | Hydrocortisone acetate | 3434 | 1 |
| Caelo | Hydrocortisone acetate | 418M-01718 | 1 |
| Caelo | Hydrocortisone acetate | 6071801 | 1 |
| Caelo | Hydrocortisone acetate | 6101707 | 1 |
| Caelo | Hydrocortisone acetate | 7051303 | 1 |
| Caelo | Hydrocortisone acetate | 7082003 | 1 |
| Caelo | Hydrocortisone acetate | 7086205 | 1 |
| Caelo | Hydrocortisone acetate | 84280411 | 1 |
| Caelo | Hydrocortisone acetate | 978004 | 1 |
| Caelo | Hydrocortisone acetate | Caelo | 2 |
| Caelo | Hydrocortisone acetate | Caelo/20004117005 | 1 |
| Caelo | Hydrocortisone acetate | Hydc01122022 | 1 |
| Caelo | Hydrocortisone acetate | NCEHAC161003 | 1 |
| Caelo | Hydrocortisone acetate | test | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caeol/Noweda | Hydrocortisone acetate | 19138307 | 1 |
| Caeol/Phoenix | Hydrocortisone acetate | 16004402 | 1 |
| Caeol/Phönix | Hydrocortisone acetate | 17219708 | 1 |
| Caeolo/Noweda | Hydrocortisone acetate | 13155303 | 1 |
| Caeolo/Spangro | Hydrocortisone acetate | 20000978004 | 1 |
| Caesar & Lorenz GmbH | Hydrocortisone acetate | 18278016 | 1 |
| Caesar & Lorenz GmbH | Hydrocortisone acetate | 19138305 | 1 |
| Caesar & Lorenz GmbH | Hydrocortisone acetate | 20000978007 | 1 |
| Caesar & Loretz /Alliance | Hydrocortisone acetate | 21002415010 | 2 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 14144806 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 19138308 | 4 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415008 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004117005 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415006 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415008 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415013 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 18278014 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004278009 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 2100355004 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21003553006 | 2 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 18278020 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004278004 | 2 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004278003 | 2 |
| Caesar & Loretz GmbH, Now | Hydrocortisone acetate | 22002539002 | 1 |
| Caesar & Loretz GmbH/ AEP | Hydrocortisone acetate | 19138305 | 1 |
| Caesar & Loretz GmbH/ AHD | Hydrocortisone acetate | 20000978010 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415011 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004117006 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004278004 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21003553006 | 2 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21003553009 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415011 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21003553004 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 18278004 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004278006 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415011 | 3 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004117001 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415004 | 1 |
| Caesar & Loretz GmbH/AEP | Hydrocortisone acetate | 18278014 | 1 |
| Caesar & Loretz GmbH/AEP | Hydrocortisone acetate | 21002415001 | 1 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone acetate | 20004278003 | 1 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone acetate | 21002415001 | 1 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone acetate | 21002415011 | 2 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone acetate | 21002415014 | 2 |
| Caesar & Loretz GmbH/AHD | Hydrocortisone acetate | 22002539003 | 1 |
| Caesar & Loretz GmbH/all | Hydrocortisone acetate | 20000978005 | 1 |
| Caesar & Loretz GmbH/Alli | Hydrocortisone acetate | 20000978004 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 191383001 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 19138307 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 21002415006 | 2 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 19138304 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004117001 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20000978007 | 1 |
| Caesar & Loretz GmbH… | Hydrocortisone acetate | 20004278004 | 1 |
| Caesar & Loretz GmbH/G | Hydrocortisone acetate | 20000978009 | 1 |
| Caesar & Loretz GmbH/G | Hydrocortisone acetate | 21002415001 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 20000978006 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 20004117001 | 1 |
| Caesar & Loretz GmbH/GEHE | Hydrocortisone acetate | 20004117001 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 20004117006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 20004117007 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 20004278004 | 3 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 21002415001 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 21002415014 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 21003553005 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydrocortisone acetate | 23001089005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000977002 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20004117004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20004278002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415014 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21003553006 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 22002539004 | 1 |
| Caesar & Loretz GmbH/GEJE | Hydrocortisone acetate | 19138302 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000978005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415002 | 3 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 17G03-B06-341843 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 18278014 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 18278021 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000977002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000978006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415011 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415015 | 2 |
| Caesar & Loretz GmbH/K | Hydrocortisone acetate | 18278015 | 1 |
| Caesar & Loretz GmbH/K | Hydrocortisone acetate | 19138301 | 1 |
| Caesar & Loretz GmbH/K | Hydrocortisone acetate | 20004278003 | 1 |
| Caesar & Loretz GmbH/Kehr | Hydrocortisone acetate | 18278016 | 1 |
| Caesar & Loretz GmbH/Kehr | Hydrocortisone acetate | 191383001 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 18278016 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000978009 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20004278003 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415001 | 1 |
| Caesar & Loretz GmbH/Now | Hydrocortisone acetate | 20004278006 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 18278017 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415001 | 3 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415014 | 3 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21003553009 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 22002539005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 191383001 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20004117005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20004278004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 18142806 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 18278005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 191383004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 19138301 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 19138304 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000978006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20004278004 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415010 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415014 | 4 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21003553006 | 2 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 22002539004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 22002539005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 22002539013 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 19138305 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 19138307 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000978005 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000978006 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20000978007 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 20004117001 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415002 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415008 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21002415010 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21003553004 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 21003553009 | 1 |
| Caesar & Loretz GmbH... | Hydrocortisone acetate | 22002539003 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 12182405 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 15067004 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 16004402 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 16004408 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 16095405 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 16095406 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 16095407 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 17219706 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 17219708 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18142804 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18142811 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18142815 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 182778014 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278003 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278004 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278005 | 11 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278006 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278007 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278008 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278010 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278014 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278015 | 11 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278016 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278018 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278019 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278020 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 18278021 | 7 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 191383001 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 191383004 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19138301 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19138302 | 4 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19138303 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19138304 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19138305 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19138307 | 11 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19138308 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 19A24 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000977002 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000978004 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000978005 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000978006 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000978007 | 12 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000978008 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000978009 | 4 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20000978010 | 4 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004117001 | 27 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004117004 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004117005 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004117006 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004117007 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004278002 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004278003 | 15 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004278004 | 15 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004278005 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004278006 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004278008 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 20004278009 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415001 | 17 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415002 | 11 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415004 | 5 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415005 | 7 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415006 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415008 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415009 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415010 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415011 | 21 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415012 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21002415014 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553002 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553003 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553004 | 4 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553005 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553006 | 9 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553007 | 8 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553009 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 21003553010 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 22002539002 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 22002539003 | 6 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 22002539004 | 3 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 22002539008 | 10 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 22002539018 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 22002539019 | 2 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 23001089005 | 1 |
| Caesar & Loretz GmbH | Hydrocortisone acetate | 23001089006 | 1 |
| Caesar & Loretz GmbHAnzag | Hydrocortisone acetate | 18278019 | 1 |
| Caesar & Loretz Hild… | Hydrocortisone acetate | 20000978004 | 1 |
| Caesar & Loretz Hilden | Hydrocortisone acetate | 18278005 | 1 |
| Caesar & Loretz Hilden | Hydrocortisone acetate | 19138307 | 1 |
| Caesar & Loretz Hilden | Hydrocortisone acetate | 20004278005 | 1 |
| Caesar & Loretz/AHD | Hydrocortisone acetate | 17219706 | 1 |
| Caesar & Loretz/Geil… | Hydrocortisone acetate | 20000978008 | 1 |
| Caesar & Loretz/Geil… | Hydrocortisone acetate | 20004278004 | 2 |
| Caesar & Loretz | Hydrocortisone acetate | 16095404 | 1 |
| Caesar & Loretz | Hydrocortisone acetate | 17086203 | 1 |
| Caesar & Loretz | Hydrocortisone acetate | 18142815 | 2 |
| Caesar & Loretz | Hydrocortisone acetate | 18278010 | 3 |
| Caesar / Gehe | Hydrocortisone acetate | 15067003 | 1 |
| Caesar Loretz | Hydrocortisone acetate | 18142809 | 1 |
| Caesar u Loretz | Hydrocortisone acetate | 15067003 | 1 |
| Caesar und Loretz GmbH | Hydrocortisone acetate | 18278020 | 1 |
| Caesar&Loretz GmbH,P… | Hydrocortisone acetate | 16238708 | 1 |
| Caesar&Loretz GmbH/AHD | Hydrocortisone acetate | 15356903 | 1 |
| Caesar&Loretz GmbH | Hydrocortisone acetate | 21002415002 | 1 |
| Caesar&loretz,Phoenix | Hydrocortisone acetate | 12182405 | 1 |
| Caesar&loretz,Phoenix | Hydrocortisone acetate | 12330103 | 1 |
| caesar&loretz,PHönix… | Hydrocortisone acetate | 15067003 | 1 |
| Caesar&LoretzGmbH, P… | Hydrocortisone acetate | 18278006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar/Gehe | Hydrocortisone acetate | 20000978005 | 1 |
| caesar | Hydrocortisone acetate | 14301402 | 1 |
| Carli/ Phoenix | Hydrocortisone acetate | 20004117004 | 1 |
| Cealo / Noweda | Hydrocortisone acetate | 13291707 | 1 |
| Cealo/ Anzag | Hydrocortisone acetate | 16238712 | 1 |
| Cealo/ Anzag | Hydrocortisone acetate | 17219702 | 1 |
| Cealo/ Noweda | Hydrocortisone acetate | 20000978008 | 1 |
| Cealo/Sanacorp | Hydrocortisone acetate | 20000978009 | 1 |
| Cealo | Hydrocortisone acetate | 1706021-01 | 1 |
| Chinosol | Hydrocortisone acetate | 2004029-01 | 7 |
| Eplus | Hydrocortisone acetate | 17219708 | 1 |
| EuRho Noweda | Hydrocortisone acetate | 1907011-02 | 1 |
| EuRho/ Anzag | Hydrocortisone acetate | 29(1907011-01) | 1 |
| Eurho/ Noweda | Hydrocortisone acetate | 1703021-01 | 1 |
| EuRho/ NOWEDA | Hydrocortisone acetate | 1805010-01 | 2 |
| EuRho/ VDL | Hydrocortisone acetate | 1706021-01 | 1 |
| EuRho/AHD | Hydrocortisone acetate | 1706021-01 | 1 |
| EuRho/Alliance Healt | Hydrocortisone acetate | 1907011-01 | 1 |
| EuRho/Kehr | Hydrocortisone acetate | 1907011-02 | 1 |
| Eurho/Noweda | Hydrocortisone acetate | 200402902 | 1 |
| EuRho/Phoenix | Hydrocortisone acetate | 1209003-01 | 1 |
| EuRho/Phönix | Hydrocortisone acetate | 2004029-01 | 1 |
| EuRho | Hydrocortisone acetate | 1107004-03 | 1 |
| Eurho | Hydrocortisone acetate | 1706021-01 | 1 |
| EuRho | Hydrocortisone acetate | 1706021-01 | 1 |
| EuRho | Hydrocortisone acetate | 17086212 | 1 |
| EuRho | Hydrocortisone acetate | 1907011-01 | 1 |
| EuRho | Hydrocortisone acetate | 2004029-01 | 3 |
| Euro OT/Anzag | Hydrocortisone acetate | 1706021-01 | 2 |
| Euro OTC | Hydrocortisone acetate | | 1 |
| Euro OTC | Hydrocortisone acetate | 1107004-03 | 2 |
| Euro OTC | Hydrocortisone acetate | 1112031-01 | 11 |
| Euro OTC | Hydrocortisone acetate | 1112031-02 | 3 |
| Euro OTC | Hydrocortisone acetate | 120503401 | 3 |
| Euro OTC | Hydrocortisone acetate | 1205034-01 | 26 |
| Euro OTC | Hydrocortisone acetate | 12090003-01 | 3 |
| Euro OTC | Hydrocortisone acetate | 120900301 | 2 |
| Euro OTC | Hydrocortisone acetate | 1209003-01 | 23 |
| Euro OTC | Hydrocortisone acetate | 1404017-01 | 13 |
| Euro OTC | Hydrocortisone acetate | 1404017-02 | 6 |
| Euro OTC | Hydrocortisone acetate | 1404017-03 | 1 |
| Euro OTC | Hydrocortisone acetate | 140900501 | 1 |
| Euro OTC | Hydrocortisone acetate | 1409005-01 | 17 |
| Euro OTC | Hydrocortisone acetate | 140900502 | 1 |
| Euro OTC | Hydrocortisone acetate | 1409005-02 | 4 |
| Euro OTC | Hydrocortisone acetate | 14301406 | 1 |
| Euro OTC | Hydrocortisone acetate | 1500829-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 150103501 | 3 |
| Euro OTC | Hydrocortisone acetate | 1501035-01 | 14 |
| Euro OTC | Hydrocortisone acetate | 1502000801 | 1 |
| Euro OTC | Hydrocortisone acetate | 1505008 | 1 |
| Euro OTC | Hydrocortisone acetate | 150500801 | 3 |
| Euro OTC | Hydrocortisone acetate | 1505008-01 | 49 |
| Euro OTC | Hydrocortisone acetate | 1508023-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 1508029 | 2 |
| Euro OTC | Hydrocortisone acetate | 150802901 | 1 |
| Euro OTC | Hydrocortisone acetate | 1508029-01 | 33 |
| Euro OTC | Hydrocortisone acetate | 1508029-02 | 4 |
| Euro OTC | Hydrocortisone acetate | 1508029-03 | 1 |
| Euro OTC | Hydrocortisone acetate | 15356903 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Hydrocortisone acetate | 16004406 | 2 |
| Euro OTC | Hydrocortisone acetate | 160405201 | 5 |
| Euro OTC | Hydrocortisone acetate | 1604052-01 | 83 |
| Euro OTC | Hydrocortisone acetate | 16238707 | 1 |
| Euro OTC | Hydrocortisone acetate | 16238708 | 3 |
| Euro OTC | Hydrocortisone acetate | 170602-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 1706021 | 1 |
| Euro OTC | Hydrocortisone acetate | 1706021-0 | 1 |
| Euro OTC | Hydrocortisone acetate | 170602101 | 1 |
| Euro OTC | Hydrocortisone acetate | 1706021-01 | 86 |
| Euro OTC | Hydrocortisone acetate | 17066021-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 170830HA/1706021-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 17086202 | 1 |
| Euro OTC | Hydrocortisone acetate | 17086203 | 1 |
| Euro OTC | Hydrocortisone acetate | 17086204 | 1 |
| Euro OTC | Hydrocortisone acetate | 17219705 | 1 |
| Euro OTC | Hydrocortisone acetate | 17219709 | 1 |
| Euro OTC | Hydrocortisone acetate | 180501001 | 8 |
| Euro OTC | Hydrocortisone acetate | 1805010-01 | 131 |
| Euro OTC | Hydrocortisone acetate | 18050101 | 1 |
| Euro OTC | Hydrocortisone acetate | 1805010-1 | 1 |
| Euro OTC | Hydrocortisone acetate | 18050101-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 180510-01 | 2 |
| Euro OTC | Hydrocortisone acetate | 18142805 | 1 |
| Euro OTC | Hydrocortisone acetate | 18142808 | 1 |
| Euro OTC | Hydrocortisone acetate | 18142811 | 3 |
| Euro OTC | Hydrocortisone acetate | 18278014 | 1 |
| Euro OTC | Hydrocortisone acetate | 1907001-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 1907011 | 1 |
| Euro OTC | Hydrocortisone acetate | 190701101 | 2 |
| Euro OTC | Hydrocortisone acetate | 1907011-01 | 30 |
| Euro OTC | Hydrocortisone acetate | 190701102 | 2 |
| Euro OTC | Hydrocortisone acetate | 1907011-02 | 33 |
| Euro OTC | Hydrocortisone acetate | 1907011-03 | 9 |
| Euro OTC | Hydrocortisone acetate | 19070111-03 | 1 |
| Euro OTC | Hydrocortisone acetate | 1907011-42 | 1 |
| Euro OTC | Hydrocortisone acetate | 1907077-02 | 1 |
| Euro OTC | Hydrocortisone acetate | 19138307 | 1 |
| Euro OTC | Hydrocortisone acetate | 2004029 | 4 |
| Euro OTC | Hydrocortisone acetate | 200402901 | 1 |
| Euro OTC | Hydrocortisone acetate | 2004029-01 | 64 |
| Euro OTC | Hydrocortisone acetate | 2004029-02 | 14 |
| Euro OTC | Hydrocortisone acetate | 22050014-01 | 2 |
| Euro OTC | Hydrocortisone acetate | 2205004_01 | 1 |
| Euro OTC | Hydrocortisone acetate | 2205004-01 | 16 |
| Euro OTC | Hydrocortisone acetate | 26(1805010-01) | 1 |
| Euro OTC | Hydrocortisone acetate | 2604052-01 | 1 |
| Euro OTC | Hydrocortisone acetate | 27(1805010-01) | 1 |
| Euro OTC | Hydrocortisone acetate | 28(1805010-01) | 1 |
| Euro OTC | Hydrocortisone acetate | 30(1805010-01) | 1 |
| Euro OTC | Hydrocortisone acetate | 31(1907011-01) | 1 |
| Euro OTC | Hydrocortisone acetate | 508029-01 | 2 |
| Euro OTC | Hydrocortisone acetate | 911I-01718 | 1 |
| Euro OTC | Hydrocortisone acetate | EuroOTC | 2 |
| Euro OTC | Hydrocortisone acetate | HCAZ11004K | 1 |
| Euro OTC | Hydrocortisone acetate | K061828180402 | 1 |
| Euro OTC | Hydrocortisone acetate | L68934 | 1 |
| Euro/ Sanacorp | Hydrocortisone acetate | 1409005-01 | 1 |
| Euro/Alliance Healthcare | Hydrocortisone acetate | 1508029-01 | 1 |
| Euro/Gehe | Hydrocortisone acetate | 1404017-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro/L10 | Hydrocortisone acetate | 190701101 | 1 |
| Euro/L10 | Hydrocortisone acetate | 1907011-01 | 1 |
| Euro/Phönix | Hydrocortisone acetate | 1805010 | 1 |
| Euro/sanacorp | Hydrocortisone acetate | 1604052-01 | 1 |
| Euro/Sanacorp | Hydrocortisone acetate | 1706021-01 | 4 |
| Euro/Sanacorp | Hydrocortisone acetate | 1805010-01 | 1 |
| Euroo/Noweda | Hydrocortisone acetate | 2004029-01 | 1 |
| Europh-Gehe | Hydrocortisone acetate | 1508029-01 | 1 |
| Fa.Anzag | Hydrocortisone acetate | 17219704 | 1 |
| Fa.Anzag | Hydrocortisone acetate | 18142807 | 1 |
| Fa.Anzag | Hydrocortisone acetate | 18142809 | 1 |
| Fa.Anzag | Hydrocortisone acetate | 18278006 | 2 |
| Fa.Anzag | Hydrocortisone acetate | 18278015 | 1 |
| Fa.Phönix | Hydrocortisone acetate | 18278016 | 1 |
| Fa.Phönix | Hydrocortisone acetate | 19138307 | 1 |
| Fa.Phönix | Hydrocortisone acetate | 20000978004 | 1 |
| Fa.Phönix | Hydrocortisone acetate | 21003553010 | 2 |
| Fagro/Gehe | Hydrocortisone acetate | 15A07-B03_306545 | 1 |
| Fagro/Noweda | Hydrocortisone acetate | 18142804 | 1 |
| Fagron | Hydrocortisone acetate | | 1 |
| Fagron | Hydrocortisone acetate | 11/01-N05 | 1 |
| Fagron | Hydrocortisone acetate | 1112031 | 1 |
| Fagron | Hydrocortisone acetate | 12330107 | 1 |
| Fagron | Hydrocortisone acetate | 12330108 | 2 |
| Fagron | Hydrocortisone acetate | 12K15-N04 | 6 |
| Fagron | Hydrocortisone acetate | 13/31-B07-290061 | 1 |
| Fagron | Hydrocortisone acetate | 13155311 | 1 |
| Fagron | Hydrocortisone acetate | 13A03-N04 | 4 |
| Fagron | Hydrocortisone acetate | 13B25-N04 | 2 |
| Fagron | Hydrocortisone acetate | 13E31-N02 | 3 |
| Fagron | Hydrocortisone acetate | 13E31-No2 | 1 |
| Fagron | Hydrocortisone acetate | 13F25-B05-300290 | 2 |
| Fagron | Hydrocortisone acetate | 13G09-N08 | 4 |
| Fagron | Hydrocortisone acetate | 13J31-B07 | 3 |
| Fagron | Hydrocortisone acetate | 13J31B07290061 | 1 |
| Fagron | Hydrocortisone acetate | 13J31-B07-290061 | 2 |
| Fagron | Hydrocortisone acetate | 13J31-B07-290062 | 2 |
| Fagron | Hydrocortisone acetate | 14043903 | 1 |
| Fagron | Hydrocortisone acetate | 14043905 | 1 |
| Fagron | Hydrocortisone acetate | 14043906 | 1 |
| Fagron | Hydrocortisone acetate | 14144804 | 1 |
| Fagron | Hydrocortisone acetate | 14301402 | 1 |
| Fagron | Hydrocortisone acetate | 14301408 | 1 |
| Fagron | Hydrocortisone acetate | 14A13-B04 | 1 |
| Fagron | Hydrocortisone acetate | 14A13-B04-294158 | 2 |
| Fagron | Hydrocortisone acetate | 14I16-B01-300292 | 2 |
| Fagron | Hydrocortisone acetate | 15067006 | 1 |
| Fagron | Hydrocortisone acetate | 157000-0002 | 1 |
| Fagron | Hydrocortisone acetate | 15A03-B09-307133 | 1 |
| Fagron | Hydrocortisone acetate | 15A03-B09-307300 | 1 |
| Fagron | Hydrocortisone acetate | 15A07-B03-306545 | 1 |
| Fagron | Hydrocortisone acetate | 15A30-B09 | 1 |
| Fagron | Hydrocortisone acetate | 15A30-B09-307133 | 2 |
| Fagron | Hydrocortisone acetate | 15H24-B01 | 1 |
| Fagron | Hydrocortisone acetate | 15h24-b01-314236 | 1 |
| Fagron | Hydrocortisone acetate | 15H24-B01-314236 | 1 |
| Fagron | Hydrocortisone acetate | 15H24-B01-316480 | 1 |
| Fagron | Hydrocortisone acetate | 15I28-B12-316481 | 1 |
| Fagron | Hydrocortisone acetate | 15J28-B12 | 1 |
| Fagron | Hydrocortisone acetate | 15J28-B12-316481 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hydrocortisone acetate | 15J28-b12-317771 | 1 |
| Fagron | Hydrocortisone acetate | 15J28-B12-317771 | 1 |
| Fagron | Hydrocortisone acetate | 16004402 | 1 |
| Fagron | Hydrocortisone acetate | 160405201 | 1 |
| Fagron | Hydrocortisone acetate | 1604052-01 | 1 |
| Fagron | Hydrocortisone acetate | 16238707 | 1 |
| Fagron | Hydrocortisone acetate | 16B03-B04 | 2 |
| Fagron | Hydrocortisone acetate | 16B03-B04-319407 | 1 |
| Fagron | Hydrocortisone acetate | 16B03-B04-320156 | 1 |
| Fagron | Hydrocortisone acetate | 16C15-B04-321458 | 3 |
| Fagron | Hydrocortisone acetate | 16C15-B04-321459 | 1 |
| Fagron | Hydrocortisone acetate | 16H18-B04 | 2 |
| Fagron | Hydrocortisone acetate | 16H18-B04-325093 | 3 |
| Fagron | Hydrocortisone acetate | 16H18B04327324 | 1 |
| Fagron | Hydrocortisone acetate | 16H18-B04-327324 | 1 |
| Fagron | Hydrocortisone acetate | 16h18-b04-327325 | 1 |
| Fagron | Hydrocortisone acetate | 16H18-B04-327325 | 2 |
| Fagron | Hydrocortisone acetate | 16J28-B05 | 1 |
| Fagron | Hydrocortisone acetate | 16J28-B05-330083 | 1 |
| Fagron | Hydrocortisone acetate | 16J28-B51-333889 | 1 |
| Fagron | Hydrocortisone acetate | 17086211 | 1 |
| Fagron | Hydrocortisone acetate | 17219706 | 1 |
| Fagron | Hydrocortisone acetate | 17219707 | 2 |
| Fagron | Hydrocortisone acetate | 17C10 | 2 |
| Fagron | Hydrocortisone acetate | 17C10-B01-333961 | 1 |
| Fagron | Hydrocortisone acetate | 17C10-B01-333962 | 3 |
| Fagron | Hydrocortisone acetate | 17C10-B01-335774 | 2 |
| Fagron | Hydrocortisone acetate | 17G03 | 1 |
| Fagron | Hydrocortisone acetate | 17G03-B06-338750 | 1 |
| Fagron | Hydrocortisone acetate | 17G03-B06-341304 | 2 |
| Fagron | Hydrocortisone acetate | 17g03-b06-341305 | 1 |
| Fagron | Hydrocortisone acetate | 17G03-B06-341305 | 2 |
| Fagron | Hydrocortisone acetate | 17G03-B06-341843 | 2 |
| Fagron | Hydrocortisone acetate | 17G03-B06-345375 | 3 |
| Fagron | Hydrocortisone acetate | 17GO3-B06-345375 | 1 |
| Fagron | Hydrocortisone acetate | 17L19 | 2 |
| Fagron | Hydrocortisone acetate | 17L19-B04 | 2 |
| Fagron | Hydrocortisone acetate | 17L19B04345374 | 1 |
| Fagron | Hydrocortisone acetate | 17L19-B04-345374 | 1 |
| Fagron | Hydrocortisone acetate | 17L19-B04-348983 | 2 |
| Fagron | Hydrocortisone acetate | 17L19-B04-350448 | 2 |
| Fagron | Hydrocortisone acetate | 18142806 | 1 |
| Fagron | Hydrocortisone acetate | 18278005 | 1 |
| Fagron | Hydrocortisone acetate | 18H07 | 1 |
| Fagron | Hydrocortisone acetate | 18H07-B03 | 3 |
| Fagron | Hydrocortisone acetate | 18H07-B03-352228 | 8 |
| Fagron | Hydrocortisone acetate | 18H07-B03-355044 | 2 |
| Fagron | Hydrocortisone acetate | 18H07-B03-356259 | 4 |
| Fagron | Hydrocortisone acetate | 18H07-B03-357240 | 9 |
| Fagron | Hydrocortisone acetate | 18H07-BO3-357240 | 1 |
| Fagron | Hydrocortisone acetate | 19090001 | 1 |
| Fagron | Hydrocortisone acetate | 19A24B05 | 1 |
| Fagron | Hydrocortisone acetate | 19A24-B05 | 3 |
| Fagron | Hydrocortisone acetate | 19A24-B05-359123 | 1 |
| Fagron | Hydrocortisone acetate | 19A24-B05359124 | 1 |
| Fagron | Hydrocortisone acetate | 19A24-B05-359124 | 7 |
| Fagron | Hydrocortisone acetate | 19A24-B05-361623 | 4 |
| Fagron | Hydrocortisone acetate | 19A24-B05-361624 | 2 |
| Fagron | Hydrocortisone acetate | 19A24-B05-361623 | 1 |
| Fagron | Hydrocortisone acetate | 19J00 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hydrocortisone acetate | 19J10-f04 | 1 |
| Fagron | Hydrocortisone acetate | 19J10-F04 | 2 |
| Fagron | Hydrocortisone acetate | 19J10-F04-36627 | 1 |
| Fagron | Hydrocortisone acetate | 19J10-F04366275 | 1 |
| Fagron | Hydrocortisone acetate | 19J10-F04-366275 | 2 |
| Fagron | Hydrocortisone acetate | 19J10-F04-366276 | 1 |
| Fagron | Hydrocortisone acetate | 19j10-f04-366277 | 1 |
| Fagron | Hydrocortisone acetate | 19J10-F04-366277 | 4 |
| Fagron | Hydrocortisone acetate | 19j10-f04-366278 | 3 |
| Fagron | Hydrocortisone acetate | 19M0-F04-366277 | 1 |
| Fagron | Hydrocortisone acetate | 200508-1 | 1 |
| Fagron | Hydrocortisone acetate | 20804-F07-370096 | 1 |
| Fagron | Hydrocortisone acetate | 20B04-F07 | 1 |
| Fagron | Hydrocortisone acetate | 20B04-F07-370094 | 2 |
| Fagron | Hydrocortisone acetate | 20B04-F07-370095 | 1 |
| Fagron | Hydrocortisone acetate | 20B04-F07-370096 | 1 |
| Fagron | Hydrocortisone acetate | 20F19-F01-371737 | 1 |
| Fagron | Hydrocortisone acetate | 20F19F01371738 | 1 |
| Fagron | Hydrocortisone acetate | 20F19-F01-371738 | 1 |
| Fagron | Hydrocortisone acetate | 20F19-F01-371740 | 3 |
| Fagron | Hydrocortisone acetate | 20J13-F10 | 2 |
| Fagron | Hydrocortisone acetate | 20J13-F10-375214 | 2 |
| Fagron | Hydrocortisone acetate | 20J13-F10-375216 | 1 |
| Fagron | Hydrocortisone acetate | 20J13-F10-375217 | 1 |
| Fagron | Hydrocortisone acetate | 21d22-f01-378700 | 1 |
| Fagron | Hydrocortisone acetate | 22A17-B07-216283 | 2 |
| Fagron | Hydrocortisone acetate | 22A17-B07-216284 | 1 |
| Fagron | Hydrocortisone acetate | 22A17-B07-216285 | 3 |
| Fagron | Hydrocortisone acetate | 22H11-B01-220314 | 2 |
| Fagron | Hydrocortisone acetate | 2OF19-F01-371737 | 1 |
| Fagron | Hydrocortisone acetate | 2OF19-F01-371738 | 1 |
| Fagron | Hydrocortisone acetate | 32(20F19-F01-371738) | 1 |
| Fagron | Hydrocortisone acetate | 33(20F19-F01-371738) | 1 |
| Fagron | Hydrocortisone acetate | 345873/P-19091821 | 1 |
| Fagron | Hydrocortisone acetate | 3613A-01718 | 1 |
| Fagron | Hydrocortisone acetate | 7C10-B01-333961 | 1 |
| Fagron | Hydrocortisone acetate | 8563642 | 1 |
| Fagron | Hydrocortisone acetate | B05-3591203 | 1 |
| Fagron | Hydrocortisone acetate | F01-3717308 | 2 |
| Fagron | Hydrocortisone acetate | F04-3662707 | 1 |
| Fagron | Hydrocortisone acetate | HC0024 | 1 |
| Fagron | Hydrocortisone acetate | M39171 | 1 |
| Fagron | Hydrocortisone acetate | NCEHAC130201 | 1 |
| Fagron | Hydrocortisone acetate | NCEHAC151101 | 1 |
| Fagron | Hydrocortisone acetate | NCEHAC170201 | 2 |
| Fagron | Hydrocortisone acetate | NCEHAC170507 | 4 |
| Fagron | Hydrocortisone acetate | NCEHAC181105 | 2 |
| Fagron | Hydrocortisone acetate | NCEHAC1900901 | 1 |
| Fargon | Hydrocortisone acetate | 17L19-B04-345373 | 1 |
| Fargon | Hydrocortisone acetate | 18H07-B03-356259 | 1 |
| Fargon | Hydrocortisone acetate | 19A24-B05-361622 | 1 |
| Fargon | Hydrocortisone acetate | F01-3717308 | 1 |
| Fargon | Hydrocortisone acetate | F04-3662705 | 2 |
| Faron/Noweda | Hydrocortisone acetate | 19A24_B05_361622 | 1 |
| Fiebig | Hydrocortisone acetate | 1209003-01 | 1 |
| Fiebig | Hydrocortisone acetate | 1605410 | 1 |
| Fiebig | Hydrocortisone acetate | 16095404 | 2 |
| Fiebig | Hydrocortisone acetate | 17219702 | 2 |
| Fiebig | Hydrocortisone acetate | 17219703 | 1 |
| Fiebig | Hydrocortisone acetate | 17219708 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fiebig | Hydrocortisone acetate | 18142803 | 1 |
| Fiebig | Hydrocortisone acetate | 18278006 | 1 |
| Fiebig | Hydrocortisone acetate | 18278010 | 1 |
| Fiebig | Hydrocortisone acetate | 23003142003 | 1 |
| Finteler Apotheke | Hydrocortisone acetate | 1604052-01 | 2 |
| Frago/Noweda | Hydrocortisone acetate | 16095410 | 2 |
| Gatt-Koller | Hydrocortisone acetate | 1734/05154415 | 1 |
| Gatt-Koller | Hydrocortisone acetate | 1802876 | 1 |
| GEHE 03.07.2014 | Hydrocortisone acetate | 14043903 | 1 |
| Gehe amax | Hydrocortisone acetate | 16238712 | 1 |
| Gehe amax | Hydrocortisone acetate | 18142807 | 2 |
| Gehe amax | Hydrocortisone acetate | 18278008 | 2 |
| Gehe amax | Hydrocortisone acetate | 18278019 | 1 |
| Gehe Rostock | Hydrocortisone acetate | 20000978010 | 1 |
| Gehe | Hydrocortisone acetate | 1205034-01 | 1 |
| Gehe | Hydrocortisone acetate | 14043905 | 1 |
| Gehe | Hydrocortisone acetate | 14144805 | 1 |
| Gehe | Hydrocortisone acetate | 1501035-01 | 1 |
| Gehe | Hydrocortisone acetate | 15356902 | 1 |
| Gehe | Hydrocortisone acetate | 16004408 | 2 |
| GEHE | Hydrocortisone acetate | 1604052-01 | 1 |
| Gehe | Hydrocortisone acetate | 16095407 | 1 |
| Gehe | Hydrocortisone acetate | 16238710 | 1 |
| GEHE | Hydrocortisone acetate | 16238712 | 1 |
| GEHE | Hydrocortisone acetate | 16238713 | 1 |
| GEHE | Hydrocortisone acetate | 1706021-01 | 2 |
| Gehe | Hydrocortisone acetate | 17086205 | 1 |
| GEHE | Hydrocortisone acetate | 17219703 | 1 |
| Gehe | Hydrocortisone acetate | 17219704 | 1 |
| Gehe | Hydrocortisone acetate | 17219705 | 3 |
| gehe | Hydrocortisone acetate | 17219707 | 1 |
| Gehe | Hydrocortisone acetate | 17219707 | 3 |
| Gehe | Hydrocortisone acetate | 1805010-01 | 4 |
| Gehe | Hydrocortisone acetate | 18142804 | 1 |
| Gehe | Hydrocortisone acetate | 18142812 | 2 |
| Gehe | Hydrocortisone acetate | 18278004 | 2 |
| Gehe | Hydrocortisone acetate | 18278010 | 1 |
| gehe | Hydrocortisone acetate | 18278014 | 1 |
| GEHE | Hydrocortisone acetate | 18278020 | 1 |
| Gehe | Hydrocortisone acetate | 190701102 | 1 |
| Gehe | Hydrocortisone acetate | 19138305 | 2 |
| Gehe | Hydrocortisone acetate | 19138307 | 4 |
| Gehe | Hydrocortisone acetate | 200004117001 | 1 |
| Gehe | Hydrocortisone acetate | 20000978006 | 1 |
| Gehe | Hydrocortisone acetate | 20000978009 | 3 |
| Gehe | Hydrocortisone acetate | 21002415001 | 1 |
| Gehe | Hydrocortisone acetate | 21002415013 | 1 |
| Gehe | Hydrocortisone acetate | 22002539004 | 1 |
| Gehe | Hydrocortisone acetate | 22002539008 | 2 |
| Gehe | Hydrocortisone acetate | 22002539015 | 1 |
| GEHE | Hydrocortisone acetate | 22002539015 | 1 |
| Gehe | Hydrocortisone acetate | 2205004-01 | 7 |
| GEHE | Hydrocortisone acetate | 2205004-01 | 1 |
| Gehe | Hydrocortisone acetate | 23001089005 | 2 |
| Gehe | Hydrocortisone acetate | 2300314003 | 1 |
| Gehe | Hydrocortisone acetate | 23003142001 | 3 |
| Gehe | Hydrocortisone acetate | 23003142011 | 1 |
| Gehe | Hydrocortisone acetate | 2306007-01 | 2 |
| Geilenkirchen | Hydrocortisone acetate | 16238710 | 1 |
| Geilenkirchen | Hydrocortisone acetate | 18142815 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Geilenkirchen | Hydrocortisone acetate | 18278016 | 1 |
| Geilenkirchen | Hydrocortisone acetate | 19138307 | 1 |
| Geilenkirchen | Hydrocortisone acetate | 20000978004 | 1 |
| Geilenkirchen | Hydrocortisone acetate | 20004117004 | 1 |
| Hedinger/Gehe | Hydrocortisone acetate | 1112031-02 | 1 |
| Hedinger/Sanacorp | Hydrocortisone acetate | 1706021-01 | 2 |
| Henan Lihua Pharma. ... | Hydrocortisone acetate | 18142806 | 1 |
| Henan Lihua Pharmace... | Hydrocortisone acetate | 20000978008 | 1 |
| Henan Lihua Pharmace... | Hydrocortisone acetate | 2004029-01 | 1 |
| Henan/Noweda | Hydrocortisone acetate | K06M20190611 | 1 |
| Henan/Noweda | Hydrocortisone acetate | KD6M20190612 | 1 |
| Henan/Phoenix | Hydrocortisone acetate | KO6M20190612 | 2 |
| Henen / Gehe | Hydrocortisone acetate | 20000978004 | 1 |
| Hepart | Hydrocortisone acetate | 14144804 | 1 |
| Holdermann | Hydrocortisone acetate | 21002415008 | 1 |
| Holdermann | Hydrocortisone acetate | 2205004-01 | 1 |
| Holdermann | Hydrocortisone acetate | 23001089008 | 1 |
| Ichthyol GmbH/Noweda | Hydrocortisone acetate | 17086205 | 1 |
| Jenne | Hydrocortisone acetate | 21002415002 | 2 |
| Jenne | Hydrocortisone acetate | 21002415006 | 1 |
| Jenne | Hydrocortisone acetate | 23001089005 | 1 |
| jenne | Hydrocortisone acetate | 23003142004 | 2 |
| Jenne | Hydrocortisone acetate | 250120(23003142001) | 1 |
| Kehr | Hydrocortisone acetate | 1706021-01 | 2 |
| Kehr | Hydrocortisone acetate | 17L19-B04-347866 | 1 |
| Kehr | Hydrocortisone acetate | 22002539008 | 1 |
| Kehr | Hydrocortisone acetate | 22002539010 | 4 |
| Kehr | Hydrocortisone acetate | 22002539013 | 2 |
| Kehr | Hydrocortisone acetate | 22002539015 | 1 |
| Kehr | Hydrocortisone acetate | 22H11-B01-224312 | 1 |
| kehr | Hydrocortisone acetate | 23001089005 | 1 |
| Kehr | Hydrocortisone acetate | 23001089005 | 2 |
| Kehr | Hydrocortisone acetate | 2303142004 | 1 |
| Kehr | Hydrocortisone acetate | 2306007-01 | 11 |
| Klenk | Hydrocortisone acetate | 1/06021-01 | 1 |
| Klenk | Hydrocortisone acetate | 1112031-01 | 1 |
| Klenk | Hydrocortisone acetate | 14301401 | 1 |
| Klenk | Hydrocortisone acetate | 18142803 | 1 |
| Krieger | Hydrocortisone acetate | 2205004-01 | 1 |
| L12 | Hydrocortisone acetate | 1604052-01 | 3 |
| L12 | Hydrocortisone acetate | 1706021-01 | 5 |
| Lihua/phönix | Hydrocortisone acetate | KO6A20140801M | 1 |
| Midas | Hydrocortisone acetate | 17219707 | 1 |
| Nachprüfung | Hydrocortisone acetate | | 1 |
| Nachprüfung | Hydrocortisone acetate | 2082019-4 | 1 |
| Neweda | Hydrocortisone acetate | 23001089008 | 1 |
| Noveda | Hydrocortisone acetate | 20000978008 | 1 |
| Noweda /Cealo | Hydrocortisone acetate | 20000978004 | 1 |
| Noweda 17.07.2015 | Hydrocortisone acetate | 14301403 | 1 |
| Noweda am 10.10.2017 | Hydrocortisone acetate | 1706021 | 1 |
| Noweda/ Pharmacia & ... | Hydrocortisone acetate | 1205034-01 | 1 |
| Noweda/apotec | Hydrocortisone acetate | 2205004-01 | 1 |
| Noweda/Euro | Hydrocortisone acetate | 1501035-01 | 1 |
| Noweda | Hydrocortisone acetate | 1112031-02 | 1 |
| Noweda | Hydrocortisone acetate | 13155302 | 2 |
| Noweda | Hydrocortisone acetate | 13G09-N08 | 1 |
| Noweda | Hydrocortisone acetate | 16095407 | 1 |
| Noweda | Hydrocortisone acetate | 16095410 | 2 |
| Noweda | Hydrocortisone acetate | 16238710 | 1 |
| Noweda | Hydrocortisone acetate | 17219705 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Hydrocortisone acetate | 17219706 | 1 |
| Noweda | Hydrocortisone acetate | 17219707 | 4 |
| Noweda | Hydrocortisone acetate | 18142804 | 2 |
| Noweda | Hydrocortisone acetate | 18142805 | 2 |
| Noweda | Hydrocortisone acetate | 18142806 | 1 |
| Noweda | Hydrocortisone acetate | 18142807 | 1 |
| Noweda | Hydrocortisone acetate | 18142808 | 1 |
| Noweda | Hydrocortisone acetate | 18278004 | 2 |
| Noweda | Hydrocortisone acetate | 18278010 | 1 |
| Noweda | Hydrocortisone acetate | 18278014 | 2 |
| Noweda | Hydrocortisone acetate | 18278015 | 1 |
| Noweda | Hydrocortisone acetate | 18278019 | 3 |
| Noweda | Hydrocortisone acetate | 18278021 | 2 |
| Noweda | Hydrocortisone acetate | 1907011-01 | 1 |
| Noweda | Hydrocortisone acetate | 19138303 | 1 |
| Noweda | Hydrocortisone acetate | 20000978005 | 1 |
| Noweda | Hydrocortisone acetate | 20000978010 | 1 |
| Noweda | Hydrocortisone acetate | 20004117005 | 2 |
| Noweda | Hydrocortisone acetate | 20004117007 | 1 |
| Noweda | Hydrocortisone acetate | 20004278004 | 1 |
| Noweda | Hydrocortisone acetate | 21002415011 | 1 |
| Noweda | Hydrocortisone acetate | 21002415014 | 1 |
| Noweda | Hydrocortisone acetate | 2200253900 | 1 |
| Noweda | Hydrocortisone acetate | 22002539001 | 1 |
| Noweda | Hydrocortisone acetate | 22002539004 | 2 |
| Noweda | Hydrocortisone acetate | 22002539008 | 2 |
| Noweda | Hydrocortisone acetate | 22002539012 | 2 |
| noweda | Hydrocortisone acetate | 22002539013 | 4 |
| Noweda | Hydrocortisone acetate | 22002539013 | 3 |
| Noweda | Hydrocortisone acetate | 22002539014 | 5 |
| Noweda | Hydrocortisone acetate | 22002539015 | 4 |
| Noweda | Hydrocortisone acetate | 22002539016 | 1 |
| Noweda | Hydrocortisone acetate | 220025391013 | 1 |
| noweda | Hydrocortisone acetate | 2205004 | 1 |
| Noweda | Hydrocortisone acetate | 2205004-01 | 2 |
| Noweda | Hydrocortisone acetate | 23001089003 | 4 |
| Noweda | Hydrocortisone acetate | 23001089004 | 1 |
| Noweda | Hydrocortisone acetate | 23001089005 | 1 |
| Noweda | Hydrocortisone acetate | 23001089008 | 2 |
| Noweda | Hydrocortisone acetate | 23003142001 | 1 |
| Noweda | Hydrocortisone acetate | 23003142003 | 2 |
| Noweda | Hydrocortisone acetate | 2306007-01 | 2 |
| Noweda | Hydrocortisone acetate | caelo | 1 |
| ph euro | Hydrocortisone acetate | 1907011-01 | 1 |
| ph euro | Hydrocortisone acetate | 1907011-02 | 1 |
| Pharmachem GmbH & Co.KG | Hydrocortisone acetate | 1505008-01 | 4 |
| Pharmacia / Gehe | Hydrocortisone acetate | 15356901 | 2 |
| Pharmacia&Upjohn Com... | Hydrocortisone acetate | 1209003-01 | 1 |
| Phoenix 14.01.2015 E... | Hydrocortisone acetate | 14043902 | 1 |
| Phoenix 24.01.2019 | Hydrocortisone acetate | 18278004 | 1 |
| Phoenix Goettin | Hydrocortisone acetate | 1209003-01 | 1 |
| Phoenix | Hydrocortisone acetate | 1209003-01 | 1 |
| Phoenix | Hydrocortisone acetate | 12182402 | 1 |
| Phoenix | Hydrocortisone acetate | 12330107 | 1 |
| Phoenix | Hydrocortisone acetate | 1568/05131813 | 1 |
| Phoenix | Hydrocortisone acetate | 15A30-B09 | 1 |
| Phoenix | Hydrocortisone acetate | 15J28-B12 | 1 |
| Phoenix | Hydrocortisone acetate | 16004403 | 1 |
| Phoenix | Hydrocortisone acetate | 17086205 | 1 |
| Phoenix | Hydrocortisone acetate | 1805010-01 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Hydrocortisone acetate | 18142802 | 1 |
| Phoenix | Hydrocortisone acetate | 18278003 | 2 |
| Phoenix | Hydrocortisone acetate | 18278015 | 1 |
| Phoenix | Hydrocortisone acetate | 18H07-B03-352227 | 1 |
| Phoenix | Hydrocortisone acetate | 1907011-03 | 2 |
| Phoenix | Hydrocortisone acetate | 19138304 | 1 |
| Phoenix | Hydrocortisone acetate | 20000978004 | 1 |
| Phoenix | Hydrocortisone acetate | 20004117001 | 1 |
| Phoenix | Hydrocortisone acetate | 20004278004 | 1 |
| Phoenix | Hydrocortisone acetate | 20004278008 | 1 |
| Phoenix | Hydrocortisone acetate | 200303103 | 1 |
| Phoenix | Hydrocortisone acetate | 2004029-01 | 2 |
| Phoenix | Hydrocortisone acetate | 200421105 | 1 |
| Phoenix | Hydrocortisone acetate | 22002539019 | 1 |
| Phoenix | Hydrocortisone acetate | 23001089004 | 2 |
| Phoenix | Hydrocortisone acetate | 23001089005 | 5 |
| Phoenix | Hydrocortisone acetate | 23003142003 | 2 |
| Phoenix | Hydrocortisone acetate | 23003142004 | 1 |
| Phoenix | Hydrocortisone acetate | 3068 | 1 |
| Phoenix | Hydrocortisone acetate | 3209 | 1 |
| Phönix Gotha | Hydrocortisone acetate | 12182405 | 1 |
| Phönix Gotha | Hydrocortisone acetate | 12330108 | 1 |
| Phönix Gotha | Hydrocortisone acetate | 17219706 | 1 |
| Phönix, Caesar&Loret… | Hydrocortisone acetate | 191383001 | 1 |
| Phönix/gepepharm GmbH | Hydrocortisone acetate | 1508029-01 | 2 |
| Phönix/Lihua | Hydrocortisone acetate | 1409005-01 | 1 |
| Phönix | Hydrocortisone acetate | 1112031-01 | 1 |
| Phönix | Hydrocortisone acetate | 1112031-02 | 1 |
| Phönix | Hydrocortisone acetate | 1205034-01 | 1 |
| Phönix | Hydrocortisone acetate | 12182405 | 1 |
| Phönix | Hydrocortisone acetate | 12A13-N02 | 1 |
| Phönix | Hydrocortisone acetate | 12K15-No4 | 1 |
| Phönix | Hydrocortisone acetate | 14144804 | 2 |
| phönix | Hydrocortisone acetate | 15356901 | 2 |
| phönix | Hydrocortisone acetate | 16238708 | 1 |
| phönix | Hydrocortisone acetate | 16238712 | 1 |
| Phönix | Hydrocortisone acetate | 1706021-01 | 1 |
| Phönix | Hydrocortisone acetate | 17086204 | 2 |
| PHÖNIX | Hydrocortisone acetate | 17086211 | 1 |
| Phönix | Hydrocortisone acetate | 17219705 | 1 |
| Phönix | Hydrocortisone acetate | 1805010-01 | 1 |
| Phönix | Hydrocortisone acetate | 18142802 | 1 |
| phönix | Hydrocortisone acetate | 18142804 | 1 |
| Phönix | Hydrocortisone acetate | 18278004 | 2 |
| Phönix | Hydrocortisone acetate | 18278005 | 1 |
| Phönix | Hydrocortisone acetate | 18278006 | 1 |
| PHÖNIX | Hydrocortisone acetate | 18278007 | 2 |
| Phönix | Hydrocortisone acetate | 18278010 | 1 |
| Phönix | Hydrocortisone acetate | 18278014 | 1 |
| Phönix | Hydrocortisone acetate | 18278016 | 1 |
| Phönix | Hydrocortisone acetate | 18278018 | 2 |
| PHÖNIX | Hydrocortisone acetate | 18278019 | 1 |
| Phönix | Hydrocortisone acetate | 19138302 | 3 |
| PHÖNIX | Hydrocortisone acetate | 19138305 | 1 |
| Phönix | Hydrocortisone acetate | 19138307 | 1 |
| Phönix | Hydrocortisone acetate | 20000978004 | 1 |
| Phönix | Hydrocortisone acetate | 20000978006 | 1 |
| Phönix | Hydrocortisone acetate | 20000978010 | 1 |
| phonix | Hydrocortisone acetate | 20004117001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Hydrocortisone acetate | 20004278002 | 1 |
| Phönix | Hydrocortisone acetate | 20004278003 | 1 |
| PHÖNIX | Hydrocortisone acetate | 20004278003 | 1 |
| Phönix | Hydrocortisone acetate | 20004278004 | 1 |
| Phönix | Hydrocortisone acetate | 2000978007 | 1 |
| Phönix | Hydrocortisone acetate | 2000978009 | 1 |
| Phönix | Hydrocortisone acetate | 2004029-01 | 4 |
| PHÖNIX | Hydrocortisone acetate | 21002415001 | 2 |
| Phönix | Hydrocortisone acetate | 21002415002 | 1 |
| Phönix | Hydrocortisone acetate | 21002415004 | 2 |
| phönix | Hydrocortisone acetate | 21003553007 | 2 |
| Phönix | Hydrocortisone acetate | 22002539013 | 4 |
| Phönix | Hydrocortisone acetate | 22002539014 | 1 |
| Phönix | Hydrocortisone acetate | 22002539018 | 2 |
| Phönix | Hydrocortisone acetate | 2200253901862/23P | 1 |
| Phönix | Hydrocortisone acetate | 22002539019 | 4 |
| Phönix | Hydrocortisone acetate | 23001089004 | 1 |
| Phönix | Hydrocortisone acetate | 23001089006 | 2 |
| Phönix | Hydrocortisone acetate | 23001089009 | 2 |
| Phönix | Hydrocortisone acetate | 230010899004 | 1 |
| phönix | Hydrocortisone acetate | 23003142003 | 1 |
| Phönix | Hydrocortisone acetate | 23003142003 | 2 |
| Phönix | Hydrocortisone acetate | 23003142004 | 1 |
| Phönix | Hydrocortisone acetate | 23003142008 | 1 |
| Phönix | Hydrocortisone acetate | AKD8 | 1 |
| Röntgen | Hydrocortisone acetate | 16095410 | 1 |
| Röntgen | Hydrocortisone acetate | 17219705 | 1 |
| Röntgen | Hydrocortisone acetate | 18278010 | 1 |
| Röntgen | Hydrocortisone acetate | 19138307 | 1 |
| Röntgen | Hydrocortisone acetate | 20000977002 | 1 |
| Röntgen | Hydrocortisone acetate | 21002415010 | 1 |
| Sanacorp | Hydrocortisone acetate | 1107004-03 | 1 |
| Sanacorp | Hydrocortisone acetate | 11263913 | 1 |
| Sanacorp | Hydrocortisone acetate | 12330103 | 1 |
| Sanacorp | Hydrocortisone acetate | 13291704 | 1 |
| Sanacorp | Hydrocortisone acetate | 14043903 | 1 |
| Sanacorp | Hydrocortisone acetate | 1409005-01 | 3 |
| sanacorp | Hydrocortisone acetate | 14301406 | 1 |
| Sanacorp | Hydrocortisone acetate | 1501035-01 | 1 |
| Sanacorp | Hydrocortisone acetate | 16095407 | 1 |
| Sanacorp | Hydrocortisone acetate | 16238706 | 1 |
| Sanacorp | Hydrocortisone acetate | 16238708 | 1 |
| Sanacorp | Hydrocortisone acetate | 16238710 | 1 |
| Sanacorp | Hydrocortisone acetate | 1706021-01 | 1 |
| Sanacorp | Hydrocortisone acetate | 17219704 | 1 |
| Sanacorp | Hydrocortisone acetate | 17219708 | 1 |
| Sanacorp | Hydrocortisone acetate | 1805010-01 | 1 |
| Sanacorp | Hydrocortisone acetate | 18142805 | 2 |
| Sanacorp | Hydrocortisone acetate | 18278006 | 1 |
| Sanacorp | Hydrocortisone acetate | 18278008 | 3 |
| Sanacorp | Hydrocortisone acetate | 185010-01 | 1 |
| Sanacorp | Hydrocortisone acetate | 191383004 | 1 |
| Sanacorp | Hydrocortisone acetate | 20004117006 | 1 |
| Sanacorp | Hydrocortisone acetate | 20004278003 | 6 |
| Sanacorp | Hydrocortisone acetate | 20004278009 | 1 |
| Sanacorp | Hydrocortisone acetate | 21002415001 | 1 |
| Sanacorp | Hydrocortisone acetate | 22002539002 | 2 |
| Sanacorp | Hydrocortisone acetate | 22002539008 | 1 |
| Sanacorp | Hydrocortisone acetate | 22002539009 | 2 |
| Sanacorp | Hydrocortisone acetate | 22002539010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Hydrocortisone acetate | 22002539014 | 2 |
| Sanacorp | Hydrocortisone acetate | 2205004-01 | 2 |
| Sanacorp | Hydrocortisone acetate | 23001089005 | 2 |
| Sanacorp | Hydrocortisone acetate | 23001089006 | 1 |
| Sanacorp | Hydrocortisone acetate | 23003142003 | 2 |
| Sanacorp | Hydrocortisone acetate | 2306007-01 | 3 |
| SanacorpWE:13.02.201… | Hydrocortisone acetate | 1604052-01 | 1 |
| sannacop | Hydrocortisone acetate | 2205004-01 | 1 |
| Tianjin Jinjin Pharm… | Hydrocortisone acetate | 19138304 | 1 |
| Tianjin Jinjin Pharm… | Hydrocortisone acetate | 18278019 | 1 |
| Tianjin Jinjin/Gehe | Hydrocortisone acetate | 17L19-B04-345373 | 1 |
| Tianjin/Noweda | Hydrocortisone acetate | HD0027 | 1 |
| Tianjin/Noweda | Hydrocortisone acetate | HD0039 | 2 |
| Wepa/Noweda | Hydrocortisone acetate | 20004117001 | 1 |
| xxx | Hydrocortisone acetate | | 1 |

- 250 659 spectra from 1666 *Apo-Ident* customers from a total of 51 528 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hydrocortisone acetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hydrocortisone acetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 429 | 0 | 157 897 |
| **Type B** | 0 | 1418 | 0 | 211 522 |
| **Type C** | 0 | 6178 | 49 | 250 659 |

The substance/substance group *Hydrocortisone acetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6014 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.5769 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.2131 % (> 99.1649 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21295 | 21889 | 6.79 | 177.33 |
| 21462 | 21889 | 6.05 | 177.22 |
| 21889 | 21889 | 0.00 | 179.91 |
| 22241 | 21889 | 4.69 | 178.13 |
| 22564 | 22564 | 0.00 | 182.00 |
| 24392 | 24392 | 0.00 | 178.38 |
| 24590 | 22564 | 8.24 | 181.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hydroquinone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20091-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hydroquinone; Hydrochinonum

### Special notes

When selecting the *Hydroquinone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hydroquinone | 8 | 4 | 84 |

### Second-stage model

For differentiation of the substance/substance group *Hydroquinone* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hydroquinone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Resocrinol | 40.27 | – |
| Sodium cromoglicate | 102.65 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hydroquinone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hydroquinone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Hydroquinone | 12288505 | 20884 | 40 | 20121015 |
| Caelo | Hydroquinone | 14026904 | 21468 | 60 | 20140122 |
| Caelo | Hydroquinone | 14281501 | 21791 | 60 | AR-15-FG-008058-01 |
| Caelo | Hydroquinone | 14280110 | 21923 | 60 | 20141017 |
| Caelo | Hydroquinone | 15057001 | 22324 | 60 | 20150306 |
| Caelo | Hydroquinone | 15057001 | 22351 | 60 | 20150306 |
| Caelo | Hydroquinone | 182306 | 24761 | 40 | 20181008* |
| Caelo | Hydroquinone | 192642 | 24890 | 40 | 20191115* |
| Gatt-Koller | Hydroquinone | 23J02483 | 27097 | 30 | 20240109 |
| Gatt-Koller | Hydroquinone | 23J02483 | 27097SI | 20 | 20240109 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 470 spectra of 10 reference samples from the substance/substance group *Hydroquinone*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 856 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 5 reference samples from the substance/substance group *Hydroquinone*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hydroquinone | 15057004 | 21975 | 60 |
| Caelo | Hydroquinone | 16023105 | 23114 | 40 |
| Caelo | Hydroquinone | 172215 | 23654 | 40 |
| Caelo | Hydroquinone | 23000425 | 27226 | 40 |
| Caelo | Hydroquinone | 23000425 | 27226SI | 20 |

- 212 740 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 567 spectra from 363 *Apo-Ident* customers from 92 batches from the substance/substance group *Hydroquinone*.

- Among them are spectra of independent samples from 84 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hydroquinone | 20001617007 | 3 |
| | Hydroquinone | 21003639007 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hydroquinone | 21003639008 | 1 |
| | Hydroquinone | 21003639010 | 8 |
| | Hydroquinone | 21003639011 | 11 |
| | Hydroquinone | 23000425005 | 13 |
| | Hydroquinone | 23000425011 | 1 |
| | Hydroquinone | 25000204003 | 1 |
| 14026902 | Hydroquinone | InterneCharge1214Q | 1 |
| 16023112 | Hydroquinone | 16023112 | 1 |
| A.H. 14.06.13 ek: 3,97EUR | Hydroquinone | 12288505 | 1 |
| ACM | Hydroquinone | KNC0635J17 | 1 |
| ACM | Hydroquinone | KNC1047J15 | 2 |
| AHD | Hydroquinone | 13105405 | 1 |
| AHD | Hydroquinone | 21003639010 | 1 |
| AHL | Hydroquinone | 16023102 | 1 |
| Alli | Hydroquinone | 21003639010 | 1 |
| Alliance Healthcare | Hydroquinone | 20001617007 | 1 |
| Allianz | Hydroquinone | 16023116 | 1 |
| Anzag | Hydroquinone | 12156705 | 1 |
| Anzag | Hydroquinone | 12288505 | 2 |
| apomix | Hydroquinone | 13105408 | 1 |
| Caelo | Hydroquinone | | 3 |
| Caelo | Hydroquinone | 1(192642008)0 | 1 |
| Caelo | Hydroquinone | 10145101 | 1 |
| Caelo | Hydroquinone | 10145103 | 1 |
| Caelo | Hydroquinone | 10145113 | 2 |
| Caelo | Hydroquinone | 11163905 | 5 |
| Caelo | Hydroquinone | 11163907 | 5 |
| Caelo | Hydroquinone | 11163912 | 4 |
| Caelo | Hydroquinone | 11163912/Int312052 | 1 |
| Caelo | Hydroquinone | 1163902 | 1 |
| Caelo | Hydroquinone | 12156703 | 1 |
| Caelo | Hydroquinone | 12156705 | 5 |
| Caelo | Hydroquinone | 12156706 | 1 |
| Caelo | Hydroquinone | 1228503 | 1 |
| Caelo | Hydroquinone | 12288502 | 2 |
| Caelo | Hydroquinone | 12288503 | 2 |
| Caelo | Hydroquinone | 12288505 | 11 |
| Caelo | Hydroquinone | 1263912 | 1 |
| Caelo | Hydroquinone | 13105402 | 5 |
| Caelo | Hydroquinone | 13105405 | 6 |
| Caelo | Hydroquinone | 13105408 | 7 |
| Caelo | Hydroquinone | 14026902 | 5 |
| Caelo | Hydroquinone | 14026904 | 1 |
| Caelo | Hydroquinone | 1410401 | 1 |
| Caelo | Hydroquinone | 14121202 | 1 |
| Caelo | Hydroquinone | 14180401 | 4 |
| Caelo | Hydroquinone | 14180406 | 3 |
| Caelo | Hydroquinone | 14180410 | 4 |
| Caelo | Hydroquinone | 14280104 | 5 |
| Caelo | Hydroquinone | 14280105 | 2 |
| Caelo | Hydroquinone | 14280110 | 1 |
| Caelo | Hydroquinone | 14281501 | 11 |
| Caelo | Hydroquinone | 14281504 | 1 |
| Caelo | Hydroquinone | 14281507 | 4 |
| Caelo | Hydroquinone | 15023105 | 1 |
| Caelo | Hydroquinone | 15057001 | 11 |
| Caelo | Hydroquinone | 15057002 | 1 |
| Caelo | Hydroquinone | 15057004 | 13 |
| Caelo | Hydroquinone | 15057010 | 17 |
| Caelo | Hydroquinone | 160123118 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydroquinone | 160223105 | 1 |
| Caelo | Hydroquinone | 16023102 | 3 |
| Caelo | Hydroquinone | 16023105 | 16 |
| Caelo | Hydroquinone | 16023112 | 11 |
| Caelo | Hydroquinone | 16023113 | 9 |
| Caelo | Hydroquinone | 160231135430 | 1 |
| Caelo | Hydroquinone | 16023116 | 25 |
| Caelo | Hydroquinone | 16023118 | 18 |
| Caelo | Hydroquinone | 16023118P-190314-1 | 1 |
| Caelo | Hydroquinone | 16051502 | 1 |
| Caelo | Hydroquinone | 17221503 | 1 |
| Caelo | Hydroquinone | 17221508 | 11 |
| Caelo | Hydroquinone | 18017902 | 28 |
| Caelo | Hydroquinone | 18017905 | 9 |
| Caelo | Hydroquinone | 1801792 | 1 |
| Caelo | Hydroquinone | 18031403 | 1 |
| Caelo | Hydroquinone | 18230602 | 15 |
| Caelo | Hydroquinone | 18230607 | 10 |
| Caelo | Hydroquinone | 192642003 | 27 |
| Caelo | Hydroquinone | 192642008 | 4 |
| Caelo | Hydroquinone | 20001617002 | 10 |
| Caelo | Hydroquinone | 20001617004 | 1 |
| Caelo | Hydroquinone | 20001617005 | 6 |
| Caelo | Hydroquinone | 20001617007 | 19 |
| Caelo | Hydroquinone | 2000167007 | 1 |
| Caelo | Hydroquinone | 20101806 | 1 |
| Caelo | Hydroquinone | 20200712-3 | 1 |
| Caelo | Hydroquinone | 21003639007 | 5 |
| Caelo | Hydroquinone | 21003639010 | 1 |
| Caelo | Hydroquinone | 21003639011 | 1 |
| Caelo | Hydroquinone | 21102014A | 1 |
| Caelo | Hydroquinone | 3281 | 1 |
| Caelo | Hydroquinone | 4017A-01717 | 1 |
| Caelo | Hydroquinone | 52840166 | 1 |
| Caelo | Hydroquinone | 8725 | 1 |
| Caelo | Hydroquinone | 8816-10-583 | 1 |
| Caeolo/Gehe | Hydroquinone | 16023116 | 1 |
| Caeolo | Hydroquinone | 16023105 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 18017902 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 192642003 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 11163912 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 18017902 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 20001617002 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 18230607 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 20001617007 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 192642003 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 20001617002 | 1 |
| Caesar & Loretz GmbH... | Hydroquinone | 20001617002 | 1 |
| Caesar & Loretz GmbH | Hydroquinone | 13105405 | 1 |
| Caesar & Loretz GmbH | Hydroquinone | 16023105 | 1 |
| Caesar & Loretz GmbH | Hydroquinone | 18017902 | 3 |
| Caesar & Loretz GmbH | Hydroquinone | 18230602 | 4 |
| Caesar & Loretz GmbH | Hydroquinone | 18230607 | 1 |
| Caesar & Loretz GmbH | Hydroquinone | 192642003 | 8 |
| Caesar & Loretz GmbH | Hydroquinone | 192642008 | 2 |
| Caesar & Loretz GmbH | Hydroquinone | 20001617002 | 6 |
| Caesar & Loretz GmbH | Hydroquinone | 20001617005 | 3 |
| Caesar & Loretz GmbH | Hydroquinone | 20001617006 | 1 |
| Caesar & Loretz GmbH | Hydroquinone | 20001617007 | 12 |
| Caesar & Loretz GmbH | Hydroquinone | 21003639002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Hydroquinone | 21003639007 | 2 |
| Caesar & Loretz GmbH | Hydroquinone | 21003639010 | 2 |
| Caesar & Loretz Hilden | Hydroquinone | 20001617002 | 1 |
| Caesar & Loretz | Hydroquinone | 16023112 | 1 |
| Caesar & Loretz | Hydroquinone | 192642008 | 1 |
| Caesar / Gehe | Hydroquinone | 16023116 | 1 |
| Caesar und Loretz | Hydroquinone | 18230607 | 1 |
| Cealo | Hydroquinone | 192642003 | 1 |
| Cesar&Loretz GmbH | Hydroquinone | 192642008 | 1 |
| E Plus | Hydroquinone | 18017902 | 1 |
| Euro/Sanacorp | Hydroquinone | 15057004 | 1 |
| Fagron | Hydroquinone | | 1 |
| Fiebig | Hydroquinone | 16023116 | 1 |
| Gatt-Koller | Hydroquinone | 1803302 | 4 |
| Gatt-Koller | Hydroquinone | 22J00202 | 1 |
| Gehe/Gehe | Hydroquinone | 14280110 | 1 |
| Gehe | Hydroquinone | 12156706 | 2 |
| GEHE | Hydroquinone | 16023105 | 1 |
| GEHE | Hydroquinone | 16023118 | 1 |
| GEHE | Hydroquinone | 18017902 | 1 |
| Gehe | Hydroquinone | 21003639007 | 2 |
| Gehe | Hydroquinone | 21003639010 | 1 |
| Kehr | Hydroquinone | 16023112 | 1 |
| Kehr | Hydroquinone | 16023113 | 1 |
| Kehr | Hydroquinone | 21003639010 | 1 |
| Noweda | Hydroquinone | 16023116 | 2 |
| noweda | Hydroquinone | 18230602 | 1 |
| Noweda | Hydroquinone | 21003639010 | 1 |
| Phoenix Goettin | Hydroquinone | 14281501 | 1 |
| Phoenix | Hydroquinone | 16023105 | 1 |
| Phoenix | Hydroquinone | 18017905 | 1 |
| Phoenix | Hydroquinone | 18230602 | 1 |
| Phoenix | Hydroquinone | 192642003 | 1 |
| Phoenix | Hydroquinone | 200671007 | 1 |
| Phönix | Hydroquinone | 12288503 | 2 |
| Phönix | Hydroquinone | 13105408 | 1 |
| phönix | Hydroquinone | 16023105 | 1 |
| Sanacorp | Hydroquinone | 12156703 | 1 |
| Sanacorp | Hydroquinone | 12288503 | 1 |
| Sanacorp | Hydroquinone | 16023103 | 1 |
| Sanacorp | Hydroquinone | 16023118 | 1 |
| Sanacorp | Hydroquinone | 18230602 | 1 |
| Sanacorp | Hydroquinone | 18230607 | 1 |
| Sanacorp | Hydroquinone | 21003639007 | 2 |
| Sanacorp | Hydroquinone | 23000425005 | 1 |
| Sanacorp | Hydroquinone | 5118M-01717 | 1 |

- 256 319 spectra from 1666 *Apo-Ident* customers from a total of 52 063 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hydroquinone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hydroquinone* and it was evaluated


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how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 470 | 0 | 157 856 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 548 | 19 | 256 319 |

The substance/substance group *Hydroquinone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7234 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 96.6490 % (> 96.1199 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20884 | 21791 | 3.55 | 54.66 |
| 21468 | 21791 | 11.38 | 52.35 |
| 21791 | 21791 | 0.00 | 53.17 |
| 21923 | 21791 | 5.54 | 53.06 |
| 22324 | 21791 | 5.03 | 52.40 |
| 22351 | 21791 | 3.88 | 52.47 |
| 24761 | 24761 | 0.00 | 53.09 |
| 24890 | 24890 | 0.00 | 53.68 |
| 27097 | 21791 | 15.47 | 58.75 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hydroxyethyl cellulose** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006129-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hydroxyethyl cellulose; Hydroxyethylcellulosum

### Special notes

When selecting the *Hydroxyethyl cellulose* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hydroxyethyl cellulose | 9 | 40 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Hydroxyethyl cellulose* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hydroxyethyl cellulose* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 58.63 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hydroxyethyl cellulose* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hydroxyethyl cellulose*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Hydroxyethyl cellulose | 181131 | 26775 | 40 | 20180612* |
| Caelo | Hydroxyethyl cellulose | 22002812 | 26779 | 40 | 20221031* |
| Caelo | Hydroxyethyl cellulose | 22002812 | 26779SI | 20 | 20221031* |
| Caelo | Hydroxyethyl cellulose | 23000202 | 26781 | 40 | 20230210* |
| Caelo | Hydroxyethyl cellulose | 23000202 | 26781SI | 20 | 20230210* |
| Caelo | Hydroxyethyl cellulose | 13378506 | 26785 | 40 | 1507205 |
| Caelo | Hydroxyethyl cellulose | 12274720 | 26789 | 20 | 20121001 |
| Caelo | Hydroxyethyl cellulose | 171151 | 26793 | 40 | 20170523* |
| Caelo | Hydroxyethyl cellulose | 22000306 | 26812 | 40 | 20220314* |
| Euro OTC | Hydroxyethyl cellulose | 2306013 | 26884 | 40 | 20230801* |
| Euro OTC | Hydroxyethyl cellulose | 2408008 | 27390 | 40 | 20241008* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 380 spectra of 11 reference samples from the substance/substance group *Hydroxyethyl cellulose*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 946 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1790 spectra of 47 reference samples from the substance/substance group *Hydroxyethyl cellulose*.

- Among them are spectra of independent samples from 40 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hydroxyethyl cellulose | 190174 | 26774 | 40 |
| Caelo | Hydroxyethyl cellulose | 191675 | 26776 | 40 |
| Caelo | Hydroxyethyl cellulose | 20000136 | 26777 | 40 |
| Caelo | Hydroxyethyl cellulose | 22000131 | 26778 | 40 |
| Caelo | Hydroxyethyl cellulose | 12249204 | 26782 | 40 |
| Caelo | Hydroxyethyl cellulose | 14352504 | 26790 | 60 |
| Caelo | Hydroxyethyl cellulose | 161006 | 26791 | 60 |
| Caelo | Hydroxyethyl cellulose | 16012909 | 26792 | 40 |
| Caelo | Hydroxyethyl cellulose | 16252003 | 26794 | 40 |
| Caelo | Hydroxyethyl cellulose | 16252008 | 26795 | 40 |
| Caelo | Hydroxyethyl cellulose | 16278705 | 26796 | 40 |
| Caelo | Hydroxyethyl cellulose | 173196 | 26798 | 40 |
| Caelo | Hydroxyethyl cellulose | 17115103 | 26799 | 40 |
| Caelo | Hydroxyethyl cellulose | 190769 | 26802 | 40 |
| Caelo | Hydroxyethyl cellulose | 190767 | 26803 | 40 |
| Caelo | Hydroxyethyl cellulose | 192602 | 26806 | 40 |
| Caelo | Hydroxyethyl cellulose | 21001636 | 26810 | 50 |
| Caelo | Hydroxyethyl cellulose | 20004006004 | 26811 | 40 |
| Caelo | Hydroxyethyl cellulose | 23001448 | 26854 | 40 |
| Caelo | Hydroxyethyl cellulose | 23002026 | 26966 | 40 |
| Caelo | Hydroxyethyl cellulose | 24001032 | 27220 | 40 |
| Caelo | Hydroxyethyl cellulose | 24002350 | 27540 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 2211007 | 26780 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 1110024-04 | 26783 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 1606030 | 26786 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 1610039 | 26787 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 1711012 | 26800 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 1804003 | 26801 | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Hydroxyethyl cellulose | 1907013 | 26804 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 1911004 | 26805 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 2008018 | 26807 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 2101017 | 26808 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 2302006 | 26814 | 40 |
| Euro OTC | Hydroxyethyl cellulose | 2305002 | 26815 | 40 |
| Fagron | Hydroxyethyl cellulose | 13H22-N11 | 26784 | 40 |
| Fagron | Hydroxyethyl cellulose | 16E09-B05-327042 | 26788 | 40 |
| Fagron | Hydroxyethyl cellulose | 20H03-B06-197061 | 26809 | 50 |
| Fagron | Hydroxyethyl cellulose | 21G14-B02-213646 | 26813 | 40 |
| Fagron | Hydroxyethyl cellulose | 23E11-B01-232178 | 26986 | 40 |
| Fagron | Hydroxyethyl cellulose | 24J15-B06-008118 | 27614 | 40 |
| Caelo | Hydroxyethyl cellulose | 22000131 | 26778SI | 10 |
| Caelo | Hydroxyethyl cellulose | 16278705 | 26797 | 40 |
| Caelo | Hydroxyethyl cellulose | 20004006004 | 26811SI | 10 |
| Caelo | Hydroxyethyl cellulose | 22000306 | 26812SI[†] | 10 |
| Euro OTC | Hydroxyethyl cellulose | 2211007 | 26780SI | 20 |
| Euro OTC | Hydroxyethyl cellulose | 2302006 | 26814SI | 20 |
| Fagron | Hydroxyethyl cellulose | 21G14-B02-213646 | 26813SI | 20 |

- 211 150 spectra from a total of 4246 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Hydroxyethyl cellulose*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hydroxyethyl cellulose* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hydroxyethyl cellulose* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 1790 | 0 | 211 150 |
| **Type C** | 0 | 0 | 0 | 256 886 |

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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The substance/substance group *Hydroxyethyl cellulose* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6648 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26775 | 26775 | 0.00 | 137.05 |
| 26779 | 26779 | 0.00 | 162.53 |
| 26781 | 26781 | 0.00 | 151.93 |
| 26785 | 26785 | 0.00 | 166.64 |
| 26789 | 26781 | 49.54 | 177.48 |
| 26793 | 26793 | 0.00 | 149.37 |
| 26812 | 26812 | 0.00 | 186.54 |
| 26884 | 26884 | 0.00 | 175.87 |
| 27390 | 27390 | 0.00 | 180.23 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hydroxytryptophan (L-5-)** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006874-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hydroxytryptophan (L-5-); Oxitriptan

### Special notes

When selecting the *Hydroxytryptophan (L-5-)* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hydroxytryptophan (L-5-) | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Hydroxytryptophan (L-5-)* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hydroxytryptophan (L-5-)* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Griffonia seed extract | 32.97 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hydroxytryptophan (L-5-)* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hydroxytryptophan (L-5-)*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Hydroxytryptophan (L-5-) | 22A17-B03-226102 | 26467 | 40 | 240603342 |
| Fagron | Hydroxytryptophan (L-5-) | 23G12-B14-231034 | 26913 | 40 | 250403127 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 80 spectra of 2 reference samples from the substance/substance group *Hydroxytryptophan (L-5-)*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

- 158 246 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 71 spectra of 3 reference samples from the substance/substance group *Hydroxytryptophan (L-5-)*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Hydroxytryptophan (L-5-) | 21G12-B06-213943 | 25939 | 40 |
| Fagron | Hydroxytryptophan (L-5-) | 21G12-B06-213943 | 25939SI | 11 |
| Fagron | Hydroxytryptophan (L-5-) | 23G12-B14-231034 | 26913SI† | 20 |

- 212 869 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Hydroxytryptophan (L-5-)*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hydroxytryptophan (L-5-)* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hydroxytryptophan (L-5-)* and it was evaluated how many matches (positive) and rejections (negative) were correct or

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 80 | 0 | 158 246 |
| **Type B** | 0 | 71 | 0 | 212 869 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Hydroxytryptophan (L-5-)* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 92.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 91.5493 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26467 | 26467 | 0.00 | 32.97 |
| 26913 | 26913 | 0.00 | 57.63 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hyoscine butylbromide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20766-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hyoscine butylbromide; Hyoscini butylbromidum

### Special notes

When selecting the *Hyoscine butylbromide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hyoscine butylbromide | 6 | 4 | 2 |

### Second-stage model

For differentiation of the substance/substance group *Hyoscine butylbromide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hyoscine butylbromide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 115.92 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hyoscine butylbromide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hyoscine butylbromide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Hyoscine butylbromide | 12K01-N07 | 20766 | 40 | 1406057 |
| Fagron | Hyoscine butylbromide | 12K01-N07 | 20897 | 40 | 20121102 |
| Fagron | Hyoscine butylbromide | 13K22-N03 | 21049 | 40 | 20131126 |
| Fagron | Hyoscine butylbromide | 15I09-B04-312245 | 21954 | 60 | 20150921 |
| Fagron | Hyoscine butylbromide | 18A03-B01-352889 | 24576 | 40 | 20180122 |
| Fagron | Hyoscine butylbromide | 21K26-B03-221816 | 26294 | 40 | 20220226 |
| Fagron | Hyoscine butylbromide | 23G12-B15-233752 | 26982 | 40 | 20230808 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 300 spectra of 7 reference samples from the substance/substance group *Hyoscine butylbromide*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 026 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 270 spectra of 8 reference samples from the substance/substance group *Hyoscine butylbromide*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Hyoscine butylbromide | 15I09-B04-316806 | 22344 | 60 |
| Fagron | Hyoscine butylbromide | 16I20-B08-326942 | 22903 | 40 |
| Fagron | Hyoscine butylbromide | 20C24-F01-369374 | 25482 | 40 |
| Fagron | Hyoscine butylbromide | 21B12-F02-377294 | 25911 | 40 |
| Fagron | Hyoscine butylbromide | 16I20-B08-326942 | 22937 | 40 |
| Fagron | Hyoscine butylbromide | 21B12-F02-377294 | 25911SI | 10 |
| Fagron | Hyoscine butylbromide | 21K26-B03-221816 | 26294SI† | 20 |
| Fagron | Hyoscine butylbromide | 23G12-B15-233752 | 26982SI† | 20 |

- 212 670 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 15 spectra from 6 *Apo-Ident* customers from 3 batches from the substance/substance group *Hyoscine butylbromide*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hyoscine butylbromide | 16I20-B08-326942 | 12 |
| Fagron | Hyoscine butylbromide | 18A03-B01-352889 | 2 |
| Fagron | Hyoscine butylbromide | 21B12-F02-377294 | 1 |

- 256 871 spectra from 1666 *Apo-Ident* customers from a total of 52 150 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hyoscine butylbromide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hyoscine butylbromide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 270 | 0 | 212 670 |
| **Type C** | 0 | 15 | 0 | 256 871 |

The substance/substance group *Hyoscine butylbromide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.7778 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20766 | 20766 | 0.00 | 248.55 |
| 20897 | 20766 | 42.98 | 246.81 |
| 21049 | 20766 | 9.15 | 246.83 |
| 21954 | 20766 | 8.98 | 247.67 |

*continued on the next page*


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*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24576 | 20766 | 20.12 | 247.90 |
| 26294 | 20766 | 18.86 | 248.48 |
| 26982 | 20766 | 15.44 | 249.17 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Hyoscine hydrobromide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21676-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Hyoscine hydrobromide; Scopolamini hydrobromidum

### Special notes

When selecting the *Hyoscine hydrobromide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Hyoscine hydrobromide | 7 | 3 | 29 |

### Second-stage model

For differentiation of the substance/substance group *Hyoscine hydrobromide* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Hyoscine hydrobromide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 78.20 | – |
| ⋮ | ⋮ | ⋮ |
| Riboflavin | >50 | 55.13 |
| Polymyxin B sulfate | >50 | 64.87 |
| Tosylchloramide sodium | >50 | 65.36 |
| Bacitracin | >50 | 82.83 |
| Colistin sulfate | >50 | 92.80 |
| Cyanocobalamin | >50 | 93.85 |
| Calcium pantothenate | >50 | 121.05 |
| Triamcinolone | >50 | 141.24 |
| Estriol | >50 | 150.29 |
| Estradiol hemihydrate | >50 | 153.07 |
| Amphotericin B | >50 | 155.29 |
| Nystatin | >50 | 158.50 |
| alpha-tocopheryl acetate dry concentrate | >50 | 177.06 |
| Calcium glycerophosphate | >50 | 183.91 |
| Methylcobalamin | >50 | 212.43 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 219.81 |
| Oxalic acid | >50 | 236.69 |
| SyrSpend® SF Alka | >50 | 259.23 |
| Gelatine, white | >50 | 262.44 |
| Rice starch | >50 | 306.72 |
| Carmellose sodium | >50 | 353.17 |
| Wheat starch | >50 | 380.46 |
| SyrSpend® SF pH4 | >50 | 457.21 |
| Potato starch | >50 | 463.81 |
| Fructose | >50 | 489.56 |
| Corn starch | >50 | 502.17 |
| Acacia, dried dispersion | >50 | 504.49 |
| Maltodextrin | >50 | 620.75 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Hyoscine hydrobromide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Hyoscine hydrobromide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Hyoscine hydrobromide | 14278801 | 21676 | 60 | 1504154 |
| Caelo | Hyoscine hydrobromide | 15054501 | 21764 | 60 | 1511156 |
| Caelo | Hyoscine hydrobromide | 15054501 | 21764SI | 28 | 1511156 |
| Caelo | Hyoscine hydrobromide | 190869 | 24880 | 40 | 20190604* |
| Caelo | Hyoscine hydrobromide | 190869 | 24880SI | 40 | 20190604* |
| Caelo | Hyoscine hydrobromide | 172303 | 24881 | 40 | 20170926* |
| Caelo | Hyoscine hydrobromide | 21001472001 | 25733 | 40 | 20210423 |
| Caelo | Hyoscine hydrobromide | 21001472001 | 25733SI | 40 | 20210423 |
| Fagron | Hyoscine hydrobromide | 15L09-B04-334706 | 23418 | 40 | 20151228 |
| Fagron | Hyoscine hydrobromide | 15L09-B04-334706 | 23418SI | 40 | 20151228 |
| Fagron | Hyoscine hydrobromide | 15L09-B04-334706 | 23419 | 40 | 20151228 |
| Fagron | Hyoscine hydrobromide | 15L09-B04-334706 | 23419SI | 40 | 20151228 |
| Fagron | Hyoscine hydrobromide | 19G29-B02-367045 | 25042 | 40 | 20191223 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 548 spectra of 13 reference samples from the substance/substance group *Hyoscine hydrobromide*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 778 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 442 spectra of 11 reference samples from the substance/substance group *Hyoscine hydrobromide*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hyoscine hydrobromide | 15054504 | 21925 | 60 |
| Caelo | Hyoscine hydrobromide | 22003532001 | 26474 | 40 |
| Fagron | Hyoscine hydrobromide | 21G10-B13-221851 | 26323 | 40 |
| Caelo | Hyoscine hydrobromide | 15054501 | 21764SI† | 32 |
| Caelo | Hyoscine hydrobromide | 15054504 | 21925SI | 30 |
| Caelo | Hyoscine hydrobromide | 15054504 | 23441 | 40 |
| Caelo | Hyoscine hydrobromide | 15054504 | 23441SI | 40 |
| Caelo | Hyoscine hydrobromide | 172303 | 24881SI† | 40 |
| Caelo | Hyoscine hydrobromide | 22003532001 | 26474SI | 40 |
| Fagron | Hyoscine hydrobromide | 19G29-B02-367045 | 25042SI† | 40 |
| Fagron | Hyoscine hydrobromide | 21G10-B13-221851 | 26323SI | 40 |

- 212 498 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 77 spectra from 35 *Apo-Ident* customers from 31 batches from the substance/substance group *Hyoscine hydrobromide*.

- Among them are spectra of independent samples from 29 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hyoscine hydrobromide | 22003532001 | 1 |
| | Hyoscine hydrobromide | 22003532004 | 2 |
| | Hyoscine hydrobromide | B06-2405500 | 1 |
| Caelo | Hyoscine hydrobromide | 14278801 | 26 |
| Caelo | Hyoscine hydrobromide | 15054505 | 1 |
| Caelo | Hyoscine hydrobromide | 15054511 | 1 |
| Caelo | Hyoscine hydrobromide | 15358901 | 1 |
| Caelo | Hyoscine hydrobromide | 16206204 | 1 |
| Caelo | Hyoscine hydrobromide | 16206208 | 1 |
| Caelo | Hyoscine hydrobromide | 17230303 | 2 |
| Caelo | Hyoscine hydrobromide | 18024806 | 4 |
| Caelo | Hyoscine hydrobromide | 18024807 | 4 |
| Caelo | Hyoscine hydrobromide | 190869002 | 1 |
| Caelo | Hyoscine hydrobromide | 19086901 | 5 |
| Caelo | Hyoscine hydrobromide | 20001949001 | 4 |
| Caelo | Hyoscine hydrobromide | 21000424002 | 1 |
| Caesar & Loretz GmbH | Hyoscine hydrobromide | 20001949001 | 1 |
| Caesar & Loretz GmbH | Hyoscine hydrobromide | 21001472001 | 1 |
| Caesar & Loretz GmbH | Hyoscine hydrobromide | 22000116002 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hyoscine hydrobromide | 14F11-B02-296840 | 1 |
| Fagron | Hyoscine hydrobromide | 14J27-B05-307020 | 2 |
| Fagron | Hyoscine hydrobromide | 15L09-B04-327494 | 1 |
| Fagron | Hyoscine hydrobromide | 17D18-B05-335528 | 3 |
| Fagron | Hyoscine hydrobromide | 18B23-B04-357420 | 1 |
| Fagron | Hyoscine hydrobromide | 19G29-B02 | 1 |
| Fagron | Hyoscine hydrobromide | 21G28-F04 | 1 |
| Fagron | Hyoscine hydrobromide | 21G28-F04-379942 | 1 |
| Fagron | Hyoscine hydrobromide | 21G28-F04-379944 | 2 |
| Fagron | Hyoscine hydrobromide | 2630421 | 1 |
| Fagron | Hyoscine hydrobromide | B02-3670405 | 1 |
| Gehe | Hyoscine hydrobromide | 19086901 | 1 |
| Phönix | Hyoscine hydrobromide | 19869002 | 1 |
| Sanacorp | Hyoscine hydrobromide | 2100424002 | 1 |

- 256 809 spectra from 1666 *Apo-Ident* customers from a total of 52 122 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Hyoscine hydrobromide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Hyoscine hydrobromide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 548 | 0 | 157 778 |
| **Type B** | 0 | 442 | 0 | 212 498 |
| **Type C** | 0 | 77 | 0 | 256 809 |

The substance/substance group *Hyoscine hydrobromide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9051 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6425 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.2078 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21676 | 21676 | 0.00 | 93.91 |
| 21764 | 21764 | 0.00 | 85.94 |
| 23418 | 21764 | 44.62 | 127.34 |
| 23419 | 21764 | 46.23 | 133.21 |
| 24880 | 24880 | 0.00 | 94.52 |
| 24881 | 24881 | 0.00 | 71.23 |
| 25042 | 21676 | 7.52 | 96.18 |
| 25733 | 21764 | 28.49 | 88.19 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ibuprofen** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20205-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ibuprofen; Ibuprofenum

### Special notes

When selecting the *Ibuprofen* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ibuprofen | 8 | 10 | 49 |

### Second-stage model

For differentiation of the substance/substance group *Ibuprofen* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ibuprofen* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Tretinoin | 96.24 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ibuprofen* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ibuprofen*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ibuprofen | 11352219 | 20774 | 40 | 20120124 |
| Caelo | Ibuprofen | 172271 | 23641 | 40 | 20170831* |
| Caelo | Ibuprofen | 19000539 | 25190 | 40 | 20200316* |
| Caelo | Ibuprofen | 22003138 | 26484 | 40 | 20221020* |
| Euro OTC | Ibuprofen | 1211011-02 | 21248 | 40 | 1501533 |
| Euro OTC | Ibuprofen | 1410025-02 | 23587 | 40 | 20141125 |
| Euro OTC | Ibuprofen | 2004027 | 25278 | 40 | 20200603* |
| Euro OTC | Ibuprofen | 2208025 | 26339 | 40 | 20220915* |
| Euro OTC | Ibuprofen | 2208025 | 26339SI | 20 | 20220915* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 340 spectra of 9 reference samples from the substance/substance group *Ibuprofen*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 986 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 430 spectra of 12 reference samples from the substance/substance group *Ibuprofen*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ibuprofen | 13105108 | 21321 | 40 |
| Caelo | Ibuprofen | 183003 | 24557 | 40 |
| Caelo | Ibuprofen | 22002352 | 26359 | 40 |
| Caelo | Ibuprofen | 22004099 | 26498 | 40 |
| Caelo | Ibuprofen | 23000201 | 26722 | 40 |
| Euro OTC | Ibuprofen | 2210019 | 26430 | 40 |
| Euro OTC | Ibuprofen | 2301018 | 26521 | 40 |
| Euro OTC | Ibuprofen | 2212017 | 26531 | 40 |
| Euro OTC | Ibuprofen | 2301054 | 26575 | 40 |
| Fagron | Ibuprofen | 23C20-B03-229831 | 26827 | 30 |
| Caelo | Ibuprofen | 22002352 | 26359SI | 20 |
| Caelo | Ibuprofen | 22003138 | 26484SI† | 20 |

- 212 510 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 226 spectra from 95 *Apo-Ident* customers from 51 batches from the substance/substance group *Ibuprofen*.

- Among them are spectra of independent samples from 48 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ibuprofen | 2210019-01 | 2 |
| | Ibuprofen | 2212017-01 | 1 |
| | Ibuprofen | 2301018-01 | 2 |
| | Ibuprofen | 2301054-01 | 2 |
| | Ibuprofen | 230817(C100-2203014M) | 1 |
| Anzag | Ibuprofen | 230101801 | 2 |
| apo-ident | Ibuprofen | 2210019-02 | 1 |
| Audor Pharma | Ibuprofen | 2210019-01 | 5 |
| Caelo | Ibuprofen | | 1 |
| Caelo | Ibuprofen | 1410025-02 | 1 |
| Caelo | Ibuprofen | 17227101 | 1 |
| Caelo | Ibuprofen | 17227102 | 1 |
| Caelo | Ibuprofen | 17351401 | 3 |
| Caelo | Ibuprofen | 17351403 | 1 |
| Caelo | Ibuprofen | 17351410 | 1 |
| Caelo | Ibuprofen | 183003002 | 1 |
| Caelo | Ibuprofen | 18300303 | 1 |
| Caelo | Ibuprofen | 18300304 | 2 |
| Caelo | Ibuprofen | 21000655001 | 1 |
| Caelo | Ibuprofen | 21000655003 | 1 |
| Caelo | Ibuprofen | 220002352001 | 1 |
| Caelo | Ibuprofen | 22003138003 | 1 |
| Caelo | Ibuprofen | 22003138004 | 3 |
| Caelo | Ibuprofen | 22003138006 | 1 |
| Caelo | Ibuprofen | 2200318010 | 1 |
| Caelo | Ibuprofen | 22004099001 | 2 |
| Caelo | Ibuprofen | 2203138003 | 1 |
| Caelo | Ibuprofen | 2208025-01 | 1 |
| Caelo | Ibuprofen | 2210019-01 | 1 |
| Caesar & Loretz GmbH... | Ibuprofen | 18300304 | 1 |
| Caesar & Loretz GmbH... | Ibuprofen | 183003002 | 1 |
| Caesar & Loretz GmbH... | Ibuprofen | 21000655003 | 1 |
| Caesar & Loretz GmbH | Ibuprofen | 183003002 | 1 |
| Caesar & Loretz GmbH | Ibuprofen | 21000655001 | 4 |
| Caesar & Loretz GmbH | Ibuprofen | 21000655004 | 1 |
| Caesar & Loretz GmbH | Ibuprofen | 21000655008 | 2 |
| Caesar & Loretz GmbH | Ibuprofen | 22002352001 | 2 |
| Caesar & Loretz GmbH | Ibuprofen | 22003138003 | 1 |
| Caesar & Loretz GmbH | Ibuprofen | 22003138004 | 3 |
| Caesar & Loretz GmbH | Ibuprofen | 22003138010 | 7 |
| Caesar & Loretz GmbH | Ibuprofen | 22004099001 | 5 |
| Caesar & Loretz GmbH | Ibuprofen | 22004099003 | 1 |
| Euro OTC | Ibuprofen | 1211011-01 | 1 |
| Euro OTC | Ibuprofen | 1410025-01 | 4 |
| Euro OTC | Ibuprofen | 1410025-02 | 7 |
| Euro OTC | Ibuprofen | 2004027-01 | 3 |
| Euro OTC | Ibuprofen | 2004027-02 | 2 |
| Euro OTC | Ibuprofen | 22028025-01 | 1 |
| Euro OTC | Ibuprofen | 2208025 | 1 |
| Euro OTC | Ibuprofen | 220802501 | 2 |
| Euro OTC | Ibuprofen | 2208025-01 | 53 |
| Euro OTC | Ibuprofen | 220825-01 | 1 |
| Euro OTC | Ibuprofen | 2210019-01 | 23 |
| Euro OTC | Ibuprofen | 2210019-02 | 19 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Ibuprofen | 221201701 | 1 |
| Euro OTC | Ibuprofen | 2212017-01 | 3 |
| Euro OTC | Ibuprofen | 2301018-01 | 6 |
| Euro OTC | Ibuprofen | 2301018-1 | 1 |
| Euro OTC | Ibuprofen | 2301054-01 | 1 |
| Euro OTC | Ibuprofen | 7050-4896 | 2 |
| Euro OTC | Ibuprofen | 9061807 | 1 |
| Euro OTC | Ibuprofen | C100-2203004M | 1 |
| Fagron | Ibuprofen | 19A28-B10-361396 | 1 |
| Fagron | Ibuprofen | 22K07-B12-224949 | 2 |
| Fagron | Ibuprofen | B10-3613906 | 1 |
| GEHE | Ibuprofen | 15103011 | 1 |
| GEHE | Ibuprofen | 22003138004 | 1 |
| Gehe | Ibuprofen | 22003138008 | 3 |
| Hubei Biocause Heile... | Ibuprofen | 2210019-01 | 1 |
| Jenne | Ibuprofen | 22003138003 | 2 |
| Noweda | Ibuprofen | 2212017-01 | 1 |
| Rondell Apotheke | Ibuprofen | 1410025-01 | 2 |
| SI Group Inc. | Ibuprofen | 2208025-01 | 4 |
| SI Group Inc. | Ibuprofen | 228025-01 | 1 |

- 256 660 spectra from 1666 *Apo-Ident* customers from a total of 52 102 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ibuprofen* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ibuprofen* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 340 | 0 | 157 986 |
| **Type B** | 0 | 430 | 0 | 212 510 |
| **Type C** | 0 | 226 | 0 | 256 660 |

The substance/substance group *Ibuprofen* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2353 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6047 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.3451 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20774 | 26339 | 12.45 | 98.84 |
| 21248 | 21248 | 0.00 | 100.21 |
| 23587 | 25278 | 6.32 | 99.72 |
| 23641 | 23641 | 0.00 | 100.66 |
| 25190 | 25190 | 0.00 | 97.93 |
| 25278 | 25278 | 0.00 | 100.23 |
| 26339 | 26339 | 0.00 | 96.24 |
| 26484 | 26484 | 0.00 | 96.43 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Indometacin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20720-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Indometacin; Indometacinum

### Special notes

When selecting the *Indometacin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Indometacin | 6 | 4 | 35 |

### Second-stage model

For differentiation of the substance/substance group *Indometacin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Indometacin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Midazolam hydrochloride | 114.45 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Indometacin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Indometacin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Indometacin | 1012009-02 | 20720 | 40 | 1402050 |
| Euro OTC | Indometacin | 1205002-01 | 21327 | 40 | 20120521 |
| Euro OTC | Indometacin | 1512031 | 22291 | 60 | 20160122* |
| Euro OTC | Indometacin | 1612017 | 22981 | 40 | 20170209* |
| Fagron | Indometacin | 18H14-B04-365453 | 25062 | 40 | 20180920 |
| Fagron | Indometacin | 21E12-F04-379312 | 25841 | 50 | 20210811 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 270 spectra of 6 reference samples from the substance/substance group *Indometacin*. These

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 056 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 6 reference samples from the substance/substance group *Indometacin*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Indometacin | 1801040 | 23969 | 40 |
| Euro OTC | Indometacin | 2106012 | 25762 | 40 |
| Fagron | Indometacin | 17I08-B06-339738 | 23715 | 40 |
| Fagron | Indometacin | 23C04-B10-230386 | 26896 | 30 |
| Fagron | Indometacin | 21E12-F04-379312 | 25841SI† | 10 |
| Fagron | Indometacin | 23C04-B10-230386 | 26896SI | 20 |

- 212 760 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 171 spectra from 87 *Apo-Ident* customers from 37 batches from the substance/substance group *Indometacin*.
- Among them are spectra of independent samples from 35 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Indometacin | 174221005 | 2 |
| | Indometacin | 2106012-01 | 4 |
| | Indometacin | 2106012-02 | 9 |
| | Indometacin | 23C04-B10-238770 | 1 |
| apo-ident | Indometacin | 1801040-01 | 1 |
| Caelo | Indometacin | 1512031-01 | 1 |
| Caelo | Indometacin | 1801040-01 | 1 |
| Caelo | Indometacin | 1801040-02 | 1 |
| Euro OTC | Indometacin | 1202002-02 | 1 |
| Euro OTC | Indometacin | 1205002-01 | 2 |
| Euro OTC | Indometacin | 1205002-02 | 2 |
| Euro OTC | Indometacin | 1512031-01 | 17 |
| Euro OTC | Indometacin | 16110102 | 1 |
| Euro OTC | Indometacin | 161201-02 | 1 |
| Euro OTC | Indometacin | 1612017-01 | 9 |
| Euro OTC | Indometacin | 1612017-02 | 9 |
| Euro OTC | Indometacin | 1612017-2 | 1 |
| Euro OTC | Indometacin | 180104001 | 2 |
| Euro OTC | Indometacin | 1801040-01 | 28 |
| Euro OTC | Indometacin | 180104002 | 1 |
| Euro OTC | Indometacin | 1801040-02 | 19 |
| Euro OTC | Indometacin | 1801040-03 | 5 |
| Euro OTC | Indometacin | 1801044-02 | 1 |
| Euro OTC | Indometacin | 201606272030 | 1 |
| Euro OTC | Indometacin | 201612162018 | 2 |
| Euro OTC | Indometacin | 2091716 | 1 |
| Euro OTC | Indometacin | 2100012-01 | 1 |
| Euro OTC | Indometacin | 2106012-01 | 19 |
| Euro OTC | Indometacin | 2106012-02 | 2 |
| Euro OTC | Indometacin | 2106012-12 | 1 |
| Euro OTC | Indometacin | 27101709 | 1 |
| Euro OTC | Indometacin | 612017-02 | 1 |
| Euro/ Euro | Indometacin | 1801040-01 | 1 |
| Euro/Krieger | Indometacin | 1801040-02 | 1 |
| Fagron | Indometacin | | 1 |
| Fagron | Indometacin | 14I08-B06-343286 | 1 |
| Fagron | Indometacin | 14I25-B02-303648 | 1 |
| Fagron | Indometacin | 15L09-B08-315982 | 1 |
| Fagron | Indometacin | 17I08B06 | 1 |
| Fagron | Indometacin | 17I08-B06-339738 | 2 |
| Fagron | Indometacin | 17I08-B06-343286 | 1 |
| Fagron | Indometacin | 18H14-B03-352947 | 1 |
| Fagron | Indometacin | 18H14-B03-359139 | 1 |
| Fagron | Indometacin | 18H14-B04-368823 | 1 |
| Gehe | Indometacin | 1512031-01 | 1 |
| Gehe | Indometacin | 1801040-01 | 2 |
| Krieger/Euro | Indometacin | 4932195 | 1 |
| Sanacorp | Indometacin | 1612017-02 | 1 |
| Sanacorp | Indometacin | 1801040-03 | 1 |
| Sanacorp | Indometacin | 2106012-01 | 2 |
| Sanacorp | Indometacin | 2106012-02 | 2 |

- 256 715 spectra from 1666 *Apo-Ident* customers from a total of 52 118 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Indometacin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Indometacin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 270 | 0 | 158 056 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 170 | 1 | 256 715 |

The substance/substance group *Indometacin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7778 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.4152 % (> 97.6608 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20720 | 20720 | 0.00 | 193.93 |
| 21327 | 20720 | 7.02 | 194.70 |
| 22291 | 22291 | 0.00 | 192.78 |
| 22981 | 22981 | 0.00 | 194.41 |
| 25062 | 22291 | 6.01 | 196.02 |
| 25841 | 22981 | 6.77 | 200.17 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Iodoform** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20094-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Iodoform; Iodoformium

### Special notes

When selecting the *Iodoform* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Iodoform | 7 | 8 | 192 |

### Second-stage model

For differentiation of the substance/substance group *Iodoform* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Iodoform* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 197.51 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Iodoform* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Iodoform*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Iodoform | 12283206 | 21297 | 40 | 20130709 |
| Caelo | Iodoform | 16012302 | 23192 | 40 | AR-17-FG-012459-01 |
| Caelo | Iodoform | 16012302 | 23407 | 40 | 20160211 |
| Caelo | Iodoform | 191132 | 24710 | 40 | 20190524* |
| Caelo | Iodoform | 21000186 | 25647 | 40 | 20210316* |
| Caelo | Iodoform | 21000181 | 25648 | 40 | 20210330* |
| Caelo | Iodoform | 22003551 | 26627 | 40 | 20230130* |
| Fagron | Iodoform | 12L11-B41 | 21278 | 40 | 20140113 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 8 reference samples from the substance/substance group *Iodoform*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 006 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 350 spectra of 11 reference samples from the substance/substance group *Iodoform*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Iodoform | 170860 | 23652 | 30 |
| Caelo | Iodoform | 180919 | 24012 | 40 |
| Caelo | Iodoform | 182495 | 24380 | 40 |
| Caelo | Iodoform | 22000203 | 26020 | 40 |
| Caelo | Iodoform | 22000204 | 26021 | 40 |
| Caelo | Iodoform | 22003550 | 26628 | 40 |
| Caelo | Iodoform | 24000893 | 27238 | 40 |
| Caelo | Iodoform | 24000892 | 27263 | 40 |
| Caelo | Iodoform | 22000203 | 26020SI | 10 |
| Caelo | Iodoform | 22000204 | 26021SI | 10 |
| Caelo | Iodoform | 22003551 | 26627SI† | 20 |

- 212 590 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 850 spectra from 316 *Apo-Ident* customers from 195 batches from the substance/substance group *Iodoform*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 192 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Iodoform | 21000186002 | 1 |
| | Iodoform | 22000203005 | 1 |
| | Iodoform | 22000203006 | 4 |
| | Iodoform | 22000204001 | 3 |
| | Iodoform | 22000204002 | 1 |
| | Iodoform | 2200020404 | 1 |
| | Iodoform | 22003550002 | 4 |
| | Iodoform | 22003550003 | 2 |
| | Iodoform | 22003550004 | 1 |
| | Iodoform | 2200355002 | 1 |
| | Iodoform | 22003551002 | 6 |
| | Iodoform | 22003551003 | 1 |
| | Iodoform | 22003551005 | 3 |
| | Iodoform | 22003607002 | 4 |
| | Iodoform | 22003607003 | 3 |
| | Iodoform | 230724 | 1 |
| | Iodoform | 24000892004 | 1 |
| | Iodoform | 24000893001 | 3 |
| | Iodoform | 240119(22003551003) | 1 |
| AHC | Iodoform | 22003550003 | 1 |
| AHC | Iodoform | 22003551002 | 1 |
| AHC | Iodoform | 22003551005 | 1 |
| AHC | Iodoform | 22003607002 | 3 |
| AHD | Iodoform | 22000204001 | 2 |
| AHD | Iodoform | 22003551002 | 2 |
| AHD | Iodoform | 22003607002 | 1 |
| Anzag | Iodoform | 241129(22003551005) | 1 |
| cae | Iodoform | 191132003 | 1 |
| Caelo | Iodoform | 1010316 | 1 |
| Caelo | Iodoform | 10320407 | 1 |
| Caelo | Iodoform | 12070102 | 2 |
| Caelo | Iodoform | 12070105 | 1 |
| Caelo | Iodoform | 12070303 | 2 |
| Caelo | Iodoform | 12070407 | 1 |
| Caelo | Iodoform | 12070501 | 1 |
| Caelo | Iodoform | 12070502 | 1 |
| Caelo | Iodoform | 12070601 | 4 |
| Caelo | Iodoform | 12070602 | 3 |
| Caelo | Iodoform | 12070605 | 1 |
| Caelo | Iodoform | 12070606 | 2 |
| Caelo | Iodoform | 12070608 | 3 |
| Caelo | Iodoform | 12150902 | 6 |
| Caelo | Iodoform | 12150903 | 1 |
| Caelo | Iodoform | 12150905 | 3 |
| Caelo | Iodoform | 12150907 | 1 |
| Caelo | Iodoform | 12150908 | 4 |
| Caelo | Iodoform | 12150910 | 6 |
| Caelo | Iodoform | 12283201 | 3 |
| Caelo | Iodoform | 12283202 | 5 |
| Caelo | Iodoform | 12283206 | 3 |
| Caelo | Iodoform | 12283303 | 2 |
| Caelo | Iodoform | 12283304 | 1 |
| Caelo | Iodoform | 12283307 | 1 |
| Caelo | Iodoform | 14077601 | 1 |
| Caelo | Iodoform | 14077602 | 1 |
| Caelo | Iodoform | 14077603 | 2 |
| Caelo | Iodoform | 14077606 | 2 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Iodoform | 14077607 | 1 |
| Caelo | Iodoform | 14077702 | 7 |
| Caelo | Iodoform | 14229504 | 2 |
| Caelo | Iodoform | 14229505 | 1 |
| Caelo | Iodoform | 14229507 | 3 |
| Caelo | Iodoform | 14229508 | 2 |
| Caelo | Iodoform | 14230001 | 6 |
| Caelo | Iodoform | 14230002 | 3 |
| Caelo | Iodoform | 14230003 | 1 |
| Caelo | Iodoform | 14230006 | 5 |
| Caelo | Iodoform | 14230007 | 3 |
| Caelo | Iodoform | 14230008 | 3 |
| Caelo | Iodoform | 14230302 | 2 |
| Caelo | Iodoform | 14230304 | 2 |
| Caelo | Iodoform | 14230305 | 9 |
| Caelo | Iodoform | 14230306 | 6 |
| Caelo | Iodoform | 14230308 | 6 |
| Caelo | Iodoform | 1527104 | 1 |
| Caelo | Iodoform | 15276001 | 3 |
| Caelo | Iodoform | 15276002 | 6 |
| Caelo | Iodoform | 15276101 | 6 |
| Caelo | Iodoform | 15276102 | 5 |
| Caelo | Iodoform | 15276103 | 5 |
| Caelo | Iodoform | 15276104 | 4 |
| Caelo | Iodoform | 15276105 | 8 |
| Caelo | Iodoform | 15276107 | 1 |
| Caelo | Iodoform | 15276108 | 3 |
| Caelo | Iodoform | 15276109 | 3 |
| Caelo | Iodoform | 1527611 | 1 |
| Caelo | Iodoform | 15276111 | 6 |
| Caelo | Iodoform | 15276113 | 1 |
| Caelo | Iodoform | 1576103 | 1 |
| Caelo | Iodoform | 16012201 | 10 |
| Caelo | Iodoform | 16012202 | 2 |
| Caelo | Iodoform | 16012204 | 6 |
| Caelo | Iodoform | 16012205 | 2 |
| Caelo | Iodoform | 16012206 | 6 |
| Caelo | Iodoform | 16012207 | 7 |
| Caelo | Iodoform | 16012210 | 6 |
| Caelo | Iodoform | 16012302 | 5 |
| Caelo | Iodoform | 16012305 | 6 |
| Caelo | Iodoform | 16012306 | 8 |
| Caelo | Iodoform | 16012308 | 3 |
| Caelo | Iodoform | 16012309 | 5 |
| Caelo | Iodoform | 16012311 | 1 |
| Caelo | Iodoform | 17086001 | 6 |
| Caelo | Iodoform | 17086002 | 4 |
| Caelo | Iodoform | 17086003 | 5 |
| Caelo | Iodoform | 17086004 | 10 |
| Caelo | Iodoform | 17086005 | 10 |
| Caelo | Iodoform | 17086006 | 12 |
| Caelo | Iodoform | 17086008 | 3 |
| Caelo | Iodoform | 17086012 | 3 |
| Caelo | Iodoform | 17086066 | 1 |
| Caelo | Iodoform | 18041821 | 1 |
| Caelo | Iodoform | 18091801 | 1 |
| Caelo | Iodoform | 18091802 | 7 |
| Caelo | Iodoform | 18091803 | 1 |
| Caelo | Iodoform | 18091804 | 4 |
| Caelo | Iodoform | 18091805 | 17 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Iodoform | 18091806 | 10 |
| Caelo | Iodoform | 18091807 | 2 |
| Caelo | Iodoform | 18091902 | 1 |
| Caelo | Iodoform | 18091904 | 1 |
| Caelo | Iodoform | 18091905 | 16 |
| Caelo | Iodoform | 18091906 | 4 |
| Caelo | Iodoform | 18091907 | 2 |
| Caelo | Iodoform | 18091909 | 4 |
| Caelo | Iodoform | 18091911 | 5 |
| Caelo | Iodoform | 18091912 | 8 |
| Caelo | Iodoform | 18091912P-200326-10 | 1 |
| Caelo | Iodoform | 18249501 | 3 |
| Caelo | Iodoform | 18249502 | 11 |
| Caelo | Iodoform | 18249503 | 6 |
| Caelo | Iodoform | 1824952 | 1 |
| Caelo | Iodoform | 1911320004 | 1 |
| Caelo | Iodoform | 191132001 | 13 |
| Caelo | Iodoform | 191132002 | 10 |
| Caelo | Iodoform | 191132004 | 19 |
| Caelo | Iodoform | 191132005 | 6 |
| Caelo | Iodoform | 19113201 | 14 |
| Caelo | Iodoform | 19113204 | 2 |
| Caelo | Iodoform | 1961132001 | 1 |
| Caelo | Iodoform | 1961132004 | 1 |
| Caelo | Iodoform | 20000241001 | 17 |
| Caelo | Iodoform | 20000241004 | 4 |
| Caelo | Iodoform | 20000241005 | 5 |
| Caelo | Iodoform | 20000241006 | 12 |
| Caelo | Iodoform | 20000241007 | 1 |
| Caelo | Iodoform | 20000241008 | 12 |
| Caelo | Iodoform | 20000241009 | 1 |
| Caelo | Iodoform | 21000181003 | 7 |
| Caelo | Iodoform | 21000181004 | 3 |
| Caelo | Iodoform | 21000186001 | 10 |
| Caelo | Iodoform | 21000186002 | 15 |
| Caelo | Iodoform | 21000186003 | 4 |
| Caelo | Iodoform | 21000186006 | 10 |
| Caelo | Iodoform | 21000186007 | 1 |
| Caelo | Iodoform | 21000186009 | 1 |
| Caelo | Iodoform | 210001866 | 2 |
| Caelo | Iodoform | 21000191003 | 1 |
| Caelo | Iodoform | 2100186006 | 1 |
| Caelo | Iodoform | 21051305 | 1 |
| Caelo | Iodoform | 22000203001 | 4 |
| Caelo | Iodoform | 22000203006 | 1 |
| Caelo | Iodoform | 22000204001 | 2 |
| Caelo | Iodoform | 22000204002 | 3 |
| Caelo | Iodoform | 22000204004 | 2 |
| Caelo | Iodoform | 22003607002 | 1 |
| Caelo | Iodoform | 22003607003 | 1 |
| Caelo | Iodoform | 220127 | 1 |
| Caelo | Iodoform | 220919(21000186006) | 1 |
| Caelo | Iodoform | 221228(22000204002) | 1 |
| Caelo | Iodoform | 230117(22000204002) | 1 |
| Caelo | Iodoform | 230210 | 1 |
| Caelo | Iodoform | 23021715 | 1 |
| Caelo | Iodoform | 230327(22000203006) | 1 |
| Caelo | Iodoform | 28011503 | 1 |
| Caelo | Iodoform | 3041407 | 1 |
| Caelo | Iodoform | 320E01726 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Iodoform | 46(18091805) | 1 |
| Caelo | Iodoform | 47(18091905) | 1 |
| Caelo | Iodoform | 48(18091905) | 1 |
| Caelo | Iodoform | 49(18091911) | 1 |
| Caelo | Iodoform | 50(18091912) | 1 |
| Caelo | Iodoform | 51(18091912) | 1 |
| Caelo | Iodoform | 52(20000241001) | 1 |
| Caelo | Iodoform | 53(20000241001) | 1 |
| Caelo | Iodoform | 54(20000241008) | 2 |
| Caelo | Iodoform | 55(20000241001) | 1 |
| Caeolo/Sanacorp | Iodoform | 21000181003 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 18091906 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 18249502 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 21000186007 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 12070501 | 3 |
| Caesar & Loretz GmbH... | Iodoform | 191132001 | 2 |
| Caesar & Loretz GmbH... | Iodoform | 19113201 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 21000186001 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 22000204001 | 2 |
| Caesar & Loretz GmbH... | Iodoform | 191132001 | 1 |
| Caesar & Loretz GmbH/Gehe | Iodoform | 21000186001 | 1 |
| Caesar & Loretz GmbH/GEHE | Iodoform | 21000186001 | 1 |
| Caesar & Loretz GmbH/Gehe | Iodoform | 22003550003 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 191132001 | 4 |
| Caesar & Loretz GmbH... | Iodoform | 191132004 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 21000186003 | 1 |
| Caesar & Loretz GmbH... | Iodoform | AP220630-03 | 1 |
| Caesar & Loretz GmbH... | Iodoform | AP221112-01 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 21000186003 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 18249502 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 191132001 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 19113203 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 19113204 | 1 |
| Caesar & Loretz GmbH... | Iodoform | 20000241002 | 2 |
| Caesar & Loretz GmbH... | Iodoform | 20000241004 | 1 |
| Caesar & Loretz GmbH... | Iodoform | AP220812-01 | 2 |
| Caesar & Loretz GmbH | Iodoform | 12150907 | 1 |
| Caesar & Loretz GmbH | Iodoform | 18091902 | 2 |
| Caesar & Loretz GmbH | Iodoform | 18091905 | 4 |
| Caesar & Loretz GmbH | Iodoform | 18091906 | 1 |
| Caesar & Loretz GmbH | Iodoform | 18091909 | 1 |
| Caesar & Loretz GmbH | Iodoform | 18091911 | 1 |
| Caesar & Loretz GmbH | Iodoform | 18091912 | 1 |
| Caesar & Loretz GmbH | Iodoform | 18249502 | 8 |
| Caesar & Loretz GmbH | Iodoform | 191132001 | 6 |
| Caesar & Loretz GmbH | Iodoform | 191132002 | 1 |
| Caesar & Loretz GmbH | Iodoform | 191132004 | 3 |
| Caesar & Loretz GmbH | Iodoform | 191132005 | 2 |
| Caesar & Loretz GmbH | Iodoform | 19113201 | 6 |
| Caesar & Loretz GmbH | Iodoform | 19113203 | 1 |
| Caesar & Loretz GmbH | Iodoform | 19113204 | 1 |
| Caesar & Loretz GmbH | Iodoform | 20000241001 | 4 |
| Caesar & Loretz GmbH | Iodoform | 20000241005 | 3 |
| Caesar & Loretz GmbH | Iodoform | 20000241006 | 2 |
| Caesar & Loretz GmbH | Iodoform | 20000241008 | 6 |
| Caesar & Loretz GmbH | Iodoform | 20000241009 | 1 |
| Caesar & Loretz GmbH | Iodoform | 21000181003 | 8 |
| Caesar & Loretz GmbH | Iodoform | 21000186001 | 1 |
| Caesar & Loretz GmbH | Iodoform | 21000186002 | 5 |
| Caesar & Loretz GmbH | Iodoform | 21000186003 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Iodoform | 21000186004 | 1 |
| Caesar & Loretz GmbH | Iodoform | 21000186006 | 1 |
| Caesar & Loretz GmbH | Iodoform | 21000186007 | 2 |
| Caesar & Loretz GmbH | Iodoform | 22000203001 | 1 |
| Caesar & Loretz GmbH | Iodoform | 22000204001 | 1 |
| Caesar & Loretz GmbH | Iodoform | 22000204002 | 1 |
| Caesar & Loretz GmbH | Iodoform | 22003607002 | 1 |
| Caesar & Loretz GmbHGehe | Iodoform | 18249502 | 1 |
| Caesar & Loretz Hilden | Iodoform | 18091905 | 2 |
| Caesar Loretz | Iodoform | 20000241001 | 1 |
| Caesar u.Loretz | Iodoform | 16012209 | 2 |
| Cao | Iodoform | 18249503 | 1 |
| Cesar&Loretz GmbH Noweda | Iodoform | 19113201 | 1 |
| Euro OTC | Iodoform | 14229504 | 2 |
| Fagron | Iodoform | 12E30-N01 | 2 |
| Fagron | Iodoform | 12L11-B41 | 1 |
| Fagron | Iodoform | 12L11-B41-290055 | 1 |
| Fagron | Iodoform | 14229508 | 1 |
| Fagron | Iodoform | 14D09-B14-293029 | 1 |
| Fagron | Iodoform | 16012302 | 1 |
| Fagron | Iodoform | 18091803 | 1 |
| Fiebig | Iodoform | 16012206 | 1 |
| fragon | Iodoform | 12283303 | 1 |
| Gehe | Iodoform | 14230008 | 1 |
| Gehe | Iodoform | 17086001 | 1 |
| GEHE | Iodoform | 17086002 | 1 |
| GEHE | Iodoform | 17086003 | 1 |
| Gehe | Iodoform | 191132001 | 1 |
| Gehe | Iodoform | 22003551003 | 1 |
| Gehe | Iodoform | 240212(22003551002) | 1 |
| Gehe | Iodoform | 240910(22003551003) | 1 |
| Henry Lamotte Oils G… | Iodoform | 16012309 | 1 |
| Jenne | Iodoform | 240103(22003551002) | 1 |
| Jenne | Iodoform | 240723(22003551003) | 1 |
| Jenne | Iodoform | 240902(22003551005) | 1 |
| Jenne | Iodoform | 241009(22003551005) | 1 |
| Jenne | Iodoform | 241010(22003551005) | 1 |
| Jenne | Iodoform | 250305(24000892004) | 1 |
| Jenne | Iodoform | 250312(24000892004) | 1 |
| Kehr | Iodoform | 22003607003 | 1 |
| Midas | Iodoform | 16012306 | 1 |
| Nachprüfung von Juni 2018 | Iodoform | 15276103 | 1 |
| Noweda /Cealo | Iodoform | 20000241005 | 1 |
| Noweda | Iodoform | 10320402 | 1 |
| Noweda | Iodoform | 12070407 | 1 |
| Noweda | Iodoform | 17086012 | 1 |
| Noweda | Iodoform | 18091805 | 1 |
| Noweda | Iodoform | 18091806 | 1 |
| Noweda | Iodoform | 18091902 | 1 |
| Noweda | Iodoform | 19113201 | 1 |
| Noweda | Iodoform | 20000241008 | 2 |
| Noweda | Iodoform | 21000186002 | 1 |
| Noweda | Iodoform | 22000204001 | 1 |
| Phoenix | Iodoform | 12070601 | 1 |
| Phoenix | Iodoform | 191132001 | 1 |
| Phoenix | Iodoform | 22003607003 | 1 |
| phönix | Iodoform | 18249502 | 2 |
| Sanacorp | Iodoform | 17086005 | 1 |
| Sanacorp | Iodoform | 18091805 | 1 |
| Sanacorp | Iodoform | 22003551002 | 1 |


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- 256 036 spectra from 1666 *Apo-Ident* customers from a total of 51 960 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Iodoform* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Iodoform* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 350 | 0 | 212 590 |
| **Type C** | 0 | 844 | 6 | 256 036 |

The substance/substance group *Iodoform* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.2857 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.2941 % (> 98.9412 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21278 | 23192 | 20.90 | 236.36 |
| 21297 | 26627 | 28.52 | 231.54 |
| 23192 | 23192 | 0.00 | 244.71 |
| 23407 | 23192 | 13.68 | 241.93 |
| 24710 | 24710 | 0.00 | 246.58 |
| 25647 | 25647 | 0.00 | 247.07 |
| 25648 | 25648 | 0.00 | 245.40 |
| 26627 | 26627 | 0.00 | 235.83 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ipratropium bromide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20911-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ipratropium bromide; Ipratropii bromidum

### Special notes

When selecting the *Ipratropium bromide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ipratropium bromide | 5 | 3 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Ipratropium bromide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ipratropium bromide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 132.83 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ipratropium bromide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ipratropium bromide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ipratropium bromide | 12C15-N01 | 20911 | 40 | 1403675 |
| Fagron | Ipratropium bromide | 12K01-N08 | 21272 | 40 | 20121025 |
| Fagron | Ipratropium bromide | 18H30-B09-359179 | 24947 | 40 | 20180918 |
| Fagron | Ipratropium bromide | 21E27-B06-213614 | 25903 | 40 | 20210908 |
| Fagron | Ipratropium bromide | 23C07-B08-230203 | 26897 | 40 | 20230418 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 5 reference samples from the substance/substance group *Ipratropium bromide*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.
- 158 126 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 5 reference samples from the substance/substance group *Ipratropium bromide*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Ipratropium bromide | 15C04-B02-321674 | 22747 | 40 |
| Fagron | Ipratropium bromide | 16K07-B05-335330 | 23597 | 40 |
| Fagron | Ipratropium bromide | 18B19-B05-346997 | 23992 | 40 |
| Fagron | Ipratropium bromide | 21E27-B06-213614 | 25903SI† | 10 |
| Fagron | Ipratropium bromide | 23C07-B08-230203 | 26897SI† | 20 |

- 212 790 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 30 spectra from 18 *Apo-Ident* customers from 13 batches from the substance/substance group *Ipratropium bromide*.
- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ipratropium bromide | 21E27-B06-213614 | 4 |
| Euro OTC | Ipratropium bromide | 18B19-B05-348556 | 1 |
| Fagron | Ipratropium bromide | 14B05-B16-294566 | 1 |
| Fagron | Ipratropium bromide | 15C04-B02-321674 | 1 |
| Fagron | Ipratropium bromide | 18B19-B05-348556 | 2 |
| Fagron | Ipratropium bromide | 18B19-B05-356276 | 8 |
| Fagron | Ipratropium bromide | 18H30-B09-359170 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Ipratropium bromide | 18H30-B09-367187/1850002262 | 1 |
| Fagron | Ipratropium bromide | 21A14-F02 | 2 |
| Fagron | Ipratropium bromide | 21A14-F02377074 | 1 |
| Fagron | Ipratropium bromide | 21A14-F02-377075 | 2 |
| Fagron | Ipratropium bromide | 21E27-B06-213614 | 3 |
| Fagron | Ipratropium bromide | F02-3770705 | 1 |
| Fargon | Ipratropium bromide | 18B19-B055-356276 | 1 |
| Fragon | Ipratropium bromide | 2050002969 | 1 |

- 256 856 spectra from 1666 *Apo-Ident* customers from a total of 52 141 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ipratropium bromide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ipratropium bromide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 30 | 0 | 256 856 |

The substance/substance group *Ipratropium bromide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 80.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20911 | 20911 | 0.00 | 185.69 |
| 21272 | 20911 | 7.72 | 186.07 |
| 24947 | 20911 | 17.02 | 189.17 |
| 25903 | 20911 | 23.62 | 187.82 |
| 26897 | 20911 | 15.51 | 185.03 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Isoleucine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21045-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Isoleucine; Isoleucinum; L-isoleucine

### Special notes

When selecting the *Isoleucine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Isoleucine | 7 | 14 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Isoleucine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Isoleucine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Leucine | 63.83 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Isoleucine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Isoleucine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Isoleucine | 1604057 | 22566 | 40 | 20160601* |
| Euro OTC | Isoleucine | 1704022 | 23386 | 40 | 20170612* |
| Euro OTC | Isoleucine | 1909025 | 24931 | 40 | 20191015* |
| Euro OTC | Isoleucine | 2301011 | 26534 | 40 | 20230201* |
| Euro OTC | Isoleucine | 2301011 | 26534SI | 20 | 20230201* |
| Fagron | Isoleucine | 13E02-B01-286930 | 21045 | 40 | 1403154 |
| Fagron | Isoleucine | 13E02-B01 | 21332 | 40 | 20130621 |
| Fagron | Isoleucine | 20B12-B01-197402 | 25441 | 40 | 20200313 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 8 reference samples from the substance/substance group *Isoleucine*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 026 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 620 spectra of 17 reference samples from the substance/substance group *Isoleucine*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Isoleucine | 1611007 | 22869 | 40 |
| Euro OTC | Isoleucine | 1708027 | 23702 | 40 |
| Euro OTC | Isoleucine | 1711034 | 23869 | 40 |
| Euro OTC | Isoleucine | 1803019 | 24080 | 40 |
| Euro OTC | Isoleucine | 1805013 | 24115 | 40 |
| Euro OTC | Isoleucine | 1901010 | 24515 | 40 |
| Euro OTC | Isoleucine | 2101041 | 25530 | 40 |
| Euro OTC | Isoleucine | 2111017 | 25891 | 50 |
| Euro OTC | Isoleucine | 2309020 | 27011 | 40 |
| Euro OTC | Isoleucine | 2404003 | 27288 | 40 |
| Fagron | Isoleucine | 21B01-B06-210568 | 26292 | 40 |
| Fagron | Isoleucine | 22G01-B04-221842 | 26682 | 40 |
| Fagron | Isoleucine | 23C07-B07-230992 | 27043 | 40 |
| Fagron | Isoleucine | 24A10-B08-235292 | 27425 | 40 |
| Euro OTC | Isoleucine | 2111017 | 25891SI | 10 |
| Fagron | Isoleucine | 21B01-B06-210568 | 26292SI | 20 |
| Fagron | Isoleucine | 22G01-B04-221842 | 26682SI | 20 |

- 212 320 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 32 spectra from 12 *Apo-Ident* customers from 17 batches from the substance/substance group *Isoleucine*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Isoleucine | 2111017-01 | 2 |
| Euro OTC | Isoleucine | 1704022-01 | 1 |
| Euro OTC | Isoleucine | 1708027-01 | 1 |
| Euro OTC | Isoleucine | 1711034-01 | 1 |
| Euro OTC | Isoleucine | 1805013-02 | 1 |
| Euro OTC | Isoleucine | 1901010-01 | 1 |
| Euro OTC | Isoleucine | 2006027-01 | 5 |
| Euro OTC | Isoleucine | 2101041-01 | 1 |
| Euro OTC | Isoleucine | 2111017-01 | 3 |
| Fagro WE:19.05.16 EK... | Isoleucine | 15A14-B09-314881 | 1 |
| Fagron | Isoleucine | 12080167 | 1 |
| Fagron | Isoleucine | 13A22-N03 | 1 |
| Fagron | Isoleucine | 13E02-B01-286930 | 1 |
| Fagron | Isoleucine | 14D08-B02-296089 | 2 |
| Fagron | Isoleucine | 16H24-B03-331739 | 1 |
| Fagron | Isoleucine | 17010483 | 2 |
| Fagron | Isoleucine | 17H14-B04-339008 | 5 |
| Sanacorp | Isoleucine | 17H14-B04-339008 | 1 |
| Synop WE:18.12.17 E... | Isoleucine | 17H14-B04-339009 | 1 |

- 256 854 spectra from 1666 *Apo-Ident* customers from a total of 52 136 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Isoleucine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Isoleucine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 620 | 0 | 212 320 |
| **Type C** | 0 | 32 | 0 | 256 854 |

The substance/substance group *Isoleucine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0323 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 81.2500 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21045 | 21045 | 0.00 | 102.28 |
| 21332 | 21045 | 4.83 | 101.82 |
| 22566 | 22566 | 0.00 | 107.11 |
| 23386 | 23386 | 0.00 | 106.85 |
| 24931 | 24931 | 0.00 | 105.60 |
| 25441 | 26534 | 5.08 | 110.14 |
| 26534 | 26534 | 0.00 | 106.76 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Isosorbide dinitrate 40%** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20213-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Isosorbide dinitrate 40%; Isorbidi dinitras 40%

### Special notes

When selecting the *Isosorbide dinitrate 40%* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Isosorbide dinitrate 40% | 5 | 3 | 239 |

### Second-stage model

For differentiation of the substance/substance group *Isosorbide dinitrate 40%* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Isosorbide dinitrate 40%* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 64.10 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Isosorbide dinitrate 40%* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Isosorbide dinitrate 40%*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Isosorbide dinitrate 40% | 12F08-N04 | 20891 | 40 | 20120801 |
| Fagron | Isosorbide dinitrate 40% | 13D15-N02 | 21347 | 39 | 20130410 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-328577 | 23200 | 40 | 1709092 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-328577 | 23598 | 30 | 20150922 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-339447 | 24057 | 40 | 20170517 |
| Fagron | Isosorbide dinitrate 40% | 23F19-B04-231383 | 27044 | 40 | 20231004 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 229 spectra of 6 reference samples from the substance/substance group *Isosorbide dinitrate 40%*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.
- 158 097 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 5 reference samples from the substance/substance group *Isosorbide dinitrate 40%*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-315217 | 22762 | 40 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-363845 | 25065 | 40 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-215487 | 26300 | 40 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-215487 | 26300SI | 10 |
| Fagron | Isosorbide dinitrate 40% | 23F19-B04-231383 | 27044SI† | 20 |

- 212 790 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1123 spectra from 476 *Apo-Ident* customers from 279 batches from the substance/substance group *Isosorbide dinitrate 40%*.
- Among them are spectra of independent samples from 237 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Isosorbide dinitrate 40% | | 1 |
| | Isosorbide dinitrate 40% | 15/10-B01-320081 | 4 |
| | Isosorbide dinitrate 40% | 17c29-b01-348859 | 1 |
| | Isosorbide dinitrate 40% | 18J18-B01-363846 | 1 |
| | Isosorbide dinitrate 40% | 2203089 | 6 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Isosorbide dinitrate 40% | 22D11-B05-215487 | 3 |
| | Isosorbide dinitrate 40% | 22D11-B05-216314 | 10 |
| | Isosorbide dinitrate 40% | 22D11-B05-225756 | 15 |
| | Isosorbide dinitrate 40% | 22D11-b05225757 | 1 |
| | Isosorbide dinitrate 40% | 22D11-B05-225757 | 12 |
| | Isosorbide dinitrate 40% | 22D11B05229443 | 1 |
| | Isosorbide dinitrate 40% | 22D11-B05-229443 | 7 |
| | Isosorbide dinitrate 40% | 22D11-B05-225756 | 1 |
| | Isosorbide dinitrate 40% | 22D11-B05-225757 | 1 |
| | Isosorbide dinitrate 40% | 2305813 | 2 |
| | Isosorbide dinitrate 40% | 23F19-B04 | 2 |
| | Isosorbide dinitrate 40% | 23F19-B04-2313803 | 1 |
| | Isosorbide dinitrate 40% | 23F19-B04-231383 | 3 |
| | Isosorbide dinitrate 40% | 23F19-B04-233748 | 1 |
| | Isosorbide dinitrate 40% | B04-2313803 | 4 |
| | Isosorbide dinitrate 40% | B04-2337408 | 1 |
| | Isosorbide dinitrate 40% | B0521631004 | 1 |
| | Isosorbide dinitrate 40% | BO4-2337408 | 2 |
| AEP GmbH | Isosorbide dinitrate 40% | B01-3638405 | 1 |
| AHD 09.03.2015 | Isosorbide dinitrate 40% | 14D09-B03-294281 | 1 |
| AHD | Isosorbide dinitrate 40% | 17C29-B01-350470 | 1 |
| Ahd | Isosorbide dinitrate 40% | 2203089 | 1 |
| AHD | Isosorbide dinitrate 40% | 23F19-B04-231383 | 1 |
| Alliance / Fargon | Isosorbide dinitrate 40% | 18J18-B01-359177 | 2 |
| Allianz Healthcare 1… | Isosorbide dinitrate 40% | 14D09-B03-300234 | 1 |
| Anzag | Isosorbide dinitrate 40% | 15/10-B01-328577 | 1 |
| Anzag | Isosorbide dinitrate 40% | 1510B01315217 | 1 |
| Anzah / Henry lammotte | Isosorbide dinitrate 40% | 14D09-B03-294281 | 2 |
| apo-ident | Isosorbide dinitrate 40% | 18J18-B01-359177 | 1 |
| Avara Shannon / Eber… | Isosorbide dinitrate 40% | 193469 | 2 |
| Avara Shannon Pharm … | Isosorbide dinitrate 40% | 195293 | 1 |
| Avara Shannon Pharm.… | Isosorbide dinitrate 40% | 18J18-B01-358247 | 1 |
| Avara Shannon Pharm/ gehe | Isosorbide dinitrate 40% | 195293 | 1 |
| Avara Shannon | Isosorbide dinitrate 40% | | 1 |
| Caelo | Isosorbide dinitrate 40% | | 1 |
| Caelo | Isosorbide dinitrate 40% | 11/17-N05 | 1 |
| Caelo | Isosorbide dinitrate 40% | 11D12-N01 | 1 |
| Caelo | Isosorbide dinitrate 40% | 13/26-N18 | 1 |
| Caelo | Isosorbide dinitrate 40% | 13D15-N02 | 3 |
| Caelo | Isosorbide dinitrate 40% | 13F27-N04 | 1 |
| Caelo | Isosorbide dinitrate 40% | 13I26-N18 | 2 |
| Caelo | Isosorbide dinitrate 40% | 149168 | 2 |
| Caelo | Isosorbide dinitrate 40% | 14D09B03294281 | 1 |
| Caelo | Isosorbide dinitrate 40% | 14D-09-B03-300234 | 1 |
| Caelo | Isosorbide dinitrate 40% | 14D09-B03-307018 | 1 |
| Caelo | Isosorbide dinitrate 40% | 14D09-B03-308419 | 4 |
| Caelo | Isosorbide dinitrate 40% | 15/10-B01-325474 | 2 |
| Caelo | Isosorbide dinitrate 40% | 15/10-B01-328577 | 1 |
| Caelo | Isosorbide dinitrate 40% | 15/10-B01-331286 | 1 |
| Caelo | Isosorbide dinitrate 40% | 1510-B01-315217 | 1 |
| Caelo | Isosorbide dinitrate 40% | 15-10b01-328132 | 1 |
| Caelo | Isosorbide dinitrate 40% | 15-10-b01-328132 | 2 |
| Caelo | Isosorbide dinitrate 40% | 1510b1320782 | 1 |
| Caelo | Isosorbide dinitrate 40% | 15I10-B01 | 1 |
| Caelo | Isosorbide dinitrate 40% | 15I10-B01-328577 | 1 |
| Caelo | Isosorbide dinitrate 40% | 15l10-B01-325474 | 1 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-335070 | 2 |
| Caelo | Isosorbide dinitrate 40% | 17c29-b01-335071 | 6 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-335071 | 1 |
| Caelo | Isosorbide dinitrate 40% | 17c29-B01-339447 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Isosorbide dinitrate 40% | 17C29B01339447 | 1 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-339447 | 2 |
| Caelo | Isosorbide dinitrate 40% | 17c29-b01-339448 | 1 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-347248 | 1 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-347589 | 3 |
| Caelo | Isosorbide dinitrate 40% | 17c29-b01-347885 | 4 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-348859 | 2 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-348860 | 1 |
| Caelo | Isosorbide dinitrate 40% | 17C29-B01-353161 | 2 |
| Caelo | Isosorbide dinitrate 40% | 18j18-b01-358247 | 1 |
| Caelo | Isosorbide dinitrate 40% | 18J18-B01-363844 | 1 |
| Caelo | Isosorbide dinitrate 40% | 18J18-B01-363845 | 1 |
| Caelo | Isosorbide dinitrate 40% | 18J18-B01-373438 | 1 |
| Caelo | Isosorbide dinitrate 40% | 193469 | 1 |
| Caelo | Isosorbide dinitrate 40% | 195293 | 1 |
| Caelo | Isosorbide dinitrate 40% | 701310-0001 | 1 |
| Caelo | Isosorbide dinitrate 40% | 701319-0003 | 1 |
| Cealo | Isosorbide dinitrate 40% | 1510-B01-320081 | 2 |
| Dipharma | Isosorbide dinitrate 40% | 22D11-B05-215487 | 1 |
| ebe a | Isosorbide dinitrate 40% | 14D09-B03-294281 | 1 |
| Ebert-Jacobi | Isosorbide dinitrate 40% | 15I10-B01-328132 | 1 |
| Euro OTC | Isosorbide dinitrate 40% | | 1 |
| Euro OTC | Isosorbide dinitrate 40% | 13126-N18 | 1 |
| Euro OTC | Isosorbide dinitrate 40% | 15I10-B01325474 | 1 |
| Euro OTC | Isosorbide dinitrate 40% | 22D11-B05-215487 | 1 |
| Fagro/Noweda | Isosorbide dinitrate 40% | 17C29-B01-335070 | 1 |
| Fagron | Isosorbide dinitrate 40% | | 10 |
| Fagron | Isosorbide dinitrate 40% | 10029-N10 | 1 |
| Fagron | Isosorbide dinitrate 40% | 101652 | 6 |
| Fagron | Isosorbide dinitrate 40% | 10-B01-320081 | 1 |
| Fagron | Isosorbide dinitrate 40% | 10C19-N01 | 1 |
| Fagron | Isosorbide dinitrate 40% | 10D29-N10 | 1 |
| Fagron | Isosorbide dinitrate 40% | 11/17-N05 | 1 |
| Fagron | Isosorbide dinitrate 40% | 11/17-No5 | 1 |
| Fagron | Isosorbide dinitrate 40% | 11D12-N01 | 2 |
| Fagron | Isosorbide dinitrate 40% | 11F28-N05 | 2 |
| Fagron | Isosorbide dinitrate 40% | 11I17-N05 | 1 |
| Fagron | Isosorbide dinitrate 40% | 11J17-N05 | 3 |
| Fagron | Isosorbide dinitrate 40% | 11l17-N05 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1216M-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 12C08-N05 | 4 |
| Fagron | Isosorbide dinitrate 40% | 12f08-n04 | 1 |
| Fagron | Isosorbide dinitrate 40% | 12F08-N04 | 8 |
| Fagron | Isosorbide dinitrate 40% | 12k14-n02 | 1 |
| Fagron | Isosorbide dinitrate 40% | 12K14N02 | 1 |
| Fagron | Isosorbide dinitrate 40% | 12K14-N02 | 6 |
| Fagron | Isosorbide dinitrate 40% | 13/26-N18 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1309210009 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1-36384005 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1373438 | 1 |
| Fagron | Isosorbide dinitrate 40% | 13A07-0003 | 1 |
| Fagron | Isosorbide dinitrate 40% | 13A07-N13 | 5 |
| Fagron | Isosorbide dinitrate 40% | 13d15-n02 | 1 |
| Fagron | Isosorbide dinitrate 40% | 13D15-N02 | 7 |
| Fagron | Isosorbide dinitrate 40% | 13F27-N04 | 6 |
| Fagron | Isosorbide dinitrate 40% | 13F27-N040234/1300 | 1 |
| Fagron | Isosorbide dinitrate 40% | 13I26-N18 | 8 |
| Fagron | Isosorbide dinitrate 40% | 149168 | 11 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03 | 9 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03_294280 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Isosorbide dinitrate 40% | 14D09-B03_294282 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03_308419 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-294280 | 9 |
| Fagron | Isosorbide dinitrate 40% | 14D09B03294281 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-294281 | 4 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-294282 | 5 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-294282Eber | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-29481 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-300234 | 16 |
| Fagron | Isosorbide dinitrate 40% | 14-D09-B03-300234 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09B03300235 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-300235 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-305633 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-307018 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-308419 | 17 |
| Fagron | Isosorbide dinitrate 40% | 14d09-b03-313566 | 1 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B03-313566 | 3 |
| Fagron | Isosorbide dinitrate 40% | 14D09-B3-308419 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15/10B01-315217 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-315217 | 8 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-318522 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-3200782 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-320081 | 12 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-320782 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-325474 | 5 |
| Fagron | Isosorbide dinitrate 40% | 15/10-b01-328132 | 3 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-328132 | 2 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-328577 | 9 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-331286 | 5 |
| Fagron | Isosorbide dinitrate 40% | 15/10-b01-331287 | 3 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-331287 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B10-331286 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15/10-B01-325474 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510-B01-315217 | 2 |
| Fagron | Isosorbide dinitrate 40% | 15-10-b01-318522 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510B01320081 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510-B01320081 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510-B01-320081 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510B01325474 | 2 |
| Fagron | Isosorbide dinitrate 40% | 1510-B01-325474 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510-b01-325475 | 3 |
| Fagron | Isosorbide dinitrate 40% | 15-10-b01-325475 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510-b01-328132 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510B01328577 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1510-B01-328577 | 2 |
| Fagron | Isosorbide dinitrate 40% | 15-10-b01-331287 | 5 |
| Fagron | Isosorbide dinitrate 40% | 151-b01-328132 | 2 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01 | 7 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-310081 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-315217 | 2 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-318522 | 2 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-320081 | 5 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-320782 | 2 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-325474 | 7 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-328132 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-328577 | 5 |
| Fagron | Isosorbide dinitrate 40% | 15I10B01331286 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15I10-B01-331286 | 3 |
| Fagron | Isosorbide dinitrate 40% | 15l10-B01-320081 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15l10-B01-325474 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Isosorbide dinitrate 40% | 15L10B01325474 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15110-B01-328577 | 1 |
| Fagron | Isosorbide dinitrate 40% | 15110-B01-331286 | 1 |
| Fagron | Isosorbide dinitrate 40% | 160629I | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C26-B01-347885 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29_B01_350469 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-801-347885 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17c29-b01 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01 | 14 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01_339447 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01_350469 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17c29b01335070 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17c29-b01-335070 | 2 |
| Fagron | Isosorbide dinitrate 40% | 17C29B01335070 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01335070 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-335070 | 18 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-335071 | 3 |
| Fagron | Isosorbide dinitrate 40% | 17C29B01339447 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-339447 | 19 |
| Fagron | Isosorbide dinitrate 40% | 17c29-b01-339448 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-b01-339448 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-339448 | 4 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-346333 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-347248 | 4 |
| Fagron | Isosorbide dinitrate 40% | 17C29B01347589 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-347589 | 16 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-347885 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17c29-b01-348859 | 3 |
| Fagron | Isosorbide dinitrate 40% | 17C29B01348859 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-348859 | 22 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-348860 | 2 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-34889 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17c29-b01-350469 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29B01350469 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-350469 | 19 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-350470 | 2 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-352558 | 4 |
| Fagron | Isosorbide dinitrate 40% | 17C29-B01-353161 | 4 |
| Fagron | Isosorbide dinitrate 40% | 17c29-B01-48859 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C29-Bo1347589 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17c9-b01-347589 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17C-B01-347589 | 1 |
| Fagron | Isosorbide dinitrate 40% | 17V29-B01-347589 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18/18-B01-358241 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18/18-B01-359177 | 2 |
| Fagron | Isosorbide dinitrate 40% | 18/18-B01-359178 | 2 |
| Fagron | Isosorbide dinitrate 40% | 18-18-b01-358242 | 2 |
| Fagron | Isosorbide dinitrate 40% | 1818b01359178 | 5 |
| Fagron | Isosorbide dinitrate 40% | 1818B01373439 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1818bo1373439 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J118-B01-363844 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18_B01_358247 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18_B01_373439 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-01-370272 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-01-373438 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18j18-B01 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01 | 20 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-258241 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-263844 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-3395177 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-358241 | 27 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01358242 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-358242 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-358247 | 16 |
| Fagron | Isosorbide dinitrate 40% | 18j18-b01-359177 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01359177 | 2 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-359177 | 39 |
| Fagron | Isosorbide dinitrate 40% | 18J-18-B01-359177 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01359178 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-359178 | 10 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01359579 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01361397 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-3638345 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-b01-363844 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-363844 | 25 |
| Fagron | Isosorbide dinitrate 40% | 18j18-b01-363845 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01363845 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01-363845 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-363845 | 26 |
| Fagron | Isosorbide dinitrate 40% | 18j18-b01-363846 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-363846 | 5 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01365264 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-3702702 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18j18-b01-370272 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01370272 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-370272 | 38 |
| Fagron | Isosorbide dinitrate 40% | 18J18b01373438 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18B01-373438 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-373438 | 12 |
| Fagron | Isosorbide dinitrate 40% | 18J18-B01-373439 | 2 |
| Fagron | Isosorbide dinitrate 40% | 18J18-BO1-359177 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-BO1-3702702 | 1 |
| Fagron | Isosorbide dinitrate 40% | 18J18-BO1-373438 | 2 |
| Fagron | Isosorbide dinitrate 40% | 18J19-B01 | 1 |
| Fagron | Isosorbide dinitrate 40% | 1934469 | 1 |
| Fagron | Isosorbide dinitrate 40% | 193469 | 12 |
| Fagron | Isosorbide dinitrate 40% | 195293 | 26 |
| Fagron | Isosorbide dinitrate 40% | 2114M3516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 2203089 | 8 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-215487 | 14 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-215525 | 8 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-216314 | 14 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-216315 | 1 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-225756 | 1 |
| Fagron | Isosorbide dinitrate 40% | 22D11-B05-225757 | 2 |
| Fagron | Isosorbide dinitrate 40% | 22D11-BO5 | 1 |
| Fagron | Isosorbide dinitrate 40% | 2413Q03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 25021711 | 1 |
| Fagron | Isosorbide dinitrate 40% | 2817E-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 3115M-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 3211U-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 3413U03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 3518M-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 359177 | 2 |
| Fagron | Isosorbide dinitrate 40% | 391311-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 4314U-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 517I-03516 | 1 |
| Fagron | Isosorbide dinitrate 40% | 701319-0001 | 1 |
| Fagron | Isosorbide dinitrate 40% | 7013190003 | 1 |
| Fagron | Isosorbide dinitrate 40% | 8564340 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Isosorbide dinitrate 40% | 9101205 | 1 |
| Fagron | Isosorbide dinitrate 40% | 9E05-N05 | 1 |
| Fagron | Isosorbide dinitrate 40% | B01-3591707 | 3 |
| Fagron | Isosorbide dinitrate 40% | B01-3591708 | 1 |
| Fagron | Isosorbide dinitrate 40% | B01-3638404 | 8 |
| Fagron | Isosorbide dinitrate 40% | B01-3638406 | 2 |
| Fagron | Isosorbide dinitrate 40% | B01-363844 | 1 |
| Fagron | Isosorbide dinitrate 40% | B01-3702702 | 10 |
| Fagron | Isosorbide dinitrate 40% | B01-3734308 | 2 |
| Fagron | Isosorbide dinitrate 40% | B013734309 | 1 |
| Fagron | Isosorbide dinitrate 40% | B01-3734309 | 1 |
| Fagron | Isosorbide dinitrate 40% | B05-2154807 | 1 |
| Fagron | Isosorbide dinitrate 40% | B05-2163104 | 1 |
| Fagron | Isosorbide dinitrate 40% | IN20012021 | 1 |
| Fagron | Isosorbide dinitrate 40% | P11008 | 1 |
| Fagron | Isosorbide dinitrate 40% | testxx | 1 |
| Fagron | Isosorbide dinitrate 40% | X12010 | 1 |
| Fargon / AHD | Isosorbide dinitrate 40% | 18J18-B01-363844 | 1 |
| Fargon/Gehe | Isosorbide dinitrate 40% | 15/10-B01-331286 | 1 |
| Fargon/Gehe | Isosorbide dinitrate 40% | 17C29-B01-339447 | 1 |
| Fargon/Gehe | Isosorbide dinitrate 40% | 17C29-B01-348859 | 1 |
| Fargon/Gehe | Isosorbide dinitrate 40% | 18J18-B01-373438 | 1 |
| Fargon/Noweda | Isosorbide dinitrate 40% | 18j18-B01-359177 | 1 |
| Fargon/Spangro | Isosorbide dinitrate 40% | 195293 | 1 |
| Fargon | Isosorbide dinitrate 40% | 15/10-B01-320081 | 1 |
| Fargon | Isosorbide dinitrate 40% | 17C29-B01 | 1 |
| Fargon | Isosorbide dinitrate 40% | 18J18-B01 | 3 |
| Fargon | Isosorbide dinitrate 40% | 18J18-B01-363845 | 1 |
| Fargron / Gehe | Isosorbide dinitrate 40% | 17C29-B01-339447 | 1 |
| Fiebig 23.05.13 ek: ... | Isosorbide dinitrate 40% | 12F08-N04 | 1 |
| Fiebig | Isosorbide dinitrate 40% | 17C29-B01-350469 | 1 |
| Fiebig | Isosorbide dinitrate 40% | 18j18-b01-358247 | 1 |
| Fiebig | Isosorbide dinitrate 40% | 18J18-B01-359177 | 1 |
| Fiebig | Isosorbide dinitrate 40% | 18J18-B01-363844 | 1 |
| Fiebig | Isosorbide dinitrate 40% | 18J18-B01-363846 | 1 |
| fiebig | Isosorbide dinitrate 40% | 22D11-B05-225756 | 1 |
| Fiebig | Isosorbide dinitrate 40% | 22D11-B05-225756 | 2 |
| Fiebig | Isosorbide dinitrate 40% | bo1-3702702 | 1 |
| Frago/Gehe | Isosorbide dinitrate 40% | 17C29-B01-335070 | 1 |
| Frago/Noweda | Isosorbide dinitrate 40% | 15I10-B01-328577 | 1 |
| Gehe amax | Isosorbide dinitrate 40% | 15I10-B01-331286 | 1 |
| Gehe amax | Isosorbide dinitrate 40% | 18J18-B01-363844 | 1 |
| Gehe amax | Isosorbide dinitrate 40% | 18J18-B01-363845 | 2 |
| Gehe amax | Isosorbide dinitrate 40% | 18J18-B01-370272 | 1 |
| Gehe | Isosorbide dinitrate 40% | 17c29-B01-335070 | 1 |
| GEHE | Isosorbide dinitrate 40% | 17C29-B01-347589 | 1 |
| Gehe | Isosorbide dinitrate 40% | 18J18-B01 | 1 |
| Gehe | Isosorbide dinitrate 40% | 18J18-B01-358241 | 1 |
| Gehe | Isosorbide dinitrate 40% | 18J18-B01-358247 | 1 |
| Gehe | Isosorbide dinitrate 40% | 18J18-B01-373438 | 1 |
| Gehe | Isosorbide dinitrate 40% | 22D11-B05-216314 | 1 |
| Gehe | Isosorbide dinitrate 40% | 22D11-B05-225756 | 1 |
| GEHE | Isosorbide dinitrate 40% | 22D11-B05-225756 | 1 |
| Gehe | Isosorbide dinitrate 40% | 23F19-B04-231383 | 1 |
| Gehe | Isosorbide dinitrate 40% | B01-3702702 | 1 |
| Ichthyol-Gesellschaft | Isosorbide dinitrate 40% | 17C29-B01-335070 | 1 |
| Kehr | Isosorbide dinitrate 40% | 200051401 | 1 |
| Kehr | Isosorbide dinitrate 40% | 22D11-B05-216314 | 1 |
| Kehr | Isosorbide dinitrate 40% | 23F19-B04-231383 | 2 |
| Klosterring | Isosorbide dinitrate 40% | 15I10-B01 | 2 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Krieger | Isosorbide dinitrate 40% | 3186 | 1 |
| L12 | Isosorbide dinitrate 40% | 149168 | 1 |
| L12 | Isosorbide dinitrate 40% | 15I10-B01-331286 | 2 |
| Noweda / Fargon | Isosorbide dinitrate 40% | 18j18-B01 | 1 |
| Noweda | Isosorbide dinitrate 40% | 15/10-B01-315217 | 1 |
| Noweda | Isosorbide dinitrate 40% | 15I10-B01-331287 | 1 |
| Noweda | Isosorbide dinitrate 40% | 17C29-B01-350469 | 1 |
| Noweda | Isosorbide dinitrate 40% | 17C29-B01-352558 | 1 |
| Noweda | Isosorbide dinitrate 40% | 195293 | 1 |
| Noweda | Isosorbide dinitrate 40% | 22D11-B05-225756 | 3 |
| Noweda | Isosorbide dinitrate 40% | 23F19-B04-231383 | 1 |
| Phoenix | Isosorbide dinitrate 40% | 3066 | 1 |
| Phoenix | Isosorbide dinitrate 40% | 3362 | 1 |
| Phönix | Isosorbide dinitrate 40% | 13A07-N13 | 3 |
| Sanacorp | Isosorbide dinitrate 40% | 11J17-N05 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 14D09-B03-294280 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 18J18-B01-358241 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 18J18-B01-358247 | 2 |
| Sanacorp | Isosorbide dinitrate 40% | 18J18-B01-359177 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 18J18-B01-363845 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 18J18-B01-363846 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 193469 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 22d11-b05-215525 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 22D11-B05-216314 | 1 |
| Sanacorp | Isosorbide dinitrate 40% | 22D11-B05-229443 | 2 |
| VDl 28.10.14 10,32 euro | Isosorbide dinitrate 40% | | 1 |
| VDL | Isosorbide dinitrate 40% | 18J18-B01-358247 | 1 |
| Wepa | Isosorbide dinitrate 40% | 14D09-B03-313566 | 1 |

- 255 763 spectra from 1666 *Apo-Ident* customers from a total of 51 875 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Isosorbide dinitrate 40%* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Isosorbide dinitrate 40%* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 229 | 0 | 158 097 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 1106 | 17 | 255 763 |

The substance/substance group *Isosorbide dinitrate 40%* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.3799 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.4862 % (> 98.2191 %) |


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In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20891 | 23200 | 14.51 | 188.62 |
| 21347 | 23200 | 7.57 | 195.07 |
| 23200 | 23200 | 0.00 | 193.11 |
| 23598 | 23200 | 8.33 | 192.25 |
| 24057 | 23200 | 10.30 | 195.35 |
| 27044 | 23200 | 8.29 | 194.85 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Isoxsuprine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22640-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Isoxsuprine hydrochloride; Isoxsuprini hydrochloridum

### Special notes

When selecting the *Isoxsuprine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Isoxsuprine hydrochloride | 7 | 3 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Isoxsuprine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Isoxsuprine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 107.50 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Isoxsuprine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Isoxsuprine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Isoxsuprine hydrochloride | 161770 | 22640 | 40 | 20160818* |
| Caelo | Isoxsuprine hydrochloride | 16177001 | 22735 | 40 | 20160818 |
| Caelo | Isoxsuprine hydrochloride | 181078 | 24252 | 40 | 20180719* |
| Euro OTC | Isoxsuprine hydrochloride | 1503008-01 | 22659 | 40 | 20150430 |
| Euro OTC | Isoxsuprine hydrochloride | 1905019 | 24920 | 40 | 20191128* |
| Euro OTC | Isoxsuprine hydrochloride | 2006035 | 25285 | 40 | 20200706* |
| Fagron | Isoxsuprine hydrochloride | 22I21-B01-233784 | 27051 | 40 | 20230714 |
| Fagron | Isoxsuprine hydrochloride | 22I21-B01-233784 | 27051SI | 20 | 20230714 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 8 reference samples from the substance/substance group *Isoxsuprine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 026 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Isoxsuprine hydrochloride*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Isoxsuprine hydrochloride | 190117 | 24547 | 40 |
| Euro OTC | Isoxsuprine hydrochloride | 2106006 | 25760 | 50 |
| Fagron | Isoxsuprine hydrochloride | 20L09-B12-213682 | 26322 | 30 |
| Fagron | Isoxsuprine hydrochloride | 20L09-B12-213682 | 26322SI | 20 |

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Isoxsuprine hydrochloride*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Isoxsuprine hydrochloride | 1905019-02 | 1 |

- 256 885 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Isoxsuprine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Isoxsuprine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 1 | 0 | 256 885 |

The substance/substance group *Isoxsuprine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9038 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22640 | 22640 | 0.00 | 199.09 |
| 22659 | 22640 | 5.22 | 200.39 |
| 22735 | 22640 | 4.92 | 196.65 |
| 24252 | 24252 | 0.00 | 201.78 |
| 24920 | 24920 | 0.00 | 192.14 |
| 25285 | 25285 | 0.00 | 195.81 |
| 27051 | 22640 | 7.57 | 198.54 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by


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laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ivermectin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006049-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ivermectin; Ivermectinum

### Special notes

When selecting the *Ivermectin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ivermectin | 3 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Ivermectin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ivermectin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 81.17 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ivermectin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ivermectin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ivermectin | 23L22-H07-00747 | 27067 | 40 | 20231228 |
| Fagron | Ivermectin | 23L22-H07-00747 | 27067SI | 20 | 20231228 |
| Fagron | Ivermectin | 24J24-H05-00747 | 27472 | 40 | 20241025 |
| FSA Chemicals | Ivermectin | 23J18-AP24014 | 27217 | 40 | 250301805 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 140 spectra of 4 reference samples from the substance/substance group *Ivermectin*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.
- 158 186 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by


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this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Ivermectin*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Ivermectin | 22E06-H05-00747 | 26404 | 40 |
| Fagron | Ivermectin | 22E06-H05-00747 | 26404SI | 20 |
| FSA Chemicals | Ivermectin | 23J18-AP24014 | 27217SI† | 20 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Ivermectin*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ivermectin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ivermectin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 140 | 0 | 158 186 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Ivermectin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.7143 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 27067 | 27217 | 71.57 | 136.79 |
| 27217 | 27217 | 0.00 | 136.11 |
| 27472 | 27217 | 61.98 | 136.21 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ketamine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20278-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ketamine hydrochloride; Ketamini hydrochloridum

### Special notes

When selecting the *Ketamine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ketamine hydrochloride | 6 | 6 | 99 |

### Second-stage model

For differentiation of the substance/substance group *Ketamine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ketamine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Omeprazole | 115.67 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ketamine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ketamine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Ketamine hydrochloride | 2304005 | 26658 | 40 | 20230419* |
| Fagron | Ketamine hydrochloride | 13H19-N01 | 21044 | 40 | 8931 |
| Fagron | Ketamine hydrochloride | 14I03-B02-303165 | 21779 | 60 | 20140926 |
| Fagron | Ketamine hydrochloride | 14I03-B02-311706 | 22533 | 40 | 20140926 |
| Fagron | Ketamine hydrochloride | 19H14-F02-364305 | 25295 | 40 | 20190918 |
| Fagron | Ketamine hydrochloride | 22F01-F01-385041 | 26909 | 40 | 20230727 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 260 spectra of 6 reference samples from the substance/substance group *Ketamine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 310 spectra of 9 reference samples from the substance/substance group *Ketamine hydrochloride*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Ketamine hydrochloride | 2504006 | 27675 | 40 |
| Fagron | Ketamine hydrochloride | 15E07-B03-322164 | 23201 | 40 |
| Fagron | Ketamine hydrochloride | 16E18-B03-339897 | 23941 | 40 |
| Fagron | Ketamine hydrochloride | 21D30-F02-378537 | 25759 | 40 |
| Gatt-Koller | Ketamine hydrochloride | 23J00824 | 26989 | 40 |
| Gatt-Koller | Ketamine hydrochloride | 23J01507 | 26990 | 40 |
| Euro OTC | Ketamine hydrochloride | 2304005 | 26658SI† | 20 |
| Fagron | Ketamine hydrochloride | 21D30-F02-378537 | 25759SI | 10 |
| Fagron | Ketamine hydrochloride | 22F01-F01-385041 | 26909SI† | 40 |

- 212 630 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 303 spectra from 132 *Apo-Ident* customers from 109 batches from the substance/substance group *Ketamine hydrochloride*.

- Among them are spectra of independent samples from 99 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ketamine hydrochloride | 22F01-385047 | 1 |
| | Ketamine hydrochloride | 22F01-F01-385041 | 9 |
| | Ketamine hydrochloride | 22F01-F01385050 | 1 |
| | Ketamine hydrochloride | 22F01-F01-385050 | 5 |
| | Ketamine hydrochloride | 2304005-01 | 5 |
| | Ketamine hydrochloride | 2304005-02 | 1 |
| | Ketamine hydrochloride | 2304005-03 | 9 |
| | Ketamine hydrochloride | 2304005-04 | 5 |
| | Ketamine hydrochloride | 2304005-05 | 3 |
| | Ketamine hydrochloride | 2304005-5 | 1 |
| | Ketamine hydrochloride | 2IL-13-F02-383873 | 1 |
| | Ketamine hydrochloride | F1-38505000 | 1 |
| | Ketamine hydrochloride | SLL/KH/0624079 | 1 |
| AHD | Ketamine hydrochloride | 2304005-02 | 1 |
| Allergika Pharma / Phönix | Ketamine hydrochloride | 21L13-F02-383872 | 1 |
| Alliance Healthcare | Ketamine hydrochloride | 21L13-F02-383872 | 1 |
| Anzag | Ketamine hydrochloride | 250428(2304005-05) | 1 |
| Caelo | Ketamine hydrochloride | 17K14-B01-355067 | 1 |
| Caelo | Ketamine hydrochloride | 21D30-F02-378863 | 1 |
| Caesar & Loretz GmbH | Ketamine hydrochloride | 700932-0001 | 1 |
| Euro OTC | Ketamine hydrochloride | 21D30-F02-378537 | 2 |
| Euro OTC | Ketamine hydrochloride | 21D3O-F02-378537 | 1 |
| Euro OTC | Ketamine hydrochloride | 2304005-01 | 1 |
| Euro OTC | Ketamine hydrochloride | 2304005-02 | 1 |
| Euro OTC | Ketamine hydrochloride | 2304005-03 | 1 |
| Euro OTC | Ketamine hydrochloride | F04-3734305 | 1 |
| Fagron | Ketamine hydrochloride | /0321025 | 1 |
| Fagron | Ketamine hydrochloride | 14/03-B02-303165 | 1 |
| Fagron | Ketamine hydrochloride | 14/03-B02-309852 | 1 |
| Fagron | Ketamine hydrochloride | 14I03-B02-303165 | 1 |
| Fagron | Ketamine hydrochloride | 14I03-B02-309852 | 1 |
| Fagron | Ketamine hydrochloride | 15E07-B03-322164 | 5 |
| Fagron | Ketamine hydrochloride | 15E07-B03-327604 | 3 |
| Fagron | Ketamine hydrochloride | 16E18-B03 | 1 |
| Fagron | Ketamine hydrochloride | 16E18-B03-328264 | 2 |
| Fagron | Ketamine hydrochloride | 16E18-B03-330627 | 1 |
| Fagron | Ketamine hydrochloride | 16E18-B03-332957 | 3 |
| Fagron | Ketamine hydrochloride | 16E18-B03-334369 | 3 |
| Fagron | Ketamine hydrochloride | 16E18-B03-334370 | 1 |
| Fagron | Ketamine hydrochloride | 16E18-B03-335529 | 1 |
| Fagron | Ketamine hydrochloride | 16e18-b03-339897 | 1 |
| Fagron | Ketamine hydrochloride | 16E18-B03-339897 | 4 |
| Fagron | Ketamine hydrochloride | 16E18-B03-339898 | 1 |
| Fagron | Ketamine hydrochloride | 16E18-B03-345971 | 2 |
| Fagron | Ketamine hydrochloride | 173017P | 3 |
| Fagron | Ketamine hydrochloride | 17K14-B01-347995 | 4 |
| Fagron | Ketamine hydrochloride | 17K14-B01-347996 | 4 |
| Fagron | Ketamine hydrochloride | 17K14-B01-347997 | 1 |
| Fagron | Ketamine hydrochloride | 17K14-B01-3533344 | 1 |
| Fagron | Ketamine hydrochloride | 17K14B01353344 | 1 |
| Fagron | Ketamine hydrochloride | 17K14-B01-353344 | 1 |
| Fagron | Ketamine hydrochloride | 17K14-B01-356831 | 6 |
| Fagron | Ketamine hydrochloride | 17K14-B01-358396 | 8 |
| Fagron | Ketamine hydrochloride | 17K14-B01-358397 | 2 |
| Fagron | Ketamine hydrochloride | 182513P | 1 |
| Fagron | Ketamine hydrochloride | 1867-66-9 | 1 |
| Fagron | Ketamine hydrochloride | 19H14-F02 | 6 |
| Fagron | Ketamine hydrochloride | 19h14-f02-364305 | 1 |
| Fagron | Ketamine hydrochloride | 19H14-F02-364305 | 9 |
| Fagron | Ketamine hydrochloride | 19H14-F02-364306 | 2 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Ketamine hydrochloride | 19H14-F02-3650504 | 1 |
| Fagron | Ketamine hydrochloride | 19H14-F02365054 | 1 |
| Fagron | Ketamine hydrochloride | 19H14-F02-365054 | 6 |
| Fagron | Ketamine hydrochloride | 19H14-F07-3643005 | 1 |
| Fagron | Ketamine hydrochloride | 20A07-F01 | 2 |
| Fagron | Ketamine hydrochloride | 20a07-f01-368076 | 1 |
| Fagron | Ketamine hydrochloride | 20A07-F01368076 | 1 |
| Fagron | Ketamine hydrochloride | 20A07-F01-368076 | 8 |
| Fagron | Ketamine hydrochloride | 20A07-F01-368077 | 5 |
| Fagron | Ketamine hydrochloride | 20A07-F01-368078 | 5 |
| Fagron | Ketamine hydrochloride | 20A07-F01-3697602 | 1 |
| Fagron | Ketamine hydrochloride | 20A07-F01-369762 | 3 |
| Fagron | Ketamine hydrochloride | 20A07-F01-369763 | 3 |
| Fagron | Ketamine hydrochloride | 20G12-F04-373435 | 1 |
| Fagron | Ketamine hydrochloride | 20G13-F04 | 8 |
| Fagron | Ketamine hydrochloride | 20G13-F04-3729706 | 1 |
| Fagron | Ketamine hydrochloride | 20G13-F04-3729707 | 1 |
| Fagron | Ketamine hydrochloride | 20G13-F04-372976 | 1 |
| Fagron | Ketamine hydrochloride | 20G13-F04-372979 | 1 |
| Fagron | Ketamine hydrochloride | 20G13-F04-372981 | 1 |
| Fagron | Ketamine hydrochloride | 20G13-F04-373435 | 4 |
| Fagron | Ketamine hydrochloride | 21D033-F02-378538 | 1 |
| Fagron | Ketamine hydrochloride | 21D03-F02-378537 | 1 |
| Fagron | Ketamine hydrochloride | 21D30-F02 | 6 |
| Fagron | Ketamine hydrochloride | 21D30-F02-378537 | 6 |
| Fagron | Ketamine hydrochloride | 21D30-F02-378538 | 4 |
| Fagron | Ketamine hydrochloride | 21d30-F02-378863 | 1 |
| Fagron | Ketamine hydrochloride | 21D30-F02-378863 | 9 |
| Fagron | Ketamine hydrochloride | 21D30Fo2378537 | 1 |
| Fagron | Ketamine hydrochloride | 21D3OFO2378537 | 1 |
| Fagron | Ketamine hydrochloride | 21L13-F02 | 1 |
| Fagron | Ketamine hydrochloride | 21L13-F02-380925 | 14 |
| Fagron | Ketamine hydrochloride | 21L13-F02-381974 | 10 |
| Fagron | Ketamine hydrochloride | 21L13-F02-383872 | 4 |
| Fagron | Ketamine hydrochloride | 21L13-F02-383873 | 2 |
| Fagron | Ketamine hydrochloride | 21L13-FO2-381974 | 2 |
| Fagron | Ketamine hydrochloride | F0136807006 | 1 |
| Fagron | Ketamine hydrochloride | F01-3680707 | 1 |
| Fagron | Ketamine hydrochloride | F02-3650504 | 1 |
| Fagron | Ketamine hydrochloride | f02-3785307 | 1 |
| Fagron | Ketamine hydrochloride | F02-3785307 | 1 |
| Fagron | Ketamine hydrochloride | F02-3785308 | 1 |
| Fagron | Ketamine hydrochloride | F04-3734305 | 3 |
| Fagron | Ketamine hydrochloride | FO2-3788603 | 1 |
| Fagron | Ketamine hydrochloride | SLL/KH/0321025 | 1 |
| Fagron | Ketamine hydrochloride | SLL/KH/0422074 | 2 |
| Fagron | Ketamine hydrochloride | SLL/KH/0520042 | 3 |
| Fagron | Ketamine hydrochloride | SLL/KH/0719030 | 1 |
| Fagron | Ketamine hydrochloride | SLL/KH71121096 | 1 |
| Fargon/Noweda | Ketamine hydrochloride | 17K14-B01-356831 | 1 |
| Fargron / Gehe | Ketamine hydrochloride | 20G13-F04-373435 | 1 |
| Gatt-Koller | Ketamine hydrochloride | 1803056 | 1 |
| GEHE 27.05.2014 | Ketamine hydrochloride | 13H19-N01 | 1 |
| Gehe | Ketamine hydrochloride | 19H14-F02-364305 | 1 |
| Gehe | Ketamine hydrochloride | 20A07-F01-368077 | 1 |
| Gehe | Ketamine hydrochloride | 20G13-F04-372976 | 1 |
| Gehe | Ketamine hydrochloride | 21D30-F02-378538 | 1 |
| Gehe | Ketamine hydrochloride | 22F01-F01-385041 | 5 |
| Gehe | Ketamine hydrochloride | 24I11-B08-003540 | 1 |
| jenne | Ketamine hydrochloride | 2304005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Ketamine hydrochloride | 14/03-B02-311706 | 1 |
| Noweda | Ketamine hydrochloride | 204005-05 | 1 |
| NOWEDA | Ketamine hydrochloride | 22F01-F01-385041 | 1 |
| Noweda | Ketamine hydrochloride | 2304005-04 | 1 |
| Noweda | Ketamine hydrochloride | 292414P | 1 |
| Phoenix | Ketamine hydrochloride | F01-3680708 | 2 |
| phönix | Ketamine hydrochloride | 14103-B02-311706 | 1 |
| Phönix | Ketamine hydrochloride | 22F01-F01-385041 | 1 |
| Sanacorp | Ketamine hydrochloride | 22F01-F01-385041 | 1 |

- 256 583 spectra from 1666 *Apo-Ident* customers from a total of 52 044 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ketamine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ketamine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 310 | 0 | 212 630 |
| **Type C** | 0 | 300 | 3 | 256 583 |

The substance/substance group *Ketamine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0645 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.0099 % (> 98.0198 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21044 | 21044 | 0.00 | 135.74 |
| 21779 | 21044 | 15.39 | 140.09 |
| 22533 | 21044 | 8.67 | 135.22 |
| 25295 | 26658 | 10.76 | 133.59 |
| 26658 | 26658 | 0.00 | 130.52 |
| 26909 | 21044 | 56.46 | 116.41 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ketoconazole** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20688-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ketoconazole; Ketoconazolum

### Special notes

When selecting the *Ketoconazole* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ketoconazole | 7 | 5 | 85 |

### Second-stage model

For differentiation of the substance/substance group *Ketoconazole* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ketoconazole* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Midazolam hydrochloride | 117.90 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ketoconazole* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ketoconazole*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ketoconazole | 12171007 | 20688 | 30 | 1401554 |
| Caelo | Ketoconazole | 13179612 | 21514 | 60 | 20130613 |
| Caelo | Ketoconazole | 13179612 | 21515 | 60 | 20130613 |
| Caelo | Ketoconazole | 153477 | 24028 | 40 | 20151113* |
| Fagron | Ketoconazole | 12A16-N06 | 20699 | 40 | 20120123 |
| Fagron | Ketoconazole | 16A26-B01-322982 | 23183 | 40 | 20160210 |
| Fagron | Ketoconazole | 20H18-F03-375993 | 25666 | 50 | 20201116 |
| Fagron | Ketoconazole | 24I12-B061 | BR20055 | 40 | 20241010* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 360 spectra of 8 reference samples from the substance/substance group *Ketoconazole*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 290 spectra of 10 reference samples from the substance/substance group *Ketoconazole*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ketoconazole | 20002966003 | 25430 | 40 |
| Fagron | Ketoconazole | 17H14-B01-339422 | 23917 | 40 |
| Fagron | Ketoconazole | 21K18-B06-213329 | 26281 | 40 |
| Fagron | Ketoconazole | 24I11-B020 | BR20053 | 40 |
| Fagron | Ketoconazole | 24H27-B052 | BR20054 | 40 |
| Fagron | Ketoconazole | 20H18-F03-375993 | 25666SI† | 10 |
| Fagron | Ketoconazole | 21K18-B06-213329 | 26281SI | 20 |
| Fagron | Ketoconazole | 24I11-B020 | BR20053SI | 20 |
| Fagron | Ketoconazole | 24H27-B052 | BR20054SI | 20 |
| Fagron | Ketoconazole | 24I12-B061 | BR20055SI† | 20 |

- 212 650 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 299 spectra from 164 *Apo-Ident* customers from 90 batches from the substance/substance group *Ketoconazole*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 85 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ketoconazole | 20003758006 | 3 |
| | Ketoconazole | 20003758008 | 1 |
| | Ketoconazole | 20003758009 | 5 |
| | Ketoconazole | 20003758013 | 2 |
| | Ketoconazole | 20003758017 | 6 |
| | Ketoconazole | 21k18-b06 | 1 |
| | Ketoconazole | 21K18-B06 | 1 |
| | Ketoconazole | 21k18-b06-213329 | 1 |
| | Ketoconazole | 21K18-B06-213329 | 8 |
| | Ketoconazole | 22J01-B03-227246 | 2 |
| | Ketoconazole | 24C05-B09-004823 | 1 |
| | Ketoconazole | 24C05-B09-235964 | 3 |
| | Ketoconazole | B09-2359604 | 1 |
| Alliance Healthcare | Ketoconazole | 20002966003 | 1 |
| ANZAG 23.07.14 | Ketoconazole | 13h09-n07 | 1 |
| Caelo | Ketoconazole | 11070001 | 1 |
| Caelo | Ketoconazole | 11070022 | 1 |
| Caelo | Ketoconazole | 12300406 | 1 |
| Caelo | Ketoconazole | 12300407 | 2 |
| Caelo | Ketoconazole | 13179601 | 2 |
| Caelo | Ketoconazole | 13179606 | 3 |
| Caelo | Ketoconazole | 13179612 | 2 |
| Caelo | Ketoconazole | 13399404 | 8 |
| Caelo | Ketoconazole | 13399408 | 7 |
| Caelo | Ketoconazole | 13399412 | 3 |
| Caelo | Ketoconazole | 14350408 | 4 |
| Caelo | Ketoconazole | 14350416 | 4 |
| Caelo | Ketoconazole | 14350419 | 1 |
| Caelo | Ketoconazole | 14350420 | 2 |
| Caelo | Ketoconazole | 14350421 | 1 |
| Caelo | Ketoconazole | 14350422 | 3 |
| Caelo | Ketoconazole | 14350427 | 2 |
| Caelo | Ketoconazole | 14350429 | 6 |
| Caelo | Ketoconazole | 14350434 | 2 |
| Caelo | Ketoconazole | 14350436 | 4 |
| Caelo | Ketoconazole | 14350437 | 7 |
| Caelo | Ketoconazole | 14350442 | 3 |
| Caelo | Ketoconazole | 14k04-b06-309671 | 1 |
| Caelo | Ketoconazole | 15347701 | 13 |
| Caelo | Ketoconazole | 18007003 | 6 |
| Caelo | Ketoconazole | 18007004 | 2 |
| Caelo | Ketoconazole | 18007011 | 6 |
| Caelo | Ketoconazole | 18007013 | 2 |
| Caelo | Ketoconazole | 18007015 | 7 |
| Caelo | Ketoconazole | 18007016 | 1 |
| Caelo | Ketoconazole | 18007020 | 2 |
| Caelo | Ketoconazole | 1906611 | 1 |
| Caelo | Ketoconazole | 19096601 | 6 |
| Caelo | Ketoconazole | 19096605 | 2 |
| Caelo | Ketoconazole | 19096609 | 1 |
| Caelo | Ketoconazole | 19096611 | 5 |
| Caelo | Ketoconazole | 20002966001 | 1 |
| Caelo | Ketoconazole | 20002966002 | 2 |
| Caelo | Ketoconazole | 20002966003 | 10 |
| Caelo | Ketoconazole | 20003758004 | 4 |
| Caelo | Ketoconazole | 20003758005 | 6 |
| Caelo | Ketoconazole | 20003758006 | 5 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ketoconazole | 20003758009 | 1 |
| Caelo | Ketoconazole | 2003758005 | 1 |
| Caelo | Ketoconazole | 53317046 | 2 |
| Caeolo /Gehe | Ketoconazole | 14350408 | 1 |
| Caesar & Loretz GmbH... | Ketoconazole | 19096601 | 1 |
| Caesar & Loretz GmbH... | Ketoconazole | 20003758004 | 1 |
| Caesar & Loretz GmbH/AHD | Ketoconazole | 19096611 | 1 |
| Caesar & Loretz GmbH/AHD | Ketoconazole | 20003758005 | 1 |
| Caesar & Loretz GmbH... | Ketoconazole | 19096601 | 1 |
| Caesar & Loretz GmbH... | Ketoconazole | 19096611 | 1 |
| Caesar & Loretz GmbH/Gehe | Ketoconazole | 20003758005 | 1 |
| Caesar & Loretz GmbH... | Ketoconazole | 20002966003 | 2 |
| Caesar & Loretz GmbH... | Ketoconazole | 20002966003 | 1 |
| Caesar & Loretz GmbH... | Ketoconazole | 20003758004 | 2 |
| Caesar & Loretz GmbH | Ketoconazole | 18007015 | 4 |
| Caesar & Loretz GmbH | Ketoconazole | 19096601 | 1 |
| Caesar & Loretz GmbH | Ketoconazole | 19096608 | 1 |
| Caesar & Loretz GmbH | Ketoconazole | 19096611 | 2 |
| Caesar & Loretz GmbH | Ketoconazole | 20002966002 | 1 |
| Caesar & Loretz GmbH | Ketoconazole | 20002966003 | 9 |
| Caesar & Loretz GmbH | Ketoconazole | 20003758004 | 4 |
| Caesar & Loretz GmbH | Ketoconazole | 20003758005 | 4 |
| Caesar & Loretz GmbH | Ketoconazole | 20003758006 | 3 |
| Caesar & Loretz/AHD | Ketoconazole | 18007015 | 1 |
| E Plus | Ketoconazole | 14350429 | 1 |
| Euro OTC | Ketoconazole | 13179615 | 1 |
| Fagron | Ketoconazole | 12I17-N02 | 1 |
| Fagron | Ketoconazole | 13179613 | 1 |
| Fagron | Ketoconazole | 13H09-N07 | 1 |
| Fagron | Ketoconazole | 13J23-N04 | 1 |
| Fagron | Ketoconazole | 14E09-B01-293736 | 3 |
| Fagron | Ketoconazole | 14E09-B01-297637 | 2 |
| Fagron | Ketoconazole | 14K04-B06-309671 | 3 |
| Fagron | Ketoconazole | 15G23-B03-312063 | 1 |
| Fagron | Ketoconazole | 15G23-B03-316596 | 2 |
| Fagron | Ketoconazole | 16A26-B01-327490 | 1 |
| Fagron | Ketoconazole | 16A26-B01-335467 | 3 |
| Fagron | Ketoconazole | 17H14-B01-339006 | 1 |
| Fagron | Ketoconazole | 17H14-B01-339422 | 1 |
| Fagron | Ketoconazole | 17H14-B01-344222 | 2 |
| Fagron | Ketoconazole | 17H14-B01-353376 | 1 |
| Fagron | Ketoconazole | 17h14-b01-353378 | 1 |
| Fagron | Ketoconazole | 17H14-B01-353378 | 1 |
| Fagron | Ketoconazole | 18E28-B02-359205 | 2 |
| Fagron | Ketoconazole | 18E28-B02-364169 | 4 |
| Fagron | Ketoconazole | 20h18-F03-375071 | 1 |
| Fagron | Ketoconazole | 20H18-F03-375071 | 2 |
| Fagron | Ketoconazole | 20H18-F03-375073 | 1 |
| Fagron | Ketoconazole | 21K18-B06-213329 | 1 |
| Fagron | Ketoconazole | 21k18-bo6 | 1 |
| Fagron | Ketoconazole | 5015E-02866 | 1 |
| Fagron | Ketoconazole | 700669-0001 | 1 |
| Fagron | Ketoconazole | KET/11707237 | 1 |
| Fagron | Ketoconazole | KET/12007311 | 1 |
| Fargon | Ketoconazole | 17h14b01344222 | 1 |
| Fiebig | Ketoconazole | 14350437 | 1 |
| Fiebig | Ketoconazole | 19096601 | 1 |
| Fiebig | Ketoconazole | 24C05-B09-235964 | 1 |
| Gehe | Ketoconazole | 11070019 | 1 |
| Gehe | Ketoconazole | 14350427 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Ketoconazole | 20003758009 | 1 |
| Noweda | Ketoconazole | 19096601 | 1 |
| Phoenix | Ketoconazole | 19096601 | 1 |
| Phönix/Caesar&Lorenz… | Ketoconazole | 20003758005 | 1 |
| Phönix | Ketoconazole | 12171018 | 1 |
| Phönix | Ketoconazole | 13179602 | 3 |
| Phönix | Ketoconazole | 18007003 | 1 |
| Sanacorp Stralsund | Ketoconazole | 20003758005 | 1 |
| Sanacorp | Ketoconazole | 20003758006 | 3 |

- 256 587 spectra from 1666 *Apo-Ident* customers from a total of 52 063 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ketoconazole* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ketoconazole* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 290 | 0 | 212 650 |
| **Type C** | 0 | 297 | 2 | 256 587 |

The substance/substance group *Ketoconazole* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.9310 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.3311 % (> 98.3278 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20688 | 20688 | 0.00 | 206.09 |
| 20699 | 24028 | 12.35 | 210.95 |
| 21514 | 24028 | 10.43 | 210.91 |
| 21515 | 24028 | 19.49 | 206.62 |
| 23183 | BR20055 | 9.00 | 210.87 |
| 24028 | 24028 | 0.00 | 212.76 |
| 25666 | BR20055 | 11.42 | 202.78 |
| BR20055 | BR20055 | 0.00 | 206.20 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ketoprofen** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21813-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ketoprofen; Ketoprofenum

### Special notes

When selecting the *Ketoprofen* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ketoprofen | 4 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Ketoprofen* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ketoprofen* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Pheniramine maleate | 78.87 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ketoprofen* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ketoprofen*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ketoprofen | 24J30-B16-003838 | 27567 | 40 | 20241121 |
| Fagron | Ketoprofen | 24J30-B17-005474 | 27568 | 40 | 20241129 |
| Fagron | Ketoprofen | 24J30-B17-005474 | 27568SI | 20 | 20241129 |
| Fagron | Ketoprofen | 24I26-B042 | BR20086 | 40 | 20241029* |
| Inresa | Ketoprofen | F1300183 | 21813 | 60 | AR-15-FG-009572-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 5 reference samples from the substance/substance group *Ketoprofen*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 126 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 100 spectra of 3 reference samples from the substance/substance group *Ketoprofen*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Inresa | Ketoprofen | F1300182 | 22310 | 60 |
| Fagron | Ketoprofen | 24J30-B16-003838 | 27567SI† | 20 |
| Fagron | Ketoprofen | 24I26-B042 | BR20086SI† | 20 |

- 212 840 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Ketoprofen*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

### Validation results

The validation runs checked whether the substance/substance group *Ketoprofen* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ketoprofen* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 100 | 0 | 212 840 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Ketoprofen* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 94.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21813 | 21813 | 0.00 | 129.91 |
| 27567 | 21813 | 10.44 | 130.20 |
| 27568 | 21813 | 10.00 | 131.74 |
| BR20086 | BR20086 | 0.00 | 138.09 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Lactose monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20029-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Lactose monohydrate; Lactosum monohydricum

### Special notes

When selecting the *Lactose monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Lactose monohydrate | 6 | 15 | 533 |

### Second-stage model

For differentiation of the substance/substance group *Lactose monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Lactose monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 48.55 | – |
| Thyroid | 57.07 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Lactose monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Lactose monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Lactose monohydrate | 12139910 | 20685 | 30 | 20120606 |
| Caelo | Lactose monohydrate | 14025601 | 21525 | 40 | 20140207 |
| Caelo | Lactose monohydrate | 14025601 | 21526 | 40 | 20140207 |
| Caelo | Lactose monohydrate | 14025601 | 21527 | 40 | 20140207 |
| Caelo | Lactose monohydrate | 14025601 | 21528 | 40 | 20140207 |
| Caelo | Lactose monohydrate | 14025601 | 21529 | 40 | 20140207 |
| Caelo | Lactose monohydrate | 160277 | 22460 | 60 | 20160321* |
| Euro OTC | Lactose monohydrate | 1509030 | 21935 | 60 | 20151013* |
| Euro OTC | Lactose monohydrate | 1606025 | 22701 | 40 | 20160628* |
| Euro OTC | Lactose monohydrate | 1909014 | 24929 | 40 | 20191015* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 430 spectra of 10 reference samples from the substance/substance group *Lactose monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 896 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 660 spectra of 18 reference samples from the substance/substance group *Lactose monohydrate*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Lactose monohydrate | 15236220 | 22584 | 40 |
| Caelo | Lactose monohydrate | 173360 | 23828 | 40 |
| Caelo | Lactose monohydrate | 192364 | 25233 | 40 |
| Caelo | Lactose monohydrate | 191376 | 25234 | 40 |
| Caelo | Lactose monohydrate | 21001507 | 25804 | 50 |
| Caelo | Lactose monohydrate | 23001015 | 26694 | 40 |
| Caelo | Lactose monohydrate | 24001886 | 27332 | 40 |
| Euro OTC | Lactose monohydrate | 1703019 | 23141 | 40 |
| Euro OTC | Lactose monohydrate | 1802002 | 23962 | 40 |
| Euro OTC | Lactose monohydrate | 1812008 | 24415 | 40 |
| Euro OTC | Lactose monohydrate | 2005026 | 25275 | 40 |
| Euro OTC | Lactose monohydrate | 2201013 | 25952 | 40 |
| Euro OTC | Lactose monohydrate | 2208008 | 26277 | 40 |
| Euro OTC | Lactose monohydrate | 2309012 | 27012 | 40 |
| Euro OTC | Lactose monohydrate | 2411005 | 27516 | 40 |
| Caelo | Lactose monohydrate | 23001015 | 26694SI | 20 |
| Euro OTC | Lactose monohydrate | 2201013 | 25952SI | 10 |
| Euro OTC | Lactose monohydrate | 2208008 | 26277SI | 20 |

- 212 280 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information

provided by the customer regarding manufacturer and batch number.

- 2641 spectra from 724 *Apo-Ident* customers from 539 batches from the substance/substance group *Lactose monohydrate*.
- Among them are spectra of independent samples from 533 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Lactose monohydrate | 14025604 | 1 |
| | Lactose monohydrate | 2005026-02 | 1 |
| | Lactose monohydrate | 21001507003 | 1 |
| | Lactose monohydrate | 22000736005 | 1 |
| | Lactose monohydrate | 22000736007 | 1 |
| | Lactose monohydrate | 22000736008 | 3 |
| | Lactose monohydrate | 22000736010 | 1 |
| | Lactose monohydrate | 22000736011 | 3 |
| | Lactose monohydrate | 22000736012 | 2 |
| | Lactose monohydrate | 22000736016 | 2 |
| | Lactose monohydrate | 22000736018 | 6 |
| | Lactose monohydrate | 2208008-01 | 2 |
| | Lactose monohydrate | 2208008-02 | 1 |
| | Lactose monohydrate | 2208008-03 | 1 |
| | Lactose monohydrate | 23001015001 | 11 |
| | Lactose monohydrate | 23001015002 | 1 |
| | Lactose monohydrate | 23001015003 | 15 |
| | Lactose monohydrate | 23001015004 | 12 |
| | Lactose monohydrate | 23001015007 | 9 |
| | Lactose monohydrate | 23002236002 | 22 |
| | Lactose monohydrate | 23002236003 | 14 |
| | Lactose monohydrate | 23002236005 | 11 |
| | Lactose monohydrate | 23003217001 | 11 |
| | Lactose monohydrate | 23003217003 | 9 |
| | Lactose monohydrate | 23003217004 | 10 |
| | Lactose monohydrate | 23003217005 | 7 |
| | Lactose monohydrate | 23003217008 | 1 |
| | Lactose monohydrate | 23003217009 | 5 |
| | Lactose monohydrate | 2303217005 | 1 |
| | Lactose monohydrate | 230901201 | 1 |
| | Lactose monohydrate | 2309012-01 | 10 |
| | Lactose monohydrate | 2309012-02 | 1 |
| | Lactose monohydrate | 24001474002 | 5 |
| | Lactose monohydrate | 24001474003 | 5 |
| | Lactose monohydrate | 24001886001 | 1 |
| | Lactose monohydrate | 24001886006 | 1 |
| | Lactose monohydrate | 309351/0 | 1 |
| | Lactose monohydrate | 309508/0 | 1 |
| 07.02.19 Phoenix | Lactose monohydrate | 1802002-01 | 3 |
| A.H.D. | Lactose monohydrate | 12336801 | 1 |
| AEP | Lactose monohydrate | 18198007 | 2 |
| AHD | Lactose monohydrate | 13I23-B03-291114 | 1 |
| AHD | Lactose monohydrate | 15236220 | 1 |
| AHD | Lactose monohydrate | 192364002 | 1 |
| AHD | Lactose monohydrate | 22000736017 | 1 |
| AHD | Lactose monohydrate | 23001015001 | 1 |
| AHD | Lactose monohydrate | 23003217005 | 1 |
| Alliance H. | Lactose monohydrate | C12H22011 | 1 |
| Alliance Healthcare | Lactose monohydrate | 22000736005 | 1 |
| Alliance | Lactose monohydrate | 20004200007 | 1 |
| Alliance | Lactose monohydrate | 22000736018 | 4 |
| Alliance | Lactose monohydrate | 23001015003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance | Lactose monohydrate | 23003217004 | 1 |
| Alliance | Lactose monohydrate | 23003217009 | 1 |
| Alte Apotheke | Lactose monohydrate | 16027708 | 1 |
| Anzag / Noweda | Lactose monohydrate | 12336815 | 1 |
| Anzag 29.11.12 ek:7,51 | Lactose monohydrate | 12139914 | 1 |
| Anzag/Fragon | Lactose monohydrate | 1005SLP | 1 |
| Anzag | Lactose monohydrate | 192364014 | 1 |
| api-ident | Lactose monohydrate | 17078312 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 120614 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 120808 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 121119 | 2 |
| Bahnhof-Apotheke | Lactose monohydrate | 130115 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 130729 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 130911 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 130925 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 131023 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 131112 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 131127 | 2 |
| Bahnhof-Apotheke | Lactose monohydrate | 131218 | 2 |
| Bahnhof-Apotheke | Lactose monohydrate | 140113 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 140206 | 2 |
| Bahnhof-Apotheke | Lactose monohydrate | 140220 | 1 |
| Bahnhof-Apotheke | Lactose monohydrate | 140310 | 2 |
| Bahnhof-Apotheke | Lactose monohydrate | 140612 | 3 |
| Bahnhof-Apotheke | Lactose monohydrate | 140630 | 1 |
| Bahnhofsapotheke | Lactose monohydrate | 140401 | 1 |
| Bären Apotheke | Lactose monohydrate | 16231206 | 1 |
| Bombastus | Lactose monohydrate | 13299108 | 1 |
| Bombastus | Lactose monohydrate | 17000754 | 1 |
| Bombastus | Lactose monohydrate | 17001199 | 1 |
| Bombastus | Lactose monohydrate | 17001212 | 1 |
| Bombastus | Lactose monohydrate | 17078302 | 1 |
| Bombastus | Lactose monohydrate | 272680/0 | 1 |
| Bombastus | Lactose monohydrate | 274926 | 1 |
| Bombastus | Lactose monohydrate | 275194/0 | 1 |
| Bombastus | Lactose monohydrate | 275225/0 | 1 |
| Bombastus | Lactose monohydrate | 282648 | 1 |
| Bombastus | Lactose monohydrate | 282696/0 | 1 |
| Bombastus | Lactose monohydrate | 283992 | 2 |
| Bombastus | Lactose monohydrate | 284321/0 | 1 |
| Bombastus | Lactose monohydrate | 285087/0 | 1 |
| Bombastus | Lactose monohydrate | 286354 | 1 |
| Bombastus | Lactose monohydrate | 286697/0 | 1 |
| Bombastus | Lactose monohydrate | 286710 | 1 |
| Bombastus | Lactose monohydrate | 288015/0 | 1 |
| Bombastus | Lactose monohydrate | 288927 | 1 |
| Bombastus | Lactose monohydrate | 289238 | 1 |
| Bombastus | Lactose monohydrate | 291464 | 1 |
| Bombastus | Lactose monohydrate | 292982 | 2 |
| Bombastus | Lactose monohydrate | 292983 | 1 |
| Bombastus | Lactose monohydrate | 292995 | 1 |
| Bombastus | Lactose monohydrate | 292996 | 1 |
| Bombastus | Lactose monohydrate | 293074 | 1 |
| Bombastus | Lactose monohydrate | 2932880 | 1 |
| Bombastus | Lactose monohydrate | 293289 | 1 |
| Bombastus | Lactose monohydrate | 293290 | 1 |
| Bombastus | Lactose monohydrate | 293649 | 1 |
| Bombastus | Lactose monohydrate | 293918/0 | 1 |
| Bombastus | Lactose monohydrate | 293970 | 1 |
| Bombastus | Lactose monohydrate | 294154 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Lactose monohydrate | 294184/0 | 1 |
| Bombastus | Lactose monohydrate | 294897/0 | 1 |
| Bombastus | Lactose monohydrate | 295011/0 | 1 |
| Bombastus | Lactose monohydrate | 295476 | 1 |
| Bombastus | Lactose monohydrate | 295714 | 1 |
| Bombastus | Lactose monohydrate | 295715 | 1 |
| Bombastus | Lactose monohydrate | 300657 | 2 |
| Bombastus | Lactose monohydrate | 3020165 | 1 |
| Bombastus | Lactose monohydrate | 303658 | 2 |
| Bombastus | Lactose monohydrate | 304755 | 1 |
| Bombastus | Lactose monohydrate | 305227 | 2 |
| Bombastus | Lactose monohydrate | 305227/0 | 1 |
| Bombastus | Lactose monohydrate | 305336 | 2 |
| Bombastus | Lactose monohydrate | 305336/0 | 1 |
| Bombastus | Lactose monohydrate | 306147 | 3 |
| Bombastus | Lactose monohydrate | 306651/0 | 1 |
| Bombastus | Lactose monohydrate | 306652 | 1 |
| Bombastus | Lactose monohydrate | 306850 | 1 |
| Bombastus | Lactose monohydrate | 306964 | 1 |
| Bombastus | Lactose monohydrate | 306989 | 2 |
| Bombastus | Lactose monohydrate | 306990 | 1 |
| Bombastus | Lactose monohydrate | 307444/0 | 1 |
| Bombastus | Lactose monohydrate | 307543 | 2 |
| Bombastus | Lactose monohydrate | 307573/0 | 1 |
| Bombastus | Lactose monohydrate | 307702/0 | 1 |
| Bombastus | Lactose monohydrate | 307741 | 1 |
| Bombastus | Lactose monohydrate | 3077410 | 1 |
| Bombastus | Lactose monohydrate | 307976/0 | 1 |
| Bombastus | Lactose monohydrate | 308117 | 1 |
| Bombastus | Lactose monohydrate | 308117/0 | 1 |
| Bombastus | Lactose monohydrate | 308118/0 | 1 |
| Bombastus | Lactose monohydrate | 308438 | 1 |
| Bombastus | Lactose monohydrate | 309351 | 1 |
| Bombastus | Lactose monohydrate | 309413/0 | 1 |
| Bombastus | Lactose monohydrate | 309508 | 1 |
| Bombastus | Lactose monohydrate | 309509 | 1 |
| Bombastus | Lactose monohydrate | 309509/0 | 1 |
| Bombastus | Lactose monohydrate | 310082/0 | 1 |
| Bombastus | Lactose monohydrate | 310691 | 1 |
| Bombastus | Lactose monohydrate | 310691/0 | 1 |
| Bombastus | Lactose monohydrate | 310905 | 1 |
| Bombastus | Lactose monohydrate | 310905/0 | 1 |
| Bombastus | Lactose monohydrate | 310912/0 | 1 |
| Bombastus | Lactose monohydrate | 311280 | 1 |
| Bombastus | Lactose monohydrate | 311280/0 | 1 |
| Bombastus | Lactose monohydrate | 311362/0 | 1 |
| C21001507004aelo/Gehe | Lactose monohydrate | 21001507004 | 1 |
| Caelo | Lactose monohydrate | | 3 |
| Caelo | Lactose monohydrate | 10071701 | 1 |
| Caelo | Lactose monohydrate | 10195107 | 2 |
| Caelo | Lactose monohydrate | 1071302 | 1 |
| Caelo | Lactose monohydrate | 1090216 | 1 |
| Caelo | Lactose monohydrate | 11014714 | 1 |
| Caelo | Lactose monohydrate | 11041801 | 1 |
| Caelo | Lactose monohydrate | 1106022-02 | 1 |
| Caelo | Lactose monohydrate | 11079002 | 2 |
| Caelo | Lactose monohydrate | 112192 | 2 |
| Caelo | Lactose monohydrate | 11219207 | 1 |
| Caelo | Lactose monohydrate | 11219208 | 3 |
| Caelo | Lactose monohydrate | 11219216 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lactose monohydrate | 12021502 | 1 |
| Caelo | Lactose monohydrate | 12021508 | 1 |
| Caelo | Lactose monohydrate | 12021518 | 5 |
| Caelo | Lactose monohydrate | 12041401 | 1 |
| Caelo | Lactose monohydrate | 12139901 | 2 |
| Caelo | Lactose monohydrate | 12139908 | 1 |
| Caelo | Lactose monohydrate | 12139909 | 1 |
| Caelo | Lactose monohydrate | 12139910 | 1 |
| Caelo | Lactose monohydrate | 12139912 | 1 |
| Caelo | Lactose monohydrate | 12139914 | 6 |
| Caelo | Lactose monohydrate | 12139915 | 4 |
| Caelo | Lactose monohydrate | 12139920 | 6 |
| Caelo | Lactose monohydrate | 12336801 | 7 |
| Caelo | Lactose monohydrate | 12336814 | 1 |
| Caelo | Lactose monohydrate | 12336815 | 9 |
| Caelo | Lactose monohydrate | 12336816 | 3 |
| Caelo | Lactose monohydrate | 12336820 | 2 |
| Caelo | Lactose monohydrate | 123446test | 1 |
| Caelo | Lactose monohydrate | 123456 | 1 |
| Caelo | Lactose monohydrate | 123456test | 1 |
| Caelo | Lactose monohydrate | 12345test | 1 |
| Caelo | Lactose monohydrate | 1234test | 1 |
| Caelo | Lactose monohydrate | 12399107 | 1 |
| Caelo | Lactose monohydrate | 123test | 6 |
| Caelo | Lactose monohydrate | 123Test | 4 |
| Caelo | Lactose monohydrate | 1301C005 | 2 |
| Caelo | Lactose monohydrate | 13081302 | 1 |
| Caelo | Lactose monohydrate | 13104901 | 7 |
| Caelo | Lactose monohydrate | 13104902 | 7 |
| Caelo | Lactose monohydrate | 13104908 | 2 |
| Caelo | Lactose monohydrate | 13104909 | 5 |
| Caelo | Lactose monohydrate | 13104909-3422310182 | 1 |
| Caelo | Lactose monohydrate | 13104909-3453311172 | 1 |
| Caelo | Lactose monohydrate | 13104910 | 2 |
| Caelo | Lactose monohydrate | 13104911 | 2 |
| Caelo | Lactose monohydrate | 13104912 | 1 |
| Caelo | Lactose monohydrate | 13299101 | 9 |
| Caelo | Lactose monohydrate | 13299102 | 12 |
| Caelo | Lactose monohydrate | 13299103 | 1 |
| Caelo | Lactose monohydrate | 13299107 | 5 |
| Caelo | Lactose monohydrate | 13299108 | 5 |
| Caelo | Lactose monohydrate | 1401003-01 | 1 |
| Caelo | Lactose monohydrate | 1402504 | 1 |
| Caelo | Lactose monohydrate | 14025601 | 3 |
| Caelo | Lactose monohydrate | 14025603 | 7 |
| Caelo | Lactose monohydrate | 14025604 | 6 |
| Caelo | Lactose monohydrate | 14025608 | 2 |
| Caelo | Lactose monohydrate | 14025615 | 1 |
| Caelo | Lactose monohydrate | 14025616 | 6 |
| Caelo | Lactose monohydrate | 14025619 | 3 |
| Caelo | Lactose monohydrate | 14025620 | 15 |
| Caelo | Lactose monohydrate | 14140302 | 4 |
| Caelo | Lactose monohydrate | 14140304 | 2 |
| Caelo | Lactose monohydrate | 14140305 | 8 |
| Caelo | Lactose monohydrate | 14140308 | 7 |
| Caelo | Lactose monohydrate | 14140309 | 2 |
| Caelo | Lactose monohydrate | 14140312 | 14 |
| Caelo | Lactose monohydrate | 14333501 | 3 |
| Caelo | Lactose monohydrate | 14333502 | 2 |
| Caelo | Lactose monohydrate | 14333503 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lactose monohydrate | 14333508 | 1 |
| Caelo | Lactose monohydrate | 14333509 | 10 |
| Caelo | Lactose monohydrate | 14333510 | 1 |
| Caelo | Lactose monohydrate | 14333511 | 5 |
| Caelo | Lactose monohydrate | 143335114 | 1 |
| Caelo | Lactose monohydrate | 14333513 | 7 |
| Caelo | Lactose monohydrate | 14333514 | 1 |
| Caelo | Lactose monohydrate | 14333518 | 4 |
| Caelo | Lactose monohydrate | 14333520 | 10 |
| Caelo | Lactose monohydrate | 14333521 | 8 |
| Caelo | Lactose monohydrate | 14333525 | 1 |
| Caelo | Lactose monohydrate | 14333528 | 2 |
| Caelo | Lactose monohydrate | 1433502 | 1 |
| Caelo | Lactose monohydrate | 1433510 | 1 |
| Caelo | Lactose monohydrate | 1433518 | 2 |
| Caelo | Lactose monohydrate | 1433520 | 1 |
| Caelo | Lactose monohydrate | 1433521 | 1 |
| Caelo | Lactose monohydrate | 1501017-01 | 4 |
| Caelo | Lactose monohydrate | 15011701 | 1 |
| Caelo | Lactose monohydrate | 15081701 | 1 |
| Caelo | Lactose monohydrate | 150903002 | 1 |
| Caelo | Lactose monohydrate | 1509030-02 | 1 |
| Caelo | Lactose monohydrate | 1523614 | 1 |
| Caelo | Lactose monohydrate | 152362 | 2 |
| Caelo | Lactose monohydrate | 15236201 | 28 |
| Caelo | Lactose monohydrate | 15236202 | 1 |
| Caelo | Lactose monohydrate | 15236203 | 5 |
| Caelo | Lactose monohydrate | 15236204 | 11 |
| Caelo | Lactose monohydrate | 15236206 | 1 |
| Caelo | Lactose monohydrate | 15236208 | 13 |
| Caelo | Lactose monohydrate | 15236209 | 12 |
| Caelo | Lactose monohydrate | 15236209I-060616/1 | 1 |
| Caelo | Lactose monohydrate | 15236210 | 2 |
| Caelo | Lactose monohydrate | 15236213 | 2 |
| Caelo | Lactose monohydrate | 15236214 | 9 |
| Caelo | Lactose monohydrate | 15236215 | 5 |
| Caelo | Lactose monohydrate | 15236217 | 1 |
| Caelo | Lactose monohydrate | 15236220 | 5 |
| Caelo | Lactose monohydrate | 15236221 | 7 |
| Caelo | Lactose monohydrate | 1526201 | 1 |
| Caelo | Lactose monohydrate | 1565555 | 1 |
| Caelo | Lactose monohydrate | 16027701 | 6 |
| Caelo | Lactose monohydrate | 16027702 | 9 |
| Caelo | Lactose monohydrate | 16027703 | 6 |
| Caelo | Lactose monohydrate | 16027704 | 3 |
| Caelo | Lactose monohydrate | 16027705 | 1 |
| Caelo | Lactose monohydrate | 16027706 | 7 |
| Caelo | Lactose monohydrate | 16027707 | 2 |
| Caelo | Lactose monohydrate | 16027708 | 12 |
| Caelo | Lactose monohydrate | 16027726 | 1 |
| Caelo | Lactose monohydrate | 1606025-01 | 2 |
| Caelo | Lactose monohydrate | 1606025-1 | 1 |
| Caelo | Lactose monohydrate | 160913PJK01 | 1 |
| Caelo | Lactose monohydrate | 16091710 | 1 |
| Caelo | Lactose monohydrate | 162310206 | 1 |
| Caelo | Lactose monohydrate | 16231201 | 10 |
| Caelo | Lactose monohydrate | 16231202 | 20 |
| Caelo | Lactose monohydrate | 16231203 | 4 |
| Caelo | Lactose monohydrate | 16231206 | 7 |
| Caelo | Lactose monohydrate | 16231207 | 12 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lactose monohydrate | 16231208 | 5 |
| Caelo | Lactose monohydrate | 1623120803815470 | 1 |
| Caelo | Lactose monohydrate | 16231211 | 27 |
| Caelo | Lactose monohydrate | 16231212 | 10 |
| Caelo | Lactose monohydrate | 16231213 | 4 |
| Caelo | Lactose monohydrate | 162312135465 | 1 |
| Caelo | Lactose monohydrate | 16231214 | 6 |
| Caelo | Lactose monohydrate | 16231215 | 5 |
| Caelo | Lactose monohydrate | 16321202 | 1 |
| Caelo | Lactose monohydrate | 17011301 | 1 |
| Caelo | Lactose monohydrate | 1703019-020 | 1 |
| Caelo | Lactose monohydrate | 17078302 | 11 |
| Caelo | Lactose monohydrate | 17078303 | 39 |
| Caelo | Lactose monohydrate | 17078303-20180619Ma2 | 1 |
| Caelo | Lactose monohydrate | 17078306 | 11 |
| Caelo | Lactose monohydrate | 17078307 | 8 |
| Caelo | Lactose monohydrate | 17078312 | 25 |
| Caelo | Lactose monohydrate | 17321001 | 38 |
| Caelo | Lactose monohydrate | 173210016 | 1 |
| Caelo | Lactose monohydrate | 17321002 | 5 |
| Caelo | Lactose monohydrate | 17321004 | 9 |
| Caelo | Lactose monohydrate | 17321005 | 4 |
| Caelo | Lactose monohydrate | 17321006 | 1 |
| Caelo | Lactose monohydrate | 1733008 | 1 |
| Caelo | Lactose monohydrate | 17336001 | 1 |
| Caelo | Lactose monohydrate | 17336002 | 16 |
| Caelo | Lactose monohydrate | 17336005 | 12 |
| Caelo | Lactose monohydrate | 17336007 | 47 |
| Caelo | Lactose monohydrate | 17336008 | 20 |
| Caelo | Lactose monohydrate | 17336009 | 12 |
| Caelo | Lactose monohydrate | 17336013 | 20 |
| Caelo | Lactose monohydrate | 17336014 | 14 |
| Caelo | Lactose monohydrate | 1733609 | 1 |
| Caelo | Lactose monohydrate | 1802002-01 | 1 |
| Caelo | Lactose monohydrate | 18169016P-191115-2 | 1 |
| Caelo | Lactose monohydrate | 1818003 | 1 |
| Caelo | Lactose monohydrate | 18192001 | 1 |
| Caelo | Lactose monohydrate | 18196004 | 1 |
| Caelo | Lactose monohydrate | 18196023 | 2 |
| Caelo | Lactose monohydrate | 18198001 | 20 |
| Caelo | Lactose monohydrate | 18198002 | 12 |
| Caelo | Lactose monohydrate | 18198003 | 4 |
| Caelo | Lactose monohydrate | 18198005 | 1 |
| Caelo | Lactose monohydrate | 18198006 | 18 |
| Caelo | Lactose monohydrate | 18198007 | 24 |
| Caelo | Lactose monohydrate | 18198008 | 4 |
| Caelo | Lactose monohydrate | 18198009 | 1 |
| Caelo | Lactose monohydrate | 18198013 | 13 |
| Caelo | Lactose monohydrate | 18198014 | 11 |
| Caelo | Lactose monohydrate | 18198015 | 3 |
| Caelo | Lactose monohydrate | 18198016 | 25 |
| Caelo | Lactose monohydrate | 18198016P-191227-1 | 1 |
| Caelo | Lactose monohydrate | 18198017 | 6 |
| Caelo | Lactose monohydrate | 18198018 | 9 |
| Caelo | Lactose monohydrate | 18198023 | 22 |
| Caelo | Lactose monohydrate | 19137601 | 13 |
| Caelo | Lactose monohydrate | 19137601P-200303-1 | 1 |
| Caelo | Lactose monohydrate | 19137601P-200612-1 | 1 |
| Caelo | Lactose monohydrate | 19137602 | 7 |
| Caelo | Lactose monohydrate | 1922364001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lactose monohydrate | 192346002 | 1 |
| Caelo | Lactose monohydrate | 192354015 | 1 |
| Caelo | Lactose monohydrate | 19236009 | 1 |
| Caelo | Lactose monohydrate | 192364001 | 6 |
| Caelo | Lactose monohydrate | 192364002 | 17 |
| Caelo | Lactose monohydrate | 192364003 | 11 |
| Caelo | Lactose monohydrate | 192364008 | 5 |
| Caelo | Lactose monohydrate | 192364009 | 15 |
| Caelo | Lactose monohydrate | 192364011 | 27 |
| Caelo | Lactose monohydrate | 192364012 | 18 |
| Caelo | Lactose monohydrate | 192364014 | 9 |
| Caelo | Lactose monohydrate | 192364015 | 16 |
| Caelo | Lactose monohydrate | 192364016 | 4 |
| Caelo | Lactose monohydrate | 19236403 | 30 |
| Caelo | Lactose monohydrate | 2000400007 | 1 |
| Caelo | Lactose monohydrate | 20004200001 | 6 |
| Caelo | Lactose monohydrate | 20004200003 | 1 |
| Caelo | Lactose monohydrate | 20004200004 | 20 |
| Caelo | Lactose monohydrate | 20004200005 | 9 |
| Caelo | Lactose monohydrate | 20004200006 | 6 |
| Caelo | Lactose monohydrate | 20004200007 | 4 |
| Caelo | Lactose monohydrate | 20004200009 | 6 |
| Caelo | Lactose monohydrate | 2000420004 | 3 |
| Caelo | Lactose monohydrate | 2000420005 | 1 |
| Caelo | Lactose monohydrate | 20021411 | 1 |
| Caelo | Lactose monohydrate | 200415HJK02 | 1 |
| Caelo | Lactose monohydrate | 2011901 | 1 |
| Caelo | Lactose monohydrate | 201910028 | 1 |
| Caelo | Lactose monohydrate | 20223445 | 1 |
| Caelo | Lactose monohydrate | 2051702 | 1 |
| Caelo | Lactose monohydrate | 21001507003 | 17 |
| Caelo | Lactose monohydrate | 21001507004 | 14 |
| Caelo | Lactose monohydrate | 21001507005 | 4 |
| Caelo | Lactose monohydrate | 21001507008 | 2 |
| Caelo | Lactose monohydrate | 2100843006 | 1 |
| Caelo | Lactose monohydrate | 21071801 | 1 |
| Caelo | Lactose monohydrate | 21111813 | 1 |
| Caelo | Lactose monohydrate | 220000736007 | 1 |
| Caelo | Lactose monohydrate | 220000736017 | 1 |
| Caelo | Lactose monohydrate | 22000736001 | 5 |
| Caelo | Lactose monohydrate | 22000736003 | 7 |
| Caelo | Lactose monohydrate | 22000736005 | 8 |
| Caelo | Lactose monohydrate | 22000736006 | 6 |
| Caelo | Lactose monohydrate | 22000736007 | 9 |
| Caelo | Lactose monohydrate | 22000736008 | 5 |
| Caelo | Lactose monohydrate | 22000736009 | 3 |
| Caelo | Lactose monohydrate | 22000736010 | 4 |
| Caelo | Lactose monohydrate | 22000736011 | 5 |
| Caelo | Lactose monohydrate | 22000736012 | 2 |
| Caelo | Lactose monohydrate | 22000736016 | 1 |
| Caelo | Lactose monohydrate | 22000736017 | 1 |
| Caelo | Lactose monohydrate | 220401LM | 1 |
| Caelo | Lactose monohydrate | 23001015002 | 1 |
| Caelo | Lactose monohydrate | 23001015003 | 3 |
| Caelo | Lactose monohydrate | 23001015007 | 1 |
| Caelo | Lactose monohydrate | 23002236003 | 2 |
| Caelo | Lactose monohydrate | 23002236005 | 1 |
| Caelo | Lactose monohydrate | 23003217004 | 2 |
| Caelo | Lactose monohydrate | 23051501 | 1 |
| Caelo | Lactose monohydrate | 23061504 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lactose monohydrate | 23101404 | 1 |
| Caelo | Lactose monohydrate | 24011405 | 1 |
| Caelo | Lactose monohydrate | 26061801 | 1 |
| Caelo | Lactose monohydrate | 26071401 | 1 |
| Caelo | Lactose monohydrate | 27101702 | 1 |
| Caelo | Lactose monohydrate | 2901312210 | 1 |
| Caelo | Lactose monohydrate | 30031503 | 1 |
| Caelo | Lactose monohydrate | 30081801 | 1 |
| Caelo | Lactose monohydrate | 30101201 | 1 |
| Caelo | Lactose monohydrate | 3031501 | 1 |
| Caelo | Lactose monohydrate | 3091405 | 1 |
| Caelo | Lactose monohydrate | 3121406 | 1 |
| Caelo | Lactose monohydrate | 3295 | 1 |
| Caelo | Lactose monohydrate | 3788916 | 1 |
| Caelo | Lactose monohydrate | 4313Q2210 | 1 |
| Caelo | Lactose monohydrate | 5011901 | 1 |
| Caelo | Lactose monohydrate | 5041702 | 1 |
| Caelo | Lactose monohydrate | 5061504 | 1 |
| Caelo | Lactose monohydrate | 6091301 | 1 |
| Caelo | Lactose monohydrate | 6101702 | 1 |
| Caelo | Lactose monohydrate | 7031402 | 1 |
| Caelo | Lactose monohydrate | 7111402 | 1 |
| Caelo | Lactose monohydrate | 8021401 | 1 |
| Caelo | Lactose monohydrate | 8071501 | 1 |
| Caelo | Lactose monohydrate | 9051401 | 1 |
| Caelo | Lactose monohydrate | 9061803 | 1 |
| Caelo | Lactose monohydrate | C1023 | 1 |
| Caelo | Lactose monohydrate | s-100513-1 | 1 |
| Caelo | Lactose monohydrate | Testmessung | 1 |
| Caeo/Noweda | Lactose monohydrate | 1523204 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198023 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198002 | 2 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198008 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198017 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 19137601 | 3 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 22000736009 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364012 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 20004200009 | 2 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198006 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364003 | 3 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364008 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198016 | 1 |
| Caesar & Loretz GmbH/AHD | Lactose monohydrate | 22000736007 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364016 | 2 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 22000736015 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198023 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364011 | 2 |
| Caesar & Loretz GmbH/Gehe | Lactose monohydrate | 18198002 | 2 |
| Caesar & Loretz GmbH/Gehe | Lactose monohydrate | 18198014 | 2 |
| Caesar & Loretz GmbH/Gehe | Lactose monohydrate | 192364002 | 1 |
| Caesar & Loretz GmbH/Gehe | Lactose monohydrate | 192364003 | 2 |
| Caesar & Loretz GmbH/Gehe | Lactose monohydrate | 192364014 | 2 |
| Caesar & Loretz GmbH/Gehe | Lactose monohydrate | 20004200001 | 1 |
| Caesar & Loretz GmbH/Gehe | Lactose monohydrate | 20004200005 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198014 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364003 | 2 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364012 | 3 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 20004200001 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 20004200005 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 20004200009 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Lactose monohydrate | 21001507005 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 22000736001 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 22000736009 | 2 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 22000736018 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198007 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 19137601 | 3 |
| Caesar & Loretz GmbH/Kehr | Lactose monohydrate | 192364012 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198022 | 3 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 19137601 | 4 |
| Caesar & Loretz GmbH/L10 | Lactose monohydrate | 192364009 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198007 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364016 | 3 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 21001507004 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 22000736008 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 18198017 | 2 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364002 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 19137601 | 2 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 192364016 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 20004200007 | 1 |
| Caesar & Loretz GmbH... | Lactose monohydrate | 20004200009 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 14140311 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 17321001 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 17336002 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 17336007 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 17336009 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 17336013 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198001 | 7 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198002 | 11 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198003 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198006 | 4 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198007 | 6 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198008 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198013 | 2 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198014 | 2 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198016 | 7 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198018 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 18198023 | 4 |
| Caesar & Loretz GmbH | Lactose monohydrate | 19137601 | 5 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364001 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364002 | 6 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364003 | 4 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364008 | 2 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364009 | 4 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364011 | 10 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364012 | 5 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364014 | 10 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364015 | 7 |
| Caesar & Loretz GmbH | Lactose monohydrate | 192364016 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 19236403 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 20004200001 | 2 |
| Caesar & Loretz GmbH | Lactose monohydrate | 20004200004 | 8 |
| Caesar & Loretz GmbH | Lactose monohydrate | 20004200005 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 20004200006 | 2 |
| Caesar & Loretz GmbH | Lactose monohydrate | 20004200007 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 21001507003 | 14 |
| Caesar & Loretz GmbH | Lactose monohydrate | 21001507004 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 21001507005 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736001 | 7 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736003 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736005 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736006 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736007 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736008 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736009 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736011 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736015 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736016 | 2 |
| Caesar & Loretz GmbH | Lactose monohydrate | 22000736018 | 3 |
| Caesar & Loretz GmbH | Lactose monohydrate | 23001015001 | 1 |
| Caesar & Loretz GmbH | Lactose monohydrate | 23001015003 | 1 |
| Caesar & Loretz Hilden | Lactose monohydrate | 18198013 | 1 |
| Caesar & Loretz Hilden | Lactose monohydrate | 192364015 | 1 |
| Caesar & Loretz Hilden | Lactose monohydrate | 19236403 | 1 |
| Caesar & Loretz/Geil... | Lactose monohydrate | 18198006 | 1 |
| Caesar & Loretz/Geil... | Lactose monohydrate | 18198018 | 1 |
| Caesar & Loretz/Geil... | Lactose monohydrate | 192364009 | 1 |
| Caesar & Loretz/Geil... | Lactose monohydrate | 192364015 | 2 |
| Caesar & Loretz/Noweda | Lactose monohydrate | 15236204 | 1 |
| Caesar & Loretz/Noweda | Lactose monohydrate | 17336013 | 1 |
| Caesar Loretz | Lactose monohydrate | 21001507004 | 1 |
| Caesar u Loretz | Lactose monohydrate | 1433520 | 1 |
| Caesar u Loretz | Lactose monohydrate | 16231202 | 1 |
| Caesar u. Loretz | Lactose monohydrate | 14025620 | 1 |
| Caesar& Loretz GmbH | Lactose monohydrate | 22000736005 | 1 |
| Cealo | Lactose monohydrate | 13104901 | 1 |
| Cealo | Lactose monohydrate | 16231202 | 1 |
| cealo | Lactose monohydrate | 1733002 | 1 |
| cealo | Lactose monohydrate | 21001507003 | 1 |
| Celo/Kehr | Lactose monohydrate | 16231213 | 2 |
| cesar&lorentz/Phönix | Lactose monohydrate | 12336815 | 1 |
| Chiesi | Lactose monohydrate | 16027708 | 1 |
| Dr.Wolff/Noweda | Lactose monohydrate | 14A30-B07-296182 | 1 |
| Ebert u. Jacobi 1... | Lactose monohydrate | 15236215 | 1 |
| Edelweiss/Fiebig | Lactose monohydrate | 279325290-0555 | 1 |
| Edelweiss/Fiebig | Lactose monohydrate | 293272062-0535 | 1 |
| Edelweiss/Fiebig | Lactose monohydrate | 294237160-1115 | 1 |
| Edelweiss/Geibo | Lactose monohydrate | 258710315-1203 | 1 |
| Edelweiss | Lactose monohydrate | 253292176-1124 | 1 |
| Edelweiss | Lactose monohydrate | 283256067-0930 | 1 |
| Edelweiss | Lactose monohydrate | 6886 | 1 |
| Eigen | Lactose monohydrate | 129I20 | 1 |
| Eigen | Lactose monohydrate | 129I21 | 1 |
| Eigenherstellung/ De... | Lactose monohydrate | 10112101 | 1 |
| Eigenherstellung | Lactose monohydrate | 110913HJK01 | 1 |
| Eigenherstellung | Lactose monohydrate | 40113HJK01 | 1 |
| Eigenherstellung | Lactose monohydrate | 40815HMS01 | 1 |
| Eigenherstellung | Lactose monohydrate | 60814HSA01 | 1 |
| Eigenherstellung | Lactose monohydrate | 70113HML01 | 1 |
| EuRho/Phoenix | Lactose monohydrate | 1301028-01 | 2 |
| EuRho | Lactose monohydrate | 1112020-01 | 1 |
| EuRho | Lactose monohydrate | 1112020-02 | 2 |
| EuRho | Lactose monohydrate | 1301028-01 | 1 |
| EuRho | Lactose monohydrate | 1401003-01 | 3 |
| EuRho | Lactose monohydrate | 1501017-01 | 1 |
| EuRho | Lactose monohydrate | 1509030-02 | 1 |
| EuRho | Lactose monohydrate | 1606025-01 | 4 |
| EuRho | Lactose monohydrate | 1606025-02 | 1 |
| EuRho | Lactose monohydrate | 170301901 | 3 |
| Eurho | Lactose monohydrate | 1802002-01 | 2 |
| Euro OTC | Lactose monohydrate | 1013Q-02210 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Lactose monohydrate | 110602202 | 1 |
| Euro OTC | Lactose monohydrate | 1112020-01 | 2 |
| Euro OTC | Lactose monohydrate | 1112020-02 | 4 |
| Euro OTC | Lactose monohydrate | 130102801 | 1 |
| Euro OTC | Lactose monohydrate | 1301028-01 | 6 |
| Euro OTC | Lactose monohydrate | 1301028-02 | 12 |
| Euro OTC | Lactose monohydrate | 1301028-03 | 2 |
| Euro OTC | Lactose monohydrate | 1401003 | 1 |
| Euro OTC | Lactose monohydrate | 1401003-01 | 10 |
| Euro OTC | Lactose monohydrate | 140-1003-01 | 1 |
| Euro OTC | Lactose monohydrate | 140100302 | 1 |
| Euro OTC | Lactose monohydrate | 1401003-02 | 7 |
| Euro OTC | Lactose monohydrate | 14025604 | 2 |
| Euro OTC | Lactose monohydrate | 15010 | 1 |
| Euro OTC | Lactose monohydrate | 150101701 | 1 |
| Euro OTC | Lactose monohydrate | 1501017-01 | 11 |
| Euro OTC | Lactose monohydrate | 1501017-02 | 1 |
| Euro OTC | Lactose monohydrate | 1509030-01 | 7 |
| Euro OTC | Lactose monohydrate | 150903002 | 1 |
| Euro OTC | Lactose monohydrate | 1509030-02 | 7 |
| Euro OTC | Lactose monohydrate | 15090-30-02 | 1 |
| Euro OTC | Lactose monohydrate | 160602501 | 1 |
| Euro OTC | Lactose monohydrate | 1606025-01 | 28 |
| Euro OTC | Lactose monohydrate | 1606025-02 | 4 |
| Euro OTC | Lactose monohydrate | 1703019-01 | 9 |
| Euro OTC | Lactose monohydrate | 1703019-02 | 6 |
| Euro OTC | Lactose monohydrate | 17A11-B01-334251 | 1 |
| Euro OTC | Lactose monohydrate | 180200201 | 2 |
| Euro OTC | Lactose monohydrate | 1802002-01 | 12 |
| Euro OTC | Lactose monohydrate | 1802002-02 | 1 |
| Euro OTC | Lactose monohydrate | 1802002-03 | 1 |
| Euro OTC | Lactose monohydrate | 180202-01 | 1 |
| Euro OTC | Lactose monohydrate | 18082014A | 1 |
| Euro OTC | Lactose monohydrate | 1812008-01 | 14 |
| Euro OTC | Lactose monohydrate | 1812008-02 | 8 |
| Euro OTC | Lactose monohydrate | 1812008-03 | 2 |
| Euro OTC | Lactose monohydrate | 1909014 | 1 |
| Euro OTC | Lactose monohydrate | 1909014-01 | 27 |
| Euro OTC | Lactose monohydrate | 1909014-02 | 2 |
| Euro OTC | Lactose monohydrate | 2005026 | 1 |
| Euro OTC | Lactose monohydrate | 200502601 | 2 |
| Euro OTC | Lactose monohydrate | 2005026-01 | 12 |
| Euro OTC | Lactose monohydrate | 2005026-0108597888 | 1 |
| Euro OTC | Lactose monohydrate | 2005026-02 | 2 |
| Euro OTC | Lactose monohydrate | 20052026-02 | 1 |
| Euro OTC | Lactose monohydrate | 2201013-01 | 5 |
| Euro OTC | Lactose monohydrate | 2208008-01 | 3 |
| Euro OTC | Lactose monohydrate | 2208008-03 | 2 |
| Euro OTC | Lactose monohydrate | 31102013A | 1 |
| Euro OTC | Lactose monohydrate | 3215A-02210 | 1 |
| Euro OTC | Lactose monohydrate | 5123 | 1 |
| Euro OTC | Lactose monohydrate | L101852618 | 1 |
| Euro OTC | Lactose monohydrate | L101854417A545 | 1 |
| Euro OTC | Lactose monohydrate | L1237A4172 | 2 |
| Euro OTC | Lactose monohydrate | UP250171017 | 1 |
| Euro/Phönix | Lactose monohydrate | 1802002-01 | 1 |
| Euro/Phönix | Lactose monohydrate | 1909014-01 | 2 |
| Euroo/Phoenix | Lactose monohydrate | 1401003-02 | 1 |
| Europ Ots Pharma | Lactose monohydrate | 1301028-02 | 3 |
| Europ Ots Pharma | Lactose monohydrate | 1401003-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Europharm/Otto | Lactose monohydrate | 1106022-01 | 1 |
| Fa.Phönix | Lactose monohydrate | 20004200007 | 1 |
| Fagron | Lactose monohydrate | 10726158 | 1 |
| Fagron | Lactose monohydrate | 10751120 | 1 |
| Fagron | Lactose monohydrate | 11C29-N06 | 1 |
| Fagron | Lactose monohydrate | 11L22-N03 | 1 |
| Fagron | Lactose monohydrate | 12/23-B02-287554 | 1 |
| Fagron | Lactose monohydrate | 12C09-N04 | 1 |
| Fagron | Lactose monohydrate | 12C26-N05 | 1 |
| Fagron | Lactose monohydrate | 12G27-N02 | 5 |
| Fagron | Lactose monohydrate | 13/23-B02-287554 | 1 |
| Fagron | Lactose monohydrate | 1301C005-278129 | 2 |
| Fagron | Lactose monohydrate | 1301C006-278128 | 6 |
| Fagron | Lactose monohydrate | 1301C007-278131 | 1 |
| Fagron | Lactose monohydrate | 1303C001 | 1 |
| Fagron | Lactose monohydrate | 1303C001-280388 | 1 |
| Fagron | Lactose monohydrate | 1303C002-280398 | 1 |
| Fagron | Lactose monohydrate | 1303C003 | 1 |
| Fagron | Lactose monohydrate | 1303C003-280390 | 1 |
| Fagron | Lactose monohydrate | 13E23-B01 | 2 |
| Fagron | Lactose monohydrate | 13E23-B01-283332 | 2 |
| Fagron | Lactose monohydrate | 13E23-B01-283334 | 1 |
| Fagron | Lactose monohydrate | 13I23-B03 | 4 |
| Fagron | Lactose monohydrate | 13I23-B03-287414 | 1 |
| Fagron | Lactose monohydrate | 13I23-B03-291115 | 1 |
| Fagron | Lactose monohydrate | 13I23-B03-291116 | 1 |
| Fagron | Lactose monohydrate | 13J23-B03-291114 | 1 |
| Fagron | Lactose monohydrate | 14140312 | 1 |
| Fagron | Lactose monohydrate | 14333518 | 1 |
| Fagron | Lactose monohydrate | 14333525 | 1 |
| Fagron | Lactose monohydrate | 14A30-B07 | 2 |
| Fagron | Lactose monohydrate | 14A30-B07-296182 | 2 |
| Fagron | Lactose monohydrate | 14H27-B01-305666 | 1 |
| Fagron | Lactose monohydrate | 14H27-B02 | 1 |
| Fagron | Lactose monohydrate | 14H27-B02-302033 | 2 |
| Fagron | Lactose monohydrate | 15A19-B06 | 4 |
| Fagron | Lactose monohydrate | 15A19-B06-303437 | 3 |
| Fagron | Lactose monohydrate | 15A19-B06-303439 | 8 |
| Fagron | Lactose monohydrate | 15H14-B03-314451 | 3 |
| Fagron | Lactose monohydrate | 16231215 | 1 |
| Fagron | Lactose monohydrate | 1623123 | 1 |
| Fagron | Lactose monohydrate | 16A05-B03 | 1 |
| Fagron | Lactose monohydrate | 17078302 | 1 |
| Fagron | Lactose monohydrate | 17321001 | 1 |
| Fagron | Lactose monohydrate | 17336007 | 2 |
| Fagron | Lactose monohydrate | 1802002-01 | 1 |
| Fagron | Lactose monohydrate | 18B15-B06-353917 | 1 |
| Fagron | Lactose monohydrate | 18B15-B06-35917 | 1 |
| Fagron | Lactose monohydrate | 2005026-02 | 2 |
| Fagron | Lactose monohydrate | 282567/0 | 1 |
| Fiebig | Lactose monohydrate | 19236403 | 2 |
| Finteler Apotheke | Lactose monohydrate | 16231211 | 1 |
| Fragon | Lactose monohydrate | 10706040 | 1 |
| Gatt-Koller | Lactose monohydrate | 1702456 | 1 |
| Gatt-Koller | Lactose monohydrate | 5580/12120813 | 2 |
| GEHE am 17.06.2014 | Lactose monohydrate | 13299108 | 1 |
| Gehe | Lactose monohydrate | 1112020-01 | 1 |
| Gehe | Lactose monohydrate | 1112020-02 | 3 |
| Gehe | Lactose monohydrate | 1301028-02 | 2 |
| Gehe | Lactose monohydrate | 14025620 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Lactose monohydrate | 14333502 | 1 |
| gehe | Lactose monohydrate | 16231211 | 1 |
| Gehe | Lactose monohydrate | 16231211 | 1 |
| GEHE | Lactose monohydrate | 17321001 | 1 |
| GEHE | Lactose monohydrate | 17321006 | 2 |
| GEHE | Lactose monohydrate | 17336005 | 1 |
| GEHE | Lactose monohydrate | 17336008 | 1 |
| GEHE | Lactose monohydrate | 17336014 | 2 |
| Gehe | Lactose monohydrate | 1802002-01 | 1 |
| Gehe | Lactose monohydrate | 18198001 | 1 |
| GEHE | Lactose monohydrate | 18198008 | 2 |
| Gehe | Lactose monohydrate | 18198014 | 1 |
| GEHE | Lactose monohydrate | 18198014 | 3 |
| GEHE | Lactose monohydrate | 18198017 | 1 |
| Gehe | Lactose monohydrate | 2208008-03 | 2 |
| Gehe | Lactose monohydrate | 2300101004 | 1 |
| Gehe | Lactose monohydrate | 23001015004 | 2 |
| Geilenkirchen | Lactose monohydrate | 17336014 | 1 |
| Geilenkirchen | Lactose monohydrate | 192364016 | 4 |
| Geilenkirchen | Lactose monohydrate | 22000736006 | 1 |
| Gutenberg-Apotheke | Lactose monohydrate | 140113 | 2 |
| Jenne | Lactose monohydrate | 192364002 | 1 |
| Jenne | Lactose monohydrate | 23002236003 | 1 |
| Kehr 15.09.2020 | Lactose monohydrate | 192364011 | 1 |
| Kehr Holderman | Lactose monohydrate | 22000736012 | 1 |
| Kehr Holdermann | Lactose monohydrate | 2208008-01 | 1 |
| Kehr | Lactose monohydrate | 17321004 | 1 |
| Kehr | Lactose monohydrate | 22000736008 | 1 |
| Kehr | Lactose monohydrate | 22000736018 | 1 |
| Kehr | Lactose monohydrate | 23001015007 | 1 |
| kölln GmbH | Lactose monohydrate | 305749041-1056 | 1 |
| Kölln GmbH | Lactose monohydrate | 316349 | 1 |
| Krieger | Lactose monohydrate | 23001015004 | 1 |
| L10 | Lactose monohydrate | 1606025-01 | 1 |
| L12 | Lactose monohydrate | 1703019-01 | 1 |
| L30 | Lactose monohydrate | 1703019-02 | 1 |
| L30 | Lactose monohydrate | 1802002-01 | 1 |
| Maros/Phoenix | Lactose monohydrate | 192364012 | 1 |
| Max Jenne | Lactose monohydrate | 23003217001 | 1 |
| Nachprüfung | Lactose monohydrate | 3712Q-02210 | 1 |
| Noweda/ Caesar&Loretz | Lactose monohydrate | 12336815 | 1 |
| Noweda | Lactose monohydrate | 14025601 | 1 |
| Noweda | Lactose monohydrate | 16231215 | 1 |
| Noweda | Lactose monohydrate | 1703019-01 | 1 |
| Noweda | Lactose monohydrate | 1703019-02 | 1 |
| Noweda | Lactose monohydrate | 17078303 | 1 |
| Noweda | Lactose monohydrate | 1802002-01 | 3 |
| Noweda | Lactose monohydrate | 1802002-02 | 1 |
| Noweda | Lactose monohydrate | 1812008-02 | 1 |
| Noweda | Lactose monohydrate | 1812008-03 | 1 |
| Noweda | Lactose monohydrate | 192364014 | 1 |
| Noweda | Lactose monohydrate | 21001507003 | 1 |
| Noweda | Lactose monohydrate | 22000736008 | 1 |
| Noweda | Lactose monohydrate | 22000736011 | 1 |
| Noweda | Lactose monohydrate | 22000736015 | 1 |
| Noweda | Lactose monohydrate | 22000736016 | 1 |
| Noweda | Lactose monohydrate | 23001015001 | 1 |
| Noweda | Lactose monohydrate | 23001015007 | 2 |
| Noweda | Lactose monohydrate | 23002236005 | 1 |
| Noweda | Lactose monohydrate | 23003217003 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Lactose monohydrate | L101854417A545 | 1 |
| Otto Fischar GmbH | Lactose monohydrate | 16231202 | 1 |
| Otto Geilenkirchen GmbH | Lactose monohydrate | 18198007 | 2 |
| otz pharma | Lactose monohydrate | 130102802 | 1 |
| Peter Kölln GmbH & C… | Lactose monohydrate | 256549266-0636 | 1 |
| Peter Kölln GmbH & C… | Lactose monohydrate | 300436259-1800 | 1 |
| Peter Kölln | Lactose monohydrate | 229719241-0640 | 1 |
| pharmachem | Lactose monohydrate | 15236208 | 1 |
| Phoenix 19.03.2014 | Lactose monohydrate | 13104909 | 1 |
| Phoenix 19.1.2019 | Lactose monohydrate | 18198001 | 1 |
| Phoenix 30.04.2014 | Lactose monohydrate | 13E23-B01-283332 | 1 |
| Phoenix | Lactose monohydrate | 1404PLV-1928 | 4 |
| Phoenix | Lactose monohydrate | 17321001 | 1 |
| Phoenix | Lactose monohydrate | 17336013 | 1 |
| Phoenix | Lactose monohydrate | 1909014-01 | 1 |
| Phoenix | Lactose monohydrate | 23003217001 | 1 |
| Phoenix | Lactose monohydrate | 23003217003 | 2 |
| Phoenix | Lactose monohydrate | 24001474002 | 2 |
| Phoenix | Lactose monohydrate | 24001474003 | 1 |
| Phoenix | Lactose monohydrate | 24001886003 | 1 |
| Phoenix | Lactose monohydrate | 3194 | 1 |
| Phönex | Lactose monohydrate | 23001015001 | 1 |
| Phönix 22.10.2019 | Lactose monohydrate | 1812008-01 | 3 |
| Phönix 28.08.2019 | Lactose monohydrate | 1812008-02 | 2 |
| Phönix | Lactose monohydrate | 10195101 | 2 |
| Phönix | Lactose monohydrate | 12336815 | 1 |
| Phönix | Lactose monohydrate | 13299102 | 2 |
| Phönix | Lactose monohydrate | 14025616 | 1 |
| Phönix | Lactose monohydrate | 15A19-B06 | 3 |
| Phönix | Lactose monohydrate | 16027701 | 1 |
| phönix | Lactose monohydrate | 16231202 | 1 |
| PHÖNIX | Lactose monohydrate | 16A05-B03-322529 | 2 |
| Phönix | Lactose monohydrate | 17078303 | 2 |
| Phönix | Lactose monohydrate | 17321001 | 1 |
| Phönix | Lactose monohydrate | 181200801 | 1 |
| Phönix | Lactose monohydrate | 18198001 | 1 |
| Phönix | Lactose monohydrate | 18198007 | 1 |
| Phönix | Lactose monohydrate | 192364012 | 1 |
| phönix | Lactose monohydrate | 22000736005 | 1 |
| Phönix | Lactose monohydrate | 22000736015 | 1 |
| Phönix | Lactose monohydrate | 23003217005 | 1 |
| Phönix | Lactose monohydrate | 24001474002 | 2 |
| Rondell Apotheke | Lactose monohydrate | 1509030-01 | 2 |
| Sana/Hanse | Lactose monohydrate | 23003217003 | 1 |
| Sanacorp,05.04.17, 5,96EUR | Lactose monohydrate | 16231202 | 1 |
| Sanacorp | Lactose monohydrate | 12139915 | 5 |
| Sanacorp | Lactose monohydrate | 12336815 | 1 |
| Sanacorp | Lactose monohydrate | 13104901 | 1 |
| Sanacorp | Lactose monohydrate | 13104909 | 1 |
| Sanacorp | Lactose monohydrate | 13299102 | 1 |
| Sanacorp | Lactose monohydrate | 13299108 | 1 |
| Sanacorp | Lactose monohydrate | 14025620 | 1 |
| Sanacorp | Lactose monohydrate | 14333509 | 1 |
| Sanacorp | Lactose monohydrate | 14333518 | 1 |
| Sanacorp | Lactose monohydrate | 16231215 | 1 |
| Sanacorp | Lactose monohydrate | 17078303 | 1 |
| Sanacorp | Lactose monohydrate | 17078306 | 1 |
| Sanacorp | Lactose monohydrate | 17078312 | 1 |
| Sanacorp | Lactose monohydrate | 17321001 | 1 |
| Sanacorp | Lactose monohydrate | 17321004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Lactose monohydrate | 1802002 | 1 |
| Sanacorp | Lactose monohydrate | 18198016 | 1 |
| Sanacorp | Lactose monohydrate | 18198017 | 3 |
| Sanacorp | Lactose monohydrate | 192364002 | 1 |
| Sanacorp | Lactose monohydrate | 22000736005 | 2 |
| sanacorp | Lactose monohydrate | 22000736008 | 1 |
| Sanacorp | Lactose monohydrate | 22000736017 | 1 |
| Sanacorp | Lactose monohydrate | 23001015004 | 1 |
| Sanacorp | Lactose monohydrate | 23001015007 | 1 |
| Sanacorp | Lactose monohydrate | 23002236003 | 2 |
| Sanacorp | Lactose monohydrate | 274600148-0724 | 1 |
| Sanacorp | Lactose monohydrate | 274600148-0726 | 1 |
| Sanacorp | Lactose monohydrate | 283259077-1133 | 2 |
| Sanacorp | Lactose monohydrate | 283259077-1214 | 1 |
| Sanacorp | Lactose monohydrate | 285739172-1842 | 2 |
| Sanacorp | Lactose monohydrate | 285739172-1852 | 2 |
| Sanacorp | Lactose monohydrate | 285739172-1853 | 1 |
| schubert / Phoenix | Lactose monohydrate | 1334PLV-1775 | 1 |
| siehe Protokoll | Lactose monohydrate | 1606025-01 | 1 |
| Spangropharm | Lactose monohydrate | 91444379 | 1 |
| vdl | Lactose monohydrate | 1112020-01 | 2 |
| Zentralapotheke Wetzlar | Lactose monohydrate | 213L20 | 1 |

- 254 245 spectra from 1666 *Apo-Ident* customers from a total of 51 634 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Lactose monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Lactose monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 430 | 0 | 157 896 |
| **Type B** | 0 | 660 | 0 | 212 280 |
| **Type C** | 0 | 2634 | 7 | 254 245 |

The substance/substance group *Lactose monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6047 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0909 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7349 % (> 99.6214 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to


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exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20685 | 22460 | 5.61 | 82.19 |
| 21525 | 22460 | 7.03 | 83.65 |
| 21526 | 22460 | 8.33 | 81.23 |
| 21527 | 22460 | 6.69 | 83.02 |
| 21528 | 22460 | 7.25 | 85.49 |
| 21529 | 22460 | 5.51 | 86.71 |
| 21935 | 21935 | 0.00 | 87.06 |
| 22460 | 22460 | 0.00 | 93.77 |
| 22701 | 22701 | 0.00 | 87.24 |
| 24929 | 24929 | 0.00 | 91.25 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **L-alanine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 23776-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

L-alanine; Alaninum

### Special notes

When selecting the *L-alanine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| L-alanine | 4 | 1 | 1 |

### Second-stage model

For differentiation of the substance/substance group *L-alanine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *L-alanine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycine | 70.41 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *L-alanine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *L-alanine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | L-alanine | 1710009 | 23776 | 40 | 20171018* |
| Euro OTC | L-alanine | 2008025 | 25396 | 40 | 20200910* |
| Fagron | L-alanine | 23F28-B02-230972 | 26905 | 40 | 20230721 |
| Fagron | L-alanine | 24I11-B04-010489 | 27647 | 40 | 20241025 |
| Fagron | L-alanine | 24I11-B04-010489 | 27647SI | 20 | 20241025 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 180 spectra of 5 reference samples from the substance/substance group *L-alanine*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 146 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 2 reference samples from the substance/substance group *L-alanine*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | L-alanine | 1601033-01 | 23905 | 40 |
| Fagron | L-alanine | 23F28-B02-230972 | 26905SI† | 20 |

- 212 880 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *L-alanine*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | L-alanine | 2008025-01 | 2 |

- 256 884 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *L-alanine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *L-alanine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 60 | 0 | 212 880 |
| **Type C** | 0 | 2 | 0 | 256 884 |

The substance/substance group *L-alanine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9032 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23776 | 23776 | 0.00 | 171.55 |
| 25396 | 25396 | 0.00 | 158.02 |
| 26905 | 25396 | 17.00 | 168.28 |
| 27647 | 23776 | 16.33 | 174.55 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Leucine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20970-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Leucine; L-Leucine; Leucinum

### Special notes

When selecting the *Leucine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Leucine | 6 | 7 | 5 |

### Second-stage model

For differentiation of the substance/substance group *Leucine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Leucine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Isoleucine | 54.45 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Leucine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Leucine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Leucine | 1302013-01 | 21612 | 60 | 20130320 |
| Euro OTC | Leucine | 1601032 | 22380 | 40 | 20160308* |
| Euro OTC | Leucine | 2004006 | 25165 | 40 | 20200507* |
| Euro OTC | Leucine | 2011008 | 25467 | 40 | 20201204* |
| Fagron | Leucine | 13J09-N03 | 20970 | 40 | 1402431 |
| Fagron | Leucine | 15D09-B06-322249 | 23199 | 40 | 20151030 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 6 reference samples from the substance/substance group *Leucine*. These samples

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 330 spectra of 10 reference samples from the substance/substance group *Leucine*.
- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Leucine | 1708010 | 23607 | 40 |
| Euro OTC | Leucine | 1901008 | 24473 | 40 |
| Euro OTC | Leucine | 2203014 | 26041 | 40 |
| Euro OTC | Leucine | 2302005 | 26646 | 40 |
| Euro OTC | Leucine | 2401011 | 27144 | 40 |
| Euro OTC | Leucine | 2404015 | 27292 | 40 |
| Fagron | Leucine | 23F15-B10-231014 | 26907 | 40 |
| Euro OTC | Leucine | 2203014 | 26041SI | 10 |
| Euro OTC | Leucine | 2302005 | 26646SI | 20 |
| Fagron | Leucine | 23F15-B10-231014 | 26907SI | 20 |

- 212 610 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6 spectra from 5 *Apo-Ident* customers from 5 batches from the substance/substance group *Leucine*.
- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Leucine | 1312032-01 | 1 |
| Euro OTC | Leucine | 1708010-01 | 2 |
| Euro OTC | Leucine | 700113 | 1 |
| Fagron | Leucine | 20J15-B02-202893 | 1 |
| Fargon | Leucine | 8160410903 | 1 |

- 256 880 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Leucine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Leucine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 330 | 0 | 212 610 |
| **Type C** | 0 | 6 | 0 | 256 880 |

The substance/substance group *Leucine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.1818 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20970 | 20970 | 0.00 | 105.55 |
| 21612 | 25165 | 18.37 | 110.22 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22380 | 22380 | 0.00 | 110.97 |
| 23199 | 25467 | 12.14 | 115.39 |
| 25165 | 25165 | 0.00 | 114.70 |
| 25467 | 25467 | 0.00 | 114.10 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Levocarnitine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20357-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Levocarnitine; Levocarnitinum

### Special notes

When selecting the *Levocarnitine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Levocarnitine | 7 | 9 | 20 |

### Second-stage model

For differentiation of the substance/substance group *Levocarnitine* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Levocarnitine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cystine | 91.02 | – |
| ⋮ | ⋮ | ⋮ |
| Valine | >50 | 79.77 |
| Oxybutynin hydrochloride | >50 | 138.61 |
| Capsaicin | >50 | 184.93 |
| Sodium citrate | >50 | 193.75 |
| Prednicarbate | >50 | 249.56 |
| Cyproterone acetate | >50 | 257.36 |
| Pyridoxal-5-phosphate hydrate | >50 | 300.14 |
| Methoxsalen | >50 | 310.39 |
| Alfatradiol | >50 | 442.36 |
| Quinine hydrochloride dihydrate | >50 | 460.44 |
| Amitriptyline hydrochloride | >50 | 465.28 |
| Tetracaine | >50 | 472.92 |
| Norethisterone acetate | >50 | 484.40 |
| Ciprofloxacin hydrochloride | >50 | 533.28 |
| Heparin sodium | >50 | 859.13 |
| Triclosan | >50 | 1334.00 |
| Amifampridine | >50 | 2270.44 |
| Sucrose | >50 | 2306.66 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Levocarnitine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Levocarnitine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Levocarnitine | 1210029-01 | 20809 | 40 | 20121130 |
| Euro OTC | Levocarnitine | 2007040-01 | 25606 | 40 | 20201215 |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Levocarnitine | 2104006 | 25681 | 40 | 20210423* |
| Fagron | Levocarnitine | 12H10-N07 | 20818 | 40 | 20120830 |
| Fagron | Levocarnitine | 14A20-B11-290728 | 21790 | 60 | AR-15-FG-016322-01 |
| Fagron | Levocarnitine | 14A20-B11-290728 | 21968 | 60 | AR-16-FG-005969-01 |
| Fagron | Levocarnitine | 15L04-B05-319229 | 23194 | 40 | AR-17-FG-012937-01 |
| Fagron | Levocarnitine | 16L06-B03-338285 | 23919 | 40 | 20161227 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 360 spectra of 8 reference samples from the substance/substance group *Levocarnitine*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 440 spectra of 12 reference samples from the substance/substance group *Levocarnitine*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Levocarnitine | 1303027-02 | 21648 | 60 |
| Euro OTC | Levocarnitine | 2203025 | 26087 | 40 |
| Euro OTC | Levocarnitine | 2301027 | 26532 | 40 |
| Euro OTC | Levocarnitine | 2406011 | 27344 | 40 |
| Euro OTC | Levocarnitine | 2410001 | 27456 | 40 |
| Fagron | Levocarnitine | 16F20-B01-326616 | 23402 | 40 |
| Fagron | Levocarnitine | 17K23-B01-345633 | 24009 | 40 |
| Fagron | Levocarnitine | 22B02-B10-220587 | 26164 | 40 |
| Fagron | Levocarnitine | 24A05-B04-235963 | 27169 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Levocarnitine | 2203025 | 26087SI | 20 |
| Euro OTC | Levocarnitine | 2301027 | 26532SI | 20 |
| Fagron | Levocarnitine | 22B02-B10-220587 | 26164SI | 20 |

- 212 500 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 38 spectra from 12 *Apo-Ident* customers from 21 batches from the substance/substance group *Levocarnitine*.
- Among them are spectra of independent samples from 20 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Levocarnitine | 2301027-01 | 1 |
| Denk | Levocarnitine | A04217 | 1 |
| EuRho | Levocarnitine | 2007040-01 | 1 |
| Euro OTC | Levocarnitine | 1303027 | 1 |
| Euro OTC | Levocarnitine | 1705006-01 | 1 |
| Euro OTC | Levocarnitine | 1808027-01 | 1 |
| Euro OTC | Levocarnitine | 200402401 | 1 |
| Euro OTC | Levocarnitine | 2007040-01 | 3 |
| Euro OTC | Levocarnitine | 2203025-01 | 1 |
| Euro OTC | Levocarnitine | L1608038-01 | 2 |
| Euro OTC | Levocarnitine | L1705006-01 | 1 |
| Euro OTC | Levocarnitine | L1801028-02 | 1 |
| Euro OTC | Levocarnitine | L180802701 | 1 |
| Fagron | Levocarnitine | 13111701 | 1 |
| Fagron | Levocarnitine | 13G19-N12 | 2 |
| Fagron | Levocarnitine | 17K23-B01-346658 | 1 |
| Fagron | Levocarnitine | 19K08-F04 | 7 |
| Fagron | Levocarnitine | 19K08F04367748 | 2 |
| Fagron | Levocarnitine | 20B21-F01-370194 | 1 |
| Fagron | Levocarnitine | 20B21-F04 | 6 |
| Fagron | Levocarnitine | 9041504 | 1 |
| Fagron | Levocarnitine | LC191017 | 1 |

- 256 848 spectra from 1666 *Apo-Ident* customers from a total of 52 133 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Levocarnitine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose,


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all relevant spectra of the various substances were compared with *Levocarnitine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 440 | 0 | 212 500 |
| **Type C** | 0 | 38 | 0 | 256 848 |

The substance/substance group *Levocarnitine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6364 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 84.2105 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20809 | 21790 | 29.22 | 207.08 |
| 20818 | 23194 | 30.18 | 208.43 |
| 21790 | 21790 | 0.00 | 197.73 |
| 21968 | 21968 | 0.00 | 186.71 |
| 23194 | 23194 | 0.00 | 197.53 |
| 23919 | 25681 | 24.08 | 206.91 |
| 25606 | 23194 | 29.65 | 210.39 |
| 25681 | 25681 | 0.00 | 182.60 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Levothyroxin sodium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21708-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Levothyroxin sodium; Levothyroxinum natrii

### Special notes

When selecting the *Levothyroxin sodium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Levothyroxin sodium | 6 | 4 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Levothyroxin sodium* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Levothyroxin sodium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 64.30 | – |
| ⋮ | ⋮ | ⋮ |
| Eosin Y | >50 | 33.58 |
| Dequalinium chloride | >50 | 71.18 |
| Tannin | >50 | 121.78 |
| Oxytetracycline hydrochloride | >50 | 166.70 |
| Acetylsalicylic acid | >50 | 477.75 |
| Dithranol | >50 | 561.99 |
| Sodium salicylate | >50 | 635.67 |
| Benzoic acid | >50 | 920.19 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Levothyroxin sodium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Levothyroxin sodium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Levothyroxin sodium | 14E28-B05-298322 | 21708 | 30 | 1506426 |
| Fagron | Levothyroxin sodium | 14E28-B05-298322 | 21708SI | 47 | 1506426 |
| Fagron | Levothyroxin sodium | 14E28-B05-306102 | 21820 | 60 | 20140915 |
| Fagron | Levothyroxin sodium | 14E28-B05-306102 | 21820SI | 53 | 20140915 |
| Fagron | Levothyroxin sodium | 18G27-B02-352032 | 24286 | 40 | 20180822 |
| Fagron | Levothyroxin sodium | 20D01-F05-370575 | 25438 | 40 | 2110083 |
| Fagron | Levothyroxin sodium | 20D01-F05-370575 | 25438SI | 39 | 2110083 |
| Fagron | Levothyroxin sodium | 20J01-F07-374963 | 25740 | 40 | 20201112 |
| Fagron | Levothyroxin sodium | 20J01-F07-374963 | 26080 | 40 | 20201112 |
| Fagron | Levothyroxin sodium | 20J01-F07-374963 | 26080SI | 40 | 20201112 |
| Fagron | Levothyroxin sodium | 22C02-B03-223067 | 26333 | 40 | 20220613 |
| Fagron | Levothyroxin sodium | 22C02-B03-223067 | 26333SI | 37 | 20220613 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 506 spectra of 12 reference samples from the substance/substance group *Levothyroxin sodium*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 820 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 364 spectra of 10 reference samples from the substance/substance group *Levothyroxin sodium*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Levothyroxin sodium | 16G25-B99-329080 | 23191 | 40 |
| Fagron | Levothyroxin sodium | 17J10-B05-348764 | 24176 | 40 |
| Fagron | Levothyroxin sodium | 21I10-B10-217006 | 26068 | 40 |
| Fagron | Levothyroxin sodium | 23D29-B02-227893 | 27066 | 40 |
| Fagron | Levothyroxin sodium | 16G25-B99-329080 | 23191SI | 24 |
| Fagron | Levothyroxin sodium | 17J10-B05-348764 | 24176SI | 30 |
| Fagron | Levothyroxin sodium | 18G27-B02-352032 | 24286SI† | 32 |
| Fagron | Levothyroxin sodium | 20J01-F07-374963 | 25740SI† | 40 |
| Fagron | Levothyroxin sodium | 21I10-B10-217006 | 26068SI | 40 |
| Fagron | Levothyroxin sodium | 23D29-B02-227893 | 27066SI | 38 |

- 212 576 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 22 spectra from 7 *Apo-Ident* customers from 5 batches from the substance/substance group *Levothyroxin sodium*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Levothyroxin sodium | 17J10-B05-345570 | 1 |
| Fagron | Levothyroxin sodium | 16G25-B99-324827 | 17 |
| Fagron | Levothyroxin sodium | 20D01-F05-370575 | 2 |
| Fagron | Levothyroxin sodium | 20J01-F07-374963 | 1 |
| Fagron | Levothyroxin sodium | 21/10-B10-217006 | 1 |

- 256 864 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Levothyroxin sodium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Levothyroxin sodium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 506 | 0 | 157 820 |
| **Type B** | 0 | 364 | 0 | 212 576 |
| **Type C** | 0 | 22 | 0 | 256 864 |

The substance/substance group *Levothyroxin sodium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8142 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.3516 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | 100.0000 % (> 72.7273 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21708 | 21708 | 0.00 | 70.27 |
| 21820 | 25438 | 37.56 | 81.70 |
| 24286 | 25438 | 15.22 | 86.35 |
| 25438 | 25438 | 0.00 | 93.26 |
| 25740 | 25438 | 5.59 | 90.16 |
| 26080 | 25438 | 7.94 | 92.43 |
| 26333 | 25438 | 8.54 | 86.38 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Lidocaine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20942-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Lidocaine; Lidocainum

### Special notes

When selecting the *Lidocaine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Lidocaine | 9 | 14 | 414 |

### Second-stage model

For differentiation of the substance/substance group *Lidocaine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Lidocaine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 126.33 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Lidocaine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Lidocaine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Lidocaine | 13352411 | 21673 | 60 | 20131115 |
| Caelo | Lidocaine | 180444 | 24031 | 40 | 20180419* |
| Euro OTC | Lidocaine | 1310023-01 | 21640 | 60 | 20131118 |
| Euro OTC | Lidocaine | 1612021 | 22984 | 40 | 20170206* |
| Euro OTC | Lidocaine | 1911005 | 24928 | 40 | 20191129* |
| Euro OTC | Lidocaine | 2101035 | 25533 | 40 | 20210304* |
| Euro OTC | Lidocaine | 2304015 | 26654 | 40 | 20230510* |
| Euro OTC | Lidocaine | 2304015 | 26654SI | 20 | 20230510* |
| Fagron | Lidocaine | 13H05-N05 | 20942 | 40 | 1401378 |
| Fagron | Lidocaine | 16F21-B06-327232 | 23019 | 40 | 20160728 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 10 reference samples from the substance/substance group *Lidocaine*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 906 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 600 spectra of 16 reference samples from the substance/substance group *Lidocaine*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Lidocaine | 162895 | 22768 | 40 |
| Caelo | Lidocaine | 171831 | 23632 | 40 |
| Caelo | Lidocaine | 190545 | 24530 | 40 |
| Caelo | Lidocaine | 22000398 | 26736 | 40 |
| Caelo | Lidocaine | 23002079 | 26964 | 40 |
| Euro OTC | Lidocaine | 1603027 | 22526 | 40 |
| Euro OTC | Lidocaine | 1801032 | 23960 | 40 |
| Euro OTC | Lidocaine | 1902003 | 24475 | 40 |
| Euro OTC | Lidocaine | 1905004 | 24610 | 40 |
| Euro OTC | Lidocaine | 1908005 | 24847 | 40 |
| Euro OTC | Lidocaine | 2006013 | 25244 | 40 |
| Euro OTC | Lidocaine | 2206002 | 26230 | 40 |
| Euro OTC | Lidocaine | 2310020 | 27075 | 40 |
| Fagron | Lidocaine | 22C15-B17-216737 | 26134 | 40 |
| Euro OTC | Lidocaine | 2206002 | 26230SI | 20 |
| Fagron | Lidocaine | 22C15-B17-216737 | 26134SI | 20 |

- 212 340 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1950 spectra from 764 *Apo-Ident* customers from 445 batches from the substance/substance group *Lidocaine*.

- Among them are spectra of independent samples from 415 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Lidocaine | 1908005-01 | 1 |
| | Lidocaine | 20003343016 | 6 |
| | Lidocaine | 20H13-F04-373497 | 1 |
| | Lidocaine | 20L11-F01-376356 | 1 |
| | Lidocaine | 2101035-03 | 1 |
| | Lidocaine | 22000398003 | 3 |
| | Lidocaine | 22000398004 | 2 |
| | Lidocaine | 22000398010 | 2 |
| | Lidocaine | 22000398011 | 21 |
| | Lidocaine | 22000398013 | 8 |
| | Lidocaine | 22000398015 | 2 |
| | Lidocaine | 22000398016 | 21 |
| | Lidocaine | 22000398017 | 2 |
| | Lidocaine | 2206002-01 | 1 |
| | Lidocaine | 2206002-02 | 3 |
| | Lidocaine | 22C15-B17 | 5 |
| | Lidocaine | 22C15-B17-216737 | 8 |
| | Lidocaine | 22C15-B17-216738 | 2 |
| | Lidocaine | 22C15-B17-216739 | 12 |
| | Lidocaine | 22c15-b17-225236 | 1 |
| | Lidocaine | 22C15-B17-225236 | 7 |
| | Lidocaine | 22C15-B17-225237 | 1 |
| | Lidocaine | 23002079001 | 2 |
| | Lidocaine | 23002079002 | 11 |
| | Lidocaine | 23002079003 | 7 |
| | Lidocaine | 23003477003 | 11 |
| | Lidocaine | 23003477004 | 4 |
| | Lidocaine | 23003477008 | 1 |
| | Lidocaine | 2300347703 | 1 |
| | Lidocaine | 2304015-01 | 1 |
| | Lidocaine | 2304015-03 | 1 |
| | Lidocaine | 2310020 | 1 |
| | Lidocaine | 2310020-01 | 1 |
| | Lidocaine | 2310020-02 | 1 |
| | Lidocaine | 23D25-B10-230220 | 3 |
| | Lidocaine | 23D25-B10-230221 | 1 |
| | Lidocaine | 23D25-B10-230226 | 2 |
| | Lidocaine | 23D25B10234510 | 1 |
| | Lidocaine | 23H-23-B01-234507 | 1 |
| | Lidocaine | B01-2345006 | 3 |
| | Lidocaine | B10-2302200 | 3 |
| | Lidocaine | B10-2302201 | 2 |
| | Lidocaine | B10-2302206 | 2 |
| | Lidocaine | B10-2345100 | 2 |
| | Lidocaine | B17-2137307 | 1 |
| | Lidocaine | LDB/123004 | 1 |
| | Lidocaine | LDB/722005 | 3 |
| AHD | Lidocaine | 15332314 | 1 |
| AHD | Lidocaine | 19054506 | 1 |
| AHD | Lidocaine | 22C15B17-225236 | 1 |
| Alliance healfcare | Lidocaine | 18j23-b02-359239 | 1 |
| Alliance Healthcare | Lidocaine | 19F27-B01-363501 | 1 |
| Alliance Healthcare | Lidocaine | 19F27-B01-363506 | 1 |
| Alliance Healthcare | Lidocaine | 20L11-F01-376356 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Healthcare | Lidocaine | 22C15-B17-225236 | 1 |
| Alliance Healthcare | Lidocaine | 23D25-B10-230220 | 1 |
| Alliance | Lidocaine | 15H27-B07-318310 | 1 |
| Alliance | Lidocaine | 22000398010 | 1 |
| Alliance | Lidocaine | 22C15-B17-216737 | 1 |
| Allianz Healthcare | Lidocaine | 8565960 | 1 |
| Alte Apotheke | Lidocaine | 16A28B06-321297 | 1 |
| Anzag | Lidocaine | 12E30-N10 | 1 |
| Anzag | Lidocaine | 250428(23003477003) | 1 |
| Audor Pharma | Lidocaine | 1911005-01 | 1 |
| Cae | Lidocaine | 20003343010 | 1 |
| Caelo | Lidocaine | 11K17-N03 | 1 |
| Caelo | Lidocaine | 12163802 | 2 |
| Caelo | Lidocaine | 12163803 | 3 |
| Caelo | Lidocaine | 12163804 | 2 |
| Caelo | Lidocaine | 12163810 | 1 |
| Caelo | Lidocaine | 12163811 | 4 |
| Caelo | Lidocaine | 12163813 | 5 |
| Caelo | Lidocaine | 122294405 | 1 |
| Caelo | Lidocaine | 12294403 | 1 |
| Caelo | Lidocaine | 12294405 | 2 |
| Caelo | Lidocaine | 12294408 | 2 |
| Caelo | Lidocaine | 12294412 | 11 |
| Caelo | Lidocaine | 12294413 | 1 |
| Caelo | Lidocaine | 12H16-N05 | 2 |
| Caelo | Lidocaine | 133522408 | 1 |
| Caelo | Lidocaine | 133524 | 1 |
| Caelo | Lidocaine | 13352403 | 1 |
| Caelo | Lidocaine | 13352405 | 1 |
| Caelo | Lidocaine | 13352406 | 1 |
| Caelo | Lidocaine | 13352408 | 9 |
| Caelo | Lidocaine | 13352411 | 6 |
| Caelo | Lidocaine | 13352413 | 3 |
| Caelo | Lidocaine | 13352414 | 2 |
| Caelo | Lidocaine | 13352415 | 3 |
| Caelo | Lidocaine | 13J30-B02-292221 | 1 |
| Caelo | Lidocaine | 14299301 | 2 |
| Caelo | Lidocaine | 14299303 | 2 |
| Caelo | Lidocaine | 14299305 | 2 |
| Caelo | Lidocaine | 1512003 | 1 |
| Caelo | Lidocaine | 15212001 | 2 |
| Caelo | Lidocaine | 15212002 | 5 |
| Caelo | Lidocaine | 15212003 | 3 |
| Caelo | Lidocaine | 15332302 | 6 |
| Caelo | Lidocaine | 15332303 | 1 |
| Caelo | Lidocaine | 15332305 | 2 |
| Caelo | Lidocaine | 15332306 | 3 |
| Caelo | Lidocaine | 15332309 | 2 |
| Caelo | Lidocaine | 15332310 | 4 |
| Caelo | Lidocaine | 15332314 | 2 |
| Caelo | Lidocaine | 15A15-B01-304284 | 3 |
| Caelo | Lidocaine | 15D23-B08 | 1 |
| Caelo | Lidocaine | 15H27-B07-318310 | 1 |
| Caelo | Lidocaine | 15H-B07-318310 | 1 |
| Caelo | Lidocaine | 16087702 | 1 |
| Caelo | Lidocaine | 16087703 | 1 |
| Caelo | Lidocaine | 16087704 | 8 |
| Caelo | Lidocaine | 16087707 | 9 |
| Caelo | Lidocaine | 16087708 | 1 |
| Caelo | Lidocaine | 16087709 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lidocaine | 16087710 | 3 |
| Caelo | Lidocaine | 16087711 | 10 |
| Caelo | Lidocaine | 16087712 | 7 |
| Caelo | Lidocaine | 1608774 | 1 |
| Caelo | Lidocaine | 160877708 | 1 |
| Caelo | Lidocaine | 1612021-04 | 1 |
| Caelo | Lidocaine | 16289502 | 11 |
| Caelo | Lidocaine | 16289503 | 10 |
| Caelo | Lidocaine | 16289504 | 2 |
| Caelo | Lidocaine | 16289507 | 2 |
| Caelo | Lidocaine | 16289508 | 21 |
| Caelo | Lidocaine | 1629508 | 1 |
| Caelo | Lidocaine | 16A28-B06-320059 | 1 |
| Caelo | Lidocaine | 16F21-806-333787 | 1 |
| Caelo | Lidocaine | 16F21-B06-323670 | 1 |
| Caelo | Lidocaine | 16F21-B06-326631 | 1 |
| Caelo | Lidocaine | 16F21-B06-328421 | 3 |
| Caelo | Lidocaine | 1718308 | 1 |
| Caelo | Lidocaine | 17183102 | 3 |
| Caelo | Lidocaine | 17183103 | 8 |
| Caelo | Lidocaine | 17183105 | 1 |
| Caelo | Lidocaine | 17183106 | 1 |
| Caelo | Lidocaine | 17183108 | 8 |
| Caelo | Lidocaine | 17183109 | 9 |
| Caelo | Lidocaine | 17348502 | 6 |
| Caelo | Lidocaine | 17348503 | 15 |
| Caelo | Lidocaine | 17348503P-190516-5 | 1 |
| Caelo | Lidocaine | 1783109 | 2 |
| Caelo | Lidocaine | 17G03-B08 | 1 |
| Caelo | Lidocaine | 17G03B08338286 | 1 |
| Caelo | Lidocaine | 17G03-B08-341306 | 3 |
| Caelo | Lidocaine | 17G03B08341308 | 1 |
| Caelo | Lidocaine | 17K23-B04-343250 | 1 |
| Caelo | Lidocaine | 17K23-B04-347473 | 1 |
| Caelo | Lidocaine | 17K23-B04-347474 | 2 |
| Caelo | Lidocaine | 17K23-B04-347475 | 1 |
| Caelo | Lidocaine | 17K23-B04-350189 | 1 |
| Caelo | Lidocaine | 17K23-B04-350543 | 1 |
| Caelo | Lidocaine | 17K23-B04-353247 | 1 |
| Caelo | Lidocaine | 17K23-B04-353427 | 1 |
| Caelo | Lidocaine | 18041812 | 1 |
| Caelo | Lidocaine | 1804404 | 1 |
| Caelo | Lidocaine | 1804410 | 1 |
| Caelo | Lidocaine | 1804413 | 2 |
| Caelo | Lidocaine | 18044402 | 5 |
| Caelo | Lidocaine | 18044404 | 9 |
| Caelo | Lidocaine | 18044405 | 9 |
| Caelo | Lidocaine | 18044408 | 4 |
| Caelo | Lidocaine | 18044410 | 12 |
| Caelo | Lidocaine | 18044412 | 2 |
| Caelo | Lidocaine | 18044413 | 17 |
| Caelo | Lidocaine | 18044414 | 1 |
| Caelo | Lidocaine | 18044415 | 6 |
| Caelo | Lidocaine | 180444404 | 1 |
| Caelo | Lidocaine | 190545001 | 15 |
| Caelo | Lidocaine | 19054503 | 15 |
| Caelo | Lidocaine | 19054503P-190909-3 | 1 |
| Caelo | Lidocaine | 19054505 | 10 |
| Caelo | Lidocaine | 19054506 | 19 |
| Caelo | Lidocaine | 19054507 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lidocaine | 192758001 | 5 |
| Caelo | Lidocaine | 192758002 | 1 |
| Caelo | Lidocaine | 192758003 | 1 |
| Caelo | Lidocaine | 192758004 | 8 |
| Caelo | Lidocaine | 192758005 | 15 |
| Caelo | Lidocaine | 19278005 | 1 |
| Caelo | Lidocaine | 1954503 | 1 |
| Caelo | Lidocaine | 19F27-B01-363506 | 1 |
| Caelo | Lidocaine | 20003343001 | 2 |
| Caelo | Lidocaine | 20003343002 | 8 |
| Caelo | Lidocaine | 20003343004 | 17 |
| Caelo | Lidocaine | 20003343006 | 4 |
| Caelo | Lidocaine | 20003343007 | 3 |
| Caelo | Lidocaine | 20003343008 | 13 |
| Caelo | Lidocaine | 20003343010 | 7 |
| Caelo | Lidocaine | 20003343011 | 7 |
| Caelo | Lidocaine | 20003343012 | 2 |
| Caelo | Lidocaine | 20003343014 | 5 |
| Caelo | Lidocaine | 20003343015 | 15 |
| Caelo | Lidocaine | 20003343016 | 8 |
| Caelo | Lidocaine | 2000334304 | 1 |
| Caelo | Lidocaine | 2000409002 | 1 |
| Caelo | Lidocaine | 20004099001 | 25 |
| Caelo | Lidocaine | 20004099002 | 2 |
| Caelo | Lidocaine | 2000409901 | 1 |
| Caelo | Lidocaine | 2003343008 | 1 |
| Caelo | Lidocaine | 200409900100 | 1 |
| Caelo | Lidocaine | 2004099002 | 1 |
| Caelo | Lidocaine | 20C13-F04-369814 | 1 |
| Caelo | Lidocaine | 20H13-F04-3734909 | 1 |
| Caelo | Lidocaine | 20L11-F01 | 2 |
| Caelo | Lidocaine | 22000398001 | 3 |
| Caelo | Lidocaine | 22000398003 | 4 |
| Caelo | Lidocaine | 22000398004 | 25 |
| Caelo | Lidocaine | 22000398010 | 2 |
| Caelo | Lidocaine | 22000398011 | 2 |
| Caelo | Lidocaine | 22000398016 | 1 |
| Caelo | Lidocaine | 220600-01 | 1 |
| Caelo | Lidocaine | 23002079003 | 1 |
| Caelo | Lidocaine | 23003477003 | 1 |
| Caelo | Lidocaine | 5111201 | 1 |
| Caelo | Lidocaine | 8629595 | 1 |
| Caelo | Lidocaine | 9205916 | 2 |
| Caelo | Lidocaine | 9205919 | 1 |
| Caelo | Lidocaine | LDB/733005 | 2 |
| Caesar & Loretz noweda | Lidocaine | 20003343015 | 2 |
| Caesar & Loretz GmbH… | Lidocaine | 18044405 | 1 |
| Caesar & Loretz GmbH… | Lidocaine | 22000398011 | 1 |
| Caesar & Loretz GmbH /E | Lidocaine | 18044413 | 1 |
| Caesar & Loretz GmbH/ AHD | Lidocaine | 20003343010 | 1 |
| Caesar & Loretz GmbH… | Lidocaine | 192758004 | 1 |
| Caesar & Loretz GmbH… | Lidocaine | 22000398010 | 1 |
| Caesar & Loretz GmbH… | Lidocaine | 20003343002 | 1 |
| Caesar & Loretz GmbH/AHC | Lidocaine | 20003343015 | 1 |
| Caesar & Loretz GmbH… | Lidocaine | 20004099001 | 1 |
| Caesar & Loretz GmbH… | Lidocaine | 19054505 | 1 |
| Caesar & Loretz GmbH/Gehe | Lidocaine | 20003343006 | 1 |
| Caesar & Loretz GmbH/Gehe | Lidocaine | 20003343011 | 2 |
| Caesar & Loretz GmbH… | Lidocaine | 22000398004 | 1 |
| Caesar & Loretz GmbH… | Lidocaine | 192758005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Lidocaine | 20003343004 | 2 |
| Caesar & Loretz GmbH... | Lidocaine | 192758004 | 2 |
| Caesar & Loretz GmbH... | Lidocaine | 22000398004 | 2 |
| Caesar & Loretz GmbH... | Lidocaine | 18044410 | 1 |
| Caesar & Loretz GmbH... | Lidocaine | 192758005 | 1 |
| Caesar & Loretz GmbH... | Lidocaine | 20003343004 | 2 |
| Caesar & Loretz GmbH... | Lidocaine | 20003343008 | 1 |
| Caesar & Loretz GmbH... | Lidocaine | 20004099001 | 1 |
| Caesar & Loretz GmbH... | Lidocaine | 19054505 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 12294412 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 17K23_B04_355709 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 18044408 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 18044410 | 2 |
| Caesar & Loretz GmbH | Lidocaine | 18044414 | 2 |
| Caesar & Loretz GmbH | Lidocaine | 18044415 | 3 |
| Caesar & Loretz GmbH | Lidocaine | 190545001 | 5 |
| Caesar & Loretz GmbH | Lidocaine | 19054503 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 19054505 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 19054506 | 2 |
| Caesar & Loretz GmbH | Lidocaine | 19054507 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 192758001 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 192758003 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 192758004 | 2 |
| Caesar & Loretz GmbH | Lidocaine | 20003343001 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 20003343002 | 8 |
| Caesar & Loretz GmbH | Lidocaine | 20003343004 | 4 |
| Caesar & Loretz GmbH | Lidocaine | 20003343006 | 3 |
| CAESAR & LORETZ GMBH | Lidocaine | 20003343006 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 20003343008 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 20003343010 | 7 |
| Caesar & Loretz GmbH | Lidocaine | 20003343011 | 3 |
| Caesar & Loretz GmbH | Lidocaine | 20003343014 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 20003343015 | 8 |
| Caesar & Loretz GmbH | Lidocaine | 20003343016 | 2 |
| Caesar & Loretz GmbH | Lidocaine | 20004099001 | 9 |
| Caesar & Loretz GmbH | Lidocaine | 22000398003 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 22000398004 | 5 |
| Caesar & Loretz GmbH | Lidocaine | 22000398009 | 1 |
| Caesar & Loretz GmbH | Lidocaine | 22C15-B17-216739 | 1 |
| Caesar & Loretz GmbHGehe | Lidocaine | 22000398016 | 1 |
| Caesar & Loretz Hilden | Lidocaine | 19054506 | 1 |
| Caesar&Loretz GmbH | Lidocaine | 16289502 | 1 |
| Caesar&Loretz,Phönix... | Lidocaine | 15332314 | 1 |
| Cealo / Anzag | Lidocaine | 211217(20003343008) | 1 |
| Cealo | Lidocaine | 17348503 | 1 |
| Ebert-Jacobi | Lidocaine | 16289504 | 1 |
| Eur Rho Gehe | Lidocaine | 1908005-92 | 1 |
| EuRho, Noweda | Lidocaine | 2101035-03 | 1 |
| EuRho | Lidocaine | 1612021-03 | 2 |
| EuRho | Lidocaine | 2101035-03 | 1 |
| EuRho | Lidocaine | 2206002-001 | 1 |
| Euro OTC | Lidocaine | 10129901 | 1 |
| Euro OTC | Lidocaine | 1310023-02 | 3 |
| Euro OTC | Lidocaine | 160302701 | 1 |
| Euro OTC | Lidocaine | 1603027-01 | 3 |
| Euro OTC | Lidocaine | 1603027-02 | 1 |
| Euro OTC | Lidocaine | 1612021-01 | 5 |
| Euro OTC | Lidocaine | 161202102 | 2 |
| Euro OTC | Lidocaine | 1612021-02 | 6 |
| Euro OTC | Lidocaine | 1612021-03 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Lidocaine | 1612021-04 | 6 |
| Euro OTC | Lidocaine | 17348503 | 1 |
| Euro OTC | Lidocaine | 17K23B04345215 | 1 |
| Euro OTC | Lidocaine | 17K23-B04-347473 | 1 |
| Euro OTC | Lidocaine | 190200301 | 1 |
| Euro OTC | Lidocaine | 1902003-01 | 4 |
| Euro OTC | Lidocaine | 1905004-01 | 1 |
| Euro OTC | Lidocaine | 190800501 | 1 |
| Euro OTC | Lidocaine | 1908005-01 | 18 |
| Euro OTC | Lidocaine | 1908005-02 | 10 |
| Euro OTC | Lidocaine | 1911005-01 | 3 |
| Euro OTC | Lidocaine | 2006013-01 | 7 |
| Euro OTC | Lidocaine | 2101035-01 | 8 |
| Euro OTC | Lidocaine | 210103502 | 1 |
| Euro OTC | Lidocaine | 2101035-02 | 7 |
| Euro OTC | Lidocaine | 2101035-03 | 6 |
| Euro OTC | Lidocaine | 2206002-01 | 4 |
| Euro OTC | Lidocaine | 2206002-02 | 3 |
| Euro OTC | Lidocaine | LD/119024 | 1 |
| Euro OTC | Lidocaine | LDB/116106 | 1 |
| Euro OTC | Lidocaine | LDB/120025 | 1 |
| EuRoh | Lidocaine | 2101035-03 | 2 |
| Fagro/Gehe | Lidocaine | 15a15b01304284 | 1 |
| Fagron | Lidocaine | | 2 |
| Fagron | Lidocaine | 1014I-07006 | 1 |
| Fagron | Lidocaine | 1113M-03584 | 1 |
| Fagron | Lidocaine | 1116E-07006 | 1 |
| Fagron | Lidocaine | 118J23-B02-359239 | 1 |
| Fagron | Lidocaine | 11C09-N07 | 2 |
| Fagron | Lidocaine | 11D28-N12 | 1 |
| Fagron | Lidocaine | 11K17-N03 | 1 |
| Fagron | Lidocaine | 12/21-N06 | 3 |
| Fagron | Lidocaine | 12C08-N11 | 2 |
| Fagron | Lidocaine | 12E30-N10 | 8 |
| Fagron | Lidocaine | 12h16_n05 | 1 |
| Fagron | Lidocaine | 12h16-N05 | 1 |
| Fagron | Lidocaine | 12H16-n05 | 1 |
| Fagron | Lidocaine | 12H16-N05 | 5 |
| Fagron | Lidocaine | 12I21N06 | 1 |
| Fagron | Lidocaine | 12I21-N06 | 3 |
| Fagron | Lidocaine | 12K13-N01 | 1 |
| Fagron | Lidocaine | 1330-B02-287641 | 1 |
| Fagron | Lidocaine | 13B27-N04 | 8 |
| Fagron | Lidocaine | 13E28-B40-289433 | 1 |
| Fagron | Lidocaine | 13H05-N05 | 13 |
| Fagron | Lidocaine | 13H05-N050171/245 | 1 |
| Fagron | Lidocaine | 13J30-B02 | 6 |
| Fagron | Lidocaine | 13J30-b02-287639 | 1 |
| Fagron | Lidocaine | 13J30-B02-287640 | 1 |
| Fagron | Lidocaine | 13J30-B02-287641 | 6 |
| Fagron | Lidocaine | 13j30B02292219 | 1 |
| Fagron | Lidocaine | 13J30-B02-292219 | 2 |
| Fagron | Lidocaine | 13J30-B02-292220 | 2 |
| Fagron | Lidocaine | 13J30-B02-292221 | 5 |
| Fagron | Lidocaine | 14E13-B05 | 2 |
| Fagron | Lidocaine | 14E13-B05-295549 | 4 |
| Fagron | Lidocaine | 14E13-B05-295550 | 2 |
| Fagron | Lidocaine | 14E13-B05-295552 | 3 |
| Fagron | Lidocaine | 15332305 | 1 |
| Fagron | Lidocaine | 15A15-B01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Lidocaine | 15A15-B01-304282 | 5 |
| Fagron | Lidocaine | 15A15-B01-304283 | 2 |
| Fagron | Lidocaine | 15A15B01304284 | 1 |
| Fagron | Lidocaine | 15A15-B01-304284 | 10 |
| Fagron | Lidocaine | 15D23-B08 | 1 |
| Fagron | Lidocaine | 15D23-B08_309882 | 1 |
| Fagron | Lidocaine | 15D23-B08_312058 | 1 |
| Fagron | Lidocaine | 15d23-b08-309882 | 1 |
| Fagron | Lidocaine | 15D23-B08-309882 | 1 |
| Fagron | Lidocaine | 15D23-B08-31058 | 1 |
| Fagron | Lidocaine | 15D23B08311708 | 1 |
| Fagron | Lidocaine | 15D23-B08-311708 | 1 |
| Fagron | Lidocaine | 15d23-b08-312058 | 2 |
| Fagron | Lidocaine | 15D23-B08-312058 | 11 |
| Fagron | Lidocaine | 15h27-b05-318310 | 1 |
| Fagron | Lidocaine | 15H27-B07 | 1 |
| Fagron | Lidocaine | 15H27-B07-315483 | 2 |
| Fagron | Lidocaine | 15H27-B07-316784 | 2 |
| Fagron | Lidocaine | 15H27-B07-318310 | 5 |
| Fagron | Lidocaine | 1612021-01 | 1 |
| Fagron | Lidocaine | 16289508 | 1 |
| Fagron | Lidocaine | 16A28B06320059 | 1 |
| Fagron | Lidocaine | 16A28-B06-320059 | 2 |
| Fagron | Lidocaine | 16A28-B06320079 | 1 |
| Fagron | Lidocaine | 16A28-B06-320079 | 1 |
| Fagron | Lidocaine | 16F21 | 2 |
| Fagron | Lidocaine | 16F21-B06 | 7 |
| Fagron | Lidocaine | 16F21-B06-323669 | 5 |
| Fagron | Lidocaine | 16F21-B06-323670 | 20 |
| Fagron | Lidocaine | 16F21B06325934 | 1 |
| Fagron | Lidocaine | 16F21-B06-325934 | 3 |
| Fagron | Lidocaine | 16F21-B06-327232 | 3 |
| Fagron | Lidocaine | 16F21-B06-328421 | 8 |
| Fagron | Lidocaine | 16F21-B06-328421 | 1 |
| Fagron | Lidocaine | 16F21-B06-329589 | 1 |
| Fagron | Lidocaine | 16F21B06332251 | 1 |
| Fagron | Lidocaine | 16F21-B06-332253 | 6 |
| Fagron | Lidocaine | 16F21-B06-332253 | 1 |
| Fagron | Lidocaine | 16F21B06333787 | 1 |
| Fagron | Lidocaine | 16F21-B06-333787 | 1 |
| Fagron | Lidocaine | 16F21-B06-333788 | 1 |
| Fagron | Lidocaine | 16f21-b06-335659 | 1 |
| Fagron | Lidocaine | 16F21-B06-335659 | 1 |
| Fagron | Lidocaine | 17G03-B08 | 5 |
| Fagron | Lidocaine | 17G03-B08-337576 | 2 |
| Fagron | Lidocaine | 17G03-B08-338284 | 1 |
| Fagron | Lidocaine | 17g03-b08-338286 | 1 |
| Fagron | Lidocaine | 17G03-B08-338286 | 6 |
| Fagron | Lidocaine | 17G03-B08-339445 | 2 |
| Fagron | Lidocaine | 17G03-B08-341306 | 5 |
| Fagron | Lidocaine | 17G03-B08-341308 | 5 |
| Fagron | Lidocaine | 17G03-B08-343251 | 4 |
| Fagron | Lidocaine | 17G23-B04-350541 | 1 |
| Fagron | Lidocaine | 17K23-B04 | 16 |
| Fagron | Lidocaine | 17K23-B04-343250 | 6 |
| Fagron | Lidocaine | 17K23-B04-345215 | 10 |
| Fagron | Lidocaine | 17K23-B04-345948 | 3 |
| Fagron | Lidocaine | 17K23B04347473 | 2 |
| Fagron | Lidocaine | 17K23-B04-347473 | 7 |
| Fagron | Lidocaine | 17K23B04347474 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Lidocaine | 17K23-B04-347474 | 2 |
| Fagron | Lidocaine | 17k23-b04-347475 | 1 |
| Fagron | Lidocaine | 17K23-B04-347475 | 9 |
| Fagron | Lidocaine | 17k23-b04-349366 | 1 |
| Fagron | Lidocaine | 17K23B04350189 | 1 |
| Fagron | Lidocaine | 17K23-B04-350189 | 5 |
| Fagron | Lidocaine | 17K23-B04-350541 | 8 |
| Fagron | Lidocaine | 17K23-B04-350542 | 2 |
| Fagron | Lidocaine | 17K23-B04-350543 | 13 |
| Fagron | Lidocaine | 17K23-B04-353247 | 7 |
| Fagron | Lidocaine | 17k23-b04-353427 | 1 |
| Fagron | Lidocaine | 17K23-B04-353427 | 7 |
| Fagron | Lidocaine | 17K23-B04-3534274 | 1 |
| Fagron | Lidocaine | 17K23B04353428 | 1 |
| Fagron | Lidocaine | 17K23-B04-353428 | 7 |
| Fagron | Lidocaine | 17K23-B04-355709 | 13 |
| Fagron | Lidocaine | 17K23-B04-355750 | 1 |
| Fagron | Lidocaine | 18/23-B02-359237 | 1 |
| Fagron | Lidocaine | 18/23-B02-359239 | 1 |
| Fagron | Lidocaine | 1823-B02-356573 | 1 |
| Fagron | Lidocaine | 18J23-B02 | 8 |
| Fagron | Lidocaine | 18J23-B02_359237 | 1 |
| Fagron | Lidocaine | 18J23-B02-3557018 | 1 |
| Fagron | Lidocaine | 18J23-B02-355708 | 4 |
| Fagron | Lidocaine | 18J23-B02356573 | 1 |
| Fagron | Lidocaine | 18J-23-B02-356573 | 1 |
| Fagron | Lidocaine | 18J23-B02-35673 | 1 |
| Fagron | Lidocaine | 18j23-B02-359237 | 1 |
| Fagron | Lidocaine | 18J23-B02-359237 | 5 |
| Fagron | Lidocaine | 18J23-B02-359238 | 3 |
| Fagron | Lidocaine | 18J23B02359239 | 1 |
| Fagron | Lidocaine | 18J23-B02-359239 | 22 |
| Fagron | Lidocaine | 18j23bo2359239 | 1 |
| Fagron | Lidocaine | 190545001 | 1 |
| Fagron | Lidocaine | 190981109 | 1 |
| Fagron | Lidocaine | 19F27-B01 | 18 |
| Fagron | Lidocaine | 19F27-B01363500 | 1 |
| Fagron | Lidocaine | 19F27-B01-363500 | 7 |
| Fagron | Lidocaine | 19F27-B01-3635005 | 1 |
| Fagron | Lidocaine | 19F27-B01-3635006 | 1 |
| Fagron | Lidocaine | 19f27-B01-363501 | 1 |
| Fagron | Lidocaine | 19F27-B01-363501 | 21 |
| Fagron | Lidocaine | 19F27-B01-363502 | 12 |
| Fagron | Lidocaine | 19f27b01363504 | 1 |
| Fagron | Lidocaine | 19F27-b01-363504 | 1 |
| Fagron | Lidocaine | 19F27-B01363504 | 1 |
| Fagron | Lidocaine | 19F27-B01-363504 | 10 |
| Fagron | Lidocaine | 19F27-B01-363505 | 8 |
| Fagron | Lidocaine | 19f27-b01-363506 | 2 |
| Fagron | Lidocaine | 19F27-B01-363506 | 15 |
| Fagron | Lidocaine | 19F27-B01-363511 | 1 |
| Fagron | Lidocaine | 19F27-Bo1-363504 | 2 |
| Fagron | Lidocaine | 19F27-BO1-363506 | 2 |
| Fagron | Lidocaine | 20C13-F04 | 4 |
| Fagron | Lidocaine | 20C13-F04-3698105 | 1 |
| Fagron | Lidocaine | 20C13-F04-3698106 | 1 |
| Fagron | Lidocaine | 20C13-F04-369814 | 6 |
| Fagron | Lidocaine | 20c13-F04-369815 | 1 |
| Fagron | Lidocaine | 20C13-F04-369815 | 7 |
| Fagron | Lidocaine | 20C13-F04-369816 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Lidocaine | 20H13-F03 | 4 |
| Fagron | Lidocaine | 20H13-F03-373500 | 1 |
| Fagron | Lidocaine | 20H13-F03-373501 | 1 |
| Fagron | Lidocaine | 20H13-F04 | 4 |
| Fagron | Lidocaine | 20H13-F04-273497 | 1 |
| Fagron | Lidocaine | 20H13-F04-3734907 | 1 |
| Fagron | Lidocaine | 20H13-f04-373497 | 1 |
| Fagron | Lidocaine | 20H13-F04-373497 | 16 |
| Fagron | Lidocaine | 20H13-F04-373499 | 3 |
| Fagron | Lidocaine | 20H13-F04-373501 | 1 |
| Fagron | Lidocaine | 20h13-f04-73497 | 1 |
| Fagron | Lidocaine | 20H13-F0-373497 | 1 |
| Fagron | Lidocaine | 20H13F04-373497 | 1 |
| Fagron | Lidocaine | 20ht3-f04-373497 | 1 |
| Fagron | Lidocaine | 20L11-F01 | 2 |
| Fagron | Lidocaine | 20L11-F01_376357 | 1 |
| Fagron | Lidocaine | 20L11-F01-376356 | 2 |
| Fagron | Lidocaine | 20l11-f01-376357 | 1 |
| Fagron | Lidocaine | 20L11-f01-376357 | 1 |
| Fagron | Lidocaine | 20L11-F01-376357 | 9 |
| Fagron | Lidocaine | 20M13-F04-373497 | 1 |
| Fagron | Lidocaine | 214U-03584 | 1 |
| Fagron | Lidocaine | 21B10-B07 | 1 |
| Fagron | Lidocaine | 21B10-B07-213330 | 1 |
| Fagron | Lidocaine | 21B10-B07-213578 | 1 |
| Fagron | Lidocaine | 21f08b14216888 | 1 |
| Fagron | Lidocaine | 22C115-B17-216739 | 1 |
| Fagron | Lidocaine | 22C15-817-216739 | 1 |
| Fagron | Lidocaine | 22C15-B17 | 2 |
| Fagron | Lidocaine | 22C15-B17_216737 | 1 |
| Fagron | Lidocaine | 22C15-B17-216737 | 14 |
| Fagron | Lidocaine | 22C15-B17-216738 | 7 |
| Fagron | Lidocaine | 22c15b17216739 | 1 |
| Fagron | Lidocaine | 22c15-b17-216739 | 1 |
| Fagron | Lidocaine | 22C15-B17-216739 | 16 |
| Fagron | Lidocaine | 22C15-B17-221066 | 1 |
| Fagron | Lidocaine | 22C15-B17-225236 | 2 |
| Fagron | Lidocaine | 22C15-B17-225237 | 1 |
| Fagron | Lidocaine | 2OL11-FO1-376357 | 1 |
| Fagron | Lidocaine | 369816 | 1 |
| Fagron | Lidocaine | 5122014A | 1 |
| Fagron | Lidocaine | 515M-07006 | 1 |
| Fagron | Lidocaine | 5742 | 1 |
| Fagron | Lidocaine | 6J23-No2 | 1 |
| Fagron | Lidocaine | 700412-0002 | 1 |
| Fagron | Lidocaine | 700412-0004 | 1 |
| Fagron | Lidocaine | 700412-0006 | 1 |
| Fagron | Lidocaine | 71-18 | 1 |
| Fagron | Lidocaine | 8J23-B02-3592391 | 1 |
| Fagron | Lidocaine | B01-3635001 | 1 |
| Fagron | Lidocaine | B01-3635002 | 1 |
| Fagron | Lidocaine | B01-3635004 | 3 |
| Fagron | Lidocaine | B01-3635006 | 2 |
| Fagron | Lidocaine | B07-318310 | 1 |
| Fagron | Lidocaine | F01-3763507 | 1 |
| Fagron | Lidocaine | F03-3735001 | 1 |
| Fagron | Lidocaine | F0-37349 | 1 |
| Fagron | Lidocaine | F04-3698104 | 1 |
| Fagron | Lidocaine | F04-3698105 | 2 |
| Fagron | Lidocaine | F04-3698106 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Lidocaine | F04-3734907 | 1 |
| Fagron | Lidocaine | F04-3734909 | 2 |
| Fagron | Lidocaine | LDB/116049 | 2 |
| Fagron | Lidocaine | LDB/117049 | 1 |
| Fagron | Lidocaine | LDB/117093 | 4 |
| Fagron | Lidocaine | LDB/118066 | 2 |
| Fagron | Lidocaine | LDB/119043 | 5 |
| Fagron | Lidocaine | LDB/119043x3 | 1 |
| Fagron | Lidocaine | ldb/120006 | 1 |
| Fagron | Lidocaine | LDB/120006 | 3 |
| Fagron | Lidocaine | LDB/120018 | 2 |
| Fagron | Lidocaine | LDB/722005 | 3 |
| Fargon/ Sanacorp Lübeck | Lidocaine | 18J23-B02-359237 | 1 |
| Fargon/AHD | Lidocaine | 17K23-B04-353428 | 1 |
| Fargon/AHD | Lidocaine | 18J23-B02-359238 | 1 |
| Fargon/Fönix | Lidocaine | 20C13-F04-369814 | 1 |
| Fargon/Noweda | Lidocaine | 17K23-B04-350543 | 1 |
| Fargon/Noweda | Lidocaine | 19F27-B01 | 1 |
| Fargon/Sanacorp | Lidocaine | 22C15-B17-216738 | 2 |
| Fargon | Lidocaine | 12E30-N10 | 1 |
| Fargron | Lidocaine | 14E13-B05-295552 | 1 |
| Fragon/ Gehe | Lidocaine | 19F27-B01-363502 | 1 |
| Gatt-Koller | Lidocaine | 1900471 | 1 |
| GEHE 02.12.2014 | Lidocaine | 13J30-B02-292220 | 1 |
| Gehe am 22.01.2014 | Lidocaine | 13H05-N05 | 2 |
| Gehe Kassel | Lidocaine | 14E13-B05-295550 | 1 |
| Gehe | Lidocaine | 12H16-N05 | 1 |
| Gehe | Lidocaine | 13B27-N04 | 1 |
| Gehe | Lidocaine | 14E13-B05-295552 | 1 |
| GEHE | Lidocaine | 16289503 | 1 |
| Gehe | Lidocaine | 16F21-B06-323670 | 1 |
| GEHE | Lidocaine | 16F21-B06-328421 | 1 |
| Gehe | Lidocaine | 17G03-B08-338286 | 2 |
| Gehe | Lidocaine | 17K23-B04-355709 | 1 |
| GEHE | Lidocaine | 18044405 | 1 |
| Gehe | Lidocaine | 18J23-B02-359239 | 1 |
| Gehe | Lidocaine | 19054506 | 1 |
| Gehe | Lidocaine | 192758005 | 2 |
| Gehe | Lidocaine | 2003343016 | 1 |
| Gehe | Lidocaine | 20C13F04369816 | 1 |
| Gehe | Lidocaine | 22000398011 | 2 |
| Gehe | Lidocaine | 22000398016 | 1 |
| Gehe | Lidocaine | 22C15-B17-216739 | 3 |
| Gehe | Lidocaine | 23D25-B10-230220 | 1 |
| Gehe | Lidocaine | 23D25-B10-230226 | 1 |
| GEHE | Lidocaine | 23D25-B10-230226 | 1 |
| Gehe | Lidocaine | 23D25-B10-234510 | 1 |
| GEHE | Lidocaine | 23D25-B10-234510 | 1 |
| Gehe | Lidocaine | 23H23-B01-234506 | 1 |
| Geilenkirchen | Lidocaine | 17G03-B08-341306 | 1 |
| Geilenkirchen | Lidocaine | LDB/117093 | 1 |
| Geilenkirchen | Lidocaine | LDB/118066 | 1 |
| GUMO | Lidocaine | 19F27-B01-3635006 | 2 |
| Gutenberg-Apotheke | Lidocaine | 13J30-B02 | 1 |
| Hedinger/Gehe | Lidocaine | 17K23-B04-343250 | 1 |
| Henry Lamotte Oils GmbH | Lidocaine | | 1 |
| Jenne | Lidocaine | 20003343015 | 1 |
| Jenne | Lidocaine | 2101035-02 | 1 |
| Kehr | Lidocaine | 16F21-B06-328421 | 1 |
| Kehr | Lidocaine | 16F21-B06-332251 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Kehr | Lidocaine | 17G03-B08-338284 | 1 |
| Kehr | Lidocaine | 22000398013 | 1 |
| Kehr | Lidocaine | 22C15-B17-216739 | 1 |
| Kehr | Lidocaine | 23D25-B10-230226 | 1 |
| Kehr | Lidocaine | 23H23-B01-234507 | 1 |
| LaVita | Lidocaine | 15H27-B07-318310 | 1 |
| Moehs BCN S.L. / Noweda | Lidocaine | 15332305 | 1 |
| Nachprüfung von Juni 2018 | Lidocaine | 12C08-N11 | 1 |
| Noweda | Lidocaine | 10129901 | 1 |
| Noweda | Lidocaine | 12H16-N05 | 1 |
| Noweda | Lidocaine | 12H16-No5 | 1 |
| Noweda | Lidocaine | 16F21-B06 | 1 |
| Noweda | Lidocaine | 17K23-B04-347473 | 1 |
| Noweda | Lidocaine | 17K23-B04-350542 | 1 |
| Noweda | Lidocaine | 18044402 | 1 |
| Noweda | Lidocaine | 18J23-B02-355708 | 3 |
| Noweda | Lidocaine | 19054503 | 1 |
| Noweda | Lidocaine | 192758005 | 1 |
| Noweda | Lidocaine | 2003343016 | 1 |
| Noweda | Lidocaine | 220003908013 | 1 |
| Noweda | Lidocaine | 22000398013 | 3 |
| Noweda | Lidocaine | 22000398016 | 1 |
| Noweda | Lidocaine | 22000398017 | 1 |
| Noweda | Lidocaine | 22C15-B17-216739 | 4 |
| Noweda | Lidocaine | 2310020-01 | 2 |
| Noweda | Lidocaine | 2310029-01 | 1 |
| Noweda | Lidocaine | 23D25-B10-230226 | 2 |
| Pharmachem | Lidocaine | 17K23-B04-350541 | 1 |
| PHOENIX 22.08.2014 | Lidocaine | | 2 |
| PHOENIX 22.08.2014 | Lidocaine | 13J30-B02-287640 | 1 |
| Phoenix/Fargon | Lidocaine | 20C13-F04-369815 | 2 |
| Phoenix | Lidocaine | 15332305 | 1 |
| phoenix | Lidocaine | 17348503 | 1 |
| Phoenix | Lidocaine | 17K23-B04-350543 | 1 |
| Phoenix | Lidocaine | 17K23-B05-345948 | 1 |
| Phoenix | Lidocaine | 18044408 | 3 |
| Phoenix | Lidocaine | 18J23-B02-359238 | 1 |
| Phoenix | Lidocaine | 1905004-01 | 1 |
| Phoenix | Lidocaine | 19054504 | 1 |
| Phoenix | Lidocaine | 19f27-b01 | 1 |
| Phoenix | Lidocaine | 20003343004 | 1 |
| Phoenix | Lidocaine | 20004099001 | 1 |
| Phoenix | Lidocaine | 20c13-f04-369815 | 1 |
| Phoenix | Lidocaine | 20h13-f03-373501 | 1 |
| Phoenix | Lidocaine | 20H13-F04-373497 | 1 |
| phoenix | Lidocaine | 22000398011 | 2 |
| Phönix Gotha | Lidocaine | 15A15-B01-304284 | 1 |
| Phönix | Lidocaine | 13352405 | 1 |
| Phönix | Lidocaine | 13B27-N04 | 1 |
| Phönix | Lidocaine | 17K23-B04-343250 | 1 |
| Phönix | Lidocaine | 17K23-B04-345215 | 1 |
| Phönix | Lidocaine | 17K23-B04-347475 | 1 |
| Phönix | Lidocaine | 19F27-B01-363505 | 1 |
| Phönix | Lidocaine | 2006013-01 | 1 |
| Phönix | Lidocaine | 200860209 | 1 |
| PHönix | Lidocaine | 20h13-f04-373499 | 1 |
| Phönix | Lidocaine | 22000398010 | 3 |
| phönix | Lidocaine | 22000398011 | 1 |
| Rondell Apotheke | Lidocaine | 15332304 | 1 |
| Sanacorp | Lidocaine | 12H16-N05 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Lidocaine | 12I21-N06 | 1 |
| Sanacorp | Lidocaine | 1603027-02 | 1 |
| Sanacorp | Lidocaine | 17183109 | 1 |
| Sanacorp | Lidocaine | 17K23-B04-350542 | 1 |
| Sanacorp | Lidocaine | 2101035-03 | 1 |
| Sanacorp | Lidocaine | 22000398013 | 4 |
| Sanacorp | Lidocaine | 22000398017 | 2 |
| Sanacorp | Lidocaine | 226002-01 | 1 |
| Sanacorp | Lidocaine | 22C15-B17-216738 | 2 |
| Sanacorp | Lidocaine | 22C15-B17-225236 | 1 |
| Sanacorp | Lidocaine | 22C15-B17-225237 | 3 |
| Sanacorp | Lidocaine | 23002079003 | 3 |
| Sanacorp | Lidocaine | 23D25-B10-230221 | 1 |
| Spangropharm | Lidocaine | 18044410 | 1 |
| Swati Pentose/ Link ... | Lidocaine | B2185 | 1 |
| Swati Spentose / Gehe | Lidocaine | 18J23-B02-359237 | 1 |
| Swati Spentose / Gehe | Lidocaine | 19F27-B01-363500 | 1 |
| Swati Spentose / Gehe | Lidocaine | B01-3635001 | 1 |
| Swati Spentose Pvt L... | Lidocaine | B2185 | 1 |
| Swati Spentose Pvt.L... | Lidocaine | 21B10-B07-213330 | 2 |
| Swati Spentose Pvt.L... | Lidocaine | 22C15-B17-216738 | 2 |
| Swati Spentose Pvt.L... | Lidocaine | 21B10-B07213330 | 1 |
| Swati Spentose Pvt.L... | Lidocaine | 21B10-B07-213330 | 1 |
| SWATI/Noweda | Lidocaine | LDB/119024 | 1 |
| Swato Spentosen/Phoenix | Lidocaine | F04-3698105 | 1 |

- 254 936 spectra from 1666 *Apo-Ident* customers from a total of 51 714 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Lidocaine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Lidocaine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 600 | 0 | 212 340 |
| **Type C** | 0 | 1939 | 11 | 254 936 |

The substance/substance group *Lidocaine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.4359 % (> 99.2821 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several

new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20942 | 20942 | 0.00 | 164.60 |
| 21640 | 24031 | 12.81 | 163.63 |
| 21673 | 24031 | 29.61 | 165.63 |
| 22984 | 22984 | 0.00 | 163.04 |
| 23019 | 22984 | 6.25 | 162.79 |
| 24031 | 24031 | 0.00 | 164.75 |
| 24928 | 24928 | 0.00 | 163.37 |
| 25533 | 25533 | 0.00 | 162.19 |
| 26654 | 26654 | 0.00 | 162.20 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Lidocaine hydrochloride monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20093-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Lidocaine hydrochloride monohydrate; Lidocaini hydrochloridum monohydricum

### Special notes

When selecting the *Lidocaine hydrochloride monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Lidocaine hydrochloride monohydrate | 7 | 14 | 516 |

### Second-stage model

For differentiation of the substance/substance group *Lidocaine hydrochloride monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Lidocaine hydrochloride monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 103.94 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Lidocaine hydrochloride monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Lidocaine hydrochloride monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Lidocaine hydrochloride m… | 12135511 | 20882 | 40 | AR-15-FG-008867-01 |
| Caelo | Lidocaine hydrochloride m… | 172923 | 23807 | 40 | 20171122* |
| Euro OTC | Lidocaine hydrochloride m… | 1403025-02 | 21613 | 60 | 20140516 |
| Euro OTC | Lidocaine hydrochloride m… | 1411010 | 21770 | 60 | 20150126* |
| Euro OTC | Lidocaine hydrochloride m… | 1907012 | 24776 | 40 | 20190801* |
| Euro OTC | Lidocaine hydrochloride m… | 2201026 | 26028 | 40 | 20220321* |
| Fagron | Lidocaine hydrochloride m… | 20C18-B02-196984 | 25446 | 40 | 20200324 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 7 reference samples from the substance/substance group *Lidocaine hydrochloride monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 006 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 620 spectra of 17 reference samples from the substance/substance group *Lidocaine hydrochloride monohydrate*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Lidocaine hydrochloride m… | 162222 | 22771 | 40 |
| Caelo | Lidocaine hydrochloride m… | 152995 | 22772 | 40 |
| Caelo | Lidocaine hydrochloride m… | 172048 | 23687 | 40 |
| Caelo | Lidocaine hydrochloride m… | 20001694 | 25626 | 40 |
| Caelo | Lidocaine hydrochloride m… | 21002505 | 25852 | 50 |
| Caelo | Lidocaine hydrochloride m… | 22003202 | 26491 | 40 |
| Caelo | Lidocaine hydrochloride m… | 23002422 | 26945 | 40 |
| Euro OTC | Lidocaine hydrochloride m… | 1606024 | 22702 | 40 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015 | 22980 | 40 |
| Euro OTC | Lidocaine hydrochloride m… | 1808031 | 24326 | 40 |
| Euro OTC | Lidocaine hydrochloride m… | 2101034 | 25572 | 40 |
| Euro OTC | Lidocaine hydrochloride m… | 2211019 | 26523 | 40 |
| Euro OTC | Lidocaine hydrochloride m… | 2405011 | 27339 | 40 |
| Fagron | Lidocaine hydrochloride m… | 22C15-B16-218866 | 26135 | 40 |
| Caelo | Lidocaine hydrochloride m… | 22003202 | 26491SI | 20 |
| Euro OTC | Lidocaine hydrochloride m… | 2201026 | 26028SI† | 10 |
| Fagron | Lidocaine hydrochloride m… | 22C15-B16-218866 | 26135SI | 20 |

- 212 320 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4128 spectra from 1233 *Apo-Ident* customers from 535 batches from the substance/substance group *Lidocaine hydrochloride monohydrate*.
- Among them are spectra of independent samples from 512 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Lidocaine hydrochloride m... | | 1 |
| | Lidocaine hydrochloride m... | 21002505006 | 2 |
| | Lidocaine hydrochloride m... | 21002505007 | 4 |
| | Lidocaine hydrochloride m... | 21002505008 | 1 |
| | Lidocaine hydrochloride m... | 21002505011 | 2 |
| | Lidocaine hydrochloride m... | 21002505012 | 6 |
| | Lidocaine hydrochloride m... | 210103403 | 1 |
| | Lidocaine hydrochloride m... | 2101034-03 | 2 |
| | Lidocaine hydrochloride m... | 220032004 | 1 |
| | Lidocaine hydrochloride m... | 22003202002 | 18 |
| | Lidocaine hydrochloride m... | 22003202003 | 18 |
| | Lidocaine hydrochloride m... | 22003202004 | 3 |
| | Lidocaine hydrochloride m... | 22003202006 | 29 |
| | Lidocaine hydrochloride m... | 22003202007 | 13 |
| | Lidocaine hydrochloride m... | 2201026-01 | 9 |
| | Lidocaine hydrochloride m... | 2201026-02 | 22 |
| | Lidocaine hydrochloride m... | 2203202007 | 1 |
| | Lidocaine hydrochloride m... | 22032202003 | 1 |
| | Lidocaine hydrochloride m... | 221019-01 | 1 |
| | Lidocaine hydrochloride m... | 22110019-003 | 1 |
| | Lidocaine hydrochloride m... | 22110119-01 | 1 |
| | Lidocaine hydrochloride m... | 221101901 | 2 |
| | Lidocaine hydrochloride m... | 2211019-01 | 117 |
| | Lidocaine hydrochloride m... | 221101902 | 1 |
| | Lidocaine hydrochloride m... | 2211019-02 | 29 |
| | Lidocaine hydrochloride m... | 2211019-03 | 19 |
| | Lidocaine hydrochloride m... | 22C15-B16-218866 | 1 |
| | Lidocaine hydrochloride m... | 22C15-B16-220953 | 3 |
| | Lidocaine hydrochloride m... | 22H22-B03-222936 | 1 |
| | Lidocaine hydrochloride m... | 22K26-B06-225243 | 2 |
| | Lidocaine hydrochloride m... | 2300344900 | 1 |
| | Lidocaine hydrochloride m... | 23003449002 | 1 |
| | Lidocaine hydrochloride m... | 23003449003 | 7 |
| | Lidocaine hydrochloride m... | 23003449004 | 5 |
| | Lidocaine hydrochloride m... | 2300345001 | 1 |
| | Lidocaine hydrochloride m... | 23003452001 | 8 |
| | Lidocaine hydrochloride m... | 23003452002 | 4 |
| | Lidocaine hydrochloride m... | 23003452004 | 28 |
| | Lidocaine hydrochloride m... | 23D25-B11-228314 | 1 |
| | Lidocaine hydrochloride m... | 23D25-B11-230225 | 3 |
| | Lidocaine hydrochloride m... | 2405011-0 | 1 |
| | Lidocaine hydrochloride m... | 2405011-01 | 12 |
| | Lidocaine hydrochloride m... | 2405011-02 | 25 |
| | Lidocaine hydrochloride m... | 240511-02 | 1 |
| | Lidocaine hydrochloride m... | 245011-02 | 1 |
| | Lidocaine hydrochloride m... | 24A03-B02-238349 | 2 |
| | Lidocaine hydrochloride m... | 24A03-B02-238353 | 1 |
| | Lidocaine hydrochloride m... | 24A03-B02-238353 | 1 |
| | Lidocaine hydrochloride m... | 24H29-B06-002781 | 1 |
| | Lidocaine hydrochloride m... | 2505012 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Lidocaine hydrochloride m... | LDH/121043 | 2 |
| | Lidocaine hydrochloride m... | LDH/723022 | 2 |
| | Lidocaine hydrochloride m... | LDH123030 | 1 |
| 01.07.14 | Lidocaine hydrochloride m... | 13343004 | 1 |
| 08597954 | Lidocaine hydrochloride m... | 1907012-01 | 1 |
| A.H.D. | Lidocaine hydrochloride m... | 1202035-02 | 1 |
| ACM | Lidocaine hydrochloride m... | KNC0625J17 | 1 |
| ACM | Lidocaine hydrochloride m... | KNC1247J15 | 1 |
| AEP | Lidocaine hydrochloride m... | 22003202003 | 1 |
| AHC | Lidocaine hydrochloride m... | 2211019-02 | 1 |
| AHD | Lidocaine hydrochloride m... | 1612015-02 | 1 |
| AHD | Lidocaine hydrochloride m... | 17292308 | 2 |
| AHD | Lidocaine hydrochloride m... | 17292311 | 1 |
| AHD | Lidocaine hydrochloride m... | 17292313 | 1 |
| AHD | Lidocaine hydrochloride m... | 18179904 | 1 |
| AHD | Lidocaine hydrochloride m... | 18179910 | 1 |
| AHD | Lidocaine hydrochloride m... | 22003202003 | 1 |
| AHD | Lidocaine hydrochloride m... | 2211019-01 | 6 |
| AHD | Lidocaine hydrochloride m... | 2211019-02 | 1 |
| AHD | Lidocaine hydrochloride m... | 23003452004 | 1 |
| AHD | Lidocaine hydrochloride m... | 2405011-01 | 1 |
| ALH/EuRho | Lidocaine hydrochloride m... | 1612015-01 | 1 |
| ALH | Lidocaine hydrochloride m... | 1606024-01 | 1 |
| Aliance Health Care | Lidocaine hydrochloride m... | 2211019-1 | 1 |
| Alliance healfcare | Lidocaine hydrochloride m... | 1808031-01 | 1 |
| Alliance healfcare | Lidocaine hydrochloride m... | 1907012-01 | 2 |
| Alliance Healt | Lidocaine hydrochloride m... | LDH/722031 | 1 |
| Alliance health | Lidocaine hydrochloride m... | 14B12-B03-292214 | 1 |
| Alliance Healthcare | Lidocaine hydrochloride m... | 20004451002 | 2 |
| Alliance Healthcare | Lidocaine hydrochloride m... | 22003202006 | 1 |
| Alliance Healthcare | Lidocaine hydrochloride m... | 23003449004 | 1 |
| Alliance | Lidocaine hydrochloride m... | 21002505012 | 1 |
| Alliance | Lidocaine hydrochloride m... | 2101034-03 | 1 |
| Alliance | Lidocaine hydrochloride m... | 2211019-01 | 6 |
| Allianz | Lidocaine hydrochloride m... | 17204804 | 2 |
| Allianz | Lidocaine hydrochloride m... | 17292308 | 1 |
| Anzag | Lidocaine hydrochloride m... | 1202035-03 | 1 |
| Anzag | Lidocaine hydrochloride m... | 1403025-01 | 1 |
| Anzag | Lidocaine hydrochloride m... | 1411010-01 | 1 |
| Anzag | Lidocaine hydrochloride m... | 14B12-B03-292214 | 1 |
| Anzag | Lidocaine hydrochloride m... | 1505023-01 | 2 |
| Anzag | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| Anzag | Lidocaine hydrochloride m... | 2101034-03 | 2 |
| Anzag | Lidocaine hydrochloride m... | 2211019-01 | 1 |
| Anzag | Lidocaine hydrochloride m... | 23003452002 | 1 |
| Anzag | Lidocaine hydrochloride m... | 230524(22003202003) | 1 |
| Anzag | Lidocaine hydrochloride m... | 250218(23003449004) | 1 |
| Apo-Ident, Phönix, 7... | Lidocaine hydrochloride m... | 1612015-01 | 1 |
| apoident/AHD | Lidocaine hydrochloride m... | 1808031-03 | 1 |
| Apo-ident | Lidocaine hydrochloride m... | 2101034-02 | 1 |
| Apo-ident | Lidocaine hydrochloride m... | 2101034-03 | 1 |
| apo-ident | Lidocaine hydrochloride m... | 220102601 | 1 |
| Apo-ident | Lidocaine hydrochloride m... | 2201026-01 | 1 |
| apo-ident | Lidocaine hydrochloride m... | LDH/12043 | 1 |
| Audor Pharma | Lidocaine hydrochloride m... | 2101034-01 | 1 |
| Bombastus | Lidocaine hydrochloride m... | 15215301 | 1 |
| Bombastus | Lidocaine hydrochloride m... | 1612015-02 | 1 |
| Bombastus | Lidocaine hydrochloride m... | 180831-01 | 1 |
| Caelo | Lidocaine hydrochloride m... | | 1 |
| Caelo | Lidocaine hydrochloride m... | 1010024-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lidocaine hydrochloride m… | 10120115 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1017Q-01775 | 1 |
| Caelo | Lidocaine hydrochloride m… | 10320703 | 1 |
| Caelo | Lidocaine hydrochloride m… | 10320704 | 1 |
| Caelo | Lidocaine hydrochloride m… | 10320707 | 2 |
| Caelo | Lidocaine hydrochloride m… | 10320717 | 1 |
| Caelo | Lidocaine hydrochloride m… | 10320719 | 1 |
| Caelo | Lidocaine hydrochloride m… | 11091203 | 1 |
| Caelo | Lidocaine hydrochloride m… | 11302902 | 2 |
| Caelo | Lidocaine hydrochloride m… | 11302904 | 1 |
| Caelo | Lidocaine hydrochloride m… | 11302905 | 1 |
| Caelo | Lidocaine hydrochloride m… | 11302906 | 3 |
| Caelo | Lidocaine hydrochloride m… | 116037 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1202035 | 1 |
| Caelo | Lidocaine hydrochloride m… | 120203501 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1202035-01 | 2 |
| Caelo | Lidocaine hydrochloride m… | 1202035-02 | 2 |
| Caelo | Lidocaine hydrochloride m… | 1202035-03 | 1 |
| Caelo | Lidocaine hydrochloride m… | 12021503 | 1 |
| Caelo | Lidocaine hydrochloride m… | 12135503 | 2 |
| Caelo | Lidocaine hydrochloride m… | 12135504 | 3 |
| Caelo | Lidocaine hydrochloride m… | 12135508 | 5 |
| Caelo | Lidocaine hydrochloride m… | 12135509 | 4 |
| Caelo | Lidocaine hydrochloride m… | 12135511 | 2 |
| Caelo | Lidocaine hydrochloride m… | 12176101 | 8 |
| Caelo | Lidocaine hydrochloride m… | 12176102 | 8 |
| Caelo | Lidocaine hydrochloride m… | 12176103 | 8 |
| Caelo | Lidocaine hydrochloride m… | 12176109 | 2 |
| Caelo | Lidocaine hydrochloride m… | 1230817/160602402 | 1 |
| Caelo | Lidocaine hydrochloride m… | 12B23-B03-352117 | 1 |
| Caelo | Lidocaine hydrochloride m… | 13(1808031-01) | 1 |
| Caelo | Lidocaine hydrochloride m… | 13118802 | 2 |
| Caelo | Lidocaine hydrochloride m… | 13118803 | 5 |
| Caelo | Lidocaine hydrochloride m… | 13118807 | 6 |
| Caelo | Lidocaine hydrochloride m… | 13118808 | 4 |
| Caelo | Lidocaine hydrochloride m… | 13118811 | 2 |
| Caelo | Lidocaine hydrochloride m… | 13118812 | 3 |
| Caelo | Lidocaine hydrochloride m… | 1317I-01775 | 1 |
| Caelo | Lidocaine hydrochloride m… | 13343001 | 2 |
| Caelo | Lidocaine hydrochloride m… | 13343002 | 3 |
| Caelo | Lidocaine hydrochloride m… | 13343003 | 5 |
| Caelo | Lidocaine hydrochloride m… | 13343004 | 7 |
| Caelo | Lidocaine hydrochloride m… | 13343007 | 12 |
| Caelo | Lidocaine hydrochloride m… | 13343008 | 5 |
| Caelo | Lidocaine hydrochloride m… | 13343011 | 3 |
| Caelo | Lidocaine hydrochloride m… | 13343012 | 17 |
| Caelo | Lidocaine hydrochloride m… | 13343014 | 5 |
| Caelo | Lidocaine hydrochloride m… | 13343015 | 2 |
| Caelo | Lidocaine hydrochloride m… | 13343016 | 2 |
| Caelo | Lidocaine hydrochloride m… | 13343017 | 5 |
| Caelo | Lidocaine hydrochloride m… | 13343019 | 4 |
| Caelo | Lidocaine hydrochloride m… | 1403025-02 | 2 |
| Caelo | Lidocaine hydrochloride m… | 1411010-01 | 4 |
| Caelo | Lidocaine hydrochloride m… | 1411010-02 | 1 |
| Caelo | Lidocaine hydrochloride m… | 14110101 | 1 |
| Caelo | Lidocaine hydrochloride m… | 14254001 | 3 |
| Caelo | Lidocaine hydrochloride m… | 14J20-B05-303131 | 1 |
| Caelo | Lidocaine hydrochloride m… | 14J20-B05-303133 | 1 |
| Caelo | Lidocaine hydrochloride m… | 15/17-B01-316805 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1505023-01 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lidocaine hydrochloride m... | 1505023-02 | 2 |
| Caelo | Lidocaine hydrochloride m... | 1505023-03 | 4 |
| Caelo | Lidocaine hydrochloride m... | 1515I-01775 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1517-B01-315828 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1521304 | 1 |
| Caelo | Lidocaine hydrochloride m... | 15215201 | 3 |
| Caelo | Lidocaine hydrochloride m... | 15215301 | 8 |
| Caelo | Lidocaine hydrochloride m... | 15215302 | 2 |
| Caelo | Lidocaine hydrochloride m... | 15215303 | 2 |
| Caelo | Lidocaine hydrochloride m... | 15215304 | 3 |
| Caelo | Lidocaine hydrochloride m... | 15215308 | 3 |
| Caelo | Lidocaine hydrochloride m... | 15215309 | 3 |
| Caelo | Lidocaine hydrochloride m... | 15215310 | 10 |
| Caelo | Lidocaine hydrochloride m... | 15215311 | 6 |
| Caelo | Lidocaine hydrochloride m... | 15215312 | 7 |
| Caelo | Lidocaine hydrochloride m... | 152951602714117 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1529906 | 1 |
| Caelo | Lidocaine hydrochloride m... | 15299502 | 1 |
| Caelo | Lidocaine hydrochloride m... | 15299503 | 11 |
| Caelo | Lidocaine hydrochloride m... | 15299506 | 6 |
| Caelo | Lidocaine hydrochloride m... | 15299509 | 3 |
| Caelo | Lidocaine hydrochloride m... | 15299513 | 9 |
| Caelo | Lidocaine hydrochloride m... | 15299514 | 10 |
| Caelo | Lidocaine hydrochloride m... | 15299516 | 12 |
| Caelo | Lidocaine hydrochloride m... | 15299816 | 1 |
| Caelo | Lidocaine hydrochloride m... | 15117-B01 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1603027-01 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1606024 | 1 |
| Caelo | Lidocaine hydrochloride m... | 160602401 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1606024-01 | 17 |
| Caelo | Lidocaine hydrochloride m... | 1606024-02 | 5 |
| Caelo | Lidocaine hydrochloride m... | 160602403 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1606024-03 | 3 |
| Caelo | Lidocaine hydrochloride m... | 160719LC | 1 |
| Caelo | Lidocaine hydrochloride m... | 16083001 | 1 |
| Caelo | Lidocaine hydrochloride m... | 16101407 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1612015 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1612015_02 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1612015-01 | 6 |
| Caelo | Lidocaine hydrochloride m... | 1612015-02 | 13 |
| Caelo | Lidocaine hydrochloride m... | 1612015-03 | 1 |
| Caelo | Lidocaine hydrochloride m... | 1612015-04 | 3 |
| Caelo | Lidocaine hydrochloride m... | 1612015-05 | 1 |
| Caelo | Lidocaine hydrochloride m... | 16120515-02 | 1 |
| Caelo | Lidocaine hydrochloride m... | 16222202 | 2 |
| Caelo | Lidocaine hydrochloride m... | 16222203 | 8 |
| Caelo | Lidocaine hydrochloride m... | 16222206 | 2 |
| Caelo | Lidocaine hydrochloride m... | 16222207 | 8 |
| Caelo | Lidocaine hydrochloride m... | 16222208 | 6 |
| Caelo | Lidocaine hydrochloride m... | 16222214 | 13 |
| Caelo | Lidocaine hydrochloride m... | 16222215 | 1 |
| Caelo | Lidocaine hydrochloride m... | 168020-0003 | 1 |
| Caelo | Lidocaine hydrochloride m... | 16C09-B03-322144 | 1 |
| Caelo | Lidocaine hydrochloride m... | 17204803 | 14 |
| Caelo | Lidocaine hydrochloride m... | 17204804 | 32 |
| Caelo | Lidocaine hydrochloride m... | 17204810 | 3 |
| Caelo | Lidocaine hydrochloride m... | 17292301 | 2 |
| Caelo | Lidocaine hydrochloride m... | 17292302 | 6 |
| Caelo | Lidocaine hydrochloride m... | 17292304 | 27 |
| Caelo | Lidocaine hydrochloride m... | 17292304907012-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lidocaine hydrochloride m… | 17292305 | 1 |
| Caelo | Lidocaine hydrochloride m… | 17292307 | 5 |
| Caelo | Lidocaine hydrochloride m… | 17292308 | 9 |
| Caelo | Lidocaine hydrochloride m… | 17292310 | 1 |
| Caelo | Lidocaine hydrochloride m… | 17292311 | 9 |
| Caelo | Lidocaine hydrochloride m… | 17292313 | 8 |
| Caelo | Lidocaine hydrochloride m… | 17292316 | 3 |
| Caelo | Lidocaine hydrochloride m… | 1729308 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1729311 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1729313 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1792304 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1792313 | 1 |
| Caelo | Lidocaine hydrochloride m… | 17A16-B07 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18041501 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1808031 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1808031-01 | 12 |
| Caelo | Lidocaine hydrochloride m… | 1808031-02 | 4 |
| Caelo | Lidocaine hydrochloride m… | 1808031-03 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1814U-01775 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18179904 | 18 |
| Caelo | Lidocaine hydrochloride m… | 18179905 | 2 |
| Caelo | Lidocaine hydrochloride m… | 18179906 | 11 |
| Caelo | Lidocaine hydrochloride m… | 18179910 | 8 |
| Caelo | Lidocaine hydrochloride m… | 18179911 | 11 |
| Caelo | Lidocaine hydrochloride m… | 18179912 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18179913 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18179914 | 5 |
| Caelo | Lidocaine hydrochloride m… | 18179915 | 10 |
| Caelo | Lidocaine hydrochloride m… | 18179917 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18179922 | 2 |
| Caelo | Lidocaine hydrochloride m… | 18179922/P-06091922 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18179923 | 4 |
| Caelo | Lidocaine hydrochloride m… | 18179924 | 10 |
| Caelo | Lidocaine hydrochloride m… | 18179924P-200319-12 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1819914 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1879904 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18B23-B03 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18B23-B03-347316 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18B23-B03-355046 | 1 |
| Caelo | Lidocaine hydrochloride m… | 18B23-B03-352117 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1907012-01 | 7 |
| Caelo | Lidocaine hydrochloride m… | 1907012-02 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1907012-03 | 5 |
| Caelo | Lidocaine hydrochloride m… | 1907012-04 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1912M-01775 | 1 |
| Caelo | Lidocaine hydrochloride m… | 1913103 | 1 |
| Caelo | Lidocaine hydrochloride m… | 191350002 | 18 |
| Caelo | Lidocaine hydrochloride m… | 191350004 | 2 |
| Caelo | Lidocaine hydrochloride m… | 191350005 | 13 |
| Caelo | Lidocaine hydrochloride m… | 191350007 | 3 |
| Caelo | Lidocaine hydrochloride m… | 191350008 | 2 |
| Caelo | Lidocaine hydrochloride m… | 191350010 | 26 |
| Caelo | Lidocaine hydrochloride m… | 19135102 | 1 |
| Caelo | Lidocaine hydrochloride m… | 19135103 | 37 |
| Caelo | Lidocaine hydrochloride m… | 19135104 | 17 |
| Caelo | Lidocaine hydrochloride m… | 20004307001 | 3 |
| Caelo | Lidocaine hydrochloride m… | 20004451001 | 4 |
| Caelo | Lidocaine hydrochloride m… | 20004451002 | 22 |
| Caelo | Lidocaine hydrochloride m… | 20004451004 | 9 |
| Caelo | Lidocaine hydrochloride m… | 20004451008 | 22 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lidocaine hydrochloride m... | 2004451002 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2021903 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2051301 | 1 |
| Caelo | Lidocaine hydrochloride m... | 210025003 | 1 |
| Caelo | Lidocaine hydrochloride m... | 21002505002 | 1 |
| Caelo | Lidocaine hydrochloride m... | 21002505003 | 9 |
| Caelo | Lidocaine hydrochloride m... | 21002505006 | 6 |
| Caelo | Lidocaine hydrochloride m... | 21002505007 | 6 |
| Caelo | Lidocaine hydrochloride m... | 21002505011 | 4 |
| Caelo | Lidocaine hydrochloride m... | 210025505007 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2100505011 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2101034/03 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2101034-01 | 3 |
| Caelo | Lidocaine hydrochloride m... | 2101034-02 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2101034-03 | 2 |
| Caelo | Lidocaine hydrochloride m... | 21101034-03 | 1 |
| Caelo | Lidocaine hydrochloride m... | 21C05-B05-210126 | 1 |
| Caelo | Lidocaine hydrochloride m... | 22003202002 | 6 |
| Caelo | Lidocaine hydrochloride m... | 22003202003 | 4 |
| Caelo | Lidocaine hydrochloride m... | 22003202007 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2201026-01 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2201026-02 | 2 |
| Caelo | Lidocaine hydrochloride m... | 22042003 | 1 |
| Caelo | Lidocaine hydrochloride m... | 2211019-01 | 2 |
| Caelo | Lidocaine hydrochloride m... | 2211o19-01 | 1 |
| Caelo | Lidocaine hydrochloride m... | 23003452004 | 1 |
| Caelo | Lidocaine hydrochloride m... | 23011403 | 1 |
| Caelo | Lidocaine hydrochloride m... | 24071401 | 1 |
| Caelo | Lidocaine hydrochloride m... | 25091202 | 1 |
| Caelo | Lidocaine hydrochloride m... | 26041401 | 1 |
| Caelo | Lidocaine hydrochloride m... | 26051802 | 1 |
| Caelo | Lidocaine hydrochloride m... | 26071303 | 1 |
| Caelo | Lidocaine hydrochloride m... | 280501 | 1 |
| Caelo | Lidocaine hydrochloride m... | 28111812 | 1 |
| Caelo | Lidocaine hydrochloride m... | 29081503 | 1 |
| Caelo | Lidocaine hydrochloride m... | 3071711 | 1 |
| Caelo | Lidocaine hydrochloride m... | 4051703 | 1 |
| Caelo | Lidocaine hydrochloride m... | 4111302 | 1 |
| Caelo | Lidocaine hydrochloride m... | 4111703 | 1 |
| Caelo | Lidocaine hydrochloride m... | 415299506 | 1 |
| Caelo | Lidocaine hydrochloride m... | 5113E-01775 | 1 |
| Caelo | Lidocaine hydrochloride m... | 5211E-01775 | 1 |
| Caelo | Lidocaine hydrochloride m... | 6121706 | 1 |
| Caelo | Lidocaine hydrochloride m... | 812-16001 | 1 |
| Caelo | Lidocaine hydrochloride m... | AKD14 | 1 |
| Caelo | Lidocaine hydrochloride m... | LDH/118024 | 1 |
| Caerlo | Lidocaine hydrochloride m... | 13118807 | 1 |
| Caesar & Lorenz GmbH | Lidocaine hydrochloride m... | 16222208 | 1 |
| Caesar & Lorenz GmbH | Lidocaine hydrochloride m... | 18179923 | 2 |
| Caesar & Lorenz GmbH | Lidocaine hydrochloride m... | 19135104 | 1 |
| Caesar & Lorenz GmbH | Lidocaine hydrochloride m... | 2273185 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 18179915 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 21002505011 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 19135103 | 1 |
| Caesar & Loretz GmbH/ AEP | Lidocaine hydrochloride m... | 191350002 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 191350002 | 1 |
| Caesar & Loretz GmbH/AHD | Lidocaine hydrochloride m... | 21002505003 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 21002505006 | 2 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 18179914 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 191350002 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 191350010 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 20004451002 | 2 |
| Caesar & Loretz GmbH/Gö | Lidocaine hydrochloride m... | 191350010 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 19135103 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 19135103 | 2 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 18179914 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 18179917 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 191350010 | 1 |
| Caesar & Loretz GmbH... | Lidocaine hydrochloride m... | 20004451002 | 3 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 13343002 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 15215201 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 1612015-03 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 16222203 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 17292311 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179903 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179904 | 4 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179905 | 3 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179906 | 2 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179911 | 4 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179912 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179914 | 4 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179915 | 2 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179916 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179922 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 18179923 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 191350002 | 4 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 191350004 | 3 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 191350005 | 2 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 191350007 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 191350010 | 10 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 19135103 | 8 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 19135104 | 4 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 20004451002 | 16 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 20004451004 | 6 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 20004451008 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 210025050004 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 21002505006 | 2 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 21002505007 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 21002505008 | 1 |
| Caesar & Loretz GmbH | Lidocaine hydrochloride m... | 22003202003 | 3 |
| Caesar & Loretz/Anza... | Lidocaine hydrochloride m... | 18179906 | 1 |
| Caesar & Loretz | Lidocaine hydrochloride m... | 1612015-01 | 2 |
| Caesar u Loretz | Lidocaine hydrochloride m... | 13343017 | 1 |
| Caesar&Loretz GmbH /Anzag | Lidocaine hydrochloride m... | 15215303 | 1 |
| Caesar&Loretz GmbH/ ... | Lidocaine hydrochloride m... | 17204803 | 1 |
| Caesar&Loretz GmbH/Anzag | Lidocaine hydrochloride m... | 13118803 | 2 |
| Caeser und Loretz GmbH | Lidocaine hydrochloride m... | 181799023 | 1 |
| Caleo/ Noweda | Lidocaine hydrochloride m... | 17204804 | 1 |
| Caleo/ Noweda | Lidocaine hydrochloride m... | 19135103 | 2 |
| Caolo | Lidocaine hydrochloride m... | 13343008 | 1 |
| Cealo | Lidocaine hydrochloride m... | 20004451008 | 1 |
| Ensbona/ Sanacorp | Lidocaine hydrochloride m... | 1606024-01 | 1 |
| EuRho / Alliance | Lidocaine hydrochloride m... | 1907012-03 | 1 |
| EuRho / Alliance | Lidocaine hydrochloride m... | 2101034-01 | 1 |
| EuRho / Phönix | Lidocaine hydrochloride m... | 2201026-01 | 1 |
| EuRho / Sanacorp | Lidocaine hydrochloride m... | 1907012-04 | 1 |
| EuRho/ Jenne | Lidocaine hydrochloride m... | 2101034-02 | 1 |
| Eurho/ Noweda | Lidocaine hydrochloride m... | 1808031-01 | 1 |
| EuRho/ Phönix | Lidocaine hydrochloride m... | 1612015-04 | 1 |

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|---|---|---|---|
| EuRho/ Sana | Lidocaine hydrochloride m... | 1808031-02 | 1 |
| EuRho/ Sanacorp | Lidocaine hydrochloride m... | 2201026-02 | 1 |
| EuRho/ VDL | Lidocaine hydrochloride m... | 1612015-04 | 1 |
| EuRho/AHD | Lidocaine hydrochloride m... | 1907012-01 | 1 |
| EuRho/AHD | Lidocaine hydrochloride m... | LDH/720023 | 2 |
| EuRho/Gehe | Lidocaine hydrochloride m... | 2101034-01 | 1 |
| EuRho/Jenne | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| Eurho/Jenne | Lidocaine hydrochloride m... | 1907012-04 | 1 |
| EuRho/Jenne | Lidocaine hydrochloride m... | 2101034-03 | 1 |
| EuRho/Noweda | Lidocaine hydrochloride m... | 1612015-02 | 2 |
| EuRho/NOWEDA | Lidocaine hydrochloride m... | 1808031-01 | 2 |
| EuRho/Noweda | Lidocaine hydrochloride m... | 2101034-01 | 1 |
| EuRho/Phoenix | Lidocaine hydrochloride m... | 1612015-01 | 1 |
| EuRho/Phoenix | Lidocaine hydrochloride m... | 2201026-02 | 1 |
| EuRho/Phönix | Lidocaine hydrochloride m... | 1808031-01 | 2 |
| EuRho/Phönix | Lidocaine hydrochloride m... | 2101034-01 | 3 |
| EuRho/Sanacorp | Lidocaine hydrochloride m... | 1612015-04 | 1 |
| EuRho/Sanacorp | Lidocaine hydrochloride m... | 1808031-01 | 3 |
| EuRho | Lidocaine hydrochloride m... | 1108017-01 | 3 |
| EuRho | Lidocaine hydrochloride m... | 140302501 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1403025-01 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1403025-02 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1505023-01 | 2 |
| EuRho | Lidocaine hydrochloride m... | 1505023-02 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1612015-01 | 2 |
| EuRho | Lidocaine hydrochloride m... | 161201502 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1612015-02 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1612015-04 | 1 |
| EuRho | Lidocaine hydrochloride m... | 18008031 | 1 |
| euRho | Lidocaine hydrochloride m... | 1808031 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1808031-02 | 2 |
| EuRho | Lidocaine hydrochloride m... | 1808031-03 | 1 |
| Eurho | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| EuRho | Lidocaine hydrochloride m... | 1907012-03 | 1 |
| euRho | Lidocaine hydrochloride m... | 1907012-04 | 1 |
| EuRho | Lidocaine hydrochloride m... | 2101034 | 1 |
| Eurho | Lidocaine hydrochloride m... | 2101034-01 | 1 |
| euRho | Lidocaine hydrochloride m... | 2101034-03 | 1 |
| EuRho | Lidocaine hydrochloride m... | 2101034-03 | 1 |
| Eurho | Lidocaine hydrochloride m... | 2101034-04 | 1 |
| EuRho | Lidocaine hydrochloride m... | 2201026-01 | 1 |
| EuRho | Lidocaine hydrochloride m... | 2201026-02 | 2 |
| EuRho | Lidocaine hydrochloride m... | 2211019-01 | 1 |
| EuRho | Lidocaine hydrochloride m... | EuRho | 1 |
| EuRho | Lidocaine hydrochloride m... | LDH720023 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | | 4 |
| Euro OTC | Lidocaine hydrochloride m... | 1004040-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1066024-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1103034-01 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 1108017-01 | 5 |
| Euro OTC | Lidocaine hydrochloride m... | 1108017-02 | 7 |
| Euro OTC | Lidocaine hydrochloride m... | 1140917/160602403 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1202034-01 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 1202035 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1202035/02 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1202035-01 | 20 |
| Euro OTC | Lidocaine hydrochloride m... | 120203502 | 3 |
| Euro OTC | Lidocaine hydrochloride m... | 1202035-02 | 39 |
| Euro OTC | Lidocaine hydrochloride m... | 1202035-03 | 11 |
| Euro OTC | Lidocaine hydrochloride m... | 1202035-1 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Lidocaine hydrochloride m… | 12020351612015-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1401010-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1403025 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 140302501 | 2 |
| Euro OTC | Lidocaine hydrochloride m… | 1403025-01 | 22 |
| Euro OTC | Lidocaine hydrochloride m… | 140302502 | 2 |
| Euro OTC | Lidocaine hydrochloride m… | 1403025-02 | 15 |
| Euro OTC | Lidocaine hydrochloride m… | 1403025-03 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 140415A | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 141101 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 141101001 | 4 |
| Euro OTC | Lidocaine hydrochloride m… | 1411010-01 | 38 |
| Euro OTC | Lidocaine hydrochloride m… | 1411010-01Mg25g | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 141101002 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | 1411010-02 | 28 |
| Euro OTC | Lidocaine hydrochloride m… | 1411010-02Mg50g | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 141101-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 14110101-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1411010-2 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 150502301 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | 1505023-01 | 67 |
| Euro OTC | Lidocaine hydrochloride m… | 1505023-02 | 22 |
| Euro OTC | Lidocaine hydrochloride m… | 1505023-03 | 14 |
| Euro OTC | Lidocaine hydrochloride m… | 150523-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1512015-04 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1600024-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 16006024-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1606021-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1606024_02 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | 160602401 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | 1606024-01 | 79 |
| Euro OTC | Lidocaine hydrochloride m… | 160602402 | 2 |
| Euro OTC | Lidocaine hydrochloride m… | 1606024-02 | 77 |
| Euro OTC | Lidocaine hydrochloride m… | 1606024-03 | 25 |
| Euro OTC | Lidocaine hydrochloride m… | 1606024-1 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 160624-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 16112015-01 | 2 |
| Euro OTC | Lidocaine hydrochloride m… | 16112015-04 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1612012015-04 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015 | 6 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015_01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 161201501 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015-01 | 51 |
| Euro OTC | Lidocaine hydrochloride m… | 161201502 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015-02 | 69 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015-03 | 30 |
| Euro OTC | Lidocaine hydrochloride m… | 161201504 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015-04 | 36 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015-05 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | 1612015-14 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 16122016-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 1618015-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 168020 | 2 |
| Euro OTC | Lidocaine hydrochloride m… | 170612182 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 171106LHC/1606024-03 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 17204803 | 2 |
| Euro OTC | Lidocaine hydrochloride m… | 17204810 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 180220L/1612015-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 18080031 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 180803-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Lidocaine hydrochloride m... | 1808031 | 5 |
| Euro OTC | Lidocaine hydrochloride m... | 180803101 | 4 |
| Euro OTC | Lidocaine hydrochloride m... | 1808031-01 | 117 |
| Euro OTC | Lidocaine hydrochloride m... | 1808031-01Retest | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 180803102 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 1808031-02 | 88 |
| Euro OTC | Lidocaine hydrochloride m... | 180803103 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1808031-03 | 43 |
| Euro OTC | Lidocaine hydrochloride m... | 1808031-04 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 18908031-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012_01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 190701201 | 4 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-01 | 156 |
| Euro OTC | Lidocaine hydrochloride m... | 190701202 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-02 | 114 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-03 | 91 |
| Euro OTC | Lidocaine hydrochloride m... | 190701204 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-04 | 66 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-1 | 3 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-12 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-42 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1907012-62 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 1907013-03 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 190720107 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 19097012-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 197012-09 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2001026-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 20131010-4 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 20C18-B02-196984 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 210034-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2101031-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2101034 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 210103401 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2101034-01 | 60 |
| Euro OTC | Lidocaine hydrochloride m... | 2101034-02 | 49 |
| Euro OTC | Lidocaine hydrochloride m... | 210103403 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2101034-03 | 48 |
| Euro OTC | Lidocaine hydrochloride m... | 2101034-034 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2101034-04 | 7 |
| Euro OTC | Lidocaine hydrochloride m... | 2101034-3 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2201026 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 2201026_01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 220102601 | 4 |
| Euro OTC | Lidocaine hydrochloride m... | 2201026-01 | 134 |
| Euro OTC | Lidocaine hydrochloride m... | 2201026-02 | 53 |
| Euro OTC | Lidocaine hydrochloride m... | 2201026-1 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2201062-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 220126-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 22101901 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 221019-01 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 221026-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 221101901 | 2 |
| Euro OTC | Lidocaine hydrochloride m... | 2211019-01 | 25 |
| Euro OTC | Lidocaine hydrochloride m... | 2211019-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2213U01775 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 23081601 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2805016-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2810029-01 | 1 |
| Euro OTC | Lidocaine hydrochloride m... | 2886 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Lidocaine hydrochloride m… | 8597977 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | 991011 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | AP220802-02 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | EuroOTCPharma | 1 |
| Euro OTC | Lidocaine hydrochloride m… | ldh/116023 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | LDH/116023 | 3 |
| Euro OTC | Lidocaine hydrochloride m… | LDH/118024 | 4 |
| Euro OTC | Lidocaine hydrochloride m… | LDH/121043 | 4 |
| Euro OTC | Lidocaine hydrochloride m… | LDH/719007 | 5 |
| Euro OTC | Lidocaine hydrochloride m… | LDH/720023 | 2 |
| Euro OTC | Lidocaine hydrochloride m… | LDH/722031 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | LDHI719007 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | LDHV121043 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | lhd719007 | 1 |
| Euro OTC | Lidocaine hydrochloride m… | LID-20-11-001 | 2 |
| Euro Pharma | Lidocaine hydrochloride m… | 1505023-01 | 1 |
| Euro/ Anzag | Lidocaine hydrochloride m… | 1606024-03 | 1 |
| Euro/ Gehe | Lidocaine hydrochloride m… | 1808031-03 | 1 |
| Euro/ Gehe | Lidocaine hydrochloride m… | 1907012-01 | 2 |
| Euro/ Gehe | Lidocaine hydrochloride m… | 1907012-02 | 1 |
| Euro/ Jenne | Lidocaine hydrochloride m… | 1907012-02 | 1 |
| EUro/AHD | Lidocaine hydrochloride m… | 1202035-01 | 2 |
| Euro/Alliance Healthcare | Lidocaine hydrochloride m… | 150523-01 | 1 |
| euro/Gehe | Lidocaine hydrochloride m… | 1907012-04 | 1 |
| Euro/Gehe | Lidocaine hydrochloride m… | 2201026-02 | 1 |
| Euro/Phoenix | Lidocaine hydrochloride m… | 1907012-01 | 3 |
| Euro/Phönix | Lidocaine hydrochloride m… | 141101010-01 | 1 |
| Euro/Phönix | Lidocaine hydrochloride m… | 1612015-01 | 1 |
| Euro/Phönix | Lidocaine hydrochloride m… | 1808031-02 | 1 |
| Euro/Phönix | Lidocaine hydrochloride m… | 1808031-03 | 1 |
| Euro/Phönix | Lidocaine hydrochloride m… | 210103401 | 1 |
| Euro/Phönix | Lidocaine hydrochloride m… | 2101034-03 | 1 |
| Euro/Sanacorp | Lidocaine hydrochloride m… | 1808031-03 | 1 |
| Euro/Sanacorp | Lidocaine hydrochloride m… | 2101034-01 | 1 |
| Euro | Lidocaine hydrochloride m… | 1505023-01 | 2 |
| Europ Ots Pharma | Lidocaine hydrochloride m… | 1403025-01 | 1 |
| EuroPharm | Lidocaine hydrochloride m… | 1907012-02 | 1 |
| EuroPharm | Lidocaine hydrochloride m… | 2101034-02 | 1 |
| Fa.Phönix | Lidocaine hydrochloride m… | 1907012-02 | 1 |
| Fagon | Lidocaine hydrochloride m… | 15/17-B01-316805 | 1 |
| Fagron | Lidocaine hydrochloride m… | 11H18-N01 | 1 |
| Fagron | Lidocaine hydrochloride m… | 11L09-N09 | 2 |
| Fagron | Lidocaine hydrochloride m… | 1202035-02 | 1 |
| Fagron | Lidocaine hydrochloride m… | 12c05-N02 | 1 |
| Fagron | Lidocaine hydrochloride m… | 12C05-N02 | 1 |
| Fagron | Lidocaine hydrochloride m… | 12E14-N04 | 2 |
| Fagron | Lidocaine hydrochloride m… | 12H09-N08 | 2 |
| Fagron | Lidocaine hydrochloride m… | 13218-B11 | 1 |
| Fagron | Lidocaine hydrochloride m… | 13F07N06 | 1 |
| Fagron | Lidocaine hydrochloride m… | 13F07-N06 | 7 |
| Fagron | Lidocaine hydrochloride m… | 13L18-B11-286901 | 1 |
| Fagron | Lidocaine hydrochloride m… | 14/20-B05 | 1 |
| Fagron | Lidocaine hydrochloride m… | 1420-b05-303 | 1 |
| Fagron | Lidocaine hydrochloride m… | 14B12-B03-292214 | 9 |
| Fagron | Lidocaine hydrochloride m… | 14e13-b06-294973 | 1 |
| Fagron | Lidocaine hydrochloride m… | 14e13-b06-294975 | 2 |
| Fagron | Lidocaine hydrochloride m… | 14E13-B06-294975 | 5 |
| Fagron | Lidocaine hydrochloride m… | 14J07-B04-299433 | 4 |
| Fagron | Lidocaine hydrochloride m… | 14J07-B04-299434 | 2 |
| Fagron | Lidocaine hydrochloride m… | 14J20-b05 | 1 |

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|---|---|---|---|
| Fagron | Lidocaine hydrochloride m... | 14J20-B05-303131 | 2 |
| Fagron | Lidocaine hydrochloride m... | 14j20-b05-303133 | 1 |
| Fagron | Lidocaine hydrochloride m... | 14J20-B05-303133 | 2 |
| Fagron | Lidocaine hydrochloride m... | 15/17-b01-315828 | 1 |
| Fagron | Lidocaine hydrochloride m... | 15/17-B01316805 | 1 |
| Fagron | Lidocaine hydrochloride m... | 15/17-B01-316805 | 8 |
| Fagron | Lidocaine hydrochloride m... | 1505023-01 | 2 |
| Fagron | Lidocaine hydrochloride m... | 1517-801 | 1 |
| Fagron | Lidocaine hydrochloride m... | 1517-B01 | 1 |
| Fagron | Lidocaine hydrochloride m... | 15215311 | 2 |
| Fagron | Lidocaine hydrochloride m... | 15299513 | 1 |
| Fagron | Lidocaine hydrochloride m... | 15299516 | 1 |
| Fagron | Lidocaine hydrochloride m... | 15I17-B01-315828 | 2 |
| Fagron | Lidocaine hydrochloride m... | 15I17-b01-316805 | 1 |
| Fagron | Lidocaine hydrochloride m... | 15I17-B01-316805 | 2 |
| Fagron | Lidocaine hydrochloride m... | 161201501 | 1 |
| Fagron | Lidocaine hydrochloride m... | 1612015-01 | 1 |
| Fagron | Lidocaine hydrochloride m... | 1612015-02 | 3 |
| Fagron | Lidocaine hydrochloride m... | 1612015-03 | 1 |
| Fagron | Lidocaine hydrochloride m... | 168020-0001 | 1 |
| Fagron | Lidocaine hydrochloride m... | 16C09-B03 | 1 |
| Fagron | Lidocaine hydrochloride m... | 16C09-B03-319230 | 1 |
| Fagron | Lidocaine hydrochloride m... | 16c09b03322144 | 1 |
| Fagron | Lidocaine hydrochloride m... | 16C09-B03-322144 | 4 |
| Fagron | Lidocaine hydrochloride m... | 16c09-b03-322145 | 2 |
| Fagron | Lidocaine hydrochloride m... | 16C09-B03-322145 | 1 |
| Fagron | Lidocaine hydrochloride m... | 16J24-B15-329421 | 1 |
| Fagron | Lidocaine hydrochloride m... | 17A16-B07 | 2 |
| Fagron | Lidocaine hydrochloride m... | 17A16-B07-331959 | 4 |
| Fagron | Lidocaine hydrochloride m... | 17A16B07333010 | 1 |
| Fagron | Lidocaine hydrochloride m... | 17A16-B07-333010 | 4 |
| Fagron | Lidocaine hydrochloride m... | 17G10-B08-342287 | 1 |
| Fagron | Lidocaine hydrochloride m... | 17G10-B08-346659 | 3 |
| Fagron | Lidocaine hydrochloride m... | 17G10-BO8-346659 | 1 |
| Fagron | Lidocaine hydrochloride m... | 1808031-01 | 1 |
| Fagron | Lidocaine hydrochloride m... | 1808031-02 | 2 |
| Fagron | Lidocaine hydrochloride m... | 1808031-03 | 1 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03 | 5 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03_355046 | 1 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-347316 | 5 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-348590 | 3 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-348748 | 1 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-352117 | 4 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-353035 | 1 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-354288 | 5 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-355046 | 1 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B03-355381 | 1 |
| Fagron | Lidocaine hydrochloride m... | 18B23-B04-348590 | 1 |
| Fagron | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| Fagron | Lidocaine hydrochloride m... | 19E22-B01-1914608 | 1 |
| Fagron | Lidocaine hydrochloride m... | 19E22-B01-191467 | 5 |
| Fagron | Lidocaine hydrochloride m... | 19E22-B01-191468 | 9 |
| Fagron | Lidocaine hydrochloride m... | 19J16-B02 | 1 |
| Fagron | Lidocaine hydrochloride m... | 19J16-B02-196983 | 1 |
| Fagron | Lidocaine hydrochloride m... | 19j16-b02-196985 | 1 |
| Fagron | Lidocaine hydrochloride m... | 19J16-B02-196993 | 2 |
| Fagron | Lidocaine hydrochloride m... | 19J16-BO2-196983 | 2 |
| Fagron | Lidocaine hydrochloride m... | 20A31-B06 | 2 |
| Fagron | Lidocaine hydrochloride m... | 20A31-B06-196986 | 1 |
| Fagron | Lidocaine hydrochloride m... | 20A31-B06-2005105 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Lidocaine hydrochloride m… | 20A31-B06-200515 | 6 |
| Fagron | Lidocaine hydrochloride m… | 20C18B02 | 1 |
| Fagron | Lidocaine hydrochloride m… | 20C18-B02 | 1 |
| Fagron | Lidocaine hydrochloride m… | 20c18-b02-196984 | 1 |
| Fagron | Lidocaine hydrochloride m… | 20C18-B02-196984 | 12 |
| Fagron | Lidocaine hydrochloride m… | 20E28-B04-201210 | 1 |
| Fagron | Lidocaine hydrochloride m… | 20e28-b04-201268 | 1 |
| Fagron | Lidocaine hydrochloride m… | 20E28-B04-201302 | 1 |
| Fagron | Lidocaine hydrochloride m… | 20E28-B04-201702 | 3 |
| Fagron | Lidocaine hydrochloride m… | 20E28-B04-2017021 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21/17-803-216827 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21/17-B03-216798 | 2 |
| Fagron | Lidocaine hydrochloride m… | 21/17-B03-216827 | 1 |
| Fagron | Lidocaine hydrochloride m… | 218I-01775 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21A12B04203052 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21A12-B04-203052 | 2 |
| Fagron | Lidocaine hydrochloride m… | 21C05-B05-210126 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21I17-B03 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21I17-B03-213766 | 2 |
| Fagron | Lidocaine hydrochloride m… | 21I17-B03-213769 | 4 |
| Fagron | Lidocaine hydrochloride m… | 21I17-B03-216798 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21I17-BO3 | 1 |
| Fagron | Lidocaine hydrochloride m… | 21l17-B03-213769 | 1 |
| Fagron | Lidocaine hydrochloride m… | 2201026-01 | 1 |
| Fagron | Lidocaine hydrochloride m… | 22C15-B16 | 1 |
| Fagron | Lidocaine hydrochloride m… | 22C15-B16-218866 | 2 |
| Fagron | Lidocaine hydrochloride m… | 22C15-B16-220955 | 2 |
| Fagron | Lidocaine hydrochloride m… | 22H22-B03-224257 | 1 |
| Fagron | Lidocaine hydrochloride m… | 4612Q-01775 | 1 |
| Fagron | Lidocaine hydrochloride m… | 812-16001 | 3 |
| Fagron | Lidocaine hydrochloride m… | 8F26-N07 | 1 |
| Fagron | Lidocaine hydrochloride m… | 9B3M1L2Fo118 | 1 |
| Fagron | Lidocaine hydrochloride m… | 9E08-N03 | 1 |
| Fagron | Lidocaine hydrochloride m… | B01-1914608 | 1 |
| Fagron | Lidocaine hydrochloride m… | B02-1969803 | 1 |
| Fagron | Lidocaine hydrochloride m… | B02-1969804 | 3 |
| Fagron | Lidocaine hydrochloride m… | B03-2167908 | 1 |
| Fagron | Lidocaine hydrochloride m… | B04-2030502 | 2 |
| Fagron | Lidocaine hydrochloride m… | LDH/116023 | 1 |
| Fagron | Lidocaine hydrochloride m… | LDH/116037 | 2 |
| Fagron | Lidocaine hydrochloride m… | LDH/117022 | 1 |
| Fagron | Lidocaine hydrochloride m… | LDH/117049 | 1 |
| Fagron | Lidocaine hydrochloride m… | LDH/118024 | 1 |
| Fagron | Lidocaine hydrochloride m… | LDH/119022 | 1 |
| Fagron | Lidocaine hydrochloride m… | LDH-721013 | 1 |
| Fargon GmbH & Co.KG | Lidocaine hydrochloride m… | 15/17-B01-316805 | 1 |
| Fargon GmbH & Co.KG | Lidocaine hydrochloride m… | 16C09-B03-322144 | 2 |
| Fargon | Lidocaine hydrochloride m… | 20C18-B02-196948 | 1 |
| fargon | Lidocaine hydrochloride m… | 720005 | 1 |
| Fiebig 04.7.13 EK 4,54 | Lidocaine hydrochloride m… | 12135511 | 1 |
| Fiebig | Lidocaine hydrochloride m… | 1808031-01 | 1 |
| Fiebig | Lidocaine hydrochloride m… | 1907012-01 | 1 |
| Fiebig | Lidocaine hydrochloride m… | 20C18-B02-196984 | 1 |
| Finze | Lidocaine hydrochloride m… | 1202035-01 | 1 |
| Frago/Noweda | Lidocaine hydrochloride m… | 6108-05-0 | 1 |
| Gatt-Koller | Lidocaine hydrochloride m… | 1801084 | 1 |
| Gehe amax | Lidocaine hydrochloride m… | 17292308 | 1 |
| Gehe amax | Lidocaine hydrochloride m… | 19135103 | 1 |
| GEHE Halle | Lidocaine hydrochloride m… | LDH/121043 | 1 |
| Gehe Rostock | Lidocaine hydrochloride m… | 2201026-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe/EuRho | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| Gehe/Euro | Lidocaine hydrochloride m... | 1612015-02 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1190313 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1202035-02 | 1 |
| Gehe | Lidocaine hydrochloride m... | 12C05-N02 | 2 |
| Gehe | Lidocaine hydrochloride m... | 1411010-01 | 1 |
| Gehe | Lidocaine hydrochloride m... | 141101002 | 1 |
| Gehe | Lidocaine hydrochloride m... | 15215304 | 1 |
| Gehe | Lidocaine hydrochloride m... | 15299513 | 1 |
| Gehe | Lidocaine hydrochloride m... | 15299516 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1606024-02 | 1 |
| GEHE | Lidocaine hydrochloride m... | 1606024-02 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1612015-01 | 1 |
| GEHE | Lidocaine hydrochloride m... | 1612015-01 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1612015-02 | 2 |
| GEHE | Lidocaine hydrochloride m... | 1612015-02 | 1 |
| Gehe | Lidocaine hydrochloride m... | 16222207 | 1 |
| GEHE | Lidocaine hydrochloride m... | 16222214 | 1 |
| GEHE | Lidocaine hydrochloride m... | 17292312 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1808031-01 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1808031-02 | 1 |
| Gehe | Lidocaine hydrochloride m... | 18179904 | 1 |
| Gehe | Lidocaine hydrochloride m... | 1907012-01 | 2 |
| Gehe | Lidocaine hydrochloride m... | 1907012-02 | 2 |
| Gehe | Lidocaine hydrochloride m... | 1907012-03 | 1 |
| Gehe | Lidocaine hydrochloride m... | 191350002 | 2 |
| Gehe | Lidocaine hydrochloride m... | 191350007 | 1 |
| Gehe | Lidocaine hydrochloride m... | 2101034-01 | 1 |
| Gehe | Lidocaine hydrochloride m... | 2101034-02 | 4 |
| Gehe | Lidocaine hydrochloride m... | 2201026-01 | 1 |
| Gehe | Lidocaine hydrochloride m... | 2201026-02 | 5 |
| GEHE | Lidocaine hydrochloride m... | 2201026-02 | 2 |
| Gehe | Lidocaine hydrochloride m... | 2203202007 | 2 |
| Gehe | Lidocaine hydrochloride m... | 221026-01 | 1 |
| Gehe | Lidocaine hydrochloride m... | 2211019-01 | 7 |
| GEHE | Lidocaine hydrochloride m... | 2211019-01 | 1 |
| Gehe | Lidocaine hydrochloride m... | 2211019-02 | 2 |
| Gehe | Lidocaine hydrochloride m... | 23003452004 | 1 |
| GEHE | Lidocaine hydrochloride m... | 24H29-B06-002785 | 1 |
| Gehe | Lidocaine hydrochloride m... | LDH/116023 | 1 |
| Gehe | Lidocaine hydrochloride m... | LDH/719007 | 1 |
| Geibo/EuRho | Lidocaine hydrochloride m... | 1515023-01 | 1 |
| Geibo/Euro 29.8. | Lidocaine hydrochloride m... | 1808031-02 | 1 |
| GMP Konform | Lidocaine hydrochloride m... | 20A31-B06 | 1 |
| Hänseler | Lidocaine hydrochloride m... | | 3 |
| Hedinger/Ebert | Lidocaine hydrochloride m... | 13118807 | 1 |
| Infectopharm/Phönix | Lidocaine hydrochloride m... | 18179904 | 2 |
| INTERN-DROGEN | Lidocaine hydrochloride m... | 19135103 | 1 |
| INTERN-DROGEN | Lidocaine hydrochloride m... | 20004451008 | 1 |
| INTERN-DROGEN | Lidocaine hydrochloride m... | 21002505006 | 1 |
| Jenne | Lidocaine hydrochloride m... | 1808031-02 | 1 |
| Jenne | Lidocaine hydrochloride m... | 1907012-04 | 1 |
| Jenne | Lidocaine hydrochloride m... | 2101034-02 | 1 |
| Jenne | Lidocaine hydrochloride m... | 230503(22003202003) | 1 |
| Kehr/EuRho | Lidocaine hydrochloride m... | 1907012-03 | 1 |
| Kehr | Lidocaine hydrochloride m... | 1606024-02 | 1 |
| Kehr | Lidocaine hydrochloride m... | 1612015-01 | 1 |
| Kehr | Lidocaine hydrochloride m... | 1612015-02 | 1 |
| Kehr | Lidocaine hydrochloride m... | 1612015-03 | 1 |
| Kehr | Lidocaine hydrochloride m... | 21002505007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Kehr | Lidocaine hydrochloride m… | 22003202003 | 1 |
| Kehr | Lidocaine hydrochloride m… | 22003202007 | 1 |
| kögl | Lidocaine hydrochloride m… | 1803832 | 1 |
| Konduskar/Phönix | Lidocaine hydrochloride m… | 1202035-03 | 1 |
| Krieger | Lidocaine hydrochloride m… | 1612015-04 | 1 |
| L10 | Lidocaine hydrochloride m… | 1612015-01 | 1 |
| L10 | Lidocaine hydrochloride m… | 1612015-03 | 1 |
| L12 | Lidocaine hydrochloride m… | 1505023-02 | 1 |
| L12 | Lidocaine hydrochloride m… | 1606024-01 | 2 |
| Lamotte/Noweda | Lidocaine hydrochloride m… | 1622207 | 1 |
| Mahendra Chem./ Phön… | Lidocaine hydrochloride m… | 1411010-01 | 1 |
| Mahendra Chem./Noweda | Lidocaine hydrochloride m… | 1505023 | 1 |
| Mahendra Chem. | Lidocaine hydrochloride m… | 1411010-01 | 1 |
| Merck | Lidocaine hydrochloride m… | K52817248 | 1 |
| Moehns BCN, S.L. | Lidocaine hydrochloride m… | 191350002 | 1 |
| Moehs / Ebert | Lidocaine hydrochloride m… | 15215201 | 1 |
| Moehs / Gehe | Lidocaine hydrochloride m… | 17292313 | 1 |
| Moehs Catalana, S.L.… | Lidocaine hydrochloride m… | | 1 |
| Noveda | Lidocaine hydrochloride m… | LDH/722031 | 1 |
| Noweda 04.12.2019 | Lidocaine hydrochloride m… | 907012-01 | 1 |
| Noweda 23.10.2019 | Lidocaine hydrochloride m… | 1808031-03 | 1 |
| Noweda/apotec | Lidocaine hydrochloride m… | 2201026-01 | 1 |
| Noweda/Eurho 18,01,2… | Lidocaine hydrochloride m… | 1907012-03 | 1 |
| Noweda/EuRho | Lidocaine hydrochloride m… | 2101034-03 | 1 |
| Noweda/EuRo | Lidocaine hydrochloride m… | 1612015-03 | 1 |
| Noweda/Mahendra Chem. | Lidocaine hydrochloride m… | 1505023-01 | 4 |
| Noweda | Lidocaine hydrochloride m… | 1108017-02 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1202035-03 | 1 |
| Noweda | Lidocaine hydrochloride m… | 141101002 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1606024-01 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1606024-02 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1612015-02 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1612015-05 | 1 |
| Noweda | Lidocaine hydrochloride m… | 16222207 | 2 |
| Noweda | Lidocaine hydrochloride m… | 16222214 | 1 |
| Noweda | Lidocaine hydrochloride m… | 17204804 | 1 |
| Noweda | Lidocaine hydrochloride m… | 17292304 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1808031-01 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1808031-02 | 2 |
| Noweda | Lidocaine hydrochloride m… | 1808031-03 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1812015-04 | 1 |
| Noweda | Lidocaine hydrochloride m… | 18179904 | 2 |
| Noweda | Lidocaine hydrochloride m… | 1907012_02 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1907012-01 | 2 |
| Noweda | Lidocaine hydrochloride m… | 1907012-02 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1907012-04 | 1 |
| Noweda | Lidocaine hydrochloride m… | 1913500010 | 1 |
| Noweda | Lidocaine hydrochloride m… | 191350007 | 2 |
| Noweda | Lidocaine hydrochloride m… | 20004451004 | 1 |
| Noweda | Lidocaine hydrochloride m… | 20004451008 | 1 |
| Noweda | Lidocaine hydrochloride m… | 21002505012 | 1 |
| Noweda | Lidocaine hydrochloride m… | 2101034-01 | 2 |
| Noweda | Lidocaine hydrochloride m… | 2101034-02 | 1 |
| Noweda | Lidocaine hydrochloride m… | 22003202002 | 1 |
| Noweda | Lidocaine hydrochloride m… | 22003202006 | 1 |
| Noweda | Lidocaine hydrochloride m… | 22003202007 | 1 |
| Noweda | Lidocaine hydrochloride m… | 2201026-01 | 5 |
| Noweda | Lidocaine hydrochloride m… | 2201026-02 | 1 |
| Noweda | Lidocaine hydrochloride m… | 2203202002 | 1 |
| Noweda | Lidocaine hydrochloride m… | 22102601 | 1 |

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|---|---|---|---|
| Noweda | Lidocaine hydrochloride m... | 2211016-01 | 1 |
| Noweda | Lidocaine hydrochloride m... | 2211019 | 1 |
| Noweda | Lidocaine hydrochloride m... | 2211019-01 | 6 |
| Noweda | Lidocaine hydrochloride m... | 2211019-02 | 1 |
| Noweda | Lidocaine hydrochloride m... | 2211019-03 | 2 |
| Noweda | Lidocaine hydrochloride m... | 2273185 | 1 |
| Noweda | Lidocaine hydrochloride m... | 2405011-02 | 2 |
| Noweda | Lidocaine hydrochloride m... | 4914889 | 1 |
| Noweda_31.07.2019 | Lidocaine hydrochloride m... | 1808031-02 | 1 |
| Otto G. Apotec | Lidocaine hydrochloride m... | 1907012-01 | 1 |
| Otto Geilenkirchen Aachen | Lidocaine hydrochloride m... | 20004307001 | 1 |
| Parthe Apotheke | Lidocaine hydrochloride m... | 192/20 | 1 |
| Ph.Eur.10.0/Gehe | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| Phoenix 03.12.2018 | Lidocaine hydrochloride m... | 1808031-01 | 1 |
| PHOENIX 17.06.2014 | Lidocaine hydrochloride m... | 1403025-01 | 1 |
| Phoenix 26.02.2014 | Lidocaine hydrochloride m... | 13118814 | 1 |
| PHOENIX am 12.02.2014 | Lidocaine hydrochloride m... | 1202035-02 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 1606024-02 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 1612015-02 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 16C09-B03-322144 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 1808031-01 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 1808031-02 | 3 |
| Phoenix | Lidocaine hydrochloride m... | 1808031-03 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 1907012-01 | 2 |
| Phoenix | Lidocaine hydrochloride m... | 1907012-03 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 1907012-04 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 19e22-b01-191467 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 200122101 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 200562306 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 2101034-01 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 2101034-02 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 2101034-03 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 2201026-02 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 2211019-01 | 6 |
| Phoenix | Lidocaine hydrochloride m... | 2211019-02 | 3 |
| Phoenix | Lidocaine hydrochloride m... | 2211019-03 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 2405011-01 | 1 |
| Phoenix | Lidocaine hydrochloride m... | 3238 | 1 |
| Phönix Gotha | Lidocaine hydrochloride m... | 1411010-02 | 1 |
| Phönix/apo ident | Lidocaine hydrochloride m... | 1808031-01 | 1 |
| Phönix/EuRo | Lidocaine hydrochloride m... | 1907012-03 | 1 |
| Phönix/Noweda | Lidocaine hydrochloride m... | 2101034-03 | 1 |
| Phönix | Lidocaine hydrochloride m... | 1122019-01 | 1 |
| Phönix | Lidocaine hydrochloride m... | 1202035-03 | 1 |
| Phönix | Lidocaine hydrochloride m... | 12176103 | 1 |
| phönix | Lidocaine hydrochloride m... | 1505023-03 | 1 |
| Phönix | Lidocaine hydrochloride m... | 1606024-01 | 2 |
| Phönix | Lidocaine hydrochloride m... | 1612015-01 | 2 |
| Phönix | Lidocaine hydrochloride m... | 1612015-03 | 2 |
| Phönix | Lidocaine hydrochloride m... | 16222207 | 2 |
| Phönix | Lidocaine hydrochloride m... | 1808031-02 | 1 |
| Phönix | Lidocaine hydrochloride m... | 18179904 | 1 |
| Phönix | Lidocaine hydrochloride m... | 1907012-01 | 3 |
| Phönix | Lidocaine hydrochloride m... | 1907012-02 | 4 |
| PHÖNIX | Lidocaine hydrochloride m... | 1907012-02 | 1 |
| Phönix | Lidocaine hydrochloride m... | 190701203 | 1 |
| Phönix | Lidocaine hydrochloride m... | 1907012-03 | 1 |
| Phönix | Lidocaine hydrochloride m... | 20004451002 | 1 |
| Phönix | Lidocaine hydrochloride m... | 21002505007 | 1 |
| Phönix | Lidocaine hydrochloride m... | 2101034-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Lidocaine hydrochloride m… | 2101034-02 | 3 |
| Phönix | Lidocaine hydrochloride m… | 2201026-01 | 2 |
| Phönix | Lidocaine hydrochloride m… | 2201026-02 | 1 |
| Phönix | Lidocaine hydrochloride m… | 220126-02 | 1 |
| Phönix | Lidocaine hydrochloride m… | 221019-01 | 1 |
| Phönix | Lidocaine hydrochloride m… | 2211019-01 | 3 |
| Phönix | Lidocaine hydrochloride m… | 2211019-02 | 3 |
| Phönix | Lidocaine hydrochloride m… | 2211019-03 | 2 |
| Phönix | Lidocaine hydrochloride m… | B02-1969804 | 1 |
| Phönix | Lidocaine hydrochloride m… | LDH/722031 | 1 |
| Rondell Apotheke | Lidocaine hydrochloride m… | 15215308 | 1 |
| sana | Lidocaine hydrochloride m… | 1403025-02 | 1 |
| Sana | Lidocaine hydrochloride m… | 2101034-03 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 1202035-01 | 3 |
| Sanacorp | Lidocaine hydrochloride m… | 13118807 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 1403025-01 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 1411010-01 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 14J07-B04-299434 | 2 |
| Sanacorp | Lidocaine hydrochloride m… | 150502302 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 15215309 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 15215312 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 15299513 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 1606024-02 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 17204804 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 17292307 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 17292313 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 1808031-02 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 18179911 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 18179914 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 19135103 | 5 |
| Sanacorp | Lidocaine hydrochloride m… | 2101034-01 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 21I17-B03-213766 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 22003202007 | 2 |
| Sanacorp | Lidocaine hydrochloride m… | 22003202008 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 2201023-02 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 221019-01 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 2211019-01 | 2 |
| Sanacorp | Lidocaine hydrochloride m… | 2211019-03 | 2 |
| Sanacorp | Lidocaine hydrochloride m… | 22H22-B03-224257 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 23003452002 | 1 |
| Sanacorp | Lidocaine hydrochloride m… | 23003452004 | 2 |
| Sanacorp | Lidocaine hydrochloride m… | 2405011-02 | 1 |
| siehe Protokoll | Lidocaine hydrochloride m… | 1606024-01 | 1 |
| Swati / Noweda | Lidocaine hydrochloride m… | 1606024-01 | 1 |
| Swati /Nowreda | Lidocaine hydrochloride m… | 1907012-03 | 1 |
| Swati Spentose Priva… | Lidocaine hydrochloride m… | 1808031-01 | 1 |
| swati spentose priva… | Lidocaine hydrochloride m… | 210103401 | 1 |
| Swati Spentose Priva… | Lidocaine hydrochloride m… | 1907012-04 | 1 |
| Swati Spentose Private | Lidocaine hydrochloride m… | 2101034-01 | 1 |
| Swati Spentose Private | Lidocaine hydrochloride m… | 2101034-02 | 1 |
| Swati Spentose Private | Lidocaine hydrochloride m… | 2201026-01 | 2 |
| Swati Spentose Pvt.Ltd. | Lidocaine hydrochloride m… | 2211019-01 | 1 |
| Swati/ Alli | Lidocaine hydrochloride m… | 2201026-02 | 1 |
| Swati/Noweda | Lidocaine hydrochloride m… | LDH/116007 | 1 |
| SWATI/Noweda | Lidocaine hydrochloride m… | LDH/719007 | 6 |
| SWATI/Noweda | Lidocaine hydrochloride m… | LDH719007 | 1 |
| SWATI/Phoenix | Lidocaine hydrochloride m… | LDH/720023 | 3 |
| Swati/Phönix | Lidocaine hydrochloride m… | 21A12-B04-203052 | 1 |
| SWATI/Phönix | Lidocaine hydrochloride m… | LDH/719007 | 1 |
| Swati/Sanacorp | Lidocaine hydrochloride m… | 2201026-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Swati | Lidocaine hydrochloride m… | 1606024-01 | 1 |
| Symbiotica | Lidocaine hydrochloride m… | 1606024-02 | 1 |

- 252 758 spectra from 1666 *Apo-Ident* customers from a total of 51 630 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Lidocaine hydrochloride monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Lidocaine hydrochloride monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 620 | 0 | 212 320 |
| **Type C** | 0 | 4117 | 11 | 252 758 |

The substance/substance group *Lidocaine hydrochloride monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0323 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7335 % (> 99.6609 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20882 | 20882 | 0.00 | 181.44 |
| 21613 | 23807 | 8.77 | 179.80 |
| 21770 | 21770 | 0.00 | 181.36 |
| 23807 | 23807 | 0.00 | 183.90 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24776 | 24776 | 0.00 | 186.37 |
| 25446 | 21770 | 11.55 | 186.57 |
| 26028 | 26028 | 0.00 | 192.63 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Lithium orotate monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21055-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Lithium orotate monohydrate; Lithii orotas monohydricum

### Special notes

When selecting the *Lithium orotate monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Lithium orotate monohydrate | 9 | 12 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Lithium orotate monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Lithium orotate monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 98.46 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Lithium orotate monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Lithium orotate monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Lithium orotate monohydrate | 2009002 | 25404 | 40 | 20201020* |
| Euro OTC | Lithium orotate monohydrate | 2102007 | 25523 | 40 | 20210222* |
| Euro OTC | Lithium orotate monohydrate | 2210011 | 26431 | 40 | 20221107* |
| Euro OTC | Lithium orotate monohydrate | 2210011 | 26431SI | 20 | 20221107* |
| Euro OTC | Lithium orotate monohydrate | 2403013 | 27207 | 40 | 20240508* |
| Fagron | Lithium orotate monohydrate | 13J04-N01 | 21055 | 40 | 1405616 |
| Fagron | Lithium orotate monohydrate | 13I09-B04-290311 | 21688 | 60 | 20130927 |
| Fagron | Lithium orotate monohydrate | 15F25-B01-315219 | 22502 | 40 | 20150716 |
| Fagron | Lithium orotate monohydrate | 18K21-B01-363417 | 25063 | 40 | 20181231 |
| Fagron | Lithium orotate monohydrate | 22B26-B12-227899 | 26541 | 40 | 20220608 |
| Fagron | Lithium orotate monohydrate | 22B26-B12-227899 | 26541SI | 20 | 20220608 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 11 reference samples from the substance/substance group *Lithium orotate monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 906 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 500 spectra of 13 reference samples from the substance/substance group *Lithium orotate monohydrate*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Lithium orotate monohydrate | 2002030 | 25146 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2110013 | 25882 | 50 |
| Euro OTC | Lithium orotate monohydrate | 2311026 | 26994 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2311003 | 26995 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2407006 | 27351 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2408005 | 27352 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2408006 | 27353 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2501004 | 27510 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2501005 | 27512 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2501027 | 27517 | 40 |
| Fagron | Lithium orotate monohydrate | 16D15-B08-321402 | 23269 | 40 |
| Fagron | Lithium orotate monohydrate | 18A19-B12-347442 | 24111 | 40 |
| Euro OTC | Lithium orotate monohydrate | 2110013 | 25882SI | 10 |

- 212 440 spectra from a total of 4275 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 21 spectra from 8 *Apo-Ident* customers from 13 batches from the substance/substance group *Lithium orotate monohydrate*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Lithium orotate monohydrate | 23K07-B10-232375 | 1 |
| | Lithium orotate monohydrate | 2403013-02 | 2 |
| | Lithium orotate monohydrate | 2408005-01 | 2 |
| | Lithium orotate monohydrate | 2411B14004474 | 1 |
| | Lithium orotate monohydrate | 2501005-01 | 1 |
| | Lithium orotate monohydrate | 2501027-01 | 1 |
| | Lithium orotate monohydrate | 25A14-B12-007341 | 1 |
| AHD | Lithium orotate monohydrate | 2407006-01 | 1 |
| Anzag | Lithium orotate monohydrate | 2408005-01 | 2 |
| Anzag | Lithium orotate monohydrate | 2408005-02 | 3 |
| Euro OTC | Lithium orotate monohydrate | 2408005-01 | 1 |
| Euro OTC | Lithium orotate monohydrate | 2408006-01 | 2 |
| Fagron | Lithium orotate monohydrate | 13J04-N01 | 1 |
| Fagron | Lithium orotate monohydrate | 24I11-B14-004475 | 1 |
| Pfannenschmidt | Lithium orotate monohydrate | ORL00212 | 1 |

- 256 865 spectra from 1666 *Apo-Ident* customers from a total of 52 140 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Lithium orotate monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Lithium orotate monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 500 | 0 | 212 440 |
| **Type C** | 0 | 21 | 0 | 256 865 |

The substance/substance group *Lithium orotate monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | 100.0000 % (> 71.4286 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21055 | 21055 | 0.00 | 195.35 |
| 21688 | 21055 | 5.80 | 193.03 |
| 22502 | 21055 | 8.68 | 194.41 |
| 25063 | 25523 | 5.45 | 193.78 |
| 25404 | 25404 | 0.00 | 190.36 |
| 25523 | 25523 | 0.00 | 191.29 |
| 26431 | 26431 | 0.00 | 195.55 |
| 26541 | 25404 | 6.39 | 192.66 |
| 27207 | 27207 | 0.00 | 191.01 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **L-Phenylalanine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21661-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

L-Phenylalanine; DL-Phenylalanine; Phenylalanine; Phenylalaninum

### Special notes

When selecting the *L-Phenylalanine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| L-Phenylalanine | 7 | 8 | 4 |

### Second-stage model

For differentiation of the substance/substance group *L-Phenylalanine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *L-Phenylalanine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dithranol | 93.72 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *L-Phenylalanine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *L-Phenylalanine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | L-Phenylalanine | 14088304 | 21661 | 60 | 1501656 |
| Euro OTC | L-Phenylalanine | 1212014-03 | 21681 | 60 | 20130111 |
| Euro OTC | L-Phenylalanine | 1704003 | 23173 | 40 | 20170425* |
| Euro OTC | L-Phenylalanine | 2307036 | 26861 | 40 | 20230823* |
| Euro OTC | L-Phenylalanine | 2307036 | 26861SI | 20 | 20230823* |
| Fagron | L-Phenylalanine | 17B13-B03-343288 | 23936 | 40 | 20170309 |
| Fagron | L-Phenylalanine | 19J23-F10-366142 | 24951 | 40 | 20191127 |
| Fagron | L-Phenylalanine | 23C07-B05-227911 | 26671 | 40 | 20230327 |
| Fagron | L-Phenylalanine | 23C07-B05-227911 | 26671SI | 20 | 20230327 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *L-Phenylalanine*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 350 spectra of 9 reference samples from the substance/substance group *L-Phenylalanine*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | L-Phenylalanine | 1409013-02 | 23024 | 40 |
| Euro OTC | L-Phenylalanine | 1808022 | 24198 | 40 |
| Euro OTC | L-Phenylalanine | 1907032 | 24846 | 40 |
| Euro OTC | L-Phenylalanine | 2006038 | 25306 | 40 |
| Euro OTC | L-Phenylalanine | 2105010 | 25711 | 50 |
| Euro OTC | L-Phenylalanine | 2306009 | 26871 | 40 |
| Euro OTC | L-Phenylalanine | 2503010 | 27671 | 40 |
| Fagron | L-Phenylalanine | 24B19-B04-004251 | 27476 | 40 |
| Euro OTC | L-Phenylalanine | 2306009 | 26871SI | 20 |

- 212 590 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 15 spectra from 7 *Apo-Ident* customers from 4 batches from the substance/substance group *L-Phenylalanine*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | L-Phenylalanine | 1409013-02 | 12 |
| Euro OTC | L-Phenylalanine | 1704003-02 | 1 |
| Euro OTC | L-Phenylalanine | 200603801 | 1 |
| Euro OTC | L-Phenylalanine | 2006038-01 | 1 |

- 256 871 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *L-Phenylalanine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *L-Phenylalanine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 350 | 0 | 212 590 |
| **Type C** | 0 | 15 | 0 | 256 871 |

The substance/substance group *L-Phenylalanine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.2857 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21661 | 21661 | 0.00 | 137.85 |
| 21681 | 21661 | 25.18 | 171.44 |
| 23173 | 23173 | 0.00 | 201.40 |

*continued on the next page*


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*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23936 | 21661 | 6.42 | 138.08 |
| 24951 | 21661 | 9.12 | 135.71 |
| 26671 | 21661 | 7.93 | 131.75 |
| 26861 | 26861 | 0.00 | 156.20 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **L-Threonine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20734-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

L-Threonine; Threonine; Threoninum

### Special notes

When selecting the *L-Threonine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| L-Threonine | 7 | 8 | 4 |

### Second-stage model

For differentiation of the substance/substance group *L-Threonine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *L-Threonine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| 5-aminolevulinic acid hydrochloride | 79.48 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *L-Threonine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *L-Threonine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | L-Threonine | 1210027-01 | 21033 | 40 | 1403152 |
| Euro OTC | L-Threonine | 1210027-01 | 22319 | 60 | 20121108 |
| Euro OTC | L-Threonine | 1601031 | 22378 | 40 | 20160225* |
| Euro OTC | L-Threonine | 1909003 | 24850 | 40 | 20190913* |
| Euro OTC | L-Threonine | 2004005 | 25145 | 40 | 20200506* |
| Euro OTC | L-Threonine | 2011021 | 25468 | 40 | 20201210* |
| Euro OTC | L-Threonine | 2304006 | 26643 | 40 | 20230510* |
| Euro OTC | L-Threonine | 2304006 | 26643SI | 20 | 20230510* |
| Fagron | L-Threonine | 12H02-N03 | 20734 | 40 | 1402580 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *L-Threonine*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 350 spectra of 10 reference samples from the substance/substance group *L-Threonine*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | L-Threonine | 1606019 | 22679 | 40 |
| Euro OTC | L-Threonine | 1609014 | 22792 | 40 |
| Euro OTC | L-Threonine | 1703035 | 23158 | 40 |
| Euro OTC | L-Threonine | 1711010 | 23738 | 40 |
| Euro OTC | L-Threonine | 1811030 | 24417 | 40 |
| Euro OTC | L-Threonine | 2201020 | 25946 | 40 |
| Euro OTC | L-Threonine | 2208023 | 26522 | 40 |
| Euro OTC | L-Threonine | 2404016 | 27279 | 40 |
| Euro OTC | L-Threonine | 2201020 | 25946SI | 10 |
| Euro OTC | L-Threonine | 2208023 | 26522SI | 20 |

- 212 590 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4 spectra from 4 *Apo-Ident* customers from 4 batches from the substance/substance group *L-Threonine*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | L-Threonine | 1606019-02 | 1 |
| Euro OTC | L-Threonine | 1811030-01 | 1 |
| Euro OTC | L-Threonine | 2011021-01 | 1 |
| Fargon | L-Threonine | 2114720407 | 1 |

- 256 882 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *L-Threonine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *L-Threonine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 350 | 0 | 212 590 |
| **Type C** | 0 | 4 | 0 | 256 882 |

The substance/substance group *L-Threonine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.2857 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20734 | 20734 | 0.00 | 139.62 |
| 21033 | 21033 | 0.00 | 138.01 |
| 22319 | 25468 | 10.72 | 139.51 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22378 | 22378 | 0.00 | 138.35 |
| 24850 | 24850 | 0.00 | 138.76 |
| 25145 | 25145 | 0.00 | 143.01 |
| 25468 | 25468 | 0.00 | 137.40 |
| 26643 | 26643 | 0.00 | 138.42 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Lysine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20385-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Lysine hydrochloride; Lysine HCl; Lysini hydrochloridum

### Special notes

When selecting the *Lysine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Lysine hydrochloride | 8 | 11 | 8 |

### Second-stage model

For differentiation of the substance/substance group *Lysine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Lysine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Levocarnitine | 97.02 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Lysine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Lysine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Lysine hydrochloride | 1611021 | 22865 | 40 | 20161202* |
| Euro OTC | Lysine hydrochloride | 1708009 | 23698 | 40 | 20170922* |
| Euro OTC | Lysine hydrochloride | 1805030 | 24123 | 40 | 20180611* |
| Euro OTC | Lysine hydrochloride | 2003009 | 25128 | 40 | 20200403* |
| Euro OTC | Lysine hydrochloride | 2010008 | 25459 | 40 | 20201124* |
| Euro OTC | Lysine hydrochloride | 2105002 | 25675 | 40 | 20210527* |
| Fagron | Lysine hydrochloride | 15B09-B06-304170 | 21963 | 60 | 20150220 |
| Fagron | Lysine hydrochloride | 14H20-B03-301894 | 21983 | 60 | AR-16-FG-005856-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 360 spectra of 8 reference samples from the substance/substance group *Lysine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 966 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 500 spectra of 14 reference samples from the substance/substance group *Lysine hydrochloride*.

- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Lysine hydrochloride | 1603011 | 22527 | 40 |
| Euro OTC | Lysine hydrochloride | 1902008 | 24622 | 40 |
| Euro OTC | Lysine hydrochloride | 1907038 | 24809 | 40 |
| Euro OTC | Lysine hydrochloride | 2006008 | 25352 | 40 |
| Euro OTC | Lysine hydrochloride | 2205013 | 26197 | 40 |
| Euro OTC | Lysine hydrochloride | 2302003 | 26657 | 40 |
| Euro OTC | Lysine hydrochloride | 2406017 | 27368 | 40 |
| Fagron | Lysine hydrochloride | 12B14-N08 | 20735 | 40 |
| Fagron | Lysine hydrochloride | 22J11-B06 | 26448 | 40 |
| Fagron | Lysine hydrochloride | 23E18-B02-231717 | 26821 | 40 |
| Fagron | Lysine hydrochloride | 24E06-B24-238724 | 27413 | 40 |
| Euro OTC | Lysine hydrochloride | 2205013 | 26197SI | 20 |
| Euro OTC | Lysine hydrochloride | 2302003 | 26657SI | 20 |
| Fagron | Lysine hydrochloride | 23E18-B02-231717 | 26821SI | 20 |

- 212 440 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 22 spectra from 4 *Apo-Ident* customers from 9 batches from the substance/substance group *Lysine hydrochloride*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Lysine hydrochloride | 1708009-01 | 2 |
| Euro OTC | Lysine hydrochloride | 1805030-01 | 1 |
| Euro OTC | Lysine hydrochloride | 1907038-01 | 1 |
| Euro OTC | Lysine hydrochloride | 2006008-01 | 11 |
| Euro OTC | Lysine hydrochloride | 2105002-02 | 2 |
| Euro OTC | Lysine hydrochloride | 2205013-01 | 2 |
| Euro OTC | Lysine hydrochloride | gjjhgjhkj | 1 |
| Fagron | Lysine hydrochloride | 14H20-B03-301894 | 1 |
| Fagron | Lysine hydrochloride | 21H23-B03-213624 | 1 |

- 256 864 spectra from 1666 *Apo-Ident* customers from a total of 52 146 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Lysine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Lysine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 460 | 40 | 212 440 |
| **Type C** | 0 | 22 | 0 | 256 864 |

The substance/substance group *Lysine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 92.0000 % (> 91.4000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | 100.0000 % (> 72.7273 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21963 | 21983 | 6.80 | 203.84 |
| 21983 | 21983 | 0.00 | 203.97 |
| 22865 | 22865 | 0.00 | 198.93 |
| 23698 | 23698 | 0.00 | 202.75 |
| 24123 | 24123 | 0.00 | 198.52 |
| 25128 | 25128 | 0.00 | 203.59 |
| 25459 | 25459 | 0.00 | 194.76 |
| 25675 | 25675 | 0.00 | 147.88 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Macrogols 1500** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20112-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Macrogols 1500; Macrogolum 1500

### Special notes

When selecting the *Macrogols 1500* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Macrogols 1500 | 9 | 7 | 46 |

### Second-stage model

For differentiation of the substance/substance group *Macrogols 1500* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Macrogols 1500* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Macrogols 4000 | 36.69 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Macrogols 1500* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Macrogols 1500*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Macrogols 1500 | 12324607 | 20977 | 40 | 1403323 |
| Caelo | Macrogols 1500 | 17120001 | 23241 | 40 | 20170519 |
| Caelo | Macrogols 1500 | 171200 | 23291 | 40 | 20170519* |
| Caelo | Macrogols 1500 | 21003420001 | 25988 | 40 | 20220103 |
| Caelo | Macrogols 1500 | 21003420001 | 25988SI | 30 | 20220103 |
| Caelo | Macrogols 1500 | 24001044 | 27236 | 40 | 20240618* |
| Caelo | Macrogols 1500 | 24001044 | 27236SI | 20 | 20240618* |
| Caelo | Macrogols 1500 | 24001643 | 27323 | 40 | 20240808* |
| Caelo | Macrogols 1500 | 24001643 | 27323SI | 20 | 20240808* |
| Euro OTC | Macrogols 1500 | 1508002 | 21948 | 60 | 20150810* |
| Euro OTC | Macrogols 1500 | 1604005 | 22544 | 40 | 20160512* |
| Euro OTC | Macrogols 1500 | 2009003 | 25302 | 40 | 20200916* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 450 spectra of 12 reference samples from the substance/substance group *Macrogols 1500*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 876 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 280 spectra of 7 reference samples from the substance/substance group *Macrogols 1500*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Macrogols 1500 | 172221 | 23625 | 40 |
| Caelo | Macrogols 1500 | 182290 | 24350 | 40 |
| Caelo | Macrogols 1500 | 24002909 | 27537 | 40 |
| Euro OTC | Macrogols 1500 | 1705004 | 23423 | 40 |
| Euro OTC | Macrogols 1500 | 1705036 | 23440 | 40 |
| Euro OTC | Macrogols 1500 | 1711032 | 23898 | 40 |
| Euro OTC | Macrogols 1500 | 1806015 | 24147 | 40 |

- 212 660 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 87 spectra from 38 *Apo-Ident* customers from 48 batches from the substance/substance group *Macrogols 1500*.

- Among them are spectra of independent samples from 46 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Macrogols 1500 | 22002416002 | 2 |
| ACM / Herba | Macrogols 1500 | KN-0826/10 | 1 |
| Caelo | Macrogols 1500 | 10105901 | 1 |
| Caelo | Macrogols 1500 | 11071309 | 1 |
| Caelo | Macrogols 1500 | 12109409 | 1 |
| Caelo | Macrogols 1500 | 13140901 | 1 |
| Caelo | Macrogols 1500 | 13140902 | 2 |
| Caelo | Macrogols 1500 | 13140906 | 1 |
| Caelo | Macrogols 1500 | 14072409 | 1 |
| Caelo | Macrogols 1500 | 14072412 | 1 |
| Caelo | Macrogols 1500 | 15120007 | 1 |
| Caelo | Macrogols 1500 | 1513101 | 1 |
| Caelo | Macrogols 1500 | 15413101 | 2 |
| Caelo | Macrogols 1500 | 15413104 | 1 |
| Caelo | Macrogols 1500 | 15413105 | 5 |
| Caelo | Macrogols 1500 | 15413111 | 2 |
| Caelo | Macrogols 1500 | 16138407 | 1 |
| Caelo | Macrogols 1500 | 17120001 | 3 |
| Caelo | Macrogols 1500 | 17120002 | 2 |
| Caelo | Macrogols 1500 | 17120009 | 1 |
| Caelo | Macrogols 1500 | 17120011 | 2 |
| Caelo | Macrogols 1500 | 17120012 | 3 |
| Caelo | Macrogols 1500 | 18045703 | 1 |
| Caelo | Macrogols 1500 | 1812905 | 1 |
| Caelo | Macrogols 1500 | 18129503 | 1 |
| Caelo | Macrogols 1500 | 18129505 | 1 |
| Caelo | Macrogols 1500 | 18129506 | 1 |
| Caelo | Macrogols 1500 | 18229002 | 2 |
| Caelo | Macrogols 1500 | 18229004 | 2 |
| Caelo | Macrogols 1500 | 192333501 | 1 |
| Caelo | Macrogols 1500 | 19233501 | 3 |
| Caelo | Macrogols 1500 | 20000729002 | 1 |
| Caelo | Macrogols 1500 | 20000729005 | 1 |
| Caesar & Loretz GmbH… | Macrogols 1500 | 21003420001 | 1 |
| Caesar & Loretz GmbH | Macrogols 1500 | 19233501 | 1 |
| Caesar & Loretz GmbH | Macrogols 1500 | 19233502 | 1 |
| Caesar & Loretz GmbH | Macrogols 1500 | 20000729004 | 1 |
| Caesar & Loretz GmbH | Macrogols 1500 | 21001042001 | 1 |
| Caesar & Loretz GmbH | Macrogols 1500 | 21001042002 | 2 |
| Caesar & Loretz GmbH | Macrogols 1500 | 21003420007 | 1 |
| Euro OTC | Macrogols 1500 | 1103017-02 | 4 |
| Euro OTC | Macrogols 1500 | 1206005-01 | 5 |
| Euro OTC | Macrogols 1500 | 1304023-01 | 7 |
| Euro OTC | Macrogols 1500 | 1406004-01 | 2 |
| Euro OTC | Macrogols 1500 | 1503026-01 | 4 |
| Euro OTC | Macrogols 1500 | 1806015-01 | 1 |
| Euro OTC | Macrogols 1500 | 2009003-01 | 1 |
| Gehe | Macrogols 1500 | 14072409 | 1 |
| Krieger | Macrogols 1500 | 1712002 | 1 |
| phoenix | Macrogols 1500 | 18229004 | 1 |
| Phönix | Macrogols 1500 | 14072402 | 1 |

- 256 799 spectra from 1666 *Apo-Ident* customers from a total of 52 106 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,


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the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Macrogols 1500* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Macrogols 1500* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 450 | 0 | 157 876 |
| **Type B** | 0 | 280 | 0 | 212 660 |
| **Type C** | 0 | 87 | 0 | 256 799 |

The substance/substance group *Macrogols 1500* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6667 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.8571 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 93.1034 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20977 | 20977 | 0.00 | 65.41 |
| 21948 | 21948 | 0.00 | 88.69 |
| 22544 | 22544 | 0.00 | 118.36 |
| 23241 | 23291 | 10.89 | 57.06 |
| 23291 | 23291 | 0.00 | 57.34 |
| 25302 | 25302 | 0.00 | 68.32 |
| 25988 | 23291 | 6.41 | 55.19 |
| 27236 | 27236 | 0.00 | 92.04 |
| 27323 | 27323 | 0.00 | 69.05 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by

laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Macrogols 4000** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20690-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Macrogols 4000; Macrogolum 4000

### Special notes

When selecting the *Macrogols 4000* substance/substance group, the following information is displayed to the user:

- Advice for the distinction from Macrogol 6000: Macrogol 4000 cannot be certainly distinct from Macrogol 6000, which is however currently not deliverable in Germany. Please decide, if an additional analysis seems reasonable.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Macrogols 4000 | 15 | 38 | 693 |

### Second-stage model

For differentiation of the substance/substance group *Macrogols 4000* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Macrogols 4000* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Macrogols 1500 | 35.90 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Macrogols 4000* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Macrogols 4000*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Macrogols 4000 | 12074116 | 20690 | 40 | 1401164 |
| Caelo | Macrogols 4000 | 12318019 | 20975 | 40 | 1403322 |
| Caelo | Macrogols 4000 | 12361502 | 21065 | 40 | 20130107 |
| Caelo | Macrogols 4000 | 13356616 | 21357 | 40 | 20131107 |
| Euro OTC | Macrogols 4000 | 1507004 | 21841 | 60 | 0000010550 |
| Euro OTC | Macrogols 4000 | 1508031 | 21903 | 60 | 20150914* |
| Euro OTC | Macrogols 4000 | 1605012 | 22567 | 40 | 20160606* |
| Euro OTC | Macrogols 4000 | 1605025 | 22570 | 40 | 20160603* |
| Euro OTC | Macrogols 4000 | 1702003 | 23174 | 40 | 20170301* |
| Euro OTC | Macrogols 4000 | 1711016 | 23902 | 40 | 20171214* |
| Euro OTC | Macrogols 4000 | 2009016 | 25414 | 40 | 20200928* |
| Euro OTC | Macrogols 4000 | 2104009 | 25713 | 50 | 20210624* |
| Euro OTC | Macrogols 4000 | 2207019 | 26262 | 40 | 20220728* |
| Euro OTC | Macrogols 4000 | 2207019 | 26262SI | 20 | 20220728* |
| Fagron | Macrogols 4000 | 15B13-B04-305461 | 21886 | 60 | AR-16-FG-004020-01 |
| Fagron | Macrogols 4000 | 16F10-B04-325645 | 23021 | 40 | 20160822 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 690 spectra of 16 reference samples from the substance/substance group *Macrogols 4000*. These samples are listed above in the *calibration samples* section. The reference samples come from 15 different batches.

- 157 636 spectra from a total of 2942 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1570 spectra of 41 reference samples from the substance/substance group *Macrogols 4000*.

- Among them are spectra of independent samples from 38 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Macrogols 4000 | 11172433 | 20692 | 40 |
| Caelo | Macrogols 4000 | 170686 | 23280 | 40 |
| Caelo | Macrogols 4000 | 171190 | 23282 | 40 |
| Caelo | Macrogols 4000 | 172081 | 23657 | 40 |
| Caelo | Macrogols 4000 | 173039 | 23825 | 40 |
| Caelo | Macrogols 4000 | 181974 | 24227 | 40 |
| Caelo | Macrogols 4000 | 182154 | 24229 | 40 |
| Caelo | Macrogols 4000 | 182448 | 24352 | 40 |
| Caelo | Macrogols 4000 | 183153 | 24360 | 40 |
| Caelo | Macrogols 4000 | 190093 | 24564 | 40 |
| Caelo | Macrogols 4000 | 191756 | 24743 | 40 |
| Caelo | Macrogols 4000 | 21001852005 | 26317 | 30 |
| Caelo | Macrogols 4000 | 22003823 | 26477 | 40 |
| Caelo | Macrogols 4000 | 22003814 | 26496 | 40 |
| Caelo | Macrogols 4000 | 23000401 | 26691 | 40 |
| Caelo | Macrogols 4000 | 24001280 | 27234 | 40 |
| Caelo | Macrogols 4000 | 24002011 | 27445 | 40 |
| Caelo | Macrogols 4000 | 24002115 | 27449 | 40 |
| Caelo | Macrogols 4000 | 24002818 | 27535 | 40 |
| Caelo | Macrogols 4000 | 25000942 | 27656 | 40 |
| Euro OTC | Macrogols 4000 | 1609018 | 22791 | 40 |
| Euro OTC | Macrogols 4000 | 1701007 | 22983 | 40 |
| Euro OTC | Macrogols 4000 | 1705019 | 23433 | 40 |
| Euro OTC | Macrogols 4000 | 1707026 | 23537 | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Macrogols 4000 | 1804001 | 24089 | 40 |
| Euro OTC | Macrogols 4000 | 1803029 | 24094 | 40 |
| Euro OTC | Macrogols 4000 | 1810003 | 24339 | 40 |
| Euro OTC | Macrogols 4000 | 1902009 | 24463 | 40 |
| Euro OTC | Macrogols 4000 | 1907002 | 24798 | 40 |
| Euro OTC | Macrogols 4000 | 1911027 | 25073 | 40 |
| Euro OTC | Macrogols 4000 | 2007005 | 25326 | 40 |
| Euro OTC | Macrogols 4000 | 2109002 | 25820 | 50 |
| Euro OTC | Macrogols 4000 | 2207018 | 26276 | 40 |
| Euro OTC | Macrogols 4000 | 2211018 | 26524 | 40 |
| Euro OTC | Macrogols 4000 | 2401006 | 27153 | 40 |
| Euro OTC | Macrogols 4000 | 2408012 | 27403 | 40 |
| Fagron | Macrogols 4000 | 22A15-B06-216742 | 26071 | 40 |
| Fagron | Macrogols 4000 | 24A19-B01-235824 | 27385 | 40 |
| Caelo | Macrogols 4000 | 21001852005 | 26317SI | 20 |
| Euro OTC | Macrogols 4000 | 2207018 | 26276SI | 20 |
| Fagron | Macrogols 4000 | 22A15-B06-216742 | 26071SI | 10 |

- 211 370 spectra from a total of 4249 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2564 spectra from 632 *Apo-Ident* customers from 700 batches from the substance/substance group *Macrogols 4000*.

- Among them are spectra of independent samples from 693 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Macrogols 4000 | 22/88 | 1 |
| | Macrogols 4000 | 22001587006 | 1 |
| | Macrogols 4000 | 22001929004 | 1 |
| | Macrogols 4000 | 22003814008 | 1 |
| | Macrogols 4000 | 22003814011 | 6 |
| | Macrogols 4000 | 22003814014 | 2 |
| | Macrogols 4000 | 22003823005 | 7 |
| | Macrogols 4000 | 22004211002 | 1 |
| | Macrogols 4000 | 22004211004 | 3 |
| | Macrogols 4000 | 22004211006 | 3 |
| | Macrogols 4000 | 22004211008 | 1 |
| | Macrogols 4000 | 22004211010 | 2 |
| | Macrogols 4000 | 22004212003 | 5 |
| | Macrogols 4000 | 22004213003 | 2 |
| | Macrogols 4000 | 22004213004 | 3 |
| | Macrogols 4000 | 22004213005 | 9 |
| | Macrogols 4000 | 2204211006 | 1 |
| | Macrogols 4000 | 23001960006 | 1 |
| | Macrogols 4000 | 23001960007 | 2 |
| | Macrogols 4000 | 23001960008 | 7 |
| | Macrogols 4000 | 23001960009 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Macrogols 4000 | 23001960010 | 10 |
| | Macrogols 4000 | 23002714001 | 1 |
| | Macrogols 4000 | 23002714002 | 2 |
| | Macrogols 4000 | 23002714003 | 3 |
| | Macrogols 4000 | 23002714004 | 2 |
| | Macrogols 4000 | 23002741005 | 1 |
| | Macrogols 4000 | 230831(23C16-B18-229949) | 1 |
| | Macrogols 4000 | 230926 | 1 |
| | Macrogols 4000 | 231011 | 1 |
| | Macrogols 4000 | 231011(23001960007) | 1 |
| | Macrogols 4000 | 23C08-B02-228457 | 10 |
| | Macrogols 4000 | 23C08-B02-229898 | 5 |
| | Macrogols 4000 | 23c16b18229946 | 1 |
| | Macrogols 4000 | 23C16-B18-229946 | 3 |
| | Macrogols 4000 | 23C16-B18-229947 | 17 |
| | Macrogols 4000 | 23C16-B18-2302203 | 2 |
| | Macrogols 4000 | 23C16-B18-230223 | 4 |
| | Macrogols 4000 | 23D21-B06-2343604 | 1 |
| | Macrogols 4000 | 23D21-B06-234478 | 2 |
| | Macrogols 4000 | 23D21-B08-2356601 | 1 |
| | Macrogols 4000 | 23D21-B08-235661 | 4 |
| | Macrogols 4000 | 23D21-B08-235662 | 2 |
| | Macrogols 4000 | 24000623001 | 1 |
| | Macrogols 4000 | 24000623002 | 6 |
| | Macrogols 4000 | 24000623004 | 1 |
| | Macrogols 4000 | 24000623005 | 3 |
| | Macrogols 4000 | 24000623006 | 2 |
| | Macrogols 4000 | 24000623010 | 2 |
| | Macrogols 4000 | 24001280001 | 3 |
| | Macrogols 4000 | 24001280002 | 2 |
| | Macrogols 4000 | 24001280005 | 3 |
| | Macrogols 4000 | 24001280006 | 10 |
| | Macrogols 4000 | 24001280012 | 4 |
| | Macrogols 4000 | 24001280014 | 1 |
| | Macrogols 4000 | 24001280015 | 1 |
| | Macrogols 4000 | 24002115001 | 4 |
| | Macrogols 4000 | 24002115002 | 2 |
| | Macrogols 4000 | 24002115004 | 1 |
| | Macrogols 4000 | 24002115006 | 1 |
| | Macrogols 4000 | 2400281006 | 1 |
| | Macrogols 4000 | 24002818001 | 2 |
| | Macrogols 4000 | 24002818002 | 3 |
| | Macrogols 4000 | 24002818004 | 1 |
| | Macrogols 4000 | 24002818006 | 1 |
| | Macrogols 4000 | 24002818008 | 3 |
| | Macrogols 4000 | 24002818011 | 1 |
| | Macrogols 4000 | 2401006-02 | 1 |
| | Macrogols 4000 | 240306 | 1 |
| | Macrogols 4000 | 240402 | 1 |
| | Macrogols 4000 | 240417 | 1 |
| | Macrogols 4000 | 240513 | 1 |
| | Macrogols 4000 | 240624 | 1 |
| | Macrogols 4000 | 240711 | 1 |
| | Macrogols 4000 | 240808 | 1 |
| | Macrogols 4000 | 241108 | 1 |
| | Macrogols 4000 | 241216(241128) | 1 |
| | Macrogols 4000 | 24J30-B06-006257 | 2 |
| | Macrogols 4000 | 250110 | 1 |
| | Macrogols 4000 | 250117 | 1 |
| | Macrogols 4000 | 250327(24002818002) | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Macrogols 4000 | 250519(24002818006) | 1 |
| | Macrogols 4000 | 250612 | 1 |
| | Macrogols 4000 | 250626 | 1 |
| | Macrogols 4000 | 25A11-B21-008575 | 1 |
| | Macrogols 4000 | B18-2299407 | 1 |
| | Macrogols 4000 | B06-2348608 | 2 |
| | Macrogols 4000 | B08-2356601 | 1 |
| ACM | Macrogols 4000 | KNC0366J15 | 2 |
| AHC | Macrogols 4000 | 19000679007 | 1 |
| AHC | Macrogols 4000 | 22004211001 | 1 |
| AHD/Caesar & Loretz GmbH | Macrogols 4000 | 21001852005 | 1 |
| AHD | Macrogols 4000 | 11H11-B05340782 | 1 |
| AHD | Macrogols 4000 | 14L12-B06-301991 | 2 |
| AHD | Macrogols 4000 | 15G15B07-313592 | 1 |
| AHD | Macrogols 4000 | 17208106 | 1 |
| AHD | Macrogols 4000 | 17E02-B03 | 1 |
| AHD | Macrogols 4000 | 17E02-B03-335507 | 3 |
| AHD | Macrogols 4000 | 17K06-B05 | 2 |
| AHD | Macrogols 4000 | 17K06-B05-345076 | 1 |
| AHD | Macrogols 4000 | 18G30-B01 | 2 |
| AHD | Macrogols 4000 | 18G30-B01-352394 | 2 |
| AHD | Macrogols 4000 | 19000679005 | 1 |
| AHD | Macrogols 4000 | 20001517005 | 1 |
| AHD | Macrogols 4000 | 22004211006 | 1 |
| AHD | Macrogols 4000 | 22004213005 | 1 |
| AHD | Macrogols 4000 | 2211018-02 | 1 |
| AHD | Macrogols 4000 | 23001960008 | 2 |
| AHD | Macrogols 4000 | 23002714002 | 1 |
| AHD | Macrogols 4000 | 23C16-B18-229946 | 1 |
| AHD | Macrogols 4000 | 23C16-B18-229947 | 1 |
| Alliance Healthcare | Macrogols 4000 | 12361512 | 2 |
| Alliance Healthcare | Macrogols 4000 | 19000679007 | 1 |
| Alliance | Macrogols 4000 | 18215403 | 1 |
| Alliance | Macrogols 4000 | 20H21-F16-374090 | 1 |
| Alliance | Macrogols 4000 | 21003792003 | 2 |
| Alliance | Macrogols 4000 | 22001587010 | 3 |
| Alliance | Macrogols 4000 | 22004211004 | 2 |
| alliance | Macrogols 4000 | 23001960009 | 1 |
| ANZAG 15.05.2014 | Macrogols 4000 | 13356616 | 1 |
| Anzag | Macrogols 4000 | 17068603 | 1 |
| Anzag | Macrogols 4000 | 230418(22004211004) | 1 |
| Anzag | Macrogols 4000 | 230710(22004213006) | 1 |
| Anzag | Macrogols 4000 | 230918 | 1 |
| Anzag | Macrogols 4000 | 231117(23001960006) | 1 |
| Anzag | Macrogols 4000 | 231123 | 1 |
| Anzag | Macrogols 4000 | 231219 | 1 |
| Anzag | Macrogols 4000 | 240212(23002714002) | 1 |
| Anzag | Macrogols 4000 | 240514(24000623007) | 1 |
| Anzag | Macrogols 4000 | 240703(24000623006) | 1 |
| Anzag | Macrogols 4000 | 240826(24001280004) | 1 |
| Anzag | Macrogols 4000 | 240903(24000623012) | 2 |
| Anzag | Macrogols 4000 | 240916 | 1 |
| Anzag | Macrogols 4000 | 240916(24001280002) | 1 |
| Anzag | Macrogols 4000 | 241015 | 1 |
| Anzag | Macrogols 4000 | 241017(24001280005) | 1 |
| Anzag | Macrogols 4000 | 241128(24001280001) | 2 |
| Anzag | Macrogols 4000 | 250110(24002115003) | 1 |
| Anzag | Macrogols 4000 | 250120(24002115003) | 1 |
| Anzag | Macrogols 4000 | 250130(24002115001) | 1 |
| Anzag | Macrogols 4000 | 250219 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag | Macrogols 4000 | 250317 | 1 |
| Anzag | Macrogols 4000 | 250317(24002115005) | 2 |
| Anzag | Macrogols 4000 | 250513 | 1 |
| Anzag | Macrogols 4000 | 250514(24002818001) | 1 |
| Anzag | Macrogols 4000 | 250528 | 1 |
| Anzag | Macrogols 4000 | 250612(24002818001) | 1 |
| Anzag | Macrogols 4000 | 250626(24002818008) | 1 |
| Anzag | Macrogols 4000 | 250710 | 1 |
| Anzag | Macrogols 4000 | 250723(24002818012) | 2 |
| apo ident | Macrogols 4000 | 16267311 | 4 |
| Audor Pharma | Macrogols 4000 | 2207018-01 | 2 |
| Bombastus | Macrogols 4000 | 13136016 | 1 |
| Cae | Macrogols 4000 | 20003827011 | 1 |
| Caelo | Macrogols 4000 | | 1 |
| Caelo | Macrogols 4000 | 1(20001517003) | 1 |
| Caelo | Macrogols 4000 | 1(20003397010) | 1 |
| Caelo | Macrogols 4000 | 1010023-02 | 1 |
| Caelo | Macrogols 4000 | 1030517 | 1 |
| Caelo | Macrogols 4000 | 11172303 | 1 |
| Caelo | Macrogols 4000 | 1131117/16358107 | 1 |
| Caelo | Macrogols 4000 | 1172404 | 1 |
| Caelo | Macrogols 4000 | 1180513 | 1 |
| Caelo | Macrogols 4000 | 1200617/16368105 | 1 |
| Caelo | Macrogols 4000 | 12074102 | 1 |
| Caelo | Macrogols 4000 | 12074109 | 3 |
| Caelo | Macrogols 4000 | 12074114 | 1 |
| Caelo | Macrogols 4000 | 12074116 | 3 |
| Caelo | Macrogols 4000 | 12149108 | 1 |
| Caelo | Macrogols 4000 | 12149113 | 2 |
| Caelo | Macrogols 4000 | 12318011 | 1 |
| Caelo | Macrogols 4000 | 12318019 | 1 |
| Caelo | Macrogols 4000 | 12318027 | 1 |
| Caelo | Macrogols 4000 | 1234 | 1 |
| Caelo | Macrogols 4000 | 12345 | 1 |
| Caelo | Macrogols 4000 | 1234Test | 1 |
| Caelo | Macrogols 4000 | 12361502 | 3 |
| Caelo | Macrogols 4000 | 12361506 | 3 |
| Caelo | Macrogols 4000 | 12361512 | 3 |
| Caelo | Macrogols 4000 | 12361513 | 3 |
| Caelo | Macrogols 4000 | 12361518 | 3 |
| Caelo | Macrogols 4000 | 123test | 1 |
| Caelo | Macrogols 4000 | 123Test | 1 |
| Caelo | Macrogols 4000 | 1260917/16358105 | 1 |
| Caelo | Macrogols 4000 | 13081501 | 1 |
| Caelo | Macrogols 4000 | 13136001 | 3 |
| Caelo | Macrogols 4000 | 13136003 | 3 |
| Caelo | Macrogols 4000 | 13136009 | 3 |
| Caelo | Macrogols 4000 | 13136010 | 1 |
| Caelo | Macrogols 4000 | 13136011 | 4 |
| Caelo | Macrogols 4000 | 1316003 | 1 |
| Caelo | Macrogols 4000 | 13335102 | 1 |
| Caelo | Macrogols 4000 | 13335106 | 1 |
| Caelo | Macrogols 4000 | 13335107 | 1 |
| Caelo | Macrogols 4000 | 13335120 | 1 |
| Caelo | Macrogols 4000 | 13356601 | 4 |
| Caelo | Macrogols 4000 | 13356602 | 3 |
| Caelo | Macrogols 4000 | 13356609 | 1 |
| Caelo | Macrogols 4000 | 13356611 | 4 |
| Caelo | Macrogols 4000 | 13356616 | 1 |
| Caelo | Macrogols 4000 | 13356617 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Macrogols 4000 | 13356621 | 1 |
| Caelo | Macrogols 4000 | 1401708 | 1 |
| Caelo | Macrogols 4000 | 14061705 | 5 |
| Caelo | Macrogols 4000 | 14061707 | 4 |
| Caelo | Macrogols 4000 | 14061708 | 9 |
| Caelo | Macrogols 4000 | 14061713 | 1 |
| Caelo | Macrogols 4000 | 14180503 | 1 |
| Caelo | Macrogols 4000 | 14180504 | 1 |
| Caelo | Macrogols 4000 | 14180508 | 2 |
| Caelo | Macrogols 4000 | 14180511 | 2 |
| Caelo | Macrogols 4000 | 14180520 | 4 |
| Caelo | Macrogols 4000 | 14180522 | 1 |
| Caelo | Macrogols 4000 | 14180524 | 1 |
| Caelo | Macrogols 4000 | 14180525 | 3 |
| Caelo | Macrogols 4000 | 14196007 | 1 |
| Caelo | Macrogols 4000 | 14196013 | 1 |
| Caelo | Macrogols 4000 | 14196017 | 1 |
| Caelo | Macrogols 4000 | 143526 | 1 |
| Caelo | Macrogols 4000 | 14352606 | 2 |
| Caelo | Macrogols 4000 | 14352607 | 2 |
| Caelo | Macrogols 4000 | 14352608 | 1 |
| Caelo | Macrogols 4000 | 14352611 | 2 |
| Caelo | Macrogols 4000 | 14352613 | 5 |
| Caelo | Macrogols 4000 | 14352614 | 1 |
| Caelo | Macrogols 4000 | 14352618 | 2 |
| Caelo | Macrogols 4000 | 14J03-B07-304700 | 3 |
| Caelo | Macrogols 4000 | 1508031-02 | 1 |
| Caelo | Macrogols 4000 | 15159502 | 3 |
| Caelo | Macrogols 4000 | 15159504 | 3 |
| Caelo | Macrogols 4000 | 15159514 | 4 |
| Caelo | Macrogols 4000 | 15159515 | 4 |
| Caelo | Macrogols 4000 | 15159516 | 1 |
| Caelo | Macrogols 4000 | 1517003 | 1 |
| Caelo | Macrogols 4000 | 15225001 | 1 |
| Caelo | Macrogols 4000 | 15225003 | 4 |
| Caelo | Macrogols 4000 | 15225013 | 1 |
| Caelo | Macrogols 4000 | 15335001 | 10 |
| Caelo | Macrogols 4000 | 15335002 | 3 |
| Caelo | Macrogols 4000 | 15335003 | 6 |
| Caelo | Macrogols 4000 | 15335004 | 1 |
| Caelo | Macrogols 4000 | 15335007 | 4 |
| Caelo | Macrogols 4000 | 1535004 | 1 |
| Caelo | Macrogols 4000 | 15376503 | 3 |
| Caelo | Macrogols 4000 | 15376515 | 1 |
| Caelo | Macrogols 4000 | 15376518 | 1 |
| Caelo | Macrogols 4000 | 15376519 | 1 |
| Caelo | Macrogols 4000 | 15406301 | 11 |
| Caelo | Macrogols 4000 | 15406302 | 2 |
| Caelo | Macrogols 4000 | 15406303 | 4 |
| Caelo | Macrogols 4000 | 15406306 | 2 |
| Caelo | Macrogols 4000 | 16023903 | 5 |
| Caelo | Macrogols 4000 | 16023904 | 4 |
| Caelo | Macrogols 4000 | 16023905 | 4 |
| Caelo | Macrogols 4000 | 16023907 | 1 |
| Caelo | Macrogols 4000 | 160912M | 1 |
| Caelo | Macrogols 4000 | 161017M/15406304 | 1 |
| Caelo | Macrogols 4000 | 161202M/16152004 | 1 |
| Caelo | Macrogols 4000 | 16152001 | 17 |
| Caelo | Macrogols 4000 | 16152002 | 2 |
| Caelo | Macrogols 4000 | 16152003 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Macrogols 4000 | 16267305 | 9 |
| Caelo | Macrogols 4000 | 16267307 | 16 |
| Caelo | Macrogols 4000 | 16267308 | 3 |
| Caelo | Macrogols 4000 | 16267308/170227M | 1 |
| Caelo | Macrogols 4000 | 16267311 | 2 |
| Caelo | Macrogols 4000 | 16308902 | 11 |
| Caelo | Macrogols 4000 | 16308904 | 7 |
| Caelo | Macrogols 4000 | 16308905 | 3 |
| Caelo | Macrogols 4000 | 16308907 | 15 |
| Caelo | Macrogols 4000 | 16308908 | 4 |
| Caelo | Macrogols 4000 | 16358101 | 2 |
| Caelo | Macrogols 4000 | 16358106 | 3 |
| Caelo | Macrogols 4000 | 16358107 | 1 |
| Caelo | Macrogols 4000 | 16358107/1111217 | 1 |
| Caelo | Macrogols 4000 | 170105M16152004 | 1 |
| Caelo | Macrogols 4000 | 170324M/16267308 | 1 |
| Caelo | Macrogols 4000 | 17035603 | 2 |
| Caelo | Macrogols 4000 | 17035604 | 4 |
| Caelo | Macrogols 4000 | 17035606 | 14 |
| Caelo | Macrogols 4000 | 17035607 | 5 |
| Caelo | Macrogols 4000 | 17035608 | 1 |
| Caelo | Macrogols 4000 | 170504M/16308906 | 1 |
| Caelo | Macrogols 4000 | 170529M/16267308 | 1 |
| Caelo | Macrogols 4000 | 170612M/17035603 | 1 |
| Caelo | Macrogols 4000 | 17068603 | 4 |
| Caelo | Macrogols 4000 | 170710M/17035603 | 1 |
| Caelo | Macrogols 4000 | 170817M/17035603 | 1 |
| Caelo | Macrogols 4000 | 170928M/17119002 | 1 |
| Caelo | Macrogols 4000 | 171103M/17119002 | 1 |
| Caelo | Macrogols 4000 | 17119001 | 2 |
| Caelo | Macrogols 4000 | 17119005 | 2 |
| Caelo | Macrogols 4000 | 171211M/17119003 | 1 |
| Caelo | Macrogols 4000 | 17185601 | 2 |
| Caelo | Macrogols 4000 | 1720103 | 1 |
| Caelo | Macrogols 4000 | 17208103 | 13 |
| Caelo | Macrogols 4000 | 17208104 | 24 |
| Caelo | Macrogols 4000 | 17208105 | 2 |
| Caelo | Macrogols 4000 | 17208106 | 2 |
| Caelo | Macrogols 4000 | 1720813 | 1 |
| Caelo | Macrogols 4000 | 17303901 | 19 |
| Caelo | Macrogols 4000 | 17303902 | 11 |
| Caelo | Macrogols 4000 | 17303903 | 1 |
| Caelo | Macrogols 4000 | 17303905 | 1 |
| Caelo | Macrogols 4000 | 17337901 | 6 |
| Caelo | Macrogols 4000 | 17337902/1250418 | 1 |
| Caelo | Macrogols 4000 | 17337902/1300518 | 1 |
| Caelo | Macrogols 4000 | 17337902/2190218 | 1 |
| Caelo | Macrogols 4000 | 17337906 | 1 |
| Caelo | Macrogols 4000 | 177337906 | 1 |
| Caelo | Macrogols 4000 | 18106101 | 2 |
| Caelo | Macrogols 4000 | 18106103 | 5 |
| Caelo | Macrogols 4000 | 18106104 | 6 |
| Caelo | Macrogols 4000 | 18106105 | 36 |
| Caelo | Macrogols 4000 | 18106106 | 9 |
| Caelo | Macrogols 4000 | 18106109 | 5 |
| Caelo | Macrogols 4000 | 18106110 | 4 |
| Caelo | Macrogols 4000 | 18215403 | 4 |
| Caelo | Macrogols 4000 | 18215404 | 5 |
| Caelo | Macrogols 4000 | 18215405 | 2 |
| Caelo | Macrogols 4000 | 18244802 | 19 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Macrogols 4000 | 18244803 | 11 |
| Caelo | Macrogols 4000 | 18244805 | 14 |
| Caelo | Macrogols 4000 | 18244806 | 4 |
| Caelo | Macrogols 4000 | 18244809 | 2 |
| Caelo | Macrogols 4000 | 18315301 | 17 |
| Caelo | Macrogols 4000 | 18315302 | 11 |
| Caelo | Macrogols 4000 | 18315303 | 13 |
| Caelo | Macrogols 4000 | 18315304 | 6 |
| Caelo | Macrogols 4000 | 18315305 | 8 |
| Caelo | Macrogols 4000 | 18315307 | 20 |
| Caelo | Macrogols 4000 | 18K01-B01-356808 | 1 |
| Caelo | Macrogols 4000 | 190000679004 | 1 |
| Caelo | Macrogols 4000 | 19000379004 | 1 |
| Caelo | Macrogols 4000 | 1900067007 | 1 |
| Caelo | Macrogols 4000 | 190006790006 | 1 |
| Caelo | Macrogols 4000 | 19000679004 | 8 |
| Caelo | Macrogols 4000 | 19000679005 | 10 |
| Caelo | Macrogols 4000 | 19000679006 | 10 |
| Caelo | Macrogols 4000 | 19000679007 | 27 |
| Caelo | Macrogols 4000 | 19000679009 | 5 |
| Caelo | Macrogols 4000 | 1900067909 | 1 |
| Caelo | Macrogols 4000 | 1900679005 | 1 |
| Caelo | Macrogols 4000 | 19009302 | 4 |
| Caelo | Macrogols 4000 | 19009303 | 5 |
| Caelo | Macrogols 4000 | 19009305 | 6 |
| Caelo | Macrogols 4000 | 19009308 | 3 |
| Caelo | Macrogols 4000 | 19009312 | 2 |
| Caelo | Macrogols 4000 | 19009313 | 1 |
| Caelo | Macrogols 4000 | 19009314 | 3 |
| Caelo | Macrogols 4000 | 190908001 | 1 |
| Caelo | Macrogols 4000 | 19090801 | 1 |
| Caelo | Macrogols 4000 | 19090804 | 1 |
| Caelo | Macrogols 4000 | 190920 | 1 |
| Caelo | Macrogols 4000 | 19142401 | 20 |
| Caelo | Macrogols 4000 | 19142402 | 9 |
| Caelo | Macrogols 4000 | 19142403 | 20 |
| Caelo | Macrogols 4000 | 19142404 | 4 |
| Caelo | Macrogols 4000 | 19142407 | 1 |
| Caelo | Macrogols 4000 | 19175603 | 6 |
| Caelo | Macrogols 4000 | 19175604 | 4 |
| Caelo | Macrogols 4000 | 19175605 | 6 |
| Caelo | Macrogols 4000 | 19175606 | 17 |
| Caelo | Macrogols 4000 | 19175607 | 4 |
| Caelo | Macrogols 4000 | 192227702 | 1 |
| Caelo | Macrogols 4000 | 192277002 | 5 |
| Caelo | Macrogols 4000 | 19227701 | 7 |
| Caelo | Macrogols 4000 | 19227702 | 27 |
| Caelo | Macrogols 4000 | 19227703 | 7 |
| Caelo | Macrogols 4000 | 19227704 | 1 |
| Caelo | Macrogols 4000 | 19227705 | 1 |
| Caelo | Macrogols 4000 | 2(20003397010) | 1 |
| Caelo | Macrogols 4000 | 200002443005 | 1 |
| Caelo | Macrogols 4000 | 200003397002 | 1 |
| Caelo | Macrogols 4000 | 200003397005 | 1 |
| Caelo | Macrogols 4000 | 200003397013 | 1 |
| Caelo | Macrogols 4000 | 200003882003 | 1 |
| Caelo | Macrogols 4000 | 20001303003 | 5 |
| Caelo | Macrogols 4000 | 20001303007 | 2 |
| Caelo | Macrogols 4000 | 2000151003 | 1 |
| Caelo | Macrogols 4000 | 20001517001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Macrogols 4000 | 20001517002 | 1 |
| Caelo | Macrogols 4000 | 20001517003 | 25 |
| Caelo | Macrogols 4000 | 20001517004 | 9 |
| Caelo | Macrogols 4000 | 20001517005 | 8 |
| Caelo | Macrogols 4000 | 20001517006 | 15 |
| Caelo | Macrogols 4000 | 20001517008 | 1 |
| Caelo | Macrogols 4000 | 20001517009 | 1 |
| Caelo | Macrogols 4000 | 20002443003 | 2 |
| Caelo | Macrogols 4000 | 20002443004 | 7 |
| Caelo | Macrogols 4000 | 20002443005 | 7 |
| Caelo | Macrogols 4000 | 20002443006 | 2 |
| Caelo | Macrogols 4000 | 20002443007 | 11 |
| Caelo | Macrogols 4000 | 20002443008 | 9 |
| Caelo | Macrogols 4000 | 20002443009 | 7 |
| Caelo | Macrogols 4000 | 20002443010 | 20 |
| Caelo | Macrogols 4000 | 20002446004 | 1 |
| Caelo | Macrogols 4000 | 20002494004 | 2 |
| Caelo | Macrogols 4000 | 20003397002 | 26 |
| Caelo | Macrogols 4000 | 20003397003 | 3 |
| Caelo | Macrogols 4000 | 20003397004 | 14 |
| Caelo | Macrogols 4000 | 20003397005 | 5 |
| Caelo | Macrogols 4000 | 20003397007 | 11 |
| Caelo | Macrogols 4000 | 20003397009 | 9 |
| Caelo | Macrogols 4000 | 20003397010 | 13 |
| Caelo | Macrogols 4000 | 20003397011 | 9 |
| Caelo | Macrogols 4000 | 20003397012 | 8 |
| Caelo | Macrogols 4000 | 20003397013 | 6 |
| Caelo | Macrogols 4000 | 20003397014 | 7 |
| Caelo | Macrogols 4000 | 20003397104 | 1 |
| Caelo | Macrogols 4000 | 20003827001 | 1 |
| Caelo | Macrogols 4000 | 20003827006 | 2 |
| Caelo | Macrogols 4000 | 20003827011 | 3 |
| Caelo | Macrogols 4000 | 20003882001 | 6 |
| Caelo | Macrogols 4000 | 20003882002 | 16 |
| Caelo | Macrogols 4000 | 20003882003 | 5 |
| Caelo | Macrogols 4000 | 20003882005 | 2 |
| Caelo | Macrogols 4000 | 2000397004 | 1 |
| Caelo | Macrogols 4000 | 2000397014 | 1 |
| Caelo | Macrogols 4000 | 2001517003 | 1 |
| Caelo | Macrogols 4000 | 2003397013 | 1 |
| Caelo | Macrogols 4000 | 200691307 | 1 |
| Caelo | Macrogols 4000 | 210003792002 | 1 |
| Caelo | Macrogols 4000 | 21001520001 | 1 |
| Caelo | Macrogols 4000 | 2100152006 | 1 |
| Caelo | Macrogols 4000 | 21001845001 | 7 |
| Caelo | Macrogols 4000 | 21001845002 | 5 |
| Caelo | Macrogols 4000 | 21001846001 | 4 |
| Caelo | Macrogols 4000 | 21001850001 | 1 |
| Caelo | Macrogols 4000 | 21001850003 | 6 |
| Caelo | Macrogols 4000 | 21001850005 | 5 |
| Caelo | Macrogols 4000 | 21001850007 | 7 |
| Caelo | Macrogols 4000 | 21001852005 | 16 |
| Caelo | Macrogols 4000 | 21001852006 | 5 |
| Caelo | Macrogols 4000 | 21001852007 | 7 |
| Caelo | Macrogols 4000 | 21001852008 | 1 |
| Caelo | Macrogols 4000 | 21003792002 | 11 |
| Caelo | Macrogols 4000 | 21003792003 | 4 |
| Caelo | Macrogols 4000 | 21003792004 | 6 |
| Caelo | Macrogols 4000 | 21003792005 | 6 |
| Caelo | Macrogols 4000 | 21003792006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Macrogols 4000 | 21003795003 | 1 |
| Caelo | Macrogols 4000 | 210037992003 | 1 |
| Caelo | Macrogols 4000 | 210906(2101845001) | 1 |
| Caelo | Macrogols 4000 | 210923(20003397010) | 1 |
| Caelo | Macrogols 4000 | 211019(21001846001) | 1 |
| Caelo | Macrogols 4000 | 211124(21001850005) | 1 |
| Caelo | Macrogols 4000 | 211215(21001850005) | 1 |
| Caelo | Macrogols 4000 | 22001201001 | 1 |
| Caelo | Macrogols 4000 | 22001587004 | 1 |
| Caelo | Macrogols 4000 | 22001587005 | 9 |
| Caelo | Macrogols 4000 | 22001587006 | 5 |
| Caelo | Macrogols 4000 | 22001587007 | 13 |
| Caelo | Macrogols 4000 | 22001587010 | 3 |
| Caelo | Macrogols 4000 | 22001587013 | 1 |
| Caelo | Macrogols 4000 | 22001587014 | 2 |
| Caelo | Macrogols 4000 | 22001587015 | 1 |
| Caelo | Macrogols 4000 | 22003814005 | 1 |
| Caelo | Macrogols 4000 | 22003814006 | 4 |
| Caelo | Macrogols 4000 | 22003814007 | 1 |
| Caelo | Macrogols 4000 | 22003814008 | 1 |
| Caelo | Macrogols 4000 | 22003814009 | 6 |
| Caelo | Macrogols 4000 | 22003814011 | 1 |
| Caelo | Macrogols 4000 | 22003814012 | 5 |
| Caelo | Macrogols 4000 | 22003814013 | 2 |
| Caelo | Macrogols 4000 | 22003814014 | 3 |
| Caelo | Macrogols 4000 | 22003823005 | 1 |
| Caelo | Macrogols 4000 | 2200421003 | 1 |
| Caelo | Macrogols 4000 | 22004211001 | 2 |
| Caelo | Macrogols 4000 | 22004211002 | 2 |
| Caelo | Macrogols 4000 | 22004211006 | 1 |
| Caelo | Macrogols 4000 | 22004211008 | 1 |
| Caelo | Macrogols 4000 | 22004213004 | 1 |
| Caelo | Macrogols 4000 | 22004213005 | 1 |
| Caelo | Macrogols 4000 | 220042163003 | 1 |
| Caelo | Macrogols 4000 | 220117 | 1 |
| Caelo | Macrogols 4000 | 220210(21001845001) | 1 |
| Caelo | Macrogols 4000 | 220210(21001852006) | 1 |
| Caelo | Macrogols 4000 | 220315(21003792002) | 2 |
| Caelo | Macrogols 4000 | 220412(21003792002) | 1 |
| Caelo | Macrogols 4000 | 220428(21003792002) | 1 |
| Caelo | Macrogols 4000 | 220516(21003792005) | 1 |
| Caelo | Macrogols 4000 | 220519(21003792005) | 1 |
| Caelo | Macrogols 4000 | 220804(22001587007) | 1 |
| Caelo | Macrogols 4000 | 220905(22001587014) | 1 |
| Caelo | Macrogols 4000 | 220908 | 1 |
| Caelo | Macrogols 4000 | 220919(22001587014) | 1 |
| Caelo | Macrogols 4000 | 220930(22001587014) | 1 |
| Caelo | Macrogols 4000 | 221012(22001587007) | 1 |
| Caelo | Macrogols 4000 | 22A15-B06 | 1 |
| Caelo | Macrogols 4000 | 23001960008 | 1 |
| Caelo | Macrogols 4000 | 23001960009 | 2 |
| Caelo | Macrogols 4000 | 23002714007 | 1 |
| Caelo | Macrogols 4000 | 23061505 | 1 |
| Caelo | Macrogols 4000 | 24000623005 | 1 |
| Caelo | Macrogols 4000 | 280913C | 2 |
| Caelo | Macrogols 4000 | 28111706 | 1 |
| Caelo | Macrogols 4000 | 3(20003397010) | 1 |
| Caelo | Macrogols 4000 | 30041803 | 1 |
| Caelo | Macrogols 4000 | 39393137 | 1 |
| Caelo | Macrogols 4000 | 3940608 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Macrogols 4000 | 4123585 | 1 |
| Caelo | Macrogols 4000 | 5041701 | 1 |
| Caelo | Macrogols 4000 | 5406301 | 1 |
| Caelo | Macrogols 4000 | 9061805 | 1 |
| Caelo | Macrogols 4000 | 90908 | 1 |
| Caelo | Macrogols 4000 | IntCh217002 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21003792003 | 3 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22003814007 | 3 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20001517003 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 18315307 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 19000679007 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 19175606 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22003823005 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 18315307 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 19142401 | 1 |
| Caesar & Loretz GmbH/ AHD | Macrogols 4000 | 19009302 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 19000679007 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003882002 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21001845001 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21001852005 | 1 |
| Caesar & Loretz GmbH/AHD | Macrogols 4000 | 19009302 | 1 |
| Caesar & Loretz GmbH/AHD | Macrogols 4000 | 20003397002 | 1 |
| Caesar & Loretz GmbH/AHD | Macrogols 4000 | 20003397007 | 2 |
| Caesar & Loretz GmbH/AHD | Macrogols 4000 | 20003397009 | 1 |
| Caesar & Loretz GmbH/AHD | Macrogols 4000 | 22004211006 | 1 |
| Caesar & Loretz GmbH/Alli | Macrogols 4000 | 22004213004 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 19227703 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003397010 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22001587014 | 1 |
| Caesar & Loretz GmbH/E | Macrogols 4000 | 19000679007 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20001517003 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003397002 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003397007 | 4 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 18244802 | 1 |
| Caesar & Loretz GmbH/GEHE | Macrogols 4000 | 19000679004 | 1 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 19000679005 | 3 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 19142401 | 1 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 20001303003 | 1 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 20001517003 | 3 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 20003397003 | 1 |
| Caesar & Loretz GmbH/gehe | Macrogols 4000 | 20003882001 | 1 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 20003882005 | 2 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 21001845001 | 1 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 21001846001 | 3 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 21003792002 | 6 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 21003792005 | 5 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 21003795003 | 1 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 22001587004 | 1 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 22001587007 | 4 |
| Caesar & Loretz GmbH/Gehe | Macrogols 4000 | 22003814014 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003882005 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 19000679004 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20002443008 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21001845001 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21003792002 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22001587007 | 3 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22003814011 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22004211006 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22004213004 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 23001960008 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Macrogols 4000 | 18315307 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003397012 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21001846001 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21001850005 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21001852005 | 1 |
| Caesar & Loretz GmbH/PH | Macrogols 4000 | 19000679007 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20002443008 | 2 |
| Caesar & Loretz GmbH/Phoe | Macrogols 4000 | 20003397011 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 19090804 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003882005 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22001587007 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21001852006 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 21003792005 | 2 |
| Caesar & Loretz GmbH/Sana | Macrogols 4000 | 20002443010 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 18106105 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003397002 | 1 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 20003397012 | 2 |
| Caesar & Loretz GmbH... | Macrogols 4000 | 22003814011 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 14180520 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 17337911 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18106105 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18244802 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18244803 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18244806 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18315301 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18315302 | 5 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18315303 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 18315307 | 6 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19000679004 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19000679006 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19000679007 | 11 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19009302 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19009303 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19009305 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19009308 | 9 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19009313 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19142401 | 8 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19142402 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19142403 | 4 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19142407 | 4 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19175605 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19175606 | 9 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19175607 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 192277002 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19227701 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19227702 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 19227703 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20001517003 | 8 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20001517006 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20001517009 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20002443004 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20002443005 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20002443007 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20002443008 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20002443010 | 6 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20002494004 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397002 | 9 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397003 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397004 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397007 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397010 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397012 | 5 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397013 | 7 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003397014 | 8 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003827006 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003882001 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 20003882002 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001845002 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001846001 | 5 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001850003 | 8 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001850005 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001850007 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001852005 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001852006 | 4 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001852007 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21001852008 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21003792002 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21003792004 | 5 |
| Caesar & Loretz GmbH | Macrogols 4000 | 21003792005 | 5 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22001587004 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22001587005 | 4 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22001587006 | 4 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22001587007 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22001587010 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22003814007 | 1 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22003814008 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22003814009 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22003814011 | 3 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22003814013 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | 22003823005 | 2 |
| Caesar & Loretz GmbH | Macrogols 4000 | F16-3740901 | 1 |
| Caesar & Loretz Hild... | Macrogols 4000 | 19000679007 | 1 |
| Caesar&Loretz GmbH/ ... | Macrogols 4000 | 17068603 | 1 |
| Caesar&Loretz GmbH/Anzag | Macrogols 4000 | 14196017 | 1 |
| Calo, Hilden/ Phönix | Macrogols 4000 | 19142401 | 1 |
| calo | Macrogols 4000 | 17303902 | 1 |
| Cealo / Anzag | Macrogols 4000 | 211020(21001846001) | 1 |
| Cealo / Anzag | Macrogols 4000 | 211115(21001846001) | 1 |
| Cealo / Anzag | Macrogols 4000 | 211217(21001850005) | 1 |
| Cealo / Anzag | Macrogols 4000 | 230209(22003814007) | 1 |
| Cealo/Anzag | Macrogols 4000 | 21001850005 | 1 |
| Cealo/Gehe | Macrogols 4000 | 16023907 | 1 |
| Cealo/Jenne | Macrogols 4000 | 220125(21001852006) | 1 |
| Cealo/Jenne | Macrogols 4000 | 221018(22001587007) | 1 |
| DIV GH | Macrogols 4000 | 13/12 | 1 |
| EuRho | Macrogols 4000 | 1206009-01 | 1 |
| Euro OTC | Macrogols 4000 | 1005011-01 | 1 |
| Euro OTC | Macrogols 4000 | 1202040-02 | 2 |
| Euro OTC | Macrogols 4000 | 130502002 | 1 |
| Euro OTC | Macrogols 4000 | 1305020-02 | 4 |
| Euro OTC | Macrogols 4000 | 140701001 | 1 |
| Euro OTC | Macrogols 4000 | 1507004-01 | 1 |
| Euro OTC | Macrogols 4000 | 1508031-01 | 1 |
| Euro OTC | Macrogols 4000 | 1508031-02 | 1 |
| Euro OTC | Macrogols 4000 | 15159515 | 1 |
| Euro OTC | Macrogols 4000 | 1705019-01 | 1 |
| Euro OTC | Macrogols 4000 | 1707026-01 | 1 |
| Euro OTC | Macrogols 4000 | 1711016-01 | 1 |
| Euro OTC | Macrogols 4000 | 17303905 | 1 |
| Euro OTC | Macrogols 4000 | 1808003-01 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Macrogols 4000 | 1808003-02 | 5 |
| Euro OTC | Macrogols 4000 | 180803-02 | 1 |
| Euro OTC | Macrogols 4000 | 1810003-01 | 2 |
| Euro OTC | Macrogols 4000 | 18315307 | 1 |
| Euro OTC | Macrogols 4000 | 1902009-01 | 4 |
| Euro OTC | Macrogols 4000 | 1911027-01 | 12 |
| Euro OTC | Macrogols 4000 | 2007005-01 | 5 |
| Euro OTC | Macrogols 4000 | 2009016-01 | 4 |
| Euro OTC | Macrogols 4000 | 210400901 | 1 |
| Euro OTC | Macrogols 4000 | 2104009-01 | 2 |
| Euro OTC | Macrogols 4000 | 2109002-01 | 2 |
| Euro OTC | Macrogols 4000 | 2109002-03 | 1 |
| Euro OTC | Macrogols 4000 | 22/28 | 1 |
| Euro OTC | Macrogols 4000 | 2207018-01 | 4 |
| Euro OTC | Macrogols 4000 | 2211018-01 | 4 |
| Facron | Macrogols 4000 | 7022014C | 1 |
| Fagron | Macrogols 4000 | 10022015A | 1 |
| Fagron | Macrogols 4000 | 10022015B | 1 |
| Fagron | Macrogols 4000 | 1112M-02103 | 1 |
| Fagron | Macrogols 4000 | 123Test | 1 |
| Fagron | Macrogols 4000 | 12F13-N01 | 2 |
| Fagron | Macrogols 4000 | 12F29-N01 | 2 |
| Fagron | Macrogols 4000 | 12F29-NO1 | 1 |
| Fagron | Macrogols 4000 | 12I20-n03 | 1 |
| Fagron | Macrogols 4000 | 12L10-N06 | 2 |
| Fagron | Macrogols 4000 | 13356608 | 1 |
| Fagron | Macrogols 4000 | 13A10-N01 | 1 |
| Fagron | Macrogols 4000 | 13B20N01 | 1 |
| Fagron | Macrogols 4000 | 13B20-N01 | 2 |
| Fagron | Macrogols 4000 | 13E22-N03 | 6 |
| Fagron | Macrogols 4000 | 13F12N09 | 1 |
| Fagron | Macrogols 4000 | 13F12-N09 | 1 |
| Fagron | Macrogols 4000 | 13G19-N08 | 2 |
| Fagron | Macrogols 4000 | 13G19-N14 | 1 |
| Fagron | Macrogols 4000 | 13I17-N03 | 1 |
| Fagron | Macrogols 4000 | 13I30-N03 | 1 |
| Fagron | Macrogols 4000 | 13L30-B31 | 1 |
| Fagron | Macrogols 4000 | 13l30-N03 | 1 |
| Fagron | Macrogols 4000 | 14A03B01 | 1 |
| Fagron | Macrogols 4000 | 14A03-B01-289602 | 3 |
| Fagron | Macrogols 4000 | 14A03-B01-289605 | 1 |
| Fagron | Macrogols 4000 | 14D14-B06 | 1 |
| Fagron | Macrogols 4000 | 14D14-B06-293453 | 2 |
| Fagron | Macrogols 4000 | 14G15-B07-295632 | 1 |
| Fagron | Macrogols 4000 | 14G21-B04-296899 | 1 |
| Fagron | Macrogols 4000 | 14J03-B07300840 | 1 |
| Fagron | Macrogols 4000 | 14J03-B07-300840 | 1 |
| Fagron | Macrogols 4000 | 14K03-_b07-300522 | 1 |
| Fagron | Macrogols 4000 | 14K03-B07-300522 | 2 |
| Fagron | Macrogols 4000 | 14L12-B06 | 1 |
| Fagron | Macrogols 4000 | 15/29-B01-318038 | 2 |
| Fagron | Macrogols 4000 | 15092014A | 1 |
| Fagron | Macrogols 4000 | 15376510 | 1 |
| Fagron | Macrogols 4000 | 15A08-B03-302761 | 1 |
| Fagron | Macrogols 4000 | 15A08B03302762 | 1 |
| Fagron | Macrogols 4000 | 15A08-B03-302762 | 3 |
| Fagron | Macrogols 4000 | 15b03-b08-304701 | 1 |
| Fagron | Macrogols 4000 | 15B13-B04-305461 | 3 |
| Fagron | Macrogols 4000 | 15G15-B07 | 1 |
| Fagron | Macrogols 4000 | 15G15-B07-313592 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Macrogols 4000 | 15H10-B04-314037 | 2 |
| Fagron | Macrogols 4000 | 15H10-B04-31407 | 1 |
| Fagron | Macrogols 4000 | 15I29-B01-318038 | 1 |
| Fagron | Macrogols 4000 | 160514a | 1 |
| Fagron | Macrogols 4000 | 16102013A | 1 |
| Fagron | Macrogols 4000 | 16152002 | 1 |
| Fagron | Macrogols 4000 | 16A20-B15-320060 | 1 |
| Fagron | Macrogols 4000 | 16a20-b15-320652 | 8 |
| Fagron | Macrogols 4000 | 16A20-B15-320652 | 6 |
| Fagron | Macrogols 4000 | 16F10-B04-324270 | 1 |
| Fagron | Macrogols 4000 | 16K25-B02-330527 | 2 |
| Fagron | Macrogols 4000 | 17012014A | 1 |
| Fagron | Macrogols 4000 | 17E02-B03-335507 | 1 |
| Fagron | Macrogols 4000 | 17E02-B03-335526 | 3 |
| Fagron | Macrogols 4000 | 17H11-B05-39499 | 1 |
| Fagron | Macrogols 4000 | 17I11-B01-341774 | 2 |
| Fagron | Macrogols 4000 | 17K06-B05-345076 | 3 |
| Fagron | Macrogols 4000 | 17K06-B05345096 | 1 |
| Fagron | Macrogols 4000 | 17K06-B05-345096 | 2 |
| Fagron | Macrogols 4000 | 1803029-01 | 2 |
| Fagron | Macrogols 4000 | 18082014C | 1 |
| Fagron | Macrogols 4000 | 18D10-B04-349676 | 1 |
| Fagron | Macrogols 4000 | 18G30-B01 | 2 |
| Fagron | Macrogols 4000 | 18G30-B01-345096 | 1 |
| Fagron | Macrogols 4000 | 18K01-B01 | 1 |
| Fagron | Macrogols 4000 | 18K01-B01-355299 | 1 |
| Fagron | Macrogols 4000 | 19142403 | 1 |
| Fagron | Macrogols 4000 | 19B06-B04 | 1 |
| Fagron | Macrogols 4000 | 19B06-B04-359646 | 2 |
| Fagron | Macrogols 4000 | 19B06-B04-359656 | 1 |
| Fagron | Macrogols 4000 | 19G17-B03-363522 | 1 |
| Fagron | Macrogols 4000 | 19H08-B03-364385 | 2 |
| Fagron | Macrogols 4000 | 19H28-F07 | 1 |
| Fagron | Macrogols 4000 | 19H28-F07-3643908 | 1 |
| Fagron | Macrogols 4000 | 19H28-F07-364398 | 2 |
| Fagron | Macrogols 4000 | 19H28-fo7-364388 | 1 |
| Fagron | Macrogols 4000 | 19J28-F03 | 3 |
| Fagron | Macrogols 4000 | 19J28-F03-366720 | 2 |
| Fagron | Macrogols 4000 | 20/46 | 1 |
| Fagron | Macrogols 4000 | 20002443007 | 1 |
| Fagron | Macrogols 4000 | 20092014A | 1 |
| Fagron | Macrogols 4000 | 20122013C | 1 |
| Fagron | Macrogols 4000 | 2022015A | 1 |
| Fagron | Macrogols 4000 | 20803-F03-369765 | 1 |
| Fagron | Macrogols 4000 | 20B03-F03 | 4 |
| Fagron | Macrogols 4000 | 20B03-F03-369410 | 7 |
| Fagron | Macrogols 4000 | 20B03-F03-369411 | 3 |
| Fagron | Macrogols 4000 | 20B03-F03-369424 | 1 |
| Fagron | Macrogols 4000 | 20B03-F03-369426 | 4 |
| Fagron | Macrogols 4000 | 20B03-F03-369765 | 2 |
| Fagron | Macrogols 4000 | 20E19-F01 | 1 |
| Fagron | Macrogols 4000 | 20E19-F01-3718706 | 1 |
| Fagron | Macrogols 4000 | 20E19-F01-371876 | 1 |
| Fagron | Macrogols 4000 | 20E19-F01-371877 | 1 |
| Fagron | Macrogols 4000 | 20-E19-F01-371877 | 1 |
| Fagron | Macrogols 4000 | 20E19-F01-371878 | 1 |
| Fagron | Macrogols 4000 | 20H21-F16 | 3 |
| Fagron | Macrogols 4000 | 20H21-F16-374092 | 2 |
| Fagron | Macrogols 4000 | 20H21-F16-374094 | 2 |
| Fagron | Macrogols 4000 | 20K16-F05 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Macrogols 4000 | 20K16-F05-376031 | 3 |
| Fagron | Macrogols 4000 | 20K16-F05-376034 | 1 |
| Fagron | Macrogols 4000 | 21/37 | 2 |
| Fagron | Macrogols 4000 | 21/42 | 1 |
| Fagron | Macrogols 4000 | 21052015A | 1 |
| Fagron | Macrogols 4000 | 2122013a | 1 |
| Fagron | Macrogols 4000 | 2122013b | 1 |
| Fagron | Macrogols 4000 | 21B12-F03-377352 | 1 |
| Fagron | Macrogols 4000 | 21B23-F01 | 2 |
| Fagron | Macrogols 4000 | 21B23-F01-377361 | 2 |
| Fagron | Macrogols 4000 | 21E8-B05-216626 | 1 |
| Fagron | Macrogols 4000 | 21K08-B09-213154 | 1 |
| Fagron | Macrogols 4000 | 22062015A | 1 |
| Fagron | Macrogols 4000 | 221117 | 1 |
| Fagron | Macrogols 4000 | 221121(22A25-B03-224251) | 1 |
| Fagron | Macrogols 4000 | 221122(22G05-B01-224252) | 1 |
| Fagron | Macrogols 4000 | 221201(22G05-B01-223076) | 1 |
| Fagron | Macrogols 4000 | 22122014A | 1 |
| Fagron | Macrogols 4000 | 2215I-02103 | 1 |
| Fagron | Macrogols 4000 | 22A15_B06_216742 | 1 |
| Fagron | Macrogols 4000 | 22A15-B06 | 1 |
| Fagron | Macrogols 4000 | 22A15-B06-216677 | 2 |
| Fagron | Macrogols 4000 | 22A15-B06-216742 | 2 |
| Fagron | Macrogols 4000 | 22A15-B06-220791 | 5 |
| Fagron | Macrogols 4000 | 22A25-B03-221082 | 3 |
| Fagron | Macrogols 4000 | 22A25B03-221660 | 1 |
| Fagron | Macrogols 4000 | 22A25-B03-221660 | 2 |
| Fagron | Macrogols 4000 | 22A25-B03-224251 | 4 |
| Fagron | Macrogols 4000 | 22G05-B01-221487 | 6 |
| Fagron | Macrogols 4000 | 22G05-B01-223076 | 2 |
| Fagron | Macrogols 4000 | 22G05-B01-224252 | 8 |
| Fagron | Macrogols 4000 | 22L07-B02-225861 | 2 |
| Fagron | Macrogols 4000 | 230810(23C16-B18-229949) | 1 |
| Fagron | Macrogols 4000 | 23C16-B18-229947 | 1 |
| Fagron | Macrogols 4000 | 23D21-B08-235661 | 1 |
| Fagron | Macrogols 4000 | 25082014A | 1 |
| Fagron | Macrogols 4000 | 25322-68-3 | 1 |
| Fagron | Macrogols 4000 | 26052014A | 1 |
| Fagron | Macrogols 4000 | 26082013A | 1 |
| Fagron | Macrogols 4000 | 28052014B | 1 |
| Fagron | Macrogols 4000 | 2818A-02103 | 1 |
| Fagron | Macrogols 4000 | 290714c | 1 |
| Fagron | Macrogols 4000 | 2OBO3-FO3 | 2 |
| Fagron | Macrogols 4000 | 30092014B | 1 |
| Fagron | Macrogols 4000 | 3032014B | 1 |
| Fagron | Macrogols 4000 | 30B03 | 1 |
| Fagron | Macrogols 4000 | 3114I-02103 | 1 |
| Fagron | Macrogols 4000 | 3217M-02103 | 1 |
| Fagron | Macrogols 4000 | 505201C | 1 |
| Fagron | Macrogols 4000 | 701014 | 1 |
| Fagron | Macrogols 4000 | 701014-0006 | 3 |
| Fagron | Macrogols 4000 | 701014-0014 | 1 |
| Fagron | Macrogols 4000 | 8012015A | 1 |
| Fagron | Macrogols 4000 | 8062015B | 1 |
| Fagron | Macrogols 4000 | 8062015C | 1 |
| Fagron | Macrogols 4000 | 914I-02103 | 1 |
| Fagron | Macrogols 4000 | F03-3667200 | 1 |
| Fagron | Macrogols 4000 | F07-3643808 | 1 |
| Fagron | Macrogols 4000 | F16-3740901 | 1 |
| Fiebig | Macrogols 4000 | 13356601 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fiebig | Macrogols 4000 | 14180506 | 1 |
| Fiebig | Macrogols 4000 | 15159514 | 1 |
| Fiebig | Macrogols 4000 | 16152001 | 1 |
| Fiebig | Macrogols 4000 | 16308907 | 1 |
| Fiebig | Macrogols 4000 | 16K25-B02-330527 | 3 |
| Fiebig | Macrogols 4000 | 17035607 | 1 |
| Finteler Apotheke | Macrogols 4000 | 17035607 | 1 |
| Gatt-Koller | Macrogols 4000 | 1420/04152915 | 1 |
| Gatt-Koller | Macrogols 4000 | 1420/04153415 | 1 |
| Gatt-Koller | Macrogols 4000 | 1802391 | 1 |
| Gatt-Koller | Macrogols 4000 | 1804126 | 1 |
| Gatt-Koller | Macrogols 4000 | 2792/07153315 | 1 |
| Gatt-Koller | Macrogols 4000 | 4643/01170417 | 2 |
| Gehe / EuRho | Macrogols 4000 | 1803029-01 | 1 |
| GEHE 06.05.2014 | Macrogols 4000 | 13356608 | 2 |
| Gehe | Macrogols 4000 | 14K03-B07-300522 | 1 |
| Gehe | Macrogols 4000 | 15159514 | 3 |
| Gehe | Macrogols 4000 | 16267307 | 1 |
| Gehe | Macrogols 4000 | 16308907 | 1 |
| Gehe | Macrogols 4000 | 17208104 | 1 |
| GEHE | Macrogols 4000 | 18106109 | 1 |
| Gehe | Macrogols 4000 | 19009303 | 1 |
| Gehe | Macrogols 4000 | 19142401 | 1 |
| Gehe | Macrogols 4000 | 19175607 | 1 |
| Gehe | Macrogols 4000 | 21001852005 | 1 |
| Gehe | Macrogols 4000 | 21003795003 | 1 |
| Gehe | Macrogols 4000 | 22003823005 | 1 |
| gehe | Macrogols 4000 | 22004213005 | 1 |
| Gepepharm/ Gehe | Macrogols 4000 | 1508031-02 | 1 |
| Gutenberg-Apotheke | Macrogols 4000 | 13356609 | 1 |
| Hedinger | Macrogols 4000 | 13G19-N08 | 1 |
| Henry Lamotte Oils GMBH | Macrogols 4000 | 16267308/170127M | 1 |
| Henry Lamotte/AHD | Macrogols 4000 | 17303901 | 1 |
| Henry Lamotte | Macrogols 4000 | 1213test | 1 |
| Jenne | Macrogols 4000 | 22004213005 | 1 |
| Jenne | Macrogols 4000 | 240104(23001960006) | 1 |
| Jenne | Macrogols 4000 | 240123 | 1 |
| Jenne | Macrogols 4000 | 240123(23002714004) | 1 |
| Jenne | Macrogols 4000 | 240206 | 1 |
| Jenne | Macrogols 4000 | 240222(23002714005) | 1 |
| Jenne | Macrogols 4000 | 240408(23002714005) | 1 |
| Jenne | Macrogols 4000 | 240515(24000623005) | 1 |
| Jenne | Macrogols 4000 | 240703(24000623005) | 1 |
| Kehr | Macrogols 4000 | 16308907 | 1 |
| Kehr | Macrogols 4000 | 18106105 | 1 |
| Kehr | Macrogols 4000 | 22003823005 | 1 |
| KÖGL | Macrogols 4000 | 1900232 | 1 |
| Macgol 4000 | Macrogols 4000 | 16267308 | 2 |
| Macgol 4000 | Macrogols 4000 | 16F10-B04 | 1 |
| Nachprüfung | Macrogols 4000 | 14A03-B01-289605 | 1 |
| Nachtestung-Verlängerung | Macrogols 4000 | 17/17 | 1 |
| Noveda | Macrogols 4000 | 18315307 | 1 |
| Noveda | Macrogols 4000 | 20002443004 | 6 |
| Noweda | Macrogols 4000 | 12361502 | 2 |
| Noweda | Macrogols 4000 | 12361512 | 1 |
| Noweda | Macrogols 4000 | 13136003 | 1 |
| Noweda | Macrogols 4000 | 17303902 | 1 |
| Noweda | Macrogols 4000 | 17E02-B03-335526 | 1 |
| Noweda | Macrogols 4000 | 18106109 | 2 |
| Noweda | Macrogols 4000 | 18315303 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Macrogols 4000 | 19H08-B03-364385 | 1 |
| Noweda | Macrogols 4000 | 20001517003 | 1 |
| Noweda | Macrogols 4000 | 20003397004 | 3 |
| Noweda | Macrogols 4000 | 20003397010 | 1 |
| Noweda | Macrogols 4000 | 20003397013 | 1 |
| Noweda | Macrogols 4000 | 21001850003 | 1 |
| Noweda | Macrogols 4000 | 22/88 | 2 |
| Noweda | Macrogols 4000 | 22001587007 | 3 |
| Noweda | Macrogols 4000 | 22003814013 | 2 |
| Noweda | Macrogols 4000 | 2200421001 | 1 |
| Noweda | Macrogols 4000 | 22004211002 | 2 |
| Noweda | Macrogols 4000 | 22004212003 | 3 |
| Noweda | Macrogols 4000 | 22004213004 | 2 |
| Noweda | Macrogols 4000 | 22A15B06216742 | 1 |
| Noweda | Macrogols 4000 | 23001960009 | 1 |
| Noweda | Macrogols 4000 | 2300196007 | 1 |
| Noweda | Macrogols 4000 | 23C08-B02-227792 | 1 |
| Noweda | Macrogols 4000 | 23C16-B18-229946 | 1 |
| Noweda | Macrogols 4000 | 23C16-B18-229947 | 1 |
| Noweda | Macrogols 4000 | 23D21-B06-234868 | 1 |
| Noweda | Macrogols 4000 | 240006223002 | 1 |
| noweda | Macrogols 4000 | 24002115002 | 1 |
| Phoenix | Macrogols 4000 | 12258901 | 1 |
| Phoenix | Macrogols 4000 | 16023905 | 1 |
| Phoenix | Macrogols 4000 | 18315307 | 2 |
| Phoenix | Macrogols 4000 | 19175606 | 1 |
| Phoenix | Macrogols 4000 | 20003397002 | 1 |
| Phoenix | Macrogols 4000 | 24002818004 | 1 |
| Phönix Pharmahandel | Macrogols 4000 | 22004211006 | 1 |
| Phönix | Macrogols 4000 | 1202040-02 | 1 |
| phönix | Macrogols 4000 | 1502031-02 | 1 |
| phönix | Macrogols 4000 | 1535007 | 1 |
| phönix | Macrogols 4000 | 15406302 | 1 |
| phönix | Macrogols 4000 | 16023904 | 1 |
| phönix | Macrogols 4000 | 1605012-01 | 1 |
| phönix | Macrogols 4000 | 1701007-01 | 3 |
| Phönix | Macrogols 4000 | 1707026-01 | 1 |
| PHÖNIX | Macrogols 4000 | 19000679007 | 1 |
| Phönix | Macrogols 4000 | 19142401 | 1 |
| Phönix | Macrogols 4000 | 20002443004 | 1 |
| Phönix | Macrogols 4000 | 20002443009 | 1 |
| PHÖNIX | Macrogols 4000 | 20003397002 | 1 |
| Phönix | Macrogols 4000 | 20003827011 | 1 |
| Phönix | Macrogols 4000 | 23002714005 | 1 |
| Phönix | Macrogols 4000 | 24001280007 | 1 |
| Rondell Apotheke | Macrogols 4000 | 16023905 | 1 |
| Sanacorp | Macrogols 4000 | 14061707 | 1 |
| Sanacorp | Macrogols 4000 | 15376520 | 1 |
| Sanacorp | Macrogols 4000 | 17208104 | 1 |
| Sanacorp | Macrogols 4000 | 17303901 | 1 |
| Sanacorp | Macrogols 4000 | 18244802 | 1 |
| Sanacorp | Macrogols 4000 | 19000679007 | 1 |
| Sanacorp | Macrogols 4000 | 19142401 | 1 |
| Sanacorp | Macrogols 4000 | 20002443004 | 1 |
| Sanacorp | Macrogols 4000 | 20003397011 | 1 |
| Sanacorp | Macrogols 4000 | 20003397014 | 1 |
| Sanacorp | Macrogols 4000 | 21003792004 | 1 |
| Sanacorp | Macrogols 4000 | 22003814013 | 1 |
| Sanacorp | Macrogols 4000 | 22003823005 | 1 |
| Sanacorp | Macrogols 4000 | 22004213005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Macrogols 4000 | 2204213005 | 1 |
| Sanacorp | Macrogols 4000 | 2207019-03 | 1 |
| Sanacorp | Macrogols 4000 | 24000623005 | 1 |
| Sanacorp | Macrogols 4000 | 2707018-01 | 2 |
| Sanacorp | Macrogols 4000 | F03-3694101 | 1 |
| VDL | Macrogols 4000 | 16308906 | 1 |
| Wolf Apotheke | Macrogols 4000 | 230116 | 1 |

- 254 322 spectra from 1666 *Apo-Ident* customers from a total of 51 462 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Macrogols 4000* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Macrogols 4000* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 690 | 0 | 157 636 |
| **Type B** | 0 | 1570 | 0 | 211 190 |
| **Type C** | 0 | 2559 | 5 | 254 319 |

The substance/substance group *Macrogols 4000* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1304 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6178 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | 99.8050 % (> 99.6880 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20690 | 20690 | 0.00 | 62.83 |
| 20975 | 20975 | 0.00 | 81.56 |
| 21065 | 21886 | 13.61 | 66.59 |
| 21357 | 21886 | 7.34 | 60.37 |
| 21841 | 21841 | 0.00 | 69.87 |
| 21886 | 21886 | 0.00 | 58.20 |
| 21903 | 21903 | 0.00 | 75.35 |
| 22567 | 22567 | 0.00 | 58.98 |
| 22570 | 22570 | 0.00 | 72.68 |
| 23021 | 21886 | 6.87 | 63.59 |
| 23174 | 23174 | 0.00 | 74.57 |
| 23902 | 23902 | 0.00 | 78.38 |
| 25414 | 25414 | 0.00 | 76.99 |
| 25713 | 25713 | 0.00 | 77.98 |
| 26262 | 26262 | 0.00 | 76.40 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Mafenide acetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24055-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Mafenide acetate; Mafenidum aceticum

### Special notes

When selecting the *Mafenide acetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Mafenide acetate | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Mafenide acetate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Mafenide acetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Clioquinol | 73.89 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Mafenide acetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Mafenide acetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Mafenide acetate | 20K06-B04-211072 | 26070 | 40 | 20201229 |
| Fagron | Mafenide acetate | 22B02-B03-222844 | 27172 | 40 | 250301806 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 80 spectra of 2 reference samples from the substance/substance group *Mafenide acetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

- 158 246 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 70 spectra of 3 reference samples from the substance/substance group *Mafenide acetate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Mafenide acetate | 15J20-B05-342526 | 24574 | 40 |
| Fagron | Mafenide acetate | 20K06-B04-211072 | 26070SI† | 10 |
| Fagron | Mafenide acetate | 22B02-B03-222844 | 27172SI† | 20 |

- 212 870 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Mafenide acetate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Mafenide acetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Mafenide acetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 80 | 0 | 158 246 |
| **Type B** | 0 | 70 | 0 | 212 870 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Mafenide acetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 92.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 91.4286 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26070 | 27172 | 18.46 | 104.84 |
| 27172 | 27172 | 0.00 | 94.71 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Magnesium chloride hexahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006390-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Magnesium chloride hexahydrate; Magnesii chloridum hexahydricum

### Special notes

When selecting the *Magnesium chloride hexahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Magnesium chloride hexahydrate | 4 | 2 | 71 |

### Second-stage model

For differentiation of the substance/substance group *Magnesium chloride hexahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Magnesium chloride hexahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 53.25 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Magnesium chloride hexahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Magnesium chloride hexahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Magnesium chloride hexahydrate | 1802023-01 | 24275 | 40 | 20180223 |
| Euro OTC | Magnesium chloride hexahydrate | 2107014 | 25790 | 50 | 20210812* |
| Euro OTC | Magnesium chloride hexahydrate | 2307025 | 27085 | 40 | 20230810* |
| Euro OTC | Magnesium chloride hexahydrate | 2307025 | 27085SI | 20 | 20230810* |
| Fagron | Magnesium chloride hexahydrate | 24G25-B01-006012 | 27564 | 40 | 20240927 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 190 spectra of 5 reference samples from the substance/substance group *Magnesium chloride hexahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 136 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 4 reference samples from the substance/substance group *Magnesium chloride hexahydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Magnesium chloride hexahydrate | 25000161 | 27539 | 40 |
| Fagron | Magnesium chloride hexahydrate | 24A22-B03-235953 | 27267 | 40 |
| Caelo | Magnesium chloride hexahydrate | 25000161 | 27539SI | 20 |
| Fagron | Magnesium chloride hexahydrate | 24A22-B03-235953 | 27267SI | 20 |

- 212 820 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 145 spectra from 54 *Apo-Ident* customers from 76 batches from the substance/substance group *Magnesium chloride hexahydrate*.

- Among them are spectra of independent samples from 70 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Magnesium chloride hexahydrate | 23000986006 | 2 |
| | Magnesium chloride hexahydrate | 24000149004 | 2 |
| | Magnesium chloride hexahydrate | 25000161002 | 1 |
| Anzag | Magnesium chloride hexahydrate | 120802501 | 1 |
| Anzag | Magnesium chloride hexahydrate | 1304003-01 | 1 |
| Caelo | Magnesium chloride hexahydrate | | 1 |
| Caelo | Magnesium chloride hexahydrate | 1108024-01 | 1 |
| Caelo | Magnesium chloride hexahydrate | 11345606 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Magnesium chloride hexahydrate | 11345609 | 1 |
| Caelo | Magnesium chloride hexahydrate | 11345623 | 2 |
| Caelo | Magnesium chloride hexahydrate | 11345624 | 1 |
| Caelo | Magnesium chloride hexahydrate | 12141803 | 1 |
| Caelo | Magnesium chloride hexahydrate | 12141806 | 2 |
| Caelo | Magnesium chloride hexahydrate | 12141807 | 3 |
| Caelo | Magnesium chloride hexahydrate | 12141808 | 1 |
| Caelo | Magnesium chloride hexahydrate | 12141811 | 2 |
| Caelo | Magnesium chloride hexahydrate | 12141814 | 1 |
| Caelo | Magnesium chloride hexahydrate | 12141817 | 2 |
| Caelo | Magnesium chloride hexahydrate | 12354604 | 4 |
| Caelo | Magnesium chloride hexahydrate | 12354605 | 4 |
| Caelo | Magnesium chloride hexahydrate | 12354606 | 4 |
| Caelo | Magnesium chloride hexahydrate | 12354608 | 1 |
| Caelo | Magnesium chloride hexahydrate | 12354609 | 7 |
| Caelo | Magnesium chloride hexahydrate | 12354610 | 2 |
| Caelo | Magnesium chloride hexahydrate | 12354612 | 7 |
| Caelo | Magnesium chloride hexahydrate | 12354613 | 4 |
| Caelo | Magnesium chloride hexahydrate | 12354615 | 8 |
| Caelo | Magnesium chloride hexahydrate | 12354618 | 2 |
| Caelo | Magnesium chloride hexahydrate | 1301C009-277802 | 2 |
| Caelo | Magnesium chloride hexahydrate | 1304C004 | 1 |
| Caelo | Magnesium chloride hexahydrate | 13194701 | 1 |
| Caelo | Magnesium chloride hexahydrate | 13194702 | 3 |
| Caelo | Magnesium chloride hexahydrate | 13194706 | 3 |
| Caelo | Magnesium chloride hexahydrate | 13194707 | 4 |
| Caelo | Magnesium chloride hexahydrate | 13194713 | 1 |
| Caelo | Magnesium chloride hexahydrate | 13194713-3490312103 | 1 |
| Caelo | Magnesium chloride hexahydrate | 13194721 | 2 |
| Caelo | Magnesium chloride hexahydrate | 1512I-01828 | 1 |
| Caelo | Magnesium chloride hexahydrate | 16094004 | 1 |
| Caelo | Magnesium chloride hexahydrate | 16094014 | 1 |
| Caelo | Magnesium chloride hexahydrate | 17034304 | 1 |
| Caelo | Magnesium chloride hexahydrate | 5210I-01828 | 1 |
| Caesar & Loretz GmbH | Magnesium chloride hexahydrate | 13064223 | 1 |
| Cealo | Magnesium chloride hexahydrate | 112354615 | 1 |
| Cealo | Magnesium chloride hexahydrate | 11354615 | 1 |
| Eu Rho | Magnesium chloride hexahydrate | 1112013-01 | 2 |
| Euro OTC | Magnesium chloride hexahydrate | 1204017-01 | 1 |
| Euro OTC | Magnesium chloride hexahydrate | 1208025-01 | 1 |
| Euro OTC | Magnesium chloride hexahydrate | 1212013-01 | 3 |
| Euro OTC | Magnesium chloride hexahydrate | 1304003-01 | 1 |
| Fagron | Magnesium chloride hexahydrate | 11K17-N10 | 1 |
| Fagron | Magnesium chloride hexahydrate | 12B16-N01 | 1 |
| Fagron | Magnesium chloride hexahydrate | 12D11-N01 | 1 |
| Fagron | Magnesium chloride hexahydrate | 12h21-N02 | 1 |
| Fagron | Magnesium chloride hexahydrate | 12H21-N02 | 9 |
| Fagron | Magnesium chloride hexahydrate | 12H21-No2 | 1 |
| Fagron | Magnesium chloride hexahydrate | 12H21-NO2 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1301c009-277802 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1301C009-277802 | 2 |
| Fagron | Magnesium chloride hexahydrate | 1301C011-277803 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1301C012-277804 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1301C10 | 3 |
| Fagron | Magnesium chloride hexahydrate | 1301C10-277801 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1304C001-281211 | 2 |
| Fagron | Magnesium chloride hexahydrate | 1304C002 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1304C003 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1304C003-281209 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1304C004 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Magnesium chloride hexahydrate | 1304c004-281210 | 1 |
| Fagron | Magnesium chloride hexahydrate | 1304C004-281210 | 1 |
| Fagron | Magnesium chloride hexahydrate | 13411207 | 1 |
| Fagron | Magnesium chloride hexahydrate | 13B14-B01-287292 | 1 |
| Fagron | Magnesium chloride hexahydrate | 26061305 | 1 |
| Fagron | Magnesium chloride hexahydrate | M1430 | 1 |
| Fagron | Magnesium chloride hexahydrate | M1555 | 1 |
| Fagron | Magnesium chloride hexahydrate | M1625 | 1 |
| Kehr | Magnesium chloride hexahydrate | 2307025-02 | 1 |
| Phönix/Euro | Magnesium chloride hexahydrate | 1208025-01 | 1 |
| stumpf | Magnesium chloride hexahydrate | 1301c012-277804 | 1 |
| unbekannt | Magnesium chloride hexahydrate | unbekannt | 1 |

- 256 741 spectra from 1666 *Apo-Ident* customers from a total of 52 078 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Magnesium chloride hexahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Magnesium chloride hexahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 190 | 0 | 158 136 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 120 | 25 | 256 741 |

The substance/substance group *Magnesium chloride hexahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.8421 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 82.7586 % (> 80.6897 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24275 | 27085 | 21.22 | 157.57 |
| 25790 | 25790 | 0.00 | 165.20 |
| 27085 | 27085 | 0.00 | 161.09 |
| 27564 | 25790 | 36.99 | 162.94 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Magnesium citrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20616-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Magnesium citrate; Magnesii citras

### Special notes

When selecting the *Magnesium citrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Magnesium citrate | 13 | 6 | 20 |

### Second-stage model

For differentiation of the substance/substance group *Magnesium citrate* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Magnesium citrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 27.00 | – |
| Cannabis flower, THC-dominant type | 37.38 | – |
| Riboflavin sodium phosphate hydrate | 39.39 | 39.30 |
| Polymyxin B sulfate | 40.76 | – |
| Cannabis flower, THC/CBD-intermedia… | 43.50 | – |
| Calcium glycerophosphate | 43.58 | – |
| Carbomers | 66.66 | 63.77 |
| ⋮ | ⋮ | ⋮ |
| Gentamicin sulfate | >50 | 103.98 |
| Zinc gluconate | >50 | 147.57 |
| Sodium tetraborate | >50 | 150.38 |
| Mg-Ca-K colamine phosphate | >50 | 169.80 |
| Tobramycin sulfate | >50 | 202.60 |
| Neomycin sulfate | >50 | 211.39 |
| Finasteride | >50 | 854.01 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Magnesium citrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Magnesium citrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Magnesium citrate | 1501031 | 21794 | 60 | AR-15-FG-007845-01 |
| Euro OTC | Magnesium citrate | 1506020 | 21829 | 60 | 20150623* |
| Euro OTC | Magnesium citrate | 1507019 | 21860 | 60 | 20150722* |
| Euro OTC | Magnesium citrate | 1511018 | 22225 | 60 | 20151130* |
| Euro OTC | Magnesium citrate | 1602028 | 22505 | 40 | 20160314* |
| Euro OTC | Magnesium citrate | 1706007 | 23549 | 40 | 20170720* |
| Euro OTC | Magnesium citrate | 1711018 | 23895 | 40 | 20171129* |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Magnesium citrate | 1803033 | 24088 | 40 | 20180403* |
| Euro OTC | Magnesium citrate | 1808020 | 24202 | 40 | 20180827* |
| Euro OTC | Magnesium citrate | 1902006 | 24480 | 40 | 20190226* |
| Euro OTC | Magnesium citrate | 2003051 | 25170 | 40 | 20200428* |
| Euro OTC | Magnesium citrate | 2012001 | 25465 | 40 | 20201216* |
| Euro OTC | Magnesium citrate | 2105003 | 25708 | 50 | 20210701* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 610 spectra of 13 reference samples from the substance/substance group *Magnesium citrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 13 different batches.

- 157 716 spectra from a total of 2944 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 280 spectra of 8 reference samples from the substance/substance group *Magnesium citrate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Magnesium citrate | 1607006 | 22673 | 40 |
| Euro OTC | Magnesium citrate | 1701018 | 22998 | 40 |
| Euro OTC | Magnesium citrate | 1810026 | 24308 | 40 |
| Euro OTC | Magnesium citrate | 1907040 | 24778 | 40 |
| Euro OTC | Magnesium citrate | 2212004 | 26530 | 40 |
| Euro OTC | Magnesium citrate | 2404010 | 27210 | 40 |
| Euro OTC | Magnesium citrate | 2212004 | 26530SI | 20 |
| Euro OTC | Magnesium citrate | 2404010 | 27210SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 660 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 37 spectra from 28 *Apo-Ident* customers from 20 batches from the substance/substance group *Magnesium citrate*.
- Among them are spectra of independent samples from 20 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Magnesium citrate | 2105003-01 | 1 |
| | Magnesium citrate | 2105003-02 | 1 |
| | Magnesium citrate | 2212004-01 | 2 |
| | Magnesium citrate | 2401010-01 | 1 |
| | Magnesium citrate | 2404010-01 | 1 |
| AHD | Magnesium citrate | 2212004-01 | 1 |
| APOrtha Deutschland GmbH | Magnesium citrate | 17000809/0 | 1 |
| Arktis | Magnesium citrate | 894P/2418 | 1 |
| Caelo | Magnesium citrate | 1701018-01 | 1 |
| Euro OTC | Magnesium citrate | 1602028-01 | 1 |
| Euro OTC | Magnesium citrate | 1706007-01 | 3 |
| Euro OTC | Magnesium citrate | 1711018-01 | 2 |
| Euro OTC | Magnesium citrate | 1808020-01 | 2 |
| Euro OTC | Magnesium citrate | 180820-01 | 1 |
| Euro OTC | Magnesium citrate | 1810026-01 | 2 |
| Euro OTC | Magnesium citrate | 1902006-01 | 3 |
| Euro OTC | Magnesium citrate | 1907040-01 | 4 |
| Euro OTC | Magnesium citrate | 2003051-01 | 3 |
| Euro OTC | Magnesium citrate | 2012001-01 | 1 |
| Euro OTC | Magnesium citrate | 2105003-01 | 1 |
| Euro OTC | Magnesium citrate | 3060884 | 2 |
| Euro OTC | Magnesium citrate | 3086441 | 1 |
| Noweda | Magnesium citrate | 2212004-01 | 1 |

- 256 849 spectra from 1666 *Apo-Ident* customers from a total of 52 133 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Magnesium citrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Magnesium citrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 610 | 0 | 157 716 |
| **Type B** | 0 | 280 | 0 | 212 660 |
| **Type C** | 0 | 37 | 0 | 256 849 |

The substance/substance group *Magnesium citrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0164 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.8571 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 83.7838 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21794 | 21794 | 0.00 | 61.22 |
| 21829 | 21829 | 0.00 | 103.85 |
| 21860 | 21860 | 0.00 | 93.76 |
| 22225 | 22225 | 0.00 | 79.19 |
| 22505 | 22505 | 0.00 | 88.21 |
| 23549 | 23549 | 0.00 | 46.78 |
| 23895 | 23895 | 0.00 | 91.49 |
| 24088 | 24088 | 0.00 | 103.32 |
| 24202 | 24202 | 0.00 | 113.19 |
| 24480 | 24480 | 0.00 | 59.43 |
| 25170 | 25170 | 0.00 | 61.63 |
| 25465 | 25465 | 0.00 | 55.59 |
| 25708 | 25708 | 0.00 | 48.71 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Magnesium hydrogen aspartate tetrahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20812-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Magnesium hydrogen aspartate tetrahydrate; Magnesii aspartas tetrahydricus

### Special notes

When selecting the *Magnesium hydrogen aspartate tetrahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Magnesium hydrogen aspartate tetrahydrate | 7 | 7 | 10 |

### Second-stage model

For differentiation of the substance/substance group *Magnesium hydrogen aspartate tetrahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Magnesium hydrogen aspartate tetrahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 74.16 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Magnesium hydrogen aspartate tetrahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Magnesium hydrogen aspartate tetrahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Magnesium hydrogen aspart… | 1204014-01 | 20812 | 40 | 1404588 |
| Euro OTC | Magnesium hydrogen aspart… | 1306045-01 | 21749 | 60 | 20130708 |
| Euro OTC | Magnesium hydrogen aspart… | 1605031 | 22682 | 40 | 20160617* |
| Euro OTC | Magnesium hydrogen aspart… | 1901036 | 24488 | 40 | 20190227* |
| Euro OTC | Magnesium hydrogen aspart… | 1906029 | 24773 | 40 | 20190712* |
| Euro OTC | Magnesium hydrogen aspart… | 2002039 | 25125 | 40 | 20200331* |
| Euro OTC | Magnesium hydrogen aspart… | 2303004 | 26645 | 40 | 20230315* |
| Euro OTC | Magnesium hydrogen aspart… | 2303004 | 26645SI | 20 | 20230315* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 8 reference samples from the substance/substance group *Magnesium hydrogen aspartate tetrahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 006 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 360 spectra of 10 reference samples from the substance/substance group *Magnesium hydrogen aspartate tetrahydrate*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Magnesium hydrogen aspart… | 1707010 | 23552 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 1806011 | 24156 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 2007041 | 25344 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 2101039 | 25737 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 2207024 | 26273 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 2407011 | 27340 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 2501015 | 27504 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 1707010 | 23608 | 40 |
| Euro OTC | Magnesium hydrogen aspart… | 2207024 | 26273SI | 20 |
| Euro OTC | Magnesium hydrogen aspart… | 2407011 | 27340SI | 20 |

- 212 580 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 18 spectra from 4 *Apo-Ident* customers from 10 batches from the substance/substance group *Magnesium hydrogen aspartate tetrahydrate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Magnesium hydrogen aspart… | 2303004-01 | 1 |
| Euro OTC | Magnesium hydrogen aspart… | 1605031-01 | 1 |
| Euro OTC | Magnesium hydrogen aspart… | 1806011-01 | 1 |
| Euro OTC | Magnesium hydrogen aspart… | 1901036-02 | 1 |
| Euro OTC | Magnesium hydrogen aspart… | 2002039-01 | 3 |
| Euro OTC | Magnesium hydrogen aspart… | 2007041-01 | 3 |
| Euro OTC | Magnesium hydrogen aspart… | 210039-01 | 1 |
| Euro OTC | Magnesium hydrogen aspart… | 2101039-01 | 5 |
| Euro OTC | Magnesium hydrogen aspart… | 3068139 | 1 |
| Euro OTC | Magnesium hydrogen aspart… | 3843631-1 | 1 |

- 256 868 spectra from 1666 *Apo-Ident* customers from a total of 52 143 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Magnesium hydrogen aspartate tetrahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Magnesium hydrogen aspartate tetrahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 360 | 0 | 212 580 |
| **Type C** | 0 | 18 | 0 | 256 868 |

The substance/substance group *Magnesium hydrogen aspartate tetrahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.3333 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20812 | 20812 | 0.00 | 148.18 |
| 21749 | 20812 | 11.78 | 149.83 |
| 22682 | 22682 | 0.00 | 145.91 |
| 24488 | 24488 | 0.00 | 145.81 |
| 24773 | 24773 | 0.00 | 146.73 |
| 25125 | 25125 | 0.00 | 150.28 |
| 26645 | 26645 | 0.00 | 150.38 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Magnesium hydrogen citrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20016-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Magnesium hydrogen citrate; Magnesii hydrogenocitras hydricus; Magnesium hydrogen citrate, hydrated

### Special notes

When selecting the *Magnesium hydrogen citrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Magnesium hydrogen citrate | 11 | 36 | 271 |

### Second-stage model

For differentiation of the substance/substance group *Magnesium hydrogen citrate* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Magnesium hydrogen citrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 48.69 | – |
| Cannabis flower, THC-dominant type | 56.70 | – |
| ⋮ | ⋮ | ⋮ |
| Atropine sulfate | >50 | 76.76 |
| Mometasone furoate | >50 | 126.54 |
| Calcium orotate dihydrate | >50 | 156.75 |
| Quinoline yellow | >50 | 166.79 |
| Saccharin sodium | >50 | 177.91 |
| Hydrocortisone | >50 | 196.65 |
| Propranolol hydrochloride | >50 | 357.41 |
| Potassium sorbate | >50 | 478.91 |
| Phenytoin | >50 | 617.57 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Magnesium hydrogen citrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Magnesium hydrogen citrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Magnesium hydrogen citrate | 13389102 | 21445 | 60 | 20131205 |
| Caelo | Magnesium hydrogen citrate | 15415014 | 23240 | 40 | 20160105 |
| Caelo | Magnesium hydrogen citrate | 22001882 | 26251 | 40 | 2211127 |
| Euro OTC | Magnesium hydrogen citrate | 1507010 | 21873 | 60 | 20150713* |
| Euro OTC | Magnesium hydrogen citrate | 1510033 | 22233 | 60 | 20151117* |
| Euro OTC | Magnesium hydrogen citrate | 1601005 | 22296 | 60 | 20160119* |
| Euro OTC | Magnesium hydrogen citrate | 1701003 | 22992 | 40 | 20170124* |
| Euro OTC | Magnesium hydrogen citrate | 2101004 | 25545 | 40 | 20210114* |
| Euro OTC | Magnesium hydrogen citrate | 2211017 | 26423 | 40 | 20221213* |
| Gatt-Koller | Magnesium hydrogen citrate | 22J01469 | 26400 | 40 | 2301186 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Gatt-Koller | Magnesium hydrogen citrate | 22J01469 | 26400SI | 20 | 2301186 |
| Gatt-Koller | Magnesium hydrogen citrate | 24J00867 | 27302 | 40 | 20240620 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 540 spectra of 12 reference samples from the substance/substance group *Magnesium hydrogen citrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 786 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1570 spectra of 42 reference samples from the substance/substance group *Magnesium hydrogen citrate*.

- Among them are spectra of independent samples from 36 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Magnesium hydrogen citrate | 173531 | 23788 | 40 |
| Caelo | Magnesium hydrogen citrate | 182746 | 24397 | 40 |
| Caelo | Magnesium hydrogen citrate | 21000135 | 25694 | 50 |
| Caelo | Magnesium hydrogen citrate | 23001929 | 26956 | 40 |
| Caelo | Magnesium hydrogen citrate | 24000609 | 27126 | 40 |
| Caelo | Magnesium hydrogen citrate | 24001460 | 27305 | 40 |
| Caelo | Magnesium hydrogen citrate | 25000158 | 27557 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1604002 | 22509 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1608004 | 22796 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1701004 | 22991 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1705010 | 23380 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Magnesium hydrogen citrate | 1705009 | 23382 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1710007 | 23771 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1802026 | 24064 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1811038 | 24425 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1904011 | 24620 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1907020 | 24777 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 1910005 | 24934 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2003064 | 25261 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2005027 | 25281 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2009007 | 25329 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2104021 | 25679 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2107008 | 25777 | 50 |
| Euro OTC | Magnesium hydrogen citrate | 2110009 | 25871 | 50 |
| Euro OTC | Magnesium hydrogen citrate | 2201004 | 25918 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2206017 | 26202 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2304016 | 26644 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2303006 | 26648 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2307001 | 26878 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2310019 | 26999 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2403003 | 27195 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2407003 | 27348 | 40 |
| Euro OTC | Magnesium hydrogen citrate | 2412008 | 27499 | 40 |
| Fagron | Magnesium hydrogen citrate | 19I23-B02-195296 | 24953 | 40 |
| Fagron | Magnesium hydrogen citrate | 22F02-B17-221504 | 26170 | 40 |
| Gatt-Koller | Magnesium hydrogen citrate | 22J00225 | 26399 | 40 |
| Caelo | Magnesium hydrogen citrate | 22001882 | 26251SI[†] | 20 |
| Euro OTC | Magnesium hydrogen citrate | 2110009 | 25871SI | 10 |
| Euro OTC | Magnesium hydrogen citrate | 2201004 | 25918SI | 10 |
| Euro OTC | Magnesium hydrogen citrate | 2206017 | 26202SI | 20 |
| Fagron | Magnesium hydrogen citrate | 22F02-B17-221504 | 26170SI | 20 |
| Gatt-Koller | Magnesium hydrogen citrate | 22J00225 | 26399SI | 20 |

- 211 370 spectra from a total of 4250 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 859 spectra from 291 *Apo-Ident* customers from 276 batches from the substance/substance group *Magnesium hydrogen citrate*.

- Among them are spectra of independent samples from 269 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Magnesium hydrogen citrate | 1311003-01 | 1 |
| | Magnesium hydrogen citrate | 1510033-01 | 1 |
| | Magnesium hydrogen citrate | 22001882002 | 1 |
| | Magnesium hydrogen citrate | 22001882003 | 1 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Magnesium hydrogen citrate | 22002876002 | 1 |
| | Magnesium hydrogen citrate | 2206017-01 | 1 |
| | Magnesium hydrogen citrate | 23001929001 | 1 |
| | Magnesium hydrogen citrate | 23002924001 | 1 |
| | Magnesium hydrogen citrate | 23002924002 | 2 |
| | Magnesium hydrogen citrate | 23002924003 | 1 |
| | Magnesium hydrogen citrate | 23002924005 | 1 |
| | Magnesium hydrogen citrate | 23002924006 | 1 |
| | Magnesium hydrogen citrate | 2303006-01 | 1 |
| | Magnesium hydrogen citrate | 2304016-01 | 4 |
| | Magnesium hydrogen citrate | 2307001-01 | 3 |
| | Magnesium hydrogen citrate | 23A24-B04-227291 | 5 |
| | Magnesium hydrogen citrate | 24001460001 | 1 |
| | Magnesium hydrogen citrate | 24001460004 | 2 |
| | Magnesium hydrogen citrate | 24001460005 | 1 |
| | Magnesium hydrogen citrate | 24001460007 | 1 |
| | Magnesium hydrogen citrate | 24001460008 | 2 |
| | Magnesium hydrogen citrate | 24001460011 | 1 |
| | Magnesium hydrogen citrate | 24001460014 | 1 |
| | Magnesium hydrogen citrate | 3129709 | 1 |
| /Sanacorp | Magnesium hydrogen citrate | 90170 | 1 |
| ACM | Magnesium hydrogen citrate | KNC0829J15 | 1 |
| ACM | Magnesium hydrogen citrate | KNC1377J15 | 2 |
| AHD | Magnesium hydrogen citrate | 13389103 | 1 |
| AHD | Magnesium hydrogen citrate | 24001460014 | 1 |
| Alliance health | Magnesium hydrogen citrate | 13389111 | 2 |
| Alliance | Magnesium hydrogen citrate | 181103801 | 1 |
| Alliance | Magnesium hydrogen citrate | 22001882003 | 1 |
| Anzag | Magnesium hydrogen citrate | 16341710 | 1 |
| AppliChem | Magnesium hydrogen citrate | 7V008966 | 1 |
| Bombastus | Magnesium hydrogen citrate | 1608004-01 | 1 |
| Caelo | Magnesium hydrogen citrate | | 1 |
| Caelo | Magnesium hydrogen citrate | 1014E-01829 | 1 |
| Caelo | Magnesium hydrogen citrate | 11021401 | 1 |
| Caelo | Magnesium hydrogen citrate | 11044103 | 2 |
| Caelo | Magnesium hydrogen citrate | 11061403 | 1 |
| Caelo | Magnesium hydrogen citrate | 11193104 | 1 |
| Caelo | Magnesium hydrogen citrate | 1119I-01829 | 1 |
| Caelo | Magnesium hydrogen citrate | 11372901 | 1 |
| Caelo | Magnesium hydrogen citrate | 11372902 | 1 |
| Caelo | Magnesium hydrogen citrate | 12091303 | 1 |
| Caelo | Magnesium hydrogen citrate | 121033-01 | 1 |
| Caelo | Magnesium hydrogen citrate | 1214 | 1 |
| Caelo | Magnesium hydrogen citrate | 12175801 | 1 |
| Caelo | Magnesium hydrogen citrate | 12175802 | 2 |
| Caelo | Magnesium hydrogen citrate | 12175807 | 3 |
| Caelo | Magnesium hydrogen citrate | 12175810 | 5 |
| Caelo | Magnesium hydrogen citrate | 12238002 | 3 |
| Caelo | Magnesium hydrogen citrate | 12238004 | 3 |
| Caelo | Magnesium hydrogen citrate | 12238012 | 1 |
| Caelo | Magnesium hydrogen citrate | 12368002 | 3 |
| Caelo | Magnesium hydrogen citrate | 12368003 | 9 |
| Caelo | Magnesium hydrogen citrate | 12368004 | 2 |
| Caelo | Magnesium hydrogen citrate | 12368005 | 1 |
| Caelo | Magnesium hydrogen citrate | 12368011 | 8 |
| Caelo | Magnesium hydrogen citrate | 12368014 | 2 |
| Caelo | Magnesium hydrogen citrate | 12368017 | 2 |
| Caelo | Magnesium hydrogen citrate | 13194601 | 4 |
| Caelo | Magnesium hydrogen citrate | 13194603 | 1 |
| Caelo | Magnesium hydrogen citrate | 13233901 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Magnesium hydrogen citrate | 13233904 | 5 |
| Caelo | Magnesium hydrogen citrate | 13233905 | 1 |
| Caelo | Magnesium hydrogen citrate | 13233906 | 9 |
| Caelo | Magnesium hydrogen citrate | 13233907 | 2 |
| Caelo | Magnesium hydrogen citrate | 13233910 | 5 |
| Caelo | Magnesium hydrogen citrate | 13233911 | 3 |
| Caelo | Magnesium hydrogen citrate | 13233913 | 4 |
| Caelo | Magnesium hydrogen citrate | 133233907 | 1 |
| Caelo | Magnesium hydrogen citrate | 133389111 | 1 |
| Caelo | Magnesium hydrogen citrate | 13389103 | 7 |
| Caelo | Magnesium hydrogen citrate | 13389106 | 2 |
| Caelo | Magnesium hydrogen citrate | 13389107 | 2 |
| Caelo | Magnesium hydrogen citrate | 13389108 | 1 |
| Caelo | Magnesium hydrogen citrate | 13389111 | 4 |
| Caelo | Magnesium hydrogen citrate | 1415013 | 1 |
| Caelo | Magnesium hydrogen citrate | 14265503 | 6 |
| Caelo | Magnesium hydrogen citrate | 14265504 | 5 |
| Caelo | Magnesium hydrogen citrate | 14265505 | 2 |
| Caelo | Magnesium hydrogen citrate | 14265511 | 1 |
| Caelo | Magnesium hydrogen citrate | 14265513 | 2 |
| Caelo | Magnesium hydrogen citrate | 14265514 | 1 |
| Caelo | Magnesium hydrogen citrate | 14265516 | 3 |
| Caelo | Magnesium hydrogen citrate | 14265517 | 1 |
| Caelo | Magnesium hydrogen citrate | 14265520 | 1 |
| Caelo | Magnesium hydrogen citrate | 14265521 | 1 |
| Caelo | Magnesium hydrogen citrate | 14I12-B02-298854 | 1 |
| Caelo | Magnesium hydrogen citrate | 15296701 | 11 |
| Caelo | Magnesium hydrogen citrate | 15296702 | 4 |
| Caelo | Magnesium hydrogen citrate | 15296709 | 6 |
| Caelo | Magnesium hydrogen citrate | 15296710 | 1 |
| Caelo | Magnesium hydrogen citrate | 15296712 | 2 |
| Caelo | Magnesium hydrogen citrate | 15296801 | 3 |
| Caelo | Magnesium hydrogen citrate | 15415001 | 6 |
| Caelo | Magnesium hydrogen citrate | 15415002 | 1 |
| Caelo | Magnesium hydrogen citrate | 15415003 | 6 |
| Caelo | Magnesium hydrogen citrate | 15415004 | 3 |
| Caelo | Magnesium hydrogen citrate | 15415005 | 3 |
| Caelo | Magnesium hydrogen citrate | 15415009 | 6 |
| Caelo | Magnesium hydrogen citrate | 15415010 | 9 |
| Caelo | Magnesium hydrogen citrate | 15415013 | 2 |
| Caelo | Magnesium hydrogen citrate | 15415014 | 6 |
| Caelo | Magnesium hydrogen citrate | 15415015 | 1 |
| Caelo | Magnesium hydrogen citrate | 160100501 | 1 |
| Caelo | Magnesium hydrogen citrate | 1601005-01 | 1 |
| Caelo | Magnesium hydrogen citrate | 1604002-01 | 3 |
| Caelo | Magnesium hydrogen citrate | 16341707 | 2 |
| Caelo | Magnesium hydrogen citrate | 16341708 | 6 |
| Caelo | Magnesium hydrogen citrate | 16341709 | 3 |
| Caelo | Magnesium hydrogen citrate | 16341710 | 6 |
| Caelo | Magnesium hydrogen citrate | 16341711 | 2 |
| Caelo | Magnesium hydrogen citrate | 16E02-B03-321485 | 1 |
| Caelo | Magnesium hydrogen citrate | 17061401 | 1 |
| Caelo | Magnesium hydrogen citrate | 1710007-01 | 2 |
| Caelo | Magnesium hydrogen citrate | 17173401 | 7 |
| Caelo | Magnesium hydrogen citrate | 17173404 | 1 |
| Caelo | Magnesium hydrogen citrate | 17173405 | 8 |
| Caelo | Magnesium hydrogen citrate | 17173406 | 3 |
| Caelo | Magnesium hydrogen citrate | 17173407 | 2 |
| Caelo | Magnesium hydrogen citrate | 17353104 | 3 |
| Caelo | Magnesium hydrogen citrate | 17353104P-180831-2 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Magnesium hydrogen citrate | 17353104P-181001-2 | 1 |
| Caelo | Magnesium hydrogen citrate | 17353105 | 1 |
| Caelo | Magnesium hydrogen citrate | 17353109 | 1 |
| Caelo | Magnesium hydrogen citrate | 18216803 | 4 |
| Caelo | Magnesium hydrogen citrate | 18216803P-181218-1 | 1 |
| Caelo | Magnesium hydrogen citrate | 18216803P-190225-5 | 1 |
| Caelo | Magnesium hydrogen citrate | 18216804 | 3 |
| Caelo | Magnesium hydrogen citrate | 18216804P-190325-1 | 1 |
| Caelo | Magnesium hydrogen citrate | 18216804P-191004-1 | 1 |
| Caelo | Magnesium hydrogen citrate | 18216806 | 6 |
| Caelo | Magnesium hydrogen citrate | 18274601 | 1 |
| Caelo | Magnesium hydrogen citrate | 18274602 | 1 |
| Caelo | Magnesium hydrogen citrate | 18274603 | 2 |
| Caelo | Magnesium hydrogen citrate | 18274604 | 3 |
| Caelo | Magnesium hydrogen citrate | 18274606 | 3 |
| Caelo | Magnesium hydrogen citrate | 18274606P-200331-3 | 1 |
| Caelo | Magnesium hydrogen citrate | 18274609 | 2 |
| Caelo | Magnesium hydrogen citrate | 18274610 | 1 |
| Caelo | Magnesium hydrogen citrate | 18274612 | 1 |
| Caelo | Magnesium hydrogen citrate | 18A08-B04-345115 | 1 |
| Caelo | Magnesium hydrogen citrate | 19000684001 | 2 |
| Caelo | Magnesium hydrogen citrate | 19000684002 | 4 |
| Caelo | Magnesium hydrogen citrate | 19000684003 | 3 |
| Caelo | Magnesium hydrogen citrate | 1904011-01 | 3 |
| Caelo | Magnesium hydrogen citrate | 19061316 | 1 |
| Caelo | Magnesium hydrogen citrate | 20002495002 | 2 |
| Caelo | Magnesium hydrogen citrate | 20002495003 | 4 |
| Caelo | Magnesium hydrogen citrate | 20002495006 | 2 |
| Caelo | Magnesium hydrogen citrate | 20002495010 | 1 |
| Caelo | Magnesium hydrogen citrate | 21000135002 | 1 |
| Caelo | Magnesium hydrogen citrate | 21000135005 | 1 |
| Caelo | Magnesium hydrogen citrate | 21000135006 | 1 |
| Caelo | Magnesium hydrogen citrate | 21000135007 | 2 |
| Caelo | Magnesium hydrogen citrate | 21000135011 | 1 |
| Caelo | Magnesium hydrogen citrate | 21003604004 | 7 |
| Caelo | Magnesium hydrogen citrate | 218U-01829 | 1 |
| Caelo | Magnesium hydrogen citrate | 2368011 | 1 |
| Caelo | Magnesium hydrogen citrate | 24001460002 | 1 |
| Caelo | Magnesium hydrogen citrate | 26101203 | 1 |
| Caelo | Magnesium hydrogen citrate | 27101704 | 1 |
| Caelo | Magnesium hydrogen citrate | 27111306 | 1 |
| Caelo | Magnesium hydrogen citrate | 315E-01829 | 1 |
| Caelo | Magnesium hydrogen citrate | 411052-2-P | 1 |
| Caelo | Magnesium hydrogen citrate | 516Q-01829 | 1 |
| Caelo | Magnesium hydrogen citrate | 6081301 | 1 |
| Caelo | Magnesium hydrogen citrate | 7011504 | 1 |
| Caelo | Magnesium hydrogen citrate | 80446188 | 1 |
| Caelo | Magnesium hydrogen citrate | 90396169 | 1 |
| Caelo | Magnesium hydrogen citrate | 913M-01829 | 1 |
| Caeol/Noweda | Magnesium hydrogen citrate | 17353105 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 18274602 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 18274601 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 18274609 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 19000684004 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 19000684002 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 20002495003 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 18274609 | 1 |
| Caesar & Loretz GmbH/Ph | Magnesium hydrogen citrate | 20002495003 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 20002495002 | 1 |
| Caesar & Loretz GmbH... | Magnesium hydrogen citrate | 21000135006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 17353109 | 1 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 18216803 | 1 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 18274602 | 1 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 18274604 | 3 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 18274605 | 1 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 18274609 | 1 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 18274610 | 3 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 19000684003 | 1 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 20002495001 | 2 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 20002495002 | 2 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 20002495003 | 2 |
| Caesar & Loretz GmbH | Magnesium hydrogen citrate | 21000135006 | 1 |
| Caesar & Loretz | Magnesium hydrogen citrate | 16341711 | 1 |
| Caleo/ Noweda | Magnesium hydrogen citrate | 18216803 | 1 |
| Cealo | Magnesium hydrogen citrate | 12368014 | 1 |
| Cealo | Magnesium hydrogen citrate | 13233907 | 2 |
| Dr. Paul Lohmann | Magnesium hydrogen citrate | 1077866 | 2 |
| Dr. Paul Lohmann | Magnesium hydrogen citrate | 1078434 | 1 |
| Dr. Paul Lohmann | Magnesium hydrogen citrate | 1079474 | 1 |
| Eu Rho | Magnesium hydrogen citrate | 110600401 | 1 |
| Eu Rho | Magnesium hydrogen citrate | 1202034-01 | 1 |
| Eu Rho | Magnesium hydrogen citrate | 1306034-01 | 1 |
| EuRho/Phönix | Magnesium hydrogen citrate | 1202034-02 | 1 |
| EuRho/Phönix | Magnesium hydrogen citrate | 1311003-01 | 1 |
| EuRho | Magnesium hydrogen citrate | 1311003-02 | 1 |
| EuRho | Magnesium hydrogen citrate | 1507010-02 | 1 |
| EuRho | Magnesium hydrogen citrate | 1910005-01 | 1 |
| Euro OTC | Magnesium hydrogen citrate | | 3 |
| Euro OTC | Magnesium hydrogen citrate | 1080144 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1085730 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 1110026-01 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 1208006-01 | 3 |
| Euro OTC | Magnesium hydrogen citrate | 120800602 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1211033-01 | 4 |
| Euro OTC | Magnesium hydrogen citrate | 1211033-02 | 4 |
| Euro OTC | Magnesium hydrogen citrate | 1306034-01 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 130603402 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1306034-02 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 1311003-01 | 7 |
| Euro OTC | Magnesium hydrogen citrate | 1311003-02 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 140402301 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1404023-01 | 5 |
| Euro OTC | Magnesium hydrogen citrate | 140704801 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1407048-01 | 4 |
| Euro OTC | Magnesium hydrogen citrate | 1407048-02 | 3 |
| Euro OTC | Magnesium hydrogen citrate | 1501026-01 | 5 |
| Euro OTC | Magnesium hydrogen citrate | 1507010-01 | 12 |
| Euro OTC | Magnesium hydrogen citrate | 1507010-02 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 151003301 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 1510033-01 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 16000456/0 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 160100501 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1601005-01 | 18 |
| Euro OTC | Magnesium hydrogen citrate | 1604002-001 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1604002-01 | 29 |
| Euro OTC | Magnesium hydrogen citrate | 1604002-012x | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1604002-02 | 8 |
| Euro OTC | Magnesium hydrogen citrate | 160800401 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 1608004-01 | 22 |
| Euro OTC | Magnesium hydrogen citrate | 1608004-02 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Magnesium hydrogen citrate | 1701003-01 | 7 |
| Euro OTC | Magnesium hydrogen citrate | 170100401 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1701004-01 | 4 |
| Euro OTC | Magnesium hydrogen citrate | 17050009-01 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1705009-01 | 5 |
| Euro OTC | Magnesium hydrogen citrate | 1705010-01 | 7 |
| Euro OTC | Magnesium hydrogen citrate | 1710001-01 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 171000701 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1710007-01 | 10 |
| Euro OTC | Magnesium hydrogen citrate | 1710007-02 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 17353105 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1802026-01 | 6 |
| Euro OTC | Magnesium hydrogen citrate | 1808006-01 | 5 |
| Euro OTC | Magnesium hydrogen citrate | 1811038-01 | 13 |
| Euro OTC | Magnesium hydrogen citrate | 190401101 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 1904011-01 | 15 |
| Euro OTC | Magnesium hydrogen citrate | 190702001 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 1907020-01 | 7 |
| Euro OTC | Magnesium hydrogen citrate | 1910005-01 | 7 |
| Euro OTC | Magnesium hydrogen citrate | 2003064-01 | 8 |
| Euro OTC | Magnesium hydrogen citrate | 2005027-01 | 14 |
| Euro OTC | Magnesium hydrogen citrate | 2009007-01 | 18 |
| Euro OTC | Magnesium hydrogen citrate | 2101004-01 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 2104021-01 | 2 |
| Euro OTC | Magnesium hydrogen citrate | 2107008-01 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 2110009-01 | 3 |
| Euro OTC | Magnesium hydrogen citrate | 2114M1829 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 220100401 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 2201004-01 | 7 |
| Euro OTC | Magnesium hydrogen citrate | 2201004-02 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 2206017-01 | 8 |
| Euro OTC | Magnesium hydrogen citrate | 3030559 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 3035708 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 3068048 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 3095909 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 3105142 | 1 |
| Euro OTC | Magnesium hydrogen citrate | 3115652 | 2 |
| Fagron | Magnesium hydrogen citrate | | 1 |
| Fagron | Magnesium hydrogen citrate | 1056239 | 1 |
| Fagron | Magnesium hydrogen citrate | 1087537 | 1 |
| Fagron | Magnesium hydrogen citrate | 11H05-N07 | 1 |
| Fagron | Magnesium hydrogen citrate | 12G10-N01 | 2 |
| Fagron | Magnesium hydrogen citrate | 13B22-N03 | 1 |
| Fagron | Magnesium hydrogen citrate | 13D30-N07 | 2 |
| Fagron | Magnesium hydrogen citrate | 13K11-B02-288161 | 1 |
| Fagron | Magnesium hydrogen citrate | 13K11-BO2-288161 | 1 |
| Fagron | Magnesium hydrogen citrate | 14/12-B02-298854 | 1 |
| Fagron | Magnesium hydrogen citrate | 14I12-B02 | 1 |
| Fagron | Magnesium hydrogen citrate | 14I12-B02-298854 | 1 |
| Fagron | Magnesium hydrogen citrate | 14K-B03-305254 | 1 |
| Fagron | Magnesium hydrogen citrate | 15296701 | 1 |
| Fagron | Magnesium hydrogen citrate | 1604002-01 | 5 |
| Fagron | Magnesium hydrogen citrate | 16E02-B03-0326874 | 1 |
| Fagron | Magnesium hydrogen citrate | 16E02-B03-326874 | 1 |
| Fagron | Magnesium hydrogen citrate | 17G24-B03-338029 | 2 |
| Fagron | Magnesium hydrogen citrate | 17G24-B03-341019 | 1 |
| Fagron | Magnesium hydrogen citrate | 18/20-B06 | 1 |
| Fagron | Magnesium hydrogen citrate | 18A08-B04-345115 | 1 |
| Fagron | Magnesium hydrogen citrate | 18A08-B04-345155 | 1 |
| Fagron | Magnesium hydrogen citrate | 18A08-B04-349372 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Magnesium hydrogen citrate | 18I20-B06-355658 | 1 |
| Fagron | Magnesium hydrogen citrate | 20A17-B08-196635 | 2 |
| Fagron | Magnesium hydrogen citrate | 20A17-B08-200819 | 1 |
| Fagron | Magnesium hydrogen citrate | 20I25-B03-201926 | 1 |
| Fagron | Magnesium hydrogen citrate | 3047166 | 2 |
| Fagron | Magnesium hydrogen citrate | B07-2136601 | 1 |
| Fiebig | Magnesium hydrogen citrate | 1802026-01 | 1 |
| Gatt-Koller | Magnesium hydrogen citrate | | 1 |
| Gatt-Koller | Magnesium hydrogen citrate | 1800208 | 1 |
| Gatt-Koller | Magnesium hydrogen citrate | 1802721 | 1 |
| Gatt-Koller | Magnesium hydrogen citrate | 1803714 | 2 |
| Gehe Kassel | Magnesium hydrogen citrate | 14/12-B02-298854 | 1 |
| GEHE | Magnesium hydrogen citrate | 1802026-01 | 1 |
| Gutenberg-Apotheke | Magnesium hydrogen citrate | 13233913 | 2 |
| Heidelberger Chlorel… | Magnesium hydrogen citrate | 10032 | 1 |
| Heidelberger Chlorella | Magnesium hydrogen citrate | 90196 | 1 |
| Ichthyol/Phönix | Magnesium hydrogen citrate | 14/12-B02-298854 | 1 |
| INTERN-DROGEN | Magnesium hydrogen citrate | 210001350007 | 1 |
| INTERN-DROGEN | Magnesium hydrogen citrate | 21000135006 | 1 |
| Kehr | Magnesium hydrogen citrate | 17173406 | 1 |
| kögl | Magnesium hydrogen citrate | 1900910 | 1 |
| L30 | Magnesium hydrogen citrate | 1608004-01 | 1 |
| lohmann | Magnesium hydrogen citrate | 3054132 | 1 |
| Nachprüfung vom 31.1… | Magnesium hydrogen citrate | 16341710 | 1 |
| Nowed18.08.2015 | Magnesium hydrogen citrate | 14265521 | 1 |
| Noweda | Magnesium hydrogen citrate | 10163306 | 1 |
| Noweda | Magnesium hydrogen citrate | 16341710 | 1 |
| Noweda | Magnesium hydrogen citrate | 18274603 | 1 |
| Noweda | Magnesium hydrogen citrate | 2005027-01 | 1 |
| Noweda | Magnesium hydrogen citrate | 22002876002 | 1 |
| Noweda | Magnesium hydrogen citrate | 2206017-01 | 1 |
| Phoenix 15.10.14 | Magnesium hydrogen citrate | 1311003-01 | 1 |
| Phönix | Magnesium hydrogen citrate | 1211033-01 | 2 |
| phönix | Magnesium hydrogen citrate | 15296702 | 1 |
| phönix | Magnesium hydrogen citrate | 15296710 | 1 |
| Phönix | Magnesium hydrogen citrate | 15415005 | 1 |
| phönix | Magnesium hydrogen citrate | 15415010 | 1 |
| phönix | Magnesium hydrogen citrate | 15415015 | 2 |
| phönix | Magnesium hydrogen citrate | 1601005-01 | 2 |
| phönix | Magnesium hydrogen citrate | 1604002-01 | 1 |
| phönix | Magnesium hydrogen citrate | 1608004-01 | 1 |
| Phönix | Magnesium hydrogen citrate | 16341709 | 2 |
| Sanacaorp | Magnesium hydrogen citrate | 13389108 | 1 |
| Sanacorp | Magnesium hydrogen citrate | 16341710 | 1 |
| Sanacorp | Magnesium hydrogen citrate | 20002495003 | 1 |
| Sanacorp | Magnesium hydrogen citrate | 20A17-B08-196635 | 1 |
| Sanacorp | Magnesium hydrogen citrate | 22001882001 | 1 |
| Sanacorp | Magnesium hydrogen citrate | 2304016-01 | 1 |
| Sanacorp | Magnesium hydrogen citrate | 3108363 | 1 |
| VDL;27.02.15 | Magnesium hydrogen citrate | 13389111 | 1 |

- 256 027 spectra from 1666 *Apo-Ident* customers from a total of 51 882 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Magnesium hydrogen citrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Magnesium hydrogen citrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 540 | 0 | 157 786 |
| **Type B** | 0 | 1570 | 0 | 211 370 |
| **Type C** | 0 | 858 | 1 | 256 027 |

The substance/substance group *Magnesium hydrogen citrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8889 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6178 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8836 % (> 99.5343 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21445 | 22233 | 5.55 | 88.80 |
| 21873 | 21873 | 0.00 | 86.87 |
| 22233 | 22233 | 0.00 | 88.18 |
| 22296 | 22296 | 0.00 | 88.03 |
| 22992 | 22992 | 0.00 | 86.44 |
| 23240 | 22992 | 4.17 | 86.47 |
| 25545 | 25545 | 0.00 | 95.61 |
| 26251 | 26251 | 0.00 | 78.95 |
| 26400 | 26400 | 0.00 | 118.71 |
| 26423 | 26423 | 0.00 | 91.08 |
| 27302 | 22233 | 40.15 | 100.57 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,

thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Magnesium orotate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20429-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Magnesium orotate dihydrate; Magnesii orotas dihydricus

### Special notes

When selecting the *Magnesium orotate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Magnesium orotate dihydrate | 7 | 19 | 36 |

### Second-stage model

For differentiation of the substance/substance group *Magnesium orotate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Magnesium orotate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Manganese orotate dihydrate | 74.75 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Magnesium orotate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Magnesium orotate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Magnesium orotate dihydrate | 162227 | 22638 | 40 | 20160809* |
| Caelo | Magnesium orotate dihydrate | 16222701 | 23236 | 40 | 20160809 |
| Euro OTC | Magnesium orotate dihydrate | 1511021 | 22287 | 60 | 20151228* |
| Euro OTC | Magnesium orotate dihydrate | 1707018 | 23615 | 40 | 20170907* |
| Euro OTC | Magnesium orotate dihydrate | 1911024 | 25069 | 40 | 20200107* |
| Euro OTC | Magnesium orotate dihydrate | 2003014 | 25147 | 40 | 20200416* |
| Euro OTC | Magnesium orotate dihydrate | 2309021 | 26926 | 40 | 20231011* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 300 spectra of 7 reference samples from the substance/substance group *Magnesium orotate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 026 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 830 spectra of 23 reference samples from the substance/substance group *Magnesium orotate dihydrate*.

- Among them are spectra of independent samples from 19 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Magnesium orotate dihydrate | 172157 | 23661 | 40 |
| Caelo | Magnesium orotate dihydrate | 172547 | 23799 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 1608017 | 22784 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 1712001 | 23874 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 1802018 | 23963 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 1808029 | 24200 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 1902007 | 24490 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 1906014 | 24797 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 1909007 | 24835 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2006004 | 25341 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2102003 | 25595 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2109023 | 25892 | 50 |
| Euro OTC | Magnesium orotate dihydrate | 2202010 | 25969 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2207009 | 26196 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2301041 | 26584 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2403014 | 27214 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2408014 | 27399 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2502002 | 27507 | 40 |
| Fagron | Magnesium orotate dihydrate | 22B26-B08-003632 | 27485 | 40 |
| Euro OTC | Magnesium orotate dihydrate | 2109023 | 25892SI | 10 |
| Euro OTC | Magnesium orotate dihydrate | 2202010 | 25969SI | 10 |
| Euro OTC | Magnesium orotate dihydrate | 2207009 | 26196SI | 20 |
| Euro OTC | Magnesium orotate dihydrate | 2301041 | 26584SI | 20 |

- 212 110 spectra from a total of 4268 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 62 spectra from 25 *Apo-Ident* customers from 36 batches from the substance/substance group *Magnesium orotate dihydrate*.
- Among them are spectra of independent samples from 36 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Magnesium orotate dihydrate | 14093607 | 2 |
| Caelo | Magnesium orotate dihydrate | 1808029-01 | 1 |
| EuRho | Magnesium orotate dihydrate | 2102003-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 1209029-01 | 3 |
| Euro OTC | Magnesium orotate dihydrate | 1305011-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 130501102 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 1305011-02 | 5 |
| Euro OTC | Magnesium orotate dihydrate | 1407005-01 | 3 |
| Euro OTC | Magnesium orotate dihydrate | 1504002-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 1504002-02 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 151102101 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 1511021-02 | 6 |
| Euro OTC | Magnesium orotate dihydrate | 1608017-01 | 2 |
| Euro OTC | Magnesium orotate dihydrate | 1608017-02 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 16085017-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 1707018-01 | 4 |
| Euro OTC | Magnesium orotate dihydrate | 1712001-01 | 2 |
| Euro OTC | Magnesium orotate dihydrate | 1802018-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 1808029-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 180802902 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 1906014-01 | 2 |
| Euro OTC | Magnesium orotate dihydrate | 1909007-01 | 2 |
| Euro OTC | Magnesium orotate dihydrate | 2003014-01 | 2 |
| Euro OTC | Magnesium orotate dihydrate | 2006004-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 2102003-01 | 1 |
| Euro OTC | Magnesium orotate dihydrate | 2109023-01 | 3 |
| Euro OTC | Magnesium orotate dihydrate | 2109023-02 | 1 |
| Fagron | Magnesium orotate dihydrate | 1000060461 | 1 |
| Fagron | Magnesium orotate dihydrate | 12G05-N03 | 1 |
| Fagron | Magnesium orotate dihydrate | 13H06-N07 | 1 |
| Fagron | Magnesium orotate dihydrate | 14/13-B05-305616 | 1 |
| Fagron | Magnesium orotate dihydrate | 14E20-B05-296005 | 1 |
| Fagron | Magnesium orotate dihydrate | 160801701 | 1 |
| Fagron | Magnesium orotate dihydrate | 16K22B01329783 | 1 |
| Fagron | Magnesium orotate dihydrate | 17H14-B02 | 1 |
| Fagron | Magnesium orotate dihydrate | 17H14B02346538 | 1 |
| Fagron | Magnesium orotate dihydrate | 354317 | 1 |
| Noweda | Magnesium orotate dihydrate | 2301041-01 | 1 |

- 256 824 spectra from 1666 *Apo-Ident* customers from a total of 52 118 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Magnesium orotate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Magnesium orotate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 830 | 0 | 212 110 |
| **Type C** | 0 | 62 | 0 | 256 824 |

The substance/substance group *Magnesium orotate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2771 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 90.3226 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22287 | 22287 | 0.00 | 139.19 |
| 22638 | 22638 | 0.00 | 153.26 |
| 23236 | 22638 | 7.72 | 153.97 |
| 23615 | 23615 | 0.00 | 141.94 |
| 25069 | 25069 | 0.00 | 151.13 |
| 25147 | 25147 | 0.00 | 150.49 |
| 26926 | 26926 | 0.00 | 143.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Magnesium stearate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20707-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Magnesium stearate; Magnesii stearas

### Special notes

When selecting the *Magnesium stearate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Magnesium stearate | 7 | 11 | 34 |

### Second-stage model

For differentiation of the substance/substance group *Magnesium stearate* the following second-stage model is used:

- Submodel 01

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Magnesium stearate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cetyl palmitate | 51.70 | 15.37 |
| ⋮ | ⋮ | ⋮ |
| Beeswax, white | >50 | 19.46 |
| Hard fat W35 | >50 | 20.81 |
| Hard fat | >50 | 22.16 |
| Paraffin, hard | >50 | 25.83 |
| Beeswax, yellow | >50 | 29.49 |
| Cocoa butter | >50 | 32.14 |
| Paraffin, microcrystalline | >50 | 36.27 |
| Sodium dodecyl sulfate | >50 | 40.52 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Magnesium stearate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Magnesium stearate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Magnesium stearate | 13095536 | 21117 | 40 | 20130405 |
| Caelo | Magnesium stearate | 14136929 | 21783 | 60 | AR-15-FG-012028-01 |
| Euro OTC | Magnesium stearate | 1502033-01 | 22817 | 40 | 20150317 |
| Euro OTC | Magnesium stearate | 1704002 | 23436 | 40 | 20170622* |
| Euro OTC | Magnesium stearate | 2301035 | 26649 | 40 | 20230323* |
| Euro OTC | Magnesium stearate | 2301035 | 26649SI | 20 | 20230323* |
| Fagron | Magnesium stearate | 12C29-N06 | 20707 | 110 | 20120418 |
| Fagron | Magnesium stearate | 12D26-B03 | 21084 | 40 | 1407310 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 390 spectra of 8 reference samples from the substance/substance group *Magnesium stearate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 936 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 480 spectra of 13 reference samples from the substance/substance group *Magnesium stearate*.

- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Magnesium stearate | 162066 | 22763 | 40 |
| Caelo | Magnesium stearate | 181533 | 24215 | 40 |
| Caelo | Magnesium stearate | 183089 | 24354 | 40 |
| Caelo | Magnesium stearate | 192527 | 24897 | 40 |
| Caelo | Magnesium stearate | 21004078013 | 26743 | 40 |
| Caelo | Magnesium stearate | 23002099 | 26973 | 40 |
| Euro OTC | Magnesium stearate | 1608022 | 22821 | 40 |
| Euro OTC | Magnesium stearate | 1901033 | 24459 | 40 |
| Euro OTC | Magnesium stearate | 2009032 | 25398 | 40 |
| Euro OTC | Magnesium stearate | 2109010 | 25886 | 50 |
| Euro OTC | Magnesium stearate | 2501036 | 27626 | 40 |
| Caelo | Magnesium stearate | 21004078013 | 26743SI | 20 |
| Euro OTC | Magnesium stearate | 2109010 | 25886SI | 10 |

- 212 460 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 68 spectra from 49 *Apo-Ident* customers from 36 batches from the substance/substance group *Magnesium stearate*.
- Among them are spectra of independent samples from 34 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Magnesium stearate | 21004078005 | 1 |
| | Magnesium stearate | 2100407813 | 1 |
| | Magnesium stearate | 23000572003 | 2 |
| Caelo | Magnesium stearate | 12040307 | 1 |
| Caelo | Magnesium stearate | 13095515 | 1 |
| Caelo | Magnesium stearate | 13095536 | 1 |
| Caelo | Magnesium stearate | 15155001 | 2 |
| Caelo | Magnesium stearate | 15305302 | 3 |
| Caelo | Magnesium stearate | 15305307 | 1 |
| Caelo | Magnesium stearate | 15305315 | 4 |
| Caelo | Magnesium stearate | 15305323 | 1 |
| Caelo | Magnesium stearate | 16206602 | 3 |
| Caelo | Magnesium stearate | 16206610 | 7 |
| Caelo | Magnesium stearate | 16206617 | 1 |
| Caelo | Magnesium stearate | 17360006 | 2 |
| Caelo | Magnesium stearate | 18153310 | 2 |
| Caelo | Magnesium stearate | 183038912 | 1 |
| Caelo | Magnesium stearate | 18308912 | 1 |
| Caelo | Magnesium stearate | 18308916 | 2 |
| Caelo | Magnesium stearate | 192527003 | 1 |
| Caelo | Magnesium stearate | 192527006 | 1 |
| Caelo | Magnesium stearate | 20004065001 | 2 |
| Caelo | Magnesium stearate | 23000572003 | 1 |
| Caesar & Loretz GmbH... | Magnesium stearate | 15322002 | 1 |
| Caesar & Loretz GmbH/AHD | Magnesium stearate | 20004065001 | 2 |
| Caesar & Loretz GmbH/Kehr | Magnesium stearate | 18153310 | 1 |
| Caesar & Loretz GmbH... | Magnesium stearate | 18153310 | 1 |
| Caesar & Loretz GmbH | Magnesium stearate | 18308912 | 1 |
| Caesar & Loretz GmbH | Magnesium stearate | 18308916 | 1 |
| Caesar & Loretz GmbH | Magnesium stearate | 192527003 | 1 |
| Caesar & Loretz GmbH | Magnesium stearate | 20004065001 | 1 |
| EuRho | Magnesium stearate | 1502033-01 | 2 |
| Euro OTC | Magnesium stearate | 1116E-01834 | 1 |
| Euro OTC | Magnesium stearate | 1119I-01834 | 1 |
| Euro OTC | Magnesium stearate | 1912I-01834 | 1 |
| Euro OTC | Magnesium stearate | 2009032-01 | 1 |
| Euro OTC | Magnesium stearate | 315E-01834 | 1 |
| Euro OTC | Magnesium stearate | 718I-01834 | 1 |
| Euro OTC | Magnesium stearate | 914I-01834 | 1 |
| Fagron | Magnesium stearate | 12D26-B03-289435 | 1 |
| FL Apotheke | Magnesium stearate | xxxxxx | 1 |
| Jenne | Magnesium stearate | 21004078010 | 1 |
| Noweda | Magnesium stearate | 21004078013 | 1 |
| Phoenix | Magnesium stearate | 23000572003 | 1 |
| ROHA | Magnesium stearate | 130230 | 1 |
| Sanacorp | Magnesium stearate | 21004078013 | 1 |
| Sanacorp | Magnesium stearate | 23000572003 | 1 |


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- 256 818 spectra from 1666 *Apo-Ident* customers from a total of 52 118 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Magnesium stearate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Magnesium stearate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 390 | 0 | 157 936 |
| **Type B** | 0 | 480 | 0 | 212 460 |
| **Type C** | 0 | 68 | 0 | 256 818 |

The substance/substance group *Magnesium stearate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4615 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 91.1765 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20707 | 21783 | 54.47 | 105.58 |
| 21084 | 21084 | 0.00 | 99.27 |
| 21117 | 26649 | 26.26 | 127.02 |
| 21783 | 21783 | 0.00 | 91.72 |
| 22817 | 21783 | 5.66 | 96.35 |
| 23436 | 23436 | 0.00 | 113.57 |
| 26649 | 26649 | 0.00 | 126.23 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Magnesium sulfate heptahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20165-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Magnesium sulfate heptahydrate; Magnesii sulfas heptahydricus; Magnesium sulphate heptahydrate

### Special notes

When selecting the *Magnesium sulfate heptahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Magnesium sulfate heptahydrate | 6 | 2 | 54 |

### Second-stage model

For differentiation of the substance/substance group *Magnesium sulfate heptahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Magnesium sulfate heptahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Zinc sulfate heptahydrate | 32.41 | – |
| Sodium cromoglicate | 51.45 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Magnesium sulfate heptahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Magnesium sulfate heptahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Magnesium sulfate heptahydrate | 22000334 | 26054 | 40 | 20220301* |
| Caelo | Magnesium sulfate heptahydrate | 21002002 | 26055 | 40 | 20210923* |
| Caelo | Magnesium sulfate heptahydrate | 22003020 | 26561 | 40 | 20221207* |
| Caelo | Magnesium sulfate heptahydrate | 22003020 | 26561SI | 20 | 20221207* |
| Caelo | Magnesium sulfate heptahydrate | 23003364 | 27105 | 40 | 20240124* |
| Caelo | Magnesium sulfate heptahydrate | 24002186 | 27431 | 40 | 20241011* |
| Euro OTC | Magnesium sulfate heptahydrate | 2308013 | 26882 | 40 | 20230829* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 260 spectra of 7 reference samples from the substance/substance group *Magnesium sulfate heptahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 110 spectra of 4 reference samples from the substance/substance group *Magnesium sulfate heptahydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Magnesium sulfate heptahydrate | 23001612 | 26849 | 40 |
| Euro OTC | Magnesium sulfate heptahydrate | 2107026 | 25789 | 50 |
| Caelo | Magnesium sulfate heptahydrate | 22000334 | 26054SI† | 10 |
| Caelo | Magnesium sulfate heptahydrate | 21002002 | 26055SI† | 10 |

- 212 830 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 143 spectra from 82 *Apo-Ident* customers from 54 batches from the substance/substance group *Magnesium sulfate heptahydrate*.

- Among them are spectra of independent samples from 54 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Magnesium sulfate heptahydrate | 1401029-01 | 1 |
| | Magnesium sulfate heptahydrate | 21002002005 | 1 |
| | Magnesium sulfate heptahydrate | 22001077002 | 5 |
| | Magnesium sulfate heptahydrate | 22003020005 | 1 |
| | Magnesium sulfate heptahydrate | 22003025001 | 3 |
| | Magnesium sulfate heptahydrate | 22003025003 | 18 |
| | Magnesium sulfate heptahydrate | 2210012-01 | 2 |
| | Magnesium sulfate heptahydrate | 24000129002 | 5 |
| | Magnesium sulfate heptahydrate | 3134859 | 1 |
| Anzag 29.04.13 ek: 4,55EUR | Magnesium sulfate heptahydrate | 12138518 | 1 |
| Anzag | Magnesium sulfate heptahydrate | 204035 | 1 |
| Bombastus | Magnesium sulfate heptahydrate | 277424 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 10104201 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 10371111 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 11194001 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 11369252 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 11369509 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 11369525 | 6 |
| Caelo | Magnesium sulfate heptahydrate | 11369526 | 12 |
| Caelo | Magnesium sulfate heptahydrate | 11369529 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 113695625 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 12119901/2 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 12138518 | 2 |
| Caelo | Magnesium sulfate heptahydrate | 12138521 | 2 |
| Caelo | Magnesium sulfate heptahydrate | 1213E-01835 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 12336914 | 5 |
| Caelo | Magnesium sulfate heptahydrate | 12336915 | 3 |
| Caelo | Magnesium sulfate heptahydrate | 12336926 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 12c27-n06 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 12E22-N02 | 2 |
| Caelo | Magnesium sulfate heptahydrate | 13030104 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 13030107 | 1 |
| Caelo | Magnesium sulfate heptahydrate | 13183702 | 2 |
| Caelo | Magnesium sulfate heptahydrate | 6012014B | 1 |
| Caelo | Magnesium sulfate heptahydrate | 90744129 | 1 |
| Eu Rho | Magnesium sulfate heptahydrate | 1206019-01 | 4 |
| EuRho/Jenne | Magnesium sulfate heptahydrate | 1202017-01 | 1 |
| EuRho | Magnesium sulfate heptahydrate | 1206019-01 | 1 |
| EuRho | Magnesium sulfate heptahydrate | 1303008-01 | 2 |
| EuRho | Magnesium sulfate heptahydrate | 3512M-01835 | 1 |
| Euro / Jenne | Magnesium sulfate heptahydrate | 1401029-01 | 1 |
| Euro OTC | Magnesium sulfate heptahydrate | 1109023-01 | 1 |
| Euro OTC | Magnesium sulfate heptahydrate | 1202017-01 | 5 |
| Euro OTC | Magnesium sulfate heptahydrate | 1211022-01 | 3 |
| Euro OTC | Magnesium sulfate heptahydrate | 130300801 | 1 |
| Euro OTC | Magnesium sulfate heptahydrate | 1303008-01 | 3 |
| Euro OTC | Magnesium sulfate heptahydrate | 1306015-01 | 1 |
| Euro OTC | Magnesium sulfate heptahydrate | 170610 | 1 |
| Fagron | Magnesium sulfate heptahydrate | 12E22-N02 | 1 |
| Fagron | Magnesium sulfate heptahydrate | 12G24-N02 | 1 |
| Fagron | Magnesium sulfate heptahydrate | 12L10-N07 | 5 |
| Fagron | Magnesium sulfate heptahydrate | 12L10-N07 | 1 |
| Fagron | Magnesium sulfate heptahydrate | 13H05-N02 | 1 |
| Fagron | Magnesium sulfate heptahydrate | 26251 | 1 |
| Fagron | Magnesium sulfate heptahydrate | 31161 | 1 |
| fargon | Magnesium sulfate heptahydrate | 12E22-N02 | 1 |
| Gehe | Magnesium sulfate heptahydrate | 12138521 | 2 |
| Gehe | Magnesium sulfate heptahydrate | 21002002001 | 1 |
| Gehe | Magnesium sulfate heptahydrate | 24000129008 | 1 |
| Hedinger | Magnesium sulfate heptahydrate | 204036 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Hedinger | Magnesium sulfate heptahydrate | 204037 | 2 |
| Noweda / 28.10.13 EuRho | Magnesium sulfate heptahydrate | 1211022-01 | 1 |
| Noweda | Magnesium sulfate heptahydrate | 1109023-01 | 1 |
| Noweda | Magnesium sulfate heptahydrate | 22003025001 | 1 |
| Phoenix | Magnesium sulfate heptahydrate | 12L10-N07 | 3 |
| Phoenix | Magnesium sulfate heptahydrate | 24000129002 | 1 |
| Phönix | Magnesium sulfate heptahydrate | 11369526 | 1 |
| Phönix | Magnesium sulfate heptahydrate | 22000333004 | 1 |
| Sanacorp | Magnesium sulfate heptahydrate | 22003025001 | 1 |

- 256 743 spectra from 1666 *Apo-Ident* customers from a total of 52 100 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Magnesium sulfate heptahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Magnesium sulfate heptahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 110 | 0 | 212 830 |
| **Type C** | 0 | 143 | 0 | 256 743 |

The substance/substance group *Magnesium sulfate heptahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 94.5455 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 95.8042 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26054 | 26054 | 0.00 | 71.29 |
| 26055 | 26055 | 0.00 | 145.57 |
| 26561 | 26561 | 0.00 | 67.88 |
| 26882 | 26882 | 0.00 | 76.16 |
| 27105 | 27105 | 0.00 | 89.60 |
| 27431 | 27431 | 0.00 | 79.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Maltodextrin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20709-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Maltodextrin; Maltodextrinum

### Special notes

When selecting the *Maltodextrin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Maltodextrin | 2 | 1 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Maltodextrin* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Maltodextrin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Rice starch | 24.19 | 15.59 |
| SyrSpend® SF pH4 neo (Maize starch) | 26.48 | 13.12 |
| Cannabis flower, THC-dominant type | 30.38 | – |
| SyrSpend® SF pH4 | 33.13 | 20.72 |
| Wheat starch | 33.93 | 17.56 |
| Corn starch | 35.62 | 24.39 |
| SyrSpend® SF Alka | 42.26 | 18.56 |
| Cannabis flower, CBD-dominant type | 48.69 | – |
| Acacia, dried dispersion | 53.26 | 30.64 |
| ⋮ | ⋮ | ⋮ |
| Potato starch | >50 | 19.31 |
| Carmellose sodium | >50 | 25.60 |
| Colistin sulfate | >50 | 30.10 |
| Polymyxin B sulfate | >50 | 37.31 |
| Calcium glycerophosphate | >50 | 43.60 |
| Bacitracin | >50 | 57.18 |
| Riboflavin | >50 | 64.38 |
| Cyanocobalamin | >50 | 67.77 |
| Tosylchloramide sodium | >50 | 81.37 |
| Fructose | >50 | 84.90 |
| Amphotericin B | >50 | 85.23 |
| Calcium pantothenate | >50 | 87.55 |
| Nystatin | >50 | 91.83 |
| Oxalic acid | >50 | 106.89 |
| Gelatine, white | >50 | 112.32 |
| Hyoscine hydrobromide | >50 | 121.91 |
| Estradiol hemihydrate | >50 | 128.86 |
| Triamcinolone | >50 | 136.90 |
| alpha-tocopheryl acetate dry concentrate | >50 | 141.66 |
| Estriol | >50 | 174.89 |
| Methylcobalamin | >50 | 191.28 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Maltodextrin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Maltodextrin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Gatt-Koller | Maltodextrin | 21J01645 | 26382 | 40 | 20210909 |
| Gatt-Koller | Maltodextrin | 21J01645 | 26382SI | 20 | 20210909 |
| Inresa | Maltodextrin | R1503902 | 21806 | 60 | AR-15-FG-008821-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 120 spectra of 3 reference samples from the substance/substance group *Maltodextrin*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

- 158 206 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 1 reference samples from the substance/substance group *Maltodextrin*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Inresa | Maltodextrin | R1600014 | 22314 | 60 |

- 212 880 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 5 spectra from 2 *Apo-Ident* customers from 3 batches from the substance/substance group *Maltodextrin*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| HBK Gesundheit | Maltodextrin | 1143 | 3 |
| HBK Gesundheit | Maltodextrin | 2343 | 1 |
| Phönix | Maltodextrin | LOT20250206JB | 1 |

- 256 881 spectra from 1666 *Apo-Ident* customers from a total of 52 150 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Maltodextrin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Maltodextrin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 120 | 0 | 158 206 |
| **Type B** | 0 | 60 | 0 | 212 880 |
| **Type C** | 0 | 5 | 0 | 256 881 |

The substance/substance group *Maltodextrin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.0000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21806 | 21806 | 0.00 | 42.77 |
| 26382 | 21806 | 14.82 | 43.91 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Manganese orotate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22311-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Manganese orotate dihydrate

### Special notes

When selecting the *Manganese orotate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Manganese orotate dihydrate | 5 | 2 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Manganese orotate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Manganese orotate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Magnesium orotate dihydrate | 83.24 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Manganese orotate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Manganese orotate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Manganese orotate dihydrate | 1601003 | 22311 | 60 | 20160113* |
| Euro OTC | Manganese orotate dihydrate | 1801031 | 23908 | 40 | 20180131* |
| Euro OTC | Manganese orotate dihydrate | 1907009 | 24787 | 40 | 20190718* |
| Euro OTC | Manganese orotate dihydrate | 2208027 | 26265 | 40 | 20220905* |
| Euro OTC | Manganese orotate dihydrate | 2311027 | 27073 | 40 | 20231221* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 220 spectra of 5 reference samples from the substance/substance group *Manganese orotate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 106 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 5 reference samples from the substance/substance group *Manganese orotate dihydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Manganese orotate dihydrate | 1605029-01 | 22654 | 40 |
| Euro OTC | Manganese orotate dihydrate | 2010007 | 25466 | 40 |
| Euro OTC | Manganese orotate dihydrate | 1605029-01 | 22737 | 40 |
| Euro OTC | Manganese orotate dihydrate | 2208027 | 26265SI† | 20 |
| Euro OTC | Manganese orotate dihydrate | 2311027 | 27073SI† | 20 |

- 212 780 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Manganese orotate dihydrate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Manganese orotate dihydrate | 1907009-02 | 1 |

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 256 885 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Manganese orotate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Manganese orotate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 220 | 0 | 158 106 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 1 | 0 | 256 885 |

The substance/substance group *Manganese orotate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.2727 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9038 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22311 | 22311 | 0.00 | 163.40 |
| 23908 | 23908 | 0.00 | 146.35 |
| 24787 | 24787 | 0.00 | 144.96 |
| 26265 | 26265 | 0.00 | 162.04 |
| 27073 | 27073 | 0.00 | 165.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Manganese sulfate monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20404-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Manganese sulfate monohydrate; Manganese sulphate monohydrate; Mangani sulfas monohydricus

### Special notes

When selecting the *Manganese sulfate monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Manganese sulfate monohydrate | 3 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Manganese sulfate monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Manganese sulfate monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 76.47 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Manganese sulfate monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Manganese sulfate monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Manganese sulfate monohydrate | 171648 | 24404 | 40 | 20170714* |
| Euro OTC | Manganese sulfate monohydrate | 2305003 | 26771 | 40 | 20230630* |
| Euro OTC | Manganese sulfate monohydrate | 2305003 | 26771SI | 20 | 20230630* |
| Euro OTC | Manganese sulfate monohydrate | 2505020 | 27674 | 40 | 20250703* |
| Euro OTC | Manganese sulfate monohydrate | 2505020 | 27674SI | 20 | 20250703* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 160 spectra of 5 reference samples from the substance/substance group *Manganese sulfate monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 166 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 50 spectra of 2 reference samples from the substance/substance group *Manganese sulfate monohydrate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Manganese sulfate monohydrate | 2202003 | 26047 | 40 |
| Euro OTC | Manganese sulfate monohydrate | 2202003 | 26047SI | 10 |

- 212 890 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Manganese sulfate monohydrate*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Manganese sulfate monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Manganese sulfate monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct

or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 160 | 0 | 158 166 |
| **Type B** | 0 | 50 | 0 | 212 890 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Manganese sulfate monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.2500 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 88.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24404 | 24404 | 0.00 | 208.61 |
| 26771 | 26771 | 0.00 | 234.58 |
| 27674 | 27674 | 0.00 | 230.24 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Mannitol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20118-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Mannitol; Mannitolum

### Special notes

When selecting the *Mannitol* substance/substance group, the following information is displayed to the user:

- Advice: The presence and absence of silica is not detectable by means of NIR. Please check the bulk density if necessary.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Mannitol | 8 | 38 | 939 |

### Second-stage model

For differentiation of the substance/substance group *Mannitol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Mannitol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 81.81 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Mannitol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Mannitol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Mannitol | 12305723 | 20980 | 40 | 1402329 |
| Caelo | Mannitol | 15197305 | 22581 | 40 | 20150720 |
| Euro OTC | Mannitol | 1508012 | 21884 | 60 | 20150827* |
| Euro OTC | Mannitol | 1511025 | 22286 | 60 | 20151228* |
| Euro OTC | Mannitol | 2011022 | 25548 | 40 | 20210112* |
| Fagron | Mannitol | 15A26-B01-305841 | 22883 | 40 | 20150204 |
| Fagron | Mannitol | 15A26-B01-305841 | 22884 | 40 | 20150204 |
| Fagron | Mannitol | 17B08-B04-352402 | 24579 | 40 | 20170517 |
| Fagron | Mannitol | 22D25-B04-224320 | 26396 | 40 | 20220629 |
| Fagron | Mannitol | 22D25-B04-224320 | 26396SI | 20 | 20220629 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 10 reference samples from the substance/substance group *Mannitol*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 906 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1750 spectra of 45 reference samples from the substance/substance group *Mannitol*.

- Among them are spectra of independent samples from 38 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Mannitol | 160140 | 22458 | 60 |
| Caelo | Mannitol | 16014013 | 22580 | 40 |
| Caelo | Mannitol | 162009 | 22614 | 40 |
| Caelo | Mannitol | 162121 | 22721 | 40 |
| Caelo | Mannitol | 170879 | 23296 | 40 |
| Caelo | Mannitol | 170450 | 23318 | 40 |
| Caelo | Mannitol | 172588 | 23800 | 40 |
| Caelo | Mannitol | 182654 | 24368 | 40 |
| Caelo | Mannitol | 182655 | 24385 | 40 |
| Caelo | Mannitol | 191654 | 24723 | 40 |
| Caelo | Mannitol | 22001495 | 26249 | 40 |
| Caelo | Mannitol | 24000339 | 27137 | 40 |
| Caelo | Mannitol | 24002856 | 27542 | 40 |
| Caelo | Mannitol | 24002857 | 27554 | 40 |
| Euro OTC | Mannitol | 1604008 | 22515 | 40 |
| Euro OTC | Mannitol | 1606031 | 22697 | 40 |
| Euro OTC | Mannitol | 1610027 | 22862 | 40 |
| Euro OTC | Mannitol | 1703043 | 23125 | 40 |
| Euro OTC | Mannitol | 1708005 | 23700 | 40 |
| Euro OTC | Mannitol | 1802004 | 23966 | 40 |
| Euro OTC | Mannitol | 1806024 | 24152 | 40 |
| Euro OTC | Mannitol | 1809008 | 24327 | 40 |
| Euro OTC | Mannitol | 1902011 | 24476 | 40 |
| Euro OTC | Mannitol | 1904025 | 24600 | 40 |
| Euro OTC | Mannitol | 1908019 | 24857 | 40 |
| Euro OTC | Mannitol | 2004015 | 25161 | 40 |
| Euro OTC | Mannitol | 2008030 | 25323 | 40 |
| Euro OTC | Mannitol | 2105014 | 25678 | 40 |
| Euro OTC | Mannitol | 2108016 | 25822 | 50 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Mannitol | 2108015 | 25826 | 50 |
| Euro OTC | Mannitol | 2108014 | 25828 | 50 |
| Euro OTC | Mannitol | 2201036 | 25957 | 40 |
| Euro OTC | Mannitol | 2205036 | 26218 | 40 |
| Euro OTC | Mannitol | 2209020 | 26343 | 40 |
| Euro OTC | Mannitol | 2301038 | 26598 | 40 |
| Euro OTC | Mannitol | 2307004 | 26858 | 40 |
| Euro OTC | Mannitol | 2401022 | 27149 | 40 |
| Fagron | Mannitol | 18H16-B01 | 24817 | 40 |
| Caelo | Mannitol | 162121 | 23066 | 30 |
| Caelo | Mannitol | 160140 | 23299 | 40 |
| Caelo | Mannitol | 170879 | 23305 | 40 |
| Caelo | Mannitol | 22001495 | 26249SI | 20 |
| Euro OTC | Mannitol | 2201036 | 25957SI | 10 |
| Euro OTC | Mannitol | 2205036 | 26218SI | 20 |
| Euro OTC | Mannitol | 2209020 | 26343SI | 20 |

- 211 190 spectra from a total of 4249 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3551 spectra from 900 *Apo-Ident* customers from 948 batches from the substance/substance group *Mannitol*.

- Among them are spectra of independent samples from 937 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Mannitol | 1310004-02 | 2 |
| | Mannitol | 20003605012 | 1 |
| | Mannitol | 201023/2 | 1 |
| | Mannitol | 21000744042 | 1 |
| | Mannitol | 21K16-B11-216336 | 4 |
| | Mannitol | 22001495005 | 2 |
| | Mannitol | 22001495015 | 8 |
| | Mannitol | 22001495017 | 3 |
| | Mannitol | 22001495019 | 1 |
| | Mannitol | 22001495023 | 4 |
| | Mannitol | 22001495041 | 3 |
| | Mannitol | 22001495046 | 2 |
| | Mannitol | 2200171200 | 1 |
| | Mannitol | 22001712003 | 1 |
| | Mannitol | 22001712004 | 2 |
| | Mannitol | 22001712007 | 1 |
| | Mannitol | 22001712008 | 7 |
| | Mannitol | 22001712009 | 1 |
| | Mannitol | 22001712010 | 3 |
| | Mannitol | 22001712011 | 14 |
| | Mannitol | 22001712012 | 7 |
| | Mannitol | 220017172004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Mannitol | 2201036-01 | 2 |
| | Mannitol | 2201495041 | 1 |
| | Mannitol | 2205036-01 | 6 |
| | Mannitol | 2209020-01 | 9 |
| | Mannitol | 22B22-F09 | 1 |
| | Mannitol | 22D25B04233813 | 1 |
| | Mannitol | 22D25-B04-233814 | 1 |
| | Mannitol | 22D25-B04-238188 | 1 |
| | Mannitol | 22E23-F15-38121 | 2 |
| | Mannitol | 22F15-F10-382723 | 1 |
| | Mannitol | 22F15-F15 | 2 |
| | Mannitol | 22F15-F19-382741 | 1 |
| | Mannitol | 22F15-F20-382742 | 1 |
| | Mannitol | 230103801 | 1 |
| | Mannitol | 2301038-01 | 3 |
| | Mannitol | 2307004-01 | 9 |
| | Mannitol | 231038-01 | 1 |
| | Mannitol | 2312007-01 | 3 |
| | Mannitol | 23A10-F03-384081 | 1 |
| | Mannitol | 23A10-F09 | 1 |
| | Mannitol | 23A10-F09-384083 | 1 |
| | Mannitol | 23A24F02-384302 | 1 |
| | Mannitol | 23A24-F02-384302 | 2 |
| | Mannitol | 23A24-F03-284303 | 1 |
| | Mannitol | 23A24-F03-38303 | 1 |
| | Mannitol | 23A24-F03-384303 | 3 |
| | Mannitol | 23A24-F05-384305 | 3 |
| | Mannitol | 23A24-F06-384306 | 2 |
| | Mannitol | 23A24-F07-384307 | 3 |
| | Mannitol | 23a24f13384485 | 1 |
| | Mannitol | 23A24-F14 | 1 |
| | Mannitol | 23A24-F14-384486 | 1 |
| | Mannitol | 23A24-F15-384487 | 3 |
| | Mannitol | 23H01-F02-385155 | 1 |
| | Mannitol | 23I01-F01-385405 | 1 |
| | Mannitol | 24/11-M07-002521 | 2 |
| | Mannitol | 24000339007 | 8 |
| | Mannitol | 24000339008 | 2 |
| | Mannitol | 24000339009 | 6 |
| | Mannitol | 24000339011 | 2 |
| | Mannitol | 24000339012 | 1 |
| | Mannitol | 24000339015 | 2 |
| | Mannitol | 24000339019 | 3 |
| | Mannitol | 24000339024 | 3 |
| | Mannitol | 24000339025 | 3 |
| | Mannitol | 24000356001 | 6 |
| | Mannitol | 24000356002 | 8 |
| | Mannitol | 24000356003 | 6 |
| | Mannitol | 24000356005 | 4 |
| | Mannitol | 24000356006 | 4 |
| | Mannitol | 24000356007 | 4 |
| | Mannitol | 24000356009 | 4 |
| | Mannitol | 24000356010 | 5 |
| | Mannitol | 24000356011 | 3 |
| | Mannitol | 24000356012 | 1 |
| | Mannitol | 24000356013 | 1 |
| | Mannitol | 24002857003 | 17 |
| | Mannitol | 2400356001 | 1 |
| | Mannitol | 240102201 | 1 |
| | Mannitol | 2401022-01 | 11 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Mannitol | 2401022-02 | 4 |
| | Mannitol | 2402857003 | 1 |
| | Mannitol | 241022-01 | 1 |
| | Mannitol | 241219(24000356011) | 1 |
| | Mannitol | 24C29-B01-239738 | 1 |
| | Mannitol | 24G11-M03-000879 | 1 |
| | Mannitol | 24G11-M04-000878 | 1 |
| | Mannitol | 24I11-M04-002456 | 1 |
| | Mannitol | 24I26-M07-003014 | 1 |
| | Mannitol | 250409(24000356012) | 1 |
| | Mannitol | 25C13-M02-009052 | 1 |
| | Mannitol | M03-00087009 | 1 |
| AEP | Mannitol | 23A24-F03_384303 | 1 |
| AEP | Mannitol | 23I06-F01-385431 | 1 |
| AEP | Mannitol | 24000356002 | 2 |
| AHC | Mannitol | 18265511 | 1 |
| AHC | Mannitol | 20000958003 | 1 |
| AHC | Mannitol | 23I01-F01 | 1 |
| AHD/EuRho02 | Mannitol | 1904025-02 | 1 |
| AHD | Mannitol | 2200195015 | 1 |
| AHD | Mannitol | 22D25-B04-233814 | 1 |
| AHD | Mannitol | 23A24-F04-384304 | 1 |
| AHD | Mannitol | 23A24-F05-384305 | 1 |
| ALH/EuRho | Mannitol | 1802004-01 | 1 |
| ALH | Mannitol | 1409016-01 | 1 |
| ALH | Mannitol | 1610027-01 | 2 |
| ALH | Mannitol | 1703043-01 | 1 |
| Alliance / Fargon | Mannitol | 19B12-B02-359604 | 1 |
| Alliance Health 17.0... | Mannitol | 1310004-01 | 3 |
| Alliance Healthcare | Mannitol | 18265409 | 1 |
| Alliance Healthcare | Mannitol | 2004015-01 | 1 |
| alliance | Mannitol | 2307004-01 | 1 |
| Allianz Healthcare 2... | Mannitol | 1502022-01 | 1 |
| allianz | Mannitol | 16212101 | 2 |
| Anzag 05.10.17 8,04EUR | Mannitol | 17045002 | 1 |
| Anzag 09.01.15 | Mannitol | 1404034-01 | 2 |
| ANZAG | Mannitol | 1211034-01 | 1 |
| Anzag | Mannitol | 1310004-02 | 1 |
| Apo Ident/ Noweda | Mannitol | 1610027-01 | 1 |
| ApoIdent/Noweda | Mannitol | 1610027-01 | 1 |
| apomix | Mannitol | 1310004-01 | 1 |
| Beiersdorf | Mannitol | 14051217 | 2 |
| Bombastus | Mannitol | 16340301 | 1 |
| Caeleo/ Kehr | Mannitol | 182654001 | 1 |
| Caelo | Mannitol | | 1 |
| Caelo | Mannitol | 10011501 | 1 |
| Caelo | Mannitol | 10100026 | 2 |
| Caelo | Mannitol | 1071701 | 1 |
| Caelo | Mannitol | 11(16200912) | 1 |
| Caelo | Mannitol | 11003611 | 1 |
| Caelo | Mannitol | 1110009-02 | 1 |
| Caelo | Mannitol | 11219121 | 1 |
| Caelo | Mannitol | 11219122 | 1 |
| Caelo | Mannitol | 11219124 | 2 |
| Caelo | Mannitol | 11308807 | 2 |
| Caelo | Mannitol | 11D01-N10 | 1 |
| Caelo | Mannitol | 12(18265410) | 1 |
| Caelo | Mannitol | 1205016-02 | 2 |
| Caelo | Mannitol | 12105403 | 3 |
| Caelo | Mannitol | 12105404 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mannitol | 12105405 | 1 |
| Caelo | Mannitol | 12105420 | 7 |
| Caelo | Mannitol | 12105421 | 9 |
| Caelo | Mannitol | 12105433 | 9 |
| Caelo | Mannitol | 12105438 | 2 |
| Caelo | Mannitol | 1211034-01 | 1 |
| Caelo | Mannitol | 12305709 | 16 |
| Caelo | Mannitol | 12305710 | 8 |
| Caelo | Mannitol | 12305723 | 4 |
| Caelo | Mannitol | 12305724 | 5 |
| Caelo | Mannitol | 12305725 | 11 |
| Caelo | Mannitol | 12305725-3444311112 | 1 |
| Caelo | Mannitol | 12305726 | 1 |
| Caelo | Mannitol | 12305728 | 2 |
| Caelo | Mannitol | 12305734 | 2 |
| Caelo | Mannitol | 12305736 | 4 |
| Caelo | Mannitol | 12305740 | 2 |
| Caelo | Mannitol | 1230578 | 1 |
| Caelo | Mannitol | 12411754 | 1 |
| Caelo | Mannitol | 13(17258819) | 1 |
| Caelo | Mannitol | 1305043-02 | 1 |
| Caelo | Mannitol | 13095013 | 1 |
| Caelo | Mannitol | 1310004-01 | 3 |
| Caelo | Mannitol | 13189201 | 8 |
| Caelo | Mannitol | 13189203 | 6 |
| Caelo | Mannitol | 13189203-3566412081 | 1 |
| Caelo | Mannitol | 13189206 | 1 |
| Caelo | Mannitol | 13189207 | 8 |
| Caelo | Mannitol | 13189208 | 6 |
| Caelo | Mannitol | 13189215 | 17 |
| Caelo | Mannitol | 13189222 | 3 |
| Caelo | Mannitol | 13189226 | 4 |
| Caelo | Mannitol | 13189227 | 11 |
| Caelo | Mannitol | 13189228 | 1 |
| Caelo | Mannitol | 13K20-B01-287704 | 1 |
| Caelo | Mannitol | 14(20000685001) | 1 |
| Caelo | Mannitol | 1400434-01 | 1 |
| Caelo | Mannitol | 1404034-01 | 2 |
| Caelo | Mannitol | 14051204 | 8 |
| Caelo | Mannitol | 14051205 | 7 |
| Caelo | Mannitol | 14051207 | 1 |
| Caelo | Mannitol | 14051208 | 2 |
| Caelo | Mannitol | 14051209 | 7 |
| Caelo | Mannitol | 14051215 | 7 |
| Caelo | Mannitol | 14051216 | 3 |
| Caelo | Mannitol | 14051223 | 1 |
| Caelo | Mannitol | 14051224 | 2 |
| Caelo | Mannitol | 14051229 | 6 |
| Caelo | Mannitol | 14051230 | 2 |
| Caelo | Mannitol | 1405127 | 1 |
| Caelo | Mannitol | 1409016-01 | 2 |
| Caelo | Mannitol | 1423120 | 1 |
| Caelo | Mannitol | 14323103 | 3 |
| Caelo | Mannitol | 14323105 | 2 |
| Caelo | Mannitol | 14323113 | 1 |
| Caelo | Mannitol | 14323114 | 3 |
| Caelo | Mannitol | 14323115 | 4 |
| Caelo | Mannitol | 14323120 | 1 |
| Caelo | Mannitol | 14323121 | 6 |
| Caelo | Mannitol | 14323124 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mannitol | 14323125 | 2 |
| Caelo | Mannitol | 14323126 | 4 |
| Caelo | Mannitol | 14323127 | 5 |
| Caelo | Mannitol | 14323129 | 1 |
| Caelo | Mannitol | 14323138 | 26 |
| Caelo | Mannitol | 14G04-B07-301693 | 2 |
| Caelo | Mannitol | 14g04-b07-30692 | 1 |
| Caelo | Mannitol | 1502022-01 | 1 |
| Caelo | Mannitol | 1508012-01 | 2 |
| Caelo | Mannitol | 1508012-02 | 1 |
| Caelo | Mannitol | 1511025-01 | 1 |
| Caelo | Mannitol | 151117 | 1 |
| Caelo | Mannitol | 15184101 | 1 |
| Caelo | Mannitol | 1519713 | 1 |
| Caelo | Mannitol | 15197219 | 1 |
| Caelo | Mannitol | 15197301 | 12 |
| Caelo | Mannitol | 15197302 | 5 |
| Caelo | Mannitol | 15197303 | 1 |
| Caelo | Mannitol | 15197312 | 1 |
| Caelo | Mannitol | 15197313 | 17 |
| Caelo | Mannitol | 15197314 | 6 |
| Caelo | Mannitol | 15197319 | 8 |
| Caelo | Mannitol | 15197327 | 1 |
| Caelo | Mannitol | 15197329 | 1 |
| Caelo | Mannitol | 15525 | 1 |
| Caelo | Mannitol | 15D28-B02-309192 | 6 |
| Caelo | Mannitol | 15K25-B04 | 1 |
| Caelo | Mannitol | 16011402 | 1 |
| Caelo | Mannitol | 16014005 | 12 |
| Caelo | Mannitol | 16014013 | 1 |
| Caelo | Mannitol | 16014014 | 1 |
| Caelo | Mannitol | 16014016 | 1 |
| Caelo | Mannitol | 160400801 | 2 |
| Caelo | Mannitol | 1606031-02 | 1 |
| Caelo | Mannitol | 16061401 | 1 |
| Caelo | Mannitol | 1610018-01 | 1 |
| Caelo | Mannitol | 1610027-01 | 1 |
| Caelo | Mannitol | 1612101 | 1 |
| Caelo | Mannitol | 16200901 | 2 |
| Caelo | Mannitol | 16200903 | 14 |
| Caelo | Mannitol | 16200904 | 2 |
| Caelo | Mannitol | 16200908 | 2 |
| Caelo | Mannitol | 16200909 | 1 |
| Caelo | Mannitol | 16200912 | 5 |
| Caelo | Mannitol | 16200913 | 4 |
| Caelo | Mannitol | 16200916 | 2 |
| Caelo | Mannitol | 16200924 | 11 |
| Caelo | Mannitol | 162121 | 1 |
| Caelo | Mannitol | 16212101 | 14 |
| Caelo | Mannitol | 16212102 | 15 |
| Caelo | Mannitol | 16212103 | 1 |
| Caelo | Mannitol | 16212104 | 2 |
| Caelo | Mannitol | 16212106 | 4 |
| Caelo | Mannitol | 16212109 | 4 |
| Caelo | Mannitol | 1621212 | 1 |
| Caelo | Mannitol | 16236603 | 1 |
| Caelo | Mannitol | 163403 | 1 |
| Caelo | Mannitol | 16340301 | 16 |
| Caelo | Mannitol | 16340302 | 8 |
| Caelo | Mannitol | 16D20-B03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mannitol | 16F27-B05-324516 | 1 |
| Caelo | Mannitol | 16G27-B03 | 1 |
| Caelo | Mannitol | 16H25-B03-326639 | 1 |
| Caelo | Mannitol | 16H29-B05-327813 | 1 |
| Caelo | Mannitol | 16L15-B04-329317 | 1 |
| Caelo | Mannitol | 17/13-B03-340967 | 1 |
| Caelo | Mannitol | 17/13-B11 | 1 |
| Caelo | Mannitol | 1703043-01 | 1 |
| Caelo | Mannitol | 170450 | 1 |
| Caelo | Mannitol | 17045001 | 4 |
| Caelo | Mannitol | 17045002 | 19 |
| Caelo | Mannitol | 17045003 | 9 |
| Caelo | Mannitol | 17045004 | 3 |
| Caelo | Mannitol | 17045006 | 2 |
| Caelo | Mannitol | 17045008 | 7 |
| Caelo | Mannitol | 17045009 | 20 |
| Caelo | Mannitol | 17045010 | 5 |
| Caelo | Mannitol | 17050032/3 | 1 |
| Caelo | Mannitol | 170800501 | 1 |
| Caelo | Mannitol | 1708005-01 | 1 |
| Caelo | Mannitol | 17087907 | 1 |
| Caelo | Mannitol | 17087908 | 9 |
| Caelo | Mannitol | 17087909 | 3 |
| Caelo | Mannitol | 17087915 | 2 |
| Caelo | Mannitol | 17087916 | 21 |
| Caelo | Mannitol | 17258808 | 5 |
| Caelo | Mannitol | 17258809 | 11 |
| Caelo | Mannitol | 17258812 | 7 |
| Caelo | Mannitol | 17258819 | 5 |
| Caelo | Mannitol | 17258820 | 7 |
| Caelo | Mannitol | 17258823 | 3 |
| Caelo | Mannitol | 17258830 | 4 |
| Caelo | Mannitol | 17258830/P-09041922 | 1 |
| Caelo | Mannitol | 17258830/P-23051923 | 1 |
| Caelo | Mannitol | 17258831 | 4 |
| Caelo | Mannitol | 17260101 | 1 |
| Caelo | Mannitol | 17360101 | 21 |
| Caelo | Mannitol | 17360108 | 22 |
| Caelo | Mannitol | 17360110 | 5 |
| Caelo | Mannitol | 17360112 | 11 |
| Caelo | Mannitol | 17360114 | 1 |
| Caelo | Mannitol | 17360115 | 8 |
| Caelo | Mannitol | 17A12-B03 | 1 |
| Caelo | Mannitol | 17I13-B02-340966 | 1 |
| Caelo | Mannitol | 17j23-B05 | 1 |
| Caelo | Mannitol | 17J30B09343413 | 1 |
| Caelo | Mannitol | 17J30-B10-3434414 | 1 |
| Caelo | Mannitol | 17K29-B07-344253 | 1 |
| Caelo | Mannitol | 1802004-01 | 2 |
| Caelo | Mannitol | 180602401 | 1 |
| Caelo | Mannitol | 1806024-01 | 2 |
| Caelo | Mannitol | 1809008-01 | 3 |
| Caelo | Mannitol | 18121701 | 1 |
| Caelo | Mannitol | 1826504001 | 1 |
| Caelo | Mannitol | 182654001 | 1 |
| Caelo | Mannitol | 18265409 | 1 |
| Caelo | Mannitol | 18265410 | 5 |
| Caelo | Mannitol | 18265411 | 7 |
| Caelo | Mannitol | 18265417 | 3 |
| Caelo | Mannitol | 18265418 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mannitol | 18265427 | 1 |
| Caelo | Mannitol | 18265428 | 2 |
| Caelo | Mannitol | 18265429 | 1 |
| Caelo | Mannitol | 18265432 | 3 |
| Caelo | Mannitol | 18265436 | 2 |
| Caelo | Mannitol | 182655001 | 16 |
| Caelo | Mannitol | 182655002 | 1 |
| Caelo | Mannitol | 182655004 | 10 |
| Caelo | Mannitol | 18265502 | 12 |
| Caelo | Mannitol | 18265503 | 1 |
| Caelo | Mannitol | 18265504 | 7 |
| Caelo | Mannitol | 18265505 | 1 |
| Caelo | Mannitol | 18265506 | 18 |
| Caelo | Mannitol | 18265507 | 7 |
| Caelo | Mannitol | 18265508 | 11 |
| Caelo | Mannitol | 18265509 | 6 |
| Caelo | Mannitol | 18265511 | 12 |
| Caelo | Mannitol | 18265512 | 11 |
| Caelo | Mannitol | 18266513 | 1 |
| Caelo | Mannitol | 18A30-B03-346849 | 1 |
| Caelo | Mannitol | 18A30-B08 | 1 |
| Caelo | Mannitol | 18b23-b09 | 1 |
| Caelo | Mannitol | 18D09-B11-351436 | 1 |
| Caelo | Mannitol | 18D09-B12-351437 | 3 |
| Caelo | Mannitol | 18D09-B13-352214 | 2 |
| Caelo | Mannitol | 18D09-B14-352215 | 1 |
| Caelo | Mannitol | 18D09-B16-252503 | 1 |
| Caelo | Mannitol | 18e25-b07-352753 | 1 |
| Caelo | Mannitol | 19120-F15 | 1 |
| Caelo | Mannitol | 191654002 | 1 |
| Caelo | Mannitol | 191654003 | 2 |
| Caelo | Mannitol | 191654004 | 1 |
| Caelo | Mannitol | 19165401 | 6 |
| Caelo | Mannitol | 191654011 | 3 |
| Caelo | Mannitol | 191654012 | 1 |
| Caelo | Mannitol | 19165402 | 3 |
| Caelo | Mannitol | 19165403 | 1 |
| Caelo | Mannitol | 19165407 | 2 |
| Caelo | Mannitol | 19654002 | 1 |
| Caelo | Mannitol | 19L19F14366950 | 1 |
| Caelo | Mannitol | 20000068507 | 1 |
| Caelo | Mannitol | 2000058001 | 1 |
| Caelo | Mannitol | 20000685001 | 10 |
| Caelo | Mannitol | 20000685006 | 2 |
| Caelo | Mannitol | 20000685007 | 2 |
| Caelo | Mannitol | 20000685008 | 1 |
| Caelo | Mannitol | 20000685012 | 12 |
| Caelo | Mannitol | 20000685013 | 3 |
| Caelo | Mannitol | 20000685014 | 2 |
| Caelo | Mannitol | 20000685017 | 1 |
| Caelo | Mannitol | 20000685021 | 1 |
| Caelo | Mannitol | 20000958001 | 11 |
| Caelo | Mannitol | 20000958003 | 7 |
| Caelo | Mannitol | 20000958006 | 7 |
| Caelo | Mannitol | 20000958007 | 6 |
| Caelo | Mannitol | 20001038003 | 1 |
| Caelo | Mannitol | 20002605010 | 1 |
| Caelo | Mannitol | 20003601002 | 1 |
| Caelo | Mannitol | 20003605002 | 8 |
| Caelo | Mannitol | 20003605003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mannitol | 20003605004 | 12 |
| Caelo | Mannitol | 20003605006 | 1 |
| Caelo | Mannitol | 20003605007 | 16 |
| Caelo | Mannitol | 20003605008 | 7 |
| Caelo | Mannitol | 20003605010 | 9 |
| Caelo | Mannitol | 20003605011 | 2 |
| Caelo | Mannitol | 20003605013 | 11 |
| Caelo | Mannitol | 20003605015 | 5 |
| Caelo | Mannitol | 2000360510 | 2 |
| Caelo | Mannitol | 20003605504 | 1 |
| Caelo | Mannitol | 20004038002 | 1 |
| Caelo | Mannitol | 20004038003 | 5 |
| Caelo | Mannitol | 20004038004 | 2 |
| Caelo | Mannitol | 20004038006 | 1 |
| Caelo | Mannitol | 20004038007 | 5 |
| Caelo | Mannitol | 2000685006 | 1 |
| Caelo | Mannitol | 2000685014 | 1 |
| Caelo | Mannitol | 2000958003 | 1 |
| Caelo | Mannitol | 200218P302 | 1 |
| Caelo | Mannitol | 2003605007 | 1 |
| Caelo | Mannitol | 2003605012 | 1 |
| Caelo | Mannitol | 20151012-2 | 1 |
| Caelo | Mannitol | 20B05-F04-369845 | 1 |
| Caelo | Mannitol | 20H21F05373849 | 1 |
| Caelo | Mannitol | 21000744006 | 1 |
| Caelo | Mannitol | 21000744014 | 2 |
| Caelo | Mannitol | 21000744015 | 4 |
| Caelo | Mannitol | 21000744021 | 1 |
| Caelo | Mannitol | 21000744029 | 1 |
| Caelo | Mannitol | 21000744033 | 1 |
| Caelo | Mannitol | 21000744042 | 1 |
| Caelo | Mannitol | 2100074412 | 1 |
| Caelo | Mannitol | 2100074414 | 1 |
| Caelo | Mannitol | 2100342002 | 1 |
| Caelo | Mannitol | 21003432001 | 8 |
| Caelo | Mannitol | 21003432002 | 11 |
| Caelo | Mannitol | 2101401 | 1 |
| Caelo | Mannitol | 210501401 | 1 |
| Caelo | Mannitol | 2105014-01 | 1 |
| Caelo | Mannitol | 22001495002 | 2 |
| Caelo | Mannitol | 22001495005 | 2 |
| Caelo | Mannitol | 22001495009 | 1 |
| Caelo | Mannitol | 2200149501 | 1 |
| Caelo | Mannitol | 22001495016 | 2 |
| Caelo | Mannitol | 22001495017 | 1 |
| Caelo | Mannitol | 22001712001 | 2 |
| Caelo | Mannitol | 22001712003 | 4 |
| Caelo | Mannitol | 22001712004 | 8 |
| Caelo | Mannitol | 22001712007 | 1 |
| Caelo | Mannitol | 22001712011 | 1 |
| Caelo | Mannitol | 221110(20003605008) | 1 |
| Caelo | Mannitol | 2274635 | 1 |
| Caelo | Mannitol | 22B01-F04-381542 | 2 |
| Caelo | Mannitol | 23082013C | 1 |
| Caelo | Mannitol | 24000356003 | 1 |
| Caelo | Mannitol | 24000356008 | 1 |
| Caelo | Mannitol | 24101306 | 1 |
| Caelo | Mannitol | 27101802 | 1 |
| Caelo | Mannitol | 30031502 | 1 |
| Caelo | Mannitol | 30121417 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mannitol | 4414E-01844 | 1 |
| Caelo | Mannitol | 4516E-01844 | 1 |
| Caelo | Mannitol | 48558 | 1 |
| Caelo | Mannitol | 5031304 | 1 |
| Caelo | Mannitol | 514E-01844 | 1 |
| Caelo | Mannitol | 7071404 | 1 |
| Caelo | Mannitol | 8031704 | 1 |
| Caelo | Mannitol | 8720 | 1 |
| Caelo | Mannitol | 9061808 | 1 |
| Caelo | Mannitol | 9081303 | 1 |
| Caelo | Mannitol | 9204719 | 1 |
| Caelo | Mannitol | E911K | 1 |
| Caelo | Mannitol | E976E | 1 |
| Caesar & Lorenz GmbH | Mannitol | 18265507 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 16200908 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 18265509 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 21003432002 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 21000744006 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 17258819 | 1 |
| Caesar & Loretz GmbH/AHD | Mannitol | 20003605011 | 1 |
| Caesar & Loretz GmbH/GEHE | Mannitol | 182655001 | 1 |
| Caesar & Loretz GmbH/GEHE | Mannitol | 20000958003 | 1 |
| Caesar & Loretz GmbH/GEHE | Mannitol | 20000958007 | 1 |
| Caesar & Loretz GmbH/GEHE | Mannitol | 20003605002 | 2 |
| Caesar & Loretz GmbH... | Mannitol | 191654004 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 20000685007 | 4 |
| Caesar & Loretz GmbH... | Mannitol | 20004038004 | 2 |
| Caesar & Loretz GmbH... | Mannitol | 18265509 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 18265512 | 1 |
| Caesar & Loretz GmbH/Kehr | Mannitol | 182655001 | 1 |
| Caesar & Loretz GmbH/Kehr | Mannitol | 18265508 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 18265417 | 3 |
| Caesar & Loretz GmbH... | Mannitol | 18265432 | 3 |
| Caesar & Loretz GmbH... | Mannitol | 17258809 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 18265511 | 2 |
| Caesar & Loretz GmbH/Phö | Mannitol | 20000958003 | 1 |
| Caesar & Loretz GmbH/Phoe | Mannitol | 20003605007 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 20003605012 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 22001712004 | 14 |
| Caesar & Loretz GmbH... | Mannitol | 20000685014 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 20003605002 | 1 |
| Caesar & Loretz GmbH/Sana | Mannitol | 20003605002 | 1 |
| Caesar & Loretz GmbH... | Mannitol | 2000058001 | 1 |
| Caesar & Loretz GmbH | Mannitol | 13189207 | 1 |
| Caesar & Loretz GmbH | Mannitol | 14323119 | 1 |
| Caesar & Loretz GmbH | Mannitol | 17087915 | 1 |
| Caesar & Loretz GmbH | Mannitol | 17258809 | 2 |
| Caesar & Loretz GmbH | Mannitol | 17258819 | 1 |
| Caesar & Loretz GmbH | Mannitol | 17258820 | 1 |
| Caesar & Loretz GmbH | Mannitol | 17258823 | 2 |
| Caesar & Loretz GmbH | Mannitol | 17360112 | 1 |
| Caesar & Loretz GmbH | Mannitol | 17360114 | 2 |
| Caesar & Loretz GmbH | Mannitol | 1826508 | 1 |
| Caesar & Loretz GmbH | Mannitol | 18265408 | 2 |
| Caesar & Loretz GmbH | Mannitol | 18265409 | 1 |
| Caesar & Loretz GmbH | Mannitol | 18265418 | 2 |
| Caesar & Loretz GmbH | Mannitol | 18265431 | 1 |
| Caesar & Loretz GmbH | Mannitol | 182655001 | 7 |
| Caesar & Loretz GmbH | Mannitol | 182655002 | 5 |
| Caesar & Loretz GmbH | Mannitol | 182655004 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Mannitol | 18265502 | 6 |
| Caesar & Loretz GmbH | Mannitol | 18265503 | 2 |
| Caesar & Loretz GmbH | Mannitol | 18265504 | 5 |
| Caesar & Loretz GmbH | Mannitol | 18265505 | 4 |
| Caesar & Loretz GmbH | Mannitol | 18265506 | 3 |
| Caesar & Loretz GmbH | Mannitol | 18265507 | 1 |
| Caesar & Loretz GmbH | Mannitol | 18265508 | 10 |
| Caesar & Loretz GmbH | Mannitol | 18265509 | 1 |
| Caesar & Loretz GmbH | Mannitol | 18265510 | 1 |
| Caesar & Loretz GmbH | Mannitol | 18265511 | 4 |
| Caesar & Loretz GmbH | Mannitol | 18265512 | 2 |
| Caesar & Loretz GmbH | Mannitol | 191654004 | 3 |
| Caesar & Loretz GmbH | Mannitol | 19165401 | 3 |
| Caesar & Loretz GmbH | Mannitol | 191654012 | 1 |
| Caesar & Loretz GmbH | Mannitol | 20000685007 | 1 |
| Caesar & Loretz GmbH | Mannitol | 20000685012 | 3 |
| Caesar & Loretz GmbH | Mannitol | 20000958001 | 5 |
| Caesar & Loretz GmbH | Mannitol | 20000958003 | 2 |
| Caesar & Loretz GmbH | Mannitol | 20000958006 | 1 |
| Caesar & Loretz GmbH | Mannitol | 20000958007 | 6 |
| Caesar & Loretz GmbH | Mannitol | 20003605002 | 3 |
| Caesar & Loretz GmbH | Mannitol | 20003605004 | 3 |
| Caesar & Loretz GmbH | Mannitol | 20003605006 | 1 |
| Caesar & Loretz GmbH | Mannitol | 20003605007 | 2 |
| Caesar & Loretz GmbH | Mannitol | 20003605008 | 1 |
| Caesar & Loretz GmbH | Mannitol | 20003605010 | 2 |
| Caesar & Loretz GmbH | Mannitol | 20003605012 | 3 |
| Caesar & Loretz GmbH | Mannitol | 20003605013 | 2 |
| Caesar & Loretz GmbH | Mannitol | 20004038004 | 3 |
| Caesar & Loretz GmbH | Mannitol | 21000744014 | 2 |
| Caesar & Loretz GmbH | Mannitol | 21000744029 | 4 |
| Caesar & Loretz GmbH | Mannitol | 21000744042 | 2 |
| Caesar & Loretz GmbH | Mannitol | 21003432001 | 2 |
| Caesar & Loretz GmbH | Mannitol | 21003432002 | 2 |
| Caesar & Loretz GmbH | Mannitol | 22001495002 | 1 |
| Caesar & Loretz GmbH | Mannitol | 22001495006 | 5 |
| Caesar & Loretz GmbH | Mannitol | 22001495017 | 1 |
| Caesar & Loretz GmbH | Mannitol | 22001712001 | 1 |
| Caesar & Loretz GmbH | Mannitol | 22001712003 | 1 |
| Caesar & Loretz GmbH | Mannitol | 22001712004 | 4 |
| Caesar & Loretz GmbH | Mannitol | 22001712006 | 1 |
| Caesar & Loretz GmbH | Mannitol | 22001712007 | 1 |
| Caesar & Loretz GmbH | Mannitol | 22001712012 | 1 |
| Caesar & Loretz/Noweda | Mannitol | 182655004 | 1 |
| Caesar & Loretz/Noweda | Mannitol | 20003605004 | 1 |
| Caesar & Loretz/Noweda | Mannitol | 20003605007 | 1 |
| Caesar/Ebert | Mannitol | 17360108 | 1 |
| Caesar | Mannitol | 1508012-1 | 1 |
| Caleo/ Noweda | Mannitol | 18J04-B05-355467 | 1 |
| Calo/Noweda | Mannitol | 23A10-F13-384084 | 1 |
| ceal | Mannitol | 17045006 | 1 |
| Cealo, Noweda | Mannitol | 20003605002 | 1 |
| Cealo/Gehe | Mannitol | 18265502 | 1 |
| cealo | Mannitol | 13189203 | 2 |
| Celo/Phoenix | Mannitol | 20003605004 | 1 |
| Celo | Mannitol | 15197313 | 1 |
| cesar&lorentz/Phönix | Mannitol | 12305710 | 1 |
| Defektur/eigen | Mannitol | 1604008-01 | 1 |
| Delta | Mannitol | 1610027-01 | 1 |
| Ebert & Jacobi | Mannitol | 12305728 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho Pharma | Mannitol | 1704010-01 | 1 |
| EuRho/GEHE | Mannitol | 1409016-01 | 1 |
| EuRho/GEHE | Mannitol | 1409016-02 | 1 |
| EuRho/Gehe | Mannitol | 1802004-01 | 1 |
| EuRho/Noweda | Mannitol | 1703043-01 | 1 |
| EuRho/Noweda | Mannitol | 1806024-01 | 1 |
| EuRho/Noweda | Mannitol | 1904025-01 | 2 |
| EuRho/Phoenix | Mannitol | 1508012-01 | 1 |
| EuRho/Sanac | Mannitol | 1305043-01 | 1 |
| EuRho | Mannitol | 1205016-01 | 1 |
| EuRho | Mannitol | 1211034-01 | 1 |
| EuRho | Mannitol | 1211034-02 | 1 |
| EuRho | Mannitol | 1404034-01 | 1 |
| EuRho | Mannitol | 1409016-01 | 3 |
| EuRho | Mannitol | 1502022-02 | 1 |
| EuRho | Mannitol | 1508012-01 | 2 |
| EuRho | Mannitol | 1511025-01 | 1 |
| EuRho | Mannitol | 1806024-01 | 3 |
| EuRho | Mannitol | 1911M-01844 | 1 |
| EuRho | Mannitol | 2108016-01 | 1 |
| EuRhoPha | Mannitol | 1404034-01 | 1 |
| Euro OTC | Mannitol | 1006019-01 | 1 |
| Euro OTC | Mannitol | 10112014E | 1 |
| Euro OTC | Mannitol | 1104028-01 | 1 |
| Euro OTC | Mannitol | 1104028-03 | 3 |
| Euro OTC | Mannitol | 1110009-01 | 10 |
| Euro OTC | Mannitol | 1110009-02 | 4 |
| Euro OTC | Mannitol | 111100009-02 | 1 |
| Euro OTC | Mannitol | 1205016 | 1 |
| Euro OTC | Mannitol | 1205016-01 | 12 |
| Euro OTC | Mannitol | 1205016-02 | 2 |
| Euro OTC | Mannitol | 1211034-01 | 9 |
| Euro OTC | Mannitol | 1211034-02 | 16 |
| Euro OTC | Mannitol | 1305043 | 1 |
| Euro OTC | Mannitol | 130504301 | 1 |
| Euro OTC | Mannitol | 1305043-01 | 12 |
| Euro OTC | Mannitol | 1305043-02 | 16 |
| Euro OTC | Mannitol | 1310004-01 | 14 |
| Euro OTC | Mannitol | 1310004-02 | 6 |
| Euro OTC | Mannitol | 13155710 | 1 |
| Euro OTC | Mannitol | 13189216 | 2 |
| Euro OTC | Mannitol | 14003402 | 1 |
| Euro OTC | Mannitol | 140403401 | 1 |
| Euro OTC | Mannitol | 1404034-01 | 15 |
| Euro OTC | Mannitol | 140403402 | 2 |
| Euro OTC | Mannitol | 1404034-02 | 18 |
| Euro OTC | Mannitol | 1404036-02 | 1 |
| Euro OTC | Mannitol | 1409016-01 | 16 |
| Euro OTC | Mannitol | 1409016-02 | 6 |
| Euro OTC | Mannitol | 1409016-1 | 1 |
| Euro OTC | Mannitol | 14323101 | 3 |
| Euro OTC | Mannitol | 15002022-01 | 1 |
| Euro OTC | Mannitol | 1502022/01 | 1 |
| Euro OTC | Mannitol | 150202201 | 2 |
| Euro OTC | Mannitol | 1502022-01 | 20 |
| Euro OTC | Mannitol | 150202202 | 1 |
| Euro OTC | Mannitol | 1502022-02 | 5 |
| Euro OTC | Mannitol | 150801 | 1 |
| Euro OTC | Mannitol | 150801201 | 1 |
| Euro OTC | Mannitol | 1508012-01 | 40 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Mannitol | 1508012-02 | 14 |
| Euro OTC | Mannitol | 150916M | 1 |
| Euro OTC | Mannitol | 1511024-01 | 1 |
| Euro OTC | Mannitol | 151102501 | 2 |
| Euro OTC | Mannitol | 1511025-01 | 44 |
| Euro OTC | Mannitol | 151105-01 | 1 |
| Euro OTC | Mannitol | 158012-01 | 1 |
| Euro OTC | Mannitol | 15K17-B01-315560 | 2 |
| Euro OTC | Mannitol | 160027-01 | 1 |
| Euro OTC | Mannitol | 16006031-01 | 1 |
| Euro OTC | Mannitol | 160400 | 2 |
| Euro OTC | Mannitol | 16040008-01 | 1 |
| Euro OTC | Mannitol | 1604002-01 | 1 |
| Euro OTC | Mannitol | 1604008 | 1 |
| Euro OTC | Mannitol | 160400801 | 1 |
| Euro OTC | Mannitol | 1604008-01 | 41 |
| Euro OTC | Mannitol | 160408-01 | 1 |
| Euro OTC | Mannitol | 160601-01 | 1 |
| Euro OTC | Mannitol | 160603101 | 1 |
| Euro OTC | Mannitol | 1606031-01 | 24 |
| Euro OTC | Mannitol | 1606031-02 | 8 |
| Euro OTC | Mannitol | 161002701 | 3 |
| Euro OTC | Mannitol | 1610027-01 | 34 |
| Euro OTC | Mannitol | 1610027-02 | 2 |
| Euro OTC | Mannitol | 1610027-1 | 1 |
| Euro OTC | Mannitol | 161129M/1604008-01 | 1 |
| Euro OTC | Mannitol | 16D20-B04-320487 | 1 |
| Euro OTC | Mannitol | 16H29-B02 | 1 |
| Euro OTC | Mannitol | 17/14 | 1 |
| Euro OTC | Mannitol | 170304301 | 3 |
| Euro OTC | Mannitol | 1703043-01 | 16 |
| Euro OTC | Mannitol | 170304302 | 1 |
| Euro OTC | Mannitol | 1703043-02 | 11 |
| Euro OTC | Mannitol | 1703049-01 | 1 |
| Euro OTC | Mannitol | 1704010-01 | 6 |
| Euro OTC | Mannitol | 1704010-10 | 1 |
| Euro OTC | Mannitol | 1708005 | 1 |
| Euro OTC | Mannitol | 170800501 | 3 |
| Euro OTC | Mannitol | 1708005-01 | 45 |
| Euro OTC | Mannitol | 1708005-02 | 4 |
| Euro OTC | Mannitol | 1708005-05 | 1 |
| Euro OTC | Mannitol | 17087908 | 1 |
| Euro OTC | Mannitol | 178005-01 | 1 |
| Euro OTC | Mannitol | 180200401 | 2 |
| Euro OTC | Mannitol | 1802004-01 | 30 |
| Euro OTC | Mannitol | 180219M/1708005-01 | 1 |
| Euro OTC | Mannitol | 1806024/01 | 1 |
| Euro OTC | Mannitol | 180602401 | 1 |
| Euro OTC | Mannitol | 1806024-01 | 19 |
| Euro OTC | Mannitol | 1806024-1 | 1 |
| Euro OTC | Mannitol | 180624-01 | 2 |
| Euro OTC | Mannitol | 1809008-001 | 1 |
| Euro OTC | Mannitol | 1809008-002 | 1 |
| Euro OTC | Mannitol | 1809008-01 | 30 |
| Euro OTC | Mannitol | 180900802 | 1 |
| Euro OTC | Mannitol | 1809008-02 | 19 |
| Euro OTC | Mannitol | 1901092 | 2 |
| Euro OTC | Mannitol | 1902011-01 | 20 |
| Euro OTC | Mannitol | 1904023-03 | 1 |
| Euro OTC | Mannitol | 1904025 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Mannitol | 190402501 | 1 |
| Euro OTC | Mannitol | 1904025-01 | 17 |
| Euro OTC | Mannitol | 190402502 | 1 |
| Euro OTC | Mannitol | 1904025-02 | 44 |
| Euro OTC | Mannitol | 1904025-03 | 19 |
| Euro OTC | Mannitol | 1904025-12 | 1 |
| Euro OTC | Mannitol | 190801901 | 1 |
| Euro OTC | Mannitol | 1908019-01 | 1 |
| Euro OTC | Mannitol | 1908019-02 | 5 |
| Euro OTC | Mannitol | 19I20-F12 | 1 |
| Euro OTC | Mannitol | 200401501 | 1 |
| Euro OTC | Mannitol | 2004015-01 | 34 |
| Euro OTC | Mannitol | 200803001 | 1 |
| Euro OTC | Mannitol | 2008030-01 | 35 |
| Euro OTC | Mannitol | 2011022-01 | 17 |
| Euro OTC | Mannitol | 2011022-011 | 1 |
| Euro OTC | Mannitol | 204015-01 | 1 |
| Euro OTC | Mannitol | 20B05-F03-369844 | 1 |
| Euro OTC | Mannitol | 2105014-01 | 15 |
| Euro OTC | Mannitol | 2108014-01 | 5 |
| Euro OTC | Mannitol | 2108015-01 | 7 |
| Euro OTC | Mannitol | 2108016-01 | 5 |
| Euro OTC | Mannitol | 2201036_01 | 1 |
| Euro OTC | Mannitol | 2201036-01 | 13 |
| Euro OTC | Mannitol | 2205036 | 1 |
| Euro OTC | Mannitol | 2205036-01 | 7 |
| Euro OTC | Mannitol | 2209020-01 | 5 |
| Euro OTC | Mannitol | 2301038-01 | 2 |
| Euro OTC | Mannitol | E112N | 2 |
| Euro OTC | Mannitol | e118t | 1 |
| Euro OTC | Mannitol | E118T | 3 |
| Euro OTC | Mannitol | E224X | 1 |
| Euro OTC | Mannitol | E235L | 1 |
| Euro OTC | Mannitol | E297L | 1 |
| Euro OTC | Mannitol | E312J | 1 |
| Euro OTC | Mannitol | E331X | 1 |
| Euro OTC | Mannitol | E671Z | 1 |
| Euro OTC | Mannitol | E976E | 2 |
| Euro OTC | Mannitol | T03-07/1409016-01 | 1 |
| Euro/Gehe | Mannitol | 1604008-01 | 3 |
| Euro/Noweda | Mannitol | 1809008-01 | 2 |
| Euro/Noweda | Mannitol | 1902011-01 | 2 |
| Euro/Phönix | Mannitol | 1904025-02 | 1 |
| Euro/Sanacorp | Mannitol | 1409016-01 | 1 |
| EURO | Mannitol | 170401001 | 1 |
| Europharm | Mannitol | 1508012-01 | 1 |
| EurpTec/ Alliance He... | Mannitol | 1610027-02 | 1 |
| Fagon | Mannitol | 13K20-B01-292064 | 1 |
| Fagron | Mannitol | | 1 |
| Fagron | Mannitol | 10974140 | 1 |
| Fagron | Mannitol | 11219122 | 1 |
| Fagron | Mannitol | 11L19-N15 | 1 |
| Fagron | Mannitol | 12E24-N03 | 1 |
| Fagron | Mannitol | 12J26-N15 | 1 |
| Fagron | Mannitol | 12K28-N01 | 1 |
| Fagron | Mannitol | 1302C004 | 2 |
| Fagron | Mannitol | 1302C005 | 1 |
| Fagron | Mannitol | 13B01-B05-283812 | 1 |
| Fagron | Mannitol | 13E24N01 | 1 |
| Fagron | Mannitol | 13K20-B01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mannitol | 13K20-B01-287698 | 2 |
| Fagron | Mannitol | 13K20-B01-287706 | 1 |
| Fagron | Mannitol | 13K20-B01-294193 | 1 |
| Fagron | Mannitol | 13K20-B01-294194 | 2 |
| Fagron | Mannitol | 14323121 | 1 |
| Fagron | Mannitol | 14G004-B07-301692 | 1 |
| Fagron | Mannitol | 14G04-B07 | 4 |
| Fagron | Mannitol | 14G04-B07-296196 | 1 |
| Fagron | Mannitol | 14G04-B07-301685 | 1 |
| Fagron | Mannitol | 14G04-B07-301692 | 15 |
| Fagron | Mannitol | 14G04-B07-301693 | 1 |
| Fagron | Mannitol | 14G04-B07-301694 | 1 |
| Fagron | Mannitol | 14G17-B06-301921 | 1 |
| Fagron | Mannitol | 15A26-B01-304717 | 4 |
| Fagron | Mannitol | 15B05-B04-304084 | 4 |
| Fagron | Mannitol | 15B05-B05-304085 | 1 |
| Fagron | Mannitol | 15C04-B04-311796 | 1 |
| Fagron | Mannitol | 15D28-B02-309192 | 2 |
| Fagron | Mannitol | 15D28-B02-309193 | 1 |
| Fagron | Mannitol | 15I24-B04 | 1 |
| Fagron | Mannitol | 15K17-B01-315560 | 1 |
| Fagron | Mannitol | 15K17-B03-314903 | 1 |
| Fagron | Mannitol | 15K25-B04-317786 | 2 |
| Fagron | Mannitol | 15K25-B06-318740 | 3 |
| Fagron | Mannitol | 16/28-B01-328593 | 1 |
| Fagron | Mannitol | 16212103 | 1 |
| Fagron | Mannitol | 16340301 | 1 |
| Fagron | Mannitol | 16B24-B09-32001 | 1 |
| Fagron | Mannitol | 16B24-B09-320013 | 2 |
| Fagron | Mannitol | 16D20-B03 | 1 |
| Fagron | Mannitol | 16D20-B03-320486 | 1 |
| Fagron | Mannitol | 16D20-B04-320487 | 1 |
| Fagron | Mannitol | 16E11-B04 | 1 |
| Fagron | Mannitol | 16E11-B06 | 1 |
| Fagron | Mannitol | 16E11B07322830 | 1 |
| Fagron | Mannitol | 16E11-B07-322830 | 2 |
| Fagron | Mannitol | 16E11-B08 | 1 |
| Fagron | Mannitol | 16E11-B08-323540 | 1 |
| Fagron | Mannitol | 16F01-B03-322189 | 1 |
| Fagron | Mannitol | 16F27-B04-32483 | 1 |
| Fagron | Mannitol | 16F27-B05-324516 | 2 |
| Fagron | Mannitol | 16G27-B03 | 1 |
| Fagron | Mannitol | 16G27-B03-324517 | 1 |
| Fagron | Mannitol | 16G27-B05-325659 | 2 |
| Fagron | Mannitol | 16H02-B01-325660 | 1 |
| Fagron | Mannitol | 16H25-B03-326639 | 3 |
| Fagron | Mannitol | 16H29-B02-326640 | 2 |
| Fagron | Mannitol | 16H29-B03-326641 | 1 |
| Fagron | Mannitol | 16H29-B05-327813 | 2 |
| Fagron | Mannitol | 16J28-B01-328593 | 2 |
| Fagron | Mannitol | 16L15-B04 | 1 |
| Fagron | Mannitol | 16L15-B04-329317 | 2 |
| Fagron | Mannitol | 16L15-B05-329316 | 1 |
| Fagron | Mannitol | 17/13-B04-340968 | 3 |
| Fagron | Mannitol | 17/13-B10 | 1 |
| Fagron | Mannitol | 17/13-B11-341331 | 1 |
| Fagron | Mannitol | 17045002 | 1 |
| Fagron | Mannitol | 170612185 | 1 |
| Fagron | Mannitol | 17123B05342007 | 1 |
| Fagron | Mannitol | 1713-B11 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mannitol | 17A12-B02 | 1 |
| Fagron | Mannitol | 17A12-B02-332068 | 2 |
| Fagron | Mannitol | 17A12-B03 | 1 |
| Fagron | Mannitol | 17A12-B04 | 1 |
| Fagron | Mannitol | 17A12-B04-330729 | 1 |
| Fagron | Mannitol | 17A12-Bo3 | 1 |
| Fagron | Mannitol | 17A27-B02 | 1 |
| Fagron | Mannitol | 17A27-B02-331292 | 4 |
| Fagron | Mannitol | 17B08-B02 | 2 |
| Fagron | Mannitol | 17B08-B04 | 3 |
| Fagron | Mannitol | 17B08-B04_352402 | 1 |
| Fagron | Mannitol | 17B08-B04-334312 | 2 |
| Fagron | Mannitol | 17B08-B04-334313 | 1 |
| Fagron | Mannitol | 17B08-B04-334314 | 1 |
| Fagron | Mannitol | 17B08-B04-352402 | 5 |
| Fagron | Mannitol | 17C28-B03-333349 | 1 |
| Fagron | Mannitol | 17C28-B05333613 | 1 |
| Fagron | Mannitol | 17C28-B06 | 2 |
| Fagron | Mannitol | 17D12-B01-334435 | 6 |
| Fagron | Mannitol | 17D18-B01 | 1 |
| Fagron | Mannitol | 17D18-B03-335437 | 2 |
| Fagron | Mannitol | 17E03-B01-336748 | 1 |
| Fagron | Mannitol | 17F27-B03-337911 | 1 |
| Fagron | Mannitol | 17F27B04337912 | 1 |
| Fagron | Mannitol | 17F27B04-337912 | 1 |
| Fagron | Mannitol | 17F27-B04-337912 | 2 |
| Fagron | Mannitol | 17F27-B05-337913 | 1 |
| Fagron | Mannitol | 17F27-B07 | 2 |
| Fagron | Mannitol | 17F27-B07-338598 | 2 |
| Fagron | Mannitol | 17F27-B08 | 1 |
| Fagron | Mannitol | 17F27-B08-338599 | 1 |
| Fagron | Mannitol | 17I13B03340967 | 1 |
| Fagron | Mannitol | 17I13-B03-340967 | 2 |
| Fagron | Mannitol | 17I13-B04-340968 | 1 |
| Fagron | Mannitol | 17I13-B10 | 1 |
| Fagron | Mannitol | 17I13-B11-341331 | 1 |
| Fagron | Mannitol | 17J04-B06 | 1 |
| Fagron | Mannitol | 17J04-B06-341798 | 2 |
| Fagron | Mannitol | 17J04-B07-341800 | 1 |
| Fagron | Mannitol | 17J23-B05 | 2 |
| Fagron | Mannitol | 17J23-B05-342007 | 4 |
| Fagron | Mannitol | 17J23-B06 | 1 |
| Fagron | Mannitol | 17J30309-343413 | 1 |
| Fagron | Mannitol | 17J30-B09-343413 | 2 |
| Fagron | Mannitol | 17J30-B10-343414 | 2 |
| Fagron | Mannitol | 17J30-B11-343939 | 1 |
| Fagron | Mannitol | 17K29-B04-343940 | 1 |
| Fagron | Mannitol | 17K29-B05 | 1 |
| Fagron | Mannitol | 17K29-B05-345229 | 3 |
| Fagron | Mannitol | 17K29-B07-344253 | 1 |
| Fagron | Mannitol | 17L04-B03-345230 | 1 |
| Fagron | Mannitol | 17L04-B04-345231 | 2 |
| Fagron | Mannitol | 17L18-B04-351506 | 1 |
| Fagron | Mannitol | 17LO4-B08 | 1 |
| Fagron | Mannitol | 18/25-B08-356984 | 2 |
| Fagron | Mannitol | 1806024-01 | 1 |
| Fagron | Mannitol | 1830-08-346849 | 1 |
| Fagron | Mannitol | 18A30-B06-346848 | 3 |
| Fagron | Mannitol | 18A30-B07-348872 | 5 |
| Fagron | Mannitol | 18A30-B08-346849 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mannitol | 18A30-B09-346850 | 1 |
| Fagron | Mannitol | 18A30-B10 | 1 |
| Fagron | Mannitol | 18B23-B10-349553 | 3 |
| Fagron | Mannitol | 18B23-B12-349972 | 3 |
| Fagron | Mannitol | 18D09-B11 | 1 |
| Fagron | Mannitol | 18D09-B11-351436 | 3 |
| Fagron | Mannitol | 18D09-B13 | 1 |
| Fagron | Mannitol | 18D09-B13-352214 | 2 |
| Fagron | Mannitol | 18D09-B15-352216 | 1 |
| Fagron | Mannitol | 18D09-B16-352503 | 1 |
| Fagron | Mannitol | 18E25-B05-352504 | 2 |
| Fagron | Mannitol | 18E25-B06-352505 | 2 |
| Fagron | Mannitol | 18E25-B07 | 1 |
| Fagron | Mannitol | 18E25-B07-352753 | 1 |
| Fagron | Mannitol | 18E25-B-07-352753 | 1 |
| Fagron | Mannitol | 18E25-B08 | 1 |
| Fagron | Mannitol | 18E25-B08-352754 | 1 |
| Fagron | Mannitol | 18E25B09352755 | 1 |
| Fagron | Mannitol | 18E25-B09-352755 | 4 |
| Fagron | Mannitol | 18g04-813-3541621 | 1 |
| Fagron | Mannitol | 18G04-B09 | 1 |
| Fagron | Mannitol | 18G04-B10-354321 | 2 |
| Fagron | Mannitol | 18G04-B11-354322 | 1 |
| Fagron | Mannitol | 18G04-B13 | 2 |
| Fagron | Mannitol | 18G04-B13-354621 | 6 |
| Fagron | Mannitol | 18H16-B01-357217 | 2 |
| Fagron | Mannitol | 18H16-B01-359311 | 1 |
| Fagron | Mannitol | 18H16-B01-3633309 | 1 |
| Fagron | Mannitol | 18H16-B01-365268 | 1 |
| Fagron | Mannitol | 18J04-B05-355467 | 5 |
| Fagron | Mannitol | 18j04B07-355587 | 1 |
| Fagron | Mannitol | 18J04-B07-355587 | 1 |
| Fagron | Mannitol | 18J04-B10-355589 | 1 |
| Fagron | Mannitol | 18J25-B05-356984 | 1 |
| Fagron | Mannitol | 18J25-B07-356983 | 1 |
| Fagron | Mannitol | 18J25-B08 | 1 |
| Fagron | Mannitol | 18J25-B08-356984 | 4 |
| Fagron | Mannitol | 18L03-B03 | 3 |
| Fagron | Mannitol | 18L03-B03-357463 | 2 |
| Fagron | Mannitol | 18L03-B06-357782 | 1 |
| Fagron | Mannitol | 18L21-B03 | 1 |
| Fagron | Mannitol | 18L21-B03-358869 | 1 |
| Fagron | Mannitol | 18L21-B04-358870 | 2 |
| Fagron | Mannitol | 18L21-B04-358879 | 1 |
| Fagron | Mannitol | 18L21-B05 | 1 |
| Fagron | Mannitol | 18L21-B05-358871 | 5 |
| Fagron | Mannitol | 18L21-B06-3558872 | 1 |
| Fagron | Mannitol | 18L21-B06-358872 | 1 |
| Fagron | Mannitol | 18L21-B08-358874 | 1 |
| Fagron | Mannitol | 19/19-F10-366892 | 1 |
| Fagron | Mannitol | 19/20-F07-366390 | 1 |
| Fagron | Mannitol | 19/20-F12-366393 | 1 |
| Fagron | Mannitol | 19120-F09-366392 | 1 |
| Fagron | Mannitol | 19120F13366394 | 1 |
| Fagron | Mannitol | 19120-F15-366395 | 1 |
| Fagron | Mannitol | 19A14-B03-360504 | 2 |
| Fagron | Mannitol | 19A14-B04_360505 | 1 |
| Fagron | Mannitol | 19A14B04360505 | 1 |
| Fagron | Mannitol | 19A14-B04-360505 | 5 |
| Fagron | Mannitol | 19A14-B05-360506 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mannitol | 19A14-B06-360507 | 1 |
| Fagron | Mannitol | 19B12-B02 | 2 |
| Fagron | Mannitol | 19B12-B02-359604 | 1 |
| Fagron | Mannitol | 19B12-B03-059605 | 1 |
| Fagron | Mannitol | 19B12-B03-359605 | 1 |
| Fagron | Mannitol | 19C11B02361201 | 1 |
| Fagron | Mannitol | 19C11B02-361201 | 1 |
| Fagron | Mannitol | 19C11-B02-361201 | 2 |
| Fagron | Mannitol | 19C11-B03-361202 | 1 |
| Fagron | Mannitol | 19C11B04361203 | 1 |
| Fagron | Mannitol | 19C11-B04-361203 | 1 |
| Fagron | Mannitol | 19C11-B05-361204 | 1 |
| Fagron | Mannitol | 19C14-B02-361206 | 1 |
| Fagron | Mannitol | 19C14-B06321213 | 1 |
| Fagron | Mannitol | 19c14-B06-361213 | 1 |
| Fagron | Mannitol | 19D16-B03 | 1 |
| Fagron | Mannitol | 19D16-B03-364401 | 3 |
| Fagron | Mannitol | 19D16-B04-364402 | 1 |
| Fagron | Mannitol | 19D16-B05 | 1 |
| Fagron | Mannitol | 19E06-B05-363487 | 3 |
| Fagron | Mannitol | 19E06B06363488 | 1 |
| Fagron | Mannitol | 19E06-B06-363488 | 6 |
| Fagron | Mannitol | 19E06-B08-363490 | 1 |
| Fagron | Mannitol | 19F12-B09-363871 | 4 |
| Fagron | Mannitol | 19F12-B10-363872 | 3 |
| Fagron | Mannitol | 19F12-B11 | 1 |
| Fagron | Mannitol | 19F12-b11-363873 | 1 |
| Fagron | Mannitol | 19F12-B11-363873 | 1 |
| Fagron | Mannitol | 19I19-F1 | 1 |
| Fagron | Mannitol | 19I19-F10 | 1 |
| Fagron | Mannitol | 19I19-F10-366892 | 3 |
| Fagron | Mannitol | 19I19-F11-366893 | 1 |
| Fagron | Mannitol | 19I19-F14-366950 | 2 |
| Fagron | Mannitol | 19I20_F13-366394 | 1 |
| Fagron | Mannitol | 19I20-F09 | 1 |
| Fagron | Mannitol | 19I20-F09-366392 | 1 |
| Fagron | Mannitol | 19I20-F12-366393 | 2 |
| Fagron | Mannitol | 19I20-F13 | 1 |
| Fagron | Mannitol | 19i20-f15 | 1 |
| Fagron | Mannitol | 19I20-F15 | 1 |
| Fagron | Mannitol | 19I20-F15-366395 | 4 |
| Fagron | Mannitol | 19J09-F03 | 1 |
| Fagron | Mannitol | 19J09-F07-366954 | 2 |
| Fagron | Mannitol | 19J09-F08-366955 | 2 |
| Fagron | Mannitol | 20006F20375113 | 1 |
| Fagron | Mannitol | 20B05-04-369845 | 1 |
| Fagron | Mannitol | 20B05-F03 | 3 |
| Fagron | Mannitol | 20B05-F04 | 1 |
| Fagron | Mannitol | 20B05F04369845 | 2 |
| Fagron | Mannitol | 20B05-F05-369846 | 1 |
| Fagron | Mannitol | 20B05-F06 | 1 |
| Fagron | Mannitol | 20B05-F06-369847 | 1 |
| Fagron | Mannitol | 20C06-F06 | 1 |
| Fagron | Mannitol | 20C06-F06-369853 | 1 |
| Fagron | Mannitol | 20C06-F07 | 1 |
| Fagron | Mannitol | 20C06-F07-369854 | 1 |
| Fagron | Mannitol | 20D16F11 | 1 |
| Fagron | Mannitol | 20D16-F11-371552 | 2 |
| Fagron | Mannitol | 20D16-F12 | 2 |
| Fagron | Mannitol | 20D16-F12-371553 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mannitol | 20D16-F13-371555 | 5 |
| Fagron | Mannitol | 20D16F14371554 | 1 |
| Fagron | Mannitol | 20D16-F15 | 1 |
| Fagron | Mannitol | 20E25-F06-372224 | 1 |
| Fagron | Mannitol | 20E25-F07-372221 | 5 |
| Fagron | Mannitol | 20E25-F08-372222 | 2 |
| Fagron | Mannitol | 20E-F05-372223 | 1 |
| Fagron | Mannitol | 20F12_F06_373767 | 1 |
| Fagron | Mannitol | 20F12-F06-373767 | 3 |
| Fagron | Mannitol | 20F12-F07 | 1 |
| Fagron | Mannitol | 20F12-F07-373768 | 3 |
| Fagron | Mannitol | 20F12-F08 | 2 |
| Fagron | Mannitol | 20F12-F08-373769 | 1 |
| Fagron | Mannitol | 20F12-F09-373770 | 3 |
| Fagron | Mannitol | 20F12-F10-373771 | 2 |
| Fagron | Mannitol | 20F12-F15-373776 | 1 |
| Fagron | Mannitol | 20F12-F-373768 | 1 |
| Fagron | Mannitol | 20H21-06 | 1 |
| Fagron | Mannitol | 20H21-F03 | 1 |
| Fagron | Mannitol | 20H21-F03-373847 | 3 |
| Fagron | Mannitol | 20h21-F04 | 1 |
| Fagron | Mannitol | 20H21-F04-373848 | 5 |
| Fagron | Mannitol | 20H21-F05-373849 | 1 |
| Fagron | Mannitol | 20H21-F06-373987 | 5 |
| Fagron | Mannitol | 20H21-F08-373989 | 2 |
| Fagron | Mannitol | 20H21-F09 | 1 |
| Fagron | Mannitol | 20H21-F09-373990 | 1 |
| Fagron | Mannitol | 20H21-F11-373992 | 1 |
| Fagron | Mannitol | 20J06F13 | 1 |
| Fagron | Mannitol | 20J06-F13 | 1 |
| Fagron | Mannitol | 20J06-F14-375107 | 2 |
| Fagron | Mannitol | 20J06-F15-375108 | 3 |
| Fagron | Mannitol | 20J06-F16 | 2 |
| Fagron | Mannitol | 20J06-F16-375109 | 2 |
| Fagron | Mannitol | 20J06-F21-375114 | 2 |
| Fagron | Mannitol | 20L1115-F10-376720 | 1 |
| Fagron | Mannitol | 20L15-F10 | 1 |
| Fagron | Mannitol | 20L15-F10-376720 | 2 |
| Fagron | Mannitol | 20L15-F15-376869 | 3 |
| Fagron | Mannitol | 21B12F04377243 | 1 |
| Fagron | Mannitol | 21B12-F04-377243 | 3 |
| Fagron | Mannitol | 21C31-F04-378222 | 5 |
| Fagron | Mannitol | 21C31-F06 | 1 |
| Fagron | Mannitol | 21C31F04 | 1 |
| Fagron | Mannitol | 21D02F05 | 1 |
| Fagron | Mannitol | 21D02-F05 | 1 |
| Fagron | Mannitol | 21D02-F06-378226 | 4 |
| Fagron | Mannitol | 21E25-F07 | 1 |
| Fagron | Mannitol | 21E25f07-379700 | 1 |
| Fagron | Mannitol | 21E25-F07-379700 | 2 |
| Fagron | Mannitol | 21E25-F08-379701 | 3 |
| Fagron | Mannitol | 21f16f05379703 | 1 |
| Fagron | Mannitol | 21H04-F05 | 3 |
| Fagron | Mannitol | 21H04-F05-379996 | 1 |
| Fagron | Mannitol | 21K10-F01-380693 | 1 |
| Fagron | Mannitol | 21K10-F04 | 2 |
| Fagron | Mannitol | 21K16-BFa11-216337 | 1 |
| Fagron | Mannitol | 22822F-06 | 1 |
| Fagron | Mannitol | 22A12-F04-381467 | 1 |
| Fagron | Mannitol | 22A12-F05-381468 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mannitol | 22A12-F07-381470 | 2 |
| Fagron | Mannitol | 22A12-F09-381478 | 1 |
| Fagron | Mannitol | 22A12-F14 | 2 |
| Fagron | Mannitol | 22A12-F14-381239 | 3 |
| Fagron | Mannitol | 22A12-F04-381467 | 1 |
| Fagron | Mannitol | 22B01-F04 | 1 |
| Fagron | Mannitol | 22B01-F04-381542 | 2 |
| Fagron | Mannitol | 22B22-F06-381606 | 6 |
| Fagron | Mannitol | 22B22F08 | 1 |
| Fagron | Mannitol | 22B22-F08-381608 | 2 |
| Fagron | Mannitol | 22B22-F09-381609 | 1 |
| Fagron | Mannitol | 22B22-F13 | 1 |
| Fagron | Mannitol | 22B22-F13-381720 | 2 |
| Fagron | Mannitol | 22B22-F14-381721 | 1 |
| Fagron | Mannitol | 22B22-F15 | 2 |
| Fagron | Mannitol | 22B22-F15-381722 | 4 |
| Fagron | Mannitol | 22E23-F06-382122 | 1 |
| Fagron | Mannitol | 22e23f12 | 1 |
| Fagron | Mannitol | 22E23-F12-382118 | 2 |
| Fagron | Mannitol | 22E23-F13-382119 | 3 |
| Fagron | Mannitol | 22E23-F14 | 3 |
| Fagron | Mannitol | 22E23-F14-382120 | 4 |
| Fagron | Mannitol | 22E23-F15 | 2 |
| Fagron | Mannitol | 22E23-F15-382121 | 1 |
| Fagron | Mannitol | 22E23-F17-382114 | 2 |
| Fagron | Mannitol | 22E23F18382115 | 1 |
| Fagron | Mannitol | 22E23-F19-382117 | 5 |
| Fagron | Mannitol | 22E23-F21-382116 | 2 |
| Fagron | Mannitol | 22E23F-F06 | 1 |
| Fagron | Mannitol | 22F15-F10-382723 | 1 |
| Fagron | Mannitol | 22F15-F12-382724 | 1 |
| Fagron | Mannitol | 22F15F15382727 | 1 |
| Fagron | Mannitol | 22F15-F15-382727 | 1 |
| Fagron | Mannitol | 22F15F16382728 | 1 |
| Fagron | Mannitol | 22F15-F17-382731 | 1 |
| Fagron | Mannitol | 22F15-F18-382732 | 2 |
| Fagron | Mannitol | 22F15-F20 | 1 |
| Fagron | Mannitol | 22F15-F20-382742 | 2 |
| Fagron | Mannitol | 23A10_F03_384081 | 1 |
| Fagron | Mannitol | 23A10-F02-384080 | 1 |
| Fagron | Mannitol | 23A10-F07-384082 | 1 |
| Fagron | Mannitol | 23A10-F09-384083 | 3 |
| Fagron | Mannitol | 23A10-F09-384303 | 1 |
| Fagron | Mannitol | 23A10-F13-384084 | 1 |
| Fagron | Mannitol | 23A10-F14-384085 | 1 |
| Fagron | Mannitol | 23a24-f03-384303 | 1 |
| Fagron | Mannitol | 23A24-F13-384485 | 1 |
| Fagron | Mannitol | 296196 | 1 |
| Fagron | Mannitol | 4092019Mi | 1 |
| Fagron | Mannitol | 5-37970003 | 1 |
| Fagron | Mannitol | 6E11-B08-323540 | 1 |
| Fagron | Mannitol | 720014-0001 | 2 |
| Fagron | Mannitol | 720014-0002 | 1 |
| Fagron | Mannitol | B04-3524002 | 1 |
| Fagron | Mannitol | E166K/21K16-B11-216336 | 1 |
| Fagron | Mannitol | E611X | 1 |
| Fagron | Mannitol | E833Z | 1 |
| Fagron | Mannitol | E911K | 1 |
| Fagron | Mannitol | f07-3814700 | 1 |
| Fagron | Mannitol | F08-3737609 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mannitol | F09-3737700 | 1 |
| Fagrron | Mannitol | 17C28-B05-33361 | 1 |
| Fargon - Alliance He... | Mannitol | 19I20-F13-366394 | 1 |
| Fargon / Noweda | Mannitol | 20J06-F20 | 1 |
| Fargon/ Noweda | Mannitol | 15A26-B01-304717 | 1 |
| Fargon/ Phoenix | Mannitol | 19I20-F13-366394 | 1 |
| Fargon/Noweda | Mannitol | 19016-B03 | 1 |
| Fargon | Mannitol | 12E24-N08 | 1 |
| Fargon | Mannitol | 18B23-B10-349553 | 1 |
| Fargon | Mannitol | 18D09-B16-352503 | 1 |
| Fiebig/Farago | Mannitol | 19E06-B06-363488 | 1 |
| FIEBIG | Mannitol | 191654012 | 1 |
| Fischar/Noweda | Mannitol | 18E25-B09 | 1 |
| Fragon/ Gehe | Mannitol | 18103b06357782 | 1 |
| Fragon | Mannitol | 18D09-B13-352214 | 1 |
| Fragron/ Alliance | Mannitol | 19C11-B04 | 1 |
| Fragron/Noweda | Mannitol | 17A12-B04-330729 | 1 |
| Gatt-Koller | Mannitol | 1803827 | 2 |
| gehe 10.12.13 | Mannitol | 1305043/01 | 1 |
| GEHE 24.07.2014 | Mannitol | 1310004-02 | 1 |
| Gehe/ Eurho | Mannitol | 1205016-02 | 1 |
| Gehe/Euro | Mannitol | 1511025-01 | 1 |
| Gehe | Mannitol | 12E24-N08 | 1 |
| Gehe | Mannitol | 12J26-N15 | 1 |
| GEHE | Mannitol | 130504301 | 1 |
| Gehe | Mannitol | 13E24-N01 | 1 |
| Gehe | Mannitol | 150202201 | 1 |
| Gehe | Mannitol | 1508012-01 | 1 |
| Gehe | Mannitol | 15197313 | 1 |
| Gehe | Mannitol | 1606031-01 | 1 |
| Gehe | Mannitol | 16200913 | 1 |
| Gehe | Mannitol | 17045009 | 1 |
| GEHE | Mannitol | 17258808 | 1 |
| Gehe | Mannitol | 17258812 | 1 |
| Gehe | Mannitol | 17360101 | 2 |
| GEHE | Mannitol | 17B08-B04-334312 | 1 |
| Gehe | Mannitol | 17F27-B05-337913 | 1 |
| Gehe | Mannitol | 17L04-B03-345230 | 1 |
| GEHE | Mannitol | 18265420 | 5 |
| Gehe | Mannitol | 1908019-01 | 1 |
| Gehe | Mannitol | 19B12-B02-359604 | 1 |
| Gehe | Mannitol | 2008030-01 | 1 |
| Gehe | Mannitol | 21003432002 | 1 |
| Gehe | Mannitol | 2108014-01 | 2 |
| Gehe | Mannitol | 21K16-B11-216336 | 1 |
| Gehe | Mannitol | 22001495041 | 1 |
| Gehe | Mannitol | 22001712010 | 3 |
| Gehe | Mannitol | 22001712012 | 1 |
| Gehe | Mannitol | 2209020-01 | 1 |
| Gehe | Mannitol | 23A10-F13-384085 | 1 |
| Gehe | Mannitol | 23A24-F05-384305 | 1 |
| Gehe | Mannitol | 24000356001 | 1 |
| Gehe | Mannitol | 24000356011 | 2 |
| Gutenberg-Apotheke | Mannitol | 1310004-01 | 4 |
| Gutenberg-Apotheke | Mannitol | 1310004-02 | 1 |
| Gutenberg-Apotheke | Mannitol | 13189221 | 1 |
| Hirsch | Mannitol | 12305725 | 1 |
| INTERN-DROGEN | Mannitol | 17258812 | 1 |
| JENNE | Mannitol | 17258811 | 1 |
| Jenne | Mannitol | 24000356001 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Jenne | Mannitol | 240103(22001712012) | 1 |
| Kehr 15.09.2020 | Mannitol | 20B05-F03-369844 | 1 |
| Kehr | Mannitol | 22F15-F18 | 1 |
| Kehr | Mannitol | 2307004-01 | 2 |
| Kehr | Mannitol | 23A24-F07-384307 | 1 |
| Klenk | Mannitol | 1606031-01 | 2 |
| Klenk | Mannitol | 17360108 | 1 |
| Klenk | Mannitol | 5224A110314 | 1 |
| Kögl | Mannitol | 1900820 | 1 |
| Krieger | Mannitol | 20F12-F10-373771 | 1 |
| Krieger | Mannitol | 20L15-F15-376869 | 1 |
| Linden-Apotheke | Mannitol | 1205016-02 | 1 |
| Noewda | Mannitol | 15197319 | 1 |
| Noweda 08.032016 | Mannitol | 14323138 | 2 |
| Noweda Essen | Mannitol | 24A03-B01-002289 | 1 |
| Noweda Frechen | Mannitol | 20J06F13375106 | 1 |
| Noweda/Fragron | Mannitol | 18E25-B07-352753 | 1 |
| Noweda/Fragron | Mannitol | 19D16-B04 | 1 |
| Noweda | Mannitol | 11219101 | 2 |
| Noweda | Mannitol | 11219138 | 1 |
| Noweda | Mannitol | 1205016-02 | 2 |
| Noweda | Mannitol | 12105404 | 1 |
| Noweda | Mannitol | 1305043-01 | 1 |
| Noweda | Mannitol | 14323124 | 1 |
| Noweda | Mannitol | 1508012-01 | 1 |
| Noweda | Mannitol | 1511025-01 | 1 |
| Noweda | Mannitol | 15B05-B06-304302 | 1 |
| Noweda | Mannitol | 15I24-B05-314323 | 1 |
| Noweda | Mannitol | 15K17-B01 | 1 |
| Noweda | Mannitol | 15l24-B05-314323 | 1 |
| Noweda | Mannitol | 16D20-B04-320487 | 1 |
| Noweda | Mannitol | 16L15-B05-329316 | 1 |
| Noweda | Mannitol | 17045002 | 1 |
| Noweda | Mannitol | 1708005-01 | 3 |
| Noweda | Mannitol | 17258812 | 1 |
| Noweda | Mannitol | 1809008-02 | 1 |
| Noweda | Mannitol | 18B23-B10 | 1 |
| Noweda | Mannitol | 18L03-B06-357782 | 1 |
| Noweda | Mannitol | 1904025-01 | 1 |
| Noweda | Mannitol | 19D16-B03 | 1 |
| Noweda | Mannitol | 20004038003 | 1 |
| Noweda | Mannitol | 21K16-B11-216336 | 1 |
| Noweda | Mannitol | 22001712011 | 1 |
| NOWEDA | Mannitol | 22001712011 | 1 |
| Noweda | Mannitol | 2201036-01 | 1 |
| Noweda | Mannitol | 2307004-01 | 1 |
| Noweda | Mannitol | 23A10-F03 | 1 |
| Noweda | Mannitol | 23A24-F05-384305 | 1 |
| Noweda | Mannitol | 240000339020 | 1 |
| Noweda | Mannitol | 24000339006 | 1 |
| Noweda | Mannitol | 24000339020 | 2 |
| noweda | Mannitol | 24000356011 | 4 |
| Noweda | Mannitol | 2401022-01 | 2 |
| Noweda | Mannitol | 2401022-02 | 1 |
| Noweda | Mannitol | P101P102P103 | 3 |
| Noweda29.04.2015 | Mannitol | 14323113 | 1 |
| Phagron | Mannitol | 1302C004-279405 | 1 |
| Phoenix WE 10.03.17 ... | Mannitol | 16340302 | 1 |
| Phoenix/Fragon | Mannitol | 17B08-B04-334314 | 1 |
| Phoenix | Mannitol | 120501602 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Mannitol | 1310004-01 | 1 |
| Phoenix | Mannitol | 15197314 | 1 |
| Phoenix | Mannitol | 15197319 | 1 |
| Phoenix | Mannitol | 1708005-01 | 2 |
| Phoenix | Mannitol | 18265503 | 1 |
| Phoenix | Mannitol | 18265506 | 1 |
| Phoenix | Mannitol | 18L21-B04-358870 | 1 |
| Phoenix | Mannitol | 19B12-B03 | 1 |
| Phoenix | Mannitol | 19C11-B03-361202 | 1 |
| Phoenix | Mannitol | 20000958001 | 1 |
| Phoenix | Mannitol | 20003605013 | 1 |
| Phoenix | Mannitol | 200180502 | 1 |
| Phoenix | Mannitol | 200331404 | 1 |
| Phönix WE:02.08.201... | Mannitol | 15197313 | 1 |
| Phönix Gotha | Mannitol | 19I20-F09 | 1 |
| Phönix/ Caesar&Loret... | Mannitol | 20000958003 | 1 |
| Phönix | Mannitol | 120501602 | 1 |
| Phönix | Mannitol | 1211034-02 | 1 |
| Phönix | Mannitol | 12305723 | 1 |
| Phönix | Mannitol | 1305043-01 | 1 |
| Phönix | Mannitol | 14051215 | 1 |
| phönix | Mannitol | 14323138 | 1 |
| Phönix | Mannitol | 15197313 | 2 |
| PHÖNIX | Mannitol | 16200923 | 1 |
| Phönix | Mannitol | 16200924 | 2 |
| PHÖNIX | Mannitol | 16212102 | 1 |
| Phönix | Mannitol | 17045008 | 1 |
| Phönix | Mannitol | 17258819 | 1 |
| PHÖNIX | Mannitol | 17258821 | 1 |
| Phönix | Mannitol | 17360109 | 1 |
| Phönix | Mannitol | 18265411 | 1 |
| Phönix | Mannitol | 18265429 | 1 |
| PHÖNIX | Mannitol | 18G04-B11 | 1 |
| PHÖNIX | Mannitol | 18121b03 | 1 |
| PHÖNIX | Mannitol | 18L21-B03-358869 | 1 |
| Phönix | Mannitol | 18L21-B04 | 1 |
| Phönix | Mannitol | 20H21-F06-373986 | 1 |
| Phönix | Mannitol | 22822-F08 | 1 |
| PHÖNIX | Mannitol | 22A12F04-381467 | 1 |
| Phönix | Mannitol | 22E23-F17-382114 | 1 |
| Phönix | Mannitol | 2307004-01 | 1 |
| Phönix | Mannitol | 23A10-F14-384085 | 1 |
| Primavera/Phoenix | Mannitol | 1708005-01 | 1 |
| Retest | Mannitol | 1409016-01 | 1 |
| Roquette / Gehe | Mannitol | E851E | 1 |
| Roquette Lestrem/Noweda | Mannitol | 1508012-01 | 1 |
| Roquette Lestrem/Noweda | Mannitol | 1511025-01 | 1 |
| Roquette/Noweda | Mannitol | E235L | 1 |
| Roquette/Phoenix | Mannitol | E118T | 1 |
| Sanac | Mannitol | 1610027-01 | 1 |
| Sanacorp E.K:19,49 ... | Mannitol | 17045009 | 1 |
| Sanacorp 06.05.22 18,91EUR | Mannitol | 22B01-F04-381542 | 1 |
| Sanacorp | Mannitol | 10974140 | 1 |
| Sanacorp | Mannitol | 1205016-01 | 2 |
| Sanacorp | Mannitol | 1310004-01 | 1 |
| Sanacorp | Mannitol | 13189215 | 1 |
| Sanacorp | Mannitol | 14051205 | 1 |
| Sanacorp | Mannitol | 16200903 | 1 |
| Sanacorp | Mannitol | 16200924 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Mannitol | 17087916 | 1 |
| Sanacorp | Mannitol | 17258808 | 1 |
| Sanacorp | Mannitol | 17258809 | 3 |
| Sanacorp | Mannitol | 17K29-B05 | 1 |
| Sanacorp | Mannitol | 1806024-01 | 1 |
| Sanacorp | Mannitol | 18265509 | 1 |
| Sanacorp | Mannitol | 1904025-02 | 1 |
| Sanacorp | Mannitol | 22001495017 | 1 |
| Sanacorp | Mannitol | 22001712004 | 2 |
| Sanacorp | Mannitol | 22001712011 | 2 |
| Sanacorp | Mannitol | 2201712011 | 1 |
| Sanacorp | Mannitol | 22E23-F18-382115 | 1 |
| Sanacorp | Mannitol | 2301038-01 | 1 |
| Sanacorp | Mannitol | 2307004-01 | 1 |
| Sanacorp | Mannitol | 23A24-F03-384303 | 2 |
| Sanacorp | Mannitol | 24000356003 | 1 |
| Sanacorp | Mannitol | 24000356005 | 1 |
| Sanacorp | Mannitol | 24000356006 | 1 |
| Sanacorp | Mannitol | 24000356007 | 1 |
| Sancorp/Euro OCT | Mannitol | 190425-02 | 1 |
| Shijiazhuang/Noweda | Mannitol | 1901092 | 2 |
| Sonnen-Apotheke Wefe… | Mannitol | | 2 |
| Sonnen-Apotheke Wefe… | Mannitol | 4/2021 | 1 |
| stumpf | Mannitol | 1104028-02 | 1 |
| VDL;21.11.14;3,98EUR | Mannitol | 13189227 | 1 |
| vwr chemicals | Mannitol | 20K134121 | 1 |
| vwr chemicals | Mannitol | 21G264113 | 1 |
| WE:16.03.2016 Sanacorp | Mannitol | 14323124 | 1 |
| WE:24.02.2016 Sanacorp | Mannitol | 15197301 | 2 |
| WE:30.03.2016 Sanacorp | Mannitol | 14323138 | 1 |
| WE:Sanacorp 02.09.16… | Mannitol | 16212101 | 1 |
| WE:Sanacorp 25.10.20… | Mannitol | 16212102 | 2 |
| Wiesen Apotheke | Mannitol | 24/26-M09-003016 | 1 |
| xxxxx | Mannitol | xxxx | 1 |

- 253 335 spectra from 1666 *Apo-Ident* customers from a total of 51 218 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Mannitol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Mannitol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 1750 | 0 | 211 110 |
| **Type C** | 0 | 3546 | 5 | 253 311 |

The substance/substance group *Mannitol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6571 %) |
| **Type C** | 100.0000 % (> 99.9024 %) | 99.8592 % (> 99.7747 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20980 | 20980 | 0.00 | 178.62 |
| 21884 | 21884 | 0.00 | 179.06 |
| 22286 | 22286 | 0.00 | 179.38 |
| 22581 | 22286 | 2.80 | 181.98 |
| 22883 | 22286 | 4.39 | 180.64 |
| 22884 | 22286 | 4.95 | 180.22 |
| 24579 | 21884 | 7.80 | 189.40 |
| 25548 | 25548 | 0.00 | 180.81 |
| 26396 | 22286 | 12.84 | 195.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Melatonin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20553-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Melatonin; Melatoninum

### Special notes

When selecting the *Melatonin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Melatonin | 11 | 16 | 353 |

### Second-stage model

For differentiation of the substance/substance group *Melatonin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Melatonin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 84.29 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Melatonin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Melatonin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Melatonin | 12321404 | 20834 | 40 | 20121107 |
| Caelo | Melatonin | 12321411 | 20835 | 40 | 20121107 |
| Caelo | Melatonin | 12321415 | 20987 | 80 | 20121107 |
| Caelo | Melatonin | 21002239029 | 26415 | 40 | 20210723 |
| Caelo | Melatonin | 21002239029 | 26415SI | 40 | 20210723 |
| Euro OTC | Melatonin | 1305029-02 | 21618 | 60 | 1411054 |
| Euro OTC | Melatonin | 1510041 | 22237 | 60 | 20151123* |
| Euro OTC | Melatonin | 1709020 | 23889 | 40 | 20180105* |
| Euro OTC | Melatonin | 1804015 | 24128 | 40 | 20180522* |
| Euro OTC | Melatonin | 1804015 | 24128SI | 40 | 20180522* |
| Euro OTC | Melatonin | 2101018 | 25542 | 40 | 20210202* |
| Euro OTC | Melatonin | 2101018 | 25542SI | 40 | 20210202* |
| Fagron | Melatonin | 15G06-B03-315183 | 22892 | 40 | 20150717 |
| Fagron | Melatonin | 15G06-B03-323733 | 22893 | 40 | 20150717 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 640 spectra of 14 reference samples from the substance/substance group *Melatonin*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 686 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1259 spectra of 31 reference samples from the substance/substance group *Melatonin*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Melatonin | 163437 | 23036 | 40 |
| Caelo | Melatonin | 190946 | 24519 | 40 |
| Caelo | Melatonin | 22003650 | 26487 | 40 |
| Caelo | Melatonin | 24002975 | 27538 | 40 |
| Euro OTC | Melatonin | 1610040 | 22871 | 40 |
| Euro OTC | Melatonin | 1811004 | 24330 | 40 |
| Euro OTC | Melatonin | 1906031 | 24767 | 40 |
| Euro OTC | Melatonin | 1906030 | 24802 | 40 |
| Euro OTC | Melatonin | 1909031 | 24924 | 40 |
| Euro OTC | Melatonin | 2002029 | 25148 | 40 |
| Euro OTC | Melatonin | 2106005 | 25766 | 50 |
| Euro OTC | Melatonin | 2110002 | 25890 | 50 |
| Euro OTC | Melatonin | 2309003 | 27283 | 40 |
| Euro OTC | Melatonin | 2411012 | 27502 | 40 |
| Fagron | Melatonin | 22I16-B05-224268 | 26458 | 40 |
| Fagron | Melatonin | 24G18-B01-010198 | 27642 | 40 |
| Caelo | Melatonin | 163437 | 23036SI | 40 |
| Caelo | Melatonin | 190946 | 24519SI | 40 |
| Caelo | Melatonin | 22003650 | 26487SI | 40 |
| Caelo | Melatonin | 24002975 | 27538SI | 40 |
| Euro OTC | Melatonin | 1510041 | 22237SI† | 60 |
| Euro OTC | Melatonin | 1811004 | 24330SI | 39 |
| Euro OTC | Melatonin | 2002029 | 25148SI | 40 |
| Euro OTC | Melatonin | 2106005 | 25766SI | 50 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Melatonin | 2110002 | 25890SI | 10 |
| Euro OTC | Melatonin | 2309003 | 27283SI | 40 |
| Euro OTC | Melatonin | 2411012 | 27502SI | 40 |
| Fagron | Melatonin | 15G06-B03-315183 | 22892SI† | 40 |
| Fagron | Melatonin | 15G06-B03-323733 | 22893SI† | 40 |
| Fagron | Melatonin | 22I16-B05-224268 | 26458SI | 40 |
| Fagron | Melatonin | 24G18-B01-010198 | 27642SI | 40 |

- 211 681 spectra from a total of 4268 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1913 spectra from 540 *Apo-Ident* customers from 363 batches from the substance/substance group *Melatonin*.
- Among them are spectra of independent samples from 353 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Melatonin | 192978006 | 2 |
| | Melatonin | 20001543009 | 1 |
| | Melatonin | 20220508 | 1 |
| | Melatonin | 20A31-F02-372824 | 1 |
| | Melatonin | 21002239013 | 1 |
| | Melatonin | 2100223902 | 1 |
| | Melatonin | 21002239023 | 1 |
| | Melatonin | 21002239028 | 2 |
| | Melatonin | 21002239030 | 4 |
| | Melatonin | 21002239034 | 2 |
| | Melatonin | 21002239035 | 1 |
| | Melatonin | 21002239038 | 15 |
| | Melatonin | 21002239039 | 8 |
| | Melatonin | 21002239041 | 2 |
| | Melatonin | 2100223908 | 1 |
| | Melatonin | 2110002-01 | 17 |
| | Melatonin | 21I24-B01-215649 | 1 |
| | Melatonin | 22003650002 | 22 |
| | Melatonin | 22003650004 | 8 |
| | Melatonin | 22003650005 | 28 |
| | Melatonin | 22003650009 | 5 |
| | Melatonin | 22003650011 | 8 |
| | Melatonin | 22003650014 | 25 |
| | Melatonin | 22003650018 | 5 |
| | Melatonin | 22003650019 | 19 |
| | Melatonin | 22003650020 | 4 |
| | Melatonin | 22003650021 | 2 |
| | Melatonin | 220036519 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Melatonin | 2203650003 | 1 |
| | Melatonin | 220365002 | 1 |
| | Melatonin | 22116-B05-228535 | 1 |
| | Melatonin | 22I16-B05-228535 | 2 |
| | Melatonin | 22I16-B05-228536 | 1 |
| | Melatonin | 22I16-B05-235144 | 1 |
| | Melatonin | 2309003-01 | 1 |
| | Melatonin | 24E09-B01-237420 | 1 |
| | Melatonin | 24E09-B01-240406 | 1 |
| | Melatonin | 24G18-B01-004997 | 1 |
| | Melatonin | 24G18-B01-005055 | 1 |
| | Melatonin | B05-2285306 | 2 |
| | Melatonin | B05-2329907 | 1 |
| AEP | Melatonin | 20001543005 | 1 |
| AHD | Melatonin | 21002239018 | 1 |
| AHD | Melatonin | 21002239038 | 3 |
| AHD | Melatonin | 22003650002 | 1 |
| AHD | Melatonin | 22003650005 | 1 |
| Alcon Biosciences Pr... | Melatonin | APALC/MLT/170301M | 1 |
| Alliance | Melatonin | 15254307 | 3 |
| Alliance | Melatonin | 15254316 | 1 |
| Alliance | Melatonin | 21002239025 | 1 |
| allianz | Melatonin | 15254324 | 1 |
| Alte Apotheke | Melatonin | 15254328 | 1 |
| Anzag | Melatonin | 12321415 | 1 |
| apo ident | Melatonin | 1610040-02 | 1 |
| apo-ident | Melatonin | 1906030-01 | 1 |
| Audor Pharma | Melatonin | ALC/MLT/170901 | 1 |
| Audor Pharma | Melatonin | APALC/MLT/150501M | 2 |
| Audor Pharma | Melatonin | APALC/MLT/170901M | 2 |
| Audor Pharma | Melatonin | APALC/MLT/17090M | 1 |
| Bionorica Ethics | Melatonin | APALC/MLT/170901M | 1 |
| Bombastus | Melatonin | 18210304 | 1 |
| Cael/Nowda | Melatonin | 13167301 | 3 |
| Caelo | Melatonin | | 1 |
| Caelo | Melatonin | 1(20001543007) | 1 |
| Caelo | Melatonin | 10071303 | 1 |
| Caelo | Melatonin | 1126109 | 1 |
| Caelo | Melatonin | 11267102 | 1 |
| Caelo | Melatonin | 11267109 | 1 |
| Caelo | Melatonin | 11267110 | 1 |
| Caelo | Melatonin | 11267111 | 1 |
| Caelo | Melatonin | 11267119 | 1 |
| Caelo | Melatonin | 11267120 | 4 |
| Caelo | Melatonin | 11267121 | 1 |
| Caelo | Melatonin | 11267122 | 1 |
| Caelo | Melatonin | 11267126 | 2 |
| Caelo | Melatonin | 117305118 | 1 |
| Caelo | Melatonin | 120009 | 1 |
| Caelo | Melatonin | 12321404 | 3 |
| Caelo | Melatonin | 12321406 | 1 |
| Caelo | Melatonin | 12321411 | 1 |
| Caelo | Melatonin | 12321415 | 3 |
| Caelo | Melatonin | 12321416 | 5 |
| Caelo | Melatonin | 12321421 | 2 |
| Caelo | Melatonin | 12321422 | 4 |
| Caelo | Melatonin | 13167301 | 5 |
| Caelo | Melatonin | 13167302 | 1 |
| Caelo | Melatonin | 13167309 | 1 |
| Caelo | Melatonin | 13167310 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Melatonin | 13167312 | 3 |
| Caelo | Melatonin | 13167314 | 5 |
| Caelo | Melatonin | 14110302 | 2 |
| Caelo | Melatonin | 14110305 | 2 |
| Caelo | Melatonin | 14110308 | 3 |
| Caelo | Melatonin | 14110314 | 2 |
| Caelo | Melatonin | 14110316 | 1 |
| Caelo | Melatonin | 150601 | 1 |
| Caelo | Melatonin | 15093001 | 7 |
| Caelo | Melatonin | 15093002 | 2 |
| Caelo | Melatonin | 15093004 | 2 |
| Caelo | Melatonin | 15093008 | 8 |
| Caelo | Melatonin | 15093010 | 5 |
| Caelo | Melatonin | 15093012 | 2 |
| Caelo | Melatonin | 15093013 | 2 |
| Caelo | Melatonin | 1514E-03554 | 1 |
| Caelo | Melatonin | 1524309 | 1 |
| Caelo | Melatonin | 15254305 | 7 |
| Caelo | Melatonin | 15254306 | 8 |
| Caelo | Melatonin | 15254307 | 14 |
| Caelo | Melatonin | 15254308 | 8 |
| Caelo | Melatonin | 15254313 | 2 |
| Caelo | Melatonin | 15254319 | 10 |
| Caelo | Melatonin | 15254320 | 4 |
| Caelo | Melatonin | 15254321 | 8 |
| Caelo | Melatonin | 15254324 | 4 |
| Caelo | Melatonin | 15254325 | 1 |
| Caelo | Melatonin | 15254327 | 1 |
| Caelo | Melatonin | 15254328 | 2 |
| Caelo | Melatonin | 15254331 | 8 |
| Caelo | Melatonin | 15254332 | 2 |
| Caelo | Melatonin | 15254333 | 1 |
| Caelo | Melatonin | 15254336 | 4 |
| Caelo | Melatonin | 15254338 | 6 |
| Caelo | Melatonin | 15C20B01306077 | 1 |
| Caelo | Melatonin | 15G06-B03-321298 | 2 |
| Caelo | Melatonin | 15G06-B03-321299 | 1 |
| Caelo | Melatonin | 15G06-B03-323733 | 1 |
| Caelo | Melatonin | 160125M | 1 |
| Caelo | Melatonin | 16121303 | 1 |
| Caelo | Melatonin | 16266901 | 9 |
| Caelo | Melatonin | 16266903 | 2 |
| Caelo | Melatonin | 16266904 | 3 |
| Caelo | Melatonin | 16266906 | 4 |
| Caelo | Melatonin | 16266908 | 7 |
| Caelo | Melatonin | 16266909 | 10 |
| Caelo | Melatonin | 16266912 | 2 |
| Caelo | Melatonin | 163437/13 | 1 |
| Caelo | Melatonin | 16343702 | 3 |
| Caelo | Melatonin | 16343705 | 2 |
| Caelo | Melatonin | 16343706 | 2 |
| Caelo | Melatonin | 16343707 | 2 |
| Caelo | Melatonin | 16343708 | 13 |
| Caelo | Melatonin | 16343709 | 13 |
| Caelo | Melatonin | 16343710 | 12 |
| Caelo | Melatonin | 16343711 | 4 |
| Caelo | Melatonin | 16343712 | 1 |
| Caelo | Melatonin | 16343713 | 12 |
| Caelo | Melatonin | 17/28-B04-345376 | 2 |
| Caelo | Melatonin | 17/28-b04-351312 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Melatonin | 1709020-01 | 2 |
| Caelo | Melatonin | 17305101 | 5 |
| Caelo | Melatonin | 17305101-20180206Ma1 | 1 |
| Caelo | Melatonin | 17305102 | 30 |
| Caelo | Melatonin | 17305104 | 4 |
| Caelo | Melatonin | 17305105 | 15 |
| Caelo | Melatonin | 17305106 | 13 |
| Caelo | Melatonin | 17305109 | 1 |
| Caelo | Melatonin | 17305110 | 7 |
| Caelo | Melatonin | 17305113 | 7 |
| Caelo | Melatonin | 17305114 | 8 |
| Caelo | Melatonin | 17305115 | 5 |
| Caelo | Melatonin | 17305116 | 4 |
| Caelo | Melatonin | 17305118 | 13 |
| Caelo | Melatonin | 17305119 | 6 |
| Caelo | Melatonin | 17305120 | 1 |
| Caelo | Melatonin | 17305121 | 5 |
| Caelo | Melatonin | 17305122 | 14 |
| Caelo | Melatonin | 17350119 | 1 |
| Caelo | Melatonin | 17C22-B01-337090 | 1 |
| Caelo | Melatonin | 17I28-B04-344439 | 2 |
| Caelo | Melatonin | 17I28-B04-345376 | 1 |
| Caelo | Melatonin | 17I28-B04-351312 | 1 |
| Caelo | Melatonin | 1810308 | 1 |
| Caelo | Melatonin | 182010312 | 1 |
| Caelo | Melatonin | 18210301 | 18 |
| Caelo | Melatonin | 18210303 | 3 |
| Caelo | Melatonin | 18210304 | 19 |
| Caelo | Melatonin | 18210306 | 7 |
| Caelo | Melatonin | 18210307 | 4 |
| Caelo | Melatonin | 18210308 | 5 |
| Caelo | Melatonin | 18210311 | 14 |
| Caelo | Melatonin | 18210312 | 10 |
| Caelo | Melatonin | 18210313 | 8 |
| Caelo | Melatonin | 18210315 | 1 |
| Caelo | Melatonin | 18210318 | 12 |
| Caelo | Melatonin | 18210319 | 4 |
| Caelo | Melatonin | 19120005 | 1 |
| Caelo | Melatonin | 191280001 | 15 |
| Caelo | Melatonin | 191280002 | 12 |
| Caelo | Melatonin | 191280003 | 1 |
| Caelo | Melatonin | 191280005 | 18 |
| Caelo | Melatonin | 191280006 | 2 |
| Caelo | Melatonin | 191280009 | 17 |
| Caelo | Melatonin | 19128001 | 1 |
| Caelo | Melatonin | 19128003 | 10 |
| Caelo | Melatonin | 19128005 | 16 |
| Caelo | Melatonin | 19128006 | 20 |
| Caelo | Melatonin | 19128007 | 12 |
| Caelo | Melatonin | 192978004 | 1 |
| Caelo | Melatonin | 192978005 | 16 |
| Caelo | Melatonin | 192978006 | 19 |
| Caelo | Melatonin | 2(20001543007) | 1 |
| Caelo | Melatonin | 20001543005 | 8 |
| Caelo | Melatonin | 20001543007 | 12 |
| Caelo | Melatonin | 20001543009 | 1 |
| Caelo | Melatonin | 20001543010 | 11 |
| Caelo | Melatonin | 20001543012 | 16 |
| Caelo | Melatonin | 20001543014 | 20 |
| Caelo | Melatonin | 20021312 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Melatonin | 20021505 | 1 |
| Caelo | Melatonin | 2002239003 | 1 |
| Caelo | Melatonin | 20A31-F02-372823 | 1 |
| Caelo | Melatonin | 21000597001 | 10 |
| Caelo | Melatonin | 21000597002 | 1 |
| Caelo | Melatonin | 21000597003 | 1 |
| Caelo | Melatonin | 2100223021 | 1 |
| Caelo | Melatonin | 21002239001 | 1 |
| Caelo | Melatonin | 21002239003 | 20 |
| Caelo | Melatonin | 21002239004 | 2 |
| Caelo | Melatonin | 21002239005 | 16 |
| Caelo | Melatonin | 21002239006 | 11 |
| Caelo | Melatonin | 21002239008 | 1 |
| Caelo | Melatonin | 21002239011 | 9 |
| Caelo | Melatonin | 21002239013 | 22 |
| Caelo | Melatonin | 21002239018 | 3 |
| Caelo | Melatonin | 21002239021 | 21 |
| Caelo | Melatonin | 21002239023 | 11 |
| Caelo | Melatonin | 21002239028 | 5 |
| Caelo | Melatonin | 21002239029 | 9 |
| Caelo | Melatonin | 21002239030 | 3 |
| Caelo | Melatonin | 21002239034 | 11 |
| Caelo | Melatonin | 21002239035 | 5 |
| Caelo | Melatonin | 21002239036 | 3 |
| Caelo | Melatonin | 21002239039 | 1 |
| Caelo | Melatonin | 2100223909 | 1 |
| Caelo | Melatonin | 2100597002 | 1 |
| Caelo | Melatonin | 211002239028 | 1 |
| Caelo | Melatonin | 22003650002 | 4 |
| Caelo | Melatonin | 22003650005 | 1 |
| Caelo | Melatonin | 22003650009 | 1 |
| Caelo | Melatonin | 2313M03554 | 1 |
| Caelo | Melatonin | 2548268 | 1 |
| Caelo | Melatonin | 26051805 | 1 |
| Caelo | Melatonin | ALC/MLT/170901 | 1 |
| Caesa / Alliance Hea... | Melatonin | 18210306 | 1 |
| Caesar & Lorenz GmbH | Melatonin | 17305106 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239013 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239035 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 17305102 | 2 |
| Caesar & Loretz GmbH... | Melatonin | 17305106 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 18210306 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239029 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 20001543007 | 2 |
| Caesar & Loretz GmbH... | Melatonin | 20001543014 | 1 |
| Caesar & Loretz GmbH/AHD | Melatonin | 20001543010 | 1 |
| Caesar & Loretz GmbH/AHD | Melatonin | 21002239013 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 192978006 | 2 |
| Caesar & Loretz GmbH... | Melatonin | 20001543009 | 1 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 192978006 | 1 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 20001543009 | 1 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 20001543012 | 1 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 21002239003 | 1 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 21002239020 | 1 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 21002239021 | 2 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 21002239039 | 2 |
| Caesar & Loretz GmbH/Gehe | Melatonin | 22003650002 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 192978004 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21000597002 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239006 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Melatonin | 21002239030 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 192978006 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239005 | 2 |
| Caesar & Loretz GmbH... | Melatonin | 191280005 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239011 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239021 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 192978006 | 2 |
| Caesar & Loretz GmbH... | Melatonin | 20001543007 | 2 |
| Caesar & Loretz GmbH... | Melatonin | 20001543010 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239008 | 1 |
| Caesar & Loretz GmbH... | Melatonin | 21002239013 | 1 |
| Caesar & Loretz GmbH | Melatonin | 1524517305113 | 1 |
| Caesar & Loretz GmbH | Melatonin | 17305105 | 1 |
| Caesar & Loretz GmbH | Melatonin | 17305106 | 1 |
| Caesar & Loretz GmbH | Melatonin | 17305118 | 1 |
| Caesar & Loretz GmbH | Melatonin | 18210301 | 2 |
| Caesar & Loretz GmbH | Melatonin | 18210304 | 1 |
| Caesar & Loretz GmbH | Melatonin | 18210305 | 2 |
| Caesar & Loretz GmbH | Melatonin | 18210306 | 3 |
| Caesar & Loretz GmbH | Melatonin | 18210307 | 1 |
| Caesar & Loretz GmbH | Melatonin | 18210311 | 2 |
| Caesar & Loretz GmbH | Melatonin | 18210312 | 2 |
| Caesar & Loretz GmbH | Melatonin | 18210313 | 1 |
| Caesar & Loretz GmbH | Melatonin | 18210318 | 2 |
| Caesar & Loretz GmbH | Melatonin | 18210319 | 1 |
| Caesar & Loretz GmbH | Melatonin | 18210320 | 1 |
| Caesar & Loretz GmbH | Melatonin | 191280001 | 6 |
| Caesar & Loretz GmbH | Melatonin | 191280002 | 4 |
| Caesar & Loretz GmbH | Melatonin | 191280003 | 1 |
| Caesar & Loretz GmbH | Melatonin | 191280005 | 7 |
| Caesar & Loretz GmbH | Melatonin | 191280006 | 3 |
| Caesar & Loretz GmbH | Melatonin | 191280008 | 2 |
| Caesar & Loretz GmbH | Melatonin | 191280009 | 7 |
| Caesar & Loretz GmbH | Melatonin | 19128003 | 1 |
| Caesar & Loretz GmbH | Melatonin | 19128005 | 7 |
| Caesar & Loretz GmbH | Melatonin | 19128007 | 2 |
| Caesar & Loretz GmbH | Melatonin | 192978004 | 4 |
| Caesar & Loretz GmbH | Melatonin | 192978005 | 5 |
| Caesar & Loretz GmbH | Melatonin | 192978006 | 16 |
| Caesar & Loretz GmbH | Melatonin | 20001543005 | 3 |
| Caesar & Loretz GmbH | Melatonin | 20001543007 | 1 |
| Caesar & Loretz GmbH | Melatonin | 20001543009 | 1 |
| Caesar & Loretz GmbH | Melatonin | 20001543010 | 3 |
| Caesar & Loretz GmbH | Melatonin | 20001543012 | 4 |
| Caesar & Loretz GmbH | Melatonin | 20001543014 | 8 |
| Caesar & Loretz GmbH | Melatonin | 2002029-01 | 2 |
| Caesar & Loretz GmbH | Melatonin | 21000597001 | 6 |
| Caesar & Loretz GmbH | Melatonin | 21000597002 | 2 |
| Caesar & Loretz GmbH | Melatonin | 21002239003 | 3 |
| Caesar & Loretz GmbH | Melatonin | 21002239004 | 3 |
| Caesar & Loretz GmbH | Melatonin | 21002239005 | 14 |
| Caesar & Loretz GmbH | Melatonin | 21002239006 | 4 |
| Caesar & Loretz GmbH | Melatonin | 21002239008 | 1 |
| Caesar & Loretz GmbH | Melatonin | 21002239011 | 2 |
| Caesar & Loretz GmbH | Melatonin | 21002239013 | 10 |
| Caesar & Loretz GmbH | Melatonin | 21002239018 | 2 |
| Caesar & Loretz GmbH | Melatonin | 21002239020 | 3 |
| Caesar & Loretz GmbH | Melatonin | 21002239021 | 11 |
| Caesar & Loretz GmbH | Melatonin | 21002239023 | 8 |
| Caesar & Loretz GmbH | Melatonin | 21002239028 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Melatonin | 21002239029 | 12 |
| Caesar & Loretz GmbH | Melatonin | 21002239030 | 4 |
| Caesar & Loretz GmbH | Melatonin | 21002239031 | 1 |
| Caesar & Loretz GmbH | Melatonin | 21002239034 | 2 |
| Caesar & Loretz GmbH | Melatonin | 21002239035 | 1 |
| Caesar & Loretz GmbH | Melatonin | 21002239036 | 2 |
| Caesar & Loretz GmbH | Melatonin | 22003650001 | 2 |
| Caesar & Loretz GmbH | Melatonin | 22003650002 | 2 |
| Caesar & Loretz Hild... | Melatonin | 19128006191280009 | 1 |
| Caesar & Loretz/Noweda | Melatonin | 19128006 | 1 |
| Caesar & Loretz/Noweda | Melatonin | 20001543012 | 1 |
| Caesar&Loretz GmbH | Melatonin | 20001543007 | 1 |
| Cealo/Gehe | Melatonin | 10296624 | 1 |
| Cealo | Melatonin | 12321422 | 1 |
| Cealo | Melatonin | 20001543010 | 1 |
| Cealo | Melatonin | 21000597001 | 2 |
| EuRho/Gehe | Melatonin | 2110002-01 | 1 |
| euRho | Melatonin | 2002029-01 | 2 |
| euRho | Melatonin | 2106005-01 | 1 |
| Euro OTC | Melatonin | 120008 | 1 |
| Euro OTC | Melatonin | 12001 | 2 |
| Euro OTC | Melatonin | 120400302 | 1 |
| Euro OTC | Melatonin | 1204003-02 | 12 |
| Euro OTC | Melatonin | 1305029-01 | 8 |
| Euro OTC | Melatonin | 1407028-01 | 1 |
| Euro OTC | Melatonin | 1407028-02 | 3 |
| Euro OTC | Melatonin | 151004101 | 3 |
| Euro OTC | Melatonin | 1510041-01 | 7 |
| Euro OTC | Melatonin | 15254316 | 1 |
| Euro OTC | Melatonin | 161004001 | 1 |
| Euro OTC | Melatonin | 1610040-01 | 6 |
| Euro OTC | Melatonin | 1610040-02 | 5 |
| Euro OTC | Melatonin | 17/28-B04-344440 | 2 |
| Euro OTC | Melatonin | 170007 | 1 |
| Euro OTC | Melatonin | 1709020-01 | 14 |
| Euro OTC | Melatonin | 170920-01 | 1 |
| Euro OTC | Melatonin | 17305106 | 1 |
| Euro OTC | Melatonin | 180401501 | 1 |
| Euro OTC | Melatonin | 1804015-01 | 7 |
| Euro OTC | Melatonin | 1804015-02 | 1 |
| Euro OTC | Melatonin | 190603001 | 1 |
| Euro OTC | Melatonin | 1906030-01 | 13 |
| Euro OTC | Melatonin | 190903101 | 1 |
| Euro OTC | Melatonin | 1909031-01 | 2 |
| Euro OTC | Melatonin | 200202901 | 1 |
| Euro OTC | Melatonin | 2002029-01 | 26 |
| Euro OTC | Melatonin | 2101018 | 1 |
| Euro OTC | Melatonin | 2101018-01 | 7 |
| Euro OTC | Melatonin | 2106005 | 1 |
| Euro OTC | Melatonin | 2106005-01 | 5 |
| Euro OTC | Melatonin | 2110002-01 | 12 |
| Euro OTC | Melatonin | 71296 | 1 |
| Fagron | Melatonin | 11/26-N07 | 1 |
| Fagron | Melatonin | 11F09-N02 | 1 |
| Fagron | Melatonin | 120009 | 2 |
| Fagron | Melatonin | 12G19-N03 | 3 |
| Fagron | Melatonin | 12I28-B04-361873 | 1 |
| Fagron | Melatonin | 12K13-N02 | 1 |
| Fagron | Melatonin | 1305029-01 | 1 |
| Fagron | Melatonin | 13D12N10 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Melatonin | 13D12-N10 | 2 |
| Fagron | Melatonin | 13e22-n12 | 1 |
| Fagron | Melatonin | 13E22N12 | 1 |
| Fagron | Melatonin | 13E22-N12 | 1 |
| Fagron | Melatonin | 13H21-N06 | 4 |
| Fagron | Melatonin | 13H21-N065x | 1 |
| Fagron | Melatonin | 13H29-B03 | 1 |
| Fagron | Melatonin | 13H29-B03-291180 | 2 |
| Fagron | Melatonin | 14G18-B01-297242 | 1 |
| Fagron | Melatonin | 14G18-B01-297244 | 1 |
| Fagron | Melatonin | 14G18-B01-297245 | 1 |
| Fagron | Melatonin | 150002 | 1 |
| Fagron | Melatonin | 15C20-B01-306077 | 1 |
| Fagron | Melatonin | 15C20-B01-306078 | 3 |
| Fagron | Melatonin | 15C20-B01-308426 | 3 |
| Fagron | Melatonin | 15C20-B01-308427 | 5 |
| Fagron | Melatonin | 15C20-B01-308428 | 1 |
| Fagron | Melatonin | 15C20-B01-327131 | 1 |
| Fagron | Melatonin | 15G06-B03-315183 | 5 |
| Fagron | Melatonin | 15G06-B03-318398 | 1 |
| Fagron | Melatonin | 15G06-B03-321298 | 3 |
| Fagron | Melatonin | 15G06-B03-321299 | 5 |
| Fagron | Melatonin | 15G06-B03-323733 | 2 |
| Fagron | Melatonin | 16343702 | 1 |
| Fagron | Melatonin | 16343708 | 1 |
| Fagron | Melatonin | 16G06-B01-324743 | 2 |
| Fagron | Melatonin | 16G06-B01-327131 | 4 |
| Fagron | Melatonin | 16G06-B01-329142 | 4 |
| Fagron | Melatonin | 17/28-B04-344438 | 2 |
| Fagron | Melatonin | 17/28-B04-344439 | 1 |
| Fagron | Melatonin | 17/28-B04-344440 | 1 |
| Fagron | Melatonin | 17/28-B04-347315 | 1 |
| Fagron | Melatonin | 17/28-B04-348747 | 1 |
| Fagron | Melatonin | 17/28-B04-353566 | 1 |
| Fagron | Melatonin | 17/28-B04-355634 | 1 |
| Fagron | Melatonin | 17/28-B04-359318 | 1 |
| Fagron | Melatonin | 170007 | 5 |
| Fagron | Melatonin | 17128-B04-344439 | 1 |
| Fagron | Melatonin | 17128-B04-355634 | 1 |
| Fagron | Melatonin | 17128B0436869 | 1 |
| Fagron | Melatonin | 1728B04347313 | 1 |
| Fagron | Melatonin | 1728B04360882 | 1 |
| Fagron | Melatonin | 17C22-B01-337089 | 3 |
| Fagron | Melatonin | 17C22-B01-337090 | 4 |
| Fagron | Melatonin | 17C22-B01-337091 | 2 |
| Fagron | Melatonin | 17I28 | 2 |
| Fagron | Melatonin | 17I28-B04 | 2 |
| Fagron | Melatonin | 17I28-B04_356971 | 1 |
| Fagron | Melatonin | 17I28-B04-344439 | 5 |
| Fagron | Melatonin | 17I28-B04-344440 | 1 |
| Fagron | Melatonin | 17I28-B04-347314 | 1 |
| Fagron | Melatonin | 17I28-B04-348747 | 3 |
| Fagron | Melatonin | 17I28-B04-351312 | 2 |
| Fagron | Melatonin | 17I28-B04-352328 | 4 |
| Fagron | Melatonin | 17I28-B04-353566 | 4 |
| Fagron | Melatonin | 17I28-B04-355634 | 2 |
| Fagron | Melatonin | 17I28-B04-355635 | 1 |
| Fagron | Melatonin | 17I28-B04-356971 | 2 |
| Fagron | Melatonin | 17I28-B04-359317 | 2 |
| Fagron | Melatonin | 17I28-B04-359318 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Melatonin | 17I28-B04-360883 | 4 |
| Fagron | Melatonin | 17I28-B04-361869 | 1 |
| Fagron | Melatonin | 17I28B04361873 | 1 |
| Fagron | Melatonin | 17I28-B04-361873 | 2 |
| Fagron | Melatonin | 17l28-B04 | 1 |
| Fagron | Melatonin | 17l28-B04-360883 | 1 |
| Fagron | Melatonin | 19002851 | 1 |
| Fagron | Melatonin | 19003987 | 2 |
| Fagron | Melatonin | 1906030-01 | 1 |
| Fagron | Melatonin | 191280006 | 1 |
| Fagron | Melatonin | 19K04-F01 | 1 |
| Fagron | Melatonin | 19K04-F01/370622 | 1 |
| Fagron | Melatonin | 19K04-F01_370622 | 1 |
| Fagron | Melatonin | 19K04-F01-370622 | 3 |
| Fagron | Melatonin | 19K04-F01-370623 | 2 |
| Fagron | Melatonin | 20A31-F02 | 5 |
| Fagron | Melatonin | 20A31-F02-372822 | 2 |
| Fagron | Melatonin | 20A31-F02-372823 | 1 |
| Fagron | Melatonin | 20A31-F02-372824 | 6 |
| Fagron | Melatonin | 20A31-F02-373915 | 2 |
| Fagron | Melatonin | 20A31-F02-377484 | 2 |
| Fagron | Melatonin | 20A31-F02-377485 | 1 |
| Fagron | Melatonin | 20A31-FO2-372823 | 2 |
| Fagron | Melatonin | 21/24-Bo1-215466 | 1 |
| Fagron | Melatonin | 21I24-B01-215466 | 1 |
| Fagron | Melatonin | 21I24-B01-215649 | 2 |
| Fagron | Melatonin | 21I24-BO1-215649 | 1 |
| Fagron | Melatonin | 22A12-B09 | 1 |
| Fagron | Melatonin | 22A12-B09-219594 | 2 |
| Fagron | Melatonin | 24E09-B01-237419 | 1 |
| Fagron | Melatonin | 24E09-B01-240405 | 1 |
| Fagron | Melatonin | 73-31-4 | 1 |
| Fagron | Melatonin | B01-2156409 | 1 |
| Fagron | Melatonin | F01-3706202 | 1 |
| Fargon GmbH & Co.KG | Melatonin | 16G06-B01-324743 | 1 |
| Fargon/AHD | Melatonin | 17I28-B04-356971 | 1 |
| Farmalabor / Farmalabor | Melatonin | P1201556-000 | 1 |
| Farmalabor | Melatonin | P1800033-000 | 1 |
| Farmalabor | Melatonin | R1804925 | 1 |
| Fgron | Melatonin | 12G19-N03 | 1 |
| GEHE 22.03.2014 | Melatonin | 13167302 | 1 |
| Gehe am 10.03.14 | Melatonin | 13167301 | 2 |
| Gehe amax | Melatonin | 1709020-01 | 1 |
| Gehe | Melatonin | 11/26-N07 | 1 |
| Gehe | Melatonin | 11L21-N04 | 1 |
| Gehe | Melatonin | 13D12-N10 | 1 |
| Gehe | Melatonin | 13E22-N12 | 1 |
| Gehe | Melatonin | 1510041-01 | 1 |
| Gehe | Melatonin | 15254324 | 1 |
| GEHE | Melatonin | 17I28-B04 | 1 |
| GEHE | Melatonin | 17I-28-B04 | 1 |
| Gehe | Melatonin | 18210311 | 1 |
| Gehe | Melatonin | 18210320 | 1 |
| gehe | Melatonin | 191280001 | 2 |
| Gehe | Melatonin | 19128003 | 5 |
| gehe | Melatonin | 21002239005 | 1 |
| GEHE | Melatonin | 21002239028 | 1 |
| Gehe | Melatonin | 21002239029 | 1 |
| Gehe | Melatonin | 21002239038 | 1 |
| Gehe | Melatonin | 21002239039 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Melatonin | 22003650011 | 1 |
| gepepharm | Melatonin | 15G06-B03-315183 | 1 |
| Ichthyol Gesellschaft | Melatonin | 16343708 | 1 |
| Inresa | Melatonin | 110005 | 1 |
| Jacoby Gatt-Koller | Melatonin | 22J00616 | 1 |
| Jenne | Melatonin | 22003650002 | 1 |
| Kehr | Melatonin | 21002239038 | 1 |
| Kehr | Melatonin | 21002239039 | 3 |
| kehr | Melatonin | 22003650009 | 1 |
| Koisser | Melatonin | 140202 | 2 |
| KS Pharma | Melatonin | XPS130428 | 1 |
| Noweda | Melatonin | 18210304 | 1 |
| Noweda | Melatonin | 18210306 | 2 |
| Noweda | Melatonin | 18210318 | 1 |
| Noweda | Melatonin | 19K04-F01-370622 | 3 |
| Noweda | Melatonin | 20220508 | 1 |
| Noweda | Melatonin | 21002239006 | 1 |
| Noweda | Melatonin | 21002239038 | 2 |
| Noweda | Melatonin | 2110002-01 | 3 |
| Noweda | Melatonin | 2200360021 | 1 |
| Noweda | Melatonin | 22003650002 | 1 |
| Noweda | Melatonin | 22003650004 | 1 |
| Phoenix 03.04.2014 | Melatonin | 12J19-N02 | 1 |
| PHOENIX 14.04.2014 | Melatonin | 13E22-N12 | 1 |
| Phoenix/Caesar & Lor… | Melatonin | 21002239028 | 1 |
| Phoenix | Melatonin | 15C20-B01 | 1 |
| Phoenix | Melatonin | 16266903 | 1 |
| Phoenix | Melatonin | 18210303 | 2 |
| Phoenix | Melatonin | 18210315 | 1 |
| Phoenix | Melatonin | 191421112 | 1 |
| Phoenix | Melatonin | 200480406 | 1 |
| Phoenix | Melatonin | 200811308 | 1 |
| Phoenix | Melatonin | 21002239028 | 2 |
| Phoenix | Melatonin | 21002239038 | 1 |
| Phoenix | Melatonin | 3368 | 1 |
| Phönix 02.01.15 | Melatonin | 13H21-N06 | 1 |
| Phönix 02.01.2014 | Melatonin | 1204003-02 | 1 |
| Phönix Gotha | Melatonin | 19128005 | 1 |
| Phönix | Melatonin | 11267111 | 1 |
| phönix | Melatonin | 15254308 | 1 |
| Phönix | Melatonin | 17305115 | 1 |
| Phönix | Melatonin | 21002239036 | 1 |
| phönix | Melatonin | 22003650018 | 1 |
| Phönix | Melatonin | APALC/MCT17030111 | 1 |
| Sanacorp Verbund | Melatonin | 20A31-F02-372823 | 1 |
| Sanacorp WE: 17.0518… | Melatonin | 1709020-01 | 1 |
| Sanacorp | Melatonin | | 1 |
| Sanacorp | Melatonin | 11267119 | 1 |
| sanacorp | Melatonin | 14110320 | 1 |
| Sanacorp | Melatonin | 161004001 | 1 |
| Sanacorp | Melatonin | 161004002 | 1 |
| Sanacorp | Melatonin | 17I28-B04 | 3 |
| Sanacorp | Melatonin | 17I28-B04-360883 | 1 |
| Sanacorp | Melatonin | 18210318 | 1 |
| Sanacorp | Melatonin | 20001543007 | 3 |
| Sanacorp | Melatonin | 20001543012 | 1 |
| Sanacorp | Melatonin | 21002239036 | 1 |
| Sanacorp | Melatonin | 22003650005 | 1 |
| Sanacorp | Melatonin | APALC/MLT/161101M | 1 |
| Sanacorp | Melatonin | APALC/MLT/170301M | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Melatonin | APALC/MLT/170901M | 1 |
| Sanacorp | Melatonin | APMLT170901M | 1 |
| Sanacorp | Melatonin | MLT/SEP/170901 | 1 |
| Sanaorp | Melatonin | 16343707 | 1 |
| SWATI/Phoenix | Melatonin | 2002029-01 | 1 |
| WE Sanacorp 28.11..2... | Melatonin | 15254324 | 1 |

- 254 973 spectra from 1666 *Apo-Ident* customers from a total of 51 791 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Melatonin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Melatonin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 640 | 0 | 157 686 |
| **Type B** | 0 | 1259 | 0 | 211 681 |
| **Type C** | 0 | 1882 | 31 | 254 973 |

The substance/substance group *Melatonin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0625 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.5234 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.3795 % (> 98.2227 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20834 | 22237 | 28.31 | 239.79 |
| 20835 | 21618 | 9.73 | 202.87 |
| 20987 | 21618 | 5.86 | 205.48 |
| 21618 | 21618 | 0.00 | 207.79 |
| 22237 | 22237 | 0.00 | 206.35 |
| 22892 | 22237 | 3.52 | 208.20 |
| 22893 | 22237 | 5.20 | 209.86 |
| 23889 | 23889 | 0.00 | 205.59 |
| 24128 | 24128 | 0.00 | 206.12 |
| 25542 | 25542 | 0.00 | 210.89 |
| 26415 | 24128 | 8.97 | 204.34 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Menthol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20036-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Menthol; Mentholum

### Special notes

When selecting the *Menthol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Menthol | 11 | 19 | 456 |

### Second-stage model

For differentiation of the substance/substance group *Menthol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Menthol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 110.42 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Menthol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Menthol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Menthol | 13377404 | 21443 | 60 | 20131212 |
| Caelo | Menthol | 181522 | 24233 | 40 | 20180625* |
| Caelo | Menthol | 2000170 | 25217 | 40 | 20200608* |
| Euro OTC | Menthol | 1403022-02 | 21601 | 45 | 20140408 |
| Euro OTC | Menthol | 1509045 | 21932 | 60 | 20151008* |
| Euro OTC | Menthol | 1603024 | 22657 | 40 | 20160429* |
| Euro OTC | Menthol | 1608012 | 22825 | 40 | 20160902* |
| Euro OTC | Menthol | 2103009 | 25591 | 40 | 20210322* |
| Euro OTC | Menthol | 2204013 | 26091 | 40 | 20220517* |
| Euro OTC | Menthol | 2204013 | 26091SI | 20 | 20220517* |
| Fagron | Menthol | 16L20-T04-044769 | 23596 | 40 | 20170116 |
| Fagron | Menthol | 18L04-T06-065445 | 24690 | 40 | 20181217 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 505 spectra of 12 reference samples from the substance/substance group *Menthol*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 821 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 845 spectra of 22 reference samples from the substance/substance group *Menthol*.

- Among them are spectra of independent samples from 19 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Menthol | 160956 | 22452 | 60 |
| Caelo | Menthol | 170927 | 23312 | 40 |
| Caelo | Menthol | 171889 | 23668 | 40 |
| Caelo | Menthol | 183286 | 24666 | 40 |
| Caelo | Menthol | 192453 | 24877 | 40 |
| Caelo | Menthol | 20003371 | 25617 | 40 |
| Caelo | Menthol | 21000696 | 25655 | 40 |
| Caelo | Menthol | 22000117 | 26019 | 40 |
| Caelo | Menthol | 23003505 | 27131 | 40 |
| Euro OTC | Menthol | 1701014 | 23005 | 40 |
| Euro OTC | Menthol | 1705022 | 23427 | 40 |
| Euro OTC | Menthol | 1802003 | 23951 | 40 |
| Euro OTC | Menthol | 1905013 | 24599 | 40 |
| Euro OTC | Menthol | 1912006 | 25089 | 40 |
| Euro OTC | Menthol | 2009021 | 25425 | 40 |
| Euro OTC | Menthol | 2301002 | 26515 | 40 |
| Euro OTC | Menthol | 2307028 | 26869 | 40 |
| Euro OTC | Menthol | 2411006 | 27497 | 40 |
| Fagron | Menthol | 22L03-B08-227346 | 26537 | 40 |
| Caelo | Menthol | 170927 | 23645 | 40 |
| Caelo | Menthol | 22000117 | 26019SI | 10 |
| Euro OTC | Menthol | 1403022-02 | 21601† | 15 |

- 212 095 spectra from a total of 4267 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2642 spectra from 1139 *Apo-Ident* customers from 469 batches from the substance/substance group *Menthol*.
- Among them are spectra of independent samples from 456 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Menthol | 1187170 | 1 |
| | Menthol | 1291910 | 1 |
| | Menthol | 133745 | 1 |
| | Menthol | 1337745 | 2 |
| | Menthol | 2009021-01 | 1 |
| | Menthol | 21000696015 | 2 |
| | Menthol | 21000696016 | 1 |
| | Menthol | 21000696018 | 2 |
| | Menthol | 21000730009 | 1 |
| | Menthol | 21000730011 | 2 |
| | Menthol | 21000730016 | 4 |
| | Menthol | 2103009-01 | 1 |
| | Menthol | 220003309003 | 1 |
| | Menthol | 22002585003 | 9 |
| | Menthol | 22002585006 | 2 |
| | Menthol | 220025855006 | 1 |
| | Menthol | 22003309002 | 1 |
| | Menthol | 22003309003 | 16 |
| | Menthol | 22003309005 | 2 |
| | Menthol | 22003309007 | 19 |
| | Menthol | 22003309012 | 7 |
| | Menthol | 2204013-01 | 5 |
| | Menthol | 2204013-02 | 2 |
| | Menthol | 22A14-B05-219347 | 5 |
| | Menthol | 22A14-B05-2193407 | 1 |
| | Menthol | 22F02-B11 | 1 |
| | Menthol | 22F02-B11-222586 | 12 |
| | Menthol | 22F02-B11-22586 | 1 |
| | Menthol | 22F02-B11-222586 | 2 |
| | Menthol | 23003319001 | 4 |
| | Menthol | 23003319006 | 2 |
| | Menthol | 23003505002 | 2 |
| | Menthol | 23010002-02 | 1 |
| | Menthol | 2301002 | 1 |
| | Menthol | 2301002-01 | 26 |
| | Menthol | 2301002-02 | 16 |
| | Menthol | 2307028-01 | 13 |
| | Menthol | 2307028-02 | 1 |
| | Menthol | 2307028-03 | 1 |
| | Menthol | 231002-02 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Menthol | 23B14B26227532 | 1 |
| | Menthol | 23B14-B26-227532 | 12 |
| | Menthol | 23G19-B06-231924 | 8 |
| | Menthol | 2405-804-005989 | 1 |
| | Menthol | 2411006-01 | 3 |
| | Menthol | 24I05-B04-005989 | 3 |
| | Menthol | 250407(22003309012) | 1 |
| | Menthol | 4137664 | 1 |
| | Menthol | B03-2193406 | 1 |
| | Menthol | MEC-1/21124 | 1 |
| 08639701 | Menthol | 2301002-01 | 1 |
| 11,22 | Menthol | 21C12-B03-211790 | 1 |
| AHC | Menthol | 22F02-B11-222586 | 1 |
| AHD | Menthol | 1305010-01 | 1 |
| AHD | Menthol | 18128014 | 1 |
| AHD | Menthol | 21000696018 | 1 |
| AHD | Menthol | 22002585006 | 1 |
| AHD | Menthol | 23G19-B06-231924 | 1 |
| Alliance Health 14.04..14 | Menthol | 1305010-02 | 1 |
| Alliance Healthcare | Menthol | 15363804 | 1 |
| Alliance Healthcare | Menthol | 19162801 | 1 |
| Alliance Healthcare | Menthol | 23G19-B06-231924 | 2 |
| alliance | Menthol | 21000730009 | 1 |
| Andreas Imhof | Menthol | 8052015 | 1 |
| Anzag | Menthol | 12/19-N10 | 1 |
| Anzag | Menthol | 16L20-T04-044769 | 1 |
| Anzag | Menthol | 230405(21000730016) | 1 |
| Anzag | Menthol | 240103(22003309007) | 1 |
| Anzag | Menthol | 240308(22003309007) | 1 |
| Apo-ident | Menthol | 1509045-03 | 1 |
| apo-ident | Menthol | 1705022-01 | 1 |
| apoident | Menthol | 1807044-01 | 1 |
| Audor Pharma | Menthol | 200902102 | 1 |
| beyvers | Menthol | 16095613 | 1 |
| Bombastus | Menthol | 16095620 | 1 |
| Bombastus | Menthol | 16L20-T04-053177 | 1 |
| Caeelo/Noweda | Menthol | 20000970006 | 1 |
| Caele | Menthol | 2004420002 | 1 |
| Caelo | Menthol | | 4 |
| Caelo | Menthol | 1/AD1 | 1 |
| Caelo | Menthol | 10008029-02 | 1 |
| Caelo | Menthol | 10157615 | 1 |
| Caelo | Menthol | 1046973 | 2 |
| Caelo | Menthol | 1087209 | 1 |
| Caelo | Menthol | 11091405 | 1 |
| Caelo | Menthol | 1115262 | 2 |
| Caelo | Menthol | 1119I-01855 | 1 |
| Caelo | Menthol | 11202901 | 1 |
| Caelo | Menthol | 11202910 | 5 |
| Caelo | Menthol | 12020402 | 5 |
| Caelo | Menthol | 1202041 | 1 |
| Caelo | Menthol | 12020410 | 1 |
| Caelo | Menthol | 12020411 | 8 |
| Caelo | Menthol | 1204036-01 | 1 |
| Caelo | Menthol | 12246203 | 1 |
| Caelo | Menthol | 12246204 | 1 |
| Caelo | Menthol | 12246205 | 8 |
| Caelo | Menthol | 12246211 | 3 |
| Caelo | Menthol | 130501001 | 1 |
| Caelo | Menthol | 13102001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Menthol | 13103802 | 1 |
| Caelo | Menthol | 13103901 | 24 |
| Caelo | Menthol | 13159104 | 4 |
| Caelo | Menthol | 13159105 | 20 |
| Caelo | Menthol | 13159110 | 2 |
| Caelo | Menthol | 1320260 | 2 |
| Caelo | Menthol | 13377402 | 3 |
| Caelo | Menthol | 13377404 | 17 |
| Caelo | Menthol | 13377407 | 2 |
| Caelo | Menthol | 13377408 | 2 |
| Caelo | Menthol | 13377409 | 9 |
| Caelo | Menthol | 133774112 | 1 |
| Caelo | Menthol | 13377412 | 3 |
| Caelo | Menthol | 13377413 | 1 |
| Caelo | Menthol | 13D1N09 | 1 |
| Caelo | Menthol | 13G09-N09 | 1 |
| Caelo | Menthol | 1403022-01 | 1 |
| Caelo | Menthol | 1403022-02 | 1 |
| Caelo | Menthol | 1410004-01 | 2 |
| Caelo | Menthol | 1410004-02 | 2 |
| Caelo | Menthol | 14183004 | 14 |
| Caelo | Menthol | 14183006 | 1 |
| Caelo | Menthol | 14183008 | 3 |
| Caelo | Menthol | 14183011 | 2 |
| Caelo | Menthol | 14183012 | 3 |
| Caelo | Menthol | 14183014 | 2 |
| Caelo | Menthol | 14183017 | 3 |
| Caelo | Menthol | 14183020 | 1 |
| Caelo | Menthol | 1507601 | 1 |
| Caelo | Menthol | 15076101 | 8 |
| Caelo | Menthol | 15076104 | 1 |
| Caelo | Menthol | 15076106 | 12 |
| Caelo | Menthol | 15076112 | 11 |
| Caelo | Menthol | 15076113 | 9 |
| Caelo | Menthol | 15076115 | 3 |
| Caelo | Menthol | 15076118 | 2 |
| Caelo | Menthol | 15076215 | 1 |
| Caelo | Menthol | 15076219 | 1 |
| Caelo | Menthol | 1509045-03 | 3 |
| Caelo | Menthol | 15286201 | 1 |
| Caelo | Menthol | 15286205 | 1 |
| Caelo | Menthol | 15286209 | 1 |
| Caelo | Menthol | 15286212 | 2 |
| Caelo | Menthol | 15286216 | 1 |
| Caelo | Menthol | 15363803 | 2 |
| Caelo | Menthol | 15363804 | 11 |
| Caelo | Menthol | 15363805 | 11 |
| Caelo | Menthol | 15363809 | 8 |
| Caelo | Menthol | 15363810 | 13 |
| Caelo | Menthol | 15363815 | 16 |
| Caelo | Menthol | 1536815 | 1 |
| Caelo | Menthol | 1603024-01 | 3 |
| Caelo | Menthol | 160719M | 1 |
| Caelo | Menthol | 1608012-01 | 2 |
| Caelo | Menthol | 1608012-02 | 4 |
| Caelo | Menthol | 16081805 | 1 |
| Caelo | Menthol | 160956 | 1 |
| Caelo | Menthol | 16095601 | 1 |
| Caelo | Menthol | 16095602 | 3 |
| Caelo | Menthol | 16095603 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Menthol | 16095604 | 1 |
| Caelo | Menthol | 16095606 | 17 |
| Caelo | Menthol | 16095609 | 1 |
| Caelo | Menthol | 16095613 | 13 |
| Caelo | Menthol | 16095614 | 16 |
| Caelo | Menthol | 16095616 | 1 |
| Caelo | Menthol | 16095617 | 2 |
| Caelo | Menthol | 16095619 | 17 |
| Caelo | Menthol | 16095620 | 9 |
| Caelo | Menthol | 160956217188904 | 1 |
| Caelo | Menthol | 16095625 | 2 |
| Caelo | Menthol | 16098614 | 1 |
| Caelo | Menthol | 161202M/15076111 | 1 |
| Caelo | Menthol | 16L20-T04-053177 | 1 |
| Caelo | Menthol | 1701014-01 | 3 |
| Caelo | Menthol | 170101402 | 1 |
| Caelo | Menthol | 1701014-02 | 2 |
| Caelo | Menthol | 170502201 | 1 |
| Caelo | Menthol | 1705022-01 | 9 |
| Caelo | Menthol | 17072001 | 1 |
| Caelo | Menthol | 17078004 | 2 |
| Caelo | Menthol | 17078006 | 2 |
| Caelo | Menthol | 17078009 | 1 |
| Caelo | Menthol | 170822M/16095616 | 1 |
| Caelo | Menthol | 17188903 | 25 |
| Caelo | Menthol | 171889035483 | 1 |
| Caelo | Menthol | 17188904 | 24 |
| Caelo | Menthol | 17188906 | 4 |
| Caelo | Menthol | 17328803 | 5 |
| Caelo | Menthol | 17328804 | 19 |
| Caelo | Menthol | 17351501 | 2 |
| Caelo | Menthol | 17351505 | 7 |
| Caelo | Menthol | 17351506 | 1 |
| Caelo | Menthol | 1738804 | 1 |
| Caelo | Menthol | 1802003-01 | 3 |
| Caelo | Menthol | 18128007 | 5 |
| Caelo | Menthol | 18128008 | 2 |
| Caelo | Menthol | 18128009 | 20 |
| Caelo | Menthol | 18128012 | 1 |
| Caelo | Menthol | 18128014 | 1 |
| Caelo | Menthol | 18128015 | 20 |
| Caelo | Menthol | 18128015P-190718-7 | 1 |
| Caelo | Menthol | 18152202 | 4 |
| Caelo | Menthol | 18152205 | 5 |
| Caelo | Menthol | 18152210 | 2 |
| Caelo | Menthol | 18152214 | 2 |
| Caelo | Menthol | 18152216 | 2 |
| Caelo | Menthol | 1832605 | 1 |
| Caelo | Menthol | 18326805 | 1 |
| Caelo | Menthol | 18328601 | 3 |
| Caelo | Menthol | 18328604 | 2 |
| Caelo | Menthol | 18328605 | 32 |
| Caelo | Menthol | 18328610 | 3 |
| Caelo | Menthol | 18328611 | 1 |
| Caelo | Menthol | 18328612 | 29 |
| Caelo | Menthol | 1838605 | 1 |
| Caelo | Menthol | 18L04-T06-065445 | 2 |
| Caelo | Menthol | 190501301 | 1 |
| Caelo | Menthol | 190513-02 | 1 |
| Caelo | Menthol | 19051401 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Menthol | 19091805 | 1 |
| Caelo | Menthol | 19162801 | 6 |
| Caelo | Menthol | 19245006 | 1 |
| Caelo | Menthol | 1924530006 | 1 |
| Caelo | Menthol | 192453004 | 1 |
| Caelo | Menthol | 192453006 | 24 |
| Caelo | Menthol | 192977003 | 2 |
| Caelo | Menthol | 192977004 | 8 |
| Caelo | Menthol | 20000970006 | 4 |
| Caelo | Menthol | 20001704005 | 3 |
| Caelo | Menthol | 20004049004 | 5 |
| Caelo | Menthol | 20004049007 | 3 |
| Caelo | Menthol | 20004420002 | 19 |
| Caelo | Menthol | 20004420003 | 1 |
| Caelo | Menthol | 2000442002 | 3 |
| Caelo | Menthol | 20044200002 | 1 |
| Caelo | Menthol | 20200712-2 | 1 |
| Caelo | Menthol | 20E22-B02-2025100 | 1 |
| Caelo | Menthol | 21000696007 | 1 |
| Caelo | Menthol | 21000696010 | 6 |
| Caelo | Menthol | 210006960100 | 1 |
| Caelo | Menthol | 21000696012 | 10 |
| Caelo | Menthol | 21000696015 | 6 |
| Caelo | Menthol | 21000696016 | 2 |
| Caelo | Menthol | 21000696017 | 1 |
| Caelo | Menthol | 21000730002 | 1 |
| Caelo | Menthol | 21000730003 | 20 |
| Caelo | Menthol | 21000730006 | 1 |
| Caelo | Menthol | 21000730007 | 1 |
| Caelo | Menthol | 21000730009 | 6 |
| Caelo | Menthol | 21000730010 | 1 |
| Caelo | Menthol | 21000730011 | 13 |
| Caelo | Menthol | 21000730012 | 1 |
| Caelo | Menthol | 21000730016 | 6 |
| Caelo | Menthol | 2100073009 | 2 |
| Caelo | Menthol | 2100073011 | 1 |
| Caelo | Menthol | 2100080011 | 1 |
| Caelo | Menthol | 2100096015 | 1 |
| Caelo | Menthol | 2100696007 | 1 |
| Caelo | Menthol | 211227(21000730003) | 1 |
| Caelo | Menthol | 21C12-B03-211790 | 3 |
| Caelo | Menthol | 21C12-B03-2117900 | 1 |
| Caelo | Menthol | 22003309003 | 1 |
| Caelo | Menthol | 2204013-01 | 1 |
| Caelo | Menthol | 22042002 | 1 |
| Caelo | Menthol | 220622(21000730009) | 1 |
| Caelo | Menthol | 2416 | 1 |
| Caelo | Menthol | 25041402 | 1 |
| Caelo | Menthol | 25051301 | 1 |
| Caelo | Menthol | 2912110З | 1 |
| Caelo | Menthol | 314Q01855 | 1 |
| Caelo | Menthol | 3912A-01855 | 1 |
| Caelo | Menthol | 4137664 | 1 |
| Caelo | Menthol | 5117A-01855 | 1 |
| Caelo | Menthol | 515M-01855 | 1 |
| Caelo | Menthol | 5315I-01855 | 1 |
| Caelo | Menthol | 617E-01855 | 1 |
| Caelo | Menthol | 62470307 | 1 |
| Caelo | Menthol | 687711 | 1 |
| Caelo | Menthol | 7111201 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Menthol | 72173258 | 1 |
| Caelo | Menthol | 750137 | 1 |
| Caelo | Menthol | 814A-01855 | 1 |
| Caelo | Menthol | 90(17328804) | 1 |
| Caelo | Menthol | 91(18128009) | 1 |
| Caelo | Menthol | 92(18128015) | 1 |
| Caelo | Menthol | 93(18328605) | 1 |
| Caelo | Menthol | 930716 | 1 |
| Caelo | Menthol | 94(18328605) | 1 |
| Caelo | Menthol | 95(18328612) | 1 |
| Caelo | Menthol | 97(192453006) | 1 |
| Caelo | Menthol | 98(20004420002) | 1 |
| Caelo | Menthol | AP210305-02 | 1 |
| Caelo | Menthol | IntCh311052 | 1 |
| Caeolo/Gehe | Menthol | 16096619 | 1 |
| Caesar & Lorenz GmbH | Menthol | 15076101 | 1 |
| Caesar & Loretz GmbH... | Menthol | 20004049007 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000696010 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000730003 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000730009 | 2 |
| Caesar & Loretz GmbH... | Menthol | 11202910 | 1 |
| Caesar & Loretz GmbH... | Menthol | 12020402 | 1 |
| Caesar & Loretz GmbH... | Menthol | 12020411 | 1 |
| Caesar & Loretz GmbH... | Menthol | 13103901 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18128009 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18328605 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18328605 | 2 |
| Caesar & Loretz GmbH... | Menthol | 1912006-01 | 3 |
| Caesar & Loretz GmbH/A | Menthol | 21003010002 | 1 |
| Caesar & Loretz GmbH/AHD | Menthol | 192453006 | 2 |
| Caesar & Loretz GmbH/AHD | Menthol | 21000730003 | 1 |
| Caesar & Loretz GmbH... | Menthol | 20004420002 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18328612 | 2 |
| Caesar & Loretz GmbH... | Menthol | 20004420002 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000730011 | 1 |
| Caesar & Loretz GmbH/G | Menthol | 20004049007 | 1 |
| Caesar & Loretz GmbH/Gehe | Menthol | 18128015 | 1 |
| Caesar & Loretz GmbH/Gehe | Menthol | 191628 | 1 |
| Caesar & Loretz GmbH/Gehe | Menthol | 20004049007 | 1 |
| Caesar & Loretz GmbH/Gehe | Menthol | 21000696010 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18328605 | 1 |
| Caesar & Loretz GmbH... | Menthol | 22002585003 | 1 |
| Caesar & Loretz GmbH... | Menthol | AP220321-05 | 1 |
| Caesar & Loretz GmbH/Nowe | Menthol | 20001704005 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18152202 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18328605 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000730003 | 1 |
| Caesar & Loretz GmbH... | Menthol | 192453006 | 1 |
| Caesar & Loretz GmbH... | Menthol | 20000970006 | 1 |
| Caesar & Loretz GmbH... | Menthol | 20004049004 | 1 |
| Caesar & Loretz GmbH... | Menthol | 18328603 | 2 |
| Caesar & Loretz GmbH... | Menthol | 192977004 | 1 |
| Caesar & Loretz GmbH... | Menthol | 192453006 | 1 |
| Caesar & Loretz GmbH... | Menthol | 20004420002 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000696012 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000730003 | 1 |
| Caesar & Loretz GmbH... | Menthol | 22003309003 | 1 |
| Caesar & Loretz GmbH/Sana | Menthol | 20000970006 | 1 |
| Caesar & Loretz GmbH... | Menthol | 17328804 | 1 |
| Caesar & Loretz GmbH... | Menthol | 192453006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Menthol | 20004049004 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000730006 | 1 |
| Caesar & Loretz GmbH... | Menthol | 21000730016 | 1 |
| Caesar & Loretz GmbH... | Menthol | AP210401-02 | 1 |
| Caesar & Loretz GmbH | Menthol | 17328804 | 1 |
| Caesar & Loretz GmbH | Menthol | 18128007 | 2 |
| Caesar & Loretz GmbH | Menthol | 18128008 | 5 |
| Caesar & Loretz GmbH | Menthol | 18128009 | 5 |
| Caesar & Loretz GmbH | Menthol | 18128015 | 2 |
| Caesar & Loretz GmbH | Menthol | 18152210 | 1 |
| Caesar & Loretz GmbH | Menthol | 183286001 | 3 |
| Caesar & Loretz GmbH | Menthol | 18328604 | 3 |
| Caesar & Loretz GmbH | Menthol | 18328605 | 7 |
| Caesar & Loretz GmbH | Menthol | 18328610 | 1 |
| Caesar & Loretz GmbH | Menthol | 18328611 | 1 |
| Caesar & Loretz GmbH | Menthol | 18328612 | 7 |
| Caesar & Loretz GmbH | Menthol | 1905013-01 | 1 |
| Caesar & Loretz GmbH | Menthol | 19162801 | 2 |
| Caesar & Loretz GmbH | Menthol | 192453004 | 3 |
| Caesar & Loretz GmbH | Menthol | 192453006 | 8 |
| Caesar & Loretz GmbH | Menthol | 192453008 | 1 |
| Caesar & Loretz GmbH | Menthol | 192977004 | 4 |
| Caesar & Loretz GmbH | Menthol | 20000970007 | 1 |
| Caesar & Loretz GmbH | Menthol | 20001704005 | 2 |
| Caesar & Loretz GmbH | Menthol | 20004049004 | 1 |
| Caesar & Loretz GmbH | Menthol | 20004049007 | 4 |
| Caesar & Loretz GmbH | Menthol | 20004420001 | 1 |
| Caesar & Loretz GmbH | Menthol | 20004420002 | 14 |
| Caesar & Loretz GmbH | Menthol | 20004420003 | 1 |
| Caesar & Loretz GmbH | Menthol | 21000696010 | 1 |
| Caesar & Loretz GmbH | Menthol | 21000696012 | 2 |
| Caesar & Loretz GmbH | Menthol | 21000730002 | 1 |
| Caesar & Loretz GmbH | Menthol | 21000730003 | 8 |
| Caesar & Loretz GmbH | Menthol | 21000730009 | 5 |
| Caesar & Loretz GmbH | Menthol | 21000730010 | 1 |
| Caesar & Loretz GmbH | Menthol | 21000730011 | 4 |
| Caesar & Loretz GmbH | Menthol | 21000730016 | 4 |
| Caesar & Loretz GmbH | Menthol | 22003309004 | 2 |
| Caesar & Loretz | Menthol | 15363809 | 1 |
| Caesar & Loretz | Menthol | 18128007 | 1 |
| Caesar&Lorenz | Menthol | 21000696007 | 1 |
| Caesar&Loretz GmbH | Menthol | 21000730003 | 1 |
| Caesar&Loretz,Phönix | Menthol | 15076106 | 1 |
| Caesar/Noweda | Menthol | 12020403 | 1 |
| Caesar/Noweda | Menthol | 12246211 | 1 |
| Caesar/Noweda | Menthol | 15076111 | 2 |
| Cealo / Anzag | Menthol | 221117(21000730016) | 1 |
| Cealo | Menthol | 1705022-01 | 1 |
| Celo/AHD | Menthol | 16095620 | 1 |
| Defektur | Menthol | 18328612 | 1 |
| E Plus | Menthol | 1705022-01 | 1 |
| Eur Rho | Menthol | 1912006-01 | 1 |
| EuRho/ Gehe | Menthol | 1807044-01 | 1 |
| EuRho/ Noweda | Menthol | 2009021-01 | 1 |
| Eurho/ Sanacorp 19.1... | Menthol | 220401301 | 1 |
| EuRho/Alliance | Menthol | 1701014-01 | 1 |
| EuRho/Alliance | Menthol | 1905013-02 | 1 |
| EuRho/Fiebig | Menthol | 1905013-01 | 1 |
| EuRho/Fiebig | Menthol | 2103009-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho/Gehe | Menthol | 1807044-01 | 1 |
| EuRho/Jenne | Menthol | 180704401 | 1 |
| EuRho/Jenne | Menthol | 2103009-01euri | 1 |
| Eurho/Noweda | Menthol | 2103009-03 | 1 |
| EuRho/Noweda | Menthol | 2301002-01 | 1 |
| EuRho/Phönix | Menthol | 1146105 | 1 |
| Eurho/Phönix | Menthol | 2009021-01 | 1 |
| Eurho/Sanacorp | Menthol | 1802003-01 | 1 |
| EuRho/sanacorp | Menthol | 1905013-01 | 1 |
| EuRho | Menthol | 1046973 | 1 |
| EuRho | Menthol | 1204036-02 | 1 |
| EuRho | Menthol | 1305010-01 | 1 |
| EuRho | Menthol | 1410004-01 | 1 |
| EuRho | Menthol | 1603024-01 | 1 |
| EuRho | Menthol | 1701014-02 | 1 |
| Eurho | Menthol | 170502201 | 1 |
| EuRho | Menthol | 1705022-01 | 2 |
| EuRho | Menthol | 1905013-01 | 1 |
| EuRho | Menthol | 1912006-01 | 1 |
| euRho | Menthol | 200902101 | 1 |
| EuRho | Menthol | 2103009-03 | 1 |
| EuRho | Menthol | 2910A-01855 | 1 |
| EuRho | Menthol | 915A-01855 | 1 |
| Eurho-Phönix | Menthol | 2204013-01 | 1 |
| Euro OTC | Menthol | 1001505 | 3 |
| Euro OTC | Menthol | 1001506 | 1 |
| Euro OTC | Menthol | 1002019-03 | 1 |
| Euro OTC | Menthol | 1008029-01 | 1 |
| Euro OTC | Menthol | 1046973 | 1 |
| Euro OTC | Menthol | 1087209 | 2 |
| Euro OTC | Menthol | 1105028-01 | 1 |
| Euro OTC | Menthol | 1111020-01 | 1 |
| Euro OTC | Menthol | 1146105 | 6 |
| Euro OTC | Menthol | 1178546 | 2 |
| Euro OTC | Menthol | 1201416 | 1 |
| Euro OTC | Menthol | 1204036-01 | 8 |
| Euro OTC | Menthol | 120403602 | 1 |
| Euro OTC | Menthol | 1204036-02 | 3 |
| Euro OTC | Menthol | 1204036-1 | 1 |
| Euro OTC | Menthol | 1210017-01 | 4 |
| Euro OTC | Menthol | 1210017-02 | 12 |
| Euro OTC | Menthol | 1221331 | 5 |
| Euro OTC | Menthol | 130501001 | 1 |
| Euro OTC | Menthol | 1305010-01 | 7 |
| Euro OTC | Menthol | 130501002 | 1 |
| Euro OTC | Menthol | 1305010-02 | 6 |
| Euro OTC | Menthol | 1310J-01855 | 1 |
| Euro OTC | Menthol | 1337745 | 1 |
| Euro OTC | Menthol | 140302201 | 2 |
| Euro OTC | Menthol | 1403022-01 | 2 |
| Euro OTC | Menthol | 1403022-02 | 11 |
| Euro OTC | Menthol | 14030222-02 | 1 |
| Euro OTC | Menthol | 140322-01 | 1 |
| Euro OTC | Menthol | 141000401 | 1 |
| Euro OTC | Menthol | 1410004-01 | 21 |
| Euro OTC | Menthol | 1410004-02 | 12 |
| Euro OTC | Menthol | 14183012 | 1 |
| Euro OTC | Menthol | 15020006-02 | 1 |
| Euro OTC | Menthol | 1502006 | 1 |
| Euro OTC | Menthol | 150200601 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Menthol | 1502006-01 | 18 |
| Euro OTC | Menthol | 1502006-02 | 17 |
| Euro OTC | Menthol | 1509045 | 2 |
| Euro OTC | Menthol | 1509045-01 | 4 |
| Euro OTC | Menthol | 150904502 | 1 |
| Euro OTC | Menthol | 1509045-02 | 11 |
| Euro OTC | Menthol | 15-0904502 | 1 |
| Euro OTC | Menthol | 1509045-03 | 13 |
| Euro OTC | Menthol | 1602024-01 | 1 |
| Euro OTC | Menthol | 1603021-01 | 1 |
| Euro OTC | Menthol | 1603024-01 | 46 |
| Euro OTC | Menthol | 160801201 | 2 |
| Euro OTC | Menthol | 1608012-01 | 26 |
| Euro OTC | Menthol | 1608012-02 | 14 |
| Euro OTC | Menthol | 1608012-1 | 1 |
| Euro OTC | Menthol | 1608012-12 | 1 |
| Euro OTC | Menthol | 16095614 | 1 |
| Euro OTC | Menthol | 16L20-T04-053177 | 1 |
| Euro OTC | Menthol | 1701014_01 | 1 |
| Euro OTC | Menthol | 17010140 | 1 |
| Euro OTC | Menthol | 170101401 | 1 |
| Euro OTC | Menthol | 1701014-01 | 20 |
| Euro OTC | Menthol | 170101402 | 4 |
| Euro OTC | Menthol | 1701014-02 | 23 |
| Euro OTC | Menthol | 1701014-2 | 1 |
| Euro OTC | Menthol | 170104-01 | 1 |
| Euro OTC | Menthol | 17050022-01 | 1 |
| Euro OTC | Menthol | 1705011-01 | 1 |
| Euro OTC | Menthol | 1705022 | 1 |
| Euro OTC | Menthol | 170502201 | 2 |
| Euro OTC | Menthol | 1705022-01 | 48 |
| Euro OTC | Menthol | 1705022011 | 1 |
| Euro OTC | Menthol | 1705022-1 | 1 |
| Euro OTC | Menthol | 1802003 | 1 |
| Euro OTC | Menthol | 1802003/01 | 1 |
| Euro OTC | Menthol | 180200301 | 4 |
| Euro OTC | Menthol | 1802003-01 | 59 |
| Euro OTC | Menthol | 1807044_01 | 1 |
| Euro OTC | Menthol | 180704401 | 1 |
| Euro OTC | Menthol | 1807044-01 | 44 |
| Euro OTC | Menthol | 180704402 | 1 |
| Euro OTC | Menthol | 1807044-02 | 5 |
| Euro OTC | Menthol | 18121718 | 1 |
| Euro OTC | Menthol | 182003-01 | 1 |
| Euro OTC | Menthol | 1905013 | 2 |
| Euro OTC | Menthol | 1905013_01 | 1 |
| Euro OTC | Menthol | 190501301 | 1 |
| Euro OTC | Menthol | 1905013-01 | 31 |
| Euro OTC | Menthol | 1905013-02 | 18 |
| Euro OTC | Menthol | 1905013-023 | 1 |
| Euro OTC | Menthol | 191080810 | 1 |
| Euro OTC | Menthol | 1912006-01 | 47 |
| Euro OTC | Menthol | 1912006-1 | 1 |
| Euro OTC | Menthol | 195013-01 | 1 |
| Euro OTC | Menthol | 1987209 | 1 |
| Euro OTC | Menthol | 20009021 | 1 |
| Euro OTC | Menthol | 200902101 | 1 |
| Euro OTC | Menthol | 2009021-01 | 59 |
| Euro OTC | Menthol | 2009021-02 | 11 |
| Euro OTC | Menthol | 20116 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Menthol | 2103009 | 1 |
| Euro OTC | Menthol | 210300901 | 5 |
| Euro OTC | Menthol | 2103009-01 | 46 |
| Euro OTC | Menthol | 2103009-02 | 13 |
| Euro OTC | Menthol | 2103009-03 | 16 |
| Euro OTC | Menthol | 2201013-01 | 1 |
| Euro OTC | Menthol | 220401301 | 1 |
| Euro OTC | Menthol | 2204013-01 | 19 |
| Euro OTC | Menthol | 2204013-02 | 6 |
| Euro OTC | Menthol | 2301002-01 | 8 |
| Euro OTC | Menthol | 25021709 | 1 |
| Euro OTC | Menthol | 5116U-01855 | 4 |
| Euro OTC | Menthol | 6102014B | 1 |
| Euro OTC | Menthol | 696773 | 1 |
| Euro OTC | Menthol | 721123 | 1 |
| Euro OTC | Menthol | 807044-011 | 1 |
| Euro OTC | Menthol | 807862 | 1 |
| Euro OTC | Menthol | 858607 | 1 |
| Euro OTC | Menthol | 902-012 | 1 |
| Euro OTC | Menthol | 973192 | 3 |
| Euro OTC | Menthol | B02-2025100 | 1 |
| Euro OTC | Menthol | EN/20/01001 | 1 |
| Euro OTC | Menthol | PM14 | 1 |
| Euro Ph. / Gehe | Menthol | 1701014-02 | 1 |
| Euro/Jenne | Menthol | 1807044-02 | 1 |
| Euro/Phönix | Menthol | 1905013-02 | 1 |
| Euron | Menthol | 1705022-01 | 1 |
| Euron | Menthol | 1905013-02 | 1 |
| Euroo/Phönix | Menthol | 210300901 | 1 |
| Europharm | Menthol | 130501-01 | 1 |
| F/P | Menthol | 20E22B022025010 | 1 |
| Fa.Phönix | Menthol | 1270077 | 1 |
| Fagron | Menthol | 1084145 | 1 |
| Fagron | Menthol | 1115262 | 4 |
| Fagron | Menthol | 11C01-N01 | 1 |
| Fagron | Menthol | 11G19-N07 | 1 |
| Fagron | Menthol | 12/19-N10 | 1 |
| Fagron | Menthol | 12/19-N100554/560 | 1 |
| Fagron | Menthol | 1201416 | 1 |
| Fagron | Menthol | 1219-N10 | 1 |
| Fagron | Menthol | 1247454 | 4 |
| Fagron | Menthol | 1289677 | 2 |
| Fagron | Menthol | 12C05-N03 | 1 |
| Fagron | Menthol | 12Cos-NO3 | 1 |
| Fagron | Menthol | 12D23-N06 | 4 |
| Fagron | Menthol | 12F01-N14 | 3 |
| Fagron | Menthol | 12G20-N02 | 3 |
| Fagron | Menthol | 12I19-N10 | 2 |
| Fagron | Menthol | 13D16-N09 | 7 |
| Fagron | Menthol | 13D16-N090631/1300 | 1 |
| Fagron | Menthol | 13G09-N09 | 1 |
| Fagron | Menthol | 13G09-N090204/520 | 1 |
| Fagron | Menthol | 13J21-N04 | 2 |
| Fagron | Menthol | 13O16-N09 | 1 |
| Fagron | Menthol | 14100041-01 | 1 |
| Fagron | Menthol | 14H29-M02 | 11 |
| Fagron | Menthol | 14H29-M04 | 1 |
| Fagron | Menthol | 15076101 | 1 |
| Fagron | Menthol | 15076115 | 1 |
| Fagron | Menthol | 1509045-03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Menthol | 16L20-T04 | 4 |
| Fagron | Menthol | 16L20-T04-044469 | 1 |
| Fagron | Menthol | 16L20T04044769 | 1 |
| Fagron | Menthol | 16L20-T04-044769 | 22 |
| Fagron | Menthol | 16l20T04-053177 | 1 |
| Fagron | Menthol | 16L20T04053177 | 1 |
| Fagron | Menthol | 16L20-T04-053177 | 13 |
| Fagron | Menthol | 16L20-To4 | 1 |
| Fagron | Menthol | 1701014-02 | 1 |
| Fagron | Menthol | 17o1014-02 | 1 |
| Fagron | Menthol | 1804T06065445 | 1 |
| Fagron | Menthol | 1807044-01 | 1 |
| Fagron | Menthol | 180L04-T06-065445 | 1 |
| Fagron | Menthol | 18204-T06 | 1 |
| Fagron | Menthol | 18G02T30 | 1 |
| Fagron | Menthol | 18G02-T30 | 3 |
| Fagron | Menthol | 18G02-T30-062159 | 26 |
| Fagron | Menthol | 18L04-T0-065445 | 1 |
| Fagron | Menthol | 18L04T06 | 1 |
| Fagron | Menthol | 18L04-T06 | 2 |
| Fagron | Menthol | 18L04-T06-065445 | 34 |
| Fagron | Menthol | 18l04-to6-065445 | 1 |
| Fagron | Menthol | 18L20-T04 | 1 |
| Fagron | Menthol | 18LO4-T06-65445 | 1 |
| Fagron | Menthol | 20A31-805-196609 | 1 |
| Fagron | Menthol | 20a31b05196609 | 1 |
| Fagron | Menthol | 20a31-b05-196609 | 1 |
| Fagron | Menthol | 20A31-b05-196609 | 1 |
| Fagron | Menthol | 20A31-B05-196609 | 16 |
| Fagron | Menthol | 20E22-B02202510 | 1 |
| Fagron | Menthol | 20E22-B02-202510 | 13 |
| Fagron | Menthol | 20e22-bo2-202510 | 1 |
| Fagron | Menthol | 21/13-B03-219346 | 2 |
| Fagron | Menthol | 2113-B03 | 1 |
| Fagron | Menthol | 2113B03219346 | 1 |
| Fagron | Menthol | 2113-BO3-219346 | 1 |
| Fagron | Menthol | 21C12-B03 | 3 |
| Fagron | Menthol | 21C12-B03_211790 | 1 |
| Fagron | Menthol | 21c12-b03-211790 | 1 |
| Fagron | Menthol | 21c12-B03-211790 | 1 |
| Fagron | Menthol | 21C12-B03-211790 | 18 |
| Fagron | Menthol | 21c12-bo3-211790 | 1 |
| Fagron | Menthol | 21C12-BO3-211790 | 1 |
| Fagron | Menthol | 21I13-B03 | 3 |
| Fagron | Menthol | 21I13-B03_219346 | 1 |
| Fagron | Menthol | 21I13-B03-219346 | 4 |
| Fagron | Menthol | 21l13-BO3-219346 | 1 |
| Fagron | Menthol | 22A14-B05-219347 | 10 |
| Fagron | Menthol | 22F02-B11-222586 | 2 |
| Fagron | Menthol | 3-21934006 | 1 |
| Fagron | Menthol | 750137 | 1 |
| Fagron | Menthol | 778301 | 1 |
| Fagron | Menthol | 858607 | 1 |
| Fagron | Menthol | 976035 | 1 |
| Fagron | Menthol | B02-2025100 | 1 |
| Fagron | Menthol | B03-2117900 | 2 |
| Fagron | Menthol | B03-2193406 | 5 |
| Fargo/Gehe | Menthol | 18G02-T30062159 | 1 |
| Fargo/Gehe | Menthol | B03-2117900 | 1 |
| Fargon/ Noweda | Menthol | 13D16-N09 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fargon/GEHE | Menthol | 18L04-T06-065445 | 1 |
| Fargon | Menthol | 18G02-T30-062159 | 1 |
| Fargon | Menthol | 18L04-T06-065445 | 1 |
| Fargon | Menthol | 20A31-B05-196609 | 1 |
| Fargon | Menthol | B05-1966009 | 1 |
| Fiebig | Menthol | 12D23-N06 | 2 |
| Fiebig | Menthol | 16095625 | 1 |
| Fiebig | Menthol | 1705022-01 | 1 |
| Fiebig | Menthol | 17328803 | 1 |
| Fiebig | Menthol | 18L04-T06-065445 | 1 |
| Finteler Apotheke | Menthol | 16095614 | 1 |
| Finze | Menthol | 9221710 | 1 |
| Fragon/Sanacorp | Menthol | 16L20-T04-053177 | 1 |
| Frey & Lau GmbH/Noweda | Menthol | 1509045-03 | 2 |
| Frey + Lau GmbH/AHD | Menthol | 20A31-B05-196609 | 1 |
| Frey + Lau GmbH | Menthol | 21/13-B03-219346 | 1 |
| Frey Lau GmbH | Menthol | 1270077 | 2 |
| Frey*Lau GmbH | Menthol | 1305010-01 | 1 |
| Frey*Lau GmbH | Menthol | 973192 | 1 |
| Frey+Lau GmbH / Noweda | Menthol | 2009021-01 | 1 |
| Frey+Lau GmbH Noweda | Menthol | 1178546 | 1 |
| Frey+Lau GmbH/Gehe | Menthol | 1001505 | 1 |
| Frey+Lau GmbH/Noweda | Menthol | 1221331 | 1 |
| Frey+Lau GmbH | Menthol | 1178546 | 1 |
| Frey+Lau GmbH | Menthol | 1509045-02 | 1 |
| Frey+Lau GmbH | Menthol | 1603024-01 | 1 |
| frey+Lau/jenne | Menthol | 1087209 | 1 |
| Frey+Lau | Menthol | 926636 | 1 |
| Gehe / Ensbona | Menthol | 16L20-T04-044769 | 1 |
| Gehe/ 27.10.12 EuRho | Menthol | 11219216 | 1 |
| Gehe | Menthol | 12020411 | 1 |
| Gehe | Menthol | 13377412 | 1 |
| Gehe | Menthol | 13D16-N09 | 1 |
| Gehe | Menthol | 1502006-02 | 2 |
| Gehe | Menthol | 1608012-01 | 2 |
| Gehe | Menthol | 16095602 | 1 |
| GEHE | Menthol | 16L20-T04-044769 | 1 |
| Gehe | Menthol | 1701014-02 | 1 |
| Gehe | Menthol | 1705022-01 | 2 |
| Gehe | Menthol | 1802003-01 | 1 |
| Gehe | Menthol | 18128009 | 1 |
| Gehe | Menthol | 18128015 | 1 |
| Gehe | Menthol | 18G02-T30-062159 | 1 |
| Gehe | Menthol | 1905013-01 | 1 |
| Gehe | Menthol | 1905013-02 | 1 |
| Gehe | Menthol | 2009021-01 | 2 |
| Gehe | Menthol | 21000696012 | 1 |
| Gehe | Menthol | 2103009-01 | 1 |
| Gehe | Menthol | 22003309007 | 1 |
| Gehe | Menthol | 22A14-B05-219347 | 1 |
| Gehe | Menthol | 22F02-B11-222586 | 2 |
| Gehe | Menthol | 2301002-01 | 1 |
| gehe | Menthol | 2301002-02 | 1 |
| Gehe | Menthol | 2301002-02 | 2 |
| Gehe | Menthol | 23G19-B06-231924 | 1 |
| GEHE | Menthol | 241217(22003309012) | 1 |
| GEHE | Menthol | B03-2193406 | 1 |
| Geibo/Euro 24.1.17 | Menthol | 1608012-01 | 3 |
| GUMO | Menthol | 20004420002 | 1 |
| Hageda | Menthol | 20A31-B05-196609 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Hedinger/Phönix | Menthol | 17328802 | 1 |
| Hepart | Menthol | 1608012-02 | 1 |
| Ichthyol / Phoenix | Menthol | 16095603 | 1 |
| Imhof | Menthol | 15-5401 | 1 |
| Jenne | Menthol | 180200301 | 1 |
| Jenne | Menthol | 230810(22003309003) | 1 |
| Jenne | Menthol | 240902(22003309007) | 1 |
| Kehr | Menthol | 16095613 | 1 |
| Kehr | Menthol | 16095620 | 1 |
| Kehr | Menthol | 1802003-01 | 1 |
| kehr | Menthol | 220401301 | 1 |
| Kehr | Menthol | 2204013-01 | 1 |
| Kloster Apotheke | Menthol | 9999999999 | 1 |
| L10 | Menthol | 1705022-01 | 1 |
| L12 | Menthol | 1603024-01 | 1 |
| L12 | Menthol | 1802003-01 | 1 |
| L12 | Menthol | 1807044-01 | 1 |
| Menthol/Phoenix | Menthol | 16L20-T04-044769 | 1 |
| Nachprüfung | Menthol | 120-4036-02 | 2 |
| Nachprüfung | Menthol | 123456 | 1 |
| Nachprüfung | Menthol | 28511041 | 1 |
| Norex Flavours Pvt. ... | Menthol | 15286205 | 2 |
| Norex Flavours Pvt. ... | Menthol | 15286207 | 1 |
| Noveda | Menthol | 22003309012 | 1 |
| Noweda | Menthol | 1001505 | 1 |
| Noweda | Menthol | 1204036-01 | 1 |
| Noweda | Menthol | 1410004-01 | 1 |
| Noweda | Menthol | 15363809 | 1 |
| Noweda | Menthol | 1701014-02 | 1 |
| Noweda | Menthol | 1705022-01 | 1 |
| Noweda | Menthol | 17188904 | 1 |
| Noweda | Menthol | 1807044 | 1 |
| Noweda | Menthol | 180704401 | 1 |
| Noweda | Menthol | 1807044-01 | 1 |
| Noweda | Menthol | 1807044-02 | 1 |
| Noweda | Menthol | 19041611 | 1 |
| Noweda | Menthol | 1905013-01 | 1 |
| Noweda | Menthol | 20004049007 | 1 |
| Noweda | Menthol | 2009021 | 1 |
| Noweda | Menthol | 21000730011 | 2 |
| Noweda | Menthol | 2100073011 | 1 |
| Noweda | Menthol | 2103009-02 | 1 |
| Noweda | Menthol | 21C12-B03 | 1 |
| Noweda | Menthol | 21C12-B03-211790 | 1 |
| Noweda | Menthol | 22002585003 | 2 |
| Noweda | Menthol | 22002986002 | 1 |
| NOWEDA | Menthol | 2204013-01 | 1 |
| Noweda | Menthol | 22F02-B11-222586 | 5 |
| Noweda | Menthol | 2301002-01 | 2 |
| Noweda | Menthol | 2301002-02 | 1 |
| Noweda | Menthol | 2307028-01 | 1 |
| Noweda | Menthol | 23G19-B06-231924 | 1 |
| Noweda | Menthol | 24I05-B04-005989 | 1 |
| Pala | Menthol | 1802003-01 | 1 |
| Ph.Eur.9.0 | Menthol | 1912006-01 | 1 |
| Phoenix 15.04.2014 | Menthol | 12246211 | 1 |
| Phoenix/Cealo | Menthol | 1509045-01/4116F-018 | 1 |
| Phoenix | Menthol | 1146105 | 1 |
| Phoenix | Menthol | 1337745 | 2 |
| Phoenix | Menthol | 1403022-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Menthol | 16095617 | 1 |
| Phoenix | Menthol | 16095619 | 1 |
| Phoenix | Menthol | 16095625 | 1 |
| phoenix | Menthol | 180704401 | 1 |
| Phoenix | Menthol | 1905013-01 | 1 |
| Phoenix | Menthol | 2204013-02 | 1 |
| Phoenix | Menthol | 2301002-01 | 1 |
| PHOENIX | Menthol | 2301002-02 | 1 |
| Phoenix | Menthol | 23B14-B26-227532 | 2 |
| Phoenix | Menthol | 3127 | 1 |
| Phoenix | Menthol | 750137 | 1 |
| Phoenix | Menthol | B04-2029402 | 1 |
| Phönix Gotha | Menthol | 1410004-01 | 1 |
| Phönix Gotha | Menthol | 18L04-T06-065445 | 1 |
| Phönix/EuRo | Menthol | 2009021-01 | 1 |
| Phönix | Menthol | 12246204 | 1 |
| Phönix | Menthol | 13159105 | 1 |
| phönix | Menthol | 15363805 | 1 |
| Phönix | Menthol | 1608012-02 | 1 |
| Phonix | Menthol | 1802003-01 | 1 |
| Phönix | Menthol | 1802003-01 | 2 |
| Phönix | Menthol | 1807044-01 | 1 |
| Phönix | Menthol | 18128015 | 1 |
| Phönix | Menthol | 1905013-01 | 1 |
| Phönix | Menthol | 1912006-01 | 1 |
| Phönix | Menthol | 2009021-01 | 1 |
| Phönix | Menthol | 2103009-01 | 1 |
| PHÖNIX | Menthol | 21C12-B03-211790 | 1 |
| Phönix | Menthol | 22F02-B11-222586 | 3 |
| Retest | Menthol | 1305010-02 | 1 |
| Sanacomp | Menthol | 22003309003 | 1 |
| Sanacorp Stralsund | Menthol | 21C12-B03-211790 | 1 |
| Sanacorp WE:02.09.16... | Menthol | 15363809 | 1 |
| Sanacorp | Menthol | 1204036-01 | 1 |
| Sanacorp | Menthol | 1210017-01 | 1 |
| Sanacorp | Menthol | 1305010-01 | 1 |
| Sanacorp | Menthol | 13103901 | 1 |
| Sanacorp | Menthol | 13377409 | 1 |
| Sanacorp | Menthol | 16095613 | 1 |
| Sanacorp | Menthol | 16095619 | 1 |
| Sanacorp | Menthol | 17188903 | 1 |
| Sanacorp | Menthol | 17188904 | 1 |
| Sanacorp | Menthol | 17328804 | 1 |
| Sanacorp | Menthol | 18328605 | 1 |
| Sanacorp | Menthol | 18328612 | 1 |
| Sanacorp | Menthol | 1912006-01 | 1 |
| Sanacorp | Menthol | 20004420002 | 1 |
| Sanacorp | Menthol | 21000696016 | 1 |
| Sanacorp | Menthol | 21000730003 | 1 |
| Sanacorp | Menthol | 21000730011 | 1 |
| Sanacorp | Menthol | 21000730019 | 1 |
| Sanacorp | Menthol | 2103009-02 | 2 |
| sanacorp | Menthol | 22003309003 | 1 |
| Sanacorp | Menthol | 22003309007 | 2 |
| Sanacorp | Menthol | 2204013-01 | 1 |
| Sanacorp | Menthol | 2301002-01 | 2 |
| Sanacorp | Menthol | 2307028-01 | 1 |
| Sanacorp | Menthol | 6/AKD3 | 1 |
| siehe protokoll | Menthol | 1008029-02 | 1 |
| Spangro_12.03.2019 | Menthol | 1802003-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| VDL; 9.23EUR; 28.09.15 | Menthol | 15076113 | 1 |
| WE:Sanacorp 03.11.20… | Menthol | 15363810 | 1 |

- 254 244 spectra from 1666 *Apo-Ident* customers from a total of 51 695 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Menthol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Menthol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 505 | 0 | 157 821 |
| **Type B** | 0 | 831 | 14 | 212 095 |
| **Type C** | 0 | 2636 | 6 | 254 244 |

The substance/substance group *Menthol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8119 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 98.3432 % (> 97.9882 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7729 % (> 99.6593 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21443 | 22657 | 3.93 | 265.05 |
| 21601 | 21932 | 21.69 | 249.78 |
| 21932 | 21932 | 0.00 | 266.28 |
| 22657 | 22657 | 0.00 | 268.12 |

*continued on the next page*


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*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22825 | 22825 | 0.00 | 255.44 |
| 23596 | 22825 | 3.81 | 252.84 |
| 24233 | 24233 | 0.00 | 276.48 |
| 24690 | 22825 | 6.45 | 255.98 |
| 25217 | 25217 | 0.00 | 272.12 |
| 25591 | 25591 | 0.00 | 255.97 |
| 26091 | 26091 | 0.00 | 271.40 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Mepivacaine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20710-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Mepivacaine hydrochloride; Mepivacaini hydrochloridum

### Special notes

When selecting the *Mepivacaine hydrochloride* substance/substance group, the following information is displayed to the user:

- Advice: Currently no longer available from major pharmaceutical manufacturers. Therefore, batch maintenance is currently not possible.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Mepivacaine hydrochloride | 5 | 1 | 10 |

### Second-stage model

For differentiation of the substance/substance group *Mepivacaine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Mepivacaine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Tretinoin | 51.59 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Mepivacaine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Mepivacaine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Mepivacaine hydrochloride | 12A20-N12 | 20710 | 40 | 1401555 |
| Fagron | Mepivacaine hydrochloride | 13L04-B07-297077 | 21672 | 60 | AR-15-FG-007876-01 |
| Fagron | Mepivacaine hydrochloride | 19F25-B02-365217 | 24950 | 40 | 2007301 |
| Fagron | Mepivacaine hydrochloride | 20D24-F01-370950 | 25368 | 40 | 20200610 |
| Fagron | Mepivacaine hydrochloride | 22C04-B01-217581 | 26733 | 40 | 20220603 |
| Fagron | Mepivacaine hydrochloride | 22C04-B01-217581 | 26733SI | 20 | 20220603 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 240 spectra of 6 reference samples from the substance/substance group *Mepivacaine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.
- 158 086 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *Mepivacaine hydrochloride*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Mepivacaine hydrochloride | 15I16-B01-322906 | 23212 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 13 spectra from 8 *Apo-Ident* customers from 11 batches from the substance/substance group *Mepivacaine hydrochloride*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mepivacaine hydrochloride | 13G05-N02 | 1 |
| Fagron | Mepivacaine hydrochloride | 12E31-B40-305570 | 1 |
| Fagron | Mepivacaine hydrochloride | 12F20-N07 | 1 |
| Fagron | Mepivacaine hydrochloride | 13G05N02 | 1 |
| Fagron | Mepivacaine hydrochloride | 13G05-N02 | 1 |
| Fagron | Mepivacaine hydrochloride | 15E04-B04-330855 | 1 |
| Fagron | Mepivacaine hydrochloride | 15I16-B01 | 1 |
| Fagron | Mepivacaine hydrochloride | 15I16-B01-341738 | 1 |
| Fagron | Mepivacaine hydrochloride | 15I16-B01-356826 | 1 |
| Fagron | Mepivacaine hydrochloride | 15I16-B-325107 | 2 |
| Fagron | Mepivacaine hydrochloride | 19F25-B02 | 1 |
| Sanacorp | Mepivacaine hydrochloride | 19F25-B02-365217 | 1 |

- 256 873 spectra from 1666 *Apo-Ident* customers from a total of 52 142 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Mepivacaine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Mepivacaine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 240 | 0 | 158 086 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 13 | 0 | 256 873 |

The substance/substance group *Mepivacaine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.5000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20710 | 20710 | 0.00 | 52.89 |
| 21672 | 21672 | 0.00 | 52.48 |
| 24950 | 24950 | 0.00 | 54.21 |
| 25368 | 21672 | 10.92 | 53.43 |
| 26733 | 24950 | 25.91 | 51.59 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by


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laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Mesalazine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21772-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Mesalazine; Mesalazinum

### Special notes

When selecting the *Mesalazine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Mesalazine | 8 | 5 | 23 |

### Second-stage model

For differentiation of the substance/substance group *Mesalazine* the following second-stage model is used:

- Submodel 12

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Mesalazine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Midazolam hydrochloride | 103.76 | – |
| ⋮ | ⋮ | ⋮ |
| Clioquinol | >50 | 30.48 |
| Nicotinic acid | >50 | 32.83 |
| Miconazole nitrate | >50 | 43.94 |
| Theophylline-ethylenediamine hydrate | >50 | 156.73 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Mesalazine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Mesalazine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Mesalazine | 1206029-04 | 21772 | 60 | AR-15-FG-011819-01 |
| Euro OTC | Mesalazine | 1206029-04 | 21887 | 60 | 20140923 |
| Euro OTC | Mesalazine | 1602005 | 22518 | 40 | 20160218* |
| Euro OTC | Mesalazine | 1602005-01 | 22925 | 40 | 20160218 |
| Euro OTC | Mesalazine | 1911016 | 25082 | 40 | 20191218* |
| Euro OTC | Mesalazine | 2009037 | 25569 | 40 | 20210114* |
| Fagron | Mesalazine | 15H13-B06-317177 | 22356 | 60 | 20150827 |
| Fagron | Mesalazine | 16I28-B02-327679 | 22929 | 40 | 20161128 |
| Fagron | Mesalazine | 22K26-B12-224459 | 26732 | 40 | 20230504 |
| Fagron | Mesalazine | 22K26-B12-224459 | 26732SI | 20 | 20230504 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 440 spectra of 10 reference samples from the substance/substance group *Mesalazine*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 886 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 7 reference samples from the substance/substance group *Mesalazine*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Mesalazine | 1611019 | 22872 | 40 |
| Euro OTC | Mesalazine | 1902013 | 24477 | 40 |
| Euro OTC | Mesalazine | 2203020 | 26094 | 40 |
| Fagron | Mesalazine | 17A17-B03-336444 | 23934 | 40 |
| Fagron | Mesalazine | 24H22-B01-007072 | 27596 | 40 |
| Euro OTC | Mesalazine | 2203020 | 26094SI | 20 |
| Fagron | Mesalazine | 24H22-B01-007072 | 27596SI | 20 |

- 212 700 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 110 spectra from 15 *Apo-Ident* customers from 28 batches from the substance/substance group *Mesalazine*.

- Among them are spectra of independent samples from 22 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Mesalazine | 21F15-F50-382143 | 1 |
| | Mesalazine | 21J12-B18-216345 | 2 |
| | Mesalazine | 2203020-01 | 6 |
| | Mesalazine | 22K26-B12-224459 | 15 |
| | Mesalazine | 24H22-B01-007072 | 3 |
| Caelo | Mesalazine | 18C30-B05-353048 | 1 |
| Euro OTC | Mesalazine | | 1 |
| Euro OTC | Mesalazine | 1206029-04 | 1 |
| Euro OTC | Mesalazine | 1602005-01 | 3 |
| Euro OTC | Mesalazine | 1602005-02 | 7 |
| Euro OTC | Mesalazine | 1611019-01 | 5 |
| Euro OTC | Mesalazine | 1611019-03 | 2 |
| Euro OTC | Mesalazine | 190201301 | 1 |
| Euro OTC | Mesalazine | 1902013-01 | 10 |
| Euro OTC | Mesalazine | 190213-01 | 1 |
| Euro OTC | Mesalazine | 1911016-01 | 3 |
| Euro OTC | Mesalazine | 2009037-01 | 4 |
| Euro OTC | Mesalazine | 200903702 | 1 |
| Euro OTC | Mesalazine | 2203020-01 | 2 |
| Euro OTC | Mesalazine | B02-3638804 | 1 |
| Fagron | Mesalazine | | 1 |
| Fagron | Mesalazine | 1100007129 | 1 |
| Fagron | Mesalazine | 16I28-B02-327679 | 24 |
| Fagron | Mesalazine | 18C30-B05-353048 | 4 |
| Fagron | Mesalazine | 19G05-B02-363884 | 1 |
| Fagron | Mesalazine | 20J13-F07-0374998 | 1 |
| Fagron | Mesalazine | 20J13-F07-374998 | 2 |
| Fagron | Mesalazine | 21F15-F02-379144 | 1 |
| Fagron | Mesalazine | 21F15-F02-379244 | 4 |
| Fagron | Mesalazine | 21F15-F02-382144 | 1 |

- 256 776 spectra from 1666 *Apo-Ident* customers from a total of 52 126 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Mesalazine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Mesalazine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 110 | 0 | 256 776 |

The substance/substance group *Mesalazine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 94.5455 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21772 | 21772 | 0.00 | 156.50 |
| 21887 | 21772 | 15.23 | 154.62 |
| 22356 | 22518 | 4.61 | 144.95 |
| 22518 | 22518 | 0.00 | 143.43 |
| 22925 | 22518 | 3.86 | 146.45 |
| 22929 | 22518 | 9.56 | 146.25 |
| 25082 | 25082 | 0.00 | 149.57 |
| 25569 | 25569 | 0.00 | 148.33 |
| 26732 | 22518 | 5.97 | 147.42 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Metamizol sodium monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22634-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Metamizol sodium monohydrate; Metamizolum natricum monohydricum

### Special notes

When selecting the *Metamizol sodium monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Metamizol sodium monohydrate | 5 | 3 | 5 |

### Second-stage model

For differentiation of the substance/substance group *Metamizol sodium monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Metamizol sodium monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 145.29 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Metamizol sodium monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Metamizol sodium monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Metamizol sodium monohydrate | 161610 | 22634 | 40 | 20160714* |
| Caelo | Metamizol sodium monohydrate | 15362816 | 22666 | 40 | 20151106 |
| Caelo | Metamizol sodium monohydrate | 161610 | 23313 | 40 | 20160714* |
| Caelo | Metamizol sodium monohydrate | 20001888002 | 25388 | 40 | 20200819 |
| Caelo | Metamizol sodium monohydrate | 22001474 | 26241 | 40 | 20220718* |
| Caelo | Metamizol sodium monohydrate | 22001474 | 26241SI | 20 | 20220718* |
| Caelo | Metamizol sodium monohydrate | 23003148 | 27111 | 40 | 20240110* |
| Caelo | Metamizol sodium monohydrate | 23003148 | 27111SI | 20 | 20240110* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 280 spectra of 8 reference samples from the substance/substance group *Metamizol sodium monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

- 158 046 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 130 spectra of 3 reference samples from the substance/substance group *Metamizol sodium monohydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Metamizol sodium monohydrate | 15362815 | 22726 | 40 |
| Caelo | Metamizol sodium monohydrate | 170584 | 23924 | 40 |
| Caelo | Metamizol sodium monohydrate | 21002292003 | 25900 | 50 |

- 212 810 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 18 spectra from 7 *Apo-Ident* customers from 6 batches from the substance/substance group *Metamizol sodium monohydrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metamizol sodium monohydrate | 16161007 | 1 |
| Caelo | Metamizol sodium monohydrate | 17058404 | 6 |
| Caelo | Metamizol sodium monohydrate | 18026504 | 3 |
| Caelo | Metamizol sodium monohydrate | 20001888002 | 3 |
| Caelo | Metamizol sodium monohydrate | 21000105002 | 2 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metamizol sodium monohydrate | 21002292003 | 2 |
| Caesar & Loretz GmbH | Metamizol sodium monohydrate | 21000105002 | 1 |

- 256 868 spectra from 1666 *Apo-Ident* customers from a total of 52 147 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Metamizol sodium monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Metamizol sodium monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 130 | 0 | 212 810 |
| **Type C** | 0 | 18 | 0 | 256 868 |

The substance/substance group *Metamizol sodium monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.3846 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22634 | 22634 | 0.00 | 201.76 |
| 22666 | 27111 | 12.27 | 202.81 |
| 23313 | 23313 | 0.00 | 199.18 |
| 25388 | 23313 | 9.45 | 201.08 |
| 26241 | 26241 | 0.00 | 199.98 |
| 27111 | 27111 | 0.00 | 199.14 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Metformin hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006050-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Metformin hydrochloride; Metformini hydrochloridum

### Special notes

When selecting the *Metformin hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Metformin hydrochloride | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Metformin hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Metformin hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 91.91 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Metformin hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Metformin hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Metformin hydrochloride | 22C04-B02-219168 | 26405 | 40 | 20220625 |
| Fagron | Metformin hydrochloride | 22C04-B02-219168 | 26405SI | 20 | 20220625 |
| Fagron | Metformin hydrochloride | 24B27-B04-239307 | 27467 | 40 | 250201361 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 100 spectra of 3 reference samples from the substance/substance group *Metformin hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.
- 158 226 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Metformin hydrochloride*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Metformin hydrochloride | 23H03-B10-234791 | 27065 | 40 |
| Fagron | Metformin hydrochloride | 23H03-B10-234791 | 27065SI | 20 |
| Fagron | Metformin hydrochloride | 24B27-B04-239307 | 27467SI† | 20 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Metformin hydrochloride*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Metformin hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Metformin hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 100 | 0 | 158 226 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Metformin hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 94.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26405 | 27467 | 17.41 | 284.37 |
| 27467 | 27467 | 0.00 | 286.90 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Methacholine chloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20733-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Methacholine chloride; Methacholinii chloridum

### Special notes

When selecting the *Methacholine chloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Methacholine chloride | 10 | 5 | 32 |

### Second-stage model

For differentiation of the substance/substance group *Methacholine chloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Methacholine chloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Ornithine aspartate | 118.85 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Methacholine chloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Methacholine chloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Methacholine chloride | 13260303 | 21251 | 40 | 20130827 |
| Caelo | Methacholine chloride | 13260302 | 21420 | 60 | 20130827 |
| Caelo | Methacholine chloride | 13260302 | 21590 | 60 | 20130827 |
| Caelo | Methacholine chloride | 13260303 | 21592 | 60 | 20130827 |
| Caelo | Methacholine chloride | 162293 | 22635 | 40 | 20160815* |
| Caelo | Methacholine chloride | 16229304 | 22661 | 40 | 20160815 |
| Caelo | Methacholine chloride | 16229301 | 22662 | 40 | 20160815 |
| Euro OTC | Methacholine chloride | 2001028 | 25249 | 40 | 20200720* |
| Fagron | Methacholine chloride | 12F01-N04 | 20733 | 60 | 1403251 |
| Fagron | Methacholine chloride | 16L20-B01-329966 | 22976 | 40 | 20170123 |
| Fagron | Methacholine chloride | 16L20-B01-329968 | 22977 | 40 | 20170123 |
| Fagron | Methacholine chloride | 24A15-B02-238091 | 27474 | 40 | 20240118 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 560 spectra of 12 reference samples from the substance/substance group *Methacholine chloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 766 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 270 spectra of 8 reference samples from the substance/substance group *Methacholine chloride*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Methacholine chloride | 163299 | 23049 | 40 |
| Caelo | Methacholine chloride | 20003216002 | 26304 | 30 |
| Caelo | Methacholine chloride | 23000519 | 26726 | 40 |
| Fagron | Methacholine chloride | 17H03-B02-346564 | 24287 | 40 |
| Fagron | Methacholine chloride | 22B07-B22-23069 | 26823 | 40 |
| Caelo | Methacholine chloride | 163299 | 23624 | 40 |
| Caelo | Methacholine chloride | 20003216002 | 26304SI | 20 |
| Caelo | Methacholine chloride | 23000519 | 26726SI | 20 |

- 212 670 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 48 spectra from 25 *Apo-Ident* customers from 34 batches from the substance/substance group *Methacholine chloride*.

- Among them are spectra of independent samples from 32 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Methacholine chloride | 14K20-B03-300973 | 2 |
| | Methacholine chloride | 23000519002 | 1 |
| | Methacholine chloride | 24A15-B02-238092 | 1 |
| anzag 18.12.14 25,19 | Methacholine chloride | 14G30-B03-296209 | 1 |
| Caelo | Methacholine chloride | 17D13-B04-334377 | 1 |
| Caelo | Methacholine chloride | 23000519001 | 1 |
| Caesar & Loretz GmbH... | Methacholine chloride | 23000519003 | 1 |
| Euro OTC | Methacholine chloride | 2001028-01 | 1 |
| Fagron | Methacholine chloride | 10031504 | 1 |
| Fagron | Methacholine chloride | 13/13-N03 | 2 |
| Fagron | Methacholine chloride | 13121712 | 1 |
| Fagron | Methacholine chloride | 13G10-N05 | 1 |
| Fagron | Methacholine chloride | 14G30-B03-296210 | 1 |
| Fagron | Methacholine chloride | 15F10-B02-312160 | 1 |
| Fagron | Methacholine chloride | 15F10-B02-315523 | 1 |
| Fagron | Methacholine chloride | 15F10-B02-315831 | 1 |
| Fagron | Methacholine chloride | 160004A | 1 |
| Fagron | Methacholine chloride | 16L20-B01 | 1 |
| Fagron | Methacholine chloride | 16L20-B01-329970 | 1 |
| Fagron | Methacholine chloride | 17D13-B04 | 1 |
| Fagron | Methacholine chloride | 17D13-B04-334377 | 2 |
| Fagron | Methacholine chloride | 17D13-B04-334378 | 1 |
| Fagron | Methacholine chloride | 17D13-B04-340803 | 1 |
| Fagron | Methacholine chloride | 17H03-B02-346563 | 3 |
| Fagron | Methacholine chloride | 17h03-b02-346564 | 1 |
| Fagron | Methacholine chloride | 17H03-B02-346564 | 7 |
| Fagron | Methacholine chloride | 19H07-B04365767 | 1 |
| Fagron | Methacholine chloride | 19H07-B04-365768 | 2 |
| Fagron | Methacholine chloride | 19H07-B08-365767 | 1 |
| Fagron | Methacholine chloride | 24061503 | 1 |
| Fagron | Methacholine chloride | 312160 | 1 |
| Flamma s.p.a | Methacholine chloride | 14G30-B03-296211 | 1 |
| Inresa | Methacholine chloride | 160P02A/09062017 | 1 |
| L12 | Methacholine chloride | 16329901 | 2 |
| Phoenix/Cealo | Methacholine chloride | 16L20-B01-329968 | 1 |

- 256 838 spectra from 1666 *Apo-Ident* customers from a total of 52 119 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Methacholine chloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Methacholine chloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 560 | 0 | 157 766 |
| **Type B** | 0 | 270 | 0 | 212 670 |
| **Type C** | 0 | 48 | 0 | 256 838 |


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The substance/substance group *Methacholine chloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9286 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.7778 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 87.5000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20733 | 20733 | 0.00 | 212.52 |
| 21251 | 20733 | 25.61 | 196.96 |
| 21420 | 25249 | 89.24 | 189.29 |
| 21590 | 22635 | 17.57 | 206.98 |
| 21592 | 20733 | 27.97 | 186.58 |
| 22635 | 22635 | 0.00 | 225.38 |
| 22661 | 20733 | 28.02 | 200.72 |
| 22662 | 22635 | 11.06 | 210.91 |
| 22976 | 20733 | 7.99 | 213.42 |
| 22977 | 20733 | 26.20 | 204.67 |
| 25249 | 25249 | 0.00 | 212.62 |
| 27474 | 22635 | 40.75 | 255.63 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Methionine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20971-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Methionine; Methioninum

### Special notes

When selecting the *Methionine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Methionine | 6 | 9 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Methionine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Methionine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Ornithine aspartate | 95.03 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Methionine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Methionine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Methionine | 1602012 | 22368 | 60 | 20160219* |
| Euro OTC | Methionine | 2011016 | 25469 | 40 | 20201130* |
| Euro OTC | Methionine | 2108013 | 25763 | 50 | 20210902* |
| Fagron | Methionine | 12K01-N03 | 20971 | 40 | 1402432 |
| Fagron | Methionine | 13L19-B36-295115 | 21786 | 60 | 20140108 |
| Fagron | Methionine | 19L20-F03-370997 | 25747 | 50 | 20200213 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 300 spectra of 6 reference samples from the substance/substance group *Methionine*. These

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 026 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 410 spectra of 12 reference samples from the substance/substance group *Methionine*.
- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Methionine | 1609024 | 22787 | 40 |
| Euro OTC | Methionine | 1703042 | 23126 | 40 |
| Euro OTC | Methionine | 1710008 | 23777 | 40 |
| Euro OTC | Methionine | 1904012 | 24674 | 40 |
| Euro OTC | Methionine | 1909004 | 24851 | 40 |
| Euro OTC | Methionine | 2205001 | 26194 | 40 |
| Euro OTC | Methionine | 2301004 | 26529 | 40 |
| Euro OTC | Methionine | 2305026 | 26769 | 30 |
| Fagron | Methionine | 23A16-B02-226111 | 26635 | 40 |
| Euro OTC | Methionine | 2205001 | 26194SI | 20 |
| Euro OTC | Methionine | 2301004 | 26529SI | 20 |
| Fagron | Methionine | 23A16-B02-226111 | 26635SI | 20 |

- 212 530 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Methionine*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Methionine | 21A08-F04-376464 | 1 |

- 256 885 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Methionine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Methionine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 410 | 0 | 212 530 |
| **Type C** | 0 | 1 | 0 | 256 885 |

The substance/substance group *Methionine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5366 %) |
| **Type C** | 100.0000 % (> 99.9038 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20971 | 20971 | 0.00 | 189.78 |
| 21786 | 22368 | 7.61 | 188.73 |
| 22368 | 22368 | 0.00 | 191.14 |
| 25469 | 25469 | 0.00 | 190.37 |
| 25747 | 25763 | 11.10 | 189.19 |
| 25763 | 25763 | 0.00 | 189.88 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Methoxsalen** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20233-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Methoxsalen; Methoxsalenum

### Special notes

When selecting the *Methoxsalen* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Methoxsalen | 8 | 11 | 126 |

### Second-stage model

For differentiation of the substance/substance group *Methoxsalen* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Methoxsalen* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 124.26 | – |
| ⋮ | ⋮ | ⋮ |
| Ciprofloxacin hydrochloride | >50 | 272.32 |
| Sodium citrate | >50 | 285.13 |
| Capsaicin | >50 | 330.27 |
| Prednicarbate | >50 | 331.73 |
| Levocarnitine | >50 | 349.48 |
| Quinine hydrochloride dihydrate | >50 | 372.64 |
| Oxybutynin hydrochloride | >50 | 379.41 |
| Cyproterone acetate | >50 | 427.69 |
| Triclosan | >50 | 428.59 |
| Pyridoxal-5-phosphate hydrate | >50 | 487.67 |
| Tetracaine | >50 | 688.28 |
| Heparin sodium | >50 | 693.88 |
| Amitriptyline hydrochloride | >50 | 898.26 |
| Alfatradiol | >50 | 968.88 |
| Valine | >50 | 975.20 |
| Norethisterone acetate | >50 | 1293.11 |
| Sucrose | >50 | 2040.18 |
| Amifampridine | >50 | 2164.61 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Methoxsalen* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Methoxsalen*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Methoxsalen | 16103003 | 23167 | 40 | 20160415 |
| Caelo | Methoxsalen | 170781 | 23333 | 40 | 20170427* |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Methoxsalen | 170781 | 23346 | 40 | 20170427* |
| Euro OTC | Methoxsalen | 130604101 | 21555 | 60 | 20130805 |
| Euro OTC | Methoxsalen | 1506013 | 21862 | 60 | 20150706* |
| Euro OTC | Methoxsalen | 1608019 | 22785 | 40 | 20160913* |
| Euro OTC | Methoxsalen | 2106002 | 25702 | 50 | 20210623* |
| Fagron | Methoxsalen | 15J15-B03-321321 | 23165 | 40 | 20151124 |
| Fagron | Methoxsalen | 18A12-B50-355102 | 24697 | 40 | 20181112 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 410 spectra of 9 reference samples from the substance/substance group *Methoxsalen*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.
- 157 916 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 480 spectra of 15 reference samples from the substance/substance group *Methoxsalen*.
- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Methoxsalen | 16103014 | 23166 | 40 |
| Caelo | Methoxsalen | 191960 | 24760 | 40 |
| Caelo | Methoxsalen | 22000545003 | 26312 | 30 |
| Caelo | Methoxsalen | 24001655 | 27312 | 30 |
| Euro OTC | Methoxsalen | 1802021 | 24070 | 40 |
| Euro OTC | Methoxsalen | 1904009 | 24774 | 40 |
| Euro OTC | Methoxsalen | 2006025 | 25319 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Methoxsalen | 2002046 | 25353 | 40 |
| Euro OTC | Methoxsalen | 2211015 | 26528 | 40 |
| Euro OTC | Methoxsalen | 2406012 | 27397 | 40 |
| Fagron | Methoxsalen | 22D19-B01-218575 | 26291 | 30 |
| Caelo | Methoxsalen | 22000545003 | 26312SI | 20 |
| Euro OTC | Methoxsalen | 2106002 | 25702SI[†] | 10 |
| Euro OTC | Methoxsalen | 2211015 | 26528SI | 20 |
| Fagron | Methoxsalen | 22D19-B01-218575 | 26291SI | 20 |

- 212 460 spectra from a total of 4275 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 448 spectra from 229 *Apo-Ident* customers from 131 batches from the substance/substance group *Methoxsalen*.

- Among them are spectra of independent samples from 126 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Methoxsalen | 2106002-01 | 7 |
| | Methoxsalen | 22000545003 | 1 |
| | Methoxsalen | 22003782001 | 1 |
| | Methoxsalen | 22003782004 | 1 |
| | Methoxsalen | 22003782005 | 1 |
| | Methoxsalen | 22003782007 | 3 |
| | Methoxsalen | 22003782008 | 5 |
| | Methoxsalen | 22003782010 | 2 |
| | Methoxsalen | 22003782011 | 1 |
| | Methoxsalen | 2211015-01 | 8 |
| | Methoxsalen | 2211015-02 | 2 |
| | Methoxsalen | 2211015-05 | 1 |
| | Methoxsalen | 221115-01 | 1 |
| | Methoxsalen | 24001655002 | 1 |
| | Methoxsalen | 24001655005 | 1 |
| | Methoxsalen | 2406012-01 | 3 |
| AHD | Methoxsalen | 15244204 | 1 |
| AHD | Methoxsalen | 1608019-02 | 1 |
| AHD | Methoxsalen | 16103019 | 1 |
| AHD | Methoxsalen | 17078101 | 1 |
| AHD | Methoxsalen | 17078108 | 2 |
| Anzag | Methoxsalen | 1306041-01 | 1 |
| Anzag | Methoxsalen | 2211015-01 | 1 |
| Anzag | Methoxsalen | APHCFMPC16011M | 1 |
| Apo-ident/Alliance | Methoxsalen | 1802021-01 | 1 |
| Audor Pharma | Methoxsalen | 1203009M | 1 |
| Audor Pharma | Methoxsalen | 15244213 | 1 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Methoxsalen | AP1011024-01M | 1 |
| Audor Pharma | Methoxsalen | AP15244213M | 6 |
| Audor Pharma | Methoxsalen | APHCFMPC16011M | 6 |
| Audor Pharma | Methoxsalen | APHCFMPC18003M | 3 |
| Bombastus | Methoxsalen | 15J15-B03-336704 | 1 |
| Caelo | Methoxsalen | 1136428 | 1 |
| Caelo | Methoxsalen | 11376413 | 2 |
| Caelo | Methoxsalen | 11376420 | 1 |
| Caelo | Methoxsalen | 11376433 | 1 |
| Caelo | Methoxsalen | 1409003-01 | 5 |
| Caelo | Methoxsalen | 1409003-02 | 1 |
| Caelo | Methoxsalen | 14F06-B05-296501 | 1 |
| Caelo | Methoxsalen | 1503009-01 | 2 |
| Caelo | Methoxsalen | 150613-01 | 1 |
| Caelo | Methoxsalen | 15099802 | 1 |
| Caelo | Methoxsalen | 15244204 | 3 |
| Caelo | Methoxsalen | 15244205 | 2 |
| Caelo | Methoxsalen | 15244209 | 1 |
| Caelo | Methoxsalen | 15244211 | 1 |
| Caelo | Methoxsalen | 15244216 | 1 |
| Caelo | Methoxsalen | 16/079/M | 1 |
| Caelo | Methoxsalen | 1608019-02 | 2 |
| Caelo | Methoxsalen | 16103004 | 1 |
| Caelo | Methoxsalen | 16103008 | 1 |
| Caelo | Methoxsalen | 17078101 | 2 |
| Caelo | Methoxsalen | 17078107 | 1 |
| Caelo | Methoxsalen | 17078108 | 3 |
| Caelo | Methoxsalen | 17078114 | 2 |
| Caelo | Methoxsalen | 1802021-01 | 3 |
| Caelo | Methoxsalen | 18A12-B50-354863 | 1 |
| Caelo | Methoxsalen | 190441001 | 1 |
| Caelo | Methoxsalen | 190441002 | 3 |
| Caelo | Methoxsalen | 19044103 | 5 |
| Caelo | Methoxsalen | 19044107 | 2 |
| Caelo | Methoxsalen | 190441074 | 1 |
| Caelo | Methoxsalen | 19044108 | 1 |
| Caelo | Methoxsalen | 19044110 | 7 |
| Caelo | Methoxsalen | 1904411002 | 1 |
| Caelo | Methoxsalen | 191960003 | 1 |
| Caelo | Methoxsalen | 191960006 | 2 |
| Caelo | Methoxsalen | 191960008 | 1 |
| Caelo | Methoxsalen | 191960009 | 3 |
| Caelo | Methoxsalen | 19196001 | 2 |
| Caelo | Methoxsalen | 20002295002 | 3 |
| Caelo | Methoxsalen | 20002295003 | 1 |
| Caelo | Methoxsalen | 20002295004 | 1 |
| Caelo | Methoxsalen | 20002295006 | 3 |
| Caelo | Methoxsalen | 20002295009 | 2 |
| Caelo | Methoxsalen | 20002295010 | 5 |
| Caelo | Methoxsalen | 20002295012 | 2 |
| Caelo | Methoxsalen | 2002046-01 | 1 |
| Caelo | Methoxsalen | 2200054006 | 1 |
| Caelo | Methoxsalen | 22000545001 | 2 |
| Caelo | Methoxsalen | 22000545003 | 1 |
| Caelo | Methoxsalen | 22000545004 | 3 |
| Caelo | Methoxsalen | 22000545006 | 1 |
| Caesar & Loretz GmbH... | Methoxsalen | 20002295003 | 1 |
| Caesar & Loretz GmbH | Methoxsalen | 190441001 | 1 |
| Caesar & Loretz GmbH | Methoxsalen | 19044103 | 2 |
| Caesar & Loretz GmbH | Methoxsalen | 19044108 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Methoxsalen | 19044110 | 2 |
| Caesar & Loretz GmbH | Methoxsalen | 20002295003 | 1 |
| Caesar & Loretz GmbH | Methoxsalen | 20002295007 | 2 |
| Caesar & Loretz GmbH | Methoxsalen | 22000545004 | 1 |
| Caesar&Lorenz | Methoxsalen | 20002295003 | 1 |
| EU.RHO.Pharm | Methoxsalen | 2006025-02 | 2 |
| EuRho/ AHD | Methoxsalen | 16103019 | 1 |
| EuRho/Fiebig | Methoxsalen | 1802021-01 | 1 |
| EuRho/VDL | Methoxsalen | 1608019-02 | 1 |
| EuRho | Methoxsalen | 1104010-01 | 1 |
| EuRho | Methoxsalen | 2106002-01 | 2 |
| Euro OCT | Methoxsalen | 1802021-01 | 1 |
| Euro OCT | Methoxsalen | 1904009-01 | 1 |
| Euro OCT | Methoxsalen | 1904009-02 | 1 |
| Euro OTC | Methoxsalen | 1104010-01 | 1 |
| Euro OTC | Methoxsalen | 1108019-01 | 1 |
| Euro OTC | Methoxsalen | 1203009-01 | 1 |
| Euro OTC | Methoxsalen | 120901501 | 1 |
| Euro OTC | Methoxsalen | 1209015-01 | 4 |
| Euro OTC | Methoxsalen | 1304009-01 | 1 |
| Euro OTC | Methoxsalen | 130604101 | 1 |
| Euro OTC | Methoxsalen | 1306041-01 | 5 |
| Euro OTC | Methoxsalen | 1409003-01 | 5 |
| Euro OTC | Methoxsalen | 140900302 | 1 |
| Euro OTC | Methoxsalen | 1409003-02 | 3 |
| Euro OTC | Methoxsalen | 150300901 | 1 |
| Euro OTC | Methoxsalen | 1503009-01 | 12 |
| Euro OTC | Methoxsalen | 1503009-02 | 9 |
| Euro OTC | Methoxsalen | 1506013_01 | 1 |
| Euro OTC | Methoxsalen | 1506013-01 | 19 |
| Euro OTC | Methoxsalen | 1506013-02 | 7 |
| Euro OTC | Methoxsalen | 1608019 | 1 |
| Euro OTC | Methoxsalen | 1608019-01 | 5 |
| Euro OTC | Methoxsalen | 160801902 | 1 |
| Euro OTC | Methoxsalen | 1608019-02 | 18 |
| Euro OTC | Methoxsalen | 1608019-1 | 1 |
| Euro OTC | Methoxsalen | 1802021/01 | 1 |
| Euro OTC | Methoxsalen | 1802021-01 | 38 |
| Euro OTC | Methoxsalen | 1904009-01 | 26 |
| Euro OTC | Methoxsalen | 1904009-02 | 1 |
| Euro OTC | Methoxsalen | 2006025-01 | 5 |
| Euro OTC | Methoxsalen | 2006025-02 | 1 |
| Euro OTC | Methoxsalen | 210600-01 | 1 |
| Euro OTC | Methoxsalen | 2106002-01 | 11 |
| Euro OTC | Methoxsalen | 2211015-01 | 1 |
| Euro/Phönix | Methoxsalen | 1608019-02 | 1 |
| Euroo | Methoxsalen | 1503009-01 | 1 |
| Fag | Methoxsalen | 20f-12-F01 | 1 |
| Fagron | Methoxsalen | 11D07-N16 | 1 |
| Fagron | Methoxsalen | 11f21-n02 | 1 |
| Fagron | Methoxsalen | 11F21-N02 | 1 |
| Fagron | Methoxsalen | 12E02-N05 | 2 |
| Fagron | Methoxsalen | 12G02-N14 | 1 |
| Fagron | Methoxsalen | 14f06-b05-296500 | 1 |
| Fagron | Methoxsalen | 14F06-B05-296500 | 1 |
| Fagron | Methoxsalen | 14F06-B05-296501 | 2 |
| Fagron | Methoxsalen | 14F06-B05-301978 | 1 |
| Fagron | Methoxsalen | 150601301 | 1 |
| Fagron | Methoxsalen | 15C10-B99-306266 | 1 |
| Fagron | Methoxsalen | 15F23-B03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Methoxsalen | 15F23-B03-309644 | 1 |
| Fagron | Methoxsalen | 15F23-B03-316262 | 1 |
| Fagron | Methoxsalen | 15F23-B03-318166 | 5 |
| Fagron | Methoxsalen | 15J15-B03-321321 | 1 |
| Fagron | Methoxsalen | 15J15-B03-341859 | 1 |
| Fagron | Methoxsalen | 18A12-B50-359351 | 1 |
| Fagron | Methoxsalen | 19H05-B02-366102 | 1 |
| Fagron | Methoxsalen | 21111814 | 1 |
| Fagron | Methoxsalen | 2111A-03262 | 2 |
| Fagron | Methoxsalen | B02-3661001 | 1 |
| Fagron | Methoxsalen | MS01/13-14 | 1 |
| Franco / Ebert | Methoxsalen | CMX-15/12 | 1 |
| Gehe | Methoxsalen | 1802021-01 | 2 |
| Gehe | Methoxsalen | 1904009-1 | 1 |
| Gehe | Methoxsalen | 24001655002 | 1 |
| Herbal Creations/AHD | Methoxsalen | APHCFMPC16011M | 1 |
| Herbal Creations/Cae... | Methoxsalen | 15244203 | 1 |
| Herbal Creations/Cae... | Methoxsalen | 15244205 | 1 |
| Herbal creations/Cae... | Methoxsalen | 15244208 | 1 |
| Herbal creations/Cae... | Methoxsalen | 15244212 | 1 |
| Herbal Creations | Methoxsalen | 1608019-01 | 1 |
| L10 | Methoxsalen | 2106002-01 | 2 |
| Nachprüfung | Methoxsalen | 4211Q-03262 | 1 |
| Noweda | Methoxsalen | 11D07-N16 | 2 |
| Noweda | Methoxsalen | 140900302 | 1 |
| Noweda | Methoxsalen | 19044103 | 2 |
| Noweda | Methoxsalen | 2006025-01 | 1 |
| Noweda | Methoxsalen | 22003782004 | 5 |
| Noweda | Methoxsalen | 2211015-01 | 2 |
| noweda | Methoxsalen | 2211015-02 | 1 |
| Noweda | Methoxsalen | 24001655002 | 1 |
| Noweda | Methoxsalen | 24001655007 | 1 |
| PHOENIX 18.02.14 | Methoxsalen | 1306041-01 | 2 |
| Phoenix | Methoxsalen | 14F06-B05-296502 | 1 |
| Phönix | Methoxsalen | 1608019-01 | 1 |
| Phönix | Methoxsalen | 1608019-02 | 1 |
| Phönix | Methoxsalen | 1802021-01 | 1 |
| Phytoceut.Ltd | Methoxsalen | 1503009-01 | 3 |
| Sanacorp | Methoxsalen | 1AKD6 | 1 |
| Say Phytoceut. Ltd/Noweda | Methoxsalen | 1209015-01 | 3 |

- 256 438 spectra from 1666 *Apo-Ident* customers from a total of 52 024 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Methoxsalen* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Methoxsalen* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 410 | 0 | 157 916 |
| **Type B** | 0 | 480 | 0 | 212 460 |
| **Type C** | 0 | 447 | 1 | 256 438 |

The substance/substance group *Methoxsalen* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5366 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7768 % (> 99.1071 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21555 | 21862 | 6.84 | 223.53 |
| 21862 | 21862 | 0.00 | 240.56 |
| 22785 | 22785 | 0.00 | 237.01 |
| 23165 | 21862 | 10.69 | 219.68 |
| 23167 | 21862 | 12.23 | 215.36 |
| 23333 | 23333 | 0.00 | 215.67 |
| 23346 | 23346 | 0.00 | 210.51 |
| 24697 | 21862 | 10.55 | 220.03 |
| 25702 | 25702 | 0.00 | 207.34 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Methyl-4-hydroxybenzoate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20345-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Methyl-4-hydroxybenzoate; Methylis parahydroxybenzoas

### Special notes

When selecting the *Methyl-4-hydroxybenzoate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Methyl-4-hydroxybenzoate | 6 | 18 | 146 |

### Second-stage model

For differentiation of the substance/substance group *Methyl-4-hydroxybenzoate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Methyl-4-hydroxybenzoate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 104.95 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Methyl-4-hydroxybenzoate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Methyl-4-hydroxybenzoate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Methyl-4-hydroxybenzoate | 11090034 | 20693 | 40 | 20110428 |
| Caelo | Methyl-4-hydroxybenzoate | 181769 | 24223 | 40 | 20180824* |
| Euro OTC | Methyl-4-hydroxybenzoate | 1205025-01 | 20697 | 40 | 20120601 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1601037 | 22305 | 60 | 20160119* |
| Fagron | Methyl-4-hydroxybenzoate | 14L30-T01-018345 | 23223 | 40 | 20150309 |
| Fagron | Methyl-4-hydroxybenzoate | 19B05-T03-062158 | 24588 | 40 | 20190228 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 260 spectra of 6 reference samples from the substance/substance group *Methyl-4-hydroxybenzoate*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 790 spectra of 21 reference samples from the substance/substance group *Methyl-4-hydroxybenzoate*.
- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Methyl-4-hydroxybenzoate | 13268813 | 21439 | 60 |
| Caelo | Methyl-4-hydroxybenzoate | 15063820 | 23216 | 40 |
| Caelo | Methyl-4-hydroxybenzoate | 171581 | 23317 | 40 |
| Caelo | Methyl-4-hydroxybenzoate | 191302 | 24711 | 40 |
| Caelo | Methyl-4-hydroxybenzoate | 192334 | 24886 | 40 |
| Caelo | Methyl-4-hydroxybenzoate | 22000388 | 26117 | 40 |
| Caelo | Methyl-4-hydroxybenzoate | 22003498 | 26475 | 40 |
| Caelo | Methyl-4-hydroxybenzoate | 23000896 | 26852 | 40 |
| Caelo | Methyl-4-hydroxybenzoate | 23003474 | 27102 | 40 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1706005 | 23703 | 40 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1807009 | 24148 | 40 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1902025 | 24568 | 40 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1909009 | 24852 | 40 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2004013 | 25155 | 40 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2010001 | 25409 | 40 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2304023 | 26639 | 40 |
| Fagron | Methyl-4-hydroxybenzoate | 22L02-B13-226168 | 26548 | 40 |
| Gatt-Koller | Methyl-4-hydroxybenzoate | 23J00964 | 27100 | 30 |
| Caelo | Methyl-4-hydroxybenzoate | 22000388 | 26117SI | 20 |
| Caelo | Methyl-4-hydroxybenzoate | 22003498 | 26475SI | 20 |
| Fagron | Methyl-4-hydroxybenzoate | 22L02-B13-226168 | 26548SI | 20 |

- 212 150 spectra from a total of 4269 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information

provided by the customer regarding manufacturer and batch number.

- 760 spectra from 521 *Apo-Ident* customers from 148 batches from the substance/substance group *Methyl-4-hydroxybenzoate*.
- Among them are spectra of independent samples from 143 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Methyl-4-hydroxybenzoate | 19130205 | 1 |
| | Methyl-4-hydroxybenzoate | 200401301 | 1 |
| | Methyl-4-hydroxybenzoate | 2010001-02 | 8 |
| | Methyl-4-hydroxybenzoate | 22000388006 | 3 |
| | Methyl-4-hydroxybenzoate | 22000388009 | 1 |
| | Methyl-4-hydroxybenzoate | 22000388010 | 1 |
| | Methyl-4-hydroxybenzoate | 22003498003 | 18 |
| | Methyl-4-hydroxybenzoate | 22J02568 | 1 |
| | Methyl-4-hydroxybenzoate | 23000896007 | 7 |
| | Methyl-4-hydroxybenzoate | 23003474008 | 1 |
| | Methyl-4-hydroxybenzoate | 23003474009 | 6 |
| | Methyl-4-hydroxybenzoate | 23003474020 | 1 |
| | Methyl-4-hydroxybenzoate | 2304023-01 | 1 |
| | Methyl-4-hydroxybenzoate | 2304023-02 | 2 |
| | Methyl-4-hydroxybenzoate | 2304023-03 | 3 |
| | Methyl-4-hydroxybenzoate | Ja0481 | 1 |
| AHD | Methyl-4-hydroxybenzoate | 12251624 | 1 |
| AHD | Methyl-4-hydroxybenzoate | 17158101 | 1 |
| AHD | Methyl-4-hydroxybenzoate | 17343002 | 1 |
| AHD | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| AHD | Methyl-4-hydroxybenzoate | 2300896007 | 1 |
| Alliance healfcare | Methyl-4-hydroxybenzoate | 18176910 | 1 |
| Alliance Healthcare | Methyl-4-hydroxybenzoate | 1507042-02 | 1 |
| Alliance | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| Anzag | Methyl-4-hydroxybenzoate | 11345115 | 1 |
| apo-ident | Methyl-4-hydroxybenzoate | 1706005-01 | 1 |
| apomix | Methyl-4-hydroxybenzoate | 13268809 | 1 |
| Bombastus | Methyl-4-hydroxybenzoate | 1212011-01 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 1000076005 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 1108211930 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 11090003 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 11090030 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 11090031 | 4 |
| Caelo | Methyl-4-hydroxybenzoate | 111003301 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 11345103 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 11345115 | 7 |
| Caelo | Methyl-4-hydroxybenzoate | 11345120 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 12081502 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 12251605 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 12251611 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 12251619 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 12251624 | 5 |
| Caelo | Methyl-4-hydroxybenzoate | 1251624 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 13081308 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 13268802 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 13268803 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 13268804 | 9 |
| Caelo | Methyl-4-hydroxybenzoate | 13268809 | 5 |
| Caelo | Methyl-4-hydroxybenzoate | 13268813 | 7 |
| Caelo | Methyl-4-hydroxybenzoate | 13268815 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 13268819 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Methyl-4-hydroxybenzoate | 13268821 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 14120207 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 14120208 | 5 |
| Caelo | Methyl-4-hydroxybenzoate | 15063802 | 8 |
| Caelo | Methyl-4-hydroxybenzoate | 15063803 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 15063806 | 8 |
| Caelo | Methyl-4-hydroxybenzoate | 15063812 | 3 |
| Caelo | Methyl-4-hydroxybenzoate | 15063813 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 15063818 | 4 |
| Caelo | Methyl-4-hydroxybenzoate | 15063819 | 4 |
| Caelo | Methyl-4-hydroxybenzoate | 15063819/1210217 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 15063820 | 4 |
| Caelo | Methyl-4-hydroxybenzoate | 15222203 | 5 |
| Caelo | Methyl-4-hydroxybenzoate | 15298101 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 15298102 | 13 |
| Caelo | Methyl-4-hydroxybenzoate | 15444905 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 15444911 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 15444913 | 4 |
| Caelo | Methyl-4-hydroxybenzoate | 15444916 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 16256103 | 6 |
| Caelo | Methyl-4-hydroxybenzoate | 16256104 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 16256114 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 16256115 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 16256117 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 16256118 | 6 |
| Caelo | Methyl-4-hydroxybenzoate | 17158101 | 29 |
| Caelo | Methyl-4-hydroxybenzoate | 17343002 | 14 |
| Caelo | Methyl-4-hydroxybenzoate | 17343009 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 17343010 | 9 |
| Caelo | Methyl-4-hydroxybenzoate | 17343013 | 20 |
| Caelo | Methyl-4-hydroxybenzoate | 1807009-01 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 1816903 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 18176903 | 27 |
| Caelo | Methyl-4-hydroxybenzoate | 18176910 | 15 |
| Caelo | Methyl-4-hydroxybenzoate | 18176919 | 2 |
| Caelo | Methyl-4-hydroxybenzoate | 190672106 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 191302001 | 36 |
| Caelo | Methyl-4-hydroxybenzoate | 191302002 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 191302003 | 8 |
| Caelo | Methyl-4-hydroxybenzoate | 19130203 | 6 |
| Caelo | Methyl-4-hydroxybenzoate | 19130205 | 20 |
| Caelo | Methyl-4-hydroxybenzoate | 1913022001 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 19132001 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 2000388006 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 21000076005 | 21 |
| Caelo | Methyl-4-hydroxybenzoate | 21000076005n | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 21000076007 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 21000076011 | 19 |
| Caelo | Methyl-4-hydroxybenzoate | 21000076015 | 11 |
| Caelo | Methyl-4-hydroxybenzoate | 21000076017 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 22000388006 | 16 |
| Caelo | Methyl-4-hydroxybenzoate | 22000388009 | 3 |
| Caelo | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 220830(22000388006) | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 22092002 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 290114PML01 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 6091402 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 713Q-01930 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 79/19 | 1 |
| Caelo | Methyl-4-hydroxybenzoate | 9011303 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Methyl-4-hydroxybenzoate | Caelo | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 22000388006 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 19130205 | 1 |
| Caesar & Loretz GmbH/Gehe | Methyl-4-hydroxybenzoate | 21000076015 | 1 |
| Caesar & Loretz GmbH/Kehr | Methyl-4-hydroxybenzoate | 191302003 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 191302001 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 18176903 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 191302003 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 19130203 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 21000076005 | 2 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 21000076005 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 22000388006 | 1 |
| Caesar & Loretz GmbH/Sa | Methyl-4-hydroxybenzoate | 19130205 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 21000076005 | 1 |
| Caesar & Loretz GmbH... | Methyl-4-hydroxybenzoate | 21000076011 | 1 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 13268809 | 1 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 17158101 | 1 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 18176903 | 3 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 18176910 | 6 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 191302001 | 8 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 191302003 | 6 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 19130205 | 5 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 21000076005 | 9 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 21000076011 | 2 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 21000076015 | 5 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 220003388006 | 1 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 22000388006 | 6 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 22000388009 | 1 |
| Caesar & Loretz GmbH | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| Caesar & Loretz Hild... | Methyl-4-hydroxybenzoate | 191302003 | 1 |
| Caesar & Loretz/Noweda | Methyl-4-hydroxybenzoate | 191302001 | 1 |
| Caesar & Loretz | Methyl-4-hydroxybenzoate | 17343002 | 1 |
| Caesar&loretz,Phoenix | Methyl-4-hydroxybenzoate | 13268821 | 1 |
| Caesar&Loretz | Methyl-4-hydroxybenzoate | 17158101 | 1 |
| Caesar/Noweda | Methyl-4-hydroxybenzoate | 15063806 | 1 |
| Cealo/Anzag | Methyl-4-hydroxybenzoate | 19130205 | 1 |
| Cealo/Gehe | Methyl-4-hydroxybenzoate | 16256104 | 1 |
| Eigenherstellung | Methyl-4-hydroxybenzoate | | 1 |
| Eigenherstellung | Methyl-4-hydroxybenzoate | 100912PML01 | 1 |
| EuRho/ NOWEDA | Methyl-4-hydroxybenzoate | EA2781 | 1 |
| EuRho | Methyl-4-hydroxybenzoate | 110403101 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1009022-01 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1212011-01 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1401027-01 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1401027-02 | 2 |
| Euro OTC | Methyl-4-hydroxybenzoate | 140600501 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1406005-01 | 2 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1502009-01 | 11 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1507042-01 | 10 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1507042-02 | 4 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1601037 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1601037-01 | 11 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1706005-01 | 9 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1706005-02 | 3 |
| Euro OTC | Methyl-4-hydroxybenzoate | 170605-01 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 172620 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1758101 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1807009-01 | 28 |
| Euro OTC | Methyl-4-hydroxybenzoate | 1902025-01 | 3 |
| Euro OTC | Methyl-4-hydroxybenzoate | 19090009-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Methyl-4-hydroxybenzoate | 1909009-01 | 8 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2004013/01 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 200401301 | 2 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2004013-01 | 6 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2010001-01 | 4 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2010001-02 | 9 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2606022 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 2717M-01930 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 280903701 | 2 |
| Euro OTC | Methyl-4-hydroxybenzoate | 3115M-01930 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 3518A-01930 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 4312I-01930 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | 4314U-01930 | 1 |
| Euro OTC | Methyl-4-hydroxybenzoate | EA2781 | 1 |
| Euro/Phönix | Methyl-4-hydroxybenzoate | 201000101 | 1 |
| Fa.Phönix | Methyl-4-hydroxybenzoate | 22000388006 | 1 |
| Fagron | Methyl-4-hydroxybenzoate | | 1 |
| Fagron | Methyl-4-hydroxybenzoate | 12D18-N01 | 1 |
| Fagron | Methyl-4-hydroxybenzoate | 12H02-N08 | 1 |
| Fagron | Methyl-4-hydroxybenzoate | 13B25-N03 | 2 |
| Fagron | Methyl-4-hydroxybenzoate | 13E27-N09 | 1 |
| Fagron | Methyl-4-hydroxybenzoate | 16256115 | 1 |
| Fagron | Methyl-4-hydroxybenzoate | 20111125-1 | 1 |
| GATT-KOLLER/PHOENIX | Methyl-4-hydroxybenzoate | 6112/01142814 | 1 |
| Gatt-Koller | Methyl-4-hydroxybenzoate | 1803308 | 1 |
| Gehe | Methyl-4-hydroxybenzoate | 11090020 | 1 |
| Gehe | Methyl-4-hydroxybenzoate | 11090031 | 1 |
| Gehe | Methyl-4-hydroxybenzoate | 15063818 | 1 |
| Gehe | Methyl-4-hydroxybenzoate | 17158101 | 1 |
| Gehe | Methyl-4-hydroxybenzoate | 1902025-01 | 1 |
| Gehe | Methyl-4-hydroxybenzoate | 2010001-02 | 1 |
| Gehe | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| Geibo | Methyl-4-hydroxybenzoate | 22000388006 | 1 |
| Hänseler | Methyl-4-hydroxybenzoate | | 2 |
| Jenne | Methyl-4-hydroxybenzoate | 21000076015 | 1 |
| Kehr | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| Nachprüfung vom 31.1... | Methyl-4-hydroxybenzoate | 12251624 | 2 |
| Nachprüfung | Methyl-4-hydroxybenzoate | 1718M-01930 | 1 |
| Noweda/Caesar & Lore... | Methyl-4-hydroxybenzoate | 22000388009 | 1 |
| Noweda | Methyl-4-hydroxybenzoate | 16256118 | 1 |
| Noweda | Methyl-4-hydroxybenzoate | 1706005-02 | 1 |
| Noweda | Methyl-4-hydroxybenzoate | 17158101 | 1 |
| Noweda | Methyl-4-hydroxybenzoate | 191302003 | 1 |
| Noweda | Methyl-4-hydroxybenzoate | 2010001-02 | 2 |
| Noweda | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| Phoenix | Methyl-4-hydroxybenzoate | 1706005-01 | 1 |
| Phoenix | Methyl-4-hydroxybenzoate | 18176910 | 1 |
| Phoenix | Methyl-4-hydroxybenzoate | 191302002 | 2 |
| Phoenix | Methyl-4-hydroxybenzoate | 200046011 | 1 |
| Phoenix | Methyl-4-hydroxybenzoate | 21000076011 | 1 |
| Phoenix | Methyl-4-hydroxybenzoate | 2100076007 | 1 |
| Phoenix | Methyl-4-hydroxybenzoate | 22000388009 | 1 |
| Phoenix | Methyl-4-hydroxybenzoate | 22003498003 | 1 |
| Phönix 14.01.2014 | Methyl-4-hydroxybenzoate | 12251624 | 1 |
| phönix 4.12.2013 | Methyl-4-hydroxybenzoate | 1212011/01 | 1 |
| Phönix Berlin | Methyl-4-hydroxybenzoate | 22000388009 | 1 |
| PHÖNIX | Methyl-4-hydroxybenzoate | 15063819 | 1 |
| Phönix | Methyl-4-hydroxybenzoate | 16256103 | 1 |
| Phönix | Methyl-4-hydroxybenzoate | 17343010 | 1 |
| Phönix | Methyl-4-hydroxybenzoate | 1807009-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Methyl-4-hydroxybenzoate | 191302001 | 1 |
| Phönix | Methyl-4-hydroxybenzoate | 2010001-01 | 2 |
| Phönix | Methyl-4-hydroxybenzoate | 2AKD3 | 1 |
| sanacorb | Methyl-4-hydroxybenzoate | 17343010 | 1 |
| Sanacorp E.K :2,76... | Methyl-4-hydroxybenzoate | 13268804 | 1 |

- 256 126 spectra from 1666 *Apo-Ident* customers from a total of 52 007 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Methyl-4-hydroxybenzoate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Methyl-4-hydroxybenzoate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 790 | 0 | 212 150 |
| **Type C** | 0 | 751 | 9 | 256 126 |

The substance/substance group *Methyl-4-hydroxybenzoate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2405 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8158 % (> 98.4211 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20693 | 22305 | 10.66 | 201.76 |
| 20697 | 22305 | 11.51 | 202.16 |
| 22305 | 22305 | 0.00 | 204.72 |
| 23223 | 22305 | 12.95 | 202.65 |
| 24223 | 24223 | 0.00 | 202.04 |
| 24588 | 22305 | 15.75 | 205.14 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Methylcellulose** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20705-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Methylcellulose; Hydroxypropylcellulose; Hydroxypropylcellulosum; Hypromellose; Hypromellosum; Methylcellulosum

### Special notes

When selecting the *Methylcellulose* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Methylcellulose | 24 | 16 | 263 |

### Second-stage model

For differentiation of the substance/substance group *Methylcellulose* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Methylcellulose* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 72.49 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Methylcellulose* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Methylcellulose*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Hydroxypropylcellulose | 12093107 | 20686 | 40 | 1402049 |
| Caelo | Hydroxypropylcellulose | 14189804 | 21767 | 60 | AR-15-FG-014922-01 |
| Caelo | Hydroxypropylcellulose | 15345001 | 22258 | 60 | 20151104 |
| Caelo | Hydroxypropylcellulose | 181146 | 24249 | 40 | 20180618* |
| Caelo | Hydroxypropylcellulose | 20000942007 | 25426 | 40 | 20200505 |
| Caelo | Hydroxypropylcellulose | 21001994001 | 25981 | 40 | 20211004 |
| Caelo | Hydroxypropylcellulose | 21001994001 | 25981SI | 30 | 20211004 |
| Caelo | Hydroxypropylcellulose | 22003732 | 26721 | 40 | 20230124* |
| Caelo | Hydroxypropylcellulose | 22003732 | 26721SI | 20 | 20230124* |
| Caelo | Hydroxypropylcellulose | 24000194 | 27139 | 40 | 20240322* |
| Caelo | Hydroxypropylcellulose | 24000194 | 27139SI | 20 | 20240322* |
| Caelo | Hypromellose | 13155006 | 20919 | 40 | 1402056 |
| Caelo | Hypromellose | 13155006 | 20931 | 40 | 20130529 |
| Caelo | Hypromellose | 14338801 | 21702 | 45 | 20141217 |
| Caelo | Hypromellose | 192852 | 25230 | 40 | 20191220* |
| Caelo | Hypromellose | 20000987 | 25231 | 40 | 20200518* |
| Caelo | Hypromellose | 21001141 | 26148 | 40 | 20210729* |
| Caelo | Hypromellose | 22003524 | 26488 | 40 | 20221220* |
| Caelo | Hypromellose | 22003524 | 26488SI | 20 | 20221220* |
| Fagron | Hypromellose | 15G08-B14-314845 | 22609 | 40 | 20150727 |
| Fagron | Hypromellose | 19G17-B04-194255 | 25060 | 40 | 20190830 |
| Fagron | Hypromellose | 22B26-B10-223114 | 26636 | 40 | 231005103 |

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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Methylcellulose | 13130115 | 21570 | 60 | 20130517 |
| Caelo | Methylcellulose | 160602 | 22457 | 60 | 20160323* |
| Caelo | Methylcellulose | 192473 | 25286 | 40 | 20191202* |
| Caelo | Methylcellulose | 20002631 | 25622 | 40 | 20201027* |
| Fagron | Methylcellulose | 12D02-N09 | 20705 | 40 | 1402447 |
| Fagron | Methylcellulose | 15H04-B07-331291 | 23224 | 40 | 20150824 |
| Fagron | Methylcellulose | 18D03-B05-361882 | 25188 | 40 | 20180507 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 1175 spectra of 29 reference samples from the substance/substance group *Methylcellulose*. These samples are listed above in the *calibration samples* section. The reference samples come from 24 different batches.

- 157 151 spectra from a total of 2933 batches from further 494 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 770 spectra of 21 reference samples from the substance/substance group *Methylcellulose*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hydroxypropylcellulose | 15345009 | 23123 | 40 |
| Caelo | Hydroxypropylcellulose | 17355801 | 23974 | 40 |
| Caelo | Hypromellose | 162244 | 22757 | 40 |
| Caelo | Hypromellose | 171150 | 23284 | 40 |
| Caelo | Hypromellose | 190696 | 24516 | 40 |
| Caelo | Hypromellose | 22001980 | 26242 | 40 |
| Caelo | Hypromellose | 23000497 | 26855 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hypromellose | 24001679 | 27434 | 40 |
| Caelo | Methylcellulose | 171704 | 23627 | 40 |
| Caelo | Methylcellulose | 183318 | 24560 | 40 |
| Caelo | Methylcellulose | 22000891 | 26107 | 40 |
| Caelo | Methylcellulose | 23001536 | 26975 | 40 |
| Caelo | Methylcellulose | 24000306 | 27130 | 40 |
| Fagron | Methylcellulose | 20E28-F04-371902 | 25724 | 50 |
| Fagron | Methylcellulose | 21F04-F05-378883 | 25937 | 40 |
| Fagron | Methylcellulose | 22K07-B14-224511 | 26547 | 40 |
| Caelo | Hypromellose | 21001141 | 26148SI[†] | 20 |
| Caelo | Hypromellose | 22001980 | 26242SI | 20 |
| Caelo | Methylcellulose | 22000891 | 26107SI | 20 |
| Fagron | Methylcellulose | 21F04-F05-378883 | 25937SI | 40 |
| Fagron | Methylcellulose | 22K07-B14-224511 | 26547SI | 20 |

- 212 170 spectra from a total of 4270 batches from further 870 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1323 spectra from 617 *Apo-Ident* customers from 278 batches from the substance/substance group *Methylcellulose*.
- Among them are spectra of independent samples from 262 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hypromellose | 18004b03-348465 | 1 |
| | Methylcellulose | 192473003 | 1 |
| | Hypromellose | 19G17-B04-194255 | 1 |
| | Methylcellulose | 22000891011 | 3 |
| | Methylcellulose | 22000891020 | 1 |
| | Methylcellulose | 22000891023 | 1 |
| | Hypromellose | 22003524002 | 3 |
| | Hypromellose | 22003524004 | 6 |
| | Hypromellose | 22003524005 | 2 |
| | Hypromellose | 22003524006 | 1 |
| | Hypromellose | 22003524007 | 4 |
| | Hypromellose | 23000497002 | 8 |
| | Hypromellose | 23000497003 | 27 |
| | Methylcellulose | 23001536003 | 15 |
| | Hypromellose | 23003602003 | 6 |
| | Hypromellose | 23003602004 | 9 |
| | Hypromellose | 23D27-B06-227933 | 1 |
| | Hypromellose | 24001679003 | 1 |
| | Hypromellose | 24001679004 | 4 |
| | Hypromellose | 24001679008 | 1 |
| | Hypromellose | 24C29-B03-236858 | 1 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hypromellose | 24L10-B05-006267 | 1 |
| | Hypromellose | B06-2279303 | 1 |
| AHD | Hypromellose | 16H23-B02-325994 | 1 |
| AHD | Methylcellulose | 192473004 | 1 |
| AHD | Hypromellose | 23000497003 | 2 |
| Alliance Health 27.1… | Hypromellose | 13D03-N03 | 1 |
| Bombastus | Methylcellulose | 17170405 | 1 |
| Caelo | Methylcellulose | | 1 |
| Caelo | Hypromellose | 10004281003 | 1 |
| Caelo | Methylcellulose | 10247604 | 1 |
| Caelo | Methylcellulose | 12044903 | 2 |
| Caelo | Methylcellulose | 12044907 | 1 |
| Caelo | Methylcellulose | 12044917 | 1 |
| Caelo | Methylcellulose | 12044918 | 2 |
| Caelo | Methylcellulose | 12044922 | 2 |
| Caelo | Methylcellulose | 12044927 | 6 |
| Caelo | Methylcellulose | 12044931 | 2 |
| Caelo | Hypromellose | 12098702 | 1 |
| Caelo | Hypromellose | 12215504 | 2 |
| Caelo | Hypromellose | 12215505 | 1 |
| Caelo | Hypromellose | 12239502 | 1 |
| Caelo | Methylcellulose | 13021401 | 1 |
| Caelo | Hydroxypropylcellulose | 13031306 | 1 |
| Caelo | Hydroxypropylcellulose | 13031309 | 1 |
| Caelo | Hypromellose | 13100304 | 2 |
| Caelo | Methylcellulose | 13130104 | 5 |
| Caelo | Methylcellulose | 13130109 | 5 |
| Caelo | Methylcellulose | 13130115 | 6 |
| Caelo | Methylcellulose | 13130121 | 3 |
| Caelo | Methylcellulose | 1313019 | 1 |
| Caelo | Hypromellose | 13155002 | 1 |
| Caelo | Hypromellose | 13155004 | 11 |
| Caelo | Hypromellose | 13d03-n03 | 1 |
| Caelo | Hydroxypropylcellulose | 14189801 | 2 |
| Caelo | Methylcellulose | 14197502 | 7 |
| Caelo | Methylcellulose | 14197513 | 1 |
| Caelo | Methylcellulose | 14197514 | 9 |
| Caelo | Hypromellose | 14338801 | 1 |
| Caelo | Hypromellose | 14338802 | 1 |
| Caelo | Hypromellose | 14338803 | 1 |
| Caelo | Hypromellose | 14C05-B03-294708 | 1 |
| Caelo | Hydroxypropylcellulose | 15129707 | 1 |
| Caelo | Methylcellulose | 15179602 | 12 |
| Caelo | Methylcellulose | 15179605 | 8 |
| Caelo | Hydroxypropylcellulose | 15345001 | 3 |
| Caelo | Hydroxypropylcellulose | 15345005 | 1 |
| Caelo | Hydroxypropylcellulose | 15345008 | 1 |
| Caelo | Hypromellose | 15B02-B05-308852 | 1 |
| Caelo | Hypromellose | 15G08-B14-310845 | 1 |
| Caelo | Hypromellose | 15G08-B14-314845 | 3 |
| Caelo | Methylcellulose | 16060202 | 1 |
| Caelo | Methylcellulose | 16060206 | 13 |
| Caelo | Methylcellulose | 16060210 | 12 |
| Caelo | Hypromellose | 16224401 | 6 |
| Caelo | Hypromellose | 16224403 | 15 |
| Caelo | Hypromellose | 16224404 | 1 |
| Caelo | Hypromellose | 16224406 | 5 |
| Caelo | Hypromellose | 16224407 | 19 |
| Caelo | Hypromellose | 16224408 | 1 |
| Caelo | Hypromellose | 16224409 | 11 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Methylcellulose | 16284003 | 11 |
| Caelo | Methylcellulose | 16284004 | 2 |
| Caelo | Methylcellulose | 16284006 | 11 |
| Caelo | Methylcellulose | 1628404 | 1 |
| Caelo | Hypromellose | 16H23-B02-325994 | 1 |
| Caelo | Hypromellose | 16H23-B02-332066 | 1 |
| Caelo | Hypromellose | 17115004 | 2 |
| Caelo | Hypromellose | 17115005 | 22 |
| Caelo | Hypromellose | 17115008 | 13 |
| Caelo | Hypromellose | 171150085501 | 1 |
| Caelo | Hypromellose | 17132101 | 1 |
| Caelo | Methylcellulose | 17170404 | 6 |
| Caelo | Methylcellulose | 17170405 | 11 |
| Caelo | Methylcellulose | 17170406 | 1 |
| Caelo | Hypromellose | 180215H/17115004 | 1 |
| Caelo | Methylcellulose | 18045101 | 11 |
| Caelo | Methylcellulose | 18045103 | 2 |
| Caelo | Methylcellulose | 18045107 | 2 |
| Caelo | Methylcellulose | 18045110 | 1 |
| Caelo | Methylcellulose | 18045114 | 3 |
| Caelo | Hydroxypropylcellulose | 18114601 | 1 |
| Caelo | Hydroxypropylcellulose | 18114607 | 2 |
| Caelo | Hypromellose | 18132101 | 16 |
| Caelo | Hypromellose | 18132102 | 6 |
| Caelo | Hypromellose | 18132105 | 21 |
| Caelo | Hypromellose | 18132106 | 2 |
| Caelo | Hypromellose | 18132109 | 11 |
| Caelo | Hypromellose | 18132111 | 6 |
| Caelo | Hypromellose | 18132111/18132109 | 1 |
| Caelo | Hypromellose | 18132116 | 1 |
| Caelo | Methylcellulose | 183318002 | 4 |
| Caelo | Methylcellulose | 18331803 | 11 |
| Caelo | Methylcellulose | 18331804 | 1 |
| Caelo | Methylcellulose | 18331806 | 21 |
| Caelo | Hypromellose | 18A17-B04-345100 | 1 |
| Caelo | Hypromellose | 18D04-B03-350745 | 2 |
| Caelo | Hypromellose | 18D04-B03-355144 | 1 |
| Caelo | Hypromellose | 1906901 | 1 |
| Caelo | Hypromellose | 1906908 | 1 |
| Caelo | Hypromellose | 19069601 | 35 |
| Caelo | Hypromellose | 19069608 | 19 |
| Caelo | Hypromellose | 19069609 | 9 |
| Caelo | Methylcellulose | 192473003 | 6 |
| Caelo | Methylcellulose | 192473004 | 6 |
| Caelo | Hypromellose | 192852004 | 4 |
| Caelo | Hypromellose | 192852005 | 27 |
| Caelo | Hypromellose | 19285205 | 1 |
| Caelo | Hypromellose | 1969609 | 1 |
| Caelo | Hypromellose | 19G17-B04-194255 | 1 |
| Caelo | Hypromellose | 200000987004 | 1 |
| Caelo | Hypromellose | 200000987006 | 1 |
| Caelo | Hypromellose | 20000987003 | 8 |
| Caelo | Hypromellose | 20000987004 | 26 |
| Caelo | Hypromellose | 20000987006 | 19 |
| Caelo | Hypromellose | 20000987007 | 5 |
| Caelo | Hypromellose | 20000987044 | 1 |
| Caelo | Methylcellulose | 200014546013 | 1 |
| Caelo | Hypromellose | 20004281002 | 4 |
| Caelo | Hypromellose | 20004281003 | 7 |
| Caelo | Methylcellulose | 20004546004 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Methylcellulose | 20004546008 | 5 |
| Caelo | Methylcellulose | 20004546009 | 5 |
| Caelo | Methylcellulose | 20004546013 | 4 |
| Caelo | Methylcellulose | 2000456009 | 1 |
| Caelo | Hypromellose | 2001980005 | 1 |
| Caelo | Methylcellulose | 20021401 | 1 |
| Caelo | Hypromellose | 21001141001 | 2 |
| Caelo | Hypromellose | 21001141002 | 10 |
| Caelo | Hypromellose | 21001141004 | 1 |
| Caelo | Hypromellose | 21001141005 | 11 |
| Caelo | Hypromellose | 21001141006 | 10 |
| Caelo | Hypromellose | 21001141009 | 1 |
| Caelo | Hypromellose | 210011411005 | 1 |
| Caelo | Hydroxypropylcellulose | 21001994001 | 1 |
| Caelo | Hydroxypropylcellulose | 21001994006 | 1 |
| Caelo | Methylcellulose | 22000891002 | 3 |
| Caelo | Methylcellulose | 22000891007 | 1 |
| Caelo | Methylcellulose | 22000891011 | 1 |
| Caelo | Hypromellose | 22001980004 | 3 |
| Caelo | Hypromellose | 22001980005 | 26 |
| Caelo | Hypromellose | 22001980009 | 1 |
| Caelo | Hypromellose | 22001982225 | 1 |
| Caelo | Hypromellose | 22003524002 | 2 |
| Caelo | Hypromellose | 22003524004 | 4 |
| Caelo | Hypromellose | 22003524005 | 2 |
| Caelo | Hypromellose | 22003524006 | 1 |
| Caelo | Hypromellose | 22003524007 | 2 |
| Caelo | Methylcellulose | 5081404 | 1 |
| Caelo | Hypromellose | 5121818 | 1 |
| Caelo | Methylcellulose | 5219Q-01882 | 1 |
| Caelo | Hypromellose | D180F8Q011 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 16224403 | 1 |
| Caesar & Loretz GmbH... | Methylcellulose | 18331803 | 1 |
| Caesar & Loretz GmbH... | Methylcellulose | 20004546008 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 20000987006 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 21001141005 | 1 |
| Caesar & Loretz GmbH/AHD | Hypromellose | 19069609 | 1 |
| Caesar & Loretz GmbH/AHD | Hypromellose | 192852005 | 3 |
| Caesar & Loretz GmbH/AHD | Hypromellose | 20000987004 | 2 |
| Caesar & Loretz GmbH... | Methylcellulose | 20004546004 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 19069601 | 1 |
| Caesar & Loretz GmbH/Gehe | Hydroxypropylcellulose | 20000942005 | 1 |
| Caesar & Loretz GmbH/GEHE | Hydroxypropylcellulose | 20000942005 | 1 |
| Caesar & Loretz GmbH/Gehe | Hypromellose | 20000987004 | 1 |
| Caesar & Loretz GmbH/Gehe | Hypromellose | 20004281003 | 1 |
| Caesar & Loretz GmbH/Gehe | Methylcellulose | 22000891002 | 2 |
| Caesar & Loretz GmbH/Gehe | Hypromellose | 22003524004 | 1 |
| Caesar & Loretz GmbH/GEHE | Hypromellose | 22003524004 | 1 |
| Caesar & Loretz GmbH/Gehe | Hypromellose | 23003602003 | 1 |
| Caesar & Loretz GmbH... | Methylcellulose | 18331806 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 19069608 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 22001980004 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 22001980005 | 1 |
| Caesar & Loretz GmbH... | Methylcellulose | 17170405 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 19069601 | 3 |
| Caesar & Loretz GmbH... | Hypromellose | 21001141005 | 1 |
| Caesar & Loretz GmbH... | Methylcellulose | 20004546004 | 1 |
| Caesar & Loretz GmbH/Ph | Hypromellose | 19069608 | 4 |
| Caesar & Loretz GmbH... | Hydroxypropylcellulose | 20003818001 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 21001141006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Sana | Hypromellose | 21001141005 | 1 |
| Caesar & Loretz GmbH... | Methylcellulose | 18331806 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 19069601 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 20000987004 | 1 |
| Caesar & Loretz GmbH... | Methylcellulose | 20004546004 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 22001980009 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 18132109 | 2 |
| Caesar & Loretz GmbH | Methylcellulose | 12044922 | 1 |
| Caesar & Loretz GmbH | Methylcellulose | 18045107 | 1 |
| Caesar & Loretz GmbH | Methylcellulose | 18045114 | 2 |
| Caesar & Loretz GmbH | Hydroxypropylcellulose | 18114605 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 18132105 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 18132109 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 18132111 | 3 |
| Caesar & Loretz GmbH | Methylcellulose | 183318022 | 1 |
| Caesar & Loretz GmbH | Methylcellulose | 18331803 | 4 |
| Caesar & Loretz GmbH | Methylcellulose | 18331806 | 9 |
| Caesar & Loretz GmbH | Hypromellose | 19069601 | 9 |
| Caesar & Loretz GmbH | Hypromellose | 19069608 | 2 |
| Caesar & Loretz GmbH | Hypromellose | 19069609 | 1 |
| Caesar & Loretz GmbH | Methylcellulose | 192473003 | 4 |
| Caesar & Loretz GmbH | Methylcellulose | 192473004 | 7 |
| Caesar & Loretz GmbH | Hypromellose | 192852004 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 192852005 | 7 |
| Caesar & Loretz GmbH | Hydroxypropylcellulose | 20000942007 | 2 |
| Caesar & Loretz GmbH | Hypromellose | 20000987003 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 20000987004 | 2 |
| Caesar & Loretz GmbH | Hypromellose | 20000987006 | 3 |
| Caesar & Loretz GmbH | Hypromellose | 20004281002 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 20004281003 | 6 |
| Caesar & Loretz GmbH | Methylcellulose | 20004546004 | 3 |
| Caesar & Loretz GmbH | Methylcellulose | 20004546008 | 4 |
| Caesar & Loretz GmbH | Methylcellulose | 20004546009 | 2 |
| Caesar & Loretz GmbH | Methylcellulose | 20004546013 | 3 |
| Caesar & Loretz GmbH | Hypromellose | 21001141002 | 7 |
| Caesar & Loretz GmbH | Hypromellose | 21001141004 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 21001141005 | 5 |
| Caesar & Loretz GmbH | Hypromellose | 21001141006 | 10 |
| Caesar & Loretz GmbH | Hypromellose | 21001141009 | 2 |
| Caesar & Loretz GmbH | Methylcellulose | 22000891002 | 4 |
| Caesar & Loretz GmbH | Methylcellulose | 22000891011 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 22001980004 | 2 |
| Caesar & Loretz GmbH | Hypromellose | 22001980005 | 9 |
| Caesar & Loretz GmbH | Hypromellose | 22001980009 | 2 |
| Caesar & Loretz GmbH | Hypromellose | 22003524004 | 1 |
| Caesar & Loretz GmbH | Hypromellose | 22003524005 | 2 |
| CAESAR & LORETZ GMBH | Hypromellose | B02-1977101 | 1 |
| Caesar & Loretz GmbH... | Hypromellose | 19069609 | 2 |
| Caesar & Loretz | Hypromellose | 17115005 | 1 |
| Caesar & Loretz | Hypromellose | 17115008 | 1 |
| Caesar & Loretz | Hypromellose | 18132116 | 1 |
| Caesar&Lorenz/AHD | Methylcellulose | 18045107 | 1 |
| Cealo / AHD 19.09.20... | Hypromellose | 19069601 | 1 |
| Cealo/Gehe | Hypromellose | 18132101 | 1 |
| cealo | Methylcellulose | 15179602 | 1 |
| Cealo | Hypromellose | 192852004 | 1 |
| DOW Chemical Company... | Hypromellose | 14G02-B11-296850 | 1 |
| DOW chemical Company... | Hypromellose | 15G08-B14-310845 | 1 |
| Euro OTC | Methylcellulose | 10247609 | 1 |
| Euro OTC | Methylcellulose | 15179602 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Methylcellulose | 16284003 | 1 |
| Euro OTC | Hypromellose | 18132105 | 1 |
| Euro OTC | Methylcellulose | 18331806 | 1 |
| Euro OTC | Hypromellose | 21001141002 | 1 |
| Fagron | Hypromellose | | 1 |
| Fagron | Hypromellose | 10G09-N03 | 1 |
| Fagron | Hypromellose | 12A30-N02 | 3 |
| Fagron | Hypromellose | 12D03-N03 | 1 |
| Fagron | Hypromellose | 12E02-N03 | 3 |
| Fagron | Hypromellose | 12G23-N03 | 1 |
| Fagron | Hypromellose | 12G23-NO3 | 1 |
| Fagron | Methylcellulose | 12H06-N06 | 2 |
| Fagron | Hypromellose | 12H20-N05 | 1 |
| Fagron | Methylcellulose | 13/26-N04 | 1 |
| Fagron | Methylcellulose | 131301(09) | 1 |
| Fagron | Hypromellose | 13D03N03 | 1 |
| Fagron | Hypromellose | 13D03-N03 | 7 |
| Fagron | Methylcellulose | 13E02-B03-290531 | 3 |
| Fagron | Hypromellose | 13E02-B03-290532 | 1 |
| Fagron | Hypromellose | 13h09-m04 | 1 |
| Fagron | Hypromellose | 13H09-N04 | 9 |
| Fagron | Hypromellose | 14338801 | 2 |
| Fagron | Methylcellulose | 14A28-B04-295982 | 1 |
| Fagron | Hypromellose | 14C05B03 | 1 |
| Fagron | Hypromellose | 14C05-B03 | 1 |
| Fagron | Hypromellose | 14C-05B03 | 1 |
| Fagron | Hypromellose | 14c05-B03-294708 | 1 |
| Fagron | Hypromellose | 14C05-B03-294708 | 4 |
| Fagron | Hypromellose | 14C05-B03-294711 | 1 |
| Fagron | Hypromellose | 14G02-B11 | 3 |
| Fagron | Hypromellose | 14G02-B11-296850 | 6 |
| Fagron | Hypromellose | 14G02-B11-296851 | 1 |
| Fagron | Hypromellose | 14g02-b11-302118 | 2 |
| Fagron | Hypromellose | 14G02-B11-302118 | 7 |
| Fagron | Hypromellose | 14G02-B11-302119 | 1 |
| Fagron | Hypromellose | 14G02-B11-302121 | 1 |
| Fagron | Hypromellose | 15B02-B05 | 1 |
| Fagron | Hypromellose | 15B02-B05-308852 | 1 |
| Fagron | Hypromellose | 15G08-B14 | 1 |
| Fagron | Hypromellose | 15g08-b14-310845 | 2 |
| Fagron | Hypromellose | 15G08-B14-310845 | 10 |
| Fagron | Hypromellose | 15G08B14314185 | 2 |
| Fagron | Hypromellose | 15g08-b14-314845 | 1 |
| Fagron | Methylcellulose | 15G08B14314845 | 1 |
| Fagron | Hypromellose | 15G08-B14-314845 | 7 |
| Fagron | Hypromellose | 16B16_B07 | 1 |
| Fagron | Hypromellose | 16B16-B07_321327 | 1 |
| Fagron | Hypromellose | 16B16-B07-318276 | 2 |
| Fagron | Hypromellose | 16b16-b07-318531 | 1 |
| Fagron | Hypromellose | 16B16-B07-318531 | 8 |
| Fagron | Hypromellose | 16B16-B07-321327 | 5 |
| Fagron | Hypromellose | 16B-16-B07-321327 | 1 |
| Fagron | Hypromellose | 16B16-B07-321328 | 1 |
| Fagron | Hypromellose | 16B16-B07-321579 | 1 |
| Fagron | Hypromellose | 16B16-B07-323114 | 3 |
| Fagron | Hypromellose | 16B16-B07-325280 | 7 |
| Fagron | Hypromellose | 16H23B-02 | 1 |
| Fagron | Hypromellose | 16H23-B02-325994 | 1 |
| Fagron | Hypromellose | 16H23-B02-332066 | 8 |
| Fagron | Hypromellose | 17115005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hypromellose | 18A17-B04 | 2 |
| Fagron | Hypromellose | 18A17-B04-345100 | 5 |
| Fagron | Hypromellose | 18A17-B04-346208 | 1 |
| Fagron | Hypromellose | 18D04-B03 | 4 |
| Fagron | Hypromellose | 18D04-B03-348465 | 6 |
| Fagron | Hypromellose | 18D04-B03-350745 | 3 |
| Fagron | Hypromellose | 18D04-B03-35144 | 1 |
| Fagron | Hypromellose | 18D04-B03-352349 | 1 |
| Fagron | Hypromellose | 18D04-B03-352746 | 4 |
| Fagron | Hypromellose | 18D04-B03-355144 | 3 |
| Fagron | Hypromellose | 18G17-B04-194255 | 1 |
| Fagron | Hypromellose | 19G17-B04 | 5 |
| Fagron | Hypromellose | 19G17-B04-194255 | 5 |
| Fagron | Hypromellose | 19G17-B04-194735 | 3 |
| Fagron | Hypromellose | 1A01012N11 | 1 |
| Fagron | Hypromellose | 1J31012N11 | 3 |
| Fagron | Hypromellose | 1K01012N11 | 1 |
| Fagron | Hypromellose | 20110612-2 | 1 |
| Fagron | Hypromellose | 20D22-B02 | 1 |
| Fagron | Hypromellose | 20D22-B02-197710 | 8 |
| Fagron | Hypromellose | 20D22-B02-1977101 | 1 |
| Fagron | Hypromellose | 20D22-B02-197711 | 4 |
| Fagron | Hypromellose | 20D2-B02-197710 | 1 |
| Fagron | Hypromellose | 20G14-B01 | 3 |
| Fagron | Hypromellose | 20G14-B01-201924 | 1 |
| Fagron | Hypromellose | 21B26-B07-218984 | 1 |
| Fagron | Hypromellose | 220401M | 1 |
| Fagron | Hypromellose | 22B26-B10-223113 | 1 |
| Fagron | Hypromellose | 2818A-01860 | 1 |
| Fagron | Hypromellose | 2H12012N12 | 1 |
| Fagron | Hypromellose | 20d22-B02-197711 | 1 |
| Fagron | Hypromellose | 20D22-BO2-197710 | 1 |
| Fagron | Hypromellose | 2x19G17-B04-194735 | 1 |
| Fagron | Hypromellose | 325994 | 1 |
| Fagron | Hypromellose | 349970 | 1 |
| Fagron | Hypromellose | 3G08012N11 | 1 |
| Fagron | Hypromellose | 615I-01860 | 1 |
| Fagron | Hypromellose | 700182-0001 | 2 |
| Fagron | Hypromellose | 9088155 | 3 |
| Fagron | Hypromellose | B01-2019204 | 2 |
| Fagron | Hypromellose | B02-1977100 | 2 |
| Fagron | Hypromellose | B04-1942505 | 1 |
| Fagron | Hypromellose | B97-2101203 | 1 |
| Fagron | Hypromellose | D180F8Q011 | 1 |
| Fagron | Hypromellose | D180HBA012 | 1 |
| Fagron | Hypromellose | D180J45013 | 1 |
| Fagron | Hypromellose | YI16012N11 | 1 |
| Fagron | Hypromellose | ZH19012N12 | 1 |
| Fargon/Gehe | Hypromellose | 18D04-B03-352746 | 1 |
| Fiebig | Methylcellulose | 18045101 | 1 |
| Fragon/Phoenix | Hypromellose | 18D04-b03-349970 | 1 |
| FRAGON/Poenix | Hypromellose | 16B16-B07-18276 | 1 |
| Gatt-Koller / Phoenix | Hypromellose | 14C05-B03-291647 | 2 |
| Gatt-Koller | Methylcellulose | 18045107 | 1 |
| Gehe / 26.10.12 Fragon | Hypromellose | 9D30-N05 | 1 |
| Gehe amax | Hypromellose | 19G17-B04-194735 | 1 |
| Gehe | Hypromellose | 14G02-B11 | 1 |
| Gehe | Hypromellose | 15G08-B14-310845 | 1 |
| Gehe | Methylcellulose | 16284003 | 1 |
| GEHE | Hypromellose | 16H23-B02 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| GEHE | Hypromellose | 17115008 | 1 |
| GEHE | Hypromellose | 18049201 | 1 |
| GEHE | Hypromellose | 18A17-B04 | 3 |
| Gehe | Hypromellose | 19069601 | 1 |
| gehe | Hypromellose | 192852004 | 1 |
| Jenne | Hypromellose | 15G08-B14 | 1 |
| Jenne | Hypromellose | 18D04-B03-350745 | 2 |
| Jenne | Hypromellose | 20G14-B01-201924 | 2 |
| Jenne | Methylcellulose | 21B26-B07-213871 | 1 |
| Kehr | Hypromellose | 17115005 | 1 |
| Klenk | Hypromellose | 19069601 | 2 |
| L12 | Hypromellose | 16224406 | 1 |
| L12 | Methylcellulose | 16284003 | 1 |
| L12 | Hypromellose | 17115008 | 1 |
| L12 | Methylcellulose | 17170405 | 1 |
| Nachprüfung 2609 | Hypromellose | 11H26-N01 | 1 |
| Nachprüfung | Hypromellose | 3082019-3 | 1 |
| Noweda | Hypromellose | 1315505 | 1 |
| Noweda | Hypromellose | 17115008 | 1 |
| Noweda | Methylcellulose | 17170405 | 1 |
| Noweda | Hydroxypropylcellulose | 18114605 | 1 |
| Noweda | Hypromellose | 18132111 | 1 |
| Noweda | Methylcellulose | 18331806 | 1 |
| Noweda | Hypromellose | 18D04-B03-355144 | 1 |
| Noweda | Hypromellose | 19069603 | 1 |
| Noweda | Hypromellose | 2003524007 | 1 |
| Noweda | Hypromellose | 22001980005 | 1 |
| Noweda | Hypromellose | 22003524004 | 2 |
| noweda | Hypromellose | 23000497003 | 1 |
| Noweda | Hypromellose | 23000497003 | 1 |
| Noweda | Hypromellose | 23D27-B06-227933 | 1 |
| Noweda | Hypromellose | 24C29-B03-236857 | 1 |
| Noweda | Hypromellose | D180HBA012 | 1 |
| Phoenix/Cealo | Methylcellulose | 17170404 | 1 |
| Phoenix | Hypromellose | 13E02-B03 | 1 |
| Phoenix | Hypromellose | 14c05-b03-294708 | 1 |
| Phoenix | Hypromellose | 16224407 | 1 |
| Phoenix | Hypromellose | 16B16-B07-321327 | 1 |
| Phoenix | Methylcellulose | 18331803 | 1 |
| Phoenix | Methylcellulose | 23001536003 | 1 |
| Phönix Gotha | Hypromellose | 14G02-B11-296850 | 1 |
| Phonix | Hypromellose | 13H09-N04 | 1 |
| Phönix | Hypromellose | 16224403 | 1 |
| PHÖNIX | Hypromellose | 16B16-B07 | 2 |
| PHÖNIX | Hypromellose | 16H23-B02-325994 | 1 |
| Phönix | Hypromellose | 2000987004 | 1 |
| Phönix | Hypromellose | 23000497003 | 1 |
| Sanacorp 08.11.21, 22,95EUR | Hypromellose | 211125H | 1 |
| Sanacorp | Methylcellulose | 1717405 | 1 |
| Sanacorp | Methylcellulose | 18331803 | 1 |
| Sanacorp | Hypromellose | 19069608 | 1 |
| Sanacorp | Methylcellulose | 22000891011 | 1 |
| Sanacorp | Hypromellose | 22001980005 | 4 |
| Sanacorp | Hypromellose | 23000497003 | 3 |
| Sanacorp | Methylcellulose | 23001536003 | 2 |
| Sanacorp | Hypromellose | 23D27-B06-227933 | 1 |
| Sanacorp | Hypromellose | 2H12012N12 | 1 |

- 255 563 spectra from 1666 *Apo-Ident* customers from a total of 51 880 batches from a further

722 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Methylcellulose* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Methylcellulose* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 1175 | 0 | 157 151 |
| **Type B** | 0 | 770 | 0 | 212 170 |
| **Type C** | 0 | 1309 | 14 | 255 563 |

The substance/substance group *Methylcellulose* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.4894 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2208 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.9418 % (> 98.7150 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20686 | 20686 | 0.00 | 178.46 |
| 20705 | 20705 | 0.00 | 155.69 |
| 20919 | 20919 | 0.00 | 163.41 |
| 20931 | 20919 | 7.50 | 166.99 |
| 21570 | 22457 | 15.40 | 156.85 |
| 21702 | 20919 | 30.06 | 159.46 |
| 21767 | 21767 | 0.00 | 171.51 |
| 22258 | 21767 | 16.27 | 176.83 |
| 22457 | 22457 | 0.00 | 155.78 |
| 22609 | 26488 | 17.01 | 173.57 |
| 23224 | 22457 | 11.20 | 156.50 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24249 | 24249 | 0.00 | 159.72 |
| 25060 | 26636 | 32.69 | 156.89 |
| 25188 | 22457 | 18.91 | 151.99 |
| 25230 | 25230 | 0.00 | 168.08 |
| 25231 | 25231 | 0.00 | 169.12 |
| 25286 | 25286 | 0.00 | 151.30 |
| 25426 | 21767 | 8.35 | 174.30 |
| 25622 | 25622 | 0.00 | 160.60 |
| 25981 | 21767 | 17.86 | 170.71 |
| 26148 | 26148 | 0.00 | 171.60 |
| 26488 | 26488 | 0.00 | 172.33 |
| 26636 | 26636 | 0.00 | 152.46 |
| 26721 | 26721 | 0.00 | 190.95 |
| 27139 | 27139 | 0.00 | 179.72 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Methylprednisolone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20953-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Methylprednisolone; Methylprednisolonum

### Special notes

When selecting the *Methylprednisolone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Methylprednisolone | 4 | 4 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Methylprednisolone* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Methylprednisolone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 79.60 | – |
| ⋮ | ⋮ | ⋮ |
| Prednisolone | >50 | 73.64 |
| Tyrothricin | >50 | 83.92 |
| Betamethasone | >50 | 87.57 |
| Triamcinolone acetonide | >50 | 94.52 |
| Fluocinolone acetonide | >50 | 97.53 |
| Gramicidin | >50 | 137.80 |
| Dexamethasone | >50 | 174.94 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Methylprednisolone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Methylprednisolone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Methylprednisolone | 13G19-N05 | 20953 | 40 | 1402438 |
| Fagron | Methylprednisolone | 15I04-B05-311572 | 22275 | 45 | AR-16-FG-009102-01 |
| Fagron | Methylprednisolone | 15I04-B05-311572 | 22275SI | 45 | AR-16-FG-009102-01 |
| Fagron | Methylprednisolone | 15I04-B05-311572 | 22354 | 45 | 20151026 |
| Fagron | Methylprednisolone | 15I04-B05-311572 | 22354SI | 45 | 20151026 |
| Fagron | Methylprednisolone | 18E16-B02-B02-358166 | 24572 | 40 | 20180611 |
| Fagron | Methylprednisolone | 21C30-F03-377878 | 25725 | 50 | 20210505 |
| Fagron | Methylprednisolone | 21C30-F03-377878 | 25725SI | 50 | 20210505 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 360 spectra of 8 reference samples from the substance/substance group *Methylprednisolone*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

- 157 966 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 310 spectra of 8 reference samples from the substance/substance group *Methylprednisolone*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Methylprednisolone | 12D17-N04 | 20650 | 40 |
| Fagron | Methylprednisolone | 15L15-B01-321887 | 23229 | 40 |
| Fagron | Methylprednisolone | 18A03-B05-345742 | 23997 | 40 |
| Fagron | Methylprednisolone | 22D14-B07-227694 | 26619 | 40 |
| Fagron | Methylprednisolone | 15L15-B01-321887 | 23229SI | 30 |
| Fagron | Methylprednisolone | 18A03-B05-345742 | 23997SI | 40 |
| Fagron | Methylprednisolone | 18E16-B02-B02-358166 | 24572SI† | 40 |
| Fagron | Methylprednisolone | 22D14-B07-227694 | 26619SI | 40 |

- 212 630 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 3 spectra from 3 *Apo-Ident* customers from 3 batches from the substance/substance group *Methylprednisolone*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Methylprednisolone | 22D14-B07-221096 | 1 |
| Fagron | Methylprednisolone | 12D17-N04 | 1 |
| Fagron | Methylprednisolone | 18A03-B05 | 1 |

- 256 883 spectra from 1666 *Apo-Ident* customers from a total of 52 150 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Methylprednisolone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Methylprednisolone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 310 | 0 | 212 630 |
| **Type C** | 0 | 3 | 0 | 256 883 |

The substance/substance group *Methylprednisolone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0645 %) |
| **Type C** | 100.0000 % (> 99.9030 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20953 | 20953 | 0.00 | 142.87 |
| 22275 | 22275 | 0.00 | 147.81 |
| 22354 | 22275 | 6.16 | 149.58 |
| 24572 | 22275 | 13.13 | 145.36 |
| 25725 | 22275 | 24.91 | 141.63 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Metoclopramide hydrochloride monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21662-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Metoclopramide hydrochloride monohydrate; Metoclopramidi hydrochloridum monohydricum

### Special notes

When selecting the *Metoclopramide hydrochloride monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Metoclopramide hydrochloride monohydrate | 6 | 3 | 5 |

### Second-stage model

For differentiation of the substance/substance group *Metoclopramide hydrochloride monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Metoclopramide hydrochloride monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 107.25 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Metoclopramide hydrochloride monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Metoclopramide hydrochloride monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Metoclopramide hydrochlor… | 14193102 | 21662 | 60 | AR-15-FG-002889-01 |
| Caelo | Metoclopramide hydrochlor… | 14193102 | 21746 | 60 | 20140725 |
| Caelo | Metoclopramide hydrochlor… | 15421101 | 23234 | 40 | 20160226 |
| Fagron | Metoclopramide hydrochlor… | 20G14-F05-374155 | 25584 | 40 | 20200826 |
| Fagron | Metoclopramide hydrochlor… | 22A14-B04-227242 | 26544 | 40 | 20220318 |
| Fagron | Metoclopramide hydrochlor… | 23J28-B01-231563 | 27040 | 40 | 20231119 |
| Gatt-Koller | Metoclopramide hydrochlor… | 20170236 | 24410 | 40 | 20170724 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 7 reference samples from the substance/substance group *Metoclopramide hydrochloride monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 190 spectra of 6 reference samples from the substance/substance group *Metoclopramide hydrochloride monohydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Metoclopramide hydrochlor… | 15421102 | 23718 | 40 |
| Fagron | Metoclopramide hydrochlor… | 21F07-B08-213763 | 25863 | 50 |
| Gatt-Koller | Metoclopramide hydrochlor… | 22J02736 | 26625 | 40 |
| Fagron | Metoclopramide hydrochlor… | 22A14-B04-227242 | 26544SI† | 20 |
| Fagron | Metoclopramide hydrochlor… | 23J28-B01-231563 | 27040SI† | 20 |
| Gatt-Koller | Metoclopramide hydrochlor… | 22J02736 | 26625SI | 20 |

- 212 750 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 23 spectra from 22 *Apo-Ident* customers from 5 batches from the substance/substance group *Metoclopramide hydrochloride monohydrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metoclopramide hydrochlor… | 14193101 | 1 |
| Caelo | Metoclopramide hydrochlor… | 15227001 | 18 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metoclopramide hydrochlor… | 2818Q-01869 | 1 |
| Caelo | Metoclopramide hydrochlor… | 3414U-018969 | 1 |
| Caesar&loretz,Phoenix | Metoclopramide hydrochlor… | 14193101 | 1 |
| Fragon/ Sanacorp | Metoclopramide hydrochlor… | 1/17M | 1 |

- 256 863 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Metoclopramide hydrochloride monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Metoclopramide hydrochloride monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 190 | 0 | 212 750 |
| **Type C** | 0 | 23 | 0 | 256 863 |

The substance/substance group *Metoclopramide hydrochloride monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.8421 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 73.9130 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21662 | 21662 | 0.00 | 210.67 |
| 21746 | 21662 | 5.25 | 210.79 |
| 23234 | 21662 | 7.75 | 212.88 |
| 24410 | 21662 | 6.72 | 212.40 |
| 25584 | 21662 | 16.12 | 214.62 |
| 26544 | 21662 | 15.14 | 216.18 |
| 27040 | 21662 | 16.41 | 215.08 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Metoprolol tartrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21753-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Metoprolol tartrate; Metoprololi tartras

### Special notes

When selecting the *Metoprolol tartrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Metoprolol tartrate | 7 | 3 | 82 |

### Second-stage model

For differentiation of the substance/substance group *Metoprolol tartrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Metoprolol tartrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 111.41 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Metoprolol tartrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Metoprolol tartrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Metoprolol tartrate | APMTP02218MT | 24596 | 40 | 20190220 |
| Euro OTC | Metoprolol tartrate | 2001021 | 25098 | 40 | 20200116* |
| Euro OTC | Metoprolol tartrate | 2211008 | 26429 | 40 | 20221215* |
| Euro OTC | Metoprolol tartrate | 2211008 | 26429SI | 20 | 20221215* |
| Fagron | Metoprolol tartrate | 16E31-B03-327107 | 22927 | 40 | 20160627 |
| Fagron | Metoprolol tartrate | 16E31-B03-327107 | 22943 | 40 | 20160627 |
| Fagron | Metoprolol tartrate | 16E31-B03-327107 | 22944 | 40 | 20160627 |
| Fagron | Metoprolol tartrate | 19K20-F03-366934 | 25061 | 40 | 20191218 |
| Inresa | Metoprolol tartrate | 30990 5RII | 21753 | 60 | AR-15-FG-006635-01 |
| Inresa | Metoprolol tartrate | 40500 5RII | 21805 | 60 | 20140430 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 10 reference samples from the substance/substance group *Metoprolol tartrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 906 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 3 reference samples from the substance/substance group *Metoprolol tartrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Metoprolol tartrate | 18K26-B01-359370 | 24825 | 40 |
| Fagron | Metoprolol tartrate | 21E10-F03-378925 | 25752 | 40 |
| Inresa | Metoprolol tartrate | 405005RIIC | 22908 | 40 |

- 212 820 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 360 spectra from 226 *Apo-Ident* customers from 88 batches from the substance/substance group *Metoprolol tartrate*.

- Among them are spectra of independent samples from 82 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Metoprolol tartrate | | 1 |
| | Metoprolol tartrate | 2001021-02 | 7 |
| | Metoprolol tartrate | 210530SRII | 1 |
| | Metoprolol tartrate | 21E10-F03-378925 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Metoprolol tartrate | 2211008-01 | 34 |
| | Metoprolol tartrate | 22F02-B19-220195 | 11 |
| | Metoprolol tartrate | 22F02-B19-220257 | 1 |
| | Metoprolol tartrate | 240131(2211008-01) | 1 |
| AHD | Metoprolol tartrate | 22F02-B19-220195 | 4 |
| Andor | Metoprolol tartrate | APMTP0117MT | 1 |
| Antares | Metoprolol tartrate | 1014Q-07308 | 1 |
| apomix | Metoprolol tartrate | 18K26-B01-355911 | 1 |
| Audor Pharma | Metoprolol tartrate | APMTP00117MT | 17 |
| Audor Pharma | Metoprolol tartrate | APMTP02218 | 1 |
| Audor Pharma | Metoprolol tartrate | APMtP02218Mt | 1 |
| Audor Pharma | Metoprolol tartrate | APMTP02218MT | 16 |
| Audor Pharma | Metoprolol tartrate | APMTPOC117MT | 1 |
| Audor Pharma | Metoprolol tartrate | MTP00117MT | 1 |
| Audor Pharma | Metoprolol tartrate | MTP02218 | 1 |
| Caelo | Metoprolol tartrate | 1729314P-200715-1 | 1 |
| Caelo | Metoprolol tartrate | 17G03-B09-351672 | 1 |
| Caelo | Metoprolol tartrate | 1919I-03763 | 1 |
| Caelo | Metoprolol tartrate | APMT00117MT | 1 |
| Euro OTC | Metoprolol tartrate | 2001021 | 1 |
| Euro OTC | Metoprolol tartrate | 200102101 | 1 |
| Euro OTC | Metoprolol tartrate | 2001021-01 | 67 |
| Euro OTC | Metoprolol tartrate | 2001021-02 | 8 |
| Euro OTC | Metoprolol tartrate | 201021-01 | 1 |
| Euro OTC | Metoprolol tartrate | 2211008-01 | 1 |
| Euro OTC | Metoprolol tartrate | AP20112701 | 1 |
| Euro OTC | Metoprolol tartrate | Meto08122022 | 1 |
| Euro OTC | Metoprolol tartrate | MTP02218 | 3 |
| Fagro | Metoprolol tartrate | 16MD000095 | 1 |
| Fagron | Metoprolol tartrate | 16E31-B03-325535 | 1 |
| Fagron | Metoprolol tartrate | 16E31-B03-327107 | 23 |
| Fagron | Metoprolol tartrate | 17003O5RII | 1 |
| Fagron | Metoprolol tartrate | 17G03-B03-353935 | 1 |
| Fagron | Metoprolol tartrate | 17G03-B09 | 1 |
| Fagron | Metoprolol tartrate | 17G03-B09-340197 | 3 |
| Fagron | Metoprolol tartrate | 17G03-B09-342813 | 2 |
| Fagron | Metoprolol tartrate | 17G03-B09-345302 | 1 |
| Fagron | Metoprolol tartrate | 17G03-B09-347089 | 1 |
| Fagron | Metoprolol tartrate | 17G03-B09-347304 | 1 |
| Fagron | Metoprolol tartrate | 17g03-B09-350669 | 1 |
| Fagron | Metoprolol tartrate | 17G03-B09-350669 | 4 |
| Fagron | Metoprolol tartrate | 17G03-B09-351672 | 1 |
| Fagron | Metoprolol tartrate | 17G03-B09-353935 | 2 |
| Fagron | Metoprolol tartrate | 18027O5RII | 2 |
| Fagron | Metoprolol tartrate | 18K26-B01 | 2 |
| Fagron | Metoprolol tartrate | 18K26-B01-355910 | 1 |
| Fagron | Metoprolol tartrate | 18K26-B01-355911 | 2 |
| Fagron | Metoprolol tartrate | 18K26-B01-359370 | 7 |
| Fagron | Metoprolol tartrate | 18K26-B01-359371 | 7 |
| Fagron | Metoprolol tartrate | 18K26-B01-362451 | 3 |
| Fagron | Metoprolol tartrate | 18KS26-B01 | 1 |
| Fagron | Metoprolol tartrate | 1902205RII | 1 |
| Fagron | Metoprolol tartrate | 19022O5RII | 1 |
| Fagron | Metoprolol tartrate | 1902O5RII | 1 |
| Fagron | Metoprolol tartrate | 19K20-F03 | 1 |
| Fagron | Metoprolol tartrate | 19K20-F03-366934 | 7 |
| Fagron | Metoprolol tartrate | 19K20-F03-366935 | 1 |
| Fagron | Metoprolol tartrate | 19K20-F03-366936 | 2 |
| Fagron | Metoprolol tartrate | 20H06-F04 | 2 |
| Fagron | Metoprolol tartrate | 20H06F04373426 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Metoprolol tartrate | 20H06-F04-373426 | 4 |
| Fagron | Metoprolol tartrate | 2100605RII | 1 |
| Fagron | Metoprolol tartrate | 21E-10-F03 | 1 |
| Fagron | Metoprolol tartrate | 21E10-F03_378925 | 1 |
| Fagron | Metoprolol tartrate | 21E10F03378925 | 1 |
| Fagron | Metoprolol tartrate | 21E10-F03-378925 | 12 |
| Fagron | Metoprolol tartrate | 21E10-F03-378925/2100605RII | 1 |
| Fagron | Metoprolol tartrate | 21E10-F03378926 | 1 |
| Fagron | Metoprolol tartrate | 21E10-F03-378926 | 3 |
| Fagron | Metoprolol tartrate | 21E10-F03-78926 | 1 |
| Fagron | Metoprolol tartrate | 21E10-F03-378925 | 1 |
| Fagron | Metoprolol tartrate | 22F02-B19-220195 | 7 |
| Fagron | Metoprolol tartrate | 22F02-B19-220257 | 1 |
| Fagron | Metoprolol tartrate | B01-3593700 | 1 |
| Fagron | Metoprolol tartrate | B01-3624501 | 1 |
| Fagron | Metoprolol tartrate | F03-3669304 | 2 |
| Fagron | Metoprolol tartrate | F03-3789205 | 4 |
| Fagron | Metoprolol tartrate | F04-3734206 | 1 |
| Fagron | Metoprolol tartrate | F03-3789205 | 1 |
| Gehe | Metoprolol tartrate | 21E-10-F03 | 1 |
| Gehe | Metoprolol tartrate | 2211008-01 | 4 |
| Gehe | Metoprolol tartrate | 22F02-B19-220195 | 1 |
| HELIOS Klinikum Erfu… | Metoprolol tartrate | 405005RIIC | 1 |
| Inresa | Metoprolol tartrate | 4050005RIIB | 1 |
| Inresa | Metoprolol tartrate | 405005RIIB | 1 |
| Inresa | Metoprolol tartrate | 504005RIIC/29082016 | 1 |
| Jenne | Metoprolol tartrate | 2211008-01 | 1 |
| Jenne | Metoprolol tartrate | 250709(2211008-01) | 1 |
| Klosterring | Metoprolol tartrate | 17G03-B09-345301 | 1 |
| Noweda 21.06.22 EK 34,95 | Metoprolol tartrate | 2001021-01 | 1 |
| Noweda | Metoprolol tartrate | 18K26-B01-3593705 | 1 |
| Noweda | Metoprolol tartrate | 18K26-B01-362451 | 1 |
| Noweda | Metoprolol tartrate | 21E10-F03 | 1 |
| Noweda | Metoprolol tartrate | 2211008-01 | 3 |
| Noweda | Metoprolol tartrate | 22F02-B19-220195 | 1 |
| Noweda | Metoprolol tartrate | F03-3789206 | 1 |
| Phönix | Metoprolol tartrate | 21E10-F03 | 1 |
| Sanacorp | Metoprolol tartrate | 2001021-01 | 1 |
| Sanacorp | Metoprolol tartrate | 2211008-01 | 3 |
| Sidonia | Metoprolol tartrate | 405005RIIC/09062017 | 1 |
| Sigma Adrich/Alliance H. | Metoprolol tartrate | PHR1076 | 1 |
| Th. Geyer | Metoprolol tartrate | 56392-17-7 | 1 |
| Th. Geyer | Metoprolol tartrate | LRAA6905 | 4 |

- 256 526 spectra from 1666 *Apo-Ident* customers from a total of 52 066 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Metoprolol tartrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Metoprolol tartrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 355 | 5 | 256 526 |

The substance/substance group *Metoprolol tartrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.6111 % (> 97.7778 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21753 | 21753 | 0.00 | 145.90 |
| 21805 | 21753 | 5.23 | 146.49 |
| 22927 | 21753 | 9.35 | 141.70 |
| 22943 | 21753 | 4.66 | 144.49 |
| 22944 | 25098 | 7.13 | 140.25 |
| 24596 | 25098 | 8.22 | 141.30 |
| 25061 | 21753 | 9.33 | 147.41 |
| 25098 | 25098 | 0.00 | 140.24 |
| 26429 | 26429 | 0.00 | 141.92 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Metronidazole** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20001-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Metronidazole; Metronidazolum

### Special notes

When selecting the *Metronidazole* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Metronidazole | 9 | 26 | 776 |

### Second-stage model

For differentiation of the substance/substance group *Metronidazole* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Metronidazole* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 94.33 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Metronidazole* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Metronidazole*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Metronidazole | 12110410 | 20857 | 40 | 20120515 |
| Caelo | Metronidazole | 13095007 | 21356 | 40 | 20130426 |
| Caelo | Metronidazole | 13095007 | 21360 | 40 | 20130426 |
| Caelo | Metronidazole | 160892 | 22472 | 60 | 20160413* |
| Caelo | Metronidazole | 20002297 | 25565 | 40 | 20200902* |
| Euro OTC | Metronidazole | 1212030-02 | 21213 | 40 | 20130627 |
| Euro OTC | Metronidazole | 1508004 | 21881 | 60 | 20150819* |
| Euro OTC | Metronidazole | 2005029 | 25330 | 40 | 20200820* |
| Fagron | Metronidazole | 13D10-N02 | 21212 | 40 | 20130516 |
| Fagron | Metronidazole | 16I19-B04-326155 | 22835 | 40 | 20161013 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 440 spectra of 10 reference samples from the substance/substance group *Metronidazole*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 886 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1130 spectra of 31 reference samples from the substance/substance group *Metronidazole*.

- Among them are spectra of independent samples from 26 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Metronidazole | 13095005 | 21214 | 40 |
| Caelo | Metronidazole | 172905 | 23808 | 40 |
| Caelo | Metronidazole | 190102 | 24558 | 40 |
| Caelo | Metronidazole | 21002293 | 25851 | 50 |
| Caelo | Metronidazole | 22002266 | 26490 | 40 |
| Caelo | Metronidazole | 23003075 | 27109 | 40 |
| Euro OTC | Metronidazole | 1609028 | 22751 | 40 |
| Euro OTC | Metronidazole | 1612013 | 22917 | 40 |
| Euro OTC | Metronidazole | 1701039 | 23132 | 40 |
| Euro OTC | Metronidazole | 1707008 | 23542 | 30 |
| Euro OTC | Metronidazole | 1706022 | 23550 | 30 |
| Euro OTC | Metronidazole | 1802007 | 23946 | 40 |
| Euro OTC | Metronidazole | 1807039 | 24203 | 40 |
| Euro OTC | Metronidazole | 1901042 | 24449 | 40 |
| Euro OTC | Metronidazole | 1906012 | 24766 | 40 |
| Euro OTC | Metronidazole | 1908028 | 24864 | 40 |
| Euro OTC | Metronidazole | 2007002 | 25328 | 40 |
| Euro OTC | Metronidazole | 2103002 | 25677 | 50 |
| Euro OTC | Metronidazole | 2207001 | 26199 | 40 |
| Euro OTC | Metronidazole | 2206031 | 26204 | 40 |
| Euro OTC | Metronidazole | 2308004 | 26888 | 40 |
| Euro OTC | Metronidazole | 2308003 | 26889 | 40 |
| Euro OTC | Metronidazole | 2402031 | 27145 | 40 |
| Euro OTC | Metronidazole | 2404007 | 27297 | 40 |
| Fagron | Metronidazole | 17C10-B04-355868 | 24586 | 40 |
| Fagron | Metronidazole | 21G29-B02-213325 | 26179 | 40 |
| Caelo | Metronidazole | 21002293 | 25851SI | 10 |
| Caelo | Metronidazole | 22002266 | 26490SI | 20 |
| Euro OTC | Metronidazole | 2207001 | 26199SI | 20 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Metronidazole | 2206031 | 26204SI | 20 |
| Fagron | Metronidazole | 21G29-B02-213325 | 26179SI | 20 |

- 211 810 spectra from a total of 4261 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 5990 spectra from 1411 *Apo-Ident* customers from 816 batches from the substance/substance group *Metronidazole*.
- Among them are spectra of independent samples from 771 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Metronidazole | | 1 |
| | Metronidazole | 15253007 | 2 |
| | Metronidazole | 181023/18 | 1 |
| | Metronidazole | 181023/9 | 1 |
| | Metronidazole | 20004568009 | 1 |
| | Metronidazole | 2005029-01 | 1 |
| | Metronidazole | 200700-02 | 1 |
| | Metronidazole | 2007002-02 | 10 |
| | Metronidazole | 20G07-F03-372291 | 2 |
| | Metronidazole | 21002293004 | 1 |
| | Metronidazole | 21002293005 | 1 |
| | Metronidazole | 21002293009 | 1 |
| | Metronidazole | 21002293011 | 2 |
| | Metronidazole | 21002293014 | 2 |
| | Metronidazole | 21002293016 | 8 |
| | Metronidazole | 21002293017 | 1 |
| | Metronidazole | 21002293019 | 1 |
| | Metronidazole | 21002293020 | 35 |
| | Metronidazole | 2100229302080/23P | 1 |
| | Metronidazole | 2103002-01 | 1 |
| | Metronidazole | 2103002-03 | 1 |
| | Metronidazole | 2103002-1 | 1 |
| | Metronidazole | 21G29-B02-213325 | 1 |
| | Metronidazole | 21G29-B02-221568 | 1 |
| | Metronidazole | 21G29-B02-221739 | 3 |
| | Metronidazole | 21G29-B02-223679 | 1 |
| | Metronidazole | 22002266002 | 5 |
| | Metronidazole | 22002266003 | 4 |
| | Metronidazole | 22002266004 | 8 |
| | Metronidazole | 22002266005 | 1 |
| | Metronidazole | 22002266006 | 12 |
| | Metronidazole | 22002266007 | 10 |
| | Metronidazole | 22002266008 | 58 |
| | Metronidazole | 22002266009 | 8 |
| | Metronidazole | 22002266010 | 49 |
| | Metronidazole | 220022660120 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Metronidazole | 2200226608 | 1 |
| | Metronidazole | 2202266003 | 1 |
| | Metronidazole | 2202266008 | 1 |
| | Metronidazole | 2202266010 | 2 |
| | Metronidazole | 2206031-01 | 5 |
| | Metronidazole | 2206031-02 | 1 |
| | Metronidazole | 2207001-01 | 7 |
| | Metronidazole | 2207001-02 | 1 |
| | Metronidazole | 230800-01 | 1 |
| | Metronidazole | 2308003-01 | 24 |
| | Metronidazole | 2308004-01 | 11 |
| | Metronidazole | 2308004-02 | 5 |
| | Metronidazole | 230804-01 | 1 |
| | Metronidazole | 231004(22002266002) | 1 |
| | Metronidazole | 24000389002 | 15 |
| | Metronidazole | 24000389003 | 45 |
| | Metronidazole | 24000389004 | 8 |
| | Metronidazole | 24000389006 | 17 |
| | Metronidazole | 24000389007 | 13 |
| | Metronidazole | 24000389011 | 2 |
| | Metronidazole | 24000389012 | 4 |
| | Metronidazole | 24000389602 | 1 |
| | Metronidazole | 2402031-01 | 10 |
| | Metronidazole | 2404007-01 | 1 |
| | Metronidazole | 2408004-01 | 1 |
| | Metronidazole | F220002 | 1 |
| 17270001 | Metronidazole | 17058026 | 1 |
| A.H. 19.02.13 ek: 5,86EUR | Metronidazole | 12G04-N15 | 1 |
| ACM | Metronidazole | | 1 |
| AEP | Metronidazole | 22002266003 | 1 |
| AEP | Metronidazole | 22002266008 | 1 |
| Aep | Metronidazole | 2202266008 | 1 |
| AHD 03.02.17 | Metronidazole | 16089212 | 1 |
| AHD 13.10.17 E.k:6,56 | Metronidazole | 17058003 | 1 |
| AHD | Metronidazole | 13214025 | 1 |
| AHD | Metronidazole | 15253005 | 1 |
| AHD | Metronidazole | 15253033 | 1 |
| AHD | Metronidazole | 16I19-B04-329160 | 2 |
| AHD | Metronidazole | 17290518 | 1 |
| AHD | Metronidazole | 19000516007 | 1 |
| AHD | Metronidazole | 21002293005 | 1 |
| AHD | Metronidazole | 21002293006 | 1 |
| AHD | Metronidazole | 21002293019 | 1 |
| AHD | Metronidazole | 22002266003 | 1 |
| AHD | Metronidazole | 22002266004 | 1 |
| AHD | Metronidazole | 220022660058 | 1 |
| AHD | Metronidazole | 22002266008 | 3 |
| AHD | Metronidazole | 22002266010 | 1 |
| ALH | Metronidazole | 1609028-01 | 1 |
| Alliance healfcare | Metronidazole | 19010215 | 1 |
| Alliance Health 20.0... | Metronidazole | 1307042-01 | 2 |
| Alliance Health 23.0... | Metronidazole | 1212001-02 | 1 |
| Alliance Healthcare | Metronidazole | 12110415 | 1 |
| Alliance Healthcare | Metronidazole | 20004568008 | 1 |
| Alliance Healthcare | Metronidazole | 20G07-F03-372290 | 1 |
| Alliance | Metronidazole | 12339502 | 1 |
| Alliance | Metronidazole | 22002266003 | 1 |
| Alliance | Metronidazole | 22002266008 | 1 |
| alliance | Metronidazole | 2206031-01 | 1 |
| Allianz Healthcare | Metronidazole | 19g02-b04 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag 21.10.14 EK 2.85 | Metronidazole | 13095007 | 1 |
| Anzag 15.12.17 3.41 | Metronidazole | 1705812 | 1 |
| Anzag | Metronidazole | 11373512 | 1 |
| Anzag | Metronidazole | 1505024-01 | 1 |
| Anzag | Metronidazole | 15253022 | 1 |
| Anzag | Metronidazole | 20004568005 | 1 |
| Anzag | Metronidazole | 22002266008 | 1 |
| Anzag | Metronidazole | 24000389003 | 1 |
| Anzag;14,21EUR;16.04.15 | Metronidazole | 13214012 | 1 |
| Anzak | Metronidazole | 220226608 | 1 |
| api-ident | Metronidazole | 16/19-B04 | 1 |
| Apo Ident | Metronidazole | 1807039-03 | 1 |
| Apoident,Phönix, 09.... | Metronidazole | 1701039-01 | 1 |
| Apo-ident | Metronidazole | 108703902 | 1 |
| apo-ident | Metronidazole | 1807039-01 | 2 |
| apo-ident | Metronidazole | 1901042-01 | 2 |
| Apotheke an der Born... | Metronidazole | 16089223 | 1 |
| Audor Pharma | Metronidazole | 1908028-02 | 1 |
| Audor Pharma | Metronidazole | 2007002-01 | 2 |
| Bombastus | Metronidazole | 123Validierung | 1 |
| Bombastus | Metronidazole | 13214018 | 1 |
| Bombastus | Metronidazole | 15253032 | 1 |
| Bombastus | Metronidazole | 16089220 | 1 |
| Bombastus | Metronidazole | 1609028-01 | 1 |
| Bombastus | Metronidazole | 17C10-B04-346280 | 1 |
| Bombastus | Metronidazole | 18026401 | 1 |
| Caelo | Metronidazole | | 8 |
| Caelo | Metronidazole | 10112903 | 1 |
| Caelo | Metronidazole | 10112907 | 1 |
| Caelo | Metronidazole | 102311870 | 1 |
| Caelo | Metronidazole | 10368310 | 1 |
| Caelo | Metronidazole | 10368311 | 1 |
| Caelo | Metronidazole | 10368313 | 1 |
| Caelo | Metronidazole | 10368318 | 1 |
| Caelo | Metronidazole | 10368319 | 1 |
| Caelo | Metronidazole | 1061804 | 2 |
| Caelo | Metronidazole | 1109030-01 | 2 |
| Caelo | Metronidazole | 1112028-01 | 1 |
| Caelo | Metronidazole | 11319807 | 1 |
| Caelo | Metronidazole | 11319810 | 2 |
| Caelo | Metronidazole | 11319812 | 1 |
| Caelo | Metronidazole | 11319816 | 2 |
| Caelo | Metronidazole | 11319818 | 2 |
| Caelo | Metronidazole | 11319819 | 1 |
| Caelo | Metronidazole | 11319823 | 5 |
| Caelo | Metronidazole | 11319824 | 2 |
| Caelo | Metronidazole | 11319825 | 3 |
| Caelo | Metronidazole | 113214021 | 1 |
| Caelo | Metronidazole | 11F15-N07 | 1 |
| Caelo | Metronidazole | 11h11-n03 | 1 |
| Caelo | Metronidazole | 1201156 | 1 |
| Caelo | Metronidazole | 12081507 | 1 |
| Caelo | Metronidazole | 12091403 | 1 |
| Caelo | Metronidazole | 1210411 | 1 |
| Caelo | Metronidazole | 12110105 | 1 |
| Caelo | Metronidazole | 12110403 | 1 |
| Caelo | Metronidazole | 12110405 | 8 |
| Caelo | Metronidazole | 121104085 | 1 |
| Caelo | Metronidazole | 12110411 | 5 |
| Caelo | Metronidazole | 12110412 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metronidazole | 12110413 | 4 |
| Caelo | Metronidazole | 12110414 | 3 |
| Caelo | Metronidazole | 12110415 | 4 |
| Caelo | Metronidazole | 12110421 | 6 |
| Caelo | Metronidazole | 12110422 | 16 |
| Caelo | Metronidazole | 12110423 | 1 |
| Caelo | Metronidazole | 121203001 | 2 |
| Caelo | Metronidazole | 1212030-21 | 1 |
| Caelo | Metronidazole | 12339501 | 7 |
| Caelo | Metronidazole | 12339502 | 18 |
| Caelo | Metronidazole | 12339503 | 6 |
| Caelo | Metronidazole | 12339504 | 6 |
| Caelo | Metronidazole | 12339507 | 7 |
| Caelo | Metronidazole | 12339508 | 4 |
| Caelo | Metronidazole | 12339509 | 4 |
| Caelo | Metronidazole | 12339510 | 10 |
| Caelo | Metronidazole | 12339511 | 14 |
| Caelo | Metronidazole | 12339519 | 12 |
| Caelo | Metronidazole | 12339520 | 4 |
| Caelo | Metronidazole | 12339521 | 1 |
| Caelo | Metronidazole | 12339526 | 1 |
| Caelo | Metronidazole | 12359501 | 1 |
| Caelo | Metronidazole | 1239504 | 1 |
| Caelo | Metronidazole | 12L17-N11 | 3 |
| Caelo | Metronidazole | 12L17-N16 | 2 |
| Caelo | Metronidazole | 13041503 | 1 |
| Caelo | Metronidazole | 1307002 | 1 |
| Caelo | Metronidazole | 1307002-02 | 1 |
| Caelo | Metronidazole | 1307042-01 | 1 |
| Caelo | Metronidazole | 13095001 | 10 |
| Caelo | Metronidazole | 13095002 | 8 |
| Caelo | Metronidazole | 13095003 | 11 |
| Caelo | Metronidazole | 13095004 | 12 |
| Caelo | Metronidazole | 13095005 | 4 |
| Caelo | Metronidazole | 13095006 | 7 |
| Caelo | Metronidazole | 13095007 | 5 |
| Caelo | Metronidazole | 13095011 | 3 |
| Caelo | Metronidazole | 13095012 | 13 |
| Caelo | Metronidazole | 13095013 | 13 |
| Caelo | Metronidazole | 13095017 | 3 |
| Caelo | Metronidazole | 13095018 | 6 |
| Caelo | Metronidazole | 13095019 | 7 |
| Caelo | Metronidazole | 13095020 | 5 |
| Caelo | Metronidazole | 1314013 | 1 |
| Caelo | Metronidazole | 13214001 | 11 |
| Caelo | Metronidazole | 13214002 | 17 |
| Caelo | Metronidazole | 132140022 | 1 |
| Caelo | Metronidazole | 13214003 | 11 |
| Caelo | Metronidazole | 13214009 | 7 |
| Caelo | Metronidazole | 13214010 | 5 |
| Caelo | Metronidazole | 13214011 | 2 |
| Caelo | Metronidazole | 13214012 | 3 |
| Caelo | Metronidazole | 13214013 | 1 |
| Caelo | Metronidazole | 13214014 | 10 |
| Caelo | Metronidazole | 13214015 | 8 |
| Caelo | Metronidazole | 13214016 | 3 |
| Caelo | Metronidazole | 13214017 | 3 |
| Caelo | Metronidazole | 13214018 | 4 |
| Caelo | Metronidazole | 13214019 | 9 |
| Caelo | Metronidazole | 13214021 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metronidazole | 13214024 | 4 |
| Caelo | Metronidazole | 13214025 | 6 |
| Caelo | Metronidazole | 13214029 | 9 |
| Caelo | Metronidazole | 1321409 | 1 |
| Caelo | Metronidazole | 13J21-N07 | 1 |
| Caelo | Metronidazole | 1407003-01 | 1 |
| Caelo | Metronidazole | 1407003-2 | 1 |
| Caelo | Metronidazole | 14111304 | 1 |
| Caelo | Metronidazole | 1412016-01 | 4 |
| Caelo | Metronidazole | 1412016-02 | 1 |
| Caelo | Metronidazole | 14b27-b31-291230 | 1 |
| Caelo | Metronidazole | 14B27-B31-291230 | 1 |
| Caelo | Metronidazole | 14B27-B31-291234 | 1 |
| Caelo | Metronidazole | 14c14-b01-295545 | 1 |
| Caelo | Metronidazole | 14C14-B01-309058 | 2 |
| Caelo | Metronidazole | 14C14-B02-291237 | 1 |
| Caelo | Metronidazole | 14C14-B02-291239 | 1 |
| Caelo | Metronidazole | 14C14-B02-291276 | 1 |
| Caelo | Metronidazole | 1505024-01 | 2 |
| Caelo | Metronidazole | 1505024-02 | 2 |
| Caelo | Metronidazole | 1508004-01 | 2 |
| Caelo | Metronidazole | 1508004-02 | 3 |
| Caelo | Metronidazole | 15121202 | 1 |
| Caelo | Metronidazole | 15215103 | 4 |
| Caelo | Metronidazole | 15215104 | 5 |
| Caelo | Metronidazole | 15215105 | 1 |
| Caelo | Metronidazole | 15215106 | 5 |
| Caelo | Metronidazole | 15215107 | 1 |
| Caelo | Metronidazole | 15215108 | 10 |
| Caelo | Metronidazole | 1523006 | 1 |
| Caelo | Metronidazole | 1523013 | 1 |
| Caelo | Metronidazole | 1523017 | 1 |
| Caelo | Metronidazole | 1523026 | 1 |
| Caelo | Metronidazole | 1525016 | 1 |
| Caelo | Metronidazole | 15253001 | 13 |
| Caelo | Metronidazole | 15253002 | 5 |
| Caelo | Metronidazole | 15253003 | 9 |
| Caelo | Metronidazole | 15253004 | 14 |
| Caelo | Metronidazole | 15253005 | 3 |
| Caelo | Metronidazole | 15253006 | 10 |
| Caelo | Metronidazole | 15253007 | 13 |
| Caelo | Metronidazole | 15253011 | 11 |
| Caelo | Metronidazole | 15253013 | 12 |
| Caelo | Metronidazole | 15253013/2016030911 | 1 |
| Caelo | Metronidazole | 15253015 | 17 |
| Caelo | Metronidazole | 15253016 | 13 |
| Caelo | Metronidazole | 15253017 | 14 |
| Caelo | Metronidazole | 15253018 | 6 |
| Caelo | Metronidazole | 15253019 | 3 |
| Caelo | Metronidazole | 15253020 | 5 |
| Caelo | Metronidazole | 15253021 | 9 |
| Caelo | Metronidazole | 15253022 | 7 |
| Caelo | Metronidazole | 15253024 | 12 |
| Caelo | Metronidazole | 15253026 | 19 |
| Caelo | Metronidazole | 15253027 | 13 |
| Caelo | Metronidazole | 15253028 | 9 |
| Caelo | Metronidazole | 15253029 | 5 |
| Caelo | Metronidazole | 15253032 | 13 |
| Caelo | Metronidazole | 15253033 | 7 |
| Caelo | Metronidazole | 15253034 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metronidazole | 15258016 | 1 |
| Caelo | Metronidazole | 15A20-B07-303293 | 1 |
| Caelo | Metronidazole | 15A20-B07-303297 | 1 |
| Caelo | Metronidazole | 15A20-B07-303298 | 1 |
| Caelo | Metronidazole | 16/19-B04-326150 | 1 |
| Caelo | Metronidazole | 16/19-B04-326155 | 1 |
| Caelo | Metronidazole | 16/19-B04-329160 | 1 |
| Caelo | Metronidazole | 16051703 | 1 |
| Caelo | Metronidazole | 16056235 | 1 |
| Caelo | Metronidazole | 16089123 | 1 |
| Caelo | Metronidazole | 1608918 | 1 |
| Caelo | Metronidazole | 16089201 | 7 |
| Caelo | Metronidazole | 16089202 | 11 |
| Caelo | Metronidazole | 16089209 | 14 |
| Caelo | Metronidazole | 16089212 | 19 |
| Caelo | Metronidazole | 16089213 | 21 |
| Caelo | Metronidazole | 16089215 | 15 |
| Caelo | Metronidazole | 16089215/1140217 | 1 |
| Caelo | Metronidazole | 16089216 | 8 |
| Caelo | Metronidazole | 16089217 | 9 |
| Caelo | Metronidazole | 16089218 | 13 |
| Caelo | Metronidazole | 16089219 | 17 |
| Caelo | Metronidazole | 16089220 | 19 |
| Caelo | Metronidazole | 16089221 | 12 |
| Caelo | Metronidazole | 16089222 | 11 |
| Caelo | Metronidazole | 16089223 | 5 |
| Caelo | Metronidazole | 16089224 | 7 |
| Caelo | Metronidazole | 16089225 | 1 |
| Caelo | Metronidazole | 16089228 | 14 |
| Caelo | Metronidazole | 16089228-20170818Ma4 | 1 |
| Caelo | Metronidazole | 16089229 | 14 |
| Caelo | Metronidazole | 16089231 | 4 |
| Caelo | Metronidazole | 16089235 | 11 |
| Caelo | Metronidazole | 16089236 | 3 |
| Caelo | Metronidazole | 160892365302 | 1 |
| Caelo | Metronidazole | 160902801 | 1 |
| Caelo | Metronidazole | 1609028-01 | 4 |
| Caelo | Metronidazole | 161201301 | 1 |
| Caelo | Metronidazole | 1612013-01 | 1 |
| Caelo | Metronidazole | 1619-b04-326150 | 1 |
| Caelo | Metronidazole | 16253015 | 1 |
| Caelo | Metronidazole | 16D15-B50-324137 | 1 |
| Caelo | Metronidazole | 16I19-B04-329167 | 1 |
| Caelo | Metronidazole | 1701039-01 | 2 |
| Caelo | Metronidazole | 170580001 | 2 |
| Caelo | Metronidazole | 17058001 | 14 |
| Caelo | Metronidazole | 17058002 | 11 |
| Caelo | Metronidazole | 17058003 | 14 |
| Caelo | Metronidazole | 170580035444 | 1 |
| Caelo | Metronidazole | 17058004 | 9 |
| Caelo | Metronidazole | 17058005 | 14 |
| Caelo | Metronidazole | 1705801 | 1 |
| Caelo | Metronidazole | 17058010 | 14 |
| Caelo | Metronidazole | 17058011 | 18 |
| Caelo | Metronidazole | 17058012 | 21 |
| Caelo | Metronidazole | 17058012/2231117 | 1 |
| Caelo | Metronidazole | 170580123 | 1 |
| Caelo | Metronidazole | 17058013 | 17 |
| Caelo | Metronidazole | 17058013-20180404Ma4 | 1 |
| Caelo | Metronidazole | 17058013-20180619Ma6 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metronidazole | 17058014 | 21 |
| Caelo | Metronidazole | 17058015 | 19 |
| Caelo | Metronidazole | 17058016 | 27 |
| Caelo | Metronidazole | 170580165554 | 1 |
| Caelo | Metronidazole | 17058017 | 16 |
| Caelo | Metronidazole | 17058018 | 24 |
| Caelo | Metronidazole | 17058019 | 22 |
| Caelo | Metronidazole | 17058026 | 19 |
| Caelo | Metronidazole | 17058027 | 15 |
| Caelo | Metronidazole | 17070008-01 | 1 |
| Caelo | Metronidazole | 1707008-01 | 6 |
| Caelo | Metronidazole | 1707008-02 | 1 |
| Caelo | Metronidazole | 17250517 | 1 |
| Caelo | Metronidazole | 1729027 | 1 |
| Caelo | Metronidazole | 17290503 | 27 |
| Caelo | Metronidazole | 17290504 | 24 |
| Caelo | Metronidazole | 17290506 | 27 |
| Caelo | Metronidazole | 17290507 | 26 |
| Caelo | Metronidazole | 17290509 | 10 |
| Caelo | Metronidazole | 17290512 | 30 |
| Caelo | Metronidazole | 172905125723 | 1 |
| Caelo | Metronidazole | 17290513 | 5 |
| Caelo | Metronidazole | 17290515 | 3 |
| Caelo | Metronidazole | 17290517 | 51 |
| Caelo | Metronidazole | 17290518 | 56 |
| Caelo | Metronidazole | 17290519 | 10 |
| Caelo | Metronidazole | 17290525 | 54 |
| Caelo | Metronidazole | 17290526 | 15 |
| Caelo | Metronidazole | 17290527 | 49 |
| Caelo | Metronidazole | 17290532 | 38 |
| Caelo | Metronidazole | 17290533 | 32 |
| Caelo | Metronidazole | 17290534 | 3 |
| Caelo | Metronidazole | 17290625 | 1 |
| Caelo | Metronidazole | 172990507 | 1 |
| Caelo | Metronidazole | 174058019 | 1 |
| Caelo | Metronidazole | 175058013 | 1 |
| Caelo | Metronidazole | 1758017 | 1 |
| Caelo | Metronidazole | 1790504 | 1 |
| Caelo | Metronidazole | 1790512 | 1 |
| Caelo | Metronidazole | 1790517 | 1 |
| Caelo | Metronidazole | 179290525 | 1 |
| Caelo | Metronidazole | 17C10 | 2 |
| Caelo | Metronidazole | 17C10-B04-346275 | 2 |
| Caelo | Metronidazole | 17C10-B04-346280 | 1 |
| Caelo | Metronidazole | 1802007-01 | 1 |
| Caelo | Metronidazole | 180264001 | 1 |
| Caelo | Metronidazole | 18026401 | 14 |
| Caelo | Metronidazole | 18051201 | 1 |
| Caelo | Metronidazole | 18061803 | 1 |
| Caelo | Metronidazole | 1807039-01 | 2 |
| Caelo | Metronidazole | 1807039-03 | 1 |
| Caelo | Metronidazole | 18071401 | 1 |
| Caelo | Metronidazole | 1873838-01 | 1 |
| Caelo | Metronidazole | 18B28-B50 | 1 |
| Caelo | Metronidazole | 190000516008 | 1 |
| Caelo | Metronidazole | 1900016019 | 1 |
| Caelo | Metronidazole | 19000512012 | 1 |
| Caelo | Metronidazole | 190005160 | 1 |
| Caelo | Metronidazole | 19000516001 | 16 |
| Caelo | Metronidazole | 190005160016 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metronidazole | 19000516002 | 45 |
| Caelo | Metronidazole | 19000516003 | 9 |
| Caelo | Metronidazole | 19000516006 | 37 |
| Caelo | Metronidazole | 19000516007 | 34 |
| Caelo | Metronidazole | 19000516008 | 27 |
| Caelo | Metronidazole | 19000516010 | 43 |
| Caelo | Metronidazole | 190005-16010 | 1 |
| Caelo | Metronidazole | 19000516012 | 13 |
| Caelo | Metronidazole | 19000516016 | 33 |
| Caelo | Metronidazole | 19000516017 | 18 |
| Caelo | Metronidazole | 19000516019 | 19 |
| Caelo | Metronidazole | 1900214 | 1 |
| Caelo | Metronidazole | 1900516010 | 2 |
| Caelo | Metronidazole | 1901020 | 1 |
| Caelo | Metronidazole | 190102003 | 4 |
| Caelo | Metronidazole | 19010201 | 25 |
| Caelo | Metronidazole | 19010202 | 25 |
| Caelo | Metronidazole | 19010203 | 35 |
| Caelo | Metronidazole | 19010210 | 25 |
| Caelo | Metronidazole | 19010211 | 36 |
| Caelo | Metronidazole | 19010212 | 35 |
| Caelo | Metronidazole | 19010213 | 25 |
| Caelo | Metronidazole | 19010214 | 21 |
| Caelo | Metronidazole | 19010215 | 26 |
| Caelo | Metronidazole | 19010216 | 20 |
| Caelo | Metronidazole | 19011909 | 1 |
| Caelo | Metronidazole | 19012011 | 1 |
| Caelo | Metronidazole | 1901210 | 1 |
| Caelo | Metronidazole | 1901214 | 1 |
| Caelo | Metronidazole | 190601201 | 1 |
| Caelo | Metronidazole | 190802802 | 1 |
| Caelo | Metronidazole | 1910203 | 1 |
| Caelo | Metronidazole | 1957059 | 1 |
| Caelo | Metronidazole | 1957069 | 1 |
| Caelo | Metronidazole | 19G02-B04-362815 | 1 |
| Caelo | Metronidazole | 200004568003 | 1 |
| Caelo | Metronidazole | 200004568004 | 1 |
| Caelo | Metronidazole | 200004568005 | 1 |
| Caelo | Metronidazole | 200004568008 | 1 |
| Caelo | Metronidazole | 20001568016 | 1 |
| Caelo | Metronidazole | 20004567001 | 8 |
| Caelo | Metronidazole | 20004568001 | 2 |
| Caelo | Metronidazole | 200045680013 | 1 |
| Caelo | Metronidazole | 200045680016 | 1 |
| Caelo | Metronidazole | 20004568003 | 44 |
| Caelo | Metronidazole | 20004568004 | 30 |
| Caelo | Metronidazole | 20004568005 | 40 |
| Caelo | Metronidazole | 20004568008 | 10 |
| Caelo | Metronidazole | 20004568009 | 52 |
| Caelo | Metronidazole | 20004568012 | 2 |
| Caelo | Metronidazole | 20004568013 | 22 |
| Caelo | Metronidazole | 20004568015 | 20 |
| Caelo | Metronidazole | 20004568016 | 23 |
| Caelo | Metronidazole | 2000456809 | 1 |
| Caelo | Metronidazole | 2004568009 | 1 |
| Caelo | Metronidazole | 2004568016 | 1 |
| Caelo | Metronidazole | 200700201 | 1 |
| Caelo | Metronidazole | 200702-01 | 1 |
| Caelo | Metronidazole | 20121121 | 1 |
| Caelo | Metronidazole | 2013U-01870 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metronidazole | 20140612-12 | 1 |
| Caelo | Metronidazole | 2022015B | 1 |
| Caelo | Metronidazole | 2071304 | 1 |
| Caelo | Metronidazole | 20G07f03372286 | 1 |
| Caelo | Metronidazole | 210002293014 | 1 |
| Caelo | Metronidazole | 210004568015 | 1 |
| Caelo | Metronidazole | 21002293002 | 7 |
| Caelo | Metronidazole | 21002293003 | 26 |
| Caelo | Metronidazole | 21002293004 | 6 |
| Caelo | Metronidazole | 21002293005 | 20 |
| Caelo | Metronidazole | 21002293006 | 27 |
| Caelo | Metronidazole | 21002293007 | 1 |
| Caelo | Metronidazole | 21002293009 | 15 |
| Caelo | Metronidazole | 21002293010 | 11 |
| Caelo | Metronidazole | 21002293011 | 13 |
| Caelo | Metronidazole | 21002293014 | 19 |
| Caelo | Metronidazole | 21002293016 | 10 |
| Caelo | Metronidazole | 21002293017 | 5 |
| Caelo | Metronidazole | 21002293018 | 1 |
| Caelo | Metronidazole | 21002293019 | 6 |
| Caelo | Metronidazole | 21002293020 | 1 |
| Caelo | Metronidazole | 2100293005 | 1 |
| Caelo | Metronidazole | 2102293005 | 1 |
| Caelo | Metronidazole | 220022656003 | 1 |
| Caelo | Metronidazole | 22002266003 | 6 |
| Caelo | Metronidazole | 22002266004 | 2 |
| Caelo | Metronidazole | 22002266006 | 7 |
| Caelo | Metronidazole | 22002266010 | 1 |
| Caelo | Metronidazole | 2200226608 | 1 |
| Caelo | Metronidazole | 2202266003 | 1 |
| Caelo | Metronidazole | 220226606 | 1 |
| Caelo | Metronidazole | 22040734 | 1 |
| Caelo | Metronidazole | 23011504 | 1 |
| Caelo | Metronidazole | 23021713 | 1 |
| Caelo | Metronidazole | 24000389006 | 1 |
| Caelo | Metronidazole | 2619A-01870 | 1 |
| Caelo | Metronidazole | 27092014A | 1 |
| Caelo | Metronidazole | 2750 | 1 |
| Caelo | Metronidazole | 280218010 | 1 |
| Caelo | Metronidazole | 28061204 | 1 |
| Caelo | Metronidazole | 2813E1870 | 1 |
| Caelo | Metronidazole | 3112M-01870 | 1 |
| Caelo | Metronidazole | 320F01870 | 1 |
| Caelo | Metronidazole | 3301 | 1 |
| Caelo | Metronidazole | 338(intern) | 1 |
| Caelo | Metronidazole | 39/AKD16 | 1 |
| Caelo | Metronidazole | 39/AKD4 | 1 |
| Caelo | Metronidazole | 3947/V04/16 | 1 |
| Caelo | Metronidazole | 473800045689 | 1 |
| Caelo | Metronidazole | 49(17290526) | 1 |
| Caelo | Metronidazole | 50(19010201) | 1 |
| Caelo | Metronidazole | 51(19000516012) | 1 |
| Caelo | Metronidazole | 6003 | 1 |
| Caelo | Metronidazole | 604081626 | 1 |
| Caelo | Metronidazole | 607211870 | 1 |
| Caelo | Metronidazole | 614U1870 | 1 |
| Caelo | Metronidazole | 7031401 | 1 |
| Caelo | Metronidazole | 7071405 | 1 |
| Caelo | Metronidazole | 7091714 | 1 |
| Caelo | Metronidazole | 8012014B | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Metronidazole | 820I-01870 | 1 |
| Caelo | Metronidazole | 9715621 | 1 |
| Caelo | Metronidazole | C04171127 | 1 |
| Caelo | Metronidazole | ch17290513 | 1 |
| Caelo | Metronidazole | F170013 | 1 |
| Caelo | Metronidazole | I-13095005 | 1 |
| Caelo | Metronidazole | MZ3847368 | 1 |
| Caeolo/Phönix | Metronidazole | 16089228 | 1 |
| Caeolo/Sanacorp | Metronidazole | 17058019 | 1 |
| Caeolo/Sanacorp | Metronidazole | 17290518 | 1 |
| Caesar & Lorenz GmbH | Metronidazole | 15253013 | 1 |
| Caesar & Lorenz | Metronidazole | 13095013 | 1 |
| Caesar & Loretz / AHD | Metronidazole | 19000516008 | 1 |
| Caesar & Loretz /Phönix | Metronidazole | 19000516007 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 17058001 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 17290532 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516007 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516017 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19010215 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 20004568009 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293019 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 22002266003 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516006 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 20004568013 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 20004568016 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293016 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 22002266003 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516010 | 2 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293003 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293011 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19010212 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19010213 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516016 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293010 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19010214 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516016 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293005 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293003 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516006 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19010211 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 17290527 | 3 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516002 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516019 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19010214 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293006 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 17290525 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293006 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293010 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516002 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19010203 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 20004568003 | 1 |
| Caesar & Loretz GmbH/AHD | Metronidazole | 19000516006 | 1 |
| Caesar & Loretz GmbH/AHD | Metronidazole | 20004568013 | 1 |
| Caesar & Loretz GmbH/AHD | Metronidazole | 21002293002 | 1 |
| Caesar & Loretz GmbH/AHD | Metronidazole | 21002293011 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 20004568004 | 2 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516002 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 19000516019 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 20004568009 | 1 |
| Caesar & Loretz GmbH… | Metronidazole | 21002293009 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/G | Metronidazole | 19010211 | 1 |
| Caesar & Loretz GmbH/G | Metronidazole | 20004568009 | 1 |
| Caesar & Loretz GmbH/Gehe | Metronidazole | 19000516001 | 1 |
| Caesar & Loretz GmbH/Gehe | Metronidazole | 19000516007 | 1 |
| Caesar & Loretz GmbH/gehe | Metronidazole | 19000516008 | 2 |
| Caesar & Loretz GmbH/Gehe | Metronidazole | 19010201 | 2 |
| Caesar & Loretz GmbH/gehe | Metronidazole | 19010202 | 1 |
| Caesar & Loretz GmbH/Gehe | Metronidazole | 1908028-01 | 1 |
| Caesar & Loretz GmbH/Gehe | Metronidazole | 20004568005 | 1 |
| Caesar & Loretz GmbH/GEHE | Metronidazole | 20004568016 | 1 |
| Caesar & Loretz GmbH/Gehe | Metronidazole | 21002293005 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516003 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19010214 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293003 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516002 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568003 | 2 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293003 | 3 |
| Caesar & Loretz GmbH... | Metronidazole | 1807039-02 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 190102003 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19010212 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19010213 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004567001 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568005 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293004 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293005 | 1 |
| Caesar & Loretz GmbH/K | Metronidazole | 20004568005 | 1 |
| Caesar & Loretz GmbH/Kehr | Metronidazole | 19000516016 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516007 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568003 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568005 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516002 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516010 | 5 |
| Caesar & Loretz GmbH... | Metronidazole | 19010203 | 2 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568009 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293009 | 1 |
| Caesar & Loretz GmbH/Ph | Metronidazole | 19010212 | 2 |
| Caesar & Loretz GmbH/PHoe | Metronidazole | 19000516010 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516007 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19010210 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 17290527 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19010215 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568003 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568004 | 2 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568009 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568013 | 2 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568016 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 22002266008 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516010 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516012 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19000516017 | 2 |
| Caesar & Loretz GmbH... | Metronidazole | 20004568009 | 2 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293004 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293009 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 21002293010 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 22002266003 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | AP220630-01 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 15253017 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 16089224 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 17058027 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 17290504 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Metronidazole | 17290512 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 17290517 | 6 |
| Caesar & Loretz GmbH | Metronidazole | 17290518 | 4 |
| Caesar & Loretz GmbH | Metronidazole | 17290525 | 8 |
| Caesar & Loretz GmbH | Metronidazole | 17290526 | 7 |
| Caesar & Loretz GmbH | Metronidazole | 17290527 | 6 |
| Caesar & Loretz GmbH | Metronidazole | 17290532 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 17290533 | 4 |
| Caesar & Loretz GmbH | Metronidazole | 17290534 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 19000516001 | 4 |
| Caesar & Loretz GmbH | Metronidazole | 19000516002 | 12 |
| Caesar & Loretz GmbH | Metronidazole | 19000516003 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 19000516006 | 11 |
| Caesar & Loretz GmbH | Metronidazole | 19000516007 | 8 |
| Caesar & Loretz GmbH | Metronidazole | 19000516008 | 13 |
| Caesar & Loretz GmbH | Metronidazole | 19000516010 | 11 |
| Caesar & Loretz GmbH | Metronidazole | 19000516012 | 11 |
| Caesar & Loretz GmbH | Metronidazole | 19000516016 | 9 |
| Caesar & Loretz GmbH | Metronidazole | 19000516017 | 10 |
| Caesar & Loretz GmbH | Metronidazole | 19000516019 | 4 |
| Caesar & Loretz GmbH | Metronidazole | 190102002 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 190102003 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 19010201 | 4 |
| Caesar & Loretz GmbH | Metronidazole | 19010202 | 11 |
| Caesar & Loretz GmbH | Metronidazole | 19010203 | 12 |
| Caesar & Loretz GmbH | Metronidazole | 19010210 | 5 |
| Caesar & Loretz GmbH | Metronidazole | 19010211 | 15 |
| Caesar & Loretz GmbH | Metronidazole | 19010212 | 8 |
| Caesar & Loretz GmbH | Metronidazole | 19010213 | 8 |
| Caesar & Loretz GmbH | Metronidazole | 19010214 | 4 |
| Caesar & Loretz GmbH | Metronidazole | 19010215 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 19010216 | 5 |
| Caesar & Loretz GmbH | Metronidazole | 19G02 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 19G02-B04 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 20004567001 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 20004568003 | 19 |
| Caesar & Loretz GmbH | Metronidazole | 20004568004 | 19 |
| Caesar & Loretz GmbH | Metronidazole | 20004568005 | 25 |
| Caesar & Loretz GmbH | Metronidazole | 20004568008 | 8 |
| Caesar & Loretz GmbH | Metronidazole | 20004568009 | 18 |
| Caesar & Loretz GmbH | Metronidazole | 20004568013 | 5 |
| Caesar & Loretz GmbH | Metronidazole | 20004568015 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 20004568016 | 11 |
| Caesar & Loretz GmbH | Metronidazole | 21002293002 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 21002293003 | 7 |
| Caesar & Loretz GmbH | Metronidazole | 21002293004 | 6 |
| Caesar & Loretz GmbH | Metronidazole | 21002293005 | 8 |
| Caesar & Loretz GmbH | Metronidazole | 21002293006 | 15 |
| Caesar & Loretz GmbH | Metronidazole | 21002293007 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 21002293009 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 21002293010 | 6 |
| Caesar & Loretz GmbH | Metronidazole | 21002293011 | 7 |
| Caesar & Loretz GmbH | Metronidazole | 21002293014 | 7 |
| Caesar & Loretz GmbH | Metronidazole | 21002293016 | 1 |
| Caesar & Loretz GmbH | Metronidazole | 21002293017 | 7 |
| Caesar & Loretz GmbH | Metronidazole | 21002293019 | 3 |
| Caesar & Loretz GmbH | Metronidazole | 21002293020 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 22002266003 | 3 |
| Caesar & Loretz GmbH | Metronidazole | 22002266006 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 22002266007 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Metronidazole | 22002266008 | 2 |
| Caesar & Loretz GmbH | Metronidazole | 9000516006 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19010202 | 1 |
| Caesar & Loretz GmbH... | Metronidazole | 19G02-B04-362816 | 1 |
| Caesar & Loretz Hilden | Metronidazole | 17290518 | 1 |
| Caesar & Loretz Hilden | Metronidazole | 19000516008 | 1 |
| Caesar & Loretz Hilden | Metronidazole | 19010212 | 1 |
| Caesar & Loretz Hilden | Metronidazole | 19010214 | 1 |
| Caesar & Loretz/AHD | Metronidazole | 19000516010 | 1 |
| Caesar & Loretz/Geil... | Metronidazole | 17290525 | 1 |
| Caesar & Loretz/Geil... | Metronidazole | 19000516008 | 1 |
| Caesar & Loretz/Geil... | Metronidazole | 19010211 | 1 |
| Caesar & Loretz/Noweda | Metronidazole | 20004568009 | 1 |
| Caesar & Loretz | Metronidazole | 16089212 | 1 |
| Caesar & Loretz | Metronidazole | 17058003 | 1 |
| Caesar & Loretz | Metronidazole | 17058019 | 1 |
| Caesar & Loretz | Metronidazole | 17290512 | 1 |
| Caesar Loretz | Metronidazole | 19000516006 | 1 |
| Caesar u. Loretz GmbH | Metronidazole | 19000516008 | 1 |
| Caesar u. Loretz GmbH | Metronidazole | 19000516016 | 1 |
| Caesar u. Loretz GmbH | Metronidazole | 20004568009 | 1 |
| Caesar und Loretz GmbH | Metronidazole | 17290503 | 1 |
| Caesar&Lorenz/AHD | Metronidazole | 17290506 | 1 |
| Caesar&Lorenz | Metronidazole | 20004568003 | 2 |
| Caesar&Lorenz | Metronidazole | 21002293002 | 3 |
| Caesar&Lorenz | Metronidazole | 21002293003 | 1 |
| Caesar&Loretz GmbH/Anzag | Metronidazole | 12339511 | 1 |
| Caesar&Loretz GmbH/S... | Metronidazole | 15253003 | 1 |
| Caesar&Loretz GmbH | Metronidazole | 19000516019 | 1 |
| Caesar&Loretz GmbH | Metronidazole | 19010210 | 1 |
| Caesar&Loretz GmbH | Metronidazole | 21002293009 | 1 |
| Caesar&loretz,Phoenix | Metronidazole | 12110410 | 1 |
| Cealo/ Gehe | Metronidazole | 19010213 | 1 |
| Cealo/Gehe | Metronidazole | 17290506 | 1 |
| cealo/Gehe | Metronidazole | 20004568003 | 1 |
| Cealo/Phoenix | Metronidazole | 21002293011 | 1 |
| Cealo/Sanacorp | Metronidazole | 13095003 | 1 |
| Cealo/Sanacorp | Metronidazole | 1900051610 | 1 |
| Cealo | Metronidazole | 16089219 | 1 |
| Cealo | Metronidazole | 19000516001 | 1 |
| Cealo | Metronidazole | 20004568015 | 1 |
| celo / Gehe | Metronidazole | 123456 | 1 |
| Corden Pharma / Gehe | Metronidazole | 17290504 | 1 |
| Corden Pharma Bergam... | Metronidazole | C3356 | 1 |
| Corden Pharma Bergam... | Metronidazole | 19010214 | 1 |
| Corden Pharma Bergam... | Metronidazole | F180012 | 1 |
| Corden Pharma | Metronidazole | 1212001-02 | 2 |
| Corden/ Gehe | Metronidazole | 2207001-01 | 1 |
| Corden/Noweda | Metronidazole | 19010210 | 1 |
| Corden/Noweda | Metronidazole | F180029 | 1 |
| Delta | Metronidazole | 17058001 | 1 |
| E Plus | Metronidazole | 1707008-01 | 1 |
| Ebert & Jacobi | Metronidazole | 1609028-01 | 2 |
| Ebert | Metronidazole | 1412016-02 | 1 |
| Ebert-Jacobi | Metronidazole | 16089224 | 1 |
| Eu Rho | Metronidazole | 2007002-02 | 1 |
| EuRho / Noweda | Metronidazole | 1807039-03 | 3 |
| EuRho / Noweda | Metronidazole | 1901042-02 | 2 |
| EuRho/AHD | Metronidazole | 1906012-01 | 1 |
| EuRho/Jenne | Metronidazole | 1802007-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho/Noweda | Metronidazole | 180601M1706022-01 | 1 |
| EuRho/Noweda | Metronidazole | 2007002-01 | 1 |
| EuRho/Phoenix | Metronidazole | 2007002-02 | 1 |
| EuRho/Phönix | Metronidazole | 1307002-01 | 1 |
| EuRho | Metronidazole | 110903002 | 1 |
| EuRho | Metronidazole | 1109030-02 | 1 |
| EuRho | Metronidazole | 1212001-02 | 1 |
| EuRho | Metronidazole | 1307042-02 | 1 |
| Eurho | Metronidazole | 1406010-01 | 1 |
| EuRho | Metronidazole | 1406010-01 | 1 |
| EuRho | Metronidazole | 1407003-01 | 1 |
| EuRho | Metronidazole | 1412016-01 | 1 |
| eurho | Metronidazole | 1612013-01 | 1 |
| EuRho | Metronidazole | 1612013-02 | 5 |
| EuRho | Metronidazole | 170103901 | 1 |
| EuRho | Metronidazole | 1701039-01 | 2 |
| EuRho | Metronidazole | 1706022-02 | 1 |
| EuRho | Metronidazole | 1707008-01 | 1 |
| Eurho | Metronidazole | 1807039-01 | 1 |
| EuRho | Metronidazole | 1807039-01 | 2 |
| EuRho | Metronidazole | 180703902 | 1 |
| EuRho | Metronidazole | 1807039-02 | 1 |
| Eurho | Metronidazole | 1908028-01 | 1 |
| euRho | Metronidazole | 1908028-02 | 1 |
| EuRho | Metronidazole | 2005029-01 | 1 |
| EuRho | Metronidazole | 2007002-01 | 2 |
| Eurho | Metronidazole | 2103002-02 | 1 |
| Eurimpharm | Metronidazole | 140601001 | 1 |
| EURO / Sanacorp | Metronidazole | 160902801 | 1 |
| Euro Gehe | Metronidazole | 1707008-01 | 1 |
| Euro OCT / Krieger | Metronidazole | 1908028-02 | 1 |
| Euro OTC | Metronidazole | | 4 |
| Euro OTC | Metronidazole | 10800401 | 1 |
| Euro OTC | Metronidazole | 1109016-01 | 1 |
| Euro OTC | Metronidazole | 1109030-01 | 5 |
| Euro OTC | Metronidazole | 110903002 | 1 |
| Euro OTC | Metronidazole | 1109030-02 | 1 |
| Euro OTC | Metronidazole | 1109030-03 | 2 |
| Euro OTC | Metronidazole | 1112028-01 | 4 |
| Euro OTC | Metronidazole | 1112028-02 | 7 |
| Euro OTC | Metronidazole | 121001-02 | 3 |
| Euro OTC | Metronidazole | 1212001-01 | 10 |
| Euro OTC | Metronidazole | 1212001-02 | 14 |
| Euro OTC | Metronidazole | 1212030-01 | 3 |
| Euro OTC | Metronidazole | 1212030-02 | 7 |
| Euro OTC | Metronidazole | 1220141155F | 1 |
| Euro OTC | Metronidazole | 128061/72 | 1 |
| Euro OTC | Metronidazole | 13070002-02 | 1 |
| Euro OTC | Metronidazole | 1307002-01 | 9 |
| Euro OTC | Metronidazole | 1307002-02 | 1 |
| Euro OTC | Metronidazole | 130704201 | 1 |
| Euro OTC | Metronidazole | 1307042-01 | 9 |
| Euro OTC | Metronidazole | 1307042-02 | 7 |
| Euro OTC | Metronidazole | 1308704201 | 1 |
| Euro OTC | Metronidazole | 13214010 | 1 |
| Euro OTC | Metronidazole | 13B06-N03 | 1 |
| Euro OTC | Metronidazole | 140601001 | 2 |
| Euro OTC | Metronidazole | 1406010-01 | 21 |
| Euro OTC | Metronidazole | 1407003 | 1 |
| Euro OTC | Metronidazole | 140700301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Metronidazole | 1407003-01 | 7 |
| Euro OTC | Metronidazole | 140700302 | 2 |
| Euro OTC | Metronidazole | 1407003-02 | 11 |
| Euro OTC | Metronidazole | 1412016 | 1 |
| Euro OTC | Metronidazole | 1412016-01 | 15 |
| Euro OTC | Metronidazole | 1412016-02 | 26 |
| Euro OTC | Metronidazole | 14120601 | 1 |
| Euro OTC | Metronidazole | 1418E-01870 | 1 |
| Euro OTC | Metronidazole | 1503004-01 | 1 |
| Euro OTC | Metronidazole | 150502401 | 4 |
| Euro OTC | Metronidazole | 1505024-01 | 13 |
| Euro OTC | Metronidazole | 150502402 | 1 |
| Euro OTC | Metronidazole | 1505024-02 | 8 |
| Euro OTC | Metronidazole | 1505024-03 | 3 |
| Euro OTC | Metronidazole | 150800 | 1 |
| Euro OTC | Metronidazole | 1508004 | 1 |
| Euro OTC | Metronidazole | 150800401 | 1 |
| Euro OTC | Metronidazole | 1508004-01 | 27 |
| Euro OTC | Metronidazole | 1508004-02 | 12 |
| Euro OTC | Metronidazole | 150804-01 | 1 |
| Euro OTC | Metronidazole | 15a20-b07-303294 | 1 |
| Euro OTC | Metronidazole | 1606028 | 1 |
| Euro OTC | Metronidazole | 16089222 | 1 |
| Euro OTC | Metronidazole | 16089224 | 1 |
| Euro OTC | Metronidazole | 1609023-01 | 1 |
| Euro OTC | Metronidazole | 1609028 | 3 |
| Euro OTC | Metronidazole | 1609028-01 | 36 |
| Euro OTC | Metronidazole | 1609028-02 | 13 |
| Euro OTC | Metronidazole | 161201301 | 1 |
| Euro OTC | Metronidazole | 1612013-01 | 30 |
| Euro OTC | Metronidazole | 1612013-02 | 3 |
| Euro OTC | Metronidazole | 169028-01 | 1 |
| Euro OTC | Metronidazole | 1701039 | 2 |
| Euro OTC | Metronidazole | 170103901 | 1 |
| Euro OTC | Metronidazole | 1701039-01 | 59 |
| Euro OTC | Metronidazole | 170139-01 | 2 |
| Euro OTC | Metronidazole | 1703028-01 | 1 |
| Euro OTC | Metronidazole | 17058005 | 1 |
| Euro OTC | Metronidazole | 1706022_01 | 1 |
| Euro OTC | Metronidazole | 170602201 | 1 |
| Euro OTC | Metronidazole | 1706022-01 | 18 |
| Euro OTC | Metronidazole | 1706022-02 | 3 |
| Euro OTC | Metronidazole | 1707008-002 | 1 |
| Euro OTC | Metronidazole | 170700801 | 3 |
| Euro OTC | Metronidazole | 1707008-01 | 58 |
| Euro OTC | Metronidazole | 170700802 | 1 |
| Euro OTC | Metronidazole | 1707008-02 | 10 |
| Euro OTC | Metronidazole | 1707039-01 | 1 |
| Euro OTC | Metronidazole | 1707088-01 | 2 |
| Euro OTC | Metronidazole | 17290513 | 1 |
| Euro OTC | Metronidazole | 176022-01 | 1 |
| Euro OTC | Metronidazole | 180200701 | 1 |
| Euro OTC | Metronidazole | 1802007-01 | 14 |
| Euro OTC | Metronidazole | 1802007-02 | 6 |
| Euro OTC | Metronidazole | 1807030-01 | 1 |
| Euro OTC | Metronidazole | 1807031-01 | 1 |
| Euro OTC | Metronidazole | 1807039 | 2 |
| Euro OTC | Metronidazole | 1807039/01 | 1 |
| Euro OTC | Metronidazole | 1807039-01 | 42 |
| Euro OTC | Metronidazole | 180703902 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Metronidazole | 1807039-02 | 36 |
| Euro OTC | Metronidazole | 1807039-03 | 20 |
| Euro OTC | Metronidazole | 19010210 | 1 |
| Euro OTC | Metronidazole | 190104201 | 3 |
| Euro OTC | Metronidazole | 1901042-01 | 14 |
| Euro OTC | Metronidazole | 190104202 | 1 |
| Euro OTC | Metronidazole | 1901042-02 | 10 |
| Euro OTC | Metronidazole | 190601201 | 1 |
| Euro OTC | Metronidazole | 1906012-01 | 32 |
| Euro OTC | Metronidazole | 1906012-02 | 23 |
| Euro OTC | Metronidazole | 1908028 | 3 |
| Euro OTC | Metronidazole | 190802801 | 2 |
| Euro OTC | Metronidazole | 1908028-01 | 10 |
| Euro OTC | Metronidazole | 190802802 | 1 |
| Euro OTC | Metronidazole | 1908028-02 | 16 |
| Euro OTC | Metronidazole | 1908028-1 | 1 |
| Euro OTC | Metronidazole | 20004568015 | 1 |
| Euro OTC | Metronidazole | 2005029-01 | 19 |
| Euro OTC | Metronidazole | 200502902 | 1 |
| Euro OTC | Metronidazole | 2005029-02 | 4 |
| Euro OTC | Metronidazole | 20070002-02 | 1 |
| Euro OTC | Metronidazole | 200700201 | 3 |
| Euro OTC | Metronidazole | 2007002-01 | 50 |
| Euro OTC | Metronidazole | 2007002-02 | 29 |
| Euro OTC | Metronidazole | 20111025 | 1 |
| Euro OTC | Metronidazole | 2103002-01 | 15 |
| Euro OTC | Metronidazole | 2103002-02 | 1 |
| Euro OTC | Metronidazole | 2103002-03 | 6 |
| Euro OTC | Metronidazole | 2206031-01 | 8 |
| Euro OTC | Metronidazole | 2207001_01 | 1 |
| Euro OTC | Metronidazole | 2207001-01 | 5 |
| Euro OTC | Metronidazole | 2207001-02 | 1 |
| Euro OTC | Metronidazole | 2308003-01 | 2 |
| Euro OTC | Metronidazole | 2308004-01 | 1 |
| Euro OTC | Metronidazole | 300915ME | 1 |
| Euro OTC | Metronidazole | 4516E-01870 | 1 |
| Euro OTC | Metronidazole | 700837 | 1 |
| Euro OTC | Metronidazole | C04-160812 | 1 |
| Euro OTC | Metronidazole | C04-171127 | 1 |
| Euro OTC | Metronidazole | c04190737 | 1 |
| Euro OTC | Metronidazole | F120017 | 1 |
| Euro OTC | Metronidazole | F160028 | 1 |
| Euro OTC | Metronidazole | F1800012 | 1 |
| Euro OTC | Metronidazole | F190012 | 1 |
| Euro OTC | Metronidazole | F200019 | 1 |
| Euro/ Sanacorp | Metronidazole | 150800402 | 1 |
| Euro/Anzag | Metronidazole | 1807039-02 | 1 |
| Euro/Jenne | Metronidazole | 1412016-01 | 1 |
| Euro/Noweda | Metronidazole | 1609028-01 | 1 |
| Euro/Sanacorp | Metronidazole | 1508004-02 | 1 |
| Euro/Sanacorp | Metronidazole | 1609028 | 1 |
| EuroPharma | Metronidazole | 141201601 | 1 |
| EurRho/Noweda | Metronidazole | 1908028-02 | 1 |
| Fa.Alliance Healtc. | Metronidazole | 16089222 | 1 |
| Fa.Phönix | Metronidazole | 1705812 | 2 |
| Fa.Phönix | Metronidazole | 20004568003 | 1 |
| Fa.Phönix | Metronidazole | 20004568004 | 1 |
| Fa.Phönix | Metronidazole | 21002293009 | 2 |
| Fagro/Sanacorp | Metronidazole | 18B28-B50 | 1 |
| Fagro | Metronidazole | 14C14-B01-295548 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Metronidazole | | 5 |
| Fagron | Metronidazole | 10F23-N05 | 1 |
| Fagron | Metronidazole | 112356 | 1 |
| Fagron | Metronidazole | 11C21-N01 | 1 |
| Fagron | Metronidazole | 11F15-N07 | 1 |
| Fagron | Metronidazole | 11J07-N07 | 1 |
| Fagron | Metronidazole | 1220141155F | 2 |
| Fagron | Metronidazole | 12A20-B07-303298 | 1 |
| Fagron | Metronidazole | 12a2o-n18 | 1 |
| Fagron | Metronidazole | 12D30-N02 | 1 |
| Fagron | Metronidazole | 12d30-n03 | 1 |
| Fagron | Metronidazole | 12D30-N03 | 4 |
| Fagron | Metronidazole | 12f15-n04 | 1 |
| Fagron | Metronidazole | 12F15-N04 | 7 |
| Fagron | Metronidazole | 12G04-N15 | 15 |
| Fagron | Metronidazole | 12L17_N16 | 1 |
| Fagron | Metronidazole | 12l17-n11 | 1 |
| Fagron | Metronidazole | 12l17-N11 | 1 |
| Fagron | Metronidazole | 12L17N11 | 1 |
| Fagron | Metronidazole | 12L17-N11 | 15 |
| Fagron | Metronidazole | 12L17-N16 | 4 |
| Fagron | Metronidazole | 12L-N11 | 1 |
| Fagron | Metronidazole | 13/10-No3 | 1 |
| Fagron | Metronidazole | 13/21-N07 | 1 |
| Fagron | Metronidazole | 13/21-N7 | 2 |
| Fagron | Metronidazole | 1307002-01 | 2 |
| Fagron | Metronidazole | 13095002 | 1 |
| Fagron | Metronidazole | 13214001 | 2 |
| Fagron | Metronidazole | 13B06N03 | 1 |
| Fagron | Metronidazole | 13B06-N03 | 10 |
| Fagron | Metronidazole | 13D08N22 | 1 |
| Fagron | Metronidazole | 13D08-N22 | 6 |
| Fagron | Metronidazole | 13D10-N02 | 4 |
| Fagron | Metronidazole | 13I10-N03 | 3 |
| Fagron | Metronidazole | 13j21-n07 | 2 |
| Fagron | Metronidazole | 13j21-N07 | 1 |
| Fagron | Metronidazole | 13J21N07 | 2 |
| Fagron | Metronidazole | 13J21-N07 | 35 |
| Fagron | Metronidazole | 140700301 | 1 |
| Fagron | Metronidazole | 1412016-01 | 1 |
| Fagron | Metronidazole | 1414-B02-291237 | 1 |
| Fagron | Metronidazole | 141C14-B02-296437 | 1 |
| Fagron | Metronidazole | 14B27-B31-291234 | 1 |
| Fagron | Metronidazole | 14B27-B31-291235 | 1 |
| Fagron | Metronidazole | 14C12-B02-300182 | 1 |
| Fagron | Metronidazole | 14C14-802-291237 | 1 |
| Fagron | Metronidazole | 14C14-B01 | 1 |
| Fagron | Metronidazole | 14c14-B01-295545 | 1 |
| Fagron | Metronidazole | 14C14-B01-295548 | 1 |
| Fagron | Metronidazole | 14C14-B01-306363 | 5 |
| Fagron | Metronidazole | 14C14B02 | 3 |
| Fagron | Metronidazole | 14C14-B02 | 4 |
| Fagron | Metronidazole | 14C14-B02_291238 | 1 |
| Fagron | Metronidazole | 14C14-B02-2911239 | 1 |
| Fagron | Metronidazole | 14C14-B02-291237 | 9 |
| Fagron | Metronidazole | 14C14-B02-291238 | 2 |
| Fagron | Metronidazole | 14c14-b02-291239 | 1 |
| Fagron | Metronidazole | 14C14-B02-291239 | 7 |
| Fagron | Metronidazole | 14C14-B02-291241 | 1 |
| Fagron | Metronidazole | 14c14-b02-291275 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Metronidazole | 14C14-B02-291275 | 4 |
| Fagron | Metronidazole | 14c14b02291276 | 1 |
| Fagron | Metronidazole | 14c14-b02-291276 | 2 |
| Fagron | Metronidazole | 14C14B02-291276 | 2 |
| Fagron | Metronidazole | 14C14-B02-291276 | 3 |
| Fagron | Metronidazole | 14C14-B02-295603 | 1 |
| Fagron | Metronidazole | 14C14-B02-296437 | 10 |
| Fagron | Metronidazole | 14-C14-B02-296437 | 1 |
| Fagron | Metronidazole | 14C14-B02-300182 | 4 |
| Fagron | Metronidazole | 14C14-B291237 | 1 |
| Fagron | Metronidazole | 14C14-Bo2-291276 | 1 |
| Fagron | Metronidazole | 1508004-01 | 1 |
| Fagron | Metronidazole | 15253017 | 2 |
| Fagron | Metronidazole | 15A20/B07-303298 | 1 |
| Fagron | Metronidazole | 15A20-B07 | 1 |
| Fagron | Metronidazole | 15A20-B07-303293 | 9 |
| Fagron | Metronidazole | 15A20-B07-303294 | 3 |
| Fagron | Metronidazole | 15A20-B07-303294Mg | 1 |
| Fagron | Metronidazole | 15A20-B07-303295 | 1 |
| Fagron | Metronidazole | 15a20b07303298 | 1 |
| Fagron | Metronidazole | 15A20-B07-303298 | 8 |
| Fagron | Metronidazole | 15a20-b07-308196 | 1 |
| Fagron | Metronidazole | 15A20-B07-308196 | 3 |
| Fagron | Metronidazole | 15A20-B07-308198 | 1 |
| Fagron | Metronidazole | 15A20B07308525 | 1 |
| Fagron | Metronidazole | 15A20-B07-308525 | 8 |
| Fagron | Metronidazole | 15a20-b07-308791 | 1 |
| Fagron | Metronidazole | 15A20-B07-308791 | 4 |
| Fagron | Metronidazole | 15A20-B07312057 | 1 |
| Fagron | Metronidazole | 15A20-B07-312057 | 4 |
| Fagron | Metronidazole | 15A20-B07-312225 | 3 |
| Fagron | Metronidazole | 15A20-B07-31225 | 1 |
| Fagron | Metronidazole | 15A20Bo7308196 | 1 |
| Fagron | Metronidazole | 16/16-B04-326151 | 1 |
| Fagron | Metronidazole | 16/19-B04 | 3 |
| Fagron | Metronidazole | 16/19-B04-326150 | 6 |
| Fagron | Metronidazole | 16/19-B04-326151 | 3 |
| Fagron | Metronidazole | 16/19-B04-326152 | 1 |
| Fagron | Metronidazole | 16/19-B04-326154 | 1 |
| Fagron | Metronidazole | 16/19-B04-326155 | 2 |
| Fagron | Metronidazole | 16/19-B04-329160 | 1 |
| Fagron | Metronidazole | 16/19-B04-329162 | 1 |
| Fagron | Metronidazole | 16/19-B04-329163 | 1 |
| Fagron | Metronidazole | 16/19-B04-329167 | 2 |
| Fagron | Metronidazole | 16/19-b04-329168 | 1 |
| Fagron | Metronidazole | 16/19-B04-329168 | 3 |
| Fagron | Metronidazole | 16/19bo4326155 | 1 |
| Fagron | Metronidazole | 160902 | 1 |
| Fagron | Metronidazole | 1612013-01 | 2 |
| Fagron | Metronidazole | 1619-B04-326150 | 1 |
| Fagron | Metronidazole | 1619b04326155 | 1 |
| Fagron | Metronidazole | 1619-B04-326155 | 1 |
| Fagron | Metronidazole | 1619B04329161 | 1 |
| Fagron | Metronidazole | 16D15-B50-324137 | 2 |
| Fagron | Metronidazole | 16H15-B50-326734 | 1 |
| Fagron | Metronidazole | 16I19-B04 | 5 |
| Fagron | Metronidazole | 16I19-B04-326150 | 3 |
| Fagron | Metronidazole | 16I19-B04-326151 | 4 |
| Fagron | Metronidazole | 16I19-B04-326152 | 4 |
| Fagron | Metronidazole | 16I19-B04-326155 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Metronidazole | 16I19-B04-329159 | 1 |
| Fagron | Metronidazole | 16I19-B04-329160 | 3 |
| Fagron | Metronidazole | 16I19-B04-329161 | 1 |
| Fagron | Metronidazole | 16I19-B04-329162 | 1 |
| Fagron | Metronidazole | 16I19-B04-329163 | 1 |
| Fagron | Metronidazole | 16I19-B04-329165 | 1 |
| Fagron | Metronidazole | 16I19-B04-329166 | 1 |
| Fagron | Metronidazole | 16I19-B04-329167 | 2 |
| Fagron | Metronidazole | 16I19-B04-329168 | 1 |
| Fagron | Metronidazole | 16J19B04 | 1 |
| Fagron | Metronidazole | 16J19-B04-326151 | 1 |
| Fagron | Metronidazole | 16J28-B50-329880 | 1 |
| Fagron | Metronidazole | 16L19_B04_326152 | 1 |
| Fagron | Metronidazole | 16l19-B04-326150 | 1 |
| Fagron | Metronidazole | 16l19-B04-329160 | 1 |
| Fagron | Metronidazole | 16l19-B04-329166 | 1 |
| Fagron | Metronidazole | 17/19-304-329168 | 1 |
| Fagron | Metronidazole | 17058003 | 1 |
| Fagron | Metronidazole | 17058013 | 1 |
| Fagron | Metronidazole | 172939-B01-295547 | 1 |
| Fagron | Metronidazole | 17A30-B01-335193 | 2 |
| Fagron | Metronidazole | 17A30-B0-335193 | 1 |
| Fagron | Metronidazole | 17C10-B04 | 6 |
| Fagron | Metronidazole | 17C-10-B04-338699 | 1 |
| Fagron | Metronidazole | 17C10-B04-338700 | 2 |
| Fagron | Metronidazole | 17C10-B04-338707 | 4 |
| Fagron | Metronidazole | 17C10-B04-346275 | 7 |
| Fagron | Metronidazole | 17c10-b04-346276 | 2 |
| Fagron | Metronidazole | 17C10-B04-346276 | 11 |
| Fagron | Metronidazole | 17C10-B04-346277 | 5 |
| Fagron | Metronidazole | 17C10-B04-346278 | 1 |
| Fagron | Metronidazole | 17C10-B04-346279 | 2 |
| Fagron | Metronidazole | 17C10-B04-346280 | 1 |
| Fagron | Metronidazole | 17C10-B04-355863 | 2 |
| Fagron | Metronidazole | 17C10-B04-355864 | 1 |
| Fagron | Metronidazole | 17C10-B04-355865 | 3 |
| Fagron | Metronidazole | 17C10-B04-355867 | 1 |
| Fagron | Metronidazole | 17C10-Bo4-346276 | 1 |
| Fagron | Metronidazole | 17C20-B04-355868 | 1 |
| Fagron | Metronidazole | 1802007-01 | 1 |
| Fagron | Metronidazole | 1802007-02 | 1 |
| Fagron | Metronidazole | 18026401 | 1 |
| Fagron | Metronidazole | 1807039-01 | 1 |
| Fagron | Metronidazole | 18B28-B50-354847 | 1 |
| Fagron | Metronidazole | 18B28B50354848 | 1 |
| Fagron | Metronidazole | 18B28-B50-354848 | 1 |
| Fagron | Metronidazole | 18B28-B50-354849 | 2 |
| Fagron | Metronidazole | 18B28-B50-354851 | 1 |
| Fagron | Metronidazole | 18B28-B50-354852 | 2 |
| Fagron | Metronidazole | 18B28-B50-3554852 | 1 |
| Fagron | Metronidazole | 1901042-01 | 1 |
| Fagron | Metronidazole | 19G002-B04-362813 | 1 |
| Fagron | Metronidazole | 19G02 | 1 |
| Fagron | Metronidazole | 19G02-B02-362815 | 1 |
| Fagron | Metronidazole | 19G02-B04 | 13 |
| Fagron | Metronidazole | 19G02-B04_362823 | 1 |
| Fagron | Metronidazole | 19G02-B04-362812 | 1 |
| Fagron | Metronidazole | 19G02B04362813 | 1 |
| Fagron | Metronidazole | 19G02-B04-362813 | 7 |
| Fagron | Metronidazole | 19G02B04362814 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Metronidazole | 19G02-B04-362814 | 6 |
| Fagron | Metronidazole | 19G02-B04-362815 | 8 |
| Fagron | Metronidazole | 19G02-B04-362816 | 11 |
| Fagron | Metronidazole | 19G02-B04-362817 | 1 |
| Fagron | Metronidazole | 19G02-B04-362818 | 2 |
| Fagron | Metronidazole | 19G02-B04-362823 | 5 |
| Fagron | Metronidazole | 19G02-B04-367358 | 1 |
| Fagron | Metronidazole | 19G02-B04-367359 | 2 |
| Fagron | Metronidazole | 19G02-B04-367360 | 1 |
| Fagron | Metronidazole | 19G02-B04-367363 | 2 |
| Fagron | Metronidazole | 19G02-B04-36763 | 1 |
| Fagron | Metronidazole | 19GO2-B04-362814 | 1 |
| Fagron | Metronidazole | 19119-B04-326154 | 1 |
| Fagron | Metronidazole | 20007-F03-0003 | 1 |
| Fagron | Metronidazole | 20121121 | 3 |
| Fagron | Metronidazole | 20130906F | 4 |
| Fagron | Metronidazole | 20140131f | 1 |
| Fagron | Metronidazole | 20140131F | 3 |
| Fagron | Metronidazole | 20G07_F03-372291 | 1 |
| Fagron | Metronidazole | 20g07-f03 | 1 |
| Fagron | Metronidazole | 20G07-F03 | 10 |
| Fagron | Metronidazole | 20G07-F03_372291 | 1 |
| Fagron | Metronidazole | 20G07F03372286 | 1 |
| Fagron | Metronidazole | 20G07-F03-372286 | 8 |
| Fagron | Metronidazole | 20g07-f03-372287 | 2 |
| Fagron | Metronidazole | 20G07-F03-372287 | 3 |
| Fagron | Metronidazole | 20G07-F03-372288 | 1 |
| Fagron | Metronidazole | 20G07-F03-372290 | 1 |
| Fagron | Metronidazole | 20G07-F03-372291 | 19 |
| Fagron | Metronidazole | 20G07-F3-372288 | 1 |
| Fagron | Metronidazole | 21G29-B02 | 1 |
| Fagron | Metronidazole | 21G29-B02-213325 | 14 |
| Fagron | Metronidazole | 21G-29-B02-213325 | 1 |
| Fagron | Metronidazole | 21G29-B02-213328 | 1 |
| Fagron | Metronidazole | 21G29-B02-221569 | 1 |
| Fagron | Metronidazole | 21G29-B02-221570 | 1 |
| Fagron | Metronidazole | 220401M | 1 |
| Fagron | Metronidazole | 2OG07-F03-372291 | 1 |
| Fagron | Metronidazole | 3212E01870 | 1 |
| Fagron | Metronidazole | 443-48-1 | 1 |
| Fagron | Metronidazole | 48(17C10-B04-346277 | 1 |
| Fagron | Metronidazole | 601021826 | 2 |
| Fagron | Metronidazole | 601062027 | 4 |
| Fagron | Metronidazole | 601072127 | 1 |
| Fagron | Metronidazole | 603041926 | 4 |
| Fagron | Metronidazole | 604081626 | 6 |
| Fagron | Metronidazole | 605021726 | 4 |
| Fagron | Metronidazole | 606/10072017 | 1 |
| Fagron | Metronidazole | 61021826 | 1 |
| Fagron | Metronidazole | 700837-0008 | 1 |
| Fagron | Metronidazole | 700837-B04-367361 | 1 |
| Fagron | Metronidazole | 9041303 | 1 |
| Fagron | Metronidazole | B04-3628104 | 1 |
| Fagron | Metronidazole | B04-3628106 | 2 |
| Fagron | Metronidazole | B04-3673509 | 1 |
| Fagron | Metronidazole | F03-3722806 | 2 |
| Fagron | Metronidazole | F03-3722807 | 2 |
| Fagron | Metronidazole | F03-3722808 | 1 |
| Fagron | Metronidazole | Metr23012023 | 1 |
| Fagron | Metronidazole | PM41 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Farchemia / Gehe | Metronidazole | 15253017 | 1 |
| Farchemia S. r. l. | Metronidazole | 1609028-01 | 1 |
| Farchemia S.R.L./ Ca... | Metronidazole | 15253032 | 1 |
| Farchemia/Phönix | Metronidazole | 1609028-02 | 1 |
| Fargon | Metronidazole | 13D08-N22 | 1 |
| Fargon | Metronidazole | 14c14-b02-291238 | 1 |
| Fargon | Metronidazole | 19G02-B04-367360 | 1 |
| Fargon | Metronidazole | 21G29-B02-213325 | 1 |
| Fiebig | Metronidazole | 16089235 | 1 |
| Fiebig | Metronidazole | 17058005 | 1 |
| Fiebig | Metronidazole | 17058027 | 1 |
| Fiebig | Metronidazole | 17290504 | 2 |
| Fiebig | Metronidazole | 17290506 | 1 |
| Fiebig | Metronidazole | 17290507 | 1 |
| Fiebig | Metronidazole | 17290517 | 2 |
| Fiebig | Metronidazole | 17290527 | 1 |
| Fiebig | Metronidazole | 17290532 | 1 |
| Fiebig | Metronidazole | b04-3673509 | 1 |
| Fiebig | Metronidazole | B04-3673509 | 1 |
| Fischer/Gehe | Metronidazole | 15A20-B07-308525 | 1 |
| Frago/Noweda | Metronidazole | 16I19-B04-329163 | 1 |
| Fragon/Jenne | Metronidazole | 19Go2-B04-367359 | 1 |
| Gatt-Koller | Metronidazole | 3728/11162017 | 1 |
| Gatt-Koller | Metronidazole | 497/03151015 | 1 |
| Gatt-Koller | Metronidazole | 497/03151515 | 1 |
| Gatt-Koller | Metronidazole | 497/03154015 | 1 |
| Gatt-Koller | Metronidazole | 606293914 | 1 |
| GEHE 11.06.2014 | Metronidazole | 1307002-01 | 1 |
| Gehe 23.11.18 | Metronidazole | 1706022-02 | 1 |
| Gehe am 04.02.14 | Metronidazole | 1212030-01 | 2 |
| Gehe amax | Metronidazole | 17058012 | 1 |
| Gehe amax | Metronidazole | 17290506 | 1 |
| Gehe amax | Metronidazole | 17290507 | 2 |
| Gehe amax | Metronidazole | 17290533 | 1 |
| Gehe amax | Metronidazole | 1807039-03 | 1 |
| Gehe amax | Metronidazole | 19000516002 | 1 |
| Gehe amax | Metronidazole | 1908028-02 | 1 |
| Gehe Rostock | Metronidazole | 1906012-01 | 1 |
| Gehe | Metronidazole | 10368318 | 1 |
| Gehe | Metronidazole | 1112028-02 | 1 |
| Gehe | Metronidazole | 12110415 | 1 |
| Gehe | Metronidazole | 12110422 | 1 |
| Gehe | Metronidazole | 1307002-01 | 1 |
| Gehe | Metronidazole | 1307002-02 | 1 |
| Gehe | Metronidazole | 140700301 | 1 |
| Gehe | Metronidazole | 1407003-01 | 2 |
| Gehe | Metronidazole | 1412016-02 | 1 |
| Gehe | Metronidazole | 1505024-01 | 1 |
| Gehe | Metronidazole | 15215108 | 1 |
| Gehe | Metronidazole | 15253017 | 1 |
| Gehe | Metronidazole | 15253026 | 1 |
| Gehe | Metronidazole | 15253032 | 1 |
| GEHE | Metronidazole | 15253032 | 1 |
| GEHE | Metronidazole | 16089216 | 1 |
| GEHE | Metronidazole | 16089229 | 1 |
| Gehe | Metronidazole | 16H15-B50-326734 | 1 |
| GEHE | Metronidazole | 17058013 | 1 |
| GEHE | Metronidazole | 17058015 | 1 |
| Gehe | Metronidazole | 17058016 | 2 |
| Gehe | Metronidazole | 17058019 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Metronidazole | 1707008 | 1 |
| Gehe | Metronidazole | 17290506 | 1 |
| Gehe | Metronidazole | 17290518 | 1 |
| Gehe | Metronidazole | 17C10B04346280 | 1 |
| Gehe | Metronidazole | 1802007-01 | 1 |
| Gehe | Metronidazole | 19000516006 | 1 |
| Gehe | Metronidazole | 19000516008 | 1 |
| Gehe | Metronidazole | 190102003 | 1 |
| Gehe | Metronidazole | 19G02-B04-362813 | 2 |
| Gehe | Metronidazole | 20004568009 | 1 |
| Gehe | Metronidazole | 2005029-02 | 1 |
| Gehe | Metronidazole | 2007002-01 | 1 |
| Gehe | Metronidazole | 2007002-02 | 1 |
| Gehe | Metronidazole | 20140131F | 1 |
| Gehe | Metronidazole | 21002293019 | 1 |
| Gehe | Metronidazole | 21002293020 | 2 |
| Gehe | Metronidazole | 22002266004 | 1 |
| GEHE | Metronidazole | 22002266007 | 1 |
| Gehe | Metronidazole | 22002266008 | 1 |
| Gehe | Metronidazole | 22002266010 | 2 |
| Gehe | Metronidazole | 220226608 | 1 |
| Gehe | Metronidazole | 220631-01 | 1 |
| Gehe | Metronidazole | 2308003-01 | 1 |
| Gehe | Metronidazole | 24000389007 | 1 |
| Gehe | Metronidazole | 2400389006 | 1 |
| Gehe | Metronidazole | 60106207 | 1 |
| Gehe | Metronidazole | F03-3722806 | 2 |
| Gehe01/2018 | Metronidazole | 14C14-B02-291237 | 1 |
| GEHE-AG | Metronidazole | 22002266008 | 1 |
| Geilenkirchen | Metronidazole | 13214018 | 1 |
| Geilenkirchen | Metronidazole | 16089222 | 1 |
| Geilenkirchen | Metronidazole | 1807039-03 | 1 |
| Geilenkirchen | Metronidazole | 2007002-02 | 2 |
| GH: ... | Metronidazole | 17290503 | 1 |
| GUMO | Metronidazole | 2007002-01 | 1 |
| Hedinger/Noweda | Metronidazole | 166089220 | 1 |
| Henry Lamotte | Metronidazole | 1212001-02 | 1 |
| Herberata Arzneimittel | Metronidazole | 15253024I-02082016 | 1 |
| Holdermann | Metronidazole | 2400089003 | 1 |
| Hubei Hongyuan | Metronidazole | 140700301 | 1 |
| Ichthyol Gesellschaft | Metronidazole | 13095005 | 1 |
| Ichthyol/ALH | Metronidazole | 1609028-02 | 1 |
| Infectopharm / Alliance | Metronidazole | 18B28-B50-354849 | 1 |
| Jenne | Metronidazole | 21002293006 | 1 |
| Jenne | Metronidazole | 22002266002 | 1 |
| Jenne | Metronidazole | 22002266008 | 1 |
| jenne | Metronidazole | 24000389002 | 1 |
| Jenne | Metronidazole | 24000389003 | 2 |
| Kehr | Metronidazole | 17058003 | 1 |
| Kehr | Metronidazole | 17290512 | 1 |
| Kehr | Metronidazole | 2007002-02 | 1 |
| Kehr | Metronidazole | 21002293020 | 1 |
| Kehr | Metronidazole | 22002266007 | 1 |
| Kehr | Metronidazole | 22002266008 | 1 |
| Kehr | Metronidazole | 2207001-01 | 1 |
| kehr | Metronidazole | 2308003-02 | 1 |
| kehr | Metronidazole | 24000389002 | 1 |
| Kehr | Metronidazole | 24000389003 | 1 |
| Kehr | Metronidazole | 24000389006 | 1 |
| Klosterring | Metronidazole | 16089235 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| krieger | Metronidazole | 19010203 | 1 |
| Kuerzel | Metronidazole | 1307002-02 | 1 |
| L10 | Metronidazole | 1807039-01 | 4 |
| L12 | Metronidazole | 1609028-01 | 1 |
| L12 | Metronidazole | 1609028-02 | 1 |
| L30 | Metronidazole | 16089209 | 2 |
| Laborch.Apolda/Gehe | Metronidazole | 17C10_B04_346278 | 1 |
| Noweda /Cealo | Metronidazole | 19000516016 | 1 |
| Noweda 19.12.22 EK 6,37 | Metronidazole | 21002293014 | 2 |
| Noweda 27.11.2019 | Metronidazole | 19010211 | 1 |
| Noweda/Wepa | Metronidazole | 13214017 | 1 |
| Noweda | Metronidazole | 11319818 | 1 |
| Noweda | Metronidazole | 12110404 | 1 |
| Noweda | Metronidazole | 12339501 | 1 |
| Noweda | Metronidazole | 12G04-N15 | 1 |
| Noweda | Metronidazole | 13095012 | 1 |
| Noweda | Metronidazole | 13214025 | 1 |
| Noweda | Metronidazole | 1407003-01 | 2 |
| Noweda | Metronidazole | 1505024-03 | 1 |
| Noweda | Metronidazole | 160902802 | 1 |
| Noweda | Metronidazole | 1619-B04-329166 | 1 |
| Noweda | Metronidazole | 16119-B04-326155 | 1 |
| Noweda | Metronidazole | 1701039-01 | 1 |
| Noweda | Metronidazole | 17058004 | 2 |
| Noweda | Metronidazole | 17058005 | 2 |
| Noweda | Metronidazole | 17058013 | 1 |
| Noweda | Metronidazole | 17058014 | 2 |
| Noweda | Metronidazole | 1706022-01 | 1 |
| Noweda | Metronidazole | 1707008-01 | 2 |
| Noweda | Metronidazole | 17290518 | 1 |
| Noweda | Metronidazole | 17290519 | 1 |
| Noweda | Metronidazole | 17290526 | 1 |
| Noweda | Metronidazole | 17290532 | 1 |
| Noweda | Metronidazole | 1807039-02 | 1 |
| Noweda | Metronidazole | 1807039-03 | 1 |
| Noweda | Metronidazole | 19000516019 | 1 |
| Noweda | Metronidazole | 19010212 | 1 |
| Noweda | Metronidazole | 19G02-B04-362814 | 1 |
| Noweda | Metronidazole | 20004568015 | 1 |
| Noweda | Metronidazole | 200700201 | 1 |
| Noweda | Metronidazole | 2007002-01 | 3 |
| noweda | Metronidazole | 2100223016 | 1 |
| Noweda | Metronidazole | 21002293016 | 1 |
| Noweda | Metronidazole | 21002293017 | 1 |
| Noweda | Metronidazole | 21002293019 | 1 |
| Noweda | Metronidazole | 21002293020 | 1 |
| Noweda | Metronidazole | 22002266002 | 1 |
| Noweda | Metronidazole | 22002266004 | 3 |
| Noweda | Metronidazole | 22002266006 | 2 |
| Noweda | Metronidazole | 22002266007 | 2 |
| noweda | Metronidazole | 22002266008 | 1 |
| Noweda | Metronidazole | 22002266008 | 1 |
| Noweda | Metronidazole | 22002266010 | 2 |
| Noweda | Metronidazole | 2206031-01 | 2 |
| Noweda | Metronidazole | 2206031-02 | 1 |
| Noweda | Metronidazole | 2207001-01 | 1 |
| Noweda | Metronidazole | 2207001-02 | 1 |
| Noweda | Metronidazole | 2308003-01 | 1 |
| Noweda | Metronidazole | 2308003-02 | 1 |
| Noweda | Metronidazole | 2308004-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Metronidazole | 2308004-02 | 1 |
| Noweda | Metronidazole | 24000389002 | 1 |
| Noweda | Metronidazole | 24000389003 | 1 |
| Noweda | Metronidazole | 24000389006 | 2 |
| Noweda | Metronidazole | 24000389007 | 1 |
| Noweda | Metronidazole | 240003892 | 1 |
| Otto Fischar GmbH&Co KG | Metronidazole | 17058017 | 1 |
| Phoenix 11.09.13 | Metronidazole | 12L17-N11 | 1 |
| Phoenix 11.05.2017 6,59EUR | Metronidazole | 16089220 | 1 |
| Phoenix 12.10.2016 6,63EUR | Metronidazole | 15253027 | 1 |
| Phoenix 15.05.18 6,52EUR | Metronidazole | 17058017 | 1 |
| Phoenix 4.3.2019 | Metronidazole | 17290526 | 1 |
| Phoenix/Cealo | Metronidazole | 17058016/0818E-0187 | 1 |
| Phoenix | Metronidazole | | 1 |
| Phoenix | Metronidazole | 121203002 | 1 |
| Phoenix | Metronidazole | 15253032 | 1 |
| Phoenix | Metronidazole | 16089201 | 1 |
| Phoenix | Metronidazole | 16089224 | 1 |
| Phoenix | Metronidazole | 17058002 | 1 |
| Phoenix | Metronidazole | 17058013 | 1 |
| Phoenix | Metronidazole | 17058026 | 1 |
| Phoenix | Metronidazole | 17058027 | 1 |
| Phoenix | Metronidazole | 17290517 | 1 |
| Phoenix | Metronidazole | 17290527 | 2 |
| Phoenix | Metronidazole | 19010202 | 2 |
| Phoenix | Metronidazole | 19010216 | 1 |
| phoenix | Metronidazole | 1908028-02 | 2 |
| Phoenix | Metronidazole | 20004568009 | 1 |
| Phoenix | Metronidazole | 200490406 | 1 |
| Phoenix | Metronidazole | 21002293017 | 1 |
| Phoenix | Metronidazole | 21002293020 | 5 |
| Phoenix | Metronidazole | 22002266002 | 2 |
| Phoenix | Metronidazole | 22002266008 | 2 |
| Phoenix | Metronidazole | 22002266010 | 1 |
| Phoenix | Metronidazole | 2206031-01 | 1 |
| Phoenix | Metronidazole | 24000389006 | 3 |
| Phoenix | Metronidazole | 24000389007 | 1 |
| Phoenix | Metronidazole | 3403 | 1 |
| Phönix Gotha | Metronidazole | 13214017 | 1 |
| Phönix Gotha | Metronidazole | 17058018 | 1 |
| Phönix/ Corden Pharm... | Metronidazole | 17290518 | 1 |
| Phönix | Metronidazole | 1109030-03 | 1 |
| Phönix | Metronidazole | 121203001 | 1 |
| Phönix | Metronidazole | 12L17-N11 | 1 |
| Phönix | Metronidazole | 13214017 | 2 |
| Phönix | Metronidazole | 13J21-N07 | 1 |
| Phönix | Metronidazole | 15253018 | 1 |
| phönix | Metronidazole | 15253026 | 1 |
| Phönix | Metronidazole | 16089212 | 1 |
| Phönix | Metronidazole | 16089223 | 1 |
| Phonix | Metronidazole | 1612013-01 | 1 |
| Phönix | Metronidazole | 1701039-01 | 1 |
| Phönix | Metronidazole | 17058003 | 1 |
| Phönix | Metronidazole | 17058005 | 1 |
| PHÖNIX | Metronidazole | 17058011 | 3 |
| Phönix | Metronidazole | 17058016 | 1 |
| Phönix | Metronidazole | 1707008-01 | 1 |
| Phönix | Metronidazole | 172905070 | 1 |
| Phönix | Metronidazole | 17290527 | 1 |
| Phönix | Metronidazole | 17290532 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| PHÖNIX | Metronidazole | 180200701 | 1 |
| Phönix | Metronidazole | 18026401 | 1 |
| Phönix | Metronidazole | 1807039-01 | 2 |
| Phönix | Metronidazole | 19000516010 | 2 |
| Phönix | Metronidazole | 19010210 | 1 |
| Phönix | Metronidazole | 19010214 | 1 |
| Phönix | Metronidazole | 200700201 | 1 |
| Phönix | Metronidazole | 2007002-01 | 1 |
| Phönix | Metronidazole | 20G07-F03-372286 | 1 |
| Phönix | Metronidazole | 21002293020 | 4 |
| Phönix | Metronidazole | 22002266007 | 2 |
| Phönix | Metronidazole | 22002266008 | 4 |
| Phönix | Metronidazole | 22002266009 | 1 |
| Phönix | Metronidazole | 22002266010 | 2 |
| Phönix | Metronidazole | 2200226606 | 1 |
| Phönix | Metronidazole | 22602266006 | 1 |
| Phönix | Metronidazole | 23008004-01 | 1 |
| Phönix | Metronidazole | 240000389003 | 1 |
| Phönix | Metronidazole | 24000389003 | 5 |
| pHÖNIX | Metronidazole | 24000389006 | 1 |
| Phönix | Metronidazole | 24000389006 | 1 |
| Phönix | Metronidazole | 24000389007 | 4 |
| Phönix | Metronidazole | 3179 | 1 |
| PHÖNIX | Metronidazole | 601062027 | 1 |
| Phönix | Metronidazole | F230073 | 1 |
| Phönix | Metronidazole | Mez5 | 1 |
| Phönix_13.12.2018 | Metronidazole | 17290518 | 1 |
| Polpharma Pharmaceut... | Metronidazole | 16I19-B04-326151 | 1 |
| Polpharma/Noweda | Metronidazole | 601062027 | 3 |
| Polpharma/Noweda | Metronidazole | 603041926 | 1 |
| Reichelt | Metronidazole | 17058013 | 1 |
| Röntgen | Metronidazole | 16I19-B04-326151 | 3 |
| Röntgen | Metronidazole | 18B28-B50-354852 | 2 |
| Röntgen | Metronidazole | 1906012-01 | 1 |
| Röntgen | Metronidazole | 2007002-01 | 2 |
| Röntgen | Metronidazole | F190012 | 1 |
| Sana | Metronidazole | 19010210 | 1 |
| Sanacorp 27.10.15 | Metronidazole | 15A20-B07-303298 | 1 |
| Sanacorp 02.03.15 | Metronidazole | 13214009 | 1 |
| Sanacorp | Metronidazole | | 2 |
| Sanacorp | Metronidazole | 12110422 | 1 |
| Sanacorp | Metronidazole | 12339519 | 1 |
| Sanacorp | Metronidazole | 12G04-N15 | 1 |
| Sanacorp | Metronidazole | 13095002 | 1 |
| Sanacorp | Metronidazole | 14C14-B02-291276 | 2 |
| Sanacorp | Metronidazole | 16G02-B04-367358 | 1 |
| Sanacorp | Metronidazole | 16I19-B04-329159 | 1 |
| Sanacorp | Metronidazole | 16I19-B04-329160 | 1 |
| Sanacorp | Metronidazole | 1701039-01 | 1 |
| Sanacorp | Metronidazole | 17058002 | 1 |
| Sanacorp | Metronidazole | 17058014 | 1 |
| Sanacorp | Metronidazole | 17058018 | 1 |
| Sanacorp | Metronidazole | 1707008-01 | 2 |
| Sanacorp | Metronidazole | 17290512 | 1 |
| Sanacorp | Metronidazole | 17290518 | 1 |
| Sanacorp | Metronidazole | 17290525 | 1 |
| Sanacorp | Metronidazole | 17290526 | 1 |
| Sanacorp | Metronidazole | 17290533 | 2 |
| Sanacorp | Metronidazole | 17C10-B04-338707 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Metronidazole | 17C10-B04-346280 | 2 |
| Sanacorp | Metronidazole | 19010201 | 1 |
| Sanacorp | Metronidazole | 19010211 | 1 |
| Sanacorp | Metronidazole | 1901042-01 | 1 |
| Sanacorp | Metronidazole | 1906012-01 | 1 |
| Sanacorp | Metronidazole | 20004568003 | 2 |
| Sanacorp | Metronidazole | 20004568008 | 1 |
| sanacorp | Metronidazole | 200700201 | 1 |
| Sanacorp | Metronidazole | 20G07-F03-372286 | 1 |
| Sanacorp | Metronidazole | 21002293020 | 1 |
| Sanacorp | Metronidazole | 2103002-03 | 1 |
| Sanacorp | Metronidazole | 21G29-B02-213325 | 1 |
| Sanacorp | Metronidazole | 22002266007 | 2 |
| Sanacorp | Metronidazole | 22002266008 | 2 |
| sanacorp | Metronidazole | 22002266009 | 2 |
| Sanacorp | Metronidazole | 22002266010 | 1 |
| Sanacorp | Metronidazole | 2206031-01 | 2 |
| Sanacorp | Metronidazole | 24000389003 | 2 |
| Sanacorp | Metronidazole | 39/AKD18 | 1 |
| Sanacorp | Metronidazole | 39/AKD6 | 1 |
| Sanacorp | Metronidazole | 39AKD15 | 1 |
| Sanacorp | Metronidazole | 601021826 | 1 |
| Sanacorp | Metronidazole | 605021726 | 1 |
| Sanacorp | Metronidazole | F200019 | 1 |
| Sanarcorp | Metronidazole | 19000516002 | 1 |
| Sanarcorp | Metronidazole | 21002293016 | 1 |
| Spangro 28.05.2014 | Metronidazole | 13/10-N03 | 1 |
| Spangropharm | Metronidazole | 11319818 | 1 |
| synthetisch | Metronidazole | 2007002-02 | 1 |
| test | Metronidazole | | 1 |
| vdl | Metronidazole | 12110421 | 1 |
| WE Alliance Healthca... | Metronidazole | 19010201 | 1 |
| WEPA/Gehe | Metronidazole | 20180515-04P | 1 |

- 250 896 spectra from 1666 *Apo-Ident* customers from a total of 51 349 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Metronidazole* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Metronidazole* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 1130 | 0 | 211 810 |
| **Type C** | 0 | 5848 | 142 | 250 896 |

The substance/substance group *Metronidazole* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4690 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.6294 % (> 97.5793 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20857 | 21881 | 8.03 | 132.87 |
| 21212 | 22472 | 7.57 | 130.71 |
| 21213 | 22472 | 6.58 | 130.25 |
| 21356 | 21881 | 5.46 | 133.23 |
| 21360 | 22472 | 4.72 | 133.00 |
| 21881 | 21881 | 0.00 | 132.25 |
| 22472 | 22472 | 0.00 | 132.59 |
| 22835 | 22472 | 2.68 | 132.58 |
| 25330 | 25330 | 0.00 | 128.27 |
| 25565 | 25565 | 0.00 | 132.27 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Miconazole nitrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20210-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Miconazole nitrate; Miconazoli nitras

### Special notes

When selecting the *Miconazole nitrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Miconazole nitrate | 7 | 17 | 507 |

### Second-stage model

For differentiation of the substance/substance group *Miconazole nitrate* the following second-stage model is used:

- Submodel 12

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Miconazole nitrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 147.98 | – |
| ⋮ | ⋮ | ⋮ |
| Mesalazine | >50 | 65.94 |
| Clioquinol | >50 | 118.15 |
| Nicotinic acid | >50 | 160.79 |
| Theophylline-ethylenediamine hydrate | >50 | 253.84 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Miconazole nitrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Miconazole nitrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Miconazole nitrate | 13185601 | 20875 | 40 | 20130704 |
| Caelo | Miconazole nitrate | 13185601 | 20905 | 80 | 20130704 |
| Caelo | Miconazole nitrate | 13352802 | 21350 | 39 | 1412250 |
| Caelo | Miconazole nitrate | 13352802 | 21351 | 40 | 20131118 |
| Caelo | Miconazole nitrate | 161447 | 22630 | 40 | 20160617* |
| Euro OTC | Miconazole nitrate | 1307025-02 | 21649 | 60 | 20130806 |
| Euro OTC | Miconazole nitrate | 1509014 | 21900 | 60 | 20150930* |
| Fagron | Miconazole nitrate | 13D22-N14 | 20817 | 100 | 20130529 |
| Fagron | Miconazole nitrate | 18C23-B02-356141 | 24593 | 40 | 20180416 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 499 spectra of 9 reference samples from the substance/substance group *Miconazole nitrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 827 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 730 spectra of 20 reference samples from the substance/substance group *Miconazole nitrate*.

- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Miconazole nitrate | 172175 | 23662 | 30 |
| Caelo | Miconazole nitrate | 182821 | 24388 | 40 |
| Caelo | Miconazole nitrate | 21000827011 | 26621 | 40 |
| Caelo | Miconazole nitrate | 24002650 | 27544 | 40 |
| Euro OTC | Miconazole nitrate | 1604004 | 22522 | 40 |
| Euro OTC | Miconazole nitrate | 1607004 | 22671 | 40 |
| Euro OTC | Miconazole nitrate | 1611024 | 22920 | 40 |
| Euro OTC | Miconazole nitrate | 1705039 | 23429 | 40 |
| Euro OTC | Miconazole nitrate | 1710020 | 23775 | 40 |
| Euro OTC | Miconazole nitrate | 1803028 | 24071 | 40 |
| Euro OTC | Miconazole nitrate | 1811015 | 24338 | 40 |
| Euro OTC | Miconazole nitrate | 1904032 | 24601 | 40 |
| Euro OTC | Miconazole nitrate | 1909029 | 24938 | 40 |
| Euro OTC | Miconazole nitrate | 2009034 | 25417 | 40 |
| Euro OTC | Miconazole nitrate | 2103012 | 25676 | 40 |
| Euro OTC | Miconazole nitrate | 2210002 | 26427 | 40 |
| Fagron | Miconazole nitrate | 22F08-B02-221067 | 26173 | 40 |
| Caelo | Miconazole nitrate | 21000827011 | 26621SI | 20 |
| Caelo | Miconazole nitrate | 24002650 | 27544SI | 20 |
| Fagron | Miconazole nitrate | 22F08-B02-221067 | 26173SI | 20 |

- 212 210 spectra from a total of 4270 batches from further 872 substances. These spectra were

recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3606 spectra from 928 *Apo-Ident* customers from 541 batches from the substance/substance group *Miconazole nitrate*.
- Among them are spectra of independent samples from 504 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Miconazole nitrate | 2009034-02 | 1 |
| | Miconazole nitrate | 210008270022 | 1 |
| | Miconazole nitrate | 21000827013 | 1 |
| | Miconazole nitrate | 21000827015 | 4 |
| | Miconazole nitrate | 21000827016 | 8 |
| | Miconazole nitrate | 21000827017 | 7 |
| | Miconazole nitrate | 21000827018 | 3 |
| | Miconazole nitrate | 21000827019 | 3 |
| | Miconazole nitrate | 21000827021 | 1 |
| | Miconazole nitrate | 21000827022 | 9 |
| | Miconazole nitrate | 21000827023 | 12 |
| | Miconazole nitrate | 21000827024 | 11 |
| | Miconazole nitrate | 21000827025 | 11 |
| | Miconazole nitrate | 21000827026 | 21 |
| | Miconazole nitrate | 2100087024 | 1 |
| | Miconazole nitrate | 2103012-02 | 1 |
| | Miconazole nitrate | 2210002 | 1 |
| | Miconazole nitrate | 2210002-0 | 1 |
| | Miconazole nitrate | 2210002-01 | 30 |
| | Miconazole nitrate | 22832-87-7 | 1 |
| | Miconazole nitrate | 22F08-B02-213149 | 2 |
| | Miconazole nitrate | 22F08-B02-213580 | 1 |
| | Miconazole nitrate | 22F08-B02-221067 | 8 |
| | Miconazole nitrate | 22F08-B02-225221 | 1 |
| | Miconazole nitrate | 23000289003 | 1 |
| | Miconazole nitrate | 23000589001 | 5 |
| | Miconazole nitrate | 23000589002 | 2 |
| | Miconazole nitrate | 23000589003 | 6 |
| | Miconazole nitrate | 23000589004 | 56 |
| | Miconazole nitrate | 23003273002 | 5 |
| | Miconazole nitrate | 23003273003 | 29 |
| | Miconazole nitrate | 23003273004 | 9 |
| | Miconazole nitrate | 23003273006 | 6 |
| | Miconazole nitrate | 2300589001 | 1 |
| | Miconazole nitrate | 2311020-01 | 9 |
| | Miconazole nitrate | 23B22-B01-227780 | 1 |
| | Miconazole nitrate | 23B22-B01-230356 | 1 |
| | Miconazole nitrate | 23BB22-B01-227780 | 1 |
| | Miconazole nitrate | 23G31-B07_232096 | 1 |
| | Miconazole nitrate | 23G31-b07-232096 | 1 |
| | Miconazole nitrate | 23G31-B07-232246 | 2 |
| | Miconazole nitrate | 23G31-B07-238306 | 1 |
| | Miconazole nitrate | 23G31-B07-232096 | 1 |
| | Miconazole nitrate | 23L22-B09-238311 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Miconazole nitrate | 24F26-B12-006743 | 2 |
| | Miconazole nitrate | B01-2302004 | 3 |
| | Miconazole nitrate | B02-221067 | 1 |
| | Miconazole nitrate | B09-2402706 | 1 |
| | Miconazole nitrate | B12-0067403 | 1 |
| 18282105 | Miconazole nitrate | 8704870 | 1 |
| 18282114 | Miconazole nitrate | CAELO | 1 |
| AEP | Miconazole nitrate | 21000827019 | 1 |
| AEP | Miconazole nitrate | 23000589004 | 1 |
| AHC | Miconazole nitrate | 23000589004 | 1 |
| AHD | Miconazole nitrate | 12374307 | 1 |
| AHD | Miconazole nitrate | 21000827018 | 1 |
| AHD | Miconazole nitrate | 21000827021 | 2 |
| AHD | Miconazole nitrate | 23000589004 | 2 |
| AHD | Miconazole nitrate | 23003273004 | 2 |
| Alliance H. | Miconazole nitrate | 5137910 | 1 |
| Alliance Health 18.0... | Miconazole nitrate | 13352801 | 2 |
| Alliance Healthcare | Miconazole nitrate | 12374307 | 1 |
| Alliance Healthcare | Miconazole nitrate | 1803028-01 | 2 |
| Alliance Healthcare | Miconazole nitrate | 1811015-01 | 2 |
| Alliance Healthcare | Miconazole nitrate | 18C23-B02-353243 | 1 |
| Alliance Healthcare | Miconazole nitrate | 18C23-B02-355295 | 1 |
| Alliance | Miconazole nitrate | 22F08-B02-213149 | 1 |
| Anzag | Miconazole nitrate | 12243802 | 1 |
| Anzag | Miconazole nitrate | 15137902 | 1 |
| Anzag | Miconazole nitrate | 15A13-B07-308432 | 1 |
| Anzag | Miconazole nitrate | 16144716 | 1 |
| Anzag | Miconazole nitrate | 18C23-B02-353243 | 1 |
| Bionorica /Phönix | Miconazole nitrate | 12C13B03-279593 | 1 |
| Bomastus / Alliance ... | Miconazole nitrate | 16E04-B03-327367 | 1 |
| Bombastus | Miconazole nitrate | 13352806 | 1 |
| Bombastus | Miconazole nitrate | 15I08-B07-318686 | 1 |
| Bombastus | Miconazole nitrate | 15I08-B07-318687 | 1 |
| Bombastus | Miconazole nitrate | 16144725 | 1 |
| Caelo | Miconazole nitrate | | 4 |
| Caelo | Miconazole nitrate | 1/AD1 | 1 |
| Caelo | Miconazole nitrate | 11104103 | 2 |
| Caelo | Miconazole nitrate | 11104108 | 1 |
| Caelo | Miconazole nitrate | 11104109 | 2 |
| Caelo | Miconazole nitrate | 11104113 | 1 |
| Caelo | Miconazole nitrate | 11104114 | 1 |
| Caelo | Miconazole nitrate | 1122014A | 1 |
| Caelo | Miconazole nitrate | 11243803 | 1 |
| Caelo | Miconazole nitrate | 11324901 | 1 |
| Caelo | Miconazole nitrate | 11324902 | 1 |
| Caelo | Miconazole nitrate | 11324905 | 4 |
| Caelo | Miconazole nitrate | 11324909 | 1 |
| Caelo | Miconazole nitrate | 11324912 | 2 |
| Caelo | Miconazole nitrate | 11324913 | 1 |
| Caelo | Miconazole nitrate | 122438 | 1 |
| Caelo | Miconazole nitrate | 12243801 | 3 |
| Caelo | Miconazole nitrate | 12243802 | 4 |
| Caelo | Miconazole nitrate | 12243803 | 9 |
| Caelo | Miconazole nitrate | 12243805 | 6 |
| Caelo | Miconazole nitrate | 12243806 | 1 |
| Caelo | Miconazole nitrate | 12243808 | 9 |
| Caelo | Miconazole nitrate | 12374301 | 4 |
| Caelo | Miconazole nitrate | 12374307 | 15 |
| Caelo | Miconazole nitrate | 12374308 | 6 |
| Caelo | Miconazole nitrate | 12k02n06 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Miconazole nitrate | 1307025-02 | 1 |
| Caelo | Miconazole nitrate | 13185601 | 4 |
| Caelo | Miconazole nitrate | 13185602 | 7 |
| Caelo | Miconazole nitrate | 13185603 | 10 |
| Caelo | Miconazole nitrate | 13185609 | 9 |
| Caelo | Miconazole nitrate | 13185610 | 6 |
| Caelo | Miconazole nitrate | 13185611 | 16 |
| Caelo | Miconazole nitrate | 13185612 | 6 |
| Caelo | Miconazole nitrate | 13282901 | 1 |
| Caelo | Miconazole nitrate | 13342801 | 1 |
| Caelo | Miconazole nitrate | 13352801 | 17 |
| Caelo | Miconazole nitrate | 13352802 | 15 |
| Caelo | Miconazole nitrate | 13352805 | 1 |
| Caelo | Miconazole nitrate | 13352806 | 14 |
| Caelo | Miconazole nitrate | 13352811 | 4 |
| Caelo | Miconazole nitrate | 13D22-N14 | 1 |
| Caelo | Miconazole nitrate | 13H28-N06 | 1 |
| Caelo | Miconazole nitrate | 14149301 | 14 |
| Caelo | Miconazole nitrate | 14149302 | 16 |
| Caelo | Miconazole nitrate | 14149303 | 5 |
| Caelo | Miconazole nitrate | 14149305 | 1 |
| Caelo | Miconazole nitrate | 14149308 | 13 |
| Caelo | Miconazole nitrate | 14149309 | 9 |
| Caelo | Miconazole nitrate | 14149310 | 9 |
| Caelo | Miconazole nitrate | 14149311 | 14 |
| Caelo | Miconazole nitrate | 14149317 | 10 |
| Caelo | Miconazole nitrate | 14149318 | 22 |
| Caelo | Miconazole nitrate | 1419301 | 1 |
| Caelo | Miconazole nitrate | 1419310 | 1 |
| Caelo | Miconazole nitrate | 14B18-B02-291233 | 1 |
| Caelo | Miconazole nitrate | 14D25-B06-294959 | 1 |
| Caelo | Miconazole nitrate | 14D25-B06-294960 | 3 |
| Caelo | Miconazole nitrate | 14H06-B01-299799 | 1 |
| Caelo | Miconazole nitrate | 15/05-B07-312317 | 1 |
| Caelo | Miconazole nitrate | 15/08-B07-315481 | 1 |
| Caelo | Miconazole nitrate | 151379 | 1 |
| Caelo | Miconazole nitrate | 15137902 | 24 |
| Caelo | Miconazole nitrate | 15137903 | 20 |
| Caelo | Miconazole nitrate | 15137905 | 11 |
| Caelo | Miconazole nitrate | 15137906 | 1 |
| Caelo | Miconazole nitrate | 15137907 | 14 |
| Caelo | Miconazole nitrate | 15137908 | 10 |
| Caelo | Miconazole nitrate | 15137909 | 13 |
| Caelo | Miconazole nitrate | 15137910 | 7 |
| Caelo | Miconazole nitrate | 15137911 | 1 |
| Caelo | Miconazole nitrate | 15137913 | 5 |
| Caelo | Miconazole nitrate | 15137914 | 6 |
| Caelo | Miconazole nitrate | 15137915 | 3 |
| Caelo | Miconazole nitrate | 15A13-B07 | 1 |
| Caelo | Miconazole nitrate | 15A13-B07-306791 | 7 |
| Caelo | Miconazole nitrate | 15A13-B07-307140 | 1 |
| Caelo | Miconazole nitrate | 15I08-B07-312317 | 3 |
| Caelo | Miconazole nitrate | 15I08-B07-315481 | 1 |
| Caelo | Miconazole nitrate | 15I08-B07-315492 | 1 |
| Caelo | Miconazole nitrate | 15I08-B07-318687 | 2 |
| Caelo | Miconazole nitrate | 15l08-B07-314838 | 1 |
| Caelo | Miconazole nitrate | 15l08-B07-315492 | 1 |
| Caelo | Miconazole nitrate | 15l08-B07-318686 | 1 |
| Caelo | Miconazole nitrate | 1607004-01 | 2 |
| Caelo | Miconazole nitrate | 16144701 | 35 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Miconazole nitrate | 16144702 | 27 |
| Caelo | Miconazole nitrate | 16144703 | 17 |
| Caelo | Miconazole nitrate | 16144704 | 14 |
| Caelo | Miconazole nitrate | 1614471 | 1 |
| Caelo | Miconazole nitrate | 16144710 | 18 |
| Caelo | Miconazole nitrate | 16144711 | 14 |
| Caelo | Miconazole nitrate | 16144716 | 30 |
| Caelo | Miconazole nitrate | 16144717 | 10 |
| Caelo | Miconazole nitrate | 16144720 | 10 |
| Caelo | Miconazole nitrate | 16144721 | 15 |
| Caelo | Miconazole nitrate | 16144725 | 40 |
| Caelo | Miconazole nitrate | 16144726 | 21 |
| Caelo | Miconazole nitrate | 16e04-b03-321367 | 1 |
| Caelo | Miconazole nitrate | 16E04-B03-321367 | 2 |
| Caelo | Miconazole nitrate | 16E04-B03-322124 | 1 |
| Caelo | Miconazole nitrate | 16E04-B03-322132 | 2 |
| Caelo | Miconazole nitrate | 16E04-B03-325448 | 1 |
| Caelo | Miconazole nitrate | 16e04b03327367 | 1 |
| Caelo | Miconazole nitrate | 16E04-B03-332373 | 1 |
| Caelo | Miconazole nitrate | 1705039-01 | 2 |
| Caelo | Miconazole nitrate | 172117505 | 1 |
| Caelo | Miconazole nitrate | 1721505 | 1 |
| Caelo | Miconazole nitrate | 17217053 | 1 |
| Caelo | Miconazole nitrate | 17217502 | 53 |
| Caelo | Miconazole nitrate | 17217503 | 27 |
| Caelo | Miconazole nitrate | 17217505 | 32 |
| Caelo | Miconazole nitrate | 17217507 | 1 |
| Caelo | Miconazole nitrate | 1727503 | 1 |
| Caelo | Miconazole nitrate | 17C01B02340778 | 1 |
| Caelo | Miconazole nitrate | 180057913 | 1 |
| Caelo | Miconazole nitrate | 1803028-01 | 1 |
| Caelo | Miconazole nitrate | 18057901 | 1 |
| Caelo | Miconazole nitrate | 18057902 | 18 |
| Caelo | Miconazole nitrate | 18057903 | 29 |
| Caelo | Miconazole nitrate | 18057904 | 1 |
| Caelo | Miconazole nitrate | 18057906 | 38 |
| Caelo | Miconazole nitrate | 18057907 | 20 |
| Ĉaelo | Miconazole nitrate | 18057907 | 1 |
| Caelo | Miconazole nitrate | 18057909 | 1 |
| Caelo | Miconazole nitrate | 18057911 | 1 |
| Caelo | Miconazole nitrate | 18057912 | 29 |
| Caelo | Miconazole nitrate | 18057913 | 34 |
| Caelo | Miconazole nitrate | 18057914 | 16 |
| Caelo | Miconazole nitrate | 18057916 | 1 |
| Caelo | Miconazole nitrate | 18067907 | 1 |
| Caelo | Miconazole nitrate | 1807902 | 1 |
| Caelo | Miconazole nitrate | 18182111 | 1 |
| Caelo | Miconazole nitrate | 1828109 | 1 |
| Caelo | Miconazole nitrate | 1828113 | 3 |
| Caelo | Miconazole nitrate | 182821002 | 1 |
| Caelo | Miconazole nitrate | 18282101 | 2 |
| Caelo | Miconazole nitrate | 18282105 | 32 |
| Caelo | Miconazole nitrate | 18282106 | 15 |
| Caelo | Miconazole nitrate | 18282107 | 2 |
| Caelo | Miconazole nitrate | 18282108 | 2 |
| Caelo | Miconazole nitrate | 18282109 | 36 |
| Caelo | Miconazole nitrate | 18282110 | 30 |
| Caelo | Miconazole nitrate | 18282111 | 29 |
| Caelo | Miconazole nitrate | 18282113 | 63 |
| Caelo | Miconazole nitrate | 18282114 | 20 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Miconazole nitrate | 1828213 | 1 |
| Caelo | Miconazole nitrate | 18282133 | 1 |
| Caelo | Miconazole nitrate | 1850000164 | 3 |
| Caelo | Miconazole nitrate | 1882105 | 1 |
| Caelo | Miconazole nitrate | 18B06_b03_34778 | 1 |
| Caelo | Miconazole nitrate | 18B06-B03-347788 | 1 |
| Caelo | Miconazole nitrate | 18C23-B02-352488 | 1 |
| Caelo | Miconazole nitrate | 18C23-B02-353243 | 1 |
| Caelo | Miconazole nitrate | 18C23-B02-355707 | 1 |
| Caelo | Miconazole nitrate | 19A31-B01-359396 | 3 |
| Caelo | Miconazole nitrate | 19A31-B01-360614 | 2 |
| Caelo | Miconazole nitrate | 200000097003 | 2 |
| Caelo | Miconazole nitrate | 20000097001 | 1 |
| Caelo | Miconazole nitrate | 20000097003 | 30 |
| Caelo | Miconazole nitrate | 20000097004 | 20 |
| Caelo | Miconazole nitrate | 20000097005 | 7 |
| Caelo | Miconazole nitrate | 20000097006 | 13 |
| Caelo | Miconazole nitrate | 20000097007 | 31 |
| Caelo | Miconazole nitrate | 20000097009 | 1 |
| Caelo | Miconazole nitrate | 2000009705 | 1 |
| Caelo | Miconazole nitrate | 2000009707 | 1 |
| Caelo | Miconazole nitrate | 200004304002 | 1 |
| Caelo | Miconazole nitrate | 200004304003 | 1 |
| Caelo | Miconazole nitrate | 2000097003 | 1 |
| Caelo | Miconazole nitrate | 2000097007 | 1 |
| Caelo | Miconazole nitrate | 20001304002 | 1 |
| Caelo | Miconazole nitrate | 20004304001 | 1 |
| Caelo | Miconazole nitrate | 20004304002 | 18 |
| Caelo | Miconazole nitrate | 20004304003 | 46 |
| Caelo | Miconazole nitrate | 20004304004 | 1 |
| Caelo | Miconazole nitrate | 20004304006 | 3 |
| Caelo | Miconazole nitrate | 2004304002 | 2 |
| Caelo | Miconazole nitrate | 2004304003 | 1 |
| Caelo | Miconazole nitrate | 2100027013 | 1 |
| Caelo | Miconazole nitrate | 21000827 | 1 |
| Caelo | Miconazole nitrate | 21000827001 | 2 |
| Caelo | Miconazole nitrate | 21000827002 | 14 |
| Caelo | Miconazole nitrate | 21000827003 | 53 |
| Caelo | Miconazole nitrate | 21000827006 | 16 |
| Caelo | Miconazole nitrate | 21000827007 | 3 |
| Caelo | Miconazole nitrate | 21000827008 | 29 |
| Caelo | Miconazole nitrate | 21000827010 | 5 |
| Caelo | Miconazole nitrate | 21000827011 | 9 |
| Caelo | Miconazole nitrate | 21000827012 | 5 |
| Caelo | Miconazole nitrate | 21000827013 | 19 |
| Caelo | Miconazole nitrate | 21000827014 | 24 |
| Caelo | Miconazole nitrate | 21000827015 | 9 |
| Caelo | Miconazole nitrate | 21000827016 | 10 |
| Caelo | Miconazole nitrate | 21000827017 | 7 |
| Caelo | Miconazole nitrate | 21000827019 | 5 |
| Caelo | Miconazole nitrate | 21000827021 | 4 |
| Caelo | Miconazole nitrate | 21000827022 | 6 |
| Caelo | Miconazole nitrate | 21000827023 | 1 |
| Caelo | Miconazole nitrate | 21000827024 | 7 |
| Caelo | Miconazole nitrate | 21000827025 | 3 |
| Caelo | Miconazole nitrate | 21000827026 | 1 |
| Caelo | Miconazole nitrate | 21000827103 | 1 |
| Caelo | Miconazole nitrate | 2100827002 | 1 |
| Caelo | Miconazole nitrate | 2100827003 | 1 |
| Caelo | Miconazole nitrate | 2100827008 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Miconazole nitrate | 2100827014 | 1 |
| Caelo | Miconazole nitrate | 2100827019 | 1 |
| Caelo | Miconazole nitrate | 2103012-01 | 1 |
| Caelo | Miconazole nitrate | 211019(20004304002) | 1 |
| Caelo | Miconazole nitrate | 211020(21000827002) | 1 |
| Caelo | Miconazole nitrate | 21C09-F01-377510 | 1 |
| Caelo | Miconazole nitrate | 21C09-F01-3775100 | 2 |
| Caelo | Miconazole nitrate | 220004304003 | 1 |
| Caelo | Miconazole nitrate | 23000589001 | 2 |
| Caelo | Miconazole nitrate | 2747 | 1 |
| Caelo | Miconazole nitrate | 2773 | 1 |
| Caelo | Miconazole nitrate | 2777 | 1 |
| Caelo | Miconazole nitrate | 2787 | 1 |
| Caelo | Miconazole nitrate | 2796 | 1 |
| Caelo | Miconazole nitrate | 28051306 | 1 |
| Caelo | Miconazole nitrate | 2900/10/14 | 1 |
| Caelo | Miconazole nitrate | 2900/11/15 | 3 |
| Caelo | Miconazole nitrate | 29001614 | 1 |
| Caelo | Miconazole nitrate | 3(18282111) | 1 |
| Caelo | Miconazole nitrate | 4(18282114) | 1 |
| Caelo | Miconazole nitrate | 4061304 | 1 |
| Caelo | Miconazole nitrate | 411092-2-P | 1 |
| Caelo | Miconazole nitrate | 5(18282114) | 1 |
| Caelo | Miconazole nitrate | 8/AKD4 | 1 |
| Caelo | Miconazole nitrate | 818A-03451 | 1 |
| Caelo | Miconazole nitrate | 8704870 | 1 |
| Caelo | Miconazole nitrate | 8716 | 1 |
| Caelo | Miconazole nitrate | 9177904 | 1 |
| Caelo | Miconazole nitrate | AKD9 | 1 |
| Caelo | Miconazole nitrate | F04-3700307 | 2 |
| Caesar & Lorenz GmbH | Miconazole nitrate | 18282113 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282111 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282110 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282113 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 20000097004 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 21000827003 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 21000827017 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 21000827008 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 20004304003 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 21000827003 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 21000827003 | 2 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 14149301 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 11324904 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 13185602 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282106 | 2 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282111 | 2 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18057914 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 21000827021 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282105 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282105 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 2000009703 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18282111 | 1 |
| Caesar & Loretz GmbH/AHD | Miconazole nitrate | 20000097003 | 1 |
| Caesar & Loretz GmbH/AHD | Miconazole nitrate | 21000827003 | 1 |
| Caesar & Loretz GmbH/AHD | Miconazole nitrate | 21000827022 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 18057906 | 1 |
| Caesar & Loretz GmbH… | Miconazole nitrate | 20004304003 | 2 |
| Caesar & Loretz GmbH/G | Miconazole nitrate | 20004304003 | 1 |
| Caesar & Loretz GmbH/Gehe | Miconazole nitrate | 20000097003 | 1 |
| Caesar & Loretz GmbH/Gehe | Miconazole nitrate | 20004304002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Miconazole nitrate | 21000827013 | 1 |
| Caesar & Loretz GmbH/Gehe | Miconazole nitrate | 21000827016 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097007 | 2 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097004 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 18057913 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 182821002 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 18282113 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097004 | 2 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097009 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20004304003 | 2 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20004304004 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 21000827001 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20004304001 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 18282114 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 21000827014 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 21000827019 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 18282105 | 2 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097004 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097007 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20004304002 | 2 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 21000827003 | 1 |
| Caesar & Loretz GmbH/S | Miconazole nitrate | 21000827008 | 2 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097004 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20000097005 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 20004304003 | 1 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 21000827003 | 2 |
| Caesar & Loretz GmbH... | Miconazole nitrate | 18282105 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 16144702 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 16144717 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18057906 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18057912 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18057913 | 12 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18057914 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18100226 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 182821002 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282105 | 7 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282106 | 2 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282108 | 2 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282109 | 15 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282110 | 7 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282111 | 5 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282112 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282113 | 21 |
| Caesar & Loretz GmbH | Miconazole nitrate | 18282114 | 7 |
| Caesar & Loretz GmbH | Miconazole nitrate | 19J16-F02 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20000097002 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20000097003 | 8 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20000097004 | 4 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20000097005 | 7 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20000097006 | 4 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20000097007 | 18 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20000097009 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 2000097004 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20004304001 | 2 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20004304002 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20004304003 | 11 |
| Caesar & Loretz GmbH | Miconazole nitrate | 20004304004 | 2 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827001 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827002 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827003 | 13 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827006 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827008 | 6 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827009 | 2 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827010 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827011 | 5 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827013 | 5 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827014 | 3 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827015 | 4 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827016 | 4 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827017 | 6 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827018 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827021 | 2 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827022 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827023 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | 21000827036 | 1 |
| Caesar & Loretz GmbH | Miconazole nitrate | F01-3775100 | 1 |
| Caesar & Loretz Hilden | Miconazole nitrate | 18057912 | 1 |
| Caesar & Loretz Hilden | Miconazole nitrate | 18057913 | 1 |
| Caesar & Loretz Hilden | Miconazole nitrate | 18282110 | 1 |
| Caesar & Loretz Hilden | Miconazole nitrate | 18282113 | 3 |
| Caesar & Loretz Hilden | Miconazole nitrate | 20000097003 | 1 |
| Caesar & Loretz Hilden | Miconazole nitrate | 20000097007 | 1 |
| Caesar & Loretz/AHC | Miconazole nitrate | 15137910 | 1 |
| Caesar & Loretz/Geil... | Miconazole nitrate | 20000097003 | 2 |
| Caesar & Loretz/Geil... | Miconazole nitrate | 20000097004 | 1 |
| Caesar & Loretz/Geil... | Miconazole nitrate | 20000097007 | 1 |
| Caesar & Loretz | Miconazole nitrate | 16144724 | 1 |
| Caesar & Loretz | Miconazole nitrate | 1850000164 | 1 |
| Caesar & Loretz | Miconazole nitrate | 21000827002 | 1 |
| Caesar Loretz Gehe | Miconazole nitrate | 21000827008 | 1 |
| Caesar und Loretz | Miconazole nitrate | 12243805 | 1 |
| Caesar&Lorenz | Miconazole nitrate | 20004304002 | 1 |
| Caesar&Loretz GmbH ... | Miconazole nitrate | 12243808 | 1 |
| Caesar&Loretz GmbH /Anzag | Miconazole nitrate | 14149310 | 1 |
| Caesar&Loretz GmbH/Anzag | Miconazole nitrate | 13185603 | 1 |
| Caesar&Loretz GmbH/Anzag | Miconazole nitrate | 13352802 | 1 |
| Caesar&loretz,Phoenix | Miconazole nitrate | 12374301 | 1 |
| Cealo / Otto Geilenk... | Miconazole nitrate | 18282106 | 1 |
| Cealo / Otto Geilenk... | Miconazole nitrate | 18282111 | 1 |
| Cealo/Gehe | Miconazole nitrate | 20000097007 | 1 |
| Dr. Wolff | Miconazole nitrate | 18E04-B03 | 1 |
| E+J, 27.09.2016 | Miconazole nitrate | 15137915 | 1 |
| Ebert & Jacobi | Miconazole nitrate | 15137914 | 1 |
| Erregierre / Gehe | Miconazole nitrate | 18282114 | 1 |
| Erregierre IT/Noweda | Miconazole nitrate | 15137905 | 1 |
| Erregierre spa | Miconazole nitrate | 18282111 | 1 |
| Erregierre/Noweda | Miconazole nitrate | A180001 | 1 |
| Erregierre/Noweda | Miconazole nitrate | A190001 | 1 |
| Eurau | Miconazole nitrate | 2103012-01 | 1 |
| EuRho/ AHD | Miconazole nitrate | 16E04-B03-332373 | 1 |
| EuRho | Miconazole nitrate | 161102401 | 1 |
| EuRho | Miconazole nitrate | 1705039-01 | 2 |
| euRho | Miconazole nitrate | 2009034-01 | 1 |
| Eurho | Miconazole nitrate | 2103012-01 | 1 |
| euro AHD | Miconazole nitrate | 1710020-015633 | 1 |
| euro AHD | Miconazole nitrate | 1710020-015639 | 1 |
| Euro OTC | Miconazole nitrate | 1307025-01 | 2 |
| Euro OTC | Miconazole nitrate | 1307025-02 | 2 |
| Euro OTC | Miconazole nitrate | 140902301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Miconazole nitrate | 1409023-01 | 1 |
| Euro OTC | Miconazole nitrate | 140902302 | 1 |
| Euro OTC | Miconazole nitrate | 1409023-02 | 4 |
| Euro OTC | Miconazole nitrate | 1504003-01 | 2 |
| Euro OTC | Miconazole nitrate | 1504903-01 | 1 |
| Euro OTC | Miconazole nitrate | 1509014-01 | 6 |
| Euro OTC | Miconazole nitrate | 1604004-01 | 5 |
| Euro OTC | Miconazole nitrate | 1607004-01 | 7 |
| Euro OTC | Miconazole nitrate | 1611024-01 | 12 |
| Euro OTC | Miconazole nitrate | 1611024-015307 | 1 |
| Euro OTC | Miconazole nitrate | 1611024-015330 | 1 |
| Euro OTC | Miconazole nitrate | 1611024-02 | 3 |
| Euro OTC | Miconazole nitrate | 16144701 | 1 |
| Euro OTC | Miconazole nitrate | 16E04-B03-321354 | 2 |
| Euro OTC | Miconazole nitrate | 16E04-B03-322124 | 1 |
| Euro OTC | Miconazole nitrate | 170503901 | 1 |
| Euro OTC | Miconazole nitrate | 1705039-01 | 12 |
| Euro OTC | Miconazole nitrate | 1705039-015371 | 1 |
| Euro OTC | Miconazole nitrate | 1705039-015432 | 1 |
| Euro OTC | Miconazole nitrate | 1705039-02 | 6 |
| Euro OTC | Miconazole nitrate | 1710020-01 | 9 |
| Euro OTC | Miconazole nitrate | 1710020-015457 | 1 |
| Euro OTC | Miconazole nitrate | 17C01-B02-339699 | 1 |
| Euro OTC | Miconazole nitrate | 17C01-B02-341814 | 1 |
| Euro OTC | Miconazole nitrate | 1803028-01 | 21 |
| Euro OTC | Miconazole nitrate | 18057907 | 1 |
| Euro OTC | Miconazole nitrate | 18057912 | 1 |
| Euro OTC | Miconazole nitrate | 1811015 | 1 |
| Euro OTC | Miconazole nitrate | 181101501 | 1 |
| Euro OTC | Miconazole nitrate | 1811015-01 | 22 |
| Euro OTC | Miconazole nitrate | 1850003395 | 1 |
| Euro OTC | Miconazole nitrate | 19009029-01 | 1 |
| Euro OTC | Miconazole nitrate | 1904032-01 | 1 |
| Euro OTC | Miconazole nitrate | 1909029-01 | 22 |
| Euro OTC | Miconazole nitrate | 190929-01 | 1 |
| Euro OTC | Miconazole nitrate | 1950000070 | 1 |
| Euro OTC | Miconazole nitrate | 1950001767 | 1 |
| Euro OTC | Miconazole nitrate | 19A31-B01-359397 | 1 |
| Euro OTC | Miconazole nitrate | 2009034-01 | 23 |
| Euro OTC | Miconazole nitrate | 200903402 | 1 |
| Euro OTC | Miconazole nitrate | 2009034-02 | 5 |
| Euro OTC | Miconazole nitrate | 2009034-03 | 4 |
| Euro OTC | Miconazole nitrate | 20180430/5 | 1 |
| Euro OTC | Miconazole nitrate | 21000827014 | 1 |
| Euro OTC | Miconazole nitrate | 210301201 | 2 |
| Euro OTC | Miconazole nitrate | 2103012-01 | 25 |
| Euro OTC | Miconazole nitrate | 2103012-02 | 4 |
| Euro OTC | Miconazole nitrate | 2103912-02 | 1 |
| Euro OTC | Miconazole nitrate | 2150000385 | 1 |
| Euro OTC | Miconazole nitrate | 22100002-01 | 1 |
| Euro OTC | Miconazole nitrate | 2210002-01 | 7 |
| Euro OTC | Miconazole nitrate | F02-3670602 | 1 |
| Euro/Phönix | Miconazole nitrate | 1803028-01 | 3 |
| Euro | Miconazole nitrate | 2103012-01 | 1 |
| EuroPTC/Phönix | Miconazole nitrate | 14149316 | 1 |
| Fa.Phönix | Miconazole nitrate | 18282114 | 1 |
| Fa.Phönix | Miconazole nitrate | 20000097007 | 1 |
| Fagron | Miconazole nitrate | | 1 |
| Fagron | Miconazole nitrate | 12/21-M03 | 1 |
| Fagron | Miconazole nitrate | 12A16-N02 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Miconazole nitrate | 12H10-N02 | 4 |
| Fagron | Miconazole nitrate | 12K02-N06 | 7 |
| Fagron | Miconazole nitrate | 13061501 | 1 |
| Fagron | Miconazole nitrate | 1316Q-03451 | 1 |
| Fagron | Miconazole nitrate | 1328-N06 | 1 |
| Fagron | Miconazole nitrate | 13352811 | 2 |
| Fagron | Miconazole nitrate | 13A14-B09 | 2 |
| Fagron | Miconazole nitrate | 13A14B09283005 | 1 |
| Fagron | Miconazole nitrate | 13A14-B09-287453 | 1 |
| Fagron | Miconazole nitrate | 13A14-B09-287486 | 5 |
| Fagron | Miconazole nitrate | 13A14-B09-287487 | 3 |
| Fagron | Miconazole nitrate | 13A14-B09-287488 | 1 |
| Fagron | Miconazole nitrate | 13D22-N14 | 6 |
| Fagron | Miconazole nitrate | 13E13-N04 | 2 |
| Fagron | Miconazole nitrate | 13E13-N08 | 2 |
| Fagron | Miconazole nitrate | 13H28_N06 | 1 |
| Fagron | Miconazole nitrate | 13H28-N06 | 13 |
| Fagron | Miconazole nitrate | 13H28-NO6 | 2 |
| Fagron | Miconazole nitrate | 14051403 | 1 |
| Fagron | Miconazole nitrate | 14149313 | 1 |
| Fagron | Miconazole nitrate | 14B18B02 | 1 |
| Fagron | Miconazole nitrate | 14B18-B02 | 4 |
| Fagron | Miconazole nitrate | 14b18-B02-291231 | 1 |
| Fagron | Miconazole nitrate | 14B18-B02-291232 | 4 |
| Fagron | Miconazole nitrate | 14b18-b02-291247 | 1 |
| Fagron | Miconazole nitrate | 14B18-B02-291247 | 2 |
| Fagron | Miconazole nitrate | 14B18-B02-291248 | 7 |
| Fagron | Miconazole nitrate | 14B18-B02-291249 | 1 |
| Fagron | Miconazole nitrate | 14B18-B02-291250 | 1 |
| Fagron | Miconazole nitrate | 14D25-B06 | 4 |
| Fagron | Miconazole nitrate | 14D25-B06-294958 | 15 |
| Fagron | Miconazole nitrate | 14D25-B06-294959 | 8 |
| Fagron | Miconazole nitrate | 14d25-b06-294960 | 1 |
| Fagron | Miconazole nitrate | 14D25-B06-294960 | 1 |
| Fagron | Miconazole nitrate | 14d25-b06-299790 | 1 |
| Fagron | Miconazole nitrate | 14D25-B06-299790 | 3 |
| Fagron | Miconazole nitrate | 14H06-B01-299798 | 1 |
| Fagron | Miconazole nitrate | 14H06-B01-299799 | 8 |
| Fagron | Miconazole nitrate | 14H06-B01-299813 | 5 |
| Fagron | Miconazole nitrate | 14H16-B01-299798 | 1 |
| Fagron | Miconazole nitrate | 15/08-B07-312317 | 2 |
| Fagron | Miconazole nitrate | 15/08-b07-314838 | 2 |
| Fagron | Miconazole nitrate | 15/08-B07-314838 | 2 |
| Fagron | Miconazole nitrate | 15/08-B07-315481 | 1 |
| Fagron | Miconazole nitrate | 15/08-b07-315492 | 2 |
| Fagron | Miconazole nitrate | 15/08-B07-316911 | 1 |
| Fagron | Miconazole nitrate | 15/08-B07-318686 | 3 |
| Fagron | Miconazole nitrate | 15/08-b07-318687 | 1 |
| Fagron | Miconazole nitrate | 1508-B07-314838 | 1 |
| Fagron | Miconazole nitrate | 1508-B07-318686 | 1 |
| Fagron | Miconazole nitrate | 15108-b07-312321 | 1 |
| Fagron | Miconazole nitrate | 15108-B07-318485 | 1 |
| Fagron | Miconazole nitrate | 15137905 | 1 |
| Fagron | Miconazole nitrate | 15137915 | 1 |
| Fagron | Miconazole nitrate | 15A13-807 | 1 |
| Fagron | Miconazole nitrate | 15A13-B07 | 7 |
| Fagron | Miconazole nitrate | 15A13-B07-306565 | 1 |
| Fagron | Miconazole nitrate | 15A13-B07-306791 | 4 |
| Fagron | Miconazole nitrate | 15A13-B07-306791nron | 1 |
| Fagron | Miconazole nitrate | 15a13-b07-307140 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Miconazole nitrate | 15A13-B07-307140 | 11 |
| Fagron | Miconazole nitrate | 15a13-b07-308432 | 1 |
| Fagron | Miconazole nitrate | 15A13-B07-308432 | 5 |
| Fagron | Miconazole nitrate | 15I08-B07 | 3 |
| Fagron | Miconazole nitrate | 15I08-B07-215492 | 1 |
| Fagron | Miconazole nitrate | 15I08-B07-3121321 | 1 |
| Fagron | Miconazole nitrate | 15i08-b07-312317 | 1 |
| Fagron | Miconazole nitrate | 15I08-B07-312317 | 3 |
| Fagron | Miconazole nitrate | 15I08-B07-312321 | 11 |
| Fagron | Miconazole nitrate | 15I08-B07-314838 | 2 |
| Fagron | Miconazole nitrate | 15I08-B07-31485 | 1 |
| Fagron | Miconazole nitrate | 15i08-b07-315481 | 1 |
| Fagron | Miconazole nitrate | 15I08-B07-315481 | 2 |
| Fagron | Miconazole nitrate | 15I08-B07-315492 | 2 |
| Fagron | Miconazole nitrate | 15I08-B07-318485 | 3 |
| Fagron | Miconazole nitrate | 15I08-B07-318686 | 2 |
| Fagron | Miconazole nitrate | 15I08-B07-318687 | 2 |
| Fagron | Miconazole nitrate | 15I18-B07-318485 | 1 |
| Fagron | Miconazole nitrate | 15l08-B07-312321 | 1 |
| Fagron | Miconazole nitrate | 15l08-B07-315492 | 3 |
| Fagron | Miconazole nitrate | 15l08-B07-318686 | 1 |
| Fagron | Miconazole nitrate | 160711M | 1 |
| Fagron | Miconazole nitrate | 16144702 | 1 |
| Fagron | Miconazole nitrate | 16144703 | 1 |
| Fagron | Miconazole nitrate | 16E04-B03 | 8 |
| Fagron | Miconazole nitrate | 16E04-B03-321354 | 1 |
| Fagron | Miconazole nitrate | 16E04-B03-321367 | 2 |
| Fagron | Miconazole nitrate | 16E04-B03-322124 | 15 |
| Fagron | Miconazole nitrate | 16e04-b03-322131 | 2 |
| Fagron | Miconazole nitrate | 16E04-B03-322131 | 9 |
| Fagron | Miconazole nitrate | 16E04-B03-322132 | 6 |
| Fagron | Miconazole nitrate | 16E04-B03-327362 | 11 |
| Fagron | Miconazole nitrate | 16E04-B03-327367 | 1 |
| Fagron | Miconazole nitrate | 16E04-B03-330082 | 9 |
| Fagron | Miconazole nitrate | 16E04-B03-332373 | 8 |
| Fagron | Miconazole nitrate | 17011307 | 1 |
| Fagron | Miconazole nitrate | 1750000983 | 1 |
| Fagron | Miconazole nitrate | 17C01B02 | 1 |
| Fagron | Miconazole nitrate | 17C01-B02 | 6 |
| Fagron | Miconazole nitrate | 17C01-B02-225671 | 1 |
| Fagron | Miconazole nitrate | 17c01-b02-334877 | 1 |
| Fagron | Miconazole nitrate | 17C01-B02-334877 | 8 |
| Fagron | Miconazole nitrate | 17C01-B02-334882 | 4 |
| Fagron | Miconazole nitrate | 17c01-b02-335671 | 1 |
| Fagron | Miconazole nitrate | 17C01-B02-335671 | 6 |
| Fagron | Miconazole nitrate | 17C01-B02-338798 | 3 |
| Fagron | Miconazole nitrate | 17c01-b02-340778 | 1 |
| Fagron | Miconazole nitrate | 17C01-B02-340778 | 15 |
| Fagron | Miconazole nitrate | 17C01-B02-341395 | 4 |
| Fagron | Miconazole nitrate | 1811015-01 | 1 |
| Fagron | Miconazole nitrate | 1850000164 | 4 |
| Fagron | Miconazole nitrate | 1850003395 | 4 |
| Fagron | Miconazole nitrate | 18B06-B03 | 5 |
| Fagron | Miconazole nitrate | 18b06-b03-345419 | 1 |
| Fagron | Miconazole nitrate | 18B06-B03-345419 | 10 |
| Fagron | Miconazole nitrate | 18B06-B03-345422 | 5 |
| Fagron | Miconazole nitrate | 18b06-b03-345423 | 2 |
| Fagron | Miconazole nitrate | 18B06-B03-345423 | 5 |
| Fagron | Miconazole nitrate | 18b06-b03-347788 | 1 |
| Fagron | Miconazole nitrate | 18B06-B03-347788 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Miconazole nitrate | 18c23-b02 | 1 |
| Fagron | Miconazole nitrate | 18C23-B02 | 13 |
| Fagron | Miconazole nitrate | 18C23-B02-248857 | 1 |
| Fagron | Miconazole nitrate | 18C23-B02-347802 | 6 |
| Fagron | Miconazole nitrate | 18c23-b02-348857 | 1 |
| Fagron | Miconazole nitrate | 18C23-B02-348857 | 5 |
| Fagron | Miconazole nitrate | 18C23-B02-350961 | 3 |
| Fagron | Miconazole nitrate | 18C23-B02-351310 | 10 |
| Fagron | Miconazole nitrate | 18C23-B02-352488 | 5 |
| Fagron | Miconazole nitrate | 18c23-b02-352489 | 1 |
| Fagron | Miconazole nitrate | 18C23-B02-352489 | 5 |
| Fagron | Miconazole nitrate | 18C23-B02-353243 | 8 |
| Fagron | Miconazole nitrate | 18c23-b02-354469 | 1 |
| Fagron | Miconazole nitrate | 18C23-B02-354469 | 5 |
| Fagron | Miconazole nitrate | 18C23-B02-355295 | 5 |
| Fagron | Miconazole nitrate | 18c23-b02-355707 | 1 |
| Fagron | Miconazole nitrate | 18C23-B02-355707 | 7 |
| Fagron | Miconazole nitrate | 18C23-B02-356141 | 5 |
| Fagron | Miconazole nitrate | 18C-B02-354469 | 1 |
| Fagron | Miconazole nitrate | 19041705 | 1 |
| Fagron | Miconazole nitrate | 19051402 | 1 |
| Fagron | Miconazole nitrate | 19500002545P-200709 | 1 |
| Fagron | Miconazole nitrate | 1950002545 | 6 |
| Fagron | Miconazole nitrate | 19A31-B01 | 11 |
| Fagron | Miconazole nitrate | 19A31B0132992 | 1 |
| Fagron | Miconazole nitrate | 19A31-B01-358150 | 3 |
| Fagron | Miconazole nitrate | 19A31-B01-359391 | 2 |
| Fagron | Miconazole nitrate | 19A31-b01-359392 | 1 |
| Fagron | Miconazole nitrate | 19A31-B01-359392 | 17 |
| Fagron | Miconazole nitrate | 19A31B01359396 | 1 |
| Fagron | Miconazole nitrate | 19A31-B01-359396 | 5 |
| Fagron | Miconazole nitrate | 19A31-B01-359397 | 8 |
| Fagron | Miconazole nitrate | 19A31-B01-360612 | 5 |
| Fagron | Miconazole nitrate | 19A31-B01-360613 | 6 |
| Fagron | Miconazole nitrate | 19A31-B01-360614 | 2 |
| Fagron | Miconazole nitrate | 19A31-BO1-359392 | 1 |
| Fagron | Miconazole nitrate | 19F16-F02-366310 | 1 |
| Fagron | Miconazole nitrate | 19J16-F01-367062 | 1 |
| Fagron | Miconazole nitrate | 19J16-F02 | 7 |
| Fagron | Miconazole nitrate | 19J16-F02-366299 | 1 |
| Fagron | Miconazole nitrate | 19J16-F02-366300 | 8 |
| Fagron | Miconazole nitrate | 19J16-F02366310 | 1 |
| Fagron | Miconazole nitrate | 19J16-F02-366310 | 7 |
| Fagron | Miconazole nitrate | 19J16-F02-3663100 | 1 |
| Fagron | Miconazole nitrate | 19J16-F02-366311 | 14 |
| Fagron | Miconazole nitrate | 19J16-F02-3670603 | 1 |
| Fagron | Miconazole nitrate | 19J16-F02-367062 | 9 |
| Fagron | Miconazole nitrate | 19J16-F02-367063 | 6 |
| Fagron | Miconazole nitrate | 19J16-F02-367064 | 1 |
| Fagron | Miconazole nitrate | 19J16-F02-37062 | 1 |
| Fagron | Miconazole nitrate | 20081201 | 1 |
| Fagron | Miconazole nitrate | 2050000157 | 7 |
| Fagron | Miconazole nitrate | 20B21-04-376344 | 1 |
| Fagron | Miconazole nitrate | 20B21-F04 | 2 |
| Fagron | Miconazole nitrate | 20B21-F04-370036 | 2 |
| Fagron | Miconazole nitrate | 20B21-F04-370037 | 15 |
| Fagron | Miconazole nitrate | 20B21-F04-370040 | 3 |
| Fagron | Miconazole nitrate | 20B21-F04-3700400 | 1 |
| Fagron | Miconazole nitrate | 20B21-F04-370270 | 8 |
| Fagron | Miconazole nitrate | 20B21-F04-376344 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Miconazole nitrate | 2150000385 | 3 |
| Fagron | Miconazole nitrate | 21C09-F01 | 5 |
| Fagron | Miconazole nitrate | 21C09-F01-277510 | 1 |
| Fagron | Miconazole nitrate | 21C09-F01-37510 | 1 |
| Fagron | Miconazole nitrate | 21C09-F01-37513 | 1 |
| Fagron | Miconazole nitrate | 21C09-F01-377509 | 1 |
| Fagron | Miconazole nitrate | 21C09-F01-377510 | 11 |
| Fagron | Miconazole nitrate | 21C09-F01-377510/215000038 | 1 |
| Fagron | Miconazole nitrate | 21C09-F01-377513 | 5 |
| Fagron | Miconazole nitrate | 22F08_B02_213580 | 1 |
| Fagron | Miconazole nitrate | 22F08-B02 | 2 |
| Fagron | Miconazole nitrate | 22f08-b02-213149 | 1 |
| Fagron | Miconazole nitrate | 22F08-B02-213149 | 14 |
| Fagron | Miconazole nitrate | 22F-08-B02-213149 | 1 |
| Fagron | Miconazole nitrate | 22F08B02213580 | 1 |
| Fagron | Miconazole nitrate | 22F08-B02-221067 | 3 |
| Fagron | Miconazole nitrate | 22F08B02213580 | 1 |
| Fagron | Miconazole nitrate | 22F08-B02-221067 | 1 |
| Fagron | Miconazole nitrate | 2366310 | 1 |
| Fagron | Miconazole nitrate | 27061202 | 1 |
| Fagron | Miconazole nitrate | 2900/03/16 | 2 |
| Fagron | Miconazole nitrate | 2900/04/14 | 2 |
| Fagron | Miconazole nitrate | 2900/08/12 | 2 |
| Fagron | Miconazole nitrate | 2900/09/16 | 4 |
| Fagron | Miconazole nitrate | 2900/10/14 | 1 |
| Fagron | Miconazole nitrate | 2900/11/15 | 2 |
| Fagron | Miconazole nitrate | 2900/15/13 | 2 |
| Fagron | Miconazole nitrate | 2900/16/14 | 4 |
| Fagron | Miconazole nitrate | 2900-03-16 | 1 |
| Fagron | Miconazole nitrate | 29091808 | 1 |
| Fagron | Miconazole nitrate | 2OB21-F04-3700400 | 1 |
| Fagron | Miconazole nitrate | 31101306 | 1 |
| Fagron | Miconazole nitrate | 3248 | 1 |
| Fagron | Miconazole nitrate | 4111301 | 1 |
| Fagron | Miconazole nitrate | 8568674 | 1 |
| Fagron | Miconazole nitrate | B01-3593902 | 1 |
| Fagron | Miconazole nitrate | B01-3593906 | 1 |
| Fagron | Miconazole nitrate | B01-359396 | 1 |
| Fagron | Miconazole nitrate | B01-3606104 | 1 |
| Fagron | Miconazole nitrate | F01-377510 | 1 |
| Fagron | Miconazole nitrate | F02-3670602 | 1 |
| Fagron | Miconazole nitrate | F04-3700307 | 2 |
| Fagron | Miconazole nitrate | F04-3700400 | 1 |
| Fagron | Miconazole nitrate | F04-3763404 | 1 |
| Fargon/Phönix | Miconazole nitrate | 19J16-F02-367063 | 1 |
| Fargon | Miconazole nitrate | 14D25-B06-294959 | 1 |
| Fargon | Miconazole nitrate | 18B06-B03-345423 | 1 |
| Fargon | Miconazole nitrate | 22F08-B02-213149 | 1 |
| Faron | Miconazole nitrate | 19A31-B01-359397 | 1 |
| Fiebig | Miconazole nitrate | 15/08-B07-314838 | 1 |
| Fiebig | Miconazole nitrate | 16144726 | 1 |
| Fischar / Geilenkirchen | Miconazole nitrate | 16144726 | 1 |
| Fragon | Miconazole nitrate | 18C23-B02-348857 | 1 |
| GEHE 13.05 | Miconazole nitrate | 14149311 | 1 |
| Gehe/Ichthyol | Miconazole nitrate | 16E04-B03-322132 | 1 |
| gehe | Miconazole nitrate | 13185611 | 2 |
| Gehe | Miconazole nitrate | 13352802 | 4 |
| Gehe | Miconazole nitrate | 13352811 | 1 |
| Gehe | Miconazole nitrate | 14149301 | 1 |
| Gehe | Miconazole nitrate | 16144702 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Miconazole nitrate | 16144704 | 1 |
| Gehe | Miconazole nitrate | 16144711 | 1 |
| GEHE | Miconazole nitrate | 16144716 | 1 |
| Gehe | Miconazole nitrate | 16144720 | 1 |
| Gehe | Miconazole nitrate | 16E04-B03-327362 | 1 |
| GEHE | Miconazole nitrate | 18057903 | 1 |
| Gehe | Miconazole nitrate | 18282105 | 1 |
| Gehe | Miconazole nitrate | 18B06-B03-345419 | 1 |
| Gehe | Miconazole nitrate | 20000097005 | 1 |
| Gehe | Miconazole nitrate | 21000827003 | 1 |
| Gehe | Miconazole nitrate | 21000827008 | 2 |
| Gehe | Miconazole nitrate | 21000827016 | 1 |
| Gehe | Miconazole nitrate | 21000827023 | 1 |
| Gehe | Miconazole nitrate | 210301201 | 1 |
| Gehe | Miconazole nitrate | 2210002-01 | 1 |
| Gehe | Miconazole nitrate | 22F08-B02-221067 | 3 |
| Gehe | Miconazole nitrate | 23000589003 | 3 |
| Gehe | Miconazole nitrate | 2311020-01 | 1 |
| gehe-06.11.18 | Miconazole nitrate | 18057906 | 1 |
| Geibo/Noweda | Miconazole nitrate | 17217503 | 1 |
| Geilenkirchen | Miconazole nitrate | 17217505 | 3 |
| Geilenkirchen | Miconazole nitrate | 18057914 | 1 |
| Hedinger | Miconazole nitrate | 16144720 | 2 |
| Hedinger | Miconazole nitrate | P2018/114 | 1 |
| Herstellung | Miconazole nitrate | 13185602 | 1 |
| Holdermann | Miconazole nitrate | 21000827026 | 3 |
| Holdermann | Miconazole nitrate | 23000589001 | 1 |
| Ichthyol/Phoenix | Miconazole nitrate | 16/098/M | 1 |
| Jenne | Miconazole nitrate | 21000827002 | 1 |
| Jenne | Miconazole nitrate | 23000589004 | 1 |
| Jenne | Miconazole nitrate | 241101(23000589003) | 1 |
| Kehr Holdermann | Miconazole nitrate | 22F08-B02-221067 | 1 |
| Kehr Holdermann | Miconazole nitrate | 23000589003 | 1 |
| Kehr | Miconazole nitrate | 17C01-B02-334877 | 1 |
| Kehr | Miconazole nitrate | 21000827022 | 2 |
| Kehr | Miconazole nitrate | 21000827024 | 3 |
| Kehr | Miconazole nitrate | 21000827026 | 2 |
| Kehr | Miconazole nitrate | 22F08-B02 | 1 |
| Kehr | Miconazole nitrate | 23000589004 | 6 |
| Kehr | Miconazole nitrate | 230027303 | 1 |
| Kehr | Miconazole nitrate | 23003273003 | 2 |
| Kehr-Holdermann | Miconazole nitrate | 22F08-B02-213149 | 1 |
| Miconazolnitrat | Miconazole nitrate | 20B21-F04-376344 | 1 |
| Noveda | Miconazole nitrate | 18282105 | 1 |
| Noweda 10.12.2019 | Miconazole nitrate | 18282106 | 1 |
| Noweda 26.11.2019 | Miconazole nitrate | 18282111 | 1 |
| Noweda | Miconazole nitrate | | 1 |
| Noweda | Miconazole nitrate | 13352806 | 1 |
| Noweda | Miconazole nitrate | 14149310 | 1 |
| Noweda | Miconazole nitrate | 14149311 | 1 |
| Noweda | Miconazole nitrate | 15137903 | 1 |
| Noweda | Miconazole nitrate | 16144704 | 1 |
| Noweda | Miconazole nitrate | 16144721 | 1 |
| Noweda | Miconazole nitrate | 16E04-B03-322124 | 1 |
| Noweda | Miconazole nitrate | 1705039-02 | 1 |
| Noweda | Miconazole nitrate | 17217502 | 1 |
| Noweda | Miconazole nitrate | 17217505 | 1 |
| Noweda | Miconazole nitrate | 18057913 | 1 |
| Noweda | Miconazole nitrate | 18282109 | 1 |
| Noweda | Miconazole nitrate | 18282113 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Miconazole nitrate | 19A31-B01-359392 | 3 |
| Noweda | Miconazole nitrate | 20000097003 | 1 |
| Noweda | Miconazole nitrate | 21000827008 | 1 |
| Noweda | Miconazole nitrate | 21000827013 | 1 |
| Noweda | Miconazole nitrate | 21000827016 | 1 |
| Noweda | Miconazole nitrate | 21000827017 | 1 |
| Noweda | Miconazole nitrate | 21000827019 | 1 |
| Noweda | Miconazole nitrate | 21000827022 | 1 |
| Noweda | Miconazole nitrate | 21000827024 | 1 |
| Noweda | Miconazole nitrate | 2210002-01 | 1 |
| Noweda | Miconazole nitrate | 221002-01 | 1 |
| Noweda | Miconazole nitrate | 22F08-B02 | 1 |
| Noweda | Miconazole nitrate | 22F08-B02-213580 | 1 |
| Noweda | Miconazole nitrate | 22F08-B02-221 | 1 |
| Noweda | Miconazole nitrate | 23003273003 | 3 |
| Noweda | Miconazole nitrate | 23003273004 | 1 |
| Noweda | Miconazole nitrate | 2311020-01 | 4 |
| Noweda | Miconazole nitrate | 23G31-B07-232096 | 2 |
| Olon (Lodiagiano)/Sa... | Miconazole nitrate | 2050000157 | 1 |
| Otto Geilenkirchen | Miconazole nitrate | 21000827024 | 1 |
| Phoenix 21.10.14 | Miconazole nitrate | 14149301 | 1 |
| Phoenix | Miconazole nitrate | 13185611 | 1 |
| Phoenix | Miconazole nitrate | 13352801 | 1 |
| Phoenix | Miconazole nitrate | 15137915 | 1 |
| Phoenix | Miconazole nitrate | 15E04-B03-327367 | 1 |
| Phoenix | Miconazole nitrate | 17C01-B02-334882 | 1 |
| Phoenix | Miconazole nitrate | 18C23-B02-352489 | 1 |
| Phoenix | Miconazole nitrate | 21000827022 | 1 |
| Phoenix | Miconazole nitrate | 22110002-01 | 1 |
| Phoenix | Miconazole nitrate | 23000589004 | 1 |
| Phoenix | Miconazole nitrate | 23003273003 | 2 |
| Phoenix | Miconazole nitrate | B01-3606104 | 1 |
| PhoenixWE: 18.05.18 ... | Miconazole nitrate | 16144726 | 2 |
| PhoenixWE: 28.04.18 ... | Miconazole nitrate | 17217505 | 1 |
| Phönix | Miconazole nitrate | 13H28-N06 | 1 |
| phönix | Miconazole nitrate | 15137907 | 1 |
| phönix | Miconazole nitrate | 16144701 | 2 |
| phönix | Miconazole nitrate | 16144716 | 1 |
| Phönix | Miconazole nitrate | 16E04-B03-322124 | 1 |
| Phönix | Miconazole nitrate | 16E04-B03-322131 | 1 |
| Phönix | Miconazole nitrate | 17217502 | 2 |
| Phönix | Miconazole nitrate | 18C23-B02-355707 | 1 |
| Phönix | Miconazole nitrate | 1909029-01 | 1 |
| Phönix | Miconazole nitrate | 2009034-01 | 1 |
| Phönix | Miconazole nitrate | 20B21f04376344 | 1 |
| Phönix | Miconazole nitrate | 20B21-F04-376344 | 1 |
| Phönix | Miconazole nitrate | 2103012-01 | 3 |
| Phönix | Miconazole nitrate | 2210002-01 | 3 |
| Phönix | Miconazole nitrate | 230003273003 | 1 |
| Phönix | Miconazole nitrate | 23000589003 | 1 |
| Phönix | Miconazole nitrate | 23003273003 | 1 |
| Phönix | Miconazole nitrate | 230033273004 | 1 |
| Phönix | Miconazole nitrate | 3133 | 1 |
| Phönixgentamy | Miconazole nitrate | 21000827024 | 1 |
| Sanacop | Miconazole nitrate | | 1 |
| Sanacorp EK:5,95 ... | Miconazole nitrate | 16144703 | 1 |
| Sanacorp | Miconazole nitrate | | 1 |
| Sanacorp | Miconazole nitrate | 12243801 | 1 |
| Sanacorp | Miconazole nitrate | 12243803 | 2 |
| Sanacorp | Miconazole nitrate | 12374301 | 3 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Miconazole nitrate | 13352801 | 1 |
| Sanacorp | Miconazole nitrate | 13352802 | 2 |
| Sanacorp | Miconazole nitrate | 16144720 | 1 |
| Sanacorp | Miconazole nitrate | 16144726 | 1 |
| Sanacorp | Miconazole nitrate | 18057903 | 1 |
| Sanacorp | Miconazole nitrate | 18057912 | 1 |
| Sanacorp | Miconazole nitrate | 18057913 | 1 |
| Sanacorp | Miconazole nitrate | 18282107 | 1 |
| Sanacorp | Miconazole nitrate | 18282108 | 1 |
| Sanacorp | Miconazole nitrate | 18282112 | 2 |
| Sanacorp | Miconazole nitrate | 18282113 | 1 |
| Sanacorp | Miconazole nitrate | 18C23-B02-351310 | 1 |
| Sanacorp | Miconazole nitrate | 21000827006 | 1 |
| Sanacorp | Miconazole nitrate | 21000827008 | 1 |
| Sanacorp | Miconazole nitrate | 21000827011 | 1 |
| Sanacorp | Miconazole nitrate | 21000827015 | 1 |
| Sanacorp | Miconazole nitrate | 21000827023 | 1 |
| Sanacorp | Miconazole nitrate | 21000827025 | 2 |
| Sanacorp | Miconazole nitrate | 21000837088 | 1 |
| Sanacorp | Miconazole nitrate | 2210002-01 | 1 |
| Sanacorp | Miconazole nitrate | 22Fo8-B02-221067 | 1 |
| Sanacorp | Miconazole nitrate | 23000589003 | 1 |
| sanacorp | Miconazole nitrate | 23003273004 | 1 |
| Sanacorp | Miconazole nitrate | 2900/09/16 | 1 |

- 253 280 spectra from 1666 *Apo-Ident* customers from a total of 51 619 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Miconazole nitrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Miconazole nitrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 499 | 0 | 157 827 |
| **Type B** | 0 | 730 | 0 | 212 210 |
| **Type C** | 0 | 3599 | 7 | 253 280 |

The substance/substance group *Miconazole nitrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7976 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.1781 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8059 % (> 99.7227 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20817 | 21900 | 6.42 | 53.14 |
| 20875 | 21350 | 8.61 | 53.21 |
| 20905 | 21900 | 7.85 | 46.85 |
| 21350 | 21350 | 0.00 | 52.40 |
| 21351 | 21350 | 2.75 | 51.04 |
| 21649 | 21900 | 6.94 | 51.56 |
| 21900 | 21900 | 0.00 | 53.79 |
| 22630 | 22630 | 0.00 | 54.85 |
| 24593 | 21900 | 6.72 | 53.40 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Minoxidil** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20879-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Minoxidil; Minoxidilum

### Special notes

When selecting the *Minoxidil* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Minoxidil | 10 | 22 | 627 |

### Second-stage model

For differentiation of the substance/substance group *Minoxidil* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Minoxidil* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 70.85 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Minoxidil* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Minoxidil*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Minoxidil | 13039501 | 20879 | 40 | 20130306 |
| Caelo | Minoxidil | 14093701 | 21359 | 40 | 20140428 |
| Caelo | Minoxidil | 14093701 | 21361 | 40 | 20140428 |
| Euro OTC | Minoxidil | 1311038-01 | 21630 | 59 | AR-15-FG-007848-01 |
| Euro OTC | Minoxidil | 1411006-01 | 21912 | 60 | 20141210 |
| Euro OTC | Minoxidil | 1509035 | 21933 | 60 | 20151016* |
| Euro OTC | Minoxidil | 1602013 | 22365 | 60 | 20160225* |
| Euro OTC | Minoxidil | 1612011 | 22982 | 40 | 20170130* |
| Euro OTC | Minoxidil | 2004030 | 25162 | 40 | 20200528* |
| Euro OTC | Minoxidil | 2109021 | 25888 | 50 | 20211104* |
| Euro OTC | Minoxidil | 2109021 | 25888SI | 50 | 20211104* |
| Euro OTC | Minoxidil | 2209016 | 26337 | 40 | 20221005* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 579 spectra of 12 reference samples from the substance/substance group *Minoxidil*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 747 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1640 spectra of 39 reference samples from the substance/substance group *Minoxidil*.

- Among them are spectra of independent samples from 22 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Minoxidil | 172278 | 23816 | 40 |
| Caelo | Minoxidil | 191957 | 24758 | 40 |
| Caelo | Minoxidil | 20001705 | 25613 | 40 |
| Caelo | Minoxidil | 23001171 | 26845 | 40 |
| Caelo | Minoxidil | 24002249 | 27436 | 40 |
| Caelo | Minoxidil | 24002248 | 27441 | 40 |
| Euro OTC | Minoxidil | 1607007 | 22688 | 40 |
| Euro OTC | Minoxidil | 1705008 | 23437 | 40 |
| Euro OTC | Minoxidil | 1710043 | 23896 | 40 |
| Euro OTC | Minoxidil | 1803004 | 24062 | 40 |
| Euro OTC | Minoxidil | 1807018-01 | 24190 | 40 |
| Euro OTC | Minoxidil | 1901005 | 24489 | 40 |
| Euro OTC | Minoxidil | 1907025 | 24803 | 40 |
| Euro OTC | Minoxidil | 2001035 | 25120 | 40 |
| Euro OTC | Minoxidil | 2008040 | 25334 | 40 |
| Euro OTC | Minoxidil | 2008039 | 25343 | 40 |
| Euro OTC | Minoxidil | 2109018 | 25866 | 50 |
| Euro OTC | Minoxidil | 2209017 | 26349 | 40 |
| Euro OTC | Minoxidil | 2311021 | 27342 | 40 |
| Euro OTC | Minoxidil | 2411007 | 27522 | 40 |
| Euro OTC | Minoxidil | 2503014 | 27620 | 40 |
| Fagron | Minoxidil | 22C01-B03-218964 | 26139 | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Minoxidil | 20001705 | 25613SI | 40 |
| Caelo | Minoxidil | 23001171 | 26845SI | 40 |
| Caelo | Minoxidil | 24002249 | 27436SI | 40 |
| Caelo | Minoxidil | 24002248 | 27441SI | 40 |
| Euro OTC | Minoxidil | 1411006-01 | 21912SI† | 60 |
| Euro OTC | Minoxidil | 1509035 | 21933SI† | 60 |
| Euro OTC | Minoxidil | 1602013 | 22365SI† | 60 |
| Euro OTC | Minoxidil | 1612011 | 22982SI† | 40 |
| Euro OTC | Minoxidil | 2008040 | 25334SI | 40 |
| Euro OTC | Minoxidil | 2008039 | 25343SI | 40 |
| Euro OTC | Minoxidil | 2109018 | 25866SI | 50 |
| Euro OTC | Minoxidil | 2209016 | 26337SI† | 40 |
| Euro OTC | Minoxidil | 2209017 | 26349SI | 40 |
| Euro OTC | Minoxidil | 2311021 | 27342SI | 40 |
| Euro OTC | Minoxidil | 2411007 | 27522SI | 40 |
| Euro OTC | Minoxidil | 2503014 | 27620SI | 40 |
| Fagron | Minoxidil | 22C01-B03-218964 | 26139SI | 40 |

- 211 300 spectra from a total of 4260 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3744 spectra from 899 *Apo-Ident* customers from 655 batches from the substance/substance group *Minoxidil*.
- Among them are spectra of independent samples from 595 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Minoxidil | | 1 |
| | Minoxidil | /23/07/3100 | 1 |
| | Minoxidil | /23/11/4909 | 1 |
| | Minoxidil | 181023/11 | 1 |
| | Minoxidil | 21002063004 | 3 |
| | Minoxidil | 21002063013 | 5 |
| | Minoxidil | 21002063017 | 1 |
| | Minoxidil | 21002063018 | 2 |
| | Minoxidil | 21002063019 | 1 |
| | Minoxidil | 21002063022 | 4 |
| | Minoxidil | 21090102 | 2 |
| | Minoxidil | 2109018-01 | 1 |
| | Minoxidil | 2109021-01 | 7 |
| | Minoxidil | 2109021-02 | 10 |
| | Minoxidil | 21F07-B06-213152 | 1 |
| | Minoxidil | 21F07-B07-216955 | 1 |
| | Minoxidil | 22000546001 | 3 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Minoxidil | 22000546002 | 2 |
| | Minoxidil | 22000546005 | 1 |
| | Minoxidil | 22000546006 | 3 |
| | Minoxidil | 22000546008 | 8 |
| | Minoxidil | 22000546010 | 8 |
| | Minoxidil | 22000546011 | 1 |
| | Minoxidil | 22001601 | 1 |
| | Minoxidil | 22003 | 1 |
| | Minoxidil | 22006 | 1 |
| | Minoxidil | 2209016 | 1 |
| | Minoxidil | 2209016-01 | 41 |
| | Minoxidil | 2209017-01 | 25 |
| | Minoxidil | 2209017-02 | 2 |
| | Minoxidil | 2209017-03 | 3 |
| | Minoxidil | 22C01-B03-220935 | 2 |
| | Minoxidil | 22c01-b03-220944 | 1 |
| | Minoxidil | 22C01-B03-220945 | 3 |
| | Minoxidil | 22I05-B04-222924 | 1 |
| | Minoxidil | 22I05-B06 | 1 |
| | Minoxidil | 22I05-B06-225227 | 1 |
| | Minoxidil | 22I05-B06-225228 | 2 |
| | Minoxidil | 23001171001 | 2 |
| | Minoxidil | 23001171003 | 6 |
| | Minoxidil | 23001171004 | 2 |
| | Minoxidil | 2300325300 | 1 |
| | Minoxidil | 23003253001 | 12 |
| | Minoxidil | 23003253003 | 4 |
| | Minoxidil | 23003253004 | 4 |
| | Minoxidil | 23003253005 | 7 |
| | Minoxidil | 23003253008 | 4 |
| | Minoxidil | 23003253009 | 3 |
| | Minoxidil | 23003253014 | 4 |
| | Minoxidil | 23003253015 | 6 |
| | Minoxidil | 23027-B04-230212 | 1 |
| | Minoxidil | 231102101 | 1 |
| | Minoxidil | 2311021-01 | 28 |
| | Minoxidil | 2311021-02 | 4 |
| | Minoxidil | 23A18-B03-227781 | 3 |
| | Minoxidil | 23A18-B04-227787 | 2 |
| | Minoxidil | 23D27-B04-230212 | 3 |
| | Minoxidil | 23H25-B13-234499 | 1 |
| | Minoxidil | 23h25-b13-234500 | 1 |
| | Minoxidil | 23H25-B13-234500 | 4 |
| | Minoxidil | 24002248001 | 6 |
| | Minoxidil | 24002248004 | 1 |
| | Minoxidil | 24002248006 | 1 |
| | Minoxidil | 24002248007 | 1 |
| | Minoxidil | 24B28-B09-237961 | 2 |
| | Minoxidil | 24B28-B09-237962 | 1 |
| | Minoxidil | 24B28-B11-236694 | 1 |
| | Minoxidil | 24B28-B11-236812 | 1 |
| | Minoxidil | 24B28-B12-237964 | 1 |
| | Minoxidil | 24G05-B04-002248 | 1 |
| | Minoxidil | 24G05-B04-002253 | 3 |
| | Minoxidil | 24G05-B04-002255 | 1 |
| | Minoxidil | 24G24-B04-004277 | 2 |
| | Minoxidil | 24G24-B04-004282 | 1 |
| | Minoxidil | B02-0022401 | 1 |
| | Minoxidil | B06-2252202 | 1 |
| | Minoxidil | B13-2345000 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Minoxidil | B14-2344904 | 1 |
| | Minoxidil | K0072/23/07/310 | 2 |
| | Minoxidil | K0072/23/12/559 | 1 |
| | Minoxidil | Minox280623 | 1 |
| /Noweda | Minoxidil | 181498002 | 1 |
| A.H.D | Minoxidil | 1210056-01 | 1 |
| AHC 14.08.13 EK40,14 | Minoxidil | 1210056-02 | 1 |
| AHD/Euro | Minoxidil | 171004301 | 1 |
| AHD | Minoxidil | 1210056-01 | 1 |
| AHD | Minoxidil | 1311038-01 | 1 |
| AHD | Minoxidil | 1504013-02 | 1 |
| AHD | Minoxidil | 15230812 | 1 |
| AHD | Minoxidil | 1602013-01 | 2 |
| AHD | Minoxidil | 18149801 | 1 |
| AHD | Minoxidil | 1907025-02 | 1 |
| AHD | Minoxidil | 200803901 | 1 |
| AHD | Minoxidil | 22000546010 | 1 |
| AHD | Minoxidil | 23003253009 | 1 |
| AHD | Minoxidil | 24B28-B11-236694 | 1 |
| Alliance health | Minoxidil | 1411006-01 | 3 |
| Alliance Healthc. 15... | Minoxidil | 1203035-03 | 1 |
| Alliance Healthcare | Minoxidil | 1210056-01 | 1 |
| Alliance Healthcare | Minoxidil | 1210056-02 | 1 |
| Alliance Healthcare | Minoxidil | 21002063013 | 1 |
| Alliance Healthcare | Minoxidil | 23G05-B06-232249 | 1 |
| Alliance Healthcare | Minoxidil | 24G05-B04-002253 | 1 |
| Alliance | Minoxidil | 21002063017 | 1 |
| Alliance | Minoxidil | 2109018-01 | 3 |
| Alliance | Minoxidil | 2209016-01 | 2 |
| Alliance | Minoxidil | 23A18-B03-227781 | 1 |
| Anzag 14.11.12 ek:40,14 | Minoxidil | 120303501 | 1 |
| Anzag 18.10.12 ek:40,14 | Minoxidil | 1203035-01 | 1 |
| Anzag | Minoxidil | 1112024-02 | 1 |
| Anzag | Minoxidil | 13E13-N10 | 1 |
| Anzag | Minoxidil | 14234505 | 1 |
| anzag | Minoxidil | 1504013-02 | 1 |
| Anzag | Minoxidil | 22000546010 | 2 |
| Anzag | Minoxidil | 2209017-01 | 1 |
| Anzag | Minoxidil | AP020/11M | 2 |
| api-ident | Minoxidil | 1710043-01 | 2 |
| apo-ident. | Minoxidil | 1607007-07 | 1 |
| apoident/ Alliance | Minoxidil | 2109018-01 | 1 |
| Apo-ident | Minoxidil | 190102502 | 1 |
| apomix | Minoxidil | 1504013-02 | 1 |
| apomix | Minoxidil | 1602013-01 | 1 |
| Audor Pharma | Minoxidil | | 51 |
| Audor Pharma | Minoxidil | 16/15M | 1 |
| Audor Pharma | Minoxidil | 1803004-01 | 2 |
| Audor Pharma | Minoxidil | 20008039-01 | 1 |
| Audor Pharma | Minoxidil | 414E-02844 | 1 |
| Audor Pharma | Minoxidil | 8/14M | 1 |
| Audor Pharma | Minoxidil | AP001/16M | 7 |
| Audor Pharma | Minoxidil | AP006/13M | 2 |
| Audor Pharma | Minoxidil | AP006/17M | 5 |
| Audor Pharma | Minoxidil | AP007/15M | 4 |
| Audor Pharma | Minoxidil | AP008/14M | 6 |
| Audor Pharma | Minoxidil | AP010/12M | 5 |
| Audor Pharma | Minoxidil | AP011/16M | 2 |
| Audor Pharma | Minoxidil | AP012/16M | 4 |
| Audor Pharma | Minoxidil | AP012/16M/5270 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Minoxidil | AP016/15M | 8 |
| Audor Pharma | Minoxidil | AP-016/15M | 1 |
| Audor Pharma | Minoxidil | AP020/11M | 1 |
| Audor Pharma | Minoxidil | AP088/14M | 1 |
| Audor Pharma | Minoxidil | APK007 | 1 |
| Audor Pharma | Minoxidil | APK0071/16/04/065-1M | 1 |
| Bombastus | Minoxidil | 1112024-03 | 1 |
| Bombastus | Minoxidil | 1411006-01 | 3 |
| Bombastus | Minoxidil | 1710043-01 | 1 |
| Bombastus | Minoxidil | 4/13 | 1 |
| Caelo | Minoxidil | | 11 |
| Caelo | Minoxidil | 1009042-01 | 3 |
| Caelo | Minoxidil | 1070318/17227803 | 1 |
| Caelo | Minoxidil | 1112024-01 | 1 |
| Caelo | Minoxidil | 11150207 | 1 |
| Caelo | Minoxidil | 11150209 | 1 |
| Caelo | Minoxidil | 11302003 | 1 |
| Caelo | Minoxidil | 11302005 | 1 |
| Caelo | Minoxidil | 11e17-n07 | 1 |
| Caelo | Minoxidil | 11K11-n09 | 1 |
| Caelo | Minoxidil | 12023901 | 2 |
| Caelo | Minoxidil | 12023902 | 1 |
| Caelo | Minoxidil | 12023907 | 4 |
| Caelo | Minoxidil | 12023908 | 1 |
| Caelo | Minoxidil | 1203035 | 1 |
| Caelo | Minoxidil | 1203035-01 | 1 |
| Caelo | Minoxidil | 121005601 | 1 |
| Caelo | Minoxidil | 1210056-01 | 2 |
| Caelo | Minoxidil | 1210056-02 | 1 |
| Caelo | Minoxidil | 12273703 | 2 |
| Caelo | Minoxidil | 12273704 | 3 |
| Caelo | Minoxidil | 12273710 | 1 |
| Caelo | Minoxidil | 12H07-N03 | 4 |
| Caelo | Minoxidil | 13/23-N07 | 1 |
| Caelo | Minoxidil | 13039501 | 7 |
| Caelo | Minoxidil | 13039503 | 3 |
| Caelo | Minoxidil | 130402901 | 1 |
| Caelo | Minoxidil | 130402902 | 1 |
| Caelo | Minoxidil | 1309501 | 1 |
| Caelo | Minoxidil | 1311038-01 | 2 |
| Caelo | Minoxidil | 13179501 | 2 |
| Caelo | Minoxidil | 13179501-3467312121 | 1 |
| Caelo | Minoxidil | 13179502 | 5 |
| Caelo | Minoxidil | 13179503 | 6 |
| Caelo | Minoxidil | 13179504 | 2 |
| Caelo | Minoxidil | 13179507 | 3 |
| Caelo | Minoxidil | 13373106 | 1 |
| Caelo | Minoxidil | 13E13-N10 | 1 |
| Caelo | Minoxidil | 13I23-N07 | 2 |
| Caelo | Minoxidil | 13K04B05290380 | 1 |
| Caelo | Minoxidil | 1405028-01 | 2 |
| Caelo | Minoxidil | 14062018-RQ-A | 1 |
| Caelo | Minoxidil | 14093702 | 2 |
| Caelo | Minoxidil | 14093703 | 4 |
| Caelo | Minoxidil | 14093706 | 3 |
| Caelo | Minoxidil | 14093707 | 1 |
| Caelo | Minoxidil | 1411006-01 | 2 |
| Caelo | Minoxidil | 14234502 | 2 |
| Caelo | Minoxidil | 14234505 | 5 |
| Caelo | Minoxidil | 14234509 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Minoxidil | 14L03-B02-301431 | 1 |
| Caelo | Minoxidil | 150401301 | 1 |
| Caelo | Minoxidil | 1504013-01 | 5 |
| Caelo | Minoxidil | 1504013-02 | 1 |
| Caelo | Minoxidil | 1509035 | 1 |
| Caelo | Minoxidil | 1509035-01 | 5 |
| Caelo | Minoxidil | 1520002455 | 1 |
| Caelo | Minoxidil | 15230802 | 4 |
| Caelo | Minoxidil | 15230803 | 3 |
| Caelo | Minoxidil | 15230804 | 7 |
| Caelo | Minoxidil | 15230806 | 4 |
| Caelo | Minoxidil | 15230811 | 5 |
| Caelo | Minoxidil | 15230812 | 1 |
| Caelo | Minoxidil | 15436024 | 1 |
| Caelo | Minoxidil | 15436201 | 8 |
| Caelo | Minoxidil | 15436202 | 7 |
| Caelo | Minoxidil | 15436202/1060217 | 1 |
| Caelo | Minoxidil | 15436204 | 3 |
| Caelo | Minoxidil | 15436404 | 4 |
| Caelo | Minoxidil | 15436406 | 5 |
| Caelo | Minoxidil | 15436408 | 8 |
| Caelo | Minoxidil | 15436412 | 2 |
| Caelo | Minoxidil | 15436414 | 6 |
| Caelo | Minoxidil | 15436415 | 2 |
| Caelo | Minoxidil | 15E19-B06-308180 | 3 |
| Caelo | Minoxidil | 15E19-B06-308182 | 1 |
| Caelo | Minoxidil | 15E19-B06-308183 | 1 |
| Caelo | Minoxidil | 15E19-B06-309180 | 1 |
| Caelo | Minoxidil | 15H07-B03-317340 | 1 |
| Caelo | Minoxidil | 15K17-B05-318240 | 1 |
| Caelo | Minoxidil | 15K17-B05-318692 | 1 |
| Caelo | Minoxidil | 15K17-B06-321926 | 1 |
| Caelo | Minoxidil | 15k17-b06-324965 | 1 |
| Caelo | Minoxidil | 160013-01 | 1 |
| Caelo | Minoxidil | 1602013-01 | 11 |
| Caelo | Minoxidil | 160201302 | 2 |
| Caelo | Minoxidil | 1602013-02 | 4 |
| Caelo | Minoxidil | 1607007-01 | 4 |
| Caelo | Minoxidil | 160707-01 | 1 |
| Caelo | Minoxidil | 161201101 | 2 |
| Caelo | Minoxidil | 1612011-01 | 10 |
| Caelo | Minoxidil | 16J24-B04-328218 | 1 |
| Caelo | Minoxidil | 16J24-B05-331128 | 1 |
| Caelo | Minoxidil | 16J24-B05-332092 | 1 |
| Caelo | Minoxidil | 170043-01 | 1 |
| Caelo | Minoxidil | 17011602 | 1 |
| Caelo | Minoxidil | 170500801 | 5 |
| Caelo | Minoxidil | 1705008-01 | 7 |
| Caelo | Minoxidil | 1710043-01 | 5 |
| Caelo | Minoxidil | 17227801 | 18 |
| Caelo | Minoxidil | 17227803 | 20 |
| Caelo | Minoxidil | 17228703 | 1 |
| Caelo | Minoxidil | 17H08-B06-341377 | 1 |
| Caelo | Minoxidil | 17H08-B06-342282 | 1 |
| Caelo | Minoxidil | 18016103 | 2 |
| Caelo | Minoxidil | 18016104 | 3 |
| Caelo | Minoxidil | 18016107 | 5 |
| Caelo | Minoxidil | 18016109 | 8 |
| Caelo | Minoxidil | 18016112 | 2 |
| Caelo | Minoxidil | 1803004-001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Minoxidil | 1803004-01 | 3 |
| Caelo | Minoxidil | 1807018_01 | 1 |
| Caelo | Minoxidil | 180701801 | 1 |
| Caelo | Minoxidil | 1807018-01 | 8 |
| Caelo | Minoxidil | 181498001 | 1 |
| Caelo | Minoxidil | 181498002 | 2 |
| Caelo | Minoxidil | 18149801 | 7 |
| Caelo | Minoxidil | 18149802 | 19 |
| Caelo | Minoxidil | 18149805 | 4 |
| Caelo | Minoxidil | 18149810 | 7 |
| Caelo | Minoxidil | 18149811 | 1 |
| Caelo | Minoxidil | 18149813 | 5 |
| Caelo | Minoxidil | 18149815 | 18 |
| Caelo | Minoxidil | 18159810 | 1 |
| Caelo | Minoxidil | 187018-01 | 1 |
| Caelo | Minoxidil | 18C20-B01-35661844 | 1 |
| Caelo | Minoxidil | 18C27-B01 | 1 |
| Caelo | Minoxidil | 1901005-01 | 3 |
| Caelo | Minoxidil | 190702501 | 1 |
| Caelo | Minoxidil | 1907025-01 | 1 |
| Caelo | Minoxidil | 190702502 | 1 |
| Caelo | Minoxidil | 19149810 | 1 |
| Caelo | Minoxidil | 19157002 | 1 |
| Caelo | Minoxidil | 19157004 | 1 |
| Caelo | Minoxidil | 191957002 | 7 |
| Caelo | Minoxidil | 191957003 | 7 |
| Caelo | Minoxidil | 191957004 | 5 |
| Caelo | Minoxidil | 191957007 | 7 |
| Caelo | Minoxidil | 191957010 | 6 |
| Caelo | Minoxidil | 200001705004 | 1 |
| Caelo | Minoxidil | 2000040 | 1 |
| Caelo | Minoxidil | 20001705004 | 4 |
| Caelo | Minoxidil | 20004048001 | 2 |
| Caelo | Minoxidil | 20004048003 | 9 |
| Caelo | Minoxidil | 20004048005 | 6 |
| Caelo | Minoxidil | 20004048008 | 2 |
| Caelo | Minoxidil | 20004048009 | 7 |
| Caelo | Minoxidil | 20004048012 | 2 |
| Caelo | Minoxidil | 2000408012 | 1 |
| Caelo | Minoxidil | 200804001 | 1 |
| Caelo | Minoxidil | 2008040-01 | 1 |
| Caelo | Minoxidil | 20151112-5 | 1 |
| Caelo | Minoxidil | 20160211-1 | 1 |
| Caelo | Minoxidil | 21002063001 | 9 |
| Caelo | Minoxidil | 21002063003 | 8 |
| Caelo | Minoxidil | 21002063004 | 2 |
| Caelo | Minoxidil | 21002063005 | 3 |
| Caelo | Minoxidil | 21002063006 | 9 |
| Caelo | Minoxidil | 21002063009 | 2 |
| Caelo | Minoxidil | 21002063010 | 1 |
| Caelo | Minoxidil | 21002063011 | 4 |
| Caelo | Minoxidil | 21002063012 | 5 |
| Caelo | Minoxidil | 21002063013 | 1 |
| Caelo | Minoxidil | 21002063015 | 2 |
| Caelo | Minoxidil | 21002063017 | 6 |
| Caelo | Minoxidil | 21002063018 | 10 |
| Caelo | Minoxidil | 2109018-01 | 1 |
| Caelo | Minoxidil | 210902101 | 1 |
| Caelo | Minoxidil | 22000546005 | 3 |
| Caelo | Minoxidil | 22000546008 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Minoxidil | 22000546010 | 1 |
| Caelo | Minoxidil | 2203140 2 | 1 |
| Caelo | Minoxidil | 23003253001 | 1 |
| Caelo | Minoxidil | 2827 | 1 |
| Caelo | Minoxidil | 2905047-01 | 1 |
| Caelo | Minoxidil | 3013M-02844 | 1 |
| Caelo | Minoxidil | 31051305 | 1 |
| Caelo | Minoxidil | 41/17 | 1 |
| Caelo | Minoxidil | 5081502 | 1 |
| Caelo | Minoxidil | 5217M-02844 | 1 |
| Caelo | Minoxidil | 8719 | 1 |
| Caelo | Minoxidil | AP006/17M | 1 |
| Caelo | Minoxidil | AP011/16M | 1 |
| Caelo | Minoxidil | K0071/16/04/065 | 1 |
| Caesaer/Jenne | Minoxidil | 18016103 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 14093702 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 14234505 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 21002063004 | 2 |
| Caesar & Loretz GmbH... | Minoxidil | 18149813 | 1 |
| Caesar & Loretz GmbH/AHD | Minoxidil | 20004048009 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 20004048005 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 20004048008 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 191957002 | 1 |
| Caesar & Loretz GmbH/Gehe | Minoxidil | 23003253014 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 20004048012 | 1 |
| Caesar & Loretz GmbH... | Minoxidil | 21002063006 | 3 |
| Caesar & Loretz GmbH | Minoxidil | | 1 |
| Caesar & Loretz GmbH | Minoxidil | 13039501 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 17227803 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 181498002 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 18149801 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 18149802 | 4 |
| Caesar & Loretz GmbH' | Minoxidil | 18149802 | 2 |
| Caesar & Loretz GmbH | Minoxidil | 18149810 | 2 |
| Caesar & Loretz GmbH | Minoxidil | 18149813 | 3 |
| Caesar & Loretz GmbH | Minoxidil | 18149815 | 5 |
| Caesar & Loretz GmbH | Minoxidil | 191957002 | 4 |
| Caesar & Loretz GmbH | Minoxidil | 191957004 | 3 |
| Caesar & Loretz GmbH | Minoxidil | 191957007 | 5 |
| Caesar & Loretz GmbH | Minoxidil | 191957010 | 3 |
| Caesar & Loretz GmbH | Minoxidil | 20001705004 | 7 |
| Caesar & Loretz GmbH | Minoxidil | 20004048003 | 2 |
| Caesar & Loretz GmbH | Minoxidil | 20004048005 | 7 |
| Caesar & Loretz GmbH | Minoxidil | 20004048008 | 4 |
| Caesar & Loretz GmbH | Minoxidil | 20004048009 | 3 |
| Caesar & Loretz GmbH | Minoxidil | 20004048012 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 21000123003 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 21002063001 | 3 |
| Caesar & Loretz GmbH | Minoxidil | 21002063003 | 5 |
| Caesar & Loretz GmbH | Minoxidil | 21002063004 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 21002063005 | 2 |
| Caesar & Loretz GmbH | Minoxidil | 21002063006 | 2 |
| Caesar & Loretz GmbH | Minoxidil | 21002063007 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 21002063011 | 2 |
| Caesar & Loretz GmbH | Minoxidil | 21002063012 | 3 |
| Caesar & Loretz GmbH | Minoxidil | 21002063017 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 21002063018 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 22000546001 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 22000546005 | 1 |
| Caesar & Loretz GmbH | Minoxidil | 22000546008 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz | Minoxidil | 15436414 | 1 |
| Caleo/ Noweda | Minoxidil | 18016104 | 1 |
| Cealo/Alliance Healthcare | Minoxidil | 22000546007 | 3 |
| Doppeleiche Apotheke | Minoxidil | 13E13-N10 | 2 |
| Dr. Wolff / Sanacorp | Minoxidil | 1901005-01 | 2 |
| Dr.August Wolff | Minoxidil | 1602013-02 | 2 |
| EuRho / 2 | Minoxidil | 2004030-01 | 1 |
| EuRho / Noweda | Minoxidil | 1304029-02 | 1 |
| EuRho / Sanacorp | Minoxidil | 1710043-01 | 1 |
| EuRho/ Alliance | Minoxidil | 1705008-01 | 1 |
| EuRho/ Alliance | Minoxidil | 1901005-01 | 1 |
| EuRho/ Noweda | Minoxidil | 1807018-01 | 1 |
| EuRho/ NOWEDA | Minoxidil | 1807018-01 | 1 |
| EuRho/ Phoenix | Minoxidil | 2008040-01 | 4 |
| EuRho/ Phoenix | Minoxidil | 2109018-01 | 2 |
| EuRho/Anzag | Minoxidil | 1411006-01 | 1 |
| EuRho/Fiebig | Minoxidil | 1411006-01 | 1 |
| EuRho/Gehe | Minoxidil | 2008039-01 | 2 |
| EuRho/Gehe | Minoxidil | 2109018-01 | 1 |
| EuRho/Kehr | Minoxidil | 1803004-01 | 2 |
| EuRho/Kehr | Minoxidil | 30/17 | 1 |
| EuRho/Noweda | Minoxidil | 1607007-01 | 1 |
| EuRho/Noweda | Minoxidil | 1710043-01 | 2 |
| euRho/Noweda | Minoxidil | 2109018-01 | 1 |
| EuRho/Noweda | Minoxidil | 2109018-01 | 3 |
| Eurho/Noweda | Minoxidil | 2109021-01 | 7 |
| EuRho/Noweda | Minoxidil | 2209017-01 | 1 |
| EuRho/Phoenix | Minoxidil | 2008040-01 | 4 |
| Eurho/Phönix | Minoxidil | 2004030-01 | 1 |
| Eurho/Phönix | Minoxidil | 2008039-01 | 1 |
| EuRho/Sanacorp | Minoxidil | 17050008-01 | 1 |
| EuRho/Sanacorp | Minoxidil | 1803004-01 | 2 |
| EuRho/Sanacorp | Minoxidil | 1901005-01 | 2 |
| EuRho/Sanacorp | Minoxidil | 1907025-01 | 2 |
| EuRho/Sanacorp | Minoxidil | 2004030-01 | 1 |
| EuRho | Minoxidil | 1105030-02 | 1 |
| EuRho | Minoxidil | 1108039-02 | 2 |
| EuRho | Minoxidil | 1411006-01 | 2 |
| EuRho | Minoxidil | 1602013-02 | 1 |
| eurho | Minoxidil | 1705008-01 | 1 |
| EuRho | Minoxidil | 1705008-01 | 1 |
| EuRho | Minoxidil | 1710043-01 | 5 |
| Eurho | Minoxidil | 1803004-01 | 2 |
| EuRho | Minoxidil | 1803004-01 | 1 |
| EuRho | Minoxidil | 1807018-01 | 3 |
| EuRho | Minoxidil | 1901005-01 | 3 |
| EuRho | Minoxidil | 2004030-01 | 5 |
| EuRho | Minoxidil | 2008039-01 | 2 |
| euRho | Minoxidil | 2008040-01 | 1 |
| Eurho | Minoxidil | 2008040-01 | 1 |
| EuRho | Minoxidil | 2008040-01 | 3 |
| EuRho | Minoxidil | 2109018-01 | 2 |
| EuRho | Minoxidil | 2109021-01 | 1 |
| Eurho | Minoxidil | 2109021-02 | 2 |
| Euro OCT / Krieger | Minoxidil | 2001035-01 | 1 |
| Euro OT/Phönix | Minoxidil | 1710043-01 | 1 |
| Euro OTC | Minoxidil | | 17 |
| Euro OTC | Minoxidil | /18/07/1402 | 1 |
| Euro OTC | Minoxidil | 10/13 | 1 |
| Euro OTC | Minoxidil | 103004-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Minoxidil | 104029-02 | 1 |
| Euro OTC | Minoxidil | 1102010-02 | 1 |
| Euro OTC | Minoxidil | 1108039-01 | 1 |
| Euro OTC | Minoxidil | 1108039-03 | 1 |
| Euro OTC | Minoxidil | 1112024-01 | 1 |
| Euro OTC | Minoxidil | 1112024-02 | 5 |
| Euro OTC | Minoxidil | 1112024-03 | 3 |
| Euro OTC | Minoxidil | 12/16 | 2 |
| Euro OTC | Minoxidil | 12/17 | 2 |
| Euro OTC | Minoxidil | 1203035 | 1 |
| Euro OTC | Minoxidil | 1203035-01 | 10 |
| Euro OTC | Minoxidil | 1203035-02 | 6 |
| Euro OTC | Minoxidil | 120303503 | 1 |
| Euro OTC | Minoxidil | 1203035-03 | 11 |
| Euro OTC | Minoxidil | 12100056-01 | 1 |
| Euro OTC | Minoxidil | 121005601 | 1 |
| Euro OTC | Minoxidil | 1210056-01 | 14 |
| Euro OTC | Minoxidil | 1210056-02 | 23 |
| Euro OTC | Minoxidil | 13001 | 1 |
| Euro OTC | Minoxidil | 130402901 | 1 |
| Euro OTC | Minoxidil | 1304029-01 | 16 |
| Euro OTC | Minoxidil | 130402902 | 1 |
| Euro OTC | Minoxidil | 1304029-02 | 15 |
| Euro OTC | Minoxidil | 1304029-C2 | 1 |
| Euro OTC | Minoxidil | 131103801 | 4 |
| Euro OTC | Minoxidil | 1311038-01 | 30 |
| Euro OTC | Minoxidil | 13110838-01 | 1 |
| Euro OTC | Minoxidil | 140502801 | 3 |
| Euro OTC | Minoxidil | 1405028-01 | 29 |
| Euro OTC | Minoxidil | 14050281 | 1 |
| Euro OTC | Minoxidil | 1405028-1 | 1 |
| Euro OTC | Minoxidil | 140528-01 | 1 |
| Euro OTC | Minoxidil | 141100601 | 5 |
| Euro OTC | Minoxidil | 1411006-01 | 38 |
| Euro OTC | Minoxidil | 1411006601 | 1 |
| Euro OTC | Minoxidil | 150401-01 | 1 |
| Euro OTC | Minoxidil | 1504013-01 | 38 |
| Euro OTC | Minoxidil | 1504013-02 | 27 |
| Euro OTC | Minoxidil | 1504013-2 | 1 |
| Euro OTC | Minoxidil | 15081829 | 1 |
| Euro OTC | Minoxidil | 1509035-01 | 40 |
| Euro OTC | Minoxidil | 15436404 | 1 |
| Euro OTC | Minoxidil | 160201301 | 1 |
| Euro OTC | Minoxidil | 1602013-01 | 44 |
| Euro OTC | Minoxidil | 1602013-02 | 12 |
| Euro OTC | Minoxidil | 1602013-1 | 1 |
| Euro OTC | Minoxidil | 1602016-01 | 1 |
| Euro OTC | Minoxidil | 16070007-01 | 1 |
| Euro OTC | Minoxidil | 1607001-01 | 1 |
| Euro OTC | Minoxidil | 1607007 | 1 |
| Euro OTC | Minoxidil | 160700701 | 3 |
| Euro OTC | Minoxidil | 1607007-01 | 43 |
| Euro OTC | Minoxidil | 16112011-01 | 2 |
| Euro OTC | Minoxidil | 16120-01 | 1 |
| Euro OTC | Minoxidil | 161201-01 | 1 |
| Euro OTC | Minoxidil | 1612011 | 1 |
| Euro OTC | Minoxidil | 161201101 | 2 |
| Euro OTC | Minoxidil | 1612011-01 | 79 |
| Euro OTC | Minoxidil | 1612011-011 | 1 |
| Euro OTC | Minoxidil | 16122011_01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Minoxidil | 17050008 | 1 |
| Euro OTC | Minoxidil | 1705008_01 | 1 |
| Euro OTC | Minoxidil | 170500801 | 3 |
| Euro OTC | Minoxidil | 1705008-01 | 59 |
| Euro OTC | Minoxidil | 1707018-01 | 1 |
| Euro OTC | Minoxidil | 170703M/1602013-02 | 1 |
| Euro OTC | Minoxidil | 1710043_01 | 1 |
| Euro OTC | Minoxidil | 171004301 | 9 |
| Euro OTC | Minoxidil | 1710043-01 | 104 |
| Euro OTC | Minoxidil | 17100-43-01 | 1 |
| Euro OTC | Minoxidil | 1710043-03 | 1 |
| Euro OTC | Minoxidil | 17H08-B06 | 1 |
| Euro OTC | Minoxidil | 17H08-B06-342282 | 1 |
| Euro OTC | Minoxidil | 17H08-B09-346945 | 1 |
| Euro OTC | Minoxidil | 18030004-01 | 1 |
| Euro OTC | Minoxidil | 1803004 | 1 |
| Euro OTC | Minoxidil | 1803004_01 | 2 |
| Euro OTC | Minoxidil | 180300401 | 7 |
| Euro OTC | Minoxidil | 1803004-01 | 113 |
| Euro OTC | Minoxidil | 180304-01 | 1 |
| Euro OTC | Minoxidil | 1807017-01 | 1 |
| Euro OTC | Minoxidil | 1807018 | 1 |
| Euro OTC | Minoxidil | 180701801 | 1 |
| Euro OTC | Minoxidil | 1807018-01 | 55 |
| Euro OTC | Minoxidil | 1807018-02 | 3 |
| Euro OTC | Minoxidil | 180708-01 | 1 |
| Euro OTC | Minoxidil | 180718-01 | 1 |
| Euro OTC | Minoxidil | 19/15 | 1 |
| Euro OTC | Minoxidil | 19/16 | 1 |
| Euro OTC | Minoxidil | 190100-01 | 1 |
| Euro OTC | Minoxidil | 19010005-01 | 1 |
| Euro OTC | Minoxidil | 190100501 | 3 |
| Euro OTC | Minoxidil | 1901005-01 | 83 |
| Euro OTC | Minoxidil | 19011005-01 | 1 |
| Euro OTC | Minoxidil | 1907025 | 1 |
| Euro OTC | Minoxidil | 1907025_01 | 1 |
| Euro OTC | Minoxidil | 190702501 | 4 |
| Euro OTC | Minoxidil | 1907025-01 | 66 |
| Euro OTC | Minoxidil | 190702502 | 4 |
| Euro OTC | Minoxidil | 1907025-02 | 38 |
| Euro OTC | Minoxidil | 1907025-41 | 1 |
| Euro OTC | Minoxidil | 1919 | 1 |
| Euro OTC | Minoxidil | 20004048005 | 1 |
| Euro OTC | Minoxidil | 2000804001 | 1 |
| Euro OTC | Minoxidil | 20008040-01 | 1 |
| Euro OTC | Minoxidil | 2001035-01 | 23 |
| Euro OTC | Minoxidil | 2002312844 | 1 |
| Euro OTC | Minoxidil | 2004020-01 | 1 |
| Euro OTC | Minoxidil | 200403001 | 9 |
| Euro OTC | Minoxidil | 2004030-01 | 125 |
| Euro OTC | Minoxidil | 2004030-1 | 2 |
| Euro OTC | Minoxidil | 20080039-01 | 1 |
| Euro OTC | Minoxidil | 200803901 | 9 |
| Euro OTC | Minoxidil | 2008039-01 | 97 |
| Euro OTC | Minoxidil | 2008040 | 2 |
| Euro OTC | Minoxidil | 2008040_01 | 2 |
| Euro OTC | Minoxidil | 200804001 | 4 |
| Euro OTC | Minoxidil | 2008040-01 | 111 |
| Euro OTC | Minoxidil | 2008040-1 | 1 |
| Euro OTC | Minoxidil | 200840-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Minoxidil | 2091714 | 1 |
| Euro OTC | Minoxidil | 210018-01 | 1 |
| Euro OTC | Minoxidil | 2103021-02 | 1 |
| Euro OTC | Minoxidil | 2109018 | 1 |
| Euro OTC | Minoxidil | 210901801 | 3 |
| Euro OTC | Minoxidil | 2109018-01 | 82 |
| Euro OTC | Minoxidil | 2109021-01 | 28 |
| Euro OTC | Minoxidil | 2109021-02 | 11 |
| Euro OTC | Minoxidil | 21090918-01 | 1 |
| Euro OTC | Minoxidil | 210918-01 | 1 |
| Euro OTC | Minoxidil | 210921-02 | 1 |
| Euro OTC | Minoxidil | 2209016-01 | 6 |
| Euro OTC | Minoxidil | 2209017-01 | 1 |
| Euro OTC | Minoxidil | 29071402 | 1 |
| Euro OTC | Minoxidil | 4/13 | 2 |
| Euro OTC | Minoxidil | 4004030-01 | 1 |
| Euro OTC | Minoxidil | 6/12 | 2 |
| Euro OTC | Minoxidil | 6614849 | 1 |
| Euro OTC | Minoxidil | 700158 | 1 |
| Euro Pharm/Gehe | Minoxidil | 1901005-01 | 1 |
| euro pharm | Minoxidil | 1590035 | 1 |
| Euro Pharma | Minoxidil | 1802013-02 | 1 |
| Euro Pharma | Minoxidil | 2209016-01 | 8 |
| Euro/ Phönix | Minoxidil | 1405028-01 | 1 |
| EUro/AHD | Minoxidil | 1203035-03 | 2 |
| Euro/Anzag | Minoxidil | 150903501 | 1 |
| Euro/Gehe | Minoxidil | 1112024-03 | 1 |
| Euro/Gehe | Minoxidil | 140528-01 | 1 |
| Euro/Jenne | Minoxidil | 1504013-01 | 1 |
| Euro/Krieger | Minoxidil | 1602013-02 | 1 |
| Euro/Krieger | Minoxidil | 1901005-01 | 3 |
| Euro/Noweda | Minoxidil | 1602013-02 | 1 |
| Euro/Noweda | Minoxidil | 1612011-01 | 1 |
| Euro/Phönix | Minoxidil | 161201101 | 2 |
| Euro/Phönix | Minoxidil | 1612011-01 | 1 |
| Euro/Phönix | Minoxidil | 1807018-01 | 2 |
| Euro/Phönix | Minoxidil | 1901005 | 1 |
| Euro/Phönix | Minoxidil | 2001035-01 | 1 |
| Euro/Phönix | Minoxidil | 20044030-01 | 1 |
| Euro/Phönix | Minoxidil | 210901801 | 2 |
| Euro/Sanacorp | Minoxidil | 1612011-01 | 1 |
| Euro | Minoxidil | 1304029-02 | 1 |
| euro | Minoxidil | 2008039-01 | 1 |
| euroct/Gehe | Minoxidil | 1210056-02 | 2 |
| euroct/Gehe | Minoxidil | 1304029-01 | 1 |
| EuRoh/ Gehe | Minoxidil | 2008039-01 | 1 |
| EuRoh | Minoxidil | 2008040-01 | 1 |
| europharm/gehe | Minoxidil | 1710043-01 | 1 |
| Europharm/Sanacorp | Minoxidil | 1210056-01 | 1 |
| EurPS | Minoxidil | 1504013-01 | 2 |
| Fa.Phönix | Minoxidil | 2001030-01 | 1 |
| Faagron/Fiebig 09.04.19 | Minoxidil | 18c27-B01-354525 | 1 |
| Fagrin | Minoxidil | 15K17-B06-321926 | 1 |
| Fagron | Minoxidil | | 2 |
| Fagron | Minoxidil | 1/16M | 2 |
| Fagron | Minoxidil | 11021402 | 1 |
| Fagron | Minoxidil | 11E17-N07 | 1 |
| Fagron | Minoxidil | 11H07-N03 | 1 |
| Fagron | Minoxidil | 11K11-N09 | 3 |
| Fagron | Minoxidil | 120303503 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Minoxidil | 1210056-02 | 4 |
| Fagron | Minoxidil | 12A25-N04 | 4 |
| Fagron | Minoxidil | 12C29-N05 | 5 |
| Fagron | Minoxidil | 12C29-N050087/240 | 1 |
| Fagron | Minoxidil | 12C29-N050145/240 | 1 |
| Fagron | Minoxidil | 12H07N03 | 1 |
| Fagron | Minoxidil | 12H07-N03 | 12 |
| Fagron | Minoxidil | 12H07-N030265/432 | 1 |
| Fagron | Minoxidil | 12H07-No3 | 1 |
| Fagron | Minoxidil | 12H07-NO3 | 1 |
| Fagron | Minoxidil | 12HO7-NO3 | 1 |
| Fagron | Minoxidil | 1311038-01 | 2 |
| Fagron | Minoxidil | 13E13N10 | 1 |
| Fagron | Minoxidil | 13E13-N10 | 9 |
| Fagron | Minoxidil | 13H07-NO3 | 1 |
| Fagron | Minoxidil | 13I23-N07 | 8 |
| Fagron | Minoxidil | 13J23N07 | 2 |
| Fagron | Minoxidil | 13J29-B02 | 1 |
| Fagron | Minoxidil | 13K04-B05-0004 | 1 |
| Fagron | Minoxidil | 13K04-B05-290377 | 6 |
| Fagron | Minoxidil | 13K04-B05-290379 | 2 |
| Fagron | Minoxidil | 13K04-B05-290380 | 3 |
| Fagron | Minoxidil | 13123-N07 | 1 |
| Fagron | Minoxidil | 1411006-01 | 2 |
| Fagron | Minoxidil | 1420001962 | 1 |
| Fagron | Minoxidil | 14B04-B07 | 1 |
| Fagron | Minoxidil | 14B04-B07-290883 | 3 |
| Fagron | Minoxidil | 14B04-B07-297364 | 1 |
| Fagron | Minoxidil | 14L03-B02 | 3 |
| Fagron | Minoxidil | 14L03-B02-30129 | 1 |
| Fagron | Minoxidil | 14L03-B02-301428 | 1 |
| Fagron | Minoxidil | 14L03-B02301429 | 1 |
| Fagron | Minoxidil | 14L03-B02-301429 | 7 |
| Fagron | Minoxidil | 14L03-B02-301430 | 2 |
| Fagron | Minoxidil | 14L03-B02-301431 | 1 |
| Fagron | Minoxidil | 14L03-B02301434 | 1 |
| Fagron | Minoxidil | 14L03-B02-301541 | 1 |
| Fagron | Minoxidil | 14L03-Bo2-301430 | 1 |
| Fagron | Minoxidil | 1510001251 | 3 |
| Fagron | Minoxidil | 1520000768 | 2 |
| Fagron | Minoxidil | 1520002631 | 2 |
| Fagron | Minoxidil | 15230805 | 2 |
| Fagron | Minoxidil | 15436408 | 1 |
| Fagron | Minoxidil | 15E19-06-308183 | 1 |
| Fagron | Minoxidil | 15E19-B06 | 1 |
| Fagron | Minoxidil | 15E19-B06-308179 | 1 |
| Fagron | Minoxidil | 15e19-b06-308180 | 1 |
| Fagron | Minoxidil | 15E19-B06-308180 | 2 |
| Fagron | Minoxidil | 15E19-B06-308181 | 6 |
| Fagron | Minoxidil | 15E19-B06-308182 | 5 |
| Fagron | Minoxidil | 15E19-B06-308183 | 6 |
| Fagron | Minoxidil | 15E19-B09-308181 | 1 |
| Fagron | Minoxidil | 15E19-BO6-308183 | 1 |
| Fagron | Minoxidil | 15F02-B08 | 1 |
| Fagron | Minoxidil | 15F02-B09-312663 | 3 |
| Fagron | Minoxidil | 15H07-B01-313607 | 1 |
| Fagron | Minoxidil | 15H07-B01-314726 | 2 |
| Fagron | Minoxidil | 15K17-B05 | 1 |
| Fagron | Minoxidil | 15K17-B05-318240 | 2 |
| Fagron | Minoxidil | 15K17-B05-318241 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Minoxidil | 15K17-B05-318411 | 2 |
| Fagron | Minoxidil | 15K17-B05-318691 | 4 |
| Fagron | Minoxidil | 15K17-B05-318692 | 1 |
| Fagron | Minoxidil | 15K17-B05-320188 | 3 |
| Fagron | Minoxidil | 15K17-B06 | 1 |
| Fagron | Minoxidil | 15K17-B06-321926 | 5 |
| Fagron | Minoxidil | 15K17-B06-321927 | 4 |
| Fagron | Minoxidil | 15K17-B06-321928 | 2 |
| Fagron | Minoxidil | 15k17-b06-324965 | 1 |
| Fagron | Minoxidil | 15K17-B06-324965 | 3 |
| Fagron | Minoxidil | 15K17-B06-325490 | 3 |
| Fagron | Minoxidil | 15K17-B06-325491 | 2 |
| Fagron | Minoxidil | 15K197-B05-318411 | 1 |
| Fagron | Minoxidil | 16/24-B04-328218 | 1 |
| Fagron | Minoxidil | 1612011-01 | 1 |
| Fagron | Minoxidil | 16j24-b04328218 | 1 |
| Fagron | Minoxidil | 16J24-B04-328218 | 6 |
| Fagron | Minoxidil | 16J24-B04-328219 | 1 |
| Fagron | Minoxidil | 16J24-B04-328224 | 2 |
| Fagron | Minoxidil | 16J24-B04-328225 | 2 |
| Fagron | Minoxidil | 16J24-B04-328226 | 3 |
| Fagron | Minoxidil | 16j24-B04-329291 | 1 |
| Fagron | Minoxidil | 16J24-B04-329291 | 1 |
| Fagron | Minoxidil | 16J24-B05 | 1 |
| Fagron | Minoxidil | 16J24-B05-332092 | 5 |
| Fagron | Minoxidil | 16J24-B05-332093 | 3 |
| Fagron | Minoxidil | 1705008-01 | 2 |
| Fagron | Minoxidil | 170612184 | 1 |
| Fagron | Minoxidil | 1722 | 1 |
| Fagron | Minoxidil | 17B22/B02/336689 | 2 |
| Fagron | Minoxidil | 17b22-b01 | 1 |
| Fagron | Minoxidil | 17B22-B01 | 2 |
| Fagron | Minoxidil | 17B22-B01-334447 | 1 |
| Fagron | Minoxidil | 17B22-B01-335427 | 8 |
| Fagron | Minoxidil | 17B22-B02 | 2 |
| Fagron | Minoxidil | 17B22-B02-336689 | 4 |
| Fagron | Minoxidil | 17B22-B02-336690 | 1 |
| Fagron | Minoxidil | 17B22-B02-336700 | 1 |
| Fagron | Minoxidil | 17B22-B02-338766 | 3 |
| Fagron | Minoxidil | 17B22-B02-338767 | 1 |
| Fagron | Minoxidil | 17H08-B06 | 1 |
| Fagron | Minoxidil | 17H08-B06-340512 | 2 |
| Fagron | Minoxidil | 17H08-B06-340514 | 2 |
| Fagron | Minoxidil | 17H08-B06-341376 | 5 |
| Fagron | Minoxidil | 17H08-B06-341377 | 5 |
| Fagron | Minoxidil | 17h08-b06-342282 | 1 |
| Fagron | Minoxidil | 17H08-B09 | 4 |
| Fagron | Minoxidil | 17H08-B09-346945 | 3 |
| Fagron | Minoxidil | 17H08-B09-346947 | 2 |
| Fagron | Minoxidil | 17H08-B09-346948 | 1 |
| Fagron | Minoxidil | 17H08-B09-347482 | 1 |
| Fagron | Minoxidil | 18002 | 2 |
| Fagron | Minoxidil | 18003 | 1 |
| Fagron | Minoxidil | 18004 | 3 |
| Fagron | Minoxidil | 18008 | 4 |
| Fagron | Minoxidil | 1803004-01 | 4 |
| Fagron | Minoxidil | 18C19-B01-348984 | 4 |
| Fagron | Minoxidil | 18C19-B01-348985 | 2 |
| Fagron | Minoxidil | 18C20-B01 | 4 |
| Fagron | Minoxidil | 18C20-b01-351844 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Minoxidil | 18C20-B01-351844 | 4 |
| Fagron | Minoxidil | 18C20-B01-352113 | 1 |
| Fagron | Minoxidil | 18C20-B01-352116 | 2 |
| Fagron | Minoxidil | 18C20-B01-352629 | 6 |
| Fagron | Minoxidil | 18C20-B01-352702 | 5 |
| Fagron | Minoxidil | 18C20-B01-352874 | 1 |
| Fagron | Minoxidil | 18C27-B01-354524 | 3 |
| Fagron | Minoxidil | 18C27-B01-354525 | 7 |
| Fagron | Minoxidil | 18C27-B01-354782 | 1 |
| Fagron | Minoxidil | 18C-B01-352116 | 1 |
| Fagron | Minoxidil | 18L19-B05-356595 | 7 |
| Fagron | Minoxidil | 18L19-BO5-356595 | 1 |
| Fagron | Minoxidil | 19002 | 2 |
| Fagron | Minoxidil | 19003 | 5 |
| Fagron | Minoxidil | 19004 | 1 |
| Fagron | Minoxidil | 1901005-01 | 1 |
| Fagron | Minoxidil | 1907025-01 | 2 |
| Fagron | Minoxidil | 19b18-b06-191023 | 1 |
| Fagron | Minoxidil | 19B21-190615 | 1 |
| Fagron | Minoxidil | 19B21-B07 | 1 |
| Fagron | Minoxidil | 19B21-B07-190615 | 9 |
| Fagron | Minoxidil | 19B21-B07-190616 | 2 |
| Fagron | Minoxidil | 19B21-B07-190617 | 6 |
| Fagron | Minoxidil | 19B21-B07-190618 | 8 |
| Fagron | Minoxidil | 19B21-B07-190628 | 1 |
| Fagron | Minoxidil | 19B21-B07-190661 | 1 |
| Fagron | Minoxidil | 19B21-B07-19618 | 1 |
| Fagron | Minoxidil | 19E28-B12 | 3 |
| Fagron | Minoxidil | 19E28-B12_193438 | 1 |
| Fagron | Minoxidil | 19E28-B12-1934308 | 1 |
| Fagron | Minoxidil | 19E28-B12-193438 | 10 |
| Fagron | Minoxidil | 19E28-B12-193440 | 1 |
| Fagron | Minoxidil | 19E28-B12-193447 | 1 |
| Fagron | Minoxidil | 19E28-B12-193449 | 4 |
| Fagron | Minoxidil | 19g22-B02 | 1 |
| Fagron | Minoxidil | 19G22-B02 | 2 |
| Fagron | Minoxidil | 19G22-B02-193448 | 10 |
| Fagron | Minoxidil | 19G22-B02-1934939 | 1 |
| Fagron | Minoxidil | 19G22-BO2-193448 | 1 |
| Fagron | Minoxidil | 2/16M | 4 |
| Fagron | Minoxidil | 2008039-01 | 1 |
| Fagron | Minoxidil | 20A07-B02-197710 | 1 |
| Fagron | Minoxidil | 20A07-b02-197718 | 1 |
| Fagron | Minoxidil | 20A07-B02-197718 | 1 |
| Fagron | Minoxidil | 20A07-B02-197719 | 3 |
| Fagron | Minoxidil | 20A07-B02-197720 | 3 |
| Fagron | Minoxidil | 20A15-B99 | 1 |
| Fagron | Minoxidil | 20A15-B99_196663 | 1 |
| Fagron | Minoxidil | 20A15-B99-196663 | 6 |
| Fagron | Minoxidil | 20A15-B99-196664 | 1 |
| Fagron | Minoxidil | 20A15-B99-196667 | 3 |
| Fagron | Minoxidil | 20A15-B99-196668 | 1 |
| Fagron | Minoxidil | 20D27-B11 | 1 |
| Fagron | Minoxidil | 20D27-B11-201184 | 3 |
| Fagron | Minoxidil | 20D27-B11-201247 | 2 |
| Fagron | Minoxidil | 20D27-B11-201331 | 2 |
| Fagron | Minoxidil | 20K05-B03-202207 | 2 |
| Fagron | Minoxidil | 21001 | 1 |
| Fagron | Minoxidil | 21B02-B13 | 2 |
| Fagron | Minoxidil | 21B02-B13-2153704 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Minoxidil | 21B02-B13-215374 | 3 |
| Fagron | Minoxidil | 21B11_B18_203082 | 1 |
| Fagron | Minoxidil | 21B11-B18 | 1 |
| Fagron | Minoxidil | 21B11-B18-203081 | 4 |
| Fagron | Minoxidil | 21B11-B18-203082 | 1 |
| Fagron | Minoxidil | 21B11-B18-203084 | 2 |
| Fagron | Minoxidil | 21B11-B20-210128 | 6 |
| Fagron | Minoxidil | 21B16-B15-220936 | 1 |
| Fagron | Minoxidil | 21B16B15220943 | 1 |
| Fagron | Minoxidil | 21F07-B05-215378 | 6 |
| Fagron | Minoxidil | 21F07-B06 | 1 |
| Fagron | Minoxidil | 21F07-B06-213151 | 1 |
| Fagron | Minoxidil | 21F07-B06-213152 | 1 |
| Fagron | Minoxidil | 21F07-B07-0004 | 1 |
| Fagron | Minoxidil | 21F07-B07-216774 | 5 |
| Fagron | Minoxidil | 21F07-B07-216859 | 2 |
| Fagron | Minoxidil | 21F07-B07-216892 | 1 |
| Fagron | Minoxidil | 21F07-B07-216984 | 1 |
| Fagron | Minoxidil | 21J06-B05-213146 | 3 |
| Fagron | Minoxidil | 21JO6-B05-213146 | 1 |
| Fagron | Minoxidil | 22C01_b03-21915 | 1 |
| Fagron | Minoxidil | 22C01-B03 | 1 |
| Fagron | Minoxidil | 22C01-B03-218964 | 4 |
| Fagron | Minoxidil | 22C01-B03-220935 | 1 |
| Fagron | Minoxidil | 22I05-B05-223060 | 1 |
| Fagron | Minoxidil | 23H25-B13-234500 | 1 |
| Fagron | Minoxidil | 26111302 | 1 |
| Fagron | Minoxidil | 27081301 | 1 |
| Fagron | Minoxidil | 2OD27-B11-201218 | 1 |
| Fagron | Minoxidil | 321926 | 1 |
| Fagron | Minoxidil | 4110I-02844 | 1 |
| Fagron | Minoxidil | 5/17M | 1 |
| Fagron | Minoxidil | 612212844 | 1 |
| Fagron | Minoxidil | 7/13 | 1 |
| Fagron | Minoxidil | B02-1934309 | 1 |
| Fagron | Minoxidil | B05-215378 | 2 |
| Fagron | Minoxidil | B11-2011804 | 1 |
| Fagron | Minoxidil | B12-1934409 | 1 |
| Fagron | Minoxidil | B13-2131407 | 1 |
| Fagron | Minoxidil | B18-2030801 | 2 |
| Fagron | Minoxidil | B99-1966607 | 3 |
| Fargon | Minoxidil | 20A15-B97-197717 | 1 |
| Fargon | Minoxidil | 20A15-B99-196666 | 1 |
| Fargon | Minoxidil | 21B11-B20-210128 | 1 |
| Fiebig ek: 36.06EUR 31.0812 | Minoxidil | 111202403 | 1 |
| Fiebig | Minoxidil | 1504013-01 | 2 |
| Fiebig | Minoxidil | 1509035-01 | 1 |
| Fiebig | Minoxidil | 1607007-01 | 1 |
| Fiebig | Minoxidil | 1612011-01 | 1 |
| Fiebig | Minoxidil | 1705008-01 | 1 |
| Fiebig | Minoxidil | 171004301 | 1 |
| Fiebig | Minoxidil | 1710043-01 | 1 |
| Fiebig | Minoxidil | 1807017-01 | 1 |
| Fiebig | Minoxidil | 1901005-01 | 1 |
| Fiebig | Minoxidil | 1907025 | 1 |
| Fiebig | Minoxidil | 1907025-02 | 1 |
| Fiebig | Minoxidil | 2004030-01 | 1 |
| fiebig | Minoxidil | 22000546008 | 1 |
| Fragon | Minoxidil | 20K05-B03-202207 | 1 |
| Gatt-Koller | Minoxidil | 1803103 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe / EuRho | Minoxidil | 1803004-01 | 1 |
| Gehe/Euro | Minoxidil | 150903501 | 1 |
| Gehe/EuRoh | Minoxidil | 1907025-02 | 1 |
| Gehe | Minoxidil | | 4 |
| Gehe | Minoxidil | 1405028-01 | 1 |
| Gehe | Minoxidil | 15436201 | 1 |
| Gehe | Minoxidil | 15436404 | 1 |
| Gehe | Minoxidil | 15436406 | 1 |
| Gehe | Minoxidil | 15436414 | 1 |
| Gehe | Minoxidil | 15K17-B06-321926 | 1 |
| Gehe | Minoxidil | 1602013-01 | 2 |
| Gehe | Minoxidil | 1612011-01 | 1 |
| Gehe | Minoxidil | 1705008-01 | 1 |
| Gehe | Minoxidil | 1710043-01 | 1 |
| Gehe | Minoxidil | 17227803 | 2 |
| Gehe | Minoxidil | 17B22-B01-335427 | 1 |
| Gehe | Minoxidil | 17H08-B06-341376 | 1 |
| Gehe | Minoxidil | 17H08-B06-341377 | 2 |
| Gehe | Minoxidil | 1803004-01 | 1 |
| Gehe | Minoxidil | 1807018-01 | 1 |
| Gehe | Minoxidil | 1901005-01 | 1 |
| Gehe | Minoxidil | 1907025-01 | 2 |
| GEHE | Minoxidil | 1907025-01 | 1 |
| Gehe | Minoxidil | 1907025-02 | 1 |
| Gehe | Minoxidil | 2004030-01 | 2 |
| Gehe | Minoxidil | 21002063013 | 4 |
| Gehe | Minoxidil | 21002063022 | 1 |
| GEHE | Minoxidil | 2109021-01 | 1 |
| GEHE | Minoxidil | 2209016-01 | 1 |
| Gehe | Minoxidil | 2311021-01 | 1 |
| Gehe | Minoxidil | 23H25-B13-234500 | 2 |
| Gehe | Minoxidil | 2411007-01 | 1 |
| Gehe | Minoxidil | AP006/13M | 1 |
| Geibo | Minoxidil | 1705008-01 | 1 |
| Geilenkirchen | Minoxidil | 14234505 | 1 |
| Hedinger/Fiebig | Minoxidil | 1612011-01 | 1 |
| Hedinger/Noweda | Minoxidil | 15436414 | 1 |
| Hedinger/Sanacorp | Minoxidil | 12C29-N05 | 1 |
| Hedinger | Minoxidil | 14B04-B07 | 2 |
| Ichthyol/Noweda | Minoxidil | 17117803 | 1 |
| Ichthyol-Gesellschaft | Minoxidil | 1311038-01 | 1 |
| Icrom / Gehe | Minoxidil | 19B21-B07-190618 | 2 |
| Icrom / Gehe | Minoxidil | 20A15-B99-1966607 | 1 |
| Icrom /Oberlinden-Ap... | Minoxidil | 1/14 | 1 |
| Icrom S.P.A./Sanacorp | Minoxidil | 1907025-01 | 1 |
| Icrom S.P.A./Sanacorp | Minoxidil | 1907025-02 | 1 |
| icrom spa | Minoxidil | 511v | 1 |
| ICROM/Gehe | Minoxidil | 12/17 | 1 |
| Icrom/Gehe | Minoxidil | 1602013-01 | 1 |
| ICROM | Minoxidil | 6/12 | 1 |
| JENNE/ EuRho | Minoxidil | 2109021-02 | 2 |
| Jenne | Minoxidil | 22C01-B03-220945 | 1 |
| Jenne | Minoxidil | 24G05-B04-002248 | 1 |
| Jenne | Minoxidil | B99-1966007 | 1 |
| Jenne | Minoxidil | P2019/93 | 1 |
| Kehr | Minoxidil | 1705008-01 | 1 |
| Kehr | Minoxidil | 1803004-01 | 1 |
| kehr | Minoxidil | 2209016-01 | 2 |
| Kehr | Minoxidil | 23003253001 | 1 |
| Krieger | Minoxidil | 171004301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Krieger | Minoxidil | 21B11-B20-210128 | 1 |
| Kumar Cigan | Minoxidil | 2004030-01 | 1 |
| Kumar Organic Produc… | Minoxidil | | 1 |
| Kumar Organics Products | Minoxidil | 2001035-01 | 1 |
| Kumar organics | Minoxidil | 200804001 | 1 |
| Kumar/Phoenix | Minoxidil | | 1 |
| Laborchemie Apolda G… | Minoxidil | 1803004-01 | 2 |
| Moweda | Minoxidil | 2311021-01 | 1 |
| Nowda | Minoxidil | 23003253009 | 1 |
| Noweda/ Infecto Pharm | Minoxidil | 1607007-01 | 1 |
| Noweda/Euro | Minoxidil | 20080440-01 | 1 |
| Noweda | Minoxidil | 13179501 | 2 |
| Noweda | Minoxidil | 13179502 | 2 |
| Noweda | Minoxidil | 14093703 | 1 |
| Noweda | Minoxidil | 15K17-B05-320189 | 2 |
| Noweda | Minoxidil | 1705008-01 | 1 |
| Noweda | Minoxidil | 1710043-01 | 6 |
| Noweda | Minoxidil | 1803004-01 | 2 |
| Noweda | Minoxidil | 18149801 | 1 |
| Noweda | Minoxidil | 18149802 | 2 |
| Noweda | Minoxidil | 1901005-01 | 1 |
| Noweda | Minoxidil | 1907025-01 | 1 |
| Noweda | Minoxidil | 191957003 | 1 |
| Noweda | Minoxidil | 19E28-B12-193438 | 1 |
| Noweda | Minoxidil | 2004030-01 | 4 |
| Noweda | Minoxidil | 20040301 | 1 |
| Noweda | Minoxidil | 21002063012 | 1 |
| Noweda | Minoxidil | 210901801 | 1 |
| Noweda | Minoxidil | 2109018-01 | 1 |
| Noweda | Minoxidil | 2109021-02 | 2 |
| Noweda | Minoxidil | 22000546010 | 1 |
| Noweda | Minoxidil | 2209016-01 | 2 |
| Noweda | Minoxidil | 2209017-01 | 6 |
| Noweda | Minoxidil | 23001171003 | 1 |
| Noweda | Minoxidil | 23003253014 | 2 |
| Noweda | Minoxidil | 2311021-01 | 1 |
| Noweda | Minoxidil | 23A18-B5-227782 | 1 |
| Oberlinden Apotheke | Minoxidil | 5-13 | 1 |
| Olon Spa | Minoxidil | 15K17-B06-321926 | 1 |
| Ph.Eur.10.0/Gehe | Minoxidil | 2001035-01 | 1 |
| phoenix /EuRho | Minoxidil | 2004030-01 | 3 |
| PhOENIX 19.03.2012 | Minoxidil | 1311038-01 | 2 |
| Phoenix Pharma | Minoxidil | 2008040-01 | 2 |
| Phoenix | Minoxidil | 1602013-02 | 1 |
| Phoenix | Minoxidil | 16J25-B05-332092 | 1 |
| Phoenix | Minoxidil | 2004030-01 | 1 |
| Phoenix | Minoxidil | 2008039-01 | 1 |
| Phoenix | Minoxidil | 2008040-01 | 1 |
| Phoenix | Minoxidil | 20A15-B99-196663 | 2 |
| Phoenix | Minoxidil | 2109021-01 | 1 |
| Phoenix | Minoxidil | 21B02-B13-215374 | 1 |
| PHOENIX | Minoxidil | 2209016-01 | 2 |
| Phoenix | Minoxidil | 24B28-B11-236694 | 2 |
| Phoenix | Minoxidil | 3057 | 1 |
| Phoenix | Minoxidil | 3399 | 1 |
| Phönix /euro | Minoxidil | 170500801 | 2 |
| phönix | Minoxidil | | 1 |
| Phönix | Minoxidil | | 1 |
| Phönix | Minoxidil | 1112024-03 | 1 |
| Phönix | Minoxidil | 1203035-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Minoxidil | 1304029-01 | 1 |
| Phönix | Minoxidil | 1504013-01 | 1 |
| phönix | Minoxidil | 1509035-01 | 1 |
| phönix | Minoxidil | 1602013-01 | 3 |
| Phönix | Minoxidil | 1602013-02 | 1 |
| phönix | Minoxidil | 1612011-01 | 2 |
| Phönix | Minoxidil | 1612011-01 | 1 |
| Phönix | Minoxidil | 170043-01 | 1 |
| Phönix | Minoxidil | 1705008-01 | 1 |
| PHÖNIX | Minoxidil | 1705008-01 | 2 |
| Phönix | Minoxidil | 18016109 | 1 |
| PHÖNIX | Minoxidil | 1807018-01 | 1 |
| Phönix | Minoxidil | 18149815 | 1 |
| Phönix | Minoxidil | 1901005-01 | 1 |
| PHÖNIX | Minoxidil | 1907025 | 1 |
| Phönix | Minoxidil | 1907025-01 | 2 |
| Phönix | Minoxidil | 19B21-B07-190661 | 1 |
| Phönix | Minoxidil | 2001030-01 | 1 |
| Phönix | Minoxidil | 2004030-01 | 3 |
| PHÖNIX | Minoxidil | 2004030-01 | 1 |
| Phönix | Minoxidil | 2008040-01 | 2 |
| Phönix | Minoxidil | 201062710 | 1 |
| Phönix | Minoxidil | 2109018-01 | 1 |
| Phönix | Minoxidil | 2109021 | 1 |
| Phönix | Minoxidil | 2109021-02 | 1 |
| Phönix | Minoxidil | 2209016-01 | 2 |
| Phonix | Minoxidil | 2311021-01 | 1 |
| PHÖNIX | Minoxidil | CB2109018-01 | 1 |
| Sana Eurho 11.11.19 ... | Minoxidil | 1907025-01 | 1 |
| sanacorb | Minoxidil | 1612011-01 | 1 |
| Sanacorp, 81,00EUR, 27.1.17 | Minoxidil | 1607007-01 | 1 |
| Sanacorp/EuRho | Minoxidil | 2001035-01 | 1 |
| Sanacorp | Minoxidil | 120056-01 | 1 |
| Sanacorp | Minoxidil | 1203035-01 | 1 |
| Sanacorp | Minoxidil | 1210056-01 | 1 |
| Sanacorp | Minoxidil | 1210056-02 | 2 |
| Sanacorp | Minoxidil | 1304029-02 | 3 |
| Sanacorp | Minoxidil | 13179507 | 1 |
| sanacorp | Minoxidil | 13K04-B05-290379 | 1 |
| sanacorp | Minoxidil | 1405028-01 | 1 |
| Sanacorp | Minoxidil | 140502801 | 1 |
| Sanacorp | Minoxidil | 1405028-01 | 1 |
| Sanacorp | Minoxidil | 14093701 | 1 |
| Sanacorp | Minoxidil | 14093702 | 1 |
| Sanacorp | Minoxidil | 1411006-01 | 1 |
| Sanacorp | Minoxidil | 1504013-01 | 1 |
| Sanacorp | Minoxidil | 1612011-01 | 1 |
| Sanacorp | Minoxidil | 180300401 | 1 |
| Sanacorp | Minoxidil | 1907025-01 | 2 |
| Sanacorp | Minoxidil | 191957010 | 1 |
| Sanacorp | Minoxidil | 2008040 | 1 |
| Sanacorp | Minoxidil | 2008040-01 | 2 |
| Sanacorp | Minoxidil | 20D27-B11-201218 | 1 |
| Sanacorp | Minoxidil | 21002063022 | 4 |
| Sanacorp | Minoxidil | 2109021-02 | 1 |
| Sanacorp | Minoxidil | 21b02-b13-215377 | 1 |
| Sanacorp | Minoxidil | 21B11-B18-203084 | 2 |
| Sanacorp | Minoxidil | 21F07-B05-215378 | 2 |
| Sanacorp | Minoxidil | 22000546001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spangro 1.10.19 | Minoxidil | 16J24-B04-328224 | 1 |
| Spangro 25.1.2014 | Minoxidil | 13/23-N07 | 1 |
| Th. Geyer | Minoxidil | 1602013-01 | 1 |
| Vdl 14.07.14 | Minoxidil | 1311038-01 | 1 |
| VDL;81,0EUR;21.05.15 | Minoxidil | 1411006-01 | 1 |

- 253 142 spectra from 1666 *Apo-Ident* customers from a total of 51 511 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Minoxidil* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Minoxidil* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 579 | 0 | 157 747 |
| **Type B** | 0 | 1638 | 2 | 211 300 |
| **Type C** | 0 | 3731 | 13 | 253 142 |

The substance/substance group *Minoxidil* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9637 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 99.8780 % (> 99.6951 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6528 % (> 99.5726 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20879 | 21630 | 7.46 | 195.51 |
| 21359 | 21630 | 5.52 | 195.08 |
| 21361 | 21630 | 5.06 | 195.62 |
| 21630 | 21630 | 0.00 | 195.28 |
| 21912 | 21933 | 5.14 | 196.54 |
| 21933 | 21933 | 0.00 | 192.91 |
| 22365 | 22365 | 0.00 | 198.60 |
| 22982 | 22982 | 0.00 | 200.73 |
| 25162 | 25162 | 0.00 | 197.24 |
| 25888 | 25888 | 0.00 | 198.79 |
| 26337 | 26337 | 0.00 | 200.00 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Mometasone furoate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20100-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Mometasone furoate; Mometasoni furoas

### Special notes

When selecting the *Mometasone furoate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Mometasone furoate | 8 | 13 | 523 |

### Second-stage model

For differentiation of the substance/substance group *Mometasone furoate* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Mometasone furoate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Naloxone hydrochloride dihydrate | 120.39 | – |
| ⋮ | ⋮ | ⋮ |
| Atropine sulfate | >50 | 50.43 |
| Potassium sorbate | >50 | 114.76 |
| Magnesium hydrogen citrate | >50 | 138.25 |
| Hydrocortisone | >50 | 167.99 |
| Quinoline yellow | >50 | 265.34 |
| Propranolol hydrochloride | >50 | 339.83 |
| Saccharin sodium | >50 | 407.72 |
| Calcium orotate dihydrate | >50 | 519.09 |
| Phenytoin | >50 | 528.80 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Mometasone furoate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Mometasone furoate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Mometasone furoate | 160286 | 22433 | 60 | 20160316* |
| Caelo | Mometasone furoate | 163532 | 23046 | 40 | 20170104* |
| Euro OTC | Mometasone furoate | 1403015-01 | 21602 | 60 | 20140503 |
| Euro OTC | Mometasone furoate | 1403015-01 | 21602SI | 31 | 20140503 |
| Euro OTC | Mometasone furoate | 1510036 | 22238 | 60 | 20151118* |
| Euro OTC | Mometasone furoate | 1510036 | 22238SI | 30 | 20151118* |
| Euro OTC | Mometasone furoate | 1610009 | 23136 | 40 | 20170321* |
| Euro OTC | Mometasone furoate | 2305005 | 26766 | 40 | 20230630* |
| Euro OTC | Mometasone furoate | 2305005 | 26766SI | 30 | 20230630* |
| Fagron | Mometasone furoate | 13F17-N01 | 20850 | 40 | 20130620 |
| Fagron | Mometasone furoate | 13F17-N01 | 20850SI | 44 | 20130620 |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Mometasone furoate | 16A20-B06-319750 | 22887 | 40 | 20160209 |
| Fagron | Mometasone furoate | 16A20-B06-319750 | 22887SI | 30 | 20160209 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 545 spectra of 13 reference samples from the substance/substance group *Mometasone furoate*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 781 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 974 spectra of 29 reference samples from the substance/substance group *Mometasone furoate*.

- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Mometasone furoate | 13304605 | 21374 | 60 |
| Caelo | Mometasone furoate | 183341 | 24563 | 40 |
| Caelo | Mometasone furoate | 23001247 | 27248 | 40 |
| Euro OTC | Mometasone furoate | 1606021 | 22715 | 40 |
| Euro OTC | Mometasone furoate | 1711027 | 23878 | 40 |
| Euro OTC | Mometasone furoate | 1810008 | 24295 | 40 |
| Euro OTC | Mometasone furoate | 1906035 | 24794 | 40 |
| Euro OTC | Mometasone furoate | 2001040 | 25159 | 40 |
| Euro OTC | Mometasone furoate | 2003056 | 25167 | 40 |
| Euro OTC | Mometasone furoate | 2008002 | 25408 | 40 |
| Euro OTC | Mometasone furoate | 2106014 | 25869 | 50 |
| Fagron | Mometasone furoate | 22C15-B06-221102 | 26295 | 35 |
| Fagron | Mometasone furoate | 24F28-B17-008407 | 27610 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Mometasone furoate | 13304605 | 21374SI | 38 |
| Caelo | Mometasone furoate | 160286 | 22433SI† | 30 |
| Caelo | Mometasone furoate | 163532 | 23046SI† | 23 |
| Caelo | Mometasone furoate | 183341 | 24563SI | 21 |
| Caelo | Mometasone furoate | 23001247 | 27248SI | 30 |
| Euro OTC | Mometasone furoate | 1606021 | 22715SI | 33 |
| Euro OTC | Mometasone furoate | 1610009 | 23136SI† | 20 |
| Euro OTC | Mometasone furoate | 1711027 | 23878SI | 27 |
| Euro OTC | Mometasone furoate | 1810008 | 24295SI | 20 |
| Euro OTC | Mometasone furoate | 1906035 | 24794SI | 24 |
| Euro OTC | Mometasone furoate | 2001040 | 25159SI | 30 |
| Euro OTC | Mometasone furoate | 2003056 | 25167SI | 22 |
| Euro OTC | Mometasone furoate | 2008002 | 25408SI | 20 |
| Euro OTC | Mometasone furoate | 2106014 | 25869SI | 31 |
| Fagron | Mometasone furoate | 22C15-B06-221102 | 26295SI | 30 |
| Fagron | Mometasone furoate | 24F28-B17-008407 | 27610SI | 30 |

- 211 966 spectra from a total of 4271 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3080 spectra from 872 *Apo-Ident* customers from 559 batches from the substance/substance group *Mometasone furoate*.
- Among them are spectra of independent samples from 522 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Mometasone furoate | 106014-01 | 1 |
| | Mometasone furoate | 20003486021 | 1 |
| | Mometasone furoate | 20003486024 | 7 |
| | Mometasone furoate | 20003486026 | 2 |
| | Mometasone furoate | 20003486027 | 2 |
| | Mometasone furoate | 20003486029 | 3 |
| | Mometasone furoate | 20003486030 | 4 |
| | Mometasone furoate | 20003486031 | 1 |
| | Mometasone furoate | 20003486034 | 19 |
| | Mometasone furoate | 20003486035 | 11 |
| | Mometasone furoate | 20003486038 | 1 |
| | Mometasone furoate | 20G24-B03-1968709 | 1 |
| | Mometasone furoate | 20G24-B03-1970806 | 1 |
| | Mometasone furoate | 20G24-B03-197086 | 3 |
| | Mometasone furoate | 20G24-B03-197480 | 2 |
| | Mometasone furoate | 2106014-01 | 28 |
| | Mometasone furoate | 21B26-B05-203100 | 9 |
| | Mometasone furoate | 21B26-B05-2031000 | 1 |
| | Mometasone furoate | 21B26-B05-210543 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Mometasone furoate | 22C15-B06-221102 | 3 |
| | Mometasone furoate | 22C15-B06-223109 | 1 |
| | Mometasone furoate | 22C15-B06-223110 | 4 |
| | Mometasone furoate | 22c15-b06-227594 | 1 |
| | Mometasone furoate | 22C15-B06-227594 | 12 |
| | Mometasone furoate | 23001247004 | 2 |
| | Mometasone furoate | 23001247005 | 18 |
| | Mometasone furoate | 23001247006 | 19 |
| | Mometasone furoate | 23001247007 | 4 |
| | Mometasone furoate | 2300147005 | 1 |
| | Mometasone furoate | 23003142001 | 1 |
| | Mometasone furoate | 230500501 | 1 |
| | Mometasone furoate | 2305005-01 | 17 |
| | Mometasone furoate | 2305005-0117/24P | 1 |
| | Mometasone furoate | 230929(20G24-B03-197086) | 1 |
| | Mometasone furoate | 23F15-B02-230394 | 1 |
| | Mometasone furoate | 23F15-B02-234649 | 1 |
| | Mometasone furoate | 23F15-B02-234650 | 1 |
| | Mometasone furoate | 23F15-B02-23465O | 1 |
| | Mometasone furoate | 24002020001 | 1 |
| | Mometasone furoate | 24002020002 | 4 |
| | Mometasone furoate | 24002020004 | 2 |
| | Mometasone furoate | 2412005-01 | 3 |
| | Mometasone furoate | 24D10-B13-236851 | 3 |
| | Mometasone furoate | 24D10-B13-236852 | 6 |
| | Mometasone furoate | 24D10-B13-236853 | 7 |
| | Mometasone furoate | 24D10-B13-236854 | 1 |
| | Mometasone furoate | 24D10-B13-238791 | 7 |
| | Mometasone furoate | 24F28-B17-005410 | 5 |
| | Mometasone furoate | 24F28-B17-005416 | 2 |
| | Mometasone furoate | 25A17-B08-010178 | 1 |
| | Mometasone furoate | 25D10-B13-236853 | 1 |
| | Mometasone furoate | 802-2346500 | 1 |
| | Mometasone furoate | B02-2346500 | 4 |
| | Mometasone furoate | B03-1968709 | 1 |
| | Mometasone furoate | B03-1970806 | 4 |
| | Mometasone furoate | B13-2368503 | 1 |
| | Mometasone furoate | B17-0054106 | 1 |
| | Mometasone furoate | HMF00224 | 1 |
| | Mometasone furoate | HMF00423 | 1 |
| 23001247005 | Mometasone furoate | 9530018 | 1 |
| 33,Caesar & Loretz GmbH | Mometasone furoate | 20003486026 | 4 |
| AARTI / Gehe | Mometasone furoate | 20000787001 | 1 |
| AARTI Industries/Phoenix | Mometasone furoate | MF-18013(JM-01)-001 | 1 |
| AARTI Industries/Phoenix | Mometasone furoate | MF-20002(JM-01)-001 | 1 |
| Ador Pharma | Mometasone furoate | APMOM006/0517M | 1 |
| AEP | Mometasone furoate | 20003486012 | 1 |
| AHD 20.06.14 EK 37,29 | Mometasone furoate | 12C07-B05-291268 | 1 |
| AHD/EuRho | Mometasone furoate | 2001040-01 | 1 |
| AHD | Mometasone furoate | 2106014-01 | 1 |
| Alliance Health 27.0... | Mometasone furoate | 13J23-N02 | 1 |
| Alliance Healthcare | Mometasone furoate | 22C15-B06-227594 | 2 |
| Alliance Healthcare | Mometasone furoate | B03-1968709 | 2 |
| Alliance | Mometasone furoate | 20003486035 | 1 |
| Alte Apotheke | Mometasone furoate | 1606021-01 | 1 |
| Anzag | Mometasone furoate | 12J29N03 | 1 |
| Anzag | Mometasone furoate | 13D08-N06 | 1 |
| Audor Pharma | Mometasone furoate | APMOM006/0117M | 4 |
| Audor Pharma | Mometasone furoate | APMOM006/0177M | 1 |
| Audor Pharma | Mometasone furoate | APMOM006/0517M | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Mometasone furoate | APMOM010/0116M | 3 |
| Audor Pharma | Mometasone furoate | APMOM301/0118-1M | 2 |
| Audor Pharma | Mometasone furoate | APMOM301/0118-8M | 1 |
| Audor Pharma | Mometasone furoate | APMOM301/0118M | 3 |
| Beiersdorf | Mometasone furoate | 18026011 | 1 |
| Bombastus | Mometasone furoate | 16J24-B11-335793 | 1 |
| Bombastus | Mometasone furoate | 18B19-B07-352632 | 1 |
| Cael Sanacorp 05.02.2016 | Mometasone furoate | 14H06-B07-298481 | 1 |
| Caelo | Mometasone furoate | | 1 |
| Caelo | Mometasone furoate | 116181714 | 1 |
| Caelo | Mometasone furoate | 12035601 | 1 |
| Caelo | Mometasone furoate | 12035607 | 2 |
| Caelo | Mometasone furoate | 12035608 | 2 |
| Caelo | Mometasone furoate | 12339604 | 1 |
| Caelo | Mometasone furoate | 12351202 | 1 |
| Caelo | Mometasone furoate | 12351205 | 2 |
| Caelo | Mometasone furoate | 12351207 | 1 |
| Caelo | Mometasone furoate | 12351208 | 1 |
| Caelo | Mometasone furoate | 12351210 | 1 |
| Caelo | Mometasone furoate | 12351215 | 4 |
| Caelo | Mometasone furoate | 13304603 | 1 |
| Caelo | Mometasone furoate | 13304604 | 2 |
| Caelo | Mometasone furoate | 13304605 | 4 |
| Caelo | Mometasone furoate | 13304606 | 4 |
| Caelo | Mometasone furoate | 13304609 | 1 |
| Caelo | Mometasone furoate | 13304612 | 1 |
| Caelo | Mometasone furoate | 13304614 | 1 |
| Caelo | Mometasone furoate | 13F27-N02 | 1 |
| Caelo | Mometasone furoate | 13H13N04 | 1 |
| Caelo | Mometasone furoate | 13H13-N04 | 1 |
| Caelo | Mometasone furoate | 13J23-N02 | 1 |
| Caelo | Mometasone furoate | 14281101 | 2 |
| Caelo | Mometasone furoate | 14281102 | 4 |
| Caelo | Mometasone furoate | 14281103 | 2 |
| Caelo | Mometasone furoate | 14C07-B05-291268 | 2 |
| Caelo | Mometasone furoate | 14E20-B04 | 1 |
| Caelo | Mometasone furoate | 14e20-b04-291267 | 1 |
| Caelo | Mometasone furoate | 14E20-B04-291267 | 4 |
| Caelo | Mometasone furoate | 14H06-B07298481 | 1 |
| Caelo | Mometasone furoate | 15/11-B02 | 3 |
| Caelo | Mometasone furoate | 15/11-B02-314479 | 1 |
| Caelo | Mometasone furoate | 15/11-Bo2-314479 | 1 |
| Caelo | Mometasone furoate | 1510036-001 | 1 |
| Caelo | Mometasone furoate | 151003601 | 1 |
| Caelo | Mometasone furoate | 1510036-02 | 2 |
| Caelo | Mometasone furoate | 15110301 | 4 |
| Caelo | Mometasone furoate | 15110305 | 4 |
| Caelo | Mometasone furoate | 15189801 | 3 |
| Caelo | Mometasone furoate | 15189802 | 5 |
| Caelo | Mometasone furoate | 15189804 | 3 |
| Caelo | Mometasone furoate | 15189806 | 1 |
| Caelo | Mometasone furoate | 15189807 | 5 |
| Caelo | Mometasone furoate | 15189809 | 5 |
| Caelo | Mometasone furoate | 15279003 | 1 |
| Caelo | Mometasone furoate | 15279004 | 7 |
| Caelo | Mometasone furoate | 15b11b03 | 1 |
| Caelo | Mometasone furoate | 15B11-B03-304121 | 2 |
| Caelo | Mometasone furoate | 15B11B03304122 | 1 |
| Caelo | Mometasone furoate | 15G08-B11-310864 | 2 |
| Caelo | Mometasone furoate | 15G08-B11-310865 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mometasone furoate | 15G08-B11-317182 | 1 |
| Caelo | Mometasone furoate | 15G08-B11-322739 | 1 |
| Caelo | Mometasone furoate | 1602809 | 1 |
| Caelo | Mometasone furoate | 16028601 | 4 |
| Caelo | Mometasone furoate | 16028602 | 7 |
| Caelo | Mometasone furoate | 16028604 | 6 |
| Caelo | Mometasone furoate | 16028605 | 2 |
| Caelo | Mometasone furoate | 16028606 | 7 |
| Caelo | Mometasone furoate | 16028607 | 8 |
| Caelo | Mometasone furoate | 16028609 | 9 |
| Caelo | Mometasone furoate | 1606021-01 | 6 |
| Caelo | Mometasone furoate | 1610009-01 | 4 |
| Caelo | Mometasone furoate | 16181703 | 1 |
| Caelo | Mometasone furoate | 16181704 | 9 |
| Caelo | Mometasone furoate | 16181705 | 4 |
| Caelo | Mometasone furoate | 16181708 | 4 |
| Caelo | Mometasone furoate | 16181709 | 6 |
| Caelo | Mometasone furoate | 16181710 | 5 |
| Caelo | Mometasone furoate | 16181714 | 1 |
| Caelo | Mometasone furoate | 16181715 | 10 |
| Caelo | Mometasone furoate | 1635206 | 1 |
| Caelo | Mometasone furoate | 1635209 | 1 |
| Caelo | Mometasone furoate | 1635211 | 1 |
| Caelo | Mometasone furoate | 16353201 | 7 |
| Caelo | Mometasone furoate | 16353204 | 2 |
| Caelo | Mometasone furoate | 16353205 | 4 |
| Caelo | Mometasone furoate | 16353206 | 14 |
| Caelo | Mometasone furoate | 16353207 | 15 |
| Caelo | Mometasone furoate | 16353208 | 5 |
| Caelo | Mometasone furoate | 16353209 | 20 |
| Caelo | Mometasone furoate | 16353210 | 4 |
| Caelo | Mometasone furoate | 16353211 | 14 |
| Caelo | Mometasone furoate | 16353212 | 2 |
| Caelo | Mometasone furoate | 1653205 | 1 |
| Caelo | Mometasone furoate | 16A20-B06-319748 | 1 |
| Caelo | Mometasone furoate | 16A20-B06-319749 | 1 |
| Caelo | Mometasone furoate | 16C24_B03_324852 | 2 |
| Caelo | Mometasone furoate | 16C24-B03-324852 | 1 |
| Caelo | Mometasone furoate | 16C24-B03-327346 | 1 |
| Caelo | Mometasone furoate | 16C24-B03-328272 | 1 |
| Caelo | Mometasone furoate | 16J24-B11 | 1 |
| Caelo | Mometasone furoate | 16J24-B11-332112 | 1 |
| Caelo | Mometasone furoate | 16J24B11-334371 | 1 |
| Caelo | Mometasone furoate | 16J24-B11-334371 | 2 |
| Caelo | Mometasone furoate | 16J24-B11-335793 | 1 |
| Caelo | Mometasone furoate | 1704012A | 1 |
| Caelo | Mometasone furoate | 1711027 | 1 |
| Caelo | Mometasone furoate | 1711027-01 | 1 |
| Caelo | Mometasone furoate | 17348901 | 10 |
| Caelo | Mometasone furoate | 17D19-B02 | 3 |
| Caelo | Mometasone furoate | 17D19-B02-339277 | 1 |
| Caelo | Mometasone furoate | 17D19-B02-342643 | 3 |
| Caelo | Mometasone furoate | 17D19-B02-34476 | 1 |
| Caelo | Mometasone furoate | 17D19-B02-347348 | 2 |
| Caelo | Mometasone furoate | 17D1-B02-344776 | 1 |
| Caelo | Mometasone furoate | 18026001 | 24 |
| Caelo | Mometasone furoate | 18026002 | 1 |
| Caelo | Mometasone furoate | 18026003 | 5 |
| Caelo | Mometasone furoate | 18026004 | 16 |
| Caelo | Mometasone furoate | 18026005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mometasone furoate | 18026006 | 6 |
| Caelo | Mometasone furoate | 18026007 | 9 |
| Caelo | Mometasone furoate | 18026008 | 5 |
| Caelo | Mometasone furoate | 18026009 | 3 |
| Caelo | Mometasone furoate | 18026010 | 1 |
| Caelo | Mometasone furoate | 18026011 | 23 |
| Caelo | Mometasone furoate | 18026012 | 14 |
| Caelo | Mometasone furoate | 18026015 | 6 |
| Caelo | Mometasone furoate | 18026017 | 6 |
| Caelo | Mometasone furoate | 1802603 | 1 |
| Caelo | Mometasone furoate | 1802611 | 1 |
| Caelo | Mometasone furoate | 1806012 | 1 |
| Caelo | Mometasone furoate | 1810008-01 | 2 |
| Caelo | Mometasone furoate | 18102013B | 1 |
| Caelo | Mometasone furoate | 18334101 | 9 |
| Caelo | Mometasone furoate | 18334102 | 19 |
| Caelo | Mometasone furoate | 18334103 | 1 |
| Caelo | Mometasone furoate | 18334104 | 20 |
| Caelo | Mometasone furoate | 18334106 | 12 |
| Caelo | Mometasone furoate | 18334108 | 12 |
| Caelo | Mometasone furoate | 18334109P-191111-4 | 1 |
| Caelo | Mometasone furoate | 18334110 | 13 |
| Caelo | Mometasone furoate | 18B19B07-351001 | 1 |
| Caelo | Mometasone furoate | 18B19-B07-351351 | 1 |
| Caelo | Mometasone furoate | 18B19-B07-352632 | 1 |
| Caelo | Mometasone furoate | 18B19-B07-354319 | 1 |
| Caelo | Mometasone furoate | 18B-B07-354320 | 1 |
| Caelo | Mometasone furoate | 192006004 | 7 |
| Caelo | Mometasone furoate | 19200601 | 21 |
| Caelo | Mometasone furoate | 19200602 | 19 |
| Caelo | Mometasone furoate | 19200603 | 14 |
| Caelo | Mometasone furoate | 19200604 | 5 |
| Caelo | Mometasone furoate | 19200605 | 9 |
| Caelo | Mometasone furoate | 19F13-B12-191761 | 1 |
| Caelo | Mometasone furoate | 200000787008 | 1 |
| Caelo | Mometasone furoate | 200003486010 | 1 |
| Caelo | Mometasone furoate | 2000078004 | 1 |
| Caelo | Mometasone furoate | 20000787001 | 21 |
| Caelo | Mometasone furoate | 20000787002 | 1 |
| Caelo | Mometasone furoate | 20000787004 | 17 |
| Caelo | Mometasone furoate | 20000787005 | 21 |
| Caelo | Mometasone furoate | 20000787007 | 12 |
| Caelo | Mometasone furoate | 20000787008 | 8 |
| Caelo | Mometasone furoate | 20000787009 | 1 |
| Caelo | Mometasone furoate | 20000787010 | 9 |
| Caelo | Mometasone furoate | 20000787012 | 15 |
| Caelo | Mometasone furoate | 20000787013 | 8 |
| Caelo | Mometasone furoate | 2000078787001 | 1 |
| Caelo | Mometasone furoate | 2000346006 | 1 |
| Caelo | Mometasone furoate | 20003486002 | 16 |
| Caelo | Mometasone furoate | 20003486004 | 34 |
| Caelo | Mometasone furoate | 20003486005 | 1 |
| Caelo | Mometasone furoate | 20003486006 | 15 |
| Caelo | Mometasone furoate | 20003486009 | 3 |
| Caelo | Mometasone furoate | 20003486010 | 11 |
| Caelo | Mometasone furoate | 20003486011 | 16 |
| Caelo | Mometasone furoate | 20003486012 | 12 |
| Caelo | Mometasone furoate | 20003486013 | 1 |
| Caelo | Mometasone furoate | 20003486016 | 11 |
| Caelo | Mometasone furoate | 20003486017 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mometasone furoate | 20003486018 | 13 |
| Caelo | Mometasone furoate | 20003486021 | 11 |
| Caelo | Mometasone furoate | 20003486024 | 18 |
| Caelo | Mometasone furoate | 20003486026 | 10 |
| Caelo | Mometasone furoate | 20003486027 | 6 |
| Caelo | Mometasone furoate | 20003486030 | 4 |
| Caelo | Mometasone furoate | 20003486034 | 4 |
| Caelo | Mometasone furoate | 20003486035 | 1 |
| Caelo | Mometasone furoate | 20003486036 | 1 |
| Caelo | Mometasone furoate | 200034866016 | 1 |
| Caelo | Mometasone furoate | 20003489021 | 1 |
| Caelo | Mometasone furoate | 200034896004 | 1 |
| Caelo | Mometasone furoate | 2000787001 | 1 |
| Caelo | Mometasone furoate | 2000787004 | 1 |
| Caelo | Mometasone furoate | 2000787007 | 1 |
| Caelo | Mometasone furoate | 2000787013 | 1 |
| Caelo | Mometasone furoate | 200315A | 1 |
| Caelo | Mometasone furoate | 2003486016 | 2 |
| Caelo | Mometasone furoate | 2003486026 | 1 |
| Caelo | Mometasone furoate | 20g24-b03-196879 | 1 |
| Caelo | Mometasone furoate | 20G24-B03-196879 | 1 |
| Caelo | Mometasone furoate | 220003486026 | 1 |
| Caelo | Mometasone furoate | 23001247005 | 1 |
| Caelo | Mometasone furoate | 240913a | 1 |
| Caelo | Mometasone furoate | 2885 | 1 |
| Caelo | Mometasone furoate | 34860062 | 1 |
| Caelo | Mometasone furoate | 701834-0002 | 1 |
| Caelo | Mometasone furoate | 9530001 | 1 |
| Caelo | Mometasone furoate | 9530018 | 1 |
| Caelo | Mometasone furoate | APMOM006/0117M | 1 |
| Caelo | Mometasone furoate | MOM001/0317 | 1 |
| Caelo | Mometasone furoate | MOM010/0116 | 3 |
| Caelo | Mometasone furoate | NO1352M | 1 |
| Caelo | Mometasone furoate | NT1568M | 1 |
| Caelo | Mometasone furoate | NU0698M | 1 |
| Caelo | Mometasone furoate | NV1000M | 1 |
| Caeo/Noweda | Mometasone furoate | 15279003 | 1 |
| Caeo | Mometasone furoate | 12351201 | 1 |
| Caeolo/Gehe | Mometasone furoate | 16J24-B11-332112 | 1 |
| Caeolo/Gehe | Mometasone furoate | 18334104 | 1 |
| Caesa / Alliance Hea... | Mometasone furoate | 18026012 | 1 |
| Caesar & Lorenz GmbH | Mometasone furoate | 18334108 | 1 |
| Caesar & Lorenz GmbH | Mometasone furoate | 20000787001 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 2000078005 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486035 | 2 |
| Caesar & Loretz GmbH... | Mometasone furoate | 19200603 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486029 | 2 |
| Caesar & Loretz GmbH... | Mometasone furoate | 2003486030 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 18026015 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20000787005 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 11H10-N04 | 1 |
| Caesar & Loretz GmbH/ AHD | Mometasone furoate | 20003486016 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20000787005 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486017 | 2 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486010 | 1 |
| Caesar & Loretz GmbH/AHD | Mometasone furoate | 20003486006 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486006 | 2 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486021 | 1 |
| Caesar & Loretz GmbH/Gehe | Mometasone furoate | 19200605 | 1 |
| Caesar & Loretz GmbH/Gehe | Mometasone furoate | 20003486016 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/GEHE | Mometasone furoate | 20003486035 | 3 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486004 | 4 |
| Caesar & Loretz GmbH... | Mometasone furoate | 18334108 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20000787001 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486026 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486034 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20000787001 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486024 | 1 |
| Caesar & Loretz GmbH/Otto | Mometasone furoate | 20000787010 | 1 |
| Caesar & Loretz GmbH/Ph | Mometasone furoate | 20003486018 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 2000078712 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20000787004 | 2 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486002 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486004 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20000787008 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486011 | 1 |
| Caesar & Loretz GmbH/S | Mometasone furoate | 20003486010 | 1 |
| Caesar & Loretz GmbH/S | Mometasone furoate | 20003486024 | 1 |
| Caesar & Loretz GmbH/Sa | Mometasone furoate | 18334108 | 1 |
| Caesar & Loretz GmbH/Sa | Mometasone furoate | 19200601 | 1 |
| Caesar & Loretz GmbH/Sana | Mometasone furoate | 20003486012 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486010 | 1 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486018 | 2 |
| Caesar & Loretz GmbH... | Mometasone furoate | 20003486024 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 12035601 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 16028609 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 18026001 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 18026012 | 5 |
| Caesar & Loretz GmbH | Mometasone furoate | 18026013 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 18026014 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 18026017 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 18072120 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 18334101 | 4 |
| Caesar & Loretz GmbH | Mometasone furoate | 18334102 | 3 |
| Caesar & Loretz GmbH | Mometasone furoate | 18334104 | 4 |
| Caesar & Loretz GmbH | Mometasone furoate | 18334106 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 18334108 | 5 |
| Caesar & Loretz GmbH | Mometasone furoate | 18334110 | 3 |
| Caesar & Loretz GmbH | Mometasone furoate | 19200601 | 4 |
| Caesar & Loretz GmbH | Mometasone furoate | 19200602 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 19200603 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 19200604 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 19200605 | 7 |
| Caesar & Loretz GmbH | Mometasone furoate | 200003486024 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787001 | 8 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787002 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787005 | 4 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787007 | 3 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787008 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787010 | 4 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787012 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 20000787013 | 3 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486002 | 7 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486004 | 25 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486006 | 8 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486008 | 4 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486010 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486011 | 13 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486012 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Mometasone furoate | 20003486016 | 3 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486017 | 5 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486018 | 12 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486020 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486021 | 18 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486024 | 4 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486026 | 8 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486027 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486030 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 20003486034 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 2001040-01 | 2 |
| Caesar & Loretz GmbH | Mometasone furoate | 22C15-B06-221102 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | 30000787007 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | B03-1968709 | 1 |
| Caesar & Loretz GmbH | Mometasone furoate | B03-1970806 | 1 |
| Caesar & Loretz Hilden | Mometasone furoate | 18026012 | 1 |
| Caesar & Loretz/Geil... | Mometasone furoate | 20003486006 | 2 |
| Caesar & Loretz/Noweda | Mometasone furoate | 18026012 | 1 |
| Caesar u Loretz | Mometasone furoate | 15279004 | 2 |
| Caesar u. Loretz GmbH | Mometasone furoate | 19200605 | 1 |
| Caesar und Loretz GmbH | Mometasone furoate | 2000787010 | 1 |
| caesar&Loretz GmbH,P... | Mometasone furoate | 16028604 | 1 |
| Caesar&loretz,AHC,08... | Mometasone furoate | | 1 |
| Calo/AHD | Mometasone furoate | 19200603 | 1 |
| Carlo/Phönix/21,89 | Mometasone furoate | 18334102 | 1 |
| Cealo/Anzag | Mometasone furoate | 18026012 | 1 |
| EuRho / 2 | Mometasone furoate | 1906035-01 | 1 |
| EuRho / 2 | Mometasone furoate | 2003056-01 | 1 |
| EuRho / Noweda | Mometasone furoate | 1906035-01 | 2 |
| EuRho/AHD | Mometasone furoate | 2003056-01 | 1 |
| EuRho/AHD | Mometasone furoate | 2008002-01 | 3 |
| EuRho/Gehe | Mometasone furoate | 2001040-01 | 1 |
| EuRho/Gehe | Mometasone furoate | 2106014-01 | 1 |
| EuRho/Ph | Mometasone furoate | 2001040-01 | 2 |
| EuRho/Phönix | Mometasone furoate | 1307037-01 | 2 |
| EuRho | Mometasone furoate | 1408010-01 | 1 |
| EuRho | Mometasone furoate | 15/11-B02-315705 | 1 |
| Eurho | Mometasone furoate | 18B19-B07-352744 | 1 |
| EuRho | Mometasone furoate | 2003056-01 | 1 |
| EuRho | Mometasone furoate | 2008002-01 | 1 |
| Eurho | Mometasone furoate | 2106014-01 | 2 |
| Euro OTC | Mometasone furoate | | 2 |
| Euro OTC | Mometasone furoate | 1203024-02 | 1 |
| Euro OTC | Mometasone furoate | 1307037-01 | 1 |
| Euro OTC | Mometasone furoate | 1408010-01 | 2 |
| Euro OTC | Mometasone furoate | 15/11B02315705 | 2 |
| Euro OTC | Mometasone furoate | 1504012-01 | 7 |
| Euro OTC | Mometasone furoate | 1504012-02 | 5 |
| Euro OTC | Mometasone furoate | 1510036-01 | 15 |
| Euro OTC | Mometasone furoate | 15G08-B11-317182 | 1 |
| Euro OTC | Mometasone furoate | 15G08-B11-322738 | 2 |
| Euro OTC | Mometasone furoate | 160009-01 | 1 |
| Euro OTC | Mometasone furoate | 160602101 | 1 |
| Euro OTC | Mometasone furoate | 1606021-01 | 8 |
| Euro OTC | Mometasone furoate | 16100009-01 | 3 |
| Euro OTC | Mometasone furoate | 1610009-001 | 1 |
| Euro OTC | Mometasone furoate | 161000901 | 1 |
| Euro OTC | Mometasone furoate | 1610009-01 | 31 |
| Euro OTC | Mometasone furoate | 16J24-b11 | 1 |
| Euro OTC | Mometasone furoate | 16j24-B11-332111 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Mometasone furoate | 1711027 | 1 |
| Euro OTC | Mometasone furoate | 171102701 | 1 |
| Euro OTC | Mometasone furoate | 1711027-01 | 9 |
| Euro OTC | Mometasone furoate | 1711027-02 | 4 |
| Euro OTC | Mometasone furoate | 17D19-B02-342643 | 1 |
| Euro OTC | Mometasone furoate | 17D19B02347349 | 1 |
| Euro OTC | Mometasone furoate | 18026006 | 1 |
| Euro OTC | Mometasone furoate | 1810002-01 | 1 |
| Euro OTC | Mometasone furoate | 1810008_01 | 1 |
| Euro OTC | Mometasone furoate | 181000801 | 2 |
| Euro OTC | Mometasone furoate | 1810008-01 | 28 |
| Euro OTC | Mometasone furoate | 1810008-01P-200331-2 | 1 |
| Euro OTC | Mometasone furoate | 18334108 | 1 |
| Euro OTC | Mometasone furoate | 18B19-B07-352632 | 1 |
| Euro OTC | Mometasone furoate | 19060035 | 1 |
| Euro OTC | Mometasone furoate | 1906035 | 2 |
| Euro OTC | Mometasone furoate | 190603501 | 2 |
| Euro OTC | Mometasone furoate | 1906035-01 | 33 |
| Euro OTC | Mometasone furoate | 20008002-01 | 1 |
| Euro OTC | Mometasone furoate | 2001040-01 | 15 |
| Euro OTC | Mometasone furoate | 2003056-01 | 45 |
| Euro OTC | Mometasone furoate | 200800-01 | 1 |
| Euro OTC | Mometasone furoate | 200800201 | 4 |
| Euro OTC | Mometasone furoate | 2008002-01 | 91 |
| Euro OTC | Mometasone furoate | 2008002-02 | 1 |
| Euro OTC | Mometasone furoate | 2106014-01 | 34 |
| Euro OTC | Mometasone furoate | 23051822 | 1 |
| Euro OTC | Mometasone furoate | 5991 | 1 |
| Euro OTC | Mometasone furoate | 83919-23-7 | 3 |
| Euro OTG | Mometasone furoate | 1403015-01 | 1 |
| EURO/Noweda | Mometasone furoate | 2003056-01 | 1 |
| EuRoh/ Gehe | Mometasone furoate | 2008002-01 | 1 |
| Fa.Phönix | Mometasone furoate | 16j24-b11-334371 | 1 |
| Fagr/sana EK: EUR 39,2... | Mometasone furoate | 18B19-B07-35151 | 1 |
| Fagro/Noweda | Mometasone furoate | 17D19-B02-339277 | 1 |
| Fagro | Mometasone furoate | 1511B02 | 1 |
| Fagron | Mometasone furoate | | 1 |
| Fagron | Mometasone furoate | 10805-N12 | 1 |
| Fagron | Mometasone furoate | 10C29-N10 | 1 |
| Fagron | Mometasone furoate | 10E31-N26 | 1 |
| Fagron | Mometasone furoate | 11C02-N03 | 2 |
| Fagron | Mometasone furoate | 11F08-N03 | 1 |
| Fagron | Mometasone furoate | 11H10-N01 | 1 |
| Fagron | Mometasone furoate | 11h10-n04 | 1 |
| Fagron | Mometasone furoate | 11H10-N04 | 2 |
| Fagron | Mometasone furoate | 11K28-N09 | 2 |
| Fagron | Mometasone furoate | 12B22-N01 | 1 |
| Fagron | Mometasone furoate | 12B22-N04 | 1 |
| Fagron | Mometasone furoate | 12e02-n11 | 1 |
| Fagron | Mometasone furoate | 12E02-N11 | 4 |
| Fagron | Mometasone furoate | 12H09-N02 | 7 |
| Fagron | Mometasone furoate | 12I29-N03 | 1 |
| Fagron | Mometasone furoate | 12J29-N01 | 1 |
| Fagron | Mometasone furoate | 12J29-N03 | 4 |
| Fagron | Mometasone furoate | 13d08-n06 | 1 |
| Fagron | Mometasone furoate | 13D08N06 | 1 |
| Fagron | Mometasone furoate | 13D08-N06 | 14 |
| Fagron | Mometasone furoate | 13Do8-N06 | 1 |
| Fagron | Mometasone furoate | 13f17-n01 | 1 |
| Fagron | Mometasone furoate | 13F17-N01 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mometasone furoate | 13F27-N02 | 7 |
| Fagron | Mometasone furoate | 13F27-NO2 | 1 |
| Fagron | Mometasone furoate | 13F7-N01 | 1 |
| Fagron | Mometasone furoate | 13H13-N04 | 11 |
| Fagron | Mometasone furoate | 13H13-NO4 | 1 |
| Fagron | Mometasone furoate | 13j23_n02 | 1 |
| Fagron | Mometasone furoate | 13j23-N02 | 1 |
| Fagron | Mometasone furoate | 13J23-N02 | 21 |
| Fagron | Mometasone furoate | 13j23-no2 | 1 |
| Fagron | Mometasone furoate | 140305MF | 1 |
| Fagron | Mometasone furoate | 14C07-B05-291264 | 2 |
| Fagron | Mometasone furoate | 14C07-B05-291266 | 2 |
| Fagron | Mometasone furoate | 14C07-B05-291268 | 11 |
| Fagron | Mometasone furoate | 14E20-B04 | 4 |
| Fagron | Mometasone furoate | 14e20b04291265 | 1 |
| Fagron | Mometasone furoate | 14e20-b04-291265 | 1 |
| Fagron | Mometasone furoate | 14E20-B04-291265 | 3 |
| Fagron | Mometasone furoate | 14e20-b04-291267 | 1 |
| Fagron | Mometasone furoate | 14E20-B04-291267 | 4 |
| Fagron | Mometasone furoate | 14E20-B04-291269 | 2 |
| Fagron | Mometasone furoate | 14E20-B04-291271 | 1 |
| Fagron | Mometasone furoate | 14E20-B04-294645 | 7 |
| Fagron | Mometasone furoate | 14E20-B04-302374 | 2 |
| Fagron | Mometasone furoate | 14H06-B07297240 | 1 |
| Fagron | Mometasone furoate | 14H06-B07-297240 | 3 |
| Fagron | Mometasone furoate | 14h06-b07-298481 | 2 |
| Fagron | Mometasone furoate | 14H06-B07-298481 | 2 |
| Fagron | Mometasone furoate | 14H06-B07-298482 | 7 |
| Fagron | Mometasone furoate | 14H06-B07-302375 | 2 |
| Fagron | Mometasone furoate | 14H06-B07-302376 | 3 |
| Fagron | Mometasone furoate | 15/11-B02 | 1 |
| Fagron | Mometasone furoate | 15/11-B02-314479 | 5 |
| Fagron | Mometasone furoate | 15/11-B02-315705 | 3 |
| Fagron | Mometasone furoate | 15/11-B02-316705 | 1 |
| Fagron | Mometasone furoate | 15B11-B03 | 3 |
| Fagron | Mometasone furoate | 15b11-b03-304120 | 1 |
| Fagron | Mometasone furoate | 15B11-B03-304120 | 7 |
| Fagron | Mometasone furoate | 15B11B03304121 | 1 |
| Fagron | Mometasone furoate | 15B11-B03-304121 | 9 |
| Fagron | Mometasone furoate | 15B11B03304122 | 1 |
| Fagron | Mometasone furoate | 15B11-B03-304122 | 6 |
| Fagron | Mometasone furoate | 15B11-B03-304123 | 14 |
| Fagron | Mometasone furoate | 15b11-b03-304124 | 1 |
| Fagron | Mometasone furoate | 15B11-B03-304124 | 2 |
| Fagron | Mometasone furoate | 15b11-b03-308276 | 2 |
| Fagron | Mometasone furoate | 15B11-B03-308276 | 3 |
| Fagron | Mometasone furoate | 15B11B03308860 | 1 |
| Fagron | Mometasone furoate | 15B11-B03-308860 | 2 |
| Fagron | Mometasone furoate | 15G08 | 1 |
| Fagron | Mometasone furoate | 15G08-B11 | 3 |
| Fagron | Mometasone furoate | 15G08-B11-0002 | 1 |
| Fagron | Mometasone furoate | 15G08-B11-310864 | 8 |
| Fagron | Mometasone furoate | 15G08-B11-312233 | 4 |
| Fagron | Mometasone furoate | 15G08-B11-317182 | 9 |
| Fagron | Mometasone furoate | 15G08-B11-322737 | 2 |
| Fagron | Mometasone furoate | 15g08-b11-322738 | 1 |
| Fagron | Mometasone furoate | 15G08B11322738 | 1 |
| Fagron | Mometasone furoate | 15G08-B11-322738 | 4 |
| Fagron | Mometasone furoate | 15G-B11-310864 | 1 |
| Fagron | Mometasone furoate | 15I11-B02-314479 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mometasone furoate | 15I11-B02-315705 | 1 |
| Fagron | Mometasone furoate | 15J11-B02-315705 | 1 |
| Fagron | Mometasone furoate | 16/24-B11-332122 | 1 |
| Fagron | Mometasone furoate | 16181709 | 1 |
| Fagron | Mometasone furoate | 16181714 | 1 |
| Fagron | Mometasone furoate | 16724-B11-332112 | 1 |
| Fagron | Mometasone furoate | 16A20-B06 | 3 |
| Fagron | Mometasone furoate | 16A20-B06-319740 | 1 |
| Fagron | Mometasone furoate | 16A20-B06-319748 | 7 |
| Fagron | Mometasone furoate | 16A20-B06319749 | 1 |
| Fagron | Mometasone furoate | 16A20-B06-319749 | 6 |
| Fagron | Mometasone furoate | 16A20-B06-322739 | 6 |
| Fagron | Mometasone furoate | 16A20-Bo6-319748 | 1 |
| Fagron | Mometasone furoate | 16C24 | 1 |
| Fagron | Mometasone furoate | 16C24-803-324851 | 1 |
| Fagron | Mometasone furoate | 16C24B03 | 1 |
| Fagron | Mometasone furoate | 16C24-B03 | 3 |
| Fagron | Mometasone furoate | 16C24B03324851 | 1 |
| Fagron | Mometasone furoate | 16C24-B03-324851 | 4 |
| Fagron | Mometasone furoate | 16C24B03324852 | 1 |
| Fagron | Mometasone furoate | 16C24-B03-324852 | 5 |
| Fagron | Mometasone furoate | 16C24-B03-325575 | 1 |
| Fagron | Mometasone furoate | 16C24-B03-326790 | 10 |
| Fagron | Mometasone furoate | 16C24-B03-327346 | 4 |
| Fagron | Mometasone furoate | 16c24-b03-327372 | 1 |
| Fagron | Mometasone furoate | 16C24-b03-327372 | 1 |
| Fagron | Mometasone furoate | 16C24-B03-327372 | 5 |
| Fagron | Mometasone furoate | 16C24-B03-328272 | 6 |
| Fagron | Mometasone furoate | 16J24-11-335793 | 1 |
| Fagron | Mometasone furoate | 16j24-b11 | 1 |
| Fagron | Mometasone furoate | 16J24-B11 | 6 |
| Fagron | Mometasone furoate | 16j24-b11-329817 | 1 |
| Fagron | Mometasone furoate | 16J24B11329817 | 1 |
| Fagron | Mometasone furoate | 16J24-B11-329817 | 4 |
| Fagron | Mometasone furoate | 16J24-B11-330978 | 5 |
| Fagron | Mometasone furoate | 16J24-B11-332110 | 3 |
| Fagron | Mometasone furoate | 16J24-B11-332111 | 5 |
| Fagron | Mometasone furoate | 16J24B11332112 | 1 |
| Fagron | Mometasone furoate | 16J24-B11-332112 | 14 |
| Fagron | Mometasone furoate | 16J24B11334371 | 1 |
| Fagron | Mometasone furoate | 16J24-B11-334371 | 9 |
| Fagron | Mometasone furoate | 16j24-b11-335792 | 1 |
| Fagron | Mometasone furoate | 16J24-B11-335792 | 1 |
| Fagron | Mometasone furoate | 16j24b11335793 | 1 |
| Fagron | Mometasone furoate | 16J24B11335793 | 1 |
| Fagron | Mometasone furoate | 16J24-B11-335793 | 13 |
| Fagron | Mometasone furoate | 17D1834 | 1 |
| Fagron | Mometasone furoate | 17D19 | 1 |
| Fagron | Mometasone furoate | 17D19_B02_339278 | 1 |
| Fagron | Mometasone furoate | 17D19-B02 | 5 |
| Fagron | Mometasone furoate | 17D19-B02_339278 | 1 |
| Fagron | Mometasone furoate | 17D19-B02-33927 | 2 |
| Fagron | Mometasone furoate | 17D19-B02-339276 | 3 |
| Fagron | Mometasone furoate | 17D19B02339277 | 1 |
| Fagron | Mometasone furoate | 17D19-B02339277 | 1 |
| Fagron | Mometasone furoate | 17D19-B02-339277 | 4 |
| Fagron | Mometasone furoate | 17D19-B02-339278 | 6 |
| Fagron | Mometasone furoate | 17D19B02342642 | 1 |
| Fagron | Mometasone furoate | 17D19-B02-342642 | 3 |
| Fagron | Mometasone furoate | 17D19-B02-342643 | 17 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mometasone furoate | 17D19-B02-344776 | 3 |
| Fagron | Mometasone furoate | 17D19-B02-347347 | 6 |
| Fagron | Mometasone furoate | 17D19-B02-347348 | 5 |
| Fagron | Mometasone furoate | 17d19-b02-347349 | 1 |
| Fagron | Mometasone furoate | 17D19B02347349 | 1 |
| Fagron | Mometasone furoate | 17D19-B02-347349 | 15 |
| Fagron | Mometasone furoate | 17D19-B02-3477347 | 1 |
| Fagron | Mometasone furoate | 1814E3640 | 1 |
| Fagron | Mometasone furoate | 18819-807 | 1 |
| Fagron | Mometasone furoate | 18819-b07 | 1 |
| Fagron | Mometasone furoate | 18819-B07-345319 | 1 |
| Fagron | Mometasone furoate | 18819-B07-356278 | 1 |
| Fagron | Mometasone furoate | 18819-B07-357640 | 3 |
| Fagron | Mometasone furoate | 18B199-B07-354320 | 1 |
| Fagron | Mometasone furoate | 18B19-B07 | 10 |
| Fagron | Mometasone furoate | 18B19-B07-341351 | 1 |
| Fagron | Mometasone furoate | 18b19-b07-351001 | 1 |
| Fagron | Mometasone furoate | 18B19-B07-351001 | 1 |
| Fagron | Mometasone furoate | 18B19-B07-351351 | 9 |
| Fagron | Mometasone furoate | 18b19-b07-352632 | 1 |
| Fagron | Mometasone furoate | 18B19B07352632 | 1 |
| Fagron | Mometasone furoate | 18B19-B07-352632 | 17 |
| Fagron | Mometasone furoate | 18B19-B07-352635 | 1 |
| Fagron | Mometasone furoate | 18B19-B07-352744 | 9 |
| Fagron | Mometasone furoate | 18B19B07352745 | 1 |
| Fagron | Mometasone furoate | 18B19-B07-352745 | 14 |
| Fagron | Mometasone furoate | 18B19-B07-354318 | 4 |
| Fagron | Mometasone furoate | 18B19-B07-354319 | 5 |
| Fagron | Mometasone furoate | 18B19-B07-354319MOM010/0118 | 1 |
| Fagron | Mometasone furoate | 18B19-B07-354320 | 19 |
| Fagron | Mometasone furoate | 18B19-B07-357228 | 3 |
| Fagron | Mometasone furoate | 18B19-B07-357640 | 12 |
| Fagron | Mometasone furoate | 191761 | 2 |
| Fagron | Mometasone furoate | 19200604 | 1 |
| Fagron | Mometasone furoate | 197086 | 1 |
| Fagron | Mometasone furoate | 19F13B12191760 | 2 |
| Fagron | Mometasone furoate | 19F13-B12-191760 | 5 |
| Fagron | Mometasone furoate | 19F13B12191761 | 1 |
| Fagron | Mometasone furoate | 19F13-B12-191761 | 22 |
| Fagron | Mometasone furoate | 19F13-B12-1917610481 | 1 |
| Fagron | Mometasone furoate | 19F13-B12-191762 | 8 |
| Fagron | Mometasone furoate | 19F13-B191761 | 1 |
| Fagron | Mometasone furoate | 20000787001 | 1 |
| Fagron | Mometasone furoate | 20G24_BO3-197086 | 1 |
| Fagron | Mometasone furoate | 20G244-BO3-196879 | 1 |
| Fagron | Mometasone furoate | 20g24-803-196879 | 1 |
| Fagron | Mometasone furoate | 20G24-B03 | 13 |
| Fagron | Mometasone furoate | 20G24-B03-1968709 | 1 |
| Fagron | Mometasone furoate | 20G24-B03-196879 | 30 |
| Fagron | Mometasone furoate | 20G24B03197086 | 4 |
| Fagron | Mometasone furoate | 20G24-B03-197086 | 25 |
| Fagron | Mometasone furoate | 20G24-B03-201311 | 2 |
| Fagron | Mometasone furoate | 20G24-BO3-196879 | 2 |
| Fagron | Mometasone furoate | 20G24-BO3-201311 | 1 |
| Fagron | Mometasone furoate | 210543 | 1 |
| Fagron | Mometasone furoate | 2114M3640 | 1 |
| Fagron | Mometasone furoate | 21B26-B05 | 2 |
| Fagron | Mometasone furoate | 21b26-b05-203100 | 1 |
| Fagron | Mometasone furoate | 21B26-B05-203100 | 30 |
| Fagron | Mometasone furoate | 21B26-B05-203101 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Mometasone furoate | 21B26B05210542 | 1 |
| Fagron | Mometasone furoate | 21B26-B05-210542 | 7 |
| Fagron | Mometasone furoate | 21B26-B05-210543 | 7 |
| Fagron | Mometasone furoate | 21B26-B05-213869 | 1 |
| Fagron | Mometasone furoate | 21B26-B05-219115 | 1 |
| Fagron | Mometasone furoate | 21B26-B05-219200 | 1 |
| Fagron | Mometasone furoate | 21B26-BO5-213869 | 1 |
| Fagron | Mometasone furoate | 21B26-BO5-219115 | 1 |
| Fagron | Mometasone furoate | 2215I-07030 | 1 |
| Fagron | Mometasone furoate | 22C15-B06-219423 | 2 |
| Fagron | Mometasone furoate | 22C15B06221102 | 1 |
| Fagron | Mometasone furoate | 22C15-B06-221102 | 3 |
| Fagron | Mometasone furoate | 22C15-B06-223110 | 3 |
| Fagron | Mometasone furoate | 22C15-B06-227594 | 1 |
| Fagron | Mometasone furoate | 22C15-BO6-221102 | 1 |
| Fagron | Mometasone furoate | 24D10-B13-236855 | 1 |
| Fagron | Mometasone furoate | 24F28-B17-005404 | 1 |
| Fagron | Mometasone furoate | 2517Q-07030 | 1 |
| Fagron | Mometasone furoate | 2714U-07030 | 1 |
| Fagron | Mometasone furoate | 2818A-07030 | 1 |
| Fagron | Mometasone furoate | 3313A-07030 | 1 |
| Fagron | Mometasone furoate | 334371 | 1 |
| Fagron | Mometasone furoate | 335793 | 1 |
| Fagron | Mometasone furoate | 339278 | 1 |
| Fagron | Mometasone furoate | 347349 | 2 |
| Fagron | Mometasone furoate | 352632 | 1 |
| Fagron | Mometasone furoate | 354319 | 1 |
| Fagron | Mometasone furoate | 4(18B19-B07-351001 | 1 |
| Fagron | Mometasone furoate | 5(MOM001/0220) | 1 |
| Fagron | Mometasone furoate | 5/0715 | 1 |
| Fagron | Mometasone furoate | 6071716 | 1 |
| Fagron | Mometasone furoate | 701834-0001 | 1 |
| Fagron | Mometasone furoate | 701834-0004 | 1 |
| Fagron | Mometasone furoate | 83919-23-7 | 1 |
| Fagron | Mometasone furoate | B03-1968709 | 7 |
| Fagron | Mometasone furoate | B03-1970806 | 5 |
| Fagron | Mometasone furoate | B03-197086 | 2 |
| Fagron | Mometasone furoate | B05-2031001 | 2 |
| Fagron | Mometasone furoate | B05-2105403 | 1 |
| Fagron | Mometasone furoate | B12-1917600 | 1 |
| Fagron | Mometasone furoate | BO3-1968709 | 1 |
| Fagron | Mometasone furoate | Fagron21B26-B05-203101 | 1 |
| Fagron | Mometasone furoate | HM01620 | 1 |
| Fagron | Mometasone furoate | HMF010620 | 1 |
| Fagron | Mometasone furoate | HMF01620 | 2 |
| Fagron | Mometasone furoate | HMFO1620 | 1 |
| Fagron | Mometasone furoate | mom001/0220 | 1 |
| Fagron | Mometasone furoate | MOM001/0220 | 9 |
| Fagron | Mometasone furoate | MOM001/0317 | 4 |
| Fagron | Mometasone furoate | MOM003/0818 | 6 |
| Fagron | Mometasone furoate | MOM004/0716 | 4 |
| Fagron | Mometasone furoate | MOM004-0716 | 1 |
| Fagron | Mometasone furoate | MOM008/0915 | 3 |
| Fagron | Mometasone furoate | MOM010/0116 | 2 |
| Fagron | Mometasone furoate | MOM010/0118 | 8 |
| Fagron | Mometasone furoate | NS1513M | 1 |
| Fagron | Mometasone furoate | NT1568M | 3 |
| Fagron | Mometasone furoate | NU0698M | 2 |
| Fagron | Mometasone furoate | NU2504M | 1 |
| Fargo / Gehe | Mometasone furoate | 20G24-B03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fargon/AHD | Mometasone furoate | 18B19-B07-351001 | 1 |
| Fargon/AHD | Mometasone furoate | 18B19-B07-354319 | 1 |
| Fargon | Mometasone furoate | 13H13-N04 | 1 |
| Fargon | Mometasone furoate | 16C24-B03-324852 | 1 |
| Fargon | Mometasone furoate | 17D19-B02-342643 | 3 |
| Fargon | Mometasone furoate | 20G24-B03-196879 | 1 |
| Fargron/Noweda | Mometasone furoate | 20G24-B03-197086 | 1 |
| Finteler Apotheke | Mometasone furoate | 16028603 | 1 |
| Finteler Apotheke | Mometasone furoate | 16028604 | 1 |
| Fragon/Phoenix | Mometasone furoate | 19F13-B12-191762 | 1 |
| Fragon/Sanacorp | Mometasone furoate | 16C24-B03-324851 | 1 |
| Fragon/Sanacorp | Mometasone furoate | 17D19-B02-339277 | 2 |
| Fragon/Sanacorp | Mometasone furoate | 17D19-B02-342642 | 1 |
| Fragon/Sanacorp | Mometasone furoate | 17D19-B02-342643 | 2 |
| Fragon/Sanacorp | Mometasone furoate | 17D19-B02-347348 | 1 |
| Fragron/ Alliance | Mometasone furoate | 20G24-B03-196879 | 1 |
| Gehe 07.12.18 | Mometasone furoate | 1711027_02 | 1 |
| GEHE 17.04.2014 | Mometasone furoate | 13J23-N02 | 1 |
| Gehe amax | Mometasone furoate | 16J24-B11-335793 | 2 |
| Gehe amax | Mometasone furoate | 17D19-B02-342643 | 1 |
| Gehe amax | Mometasone furoate | 1906035-01 | 1 |
| Gehe amax | Mometasone furoate | 19F13-B12-191761 | 1 |
| Gehe/Caesar & Loretz GmbH | Mometasone furoate | 20003486021 | 1 |
| Gehe/EuRoh | Mometasone furoate | 2003056-01 | 1 |
| Gehe | Mometasone furoate | 13D08-N06 | 1 |
| Gehe | Mometasone furoate | 13H13-N04 | 2 |
| Gehe | Mometasone furoate | 15B11-B03-304123 | 1 |
| Gehe | Mometasone furoate | 15G08-B11-312233 | 1 |
| Gehe | Mometasone furoate | 15G08-B11-317182 | 1 |
| Gehe | Mometasone furoate | 16181704 | 1 |
| Gehe | Mometasone furoate | 16353201 | 1 |
| Gehe | Mometasone furoate | 16353206 | 1 |
| Gehe | Mometasone furoate | 16353207 | 1 |
| Gehe | Mometasone furoate | 16C24-B03-324852 | 1 |
| Gehe | Mometasone furoate | 16C24-B03-327346 | 1 |
| Gehe | Mometasone furoate | 16J24-B11-332112 | 2 |
| Gehe | Mometasone furoate | 17D19-B02 | 1 |
| Gehe | Mometasone furoate | 17D19-B02-339278 | 1 |
| Gehe | Mometasone furoate | 17D19-B02-342642 | 2 |
| GEHE | Mometasone furoate | 17D19-B02-344776 | 1 |
| GEHE | Mometasone furoate | 18026006 | 1 |
| Gehe | Mometasone furoate | 18334101 | 1 |
| gehe | Mometasone furoate | 18334104 | 1 |
| Gehe | Mometasone furoate | 18B19-B07-352745 | 4 |
| Gehe | Mometasone furoate | 18B19-B07-354318 | 1 |
| Gehe | Mometasone furoate | 18B19-B07-354319 | 3 |
| Gehe | Mometasone furoate | 18B19-B07-354319 | 1 |
| Gehe | Mometasone furoate | 1906035-01 | 3 |
| Gehe | Mometasone furoate | 19F13-B12-191761 | 1 |
| Gehe | Mometasone furoate | 20003486002 | 1 |
| Gehe | Mometasone furoate | 20003486026 | 1 |
| Gehe | Mometasone furoate | 20003486034 | 1 |
| Gehe | Mometasone furoate | 20003486035 | 1 |
| Gehe | Mometasone furoate | 20G24-B03-197086 | 3 |
| gehe | Mometasone furoate | 20G24-Bo3-196879 | 1 |
| Gehe | Mometasone furoate | 2106014-01 | 9 |
| Gehe | Mometasone furoate | 22C15-B06-221102 | 1 |
| Gehe | Mometasone furoate | 2305005-01 | 1 |
| Gehe | Mometasone furoate | 23F15-B02-234650 | 1 |
| Gehe | Mometasone furoate | 24D10-B13-236852 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Mometasone furoate | 250502(24002020002) | 1 |
| Geibo/ Fargron | Mometasone furoate | 16J24-b11-335792 | 1 |
| Geibo | Mometasone furoate | 18B19-B07-354320 | 1 |
| Hedinger/Gehe | Mometasone furoate | 1896223 | 1 |
| Holdermann | Mometasone furoate | 13D08-N06 | 1 |
| Holdermann | Mometasone furoate | 14C07-B05-29126 | 1 |
| Holdermann | Mometasone furoate | 21B26-B05-210543 | 1 |
| Holdermann | Mometasone furoate | 24D10-B13-238791 | 1 |
| Jenne | Mometasone furoate | 18026012 | 1 |
| Jenne | Mometasone furoate | 1802612 | 1 |
| Jenne | Mometasone furoate | 20003486030 | 1 |
| Jenne | Mometasone furoate | 20003486034 | 1 |
| Jenne | Mometasone furoate | 21B26-805-203100 | 1 |
| Kehr Holdermann | Mometasone furoate | 20G24-B03-197480 | 1 |
| Kehr | Mometasone furoate | 16353206 | 1 |
| Kehr | Mometasone furoate | 2300124706 | 1 |
| kehr | Mometasone furoate | 230500501-01 | 2 |
| Kehr | Mometasone furoate | 24002020002 | 1 |
| Nachprüfung | Mometasone furoate | 1628604 | 1 |
| Nachprüfung | Mometasone furoate | 16J24-B11-329817 | 1 |
| Newchem / Gehe | Mometasone furoate | 16181715 | 1 |
| Noveda | Mometasone furoate | 18334101 | 1 |
| Noveda | Mometasone furoate | 20000787010 | 1 |
| Noweda /Cealo | Mometasone furoate | 19200601 | 2 |
| Noweda Taucha | Mometasone furoate | 20003486011 | 1 |
| Noweda Taucha | Mometasone furoate | 2008002-01 | 2 |
| Noweda | Mometasone furoate | 15G08-B11 | 1 |
| Noweda | Mometasone furoate | 16C24-B03-328272 | 1 |
| Noweda | Mometasone furoate | 16J24-B11-332111 | 1 |
| Noweda | Mometasone furoate | 1711027-02 | 1 |
| Noweda | Mometasone furoate | 17D19-B02-347349 | 1 |
| Noweda | Mometasone furoate | 18026009 | 1 |
| Noweda | Mometasone furoate | 18334110 | 1 |
| Noweda | Mometasone furoate | 18B19-B07-351351 | 1 |
| Noweda | Mometasone furoate | 20003486034 | 1 |
| Noweda | Mometasone furoate | 20G24-B03-196879 | 1 |
| Noweda | Mometasone furoate | 20G24-B03-197086 | 1 |
| Noweda | Mometasone furoate | 2106014-01 | 2 |
| Noweda | Mometasone furoate | 21B26-B05-203100 | 2 |
| Noweda | Mometasone furoate | 22C15-B06-223110 | 1 |
| Noweda | Mometasone furoate | 22C-B06 | 1 |
| Noweda | Mometasone furoate | 23001247005 | 2 |
| Noweda | Mometasone furoate | 23001247006 | 2 |
| Noweda | Mometasone furoate | 2305005-01 | 2 |
| Noweda | Mometasone furoate | 23F15-B02-234650 | 1 |
| Noweda | Mometasone furoate | 24D10-B13-236852 | 1 |
| Noweda | Mometasone furoate | 24D10-B13-236853 | 1 |
| Noweda | Mometasone furoate | 24D10-B13-238791 | 1 |
| Noweda | Mometasone furoate | 24F28-B17-005410 | 1 |
| Phagron | Mometasone furoate | 19F13-B12-191761 | 1 |
| Phoenix 03.08.2017 | Mometasone furoate | 16C24-B03-328272 | 1 |
| Phoenix | Mometasone furoate | 14C07-B05-291268 | 1 |
| Phoenix | Mometasone furoate | 16181714 | 1 |
| Phoenix | Mometasone furoate | 17D19-B02-339277 | 1 |
| Phoenix | Mometasone furoate | 1810008-01 | 1 |
| phoenix | Mometasone furoate | 18334108 | 1 |
| Phoenix | Mometasone furoate | 18B19-B07-352745 | 1 |
| Phoenix | Mometasone furoate | 19F13-B12-191760 | 1 |
| Phoenix | Mometasone furoate | 20003486036 | 1 |
| phoenix | Mometasone furoate | 2008002-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Mometasone furoate | 20G24-B03-196879 | 1 |
| Phoenix | Mometasone furoate | 2106014-01 | 2 |
| Phoenix | Mometasone furoate | 2305005-01 | 1 |
| Phoenix | Mometasone furoate | 3406 | 1 |
| Phoenix | Mometasone furoate | MOM004/0716 | 1 |
| Phönix Gotha | Mometasone furoate | 1403015-01 | 1 |
| Phönix | Mometasone furoate | 13/23-N02 | 2 |
| Phönix | Mometasone furoate | 13D08-N06 | 1 |
| Phönix | Mometasone furoate | 14E20-B04-291267 | 1 |
| phönix | Mometasone furoate | 15B11-b03 | 1 |
| Phönix | Mometasone furoate | 15G08-B11-322737 | 1 |
| Phönix | Mometasone furoate | 16C24-B03 | 1 |
| Phönix | Mometasone furoate | 16c24-b03-327346 | 1 |
| Phönix | Mometasone furoate | 171102702 | 1 |
| Phönix | Mometasone furoate | 17D19-B02-342642 | 1 |
| Phönix | Mometasone furoate | 18026012 | 1 |
| Phönix | Mometasone furoate | 20003486017 | 1 |
| Phönix | Mometasone furoate | 20003486018 | 1 |
| Phönix | Mometasone furoate | 20003486024 | 1 |
| Phönix | Mometasone furoate | 20003486034 | 1 |
| Phönix | Mometasone furoate | 20003486035 | 2 |
| Phönix | Mometasone furoate | 2008002-01 | 4 |
| Phönix | Mometasone furoate | 20G24-B03 | 1 |
| phönix | Mometasone furoate | 2106014-01 | 1 |
| Phönix | Mometasone furoate | 2106014-01 | 2 |
| Sana | Mometasone furoate | MF-18009(JM-01)001 | 1 |
| Sanacorp /Fargron | Mometasone furoate | 15G08-B11-310864 | 1 |
| Sanacorp /Fargron | Mometasone furoate | 16J24-B11-335792 | 1 |
| Sanacorp | Mometasone furoate | 1/AKD4 | 1 |
| Sanacorp | Mometasone furoate | 14E20-B04-291267 | 1 |
| Sanacorp | Mometasone furoate | 15189801 | 1 |
| Sanacorp | Mometasone furoate | 16353211 | 1 |
| Sanacorp | Mometasone furoate | 17D19-B02-339276 | 1 |
| Sanacorp | Mometasone furoate | 17D19-B02-344776 | 2 |
| Sanacorp | Mometasone furoate | 18026001 | 1 |
| Sanacorp | Mometasone furoate | 20000787007 | 1 |
| Sanacorp | Mometasone furoate | 2008002-01 | 5 |
| Sanacorp | Mometasone furoate | 20G24-B03-197086 | 2 |
| Sanacorp | Mometasone furoate | 21B26-B05 | 1 |
| Sanacorp | Mometasone furoate | 21B26-B05-203100 | 2 |
| Sanacorp | Mometasone furoate | 22C15-B06-227594 | 1 |
| Sanacorp | Mometasone furoate | 23001247005 | 4 |
| Sanacorp | Mometasone furoate | 23001247006 | 1 |
| Sanacorp | Mometasone furoate | 2305005-01 | 1 |
| Sanacorp | Mometasone furoate | 23F15-B02-234649 | 1 |
| Sanacorp | Mometasone furoate | 23F15-B02-234650 | 1 |
| Sanacorp | Mometasone furoate | MOM001/0317 | 1 |
| SanacorpWE:12.01.201… | Mometasone furoate | 16028602 | 1 |
| sidonia | Mometasone furoate | 18334110 | 1 |
| Symbiotic/Phoenix | Mometasone furoate | 2001040-01 | 2 |
| Symbiotica / Gehe | Mometasone furoate | MOM008/0915 | 2 |
| Symbiotica Malaysia/ AHD | Mometasone furoate | 2001040-01 | 1 |
| Symbiotica/Phoenix | Mometasone furoate | MOM001/0317 | 1 |
| Symbiotica/Phoenix | Mometasone furoate | MOM003/0818 | 2 |
| Wiesen Apotheke | Mometasone furoate | 20003486035 | 1 |

- 253 806 spectra from 1665 *Apo-Ident* customers from a total of 51 601 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Mometasone furoate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Mometasone furoate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 545 | 0 | 157 781 |
| **Type B** | 0 | 972 | 2 | 211 966 |
| **Type C** | 0 | 3067 | 13 | 253 806 |

The substance/substance group *Mometasone furoate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8991 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 99.7947 % (> 99.4867 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.5779 % (> 99.4805 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20850 | 22433 | 5.73 | 182.28 |
| 21602 | 22433 | 9.41 | 183.83 |
| 22238 | 22238 | 0.00 | 180.86 |
| 22433 | 22433 | 0.00 | 184.83 |
| 22887 | 23136 | 8.36 | 184.33 |
| 23046 | 23046 | 0.00 | 180.44 |
| 23136 | 23136 | 0.00 | 183.86 |
| 26766 | 26766 | 0.00 | 184.85 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Monostereates** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20691-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Monostereates; Glycerol monostearate 40-55; Glycerol monostearate 60; Glycerol monostearate, emulsifying; Glyceroli monostearas 40–55; Glyceroli monostearates 60; Glyceroli monostearates emulsificantes; Sorbitan stearate; Sorbitani stearas

### Special notes

When selecting the *Monostereates* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Monostereates | 37 | 22 | 145 |

### Second-stage model

For differentiation of the substance/substance group *Monostereates* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Monostereates* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Emulsifying cetostearyl alcohol (type A) | 48.58 | – |
| Non-ionic emulsifying alcohol | 52.05 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Monostereates* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Monostereates*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Glycerol monostearate 40-55 | 12105705 | 20691 | 80 | 20120424 |
| Caelo | Glycerol monostearate 40-55 | 12105720 | 20867 | 40 | 20120424 |
| Caelo | Glycerol monostearate 40-55 | 14099903 | 21446 | 60 | AR-15-FG-000732-02 |
| Caelo | Glycerol monostearate 40-55 | 154450 | 22464 | 60 | 20160225* |
| Caelo | Glycerol monostearate 40-55 | 20002884 | 25620 | 40 | 20200916* |
| Caelo | Glycerol monostearate 40-55 | 22000532 | 26018 | 40 | 20220331* |
| Caelo | Glycerol monostearate 40-55 | 23000431 | 26729 | 40 | 20230526* |
| Caelo | Glycerol monostearate 40-55 | 23000431 | 26729SI | 20 | 20230526* |
| Fagron | Glycerol monostearate 40-55 | 14C12-B40-292622 | 21545 | 60 | 20140404 |
| Fagron | Glycerol monostearate 40-55 | 15E13-B03-305532 | 22277 | 60 | 20150703 |
| Caelo | Glycerol monostearate 60 | 13109304 | 21093 | 40 | 1407633 |
| Caelo | Glycerol monostearate 60 | 13232604 | 21437 | 60 | 1504599 |
| Caelo | Glycerol monostearate 60 | 15286302 | 21982 | 60 | 20150911 |
| Caelo | Glycerol monostearate 60 | 15286302 | 22320 | 60 | AR-16-FG-009226-01 |
| Caelo | Glycerol monostearate 60 | 16233804 | 23188 | 40 | 10052 |
| Caelo | Glycerol monostearate 60 | 180683 | 24025 | 40 | 20180430* |
| Caelo | Glycerol monostearate 60 | 182462 | 24371 | 40 | 20181008* |
| Caelo | Glycerol monostearate 60 | 190547 | 24673 | 40 | 20190423* |
| Caelo | Glycerol monostearate 60 | 192857002 | 25385 | 40 | 20191216 |
| Caelo | Glycerol monostearate 60 | 21003001 | 26004 | 40 | 20211109* |
| Caelo | Glycerol monostearate 60 | 21003001 | 26004SI | 30 | 20211109* |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Glycerol monostearate 60 | 22003434 | 26728 | 40 | 20230213* |
| Caelo | Glycerol monostearate 60 | 22003434 | 26728SI | 20 | 20230213* |
| Caelo | Glycerol monostearate 60 | 24001839 | 27316 | 40 | 20240829* |
| Caelo | Glycerol monostearate 60 | 24001839 | 27316SI | 20 | 20240829* |
| Caelo | Glycerol monostearate, em... | 12210401 | 20751 | 80 | 1407214 |
| Caelo | Glycerol monostearate, em... | 12210401 | 20783 | 40 | 20120726 |
| Caelo | Glycerol monostearate, em... | 14240607 | 21576 | 60 | 1412120 |
| Caelo | Glycerol monostearate, em... | 14240607 | 21585 | 60 | 20140815 |
| Caelo | Glycerol monostearate, em... | 161646 | 22623 | 40 | 20160727* |
| Caelo | Glycerol monostearate, em... | 16030301 | 22667 | 40 | 20160204 |
| Caelo | Glycerol monostearate, em... | 21000650 | 25618 | 40 | 20210310* |
| Caelo | Glycerol monostearate, em... | 21002557002 | 26235 | 40 | 20210920 |
| Caelo | Glycerol monostearate, em... | 21002557002 | 26235SI | 20 | 20210920 |
| Caelo | Glycerol monostearate, em... | 22003075 | 26480 | 40 | 20221121* |
| Caelo | Glycerol monostearate, em... | 22003075 | 26480SI | 20 | 20221121* |
| Caelo | Glycerol monostearate, em... | 23002137 | 26958 | 40 | 20230829* |
| Caelo | Glycerol monostearate, em... | 23002137 | 26958SI | 20 | 20230829* |
| Caelo | Sorbitan stearate | 12274801 | 20828 | 40 | 20120924 |
| Caelo | Sorbitan stearate | 162352 | 22764 | 40 | 20160826* |
| Caelo | Sorbitan stearate | 17030805 | 23706 | 40 | 20170210 |
| Caelo | Sorbitan stearate | 172564 | 23831 | 40 | 20171027* |
| Caelo | Sorbitan stearate | 192928 | 25094 | 40 | 20191122* |
| Caelo | Sorbitan stearate | 20002274 | 25564 | 40 | 20201009* |
| Caelo | Sorbitan stearate | 22002437 | 26369 | 40 | 20220819* |
| Caelo | Sorbitan stearate | 22002437 | 26369SI | 20 | 20220819* |
| Caelo | Sorbitan stearate | 24000967 | 27257 | 40 | 20240529* |
| Fagron | Sorbitan stearate | 14J07-B02-299399 | 21885 | 60 | AR-16-FG-004368-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 2050 spectra of 48 reference samples from the substance/substance group *Monostereates*. These samples are listed above in the *calibration samples* section. The reference samples come from 37 different batches.
- 156 276 spectra from a total of 2920 batches from further 493 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1330 spectra of 32 reference samples from the substance/substance group *Monostereates*.
- Among them are spectra of independent samples from 22 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Glycerol monostearate 40-55 | 180447 | 24267 | 40 |
| Caelo | Glycerol monostearate 40-55 | 190794 | 24709 | 40 |
| Caelo | Glycerol monostearate 40-55 | 191186 | 24713 | 40 |
| Caelo | Glycerol monostearate 40-55 | 24000632 | 27255 | 40 |
| Caelo | Glycerol monostearate 40-55 | 25000747 | 27663 | 40 |
| Caelo | Glycerol monostearate 60 | 11272902 | 20677 | 80 |
| Caelo | Glycerol monostearate 60 | 162338 | 22646 | 40 |
| Caelo | Glycerol monostearate 60 | 20002478 | 25505 | 40 |
| Caelo | Glycerol monostearate, em… | 14308310 | 21993 | 60 |
| Caelo | Glycerol monostearate, em… | 172585 | 23822 | 40 |
| Caelo | Glycerol monostearate, em… | 24002942 | 27546 | 40 |
| Fagron | Glycerol monostearate, em… | 11I15-N09 | 20746 | 80 |
| Fagron | Glycerol monostearate, em… | 12B14-N10 | 20786 | 40 |
| Caelo | Sorbitan stearate | 171781 | 23622 | 40 |
| Caelo | Sorbitan stearate | 180432 | 24021 | 40 |
| Caelo | Sorbitan stearate | 183125 | 24377 | 40 |
| Caelo | Sorbitan stearate | 192168 | 24900 | 40 |
| Caelo | Sorbitan stearate | 21001797 | 25807 | 50 |
| Caelo | Sorbitan stearate | 21004159 | 25991 | 40 |
| Caelo | Sorbitan stearate | 24002443 | 27435 | 40 |
| Caelo | Sorbitan stearate | 25000295 | 27659 | 40 |
| Fagron | Sorbitan stearate | 11I26-N09 | 20736 | 40 |
| Caelo | Glycerol monostearate 40-55 | 22000532 | 26018SI† | 10 |
| Caelo | Glycerol monostearate 40-55 | 24000632 | 27255SI | 20 |
| Caelo | Glycerol monostearate 60 | 162338 | 22741 | 40 |
| Caelo | Glycerol monostearate 60 | 162338 | 22742 | 40 |
| Caelo | Glycerol monostearate 60 | 162338 | 22743 | 40 |
| Caelo | Glycerol monostearate 60 | 162338 | 22744 | 40 |
| Caelo | Glycerol monostearate, em… | 14308310 | 22278 | 60 |
| Caelo | Glycerol monostearate, em… | 14308310 | 22341 | 60 |
| Caelo | Sorbitan stearate | 21004159 | 25991SI | 10 |
| Caelo | Sorbitan stearate | 24000967 | 27257SI† | 20 |

- 211 610 spectra from a total of 4263 batches from further 869 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 464 spectra from 239 *Apo-Ident* customers from 152 batches from the substance/substance group *Monostereates*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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- Among them are spectra of independent samples from 140 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Glycerol monostearate 40-55 | 22000532003 | 1 |
| | Glycerol monostearate 60 | 22001891001 | 1 |
| | Glycerol monostearate 60 | 22001891004 | 1 |
| | Sorbitan stearate | 22002437005 | 1 |
| | Sorbitan stearate | 22002437008 | 1 |
| | Glycerol monostearate, em... | 22003075002 | 1 |
| | Sorbitan stearate | 22003955002 | 2 |
| | Sorbitan stearate | 23000412001 | 2 |
| | Glycerol monostearate 60 | 23001269003 | 2 |
| | Sorbitan stearate | 23002775007 | 1 |
| | Glycerol monostearate 60 | 23003347002 | 2 |
| ALH | Sorbitan stearate | 16235202 | 1 |
| Alliance | Sorbitan stearate | 21004159001 | 1 |
| Anzag | Glycerol monostearate 60 | 12180502 | 1 |
| anzag | Sorbitan stearate | 14195 | 1 |
| apomix | Sorbitan stearate | 13209417 | 1 |
| Audor Pharma | Glycerol monostearate 60 | 13232604 | 1 |
| Bombastus | Glycerol monostearate 40-55 | 18044701 | 1 |
| Caelo | Glycerol monostearate 60 | | 1 |
| Caelo | Glycerol monostearate, em... | 11079308 | 1 |
| Caelo | Glycerol monostearate 60 | 12001001 | 1 |
| Caelo | Glycerol monostearate 40-55 | 12105704 | 1 |
| Caelo | Glycerol monostearate 40-55 | 12105729 | 1 |
| Caelo | Glycerol monostearate 60 | 12180502 | 1 |
| Caelo | Sorbitan stearate | 12274807 | 1 |
| Caelo | Sorbitan stearate | 12274813 | 2 |
| Caelo | Glycerol monostearate 60 | 13018201 | 3 |
| Caelo | Glycerol monostearate 60 | 1301821 | 1 |
| Caelo | Glycerol monostearate 60 | 13109304 | 9 |
| Caelo | Glycerol monostearate, em... | 13109402 | 1 |
| Caelo | Glycerol monostearate, em... | 13109405 | 2 |
| Caelo | Glycerol monostearate, em... | 13109410 | 1 |
| Caelo | Glycerol monostearate 40-55 | 131156602 | 1 |
| Caelo | Glycerol monostearate 40-55 | 13156601 | 2 |
| Caelo | Sorbitan stearate | 13209409 | 2 |
| Caelo | Sorbitan stearate | 13209410 | 1 |
| Caelo | Sorbitan stearate | 13209417 | 3 |
| Caelo | Sorbitan stearate | 13209418 | 2 |
| Caelo | Sorbitan stearate | 13209419 | 3 |
| Caelo | Glycerol monostearate 40-55 | 13221303 | 2 |
| Caelo | Glycerol monostearate 40-55 | 13221308 | 1 |
| Caelo | Glycerol monostearate 60 | 13232604 | 3 |
| Caelo | Sorbitan stearate | 13B19-N01 | 1 |
| Caelo | Glycerol monostearate 60 | 14012002 | 4 |
| Caelo | Sorbitan stearate | 14038504 | 1 |
| Caelo | Sorbitan stearate | 14038510 | 1 |
| Caelo | Sorbitan stearate | 14038511 | 2 |
| Caelo | Glycerol monostearate 40-55 | 14169710 | 1 |
| Caelo | Glycerol monostearate, em... | 1420607 | 1 |
| Caelo | Sorbitan stearate | 14218803 | 3 |
| Caelo | Sorbitan stearate | 14218804 | 1 |
| Caelo | Sorbitan stearate | 14218808 | 5 |
| Caelo | Sorbitan stearate | 14218809 | 1 |
| Caelo | Glycerol monostearate, em... | 14240607 | 1 |
| Caelo | Glycerol monostearate, em... | 14240611 | 1 |
| Caelo | Glycerol monostearate, em... | 14308310 | 4 |
| Caelo | Glycerol monostearate 40-55 | 14359407 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sorbitan stearate | 14372803 | 1 |
| Caelo | Glycerol monostearate 60 | 15009203 | 13 |
| Caelo | Glycerol monostearate 40-55 | 15130501 | 1 |
| Caelo | Glycerol monostearate 40-55 | 15280902 | 1 |
| Caelo | Glycerol monostearate 40-55 | 15280903 | 2 |
| Caelo | Glycerol monostearate 40-55 | 15280904 | 2 |
| Caelo | Glycerol monostearate 40-55 | 15280912 | 1 |
| Caelo | Glycerol monostearate 60 | 15286302 | 4 |
| Caelo | Glycerol monostearate 60 | 15286307 | 3 |
| Caelo | Glycerol monostearate 60 | 15286308 | 4 |
| Caelo | Sorbitan stearate | 15300302 | 7 |
| Caelo | Sorbitan stearate | 15300308 | 5 |
| Caelo | Sorbitan stearate | 15415202 | 9 |
| Caelo | Glycerol monostearate 40-55 | 15445007 | 6 |
| Caelo | Glycerol monostearate 40-55 | 15445010 | 1 |
| Caelo | Glycerol monostearate 40-55 | 15445011 | 1 |
| Caelo | Glycerol monostearate 40-55 | 15445014 | 2 |
| Caelo | Glycerol monostearate, em… | 16030301 | 3 |
| Caelo | Glycerol monostearate, em… | 16030304 | 2 |
| Caelo | Glycerol monostearate, em… | 16164604 | 1 |
| Caelo | Glycerol monostearate, em… | 16164606 | 1 |
| Caelo | Glycerol monostearate 60 | 16233802 | 2 |
| Caelo | Glycerol monostearate 60 | 16233804 | 6 |
| Caelo | Sorbitan stearate | 16235202 | 5 |
| Caelo | Sorbitan stearate | 16235207 | 11 |
| Caelo | Sorbitan stearate | 17030805 | 7 |
| Caelo | Sorbitan stearate | 17030806 | 2 |
| Caelo | Glycerol monostearate 60 | 17061703 | 5 |
| Caelo | Glycerol monostearate 60 | 17167803 | 7 |
| Caelo | Glycerol monostearate 60 | 17167804 | 6 |
| Caelo | Sorbitan stearate | 17178102 | 21 |
| Caelo | Glycerol monostearate, em… | 17258501 | 2 |
| Caelo | Glycerol monostearate, em… | 17258505 | 2 |
| Caelo | Sorbitan stearate | 17345402 | 6 |
| Caelo | Sorbitan stearate | 17345403P-181005-2 | 1 |
| Caelo | Sorbitan stearate | 17345403P-181227-8 | 1 |
| Caelo | Glycerol monostearate 40-55 | 18044701 | 2 |
| Caelo | Glycerol monostearate 40-55 | 18044702 | 1 |
| Caelo | Glycerol monostearate 60 | 18068303 | 4 |
| Caelo | Sorbitan stearate | 18204705 | 8 |
| Caelo | Glycerol monostearate 60 | 18246203 | 3 |
| Caelo | Glycerol monostearate 60 | 18246207 | 5 |
| Caelo | Sorbitan stearate | 18312504P-190502-1 | 1 |
| Caelo | Sorbitan stearate | 18312504P-190627-8 | 1 |
| Caelo | Sorbitan stearate | 18312507P-191230-1 | 1 |
| Caelo | Glycerol monostearate, em… | 18328702 | 4 |
| Caelo | Glycerol monostearate, em… | 18328705 | 2 |
| Caelo | Glycerol monostearate 40-55 | 18334601 | 1 |
| Caelo | Glycerol monostearate 40-55 | 18334601P-190405-2 | 1 |
| Caelo | Glycerol monostearate 60 | 19054702 | 13 |
| Caelo | Glycerol monostearate 40-55 | 190794001 | 2 |
| Caelo | Glycerol monostearate 40-55 | 19079401 | 8 |
| Caelo | Sorbitan stearate | 19101301 | 1 |
| Caelo | Sorbitan stearate | 19101302P-190718-8 | 1 |
| Caelo | Sorbitan stearate | 19101302P-190926-7 | 1 |
| Caelo | Sorbitan stearate | 19101305 | 4 |
| Caelo | Sorbitan stearate | 19101306P-200326-8 | 1 |
| Caelo | Sorbitan stearate | 19101306P-200709-5 | 1 |
| Caelo | Glycerol monostearate 60 | 191258003 | 7 |
| Caelo | Glycerol monostearate, em… | 192039002 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Glycerol monostearate, em… | 192039003 | 1 |
| Caelo | Sorbitan stearate | 192168003 | 1 |
| Caelo | Glycerol monostearate 60 | 192857001 | 1 |
| Caelo | Glycerol monostearate 60 | 192857002 | 2 |
| Caelo | Sorbitan stearate | 20001211004 | 1 |
| Caelo | Glycerol monostearate 40-55 | 20001564002 | 2 |
| Caelo | Glycerol monostearate 60 | 20002478004 | 1 |
| Caelo | Glycerol monostearate 40-55 | 200028840001 | 1 |
| Caelo | Glycerol monostearate 40-55 | 20002884001 | 1 |
| Caelo | Glycerol monostearate 40-55 | 20002884002 | 1 |
| Caelo | Sorbitan stearate | 20003871004 | 1 |
| Caelo | Glycerol monostearate 60 | 21000650001 | 6 |
| Caelo | Glycerol monostearate, em… | 21000650004 | 1 |
| Caelo | Glycerol monostearate, em… | 2100065001 | 1 |
| Caelo | Glycerol monostearate 60 | 21001621002 | 5 |
| Caelo | Glycerol monostearate 60 | 21001621004 | 3 |
| Caelo | Sorbitan stearate | 21001797001 | 3 |
| Caelo | Glycerol monostearate, em… | 21002557002 | 1 |
| Caelo | Glycerol monostearate 40-55 | 21002567002 | 1 |
| Caelo | Glycerol monostearate 60 | 21003001004 | 8 |
| Caelo | Sorbitan stearate | 21004159001 | 3 |
| Caelo | Sorbitan stearate | 22001545003 | 2 |
| Caelo | Glycerol monostearate 60 | 22001891004 | 1 |
| Caelo | Sorbitan stearate | 22002437005 | 1 |
| Caelo | Sorbitan stearate | 26031507 | 1 |
| Caelo | Glycerol monostearate 60 | 7035059 | 1 |
| Caesar & Loretz GmbH… | Glycerol monostearate, em… | 21000650001 | 1 |
| Caesar & Loretz GmbH… | Sorbitan stearate | 22001545003 | 1 |
| Caesar & Loretz GmbH/Gehe | Sorbitan stearate | 20003871007 | 1 |
| Caesar & Loretz GmbH/Kehr | Sorbitan stearate | 20003871004 | 1 |
| Caesar & Loretz GmbH… | Glycerol monostearate 60 | 19054702 | 1 |
| Caesar & Loretz GmbH… | Sorbitan stearate | 18204705 | 1 |
| Caesar & Loretz GmbH… | Glycerol monostearate 60 | 18246203 | 1 |
| Caesar & Loretz GmbH/Sa | Glycerol monostearate 40-55 | 19079404 | 1 |
| Caesar & Loretz GmbH/Sa | Glycerol monostearate 40-55 | 20001564002 | 1 |
| Caesar & Loretz GmbH… | Sorbitan stearate | 19101301 | 1 |
| Caesar & Loretz GmbH… | Sorbitan stearate | 21001797001 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 60 | 18068303 | 1 |
| Caesar & Loretz GmbH | Sorbitan stearate | 18204705 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate, em… | 18328702 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 40-55 | 18328705 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 60 | 19054702 | 3 |
| Caesar & Loretz GmbH | Glycerol monostearate 40-55 | 19079401 | 2 |
| Caesar & Loretz GmbH | Sorbitan stearate | 19101305 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 60 | 191258003 | 2 |
| Caesar & Loretz GmbH | Glycerol monostearate, em… | 192039002 | 3 |
| Caesar & Loretz GmbH | Sorbitan stearate | 192168003 | 2 |
| Caesar & Loretz GmbH | Glycerol monostearate 60 | 192857002 | 3 |
| Caesar & Loretz GmbH | Sorbitan stearate | 20001211004 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 40-55 | 20003935003 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 60 | 21001621002 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 60 | 21001621004 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate, em… | 21002557002 | 4 |
| Caesar & Loretz GmbH | Glycerol monostearate 40-55 | 22000532003 | 1 |
| Caesar & Loretz GmbH | Glycerol monostearate 40-55 | 22000532004 | 1 |
| Caesar & Loretz GmbH | Sorbitan stearate | 22001545003 | 1 |
| Caesar & Loretz GmbH | Sorbitan stearate | 22002437005 | 1 |
| Caesar & Loretz Hild… | Sorbitan stearate | 19101305 | 1 |
| Caesar & Loretz/Noweda | Glycerol monostearate 60 | 15009203 | 1 |
| Caesar u Loretz | Glycerol monostearate 60 | 13109304 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar u Loretz | Glycerol monostearate 60 | 14012002 | 1 |
| Caesar&Loretz GmbH/Gehe | Glycerol monostearate, em… | 17258505 | 1 |
| Caesar/Noweda | Glycerol monostearate 60 | 13109304 | 1 |
| Caesar/Noweda | Glycerol monostearate 40-55 | 13221311 | 2 |
| cealo sanacorp | Glycerol monostearate 60 | 20002478004 | 1 |
| Cealo | Sorbitan stearate | 13209409 | 1 |
| Euro OTC | Glycerol monostearate 60 | 16233804 | 1 |
| Fagron | Glycerol monostearate 40-55 | 12A27-N11 | 1 |
| Fagron | Sorbitan stearate | 12E30-N14 | 1 |
| Fagron | Glycerol monostearate 40-55 | 12K05-N06 | 1 |
| Fagron | Sorbitan stearate | 13B19-N01 | 1 |
| Fagron | Sorbitan stearate | 13D10_N10 | 1 |
| Fagron | Sorbitan stearate | 13D10-N10 | 1 |
| Fagron | Sorbitan stearate | 14J07-B02-299399 | 1 |
| Fagron | Glycerol monostearate 60 | 15009203 | 1 |
| Fagron | Glycerol monostearate 40-55 | 15280903 | 1 |
| Fagron | Sorbitan stearate | 5052 | 1 |
| Fagron | Glycerol monostearate 40-55 | 7G19-N09 | 1 |
| Fiebig | Glycerol monostearate 40-55 | 20001564002 | 1 |
| Gehe | Glycerol monostearate, em… | 14240605 | 2 |
| Gehe | Glycerol monostearate, em… | 18328702 | 1 |
| Gehe | Glycerol monostearate 60 | 19054702 | 1 |
| Gehe | Glycerol monostearate 40-55 | 20001564002 | 1 |
| Ichthyol/Phoenix | Sorbitan stearate | 14372803 | 1 |
| Krieger | Glycerol monostearate 60 | 19054702 | 1 |
| L12 | Glycerol monostearate 60 | 16233802 | 2 |
| Nachprüfung | Sorbitan stearate | | 1 |
| Noweda | Glycerol monostearate, em… | 11079301 | 1 |
| Noweda | Glycerol monostearate 60 | 15009203 | 1 |
| Noweda | Sorbitan stearate | 17178102 | 1 |
| Noweda | Sorbitan stearate | 21001797001 | 1 |
| Noweda | Sorbitan stearate | 22002437005 | 1 |
| Phonix | Glycerol monostearate 60 | 13109304 | 1 |
| Phonix | Sorbitan stearate | 13209418 | 1 |
| Sanacorp | Sorbitan stearate | 22002437005 | 1 |
| Spangropharm | Glycerol monostearate 40-55 | 80402468 | 1 |

- 256 422 spectra from 1666 *Apo-Ident* customers from a total of 52 003 batches from a further 721 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Monostereates* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Monostereates* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 2050 | 0 | 156 276 |
| **Type B** | 0 | 1329 | 1 | 211 610 |
| **Type C** | 0 | 462 | 2 | 256 422 |


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The substance/substance group *Monostereates* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.7073 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 99.9248 % (> 99.6992 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.5690 % (> 98.9224 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20691 | 21446 | 21.77 | 66.22 |
| 20751 | 20751 | 0.00 | 152.57 |
| 20783 | 20751 | 4.27 | 148.37 |
| 20828 | 22764 | 35.53 | 95.53 |
| 20867 | 21446 | 34.29 | 71.30 |
| 21093 | 21093 | 0.00 | 108.64 |
| 21437 | 21437 | 0.00 | 100.36 |
| 21446 | 21446 | 0.00 | 65.71 |
| 21545 | 21446 | 32.13 | 70.46 |
| 21576 | 21576 | 0.00 | 132.82 |
| 21585 | 21576 | 2.49 | 133.52 |
| 21885 | 21885 | 0.00 | 116.19 |
| 21982 | 22320 | 6.20 | 104.70 |
| 22277 | 25620 | 23.22 | 61.58 |
| 22320 | 22320 | 0.00 | 102.27 |
| 22464 | 22464 | 0.00 | 73.40 |
| 22623 | 22623 | 0.00 | 127.90 |
| 22667 | 20751 | 19.24 | 168.07 |
| 22764 | 22764 | 0.00 | 95.50 |
| 23188 | 23188 | 0.00 | 91.18 |
| 23706 | 22764 | 6.56 | 97.30 |
| 23831 | 23831 | 0.00 | 110.87 |
| 24025 | 24025 | 0.00 | 121.72 |
| 24371 | 24371 | 0.00 | 120.17 |
| 24673 | 24673 | 0.00 | 122.90 |
| 25094 | 25094 | 0.00 | 100.00 |
| 25385 | 22320 | 30.86 | 124.67 |
| 25564 | 25564 | 0.00 | 101.69 |

*continued on the next page*

*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25618 | 25618 | 0.00 | 120.38 |
| 25620 | 25620 | 0.00 | 61.34 |
| 26004 | 26004 | 0.00 | 105.65 |
| 26018 | 26018 | 0.00 | 71.70 |
| 26235 | 25618 | 20.76 | 127.18 |
| 26369 | 26369 | 0.00 | 110.66 |
| 26480 | 26480 | 0.00 | 121.91 |
| 26728 | 26728 | 0.00 | 101.43 |
| 26729 | 26729 | 0.00 | 62.16 |
| 26958 | 26958 | 0.00 | 123.20 |
| 27257 | 27257 | 0.00 | 111.88 |
| 27316 | 27316 | 0.00 | 113.09 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Mupirocin calcium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20781-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Mupirocin calcium; Mupirocinum calcicum

### Special notes

When selecting the *Mupirocin calcium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Mupirocin calcium | 8 | 5 | 14 |

### Second-stage model

For differentiation of the substance/substance group *Mupirocin calcium* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Mupirocin calcium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 52.03 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Mupirocin calcium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Mupirocin calcium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Mupirocin calcium | 14276602 | 21745 | 60 | 20141103 |
| Caelo | Mupirocin calcium | 161184 | 22454 | 60 | 20160504* |
| Caelo | Mupirocin calcium | 18191606 | 25376 | 40 | 20180813 |
| Caelo | Mupirocin calcium | 23003561 | 27116 | 40 | 20240202* |
| Caelo | Mupirocin calcium | 23003561 | 27116SI | 20 | 20240202* |
| Fagron | Mupirocin calcium | 12E02-N07 | 20781 | 40 | 1401556 |
| Fagron | Mupirocin calcium | 15H13-B01-316111 | 23213 | 40 | 20150909 |
| Fagron | Mupirocin calcium | 18A16-B02-349169 | 25373 | 40 | 20180226 |
| Fagron | Mupirocin calcium | 21K17-B01-219626 | 26152 | 40 | 20220426 |
| Fagron | Mupirocin calcium | 21K17-B01-219626 | 26152SI | 20 | 20220426 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 10 reference samples from the substance/substance group *Mupirocin calcium*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 926 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 230 spectra of 6 reference samples from the substance/substance group *Mupirocin calcium*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Mupirocin calcium | 161608 | 23860 | 40 |
| Caelo | Mupirocin calcium | 21003209003 | 25856 | 50 |
| Caelo | Mupirocin calcium | 22001500 | 26259 | 40 |
| Euro OTC | Mupirocin calcium | 2001029 | 25297 | 40 |
| Fagron | Mupirocin calcium | 24J11-B12-006951 | 27604 | 40 |
| Caelo | Mupirocin calcium | 22001500 | 26259SI | 20 |

- 212 710 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 14 spectra from 11 *Apo-Ident* customers from 14 batches from the substance/substance group *Mupirocin calcium*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mupirocin calcium | 17356502 | 1 |
| Caelo | Mupirocin calcium | 17356506 | 1 |
| Caelo | Mupirocin calcium | 17356509 | 1 |
| Caelo | Mupirocin calcium | 17F21-B03-34519 | 1 |
| Caelo | Mupirocin calcium | 18191601 | 1 |
| Caelo | Mupirocin calcium | 24041801 | 1 |
| Caelo | Mupirocin calcium | 83200301013 | 1 |
| Caelo | Mupirocin calcium | 9041801 | 1 |
| Fagron | Mupirocin calcium | 14B03-B30-297291 | 1 |
| Fagron | Mupirocin calcium | 15H13-B01 | 1 |
| Fagron | Mupirocin calcium | 17F21-B03 | 1 |
| Fagron | Mupirocin calcium | 17F21-B03-338597 | 1 |
| Fagron | Mupirocin calcium | 17F21-B03-339080 | 1 |
| Fagron | Mupirocin calcium | 83200340116 | 1 |

- 256 872 spectra from 1666 *Apo-Ident* customers from a total of 52 139 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Mupirocin calcium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Mupirocin calcium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 230 | 0 | 212 710 |
| **Type C** | 0 | 14 | 0 | 256 872 |

The substance/substance group *Mupirocin calcium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.3913 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested


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reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20781 | 20781 | 0.00 | 102.62 |
| 21745 | 22454 | 14.48 | 102.72 |
| 22454 | 22454 | 0.00 | 103.60 |
| 23213 | 27116 | 13.62 | 104.70 |
| 25373 | 27116 | 37.31 | 105.81 |
| 25376 | 27116 | 9.81 | 104.22 |
| 26152 | 27116 | 16.88 | 105.45 |
| 27116 | 27116 | 0.00 | 104.40 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **myo-Inositol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20420-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

myo-Inositol; myo-Inositolum

### Special notes

When selecting the *myo-Inositol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| myo-Inositol | 3 | 2 | 6 |

### Second-stage model

For differentiation of the substance/substance group *myo-Inositol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *myo-Inositol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 75.71 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *myo-Inositol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *myo-Inositol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | myo-Inositol | 1206032-01 | 21280 | 40 | 20120814 |
| Fagron | myo-Inositol | 13D15-B40-328250 | 23405 | 40 | 20140812 |
| Fagron | myo-Inositol | 13D15-B40-328250 | 23406 | 40 | AR-17-FG-016393-01 |
| Fagron | myo-Inositol | 23D12-B07-223058 | 26730 | 40 | 20230517 |
| Fagron | myo-Inositol | 23D12-B07-223058 | 26730SI | 20 | 20230517 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 180 spectra of 5 reference samples from the substance/substance group *myo-Inositol*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.
- 158 146 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 100 spectra of 3 reference samples from the substance/substance group *myo-Inositol*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | myo-Inositol | 2502019 | 27629 | 40 |
| Fagron | myo-Inositol | 18A03-B04-344527 | 23999 | 40 |
| Euro OTC | myo-Inositol | 2502019 | 27629SI | 20 |

- 212 840 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6 spectra from 6 *Apo-Ident* customers from 6 batches from the substance/substance group *myo-Inositol*.
- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | myo-Inositol | L1609025-01 | 1 |
| Euro OTC | myo-Inositol | 130400901 | 1 |
| Euro OTC | myo-Inositol | 1304009-01 | 1 |
| Euro OTC | myo-Inositol | 1609025-01 | 1 |
| Euro OTC | myo-Inositol | L2010021-01 | 1 |
| Fagron | myo-Inositol | L13090200 | 1 |

- 256 880 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *myo-Inositol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *myo-Inositol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 100 | 0 | 212 840 |
| **Type C** | 0 | 6 | 0 | 256 880 |

The substance/substance group *myo-Inositol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 94.0000 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21280 | 23406 | 5.88 | 185.13 |
| 23405 | 23406 | 3.06 | 176.10 |
| 23406 | 23406 | 0.00 | 176.47 |
| 26730 | 23406 | 6.57 | 184.85 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Naloxone hydrochloride dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20957-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Naloxone hydrochloride dihydrate; Naloxoni hydrochloridum dihydricum

### Special notes

When selecting the *Naloxone hydrochloride dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Naloxone hydrochloride dihydrate | 9 | 10 | 44 |

### Second-stage model

For differentiation of the substance/substance group *Naloxone hydrochloride dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Naloxone hydrochloride dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 72.82 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Naloxone hydrochloride dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Naloxone hydrochloride dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Naloxone hydrochloride di… | AP13501078IIN | 22811 | 40 | 20160429 |
| Audor Pharma | Naloxone hydrochloride di… | AP1547I022-1N | 24707 | 40 | 20180629 |
| Caelo | Naloxone hydrochloride di… | 163577 | 23039 | 40 | 20170306* |
| Caelo | Naloxone hydrochloride di… | 170441 | 23862 | 40 | 20170306* |
| Caelo | Naloxone hydrochloride di… | 20001602 | 25447 | 40 | 20200604* |
| Euro OTC | Naloxone hydrochloride di… | 2103008 | 25682 | 40 | 20210430* |
| Fagron | Naloxone hydrochloride di… | 13D22-N07 | 20957 | 40 | 1402059 |
| Fagron | Naloxone hydrochloride di… | 13L12-B03 | 21271 | 40 | 20140113 |
| Fagron | Naloxone hydrochloride di… | 21J11-B10-216368 | 26175 | 40 | 20211118 |
| Fagron | Naloxone hydrochloride di… | 21J11-B10-216368 | 26175SI | 40 | 20211118 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 10 reference samples from the substance/substance group *Naloxone hydrochloride dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 926 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 450 spectra of 12 reference samples from the substance/substance group *Naloxone hydrochloride dihydrate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Naloxone hydrochloride di… | 15322517 | 22828 | 40 |
| Caelo | Naloxone hydrochloride di… | 190088 | 24537 | 40 |
| Caelo | Naloxone hydrochloride di… | 21000770009 | 26316 | 30 |
| Caelo | Naloxone hydrochloride di… | 22001102 | 27112 | 40 |
| Caelo | Naloxone hydrochloride di… | 24001816003 | 27582 | 40 |
| Euro OTC | Naloxone hydrochloride di… | 2002011 | 25134 | 40 |
| Euro OTC | Naloxone hydrochloride di… | 2003062 | 25246 | 40 |
| Euro OTC | Naloxone hydrochloride di… | 2206005 | 26220 | 40 |
| Euro OTC | Naloxone hydrochloride di… | 2402028 | 27274 | 40 |
| Fagron | Naloxone hydrochloride di… | 25B17-B08-009984 | 27644 | 40 |
| Caelo | Naloxone hydrochloride di… | 21000770009 | 26316SI | 20 |
| Euro OTC | Naloxone hydrochloride di… | 2206005 | 26220SI | 40 |

- 212 490 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 76 spectra from 28 *Apo-Ident* customers from 45 batches from the substance/substance group *Naloxone hydrochloride dihydrate*.

- Among them are spectra of independent samples from 44 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Naloxone hydrochloride di… | 22001102004 | 1 |
| | Naloxone hydrochloride di… | 22001102008 | 1 |
| | Naloxone hydrochloride di… | 23J17-B02-233756 | 1 |
| Audor Pharma | Naloxone hydrochloride di… | AP13501078N | 1 |
| Audor Pharma | Naloxone hydrochloride di… | AP1547I022N | 1 |
| Caelo | Naloxone hydrochloride di… | 15322501 | 1 |
| Caelo | Naloxone hydrochloride di… | 15322504 | 2 |
| Caelo | Naloxone hydrochloride di… | 15322517 | 1 |
| Caelo | Naloxone hydrochloride di… | 17044103 | 2 |
| Caelo | Naloxone hydrochloride di… | 18134202 | 3 |
| Caelo | Naloxone hydrochloride di… | 19008803 | 1 |
| Caelo | Naloxone hydrochloride di… | 20001602003 | 1 |
| Caelo | Naloxone hydrochloride di… | 2001602303 | 1 |
| Caesar & Loretz GmbH | Naloxone hydrochloride di… | 19008803 | 2 |
| Caesar & Loretz GmbH | Naloxone hydrochloride di… | 20001602003 | 1 |
| Euro OTC | Naloxone hydrochloride di… | 2002011-01 | 1 |
| Euro OTC | Naloxone hydrochloride di… | 2003062-01 | 1 |
| Fagron | Naloxone hydrochloride di… | 11/23-N01 | 1 |
| Fagron | Naloxone hydrochloride di… | 12-00071 | 2 |
| Fagron | Naloxone hydrochloride di… | 12G19-N02 | 2 |
| Fagron | Naloxone hydrochloride di… | 12G19-NO2 | 1 |
| Fagron | Naloxone hydrochloride di… | 13-00660 | 1 |
| Fagron | Naloxone hydrochloride di… | 1350I078 | 1 |
| Fagron | Naloxone hydrochloride di… | 13L12-B03-289511 | 1 |
| Fagron | Naloxone hydrochloride di… | 14A28-B33-296076 | 1 |
| Fagron | Naloxone hydrochloride di… | 14F20-B02-296077 | 1 |
| Fagron | Naloxone hydrochloride di… | 15B06-B02-304420 | 2 |
| Fagron | Naloxone hydrochloride di… | 15B06-B02-304421 | 1 |
| Fagron | Naloxone hydrochloride di… | 15E28-B01-308324 | 5 |
| Fagron | Naloxone hydrochloride di… | 15H04-B09 | 3 |
| Fagron | Naloxone hydrochloride di… | 15H04-B09-314068 | 5 |
| Fagron | Naloxone hydrochloride di… | 15K11-B05_319571 | 1 |
| Fagron | Naloxone hydrochloride di… | 15K11-B05-319571 | 4 |
| Fagron | Naloxone hydrochloride di… | 18-00116 | 1 |
| Fagron | Naloxone hydrochloride di… | 18452304 | 1 |
| Fagron | Naloxone hydrochloride di… | 18C30-B04-349699 | 2 |
| Fagron | Naloxone hydrochloride di… | 18K20-B05-356947 | 4 |
| Fagron | Naloxone hydrochloride di… | 18K20-B05-356948 | 1 |
| Fagron | Naloxone hydrochloride di… | 19J22-F03 | 1 |
| Fagron | Naloxone hydrochloride di… | 19J22-F03-367715 | 2 |
| Fagron | Naloxone hydrochloride di… | 19J22-F03-367716 | 1 |
| Fagron | Naloxone hydrochloride di… | 19J22-F03-368419 | 1 |
| Fagron | Naloxone hydrochloride di… | 19J22-F03-367715 | 1 |
| Fagron | Naloxone hydrochloride di… | 20F15-01-372577 | 1 |
| Fagron | Naloxone hydrochloride di… | 20F15-F01-372577 | 2 |
| Fagron | Naloxone hydrochloride di… | 20f15-f01-372581 | 2 |
| Fagron | Naloxone hydrochloride di… | 20F15-F01-372581 | 2 |

- 256 810 spectra from 1666 *Apo-Ident* customers from a total of 52 108 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Naloxone hydrochloride dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Naloxone hydrochloride dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 450 | 0 | 212 490 |
| **Type C** | 0 | 76 | 0 | 256 810 |

The substance/substance group *Naloxone hydrochloride dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.1053 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20957 | 20957 | 0.00 | 89.89 |
| 21271 | 20957 | 10.93 | 86.20 |
| 22811 | 20957 | 21.11 | 92.53 |
| 23039 | 23039 | 0.00 | 93.81 |
| 23862 | 23862 | 0.00 | 92.78 |
| 24707 | 23039 | 20.56 | 96.21 |
| 25447 | 25447 | 0.00 | 81.65 |
| 25682 | 25682 | 0.00 | 88.94 |
| 26175 | 25682 | 22.36 | 86.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Naltrexone hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006052-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Naltrexone hydrochloride; Naltrexoni hydrochloridum

### Special notes

When selecting the *Naltrexone hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Naltrexone hydrochloride | 5 | 1 | 2 |

### Second-stage model

For differentiation of the substance/substance group *Naltrexone hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Naltrexone hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Naloxone hydrochloride dihydrate | 69.13 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Naltrexone hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Naltrexone hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Naltrexone hydrochloride | 2212013 | 26512 | 30 | 20221222* |
| Euro OTC | Naltrexone hydrochloride | 2212013 | 26512SI | 20 | 20221222* |
| Euro OTC | Naltrexone hydrochloride | 2307013 | 26864 | 40 | 20230821* |
| Euro OTC | Naltrexone hydrochloride | 2307013 | 26864SI | 20 | 20230821* |
| Euro OTC | Naltrexone hydrochloride | 2401025 | 27343 | 40 | 20240812* |
| Euro OTC | Naltrexone hydrochloride | 2401025 | 27343SI | 20 | 20240812* |
| Fagron | Naltrexone hydrochloride | 22G14-B03-226174 | 26454 | 40 | 240401868 |
| Fagron | Naltrexone hydrochloride | 22G14-B03-226174 | 26454SI | 20 | 240401868 |
| Fagron | Naltrexone hydrochloride | 24A19-B02-237101 | 27183 | 40 | 240704587 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 270 spectra of 9 reference samples from the substance/substance group *Naltrexone hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

- 158 056 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *Naltrexone hydrochloride*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Naltrexone hydrochloride | 23E16-B06-232752 | 26979 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2 spectra from 2 *Apo-Ident* customers from 2 batches from the substance/substance group *Naltrexone hydrochloride*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Naltrexone hydrochloride | 24A19B03001901 | 1 |
| Anzag | Naltrexone hydrochloride | 2307013-01 | 1 |

- 256 884 spectra from 1666 *Apo-Ident* customers from a total of 52 151 batches from a further

724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Naltrexone hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Naltrexone hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 270 | 0 | 158 056 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 2 | 0 | 256 884 |

The substance/substance group *Naltrexone hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7778 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9032 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26454 | 26454 | 0.00 | 235.18 |
| 26512 | 26512 | 0.00 | 259.32 |
| 26864 | 26864 | 0.00 | 115.42 |
| 27183 | 27183 | 0.00 | 245.35 |
| 27343 | 27343 | 0.00 | 181.16 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Naphazoline hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20899-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Naphazoline hydrochloride; Naphazolini hydrochloridum

### Special notes

When selecting the *Naphazoline hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Naphazoline hydrochloride | 7 | 7 | 137 |

### Second-stage model

For differentiation of the substance/substance group *Naphazoline hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Naphazoline hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dexamphetamine sulfate | 93.46 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Naphazoline hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Naphazoline hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Naphazoline hydrochloride | 12375211 | 20899 | 40 | 20130108 |
| Caelo | Naphazoline hydrochloride | 12375211 | 21397 | 60 | 20130108 |
| Caelo | Naphazoline hydrochloride | 12375211 | 21398 | 60 | 20130108 |
| Caelo | Naphazoline hydrochloride | 181193 | 24498 | 40 | 20180504* |
| Euro OTC | Naphazoline hydrochloride | 1407034-01 | 21623 | 60 | AR-15-FG-007847-01 |
| Euro OTC | Naphazoline hydrochloride | 1506015 | 21859 | 60 | 20150727* |
| Euro OTC | Naphazoline hydrochloride | 2003020 | 25260 | 40 | 20200706* |
| Euro OTC | Naphazoline hydrochloride | 2008029 | 25304 | 40 | 20200908* |
| Fagron | Naphazoline hydrochloride | 22K15-B02-223680 | 26449 | 40 | 20221129 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 440 spectra of 9 reference samples from the substance/substance group *Naphazoline hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 886 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 340 spectra of 10 reference samples from the substance/substance group *Naphazoline hydrochloride*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Naphazoline hydrochloride | 161741 | 24496 | 40 |
| Caelo | Naphazoline hydrochloride | 21000140004 | 26620 | 40 |
| Caelo | Naphazoline hydrochloride | 24001857006 | 27583 | 40 |
| Caelo | Naphazoline hydrochloride | 25001252 | 27661 | 40 |
| Euro OTC | Naphazoline hydrochloride | 1607041 | 22753 | 40 |
| Euro OTC | Naphazoline hydrochloride | 1704005 | 23385 | 40 |
| Euro OTC | Naphazoline hydrochloride | 1903006 | 24613 | 40 |
| Caelo | Naphazoline hydrochloride | 21000140004 | 26620SI | 20 |
| Caelo | Naphazoline hydrochloride | 24001857006 | 27583SI | 20 |
| Fagron | Naphazoline hydrochloride | 22K15-B02-223680 | 26449SI† | 20 |

- 212 600 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 391 spectra from 275 *Apo-Ident* customers from 146 batches from the substance/substance group *Naphazoline hydrochloride*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 137 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Naphazoline hydrochloride | 2008029-01 | 9 |
| | Naphazoline hydrochloride | 20E29-B01-215556 | 2 |
| | Naphazoline hydrochloride | 21000140004 | 7 |
| | Naphazoline hydrochloride | 22K15-B02-223680 | 5 |
| | Naphazoline hydrochloride | 22K15-B02-228533 | 4 |
| | Naphazoline hydrochloride | 23H14-B04-2291506 | 1 |
| | Naphazoline hydrochloride | 23H14-B04-229156 | 2 |
| | Naphazoline hydrochloride | 24001857004 | 1 |
| | Naphazoline hydrochloride | 24001857006 | 1 |
| | Naphazoline hydrochloride | 24D03-B03-002532 | 3 |
| | Naphazoline hydrochloride | 24I30-B03-006752 | 2 |
| | Naphazoline hydrochloride | B02-2236800 | 1 |
| Anzag | Naphazoline hydrochloride | 23H14-B04-229156 | 1 |
| apo-ident | Naphazoline hydrochloride | 200802901 | 1 |
| Caelo | Naphazoline hydrochloride | 11081107 | 2 |
| Caelo | Naphazoline hydrochloride | 1206037 | 1 |
| Caelo | Naphazoline hydrochloride | 1216203 | 1 |
| Caelo | Naphazoline hydrochloride | 12176203 | 2 |
| Caelo | Naphazoline hydrochloride | 12375203 | 1 |
| Caelo | Naphazoline hydrochloride | 12375211 | 1 |
| Caelo | Naphazoline hydrochloride | 1307020-02 | 1 |
| Caelo | Naphazoline hydrochloride | 140703402 | 1 |
| Caelo | Naphazoline hydrochloride | 1506015-02 | 4 |
| Caelo | Naphazoline hydrochloride | 1506015-2 | 1 |
| Caelo | Naphazoline hydrochloride | 15071404 | 1 |
| Caelo | Naphazoline hydrochloride | 15223301 | 2 |
| Caelo | Naphazoline hydrochloride | 15223303 | 1 |
| Caelo | Naphazoline hydrochloride | 15J05-B05/171025NHC | 1 |
| Caelo | Naphazoline hydrochloride | 160704101 | 1 |
| Caelo | Naphazoline hydrochloride | 1607041-01 | 1 |
| Caelo | Naphazoline hydrochloride | 16174101 | 5 |
| Caelo | Naphazoline hydrochloride | 1704005-02 | 2 |
| Caelo | Naphazoline hydrochloride | 1704005-03 | 1 |
| Caelo | Naphazoline hydrochloride | 17C02-805 | 1 |
| Caelo | Naphazoline hydrochloride | 17C02-B05-341579 | 1 |
| Caelo | Naphazoline hydrochloride | 18119302 | 12 |
| Caelo | Naphazoline hydrochloride | 18119311 | 1 |
| Caelo | Naphazoline hydrochloride | 18D09-B08-350950 | 2 |
| Caelo | Naphazoline hydrochloride | 18D09-B08-352462 | 1 |
| Caelo | Naphazoline hydrochloride | 18D09-B08-354882 | 1 |
| Caelo | Naphazoline hydrochloride | 1900054002 | 1 |
| Caelo | Naphazoline hydrochloride | 19000544002 | 6 |
| Caelo | Naphazoline hydrochloride | 19000544006 | 3 |
| Caelo | Naphazoline hydrochloride | 20002382001 | 1 |
| Caelo | Naphazoline hydrochloride | 20002392001 | 2 |
| Caelo | Naphazoline hydrochloride | 20E29-B01-196687 | 1 |
| Caelo | Naphazoline hydrochloride | 2275310 | 1 |
| Caelo | Naphazoline hydrochloride | 732570001 | 1 |
| Caelo | Naphazoline hydrochloride | 9285103 | 2 |
| Caesar & Loretz GmbH Og | Naphazoline hydrochloride | 20002392001 | 1 |
| Caesar & Loretz GmbH/Gehe | Naphazoline hydrochloride | 18119302 | 1 |
| Caesar & Loretz GmbH | Naphazoline hydrochloride | 18119302 | 1 |
| Caesar & Loretz GmbH | Naphazoline hydrochloride | 19000544002 | 3 |
| Caesar & Loretz GmbH | Naphazoline hydrochloride | 20002392001 | 1 |
| Caesar & Loretz GmbH | Naphazoline hydrochloride | 20002392004 | 2 |
| Caesar & Loretz GmbH | Naphazoline hydrochloride | 21000140004 | 1 |
| Caesar & Loretz GmbH | Naphazoline hydrochloride | 21001702002 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar / Ebert | Naphazoline hydrochloride | 17C02-B05-341579 | 1 |
| Caleo /Herba | Naphazoline hydrochloride | 9285103 | 1 |
| Eurho/Phoenix | Naphazoline hydrochloride | 4413I-01885 | 1 |
| EuRho/Phönix | Naphazoline hydrochloride | 1704005-03 | 1 |
| EuRho | Naphazoline hydrochloride | 1114I-001885 | 1 |
| Euro OTC | Naphazoline hydrochloride | 1(1903006-01) | 1 |
| Euro OTC | Naphazoline hydrochloride | 1103031-02 | 1 |
| Euro OTC | Naphazoline hydrochloride | 113031-01 | 1 |
| Euro OTC | Naphazoline hydrochloride | 1206037-01 | 3 |
| Euro OTC | Naphazoline hydrochloride | 1206037-02 | 4 |
| Euro OTC | Naphazoline hydrochloride | 1307020-03 | 2 |
| Euro OTC | Naphazoline hydrochloride | 14070034-01 | 1 |
| Euro OTC | Naphazoline hydrochloride | 1407034-01 | 2 |
| Euro OTC | Naphazoline hydrochloride | 1407034-02 | 4 |
| Euro OTC | Naphazoline hydrochloride | 1407034-03 | 1 |
| Euro OTC | Naphazoline hydrochloride | 1506015-01 | 3 |
| Euro OTC | Naphazoline hydrochloride | 150601502 | 1 |
| Euro OTC | Naphazoline hydrochloride | 1506015-02 | 4 |
| Euro OTC | Naphazoline hydrochloride | 1607041 | 1 |
| Euro OTC | Naphazoline hydrochloride | 1607041-01 | 7 |
| Euro OTC | Naphazoline hydrochloride | 1704005-02 | 5 |
| Euro OTC | Naphazoline hydrochloride | 1704005-03 | 2 |
| Euro OTC | Naphazoline hydrochloride | 19030006-01 | 1 |
| Euro OTC | Naphazoline hydrochloride | 190300601 | 1 |
| Euro OTC | Naphazoline hydrochloride | 1903006-01 | 6 |
| Euro OTC | Naphazoline hydrochloride | 2003020-01 | 2 |
| Euro OTC | Naphazoline hydrochloride | 2008029-01 | 1 |
| Euro OTC | Naphazoline hydrochloride | 616620001 | 1 |
| Euro/Sanacorp | Naphazoline hydrochloride | 1704005-03 | 1 |
| Fagron | Naphazoline hydrochloride | 11/05-N02 | 1 |
| Fagron | Naphazoline hydrochloride | 1196687 | 1 |
| Fagron | Naphazoline hydrochloride | 11I05-N02 | 2 |
| Fagron | Naphazoline hydrochloride | 11J13-N08 | 1 |
| Fagron | Naphazoline hydrochloride | 11K25-N03 | 2 |
| Fagron | Naphazoline hydrochloride | 12K29-N01 | 1 |
| Fagron | Naphazoline hydrochloride | 12K29-N01o256/310 | 1 |
| Fagron | Naphazoline hydrochloride | 13/03-B03 | 1 |
| Fagron | Naphazoline hydrochloride | 13/03-B03-295105 | 2 |
| Fagron | Naphazoline hydrochloride | 13/03-B03305291 | 1 |
| Fagron | Naphazoline hydrochloride | 13/03-B03-305291 | 1 |
| Fagron | Naphazoline hydrochloride | 1303-B03 | 1 |
| Fagron | Naphazoline hydrochloride | 1303B03305291 | 1 |
| Fagron | Naphazoline hydrochloride | 13103-803-305291 | 1 |
| Fagron | Naphazoline hydrochloride | 13A07-N06 | 4 |
| Fagron | Naphazoline hydrochloride | 13C11N07 | 1 |
| Fagron | Naphazoline hydrochloride | 13C11-N07 | 5 |
| Fagron | Naphazoline hydrochloride | 13C11-NO7 | 1 |
| Fagron | Naphazoline hydrochloride | 13I03-B03 | 2 |
| Fagron | Naphazoline hydrochloride | 13I03-B03-295105 | 3 |
| Fagron | Naphazoline hydrochloride | 13I03-B03-305291 | 2 |
| Fagron | Naphazoline hydrochloride | 13k27-n04 | 1 |
| Fagron | Naphazoline hydrochloride | 13K27-N04 | 14 |
| Fagron | Naphazoline hydrochloride | 13l03-B03-295105 | 3 |
| Fagron | Naphazoline hydrochloride | 15J05-B05 | 2 |
| Fagron | Naphazoline hydrochloride | 15J05-B05-322527 | 4 |
| Fagron | Naphazoline hydrochloride | 15J05B05326850 | 1 |
| Fagron | Naphazoline hydrochloride | 15J05-B05-326850 | 3 |
| Fagron | Naphazoline hydrochloride | 15J05-B05-330834 | 3 |
| Fagron | Naphazoline hydrochloride | 17c02-b05 | 1 |
| Fagron | Naphazoline hydrochloride | 17C02-B05 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Naphazoline hydrochloride | 17C02-B05-332933 | 5 |
| Fagron | Naphazoline hydrochloride | 17C02-B05-335113 | 1 |
| Fagron | Naphazoline hydrochloride | 17c02-b05-335313 | 1 |
| Fagron | Naphazoline hydrochloride | 17C02-B05-335313 | 5 |
| Fagron | Naphazoline hydrochloride | 17C02-B05-341579 | 5 |
| Fagron | Naphazoline hydrochloride | 17C02-B05-343566 | 4 |
| Fagron | Naphazoline hydrochloride | 17C02-B05-346657 | 2 |
| Fagron | Naphazoline hydrochloride | 17C02-BO5-346657 | 1 |
| Fagron | Naphazoline hydrochloride | 1802201903 | 1 |
| Fagron | Naphazoline hydrochloride | 18D09 | 1 |
| Fagron | Naphazoline hydrochloride | 18D09-B08 | 2 |
| Fagron | Naphazoline hydrochloride | 18D09-B08-350950 | 3 |
| Fagron | Naphazoline hydrochloride | 18D09B08352462 | 1 |
| Fagron | Naphazoline hydrochloride | 18D09-B08-35462 | 1 |
| Fagron | Naphazoline hydrochloride | 18d09-b08-354882 | 1 |
| Fagron | Naphazoline hydrochloride | 18D09-B08-354882 | 7 |
| Fagron | Naphazoline hydrochloride | 18D09-B08-52462 | 1 |
| Fagron | Naphazoline hydrochloride | 18DO9-BO8-352462 | 1 |
| Fagron | Naphazoline hydrochloride | 19D03B02362717 | 1 |
| Fagron | Naphazoline hydrochloride | 19D03-B02-362717 | 5 |
| Fagron | Naphazoline hydrochloride | 20E29-801-196687 | 1 |
| Fagron | Naphazoline hydrochloride | 20E29-B01_196687 | 1 |
| Fagron | Naphazoline hydrochloride | 20e29b01196687 | 1 |
| Fagron | Naphazoline hydrochloride | 20E29B01196687 | 1 |
| Fagron | Naphazoline hydrochloride | 20E29-B01-196687 | 24 |
| Fagron | Naphazoline hydrochloride | 20E29-B01-215556 | 1 |
| Fagron | Naphazoline hydrochloride | 20E29-BO1-196687 | 1 |
| Fagron | Naphazoline hydrochloride | 20E801196687 | 1 |
| Fagron | Naphazoline hydrochloride | 22K15-B02-223680 | 2 |
| Fagron | Naphazoline hydrochloride | 2OE29B01196687 | 1 |
| Fagron | Naphazoline hydrochloride | 4309I-01885 | 1 |
| Fagron | Naphazoline hydrochloride | 4509E-01885 | 2 |
| Fagron | Naphazoline hydrochloride | 60494000113K27-N04 | 1 |
| Fagron | Naphazoline hydrochloride | 672530001 | 2 |
| Fagron | Naphazoline hydrochloride | 7001260012 | 1 |
| Fagron | Naphazoline hydrochloride | 700126-0012 | 1 |
| Fagron | Naphazoline hydrochloride | 706230001 | 3 |
| Fagron | Naphazoline hydrochloride | 708360002 | 1 |
| Fagron | Naphazoline hydrochloride | 9A09-N28 | 1 |
| Fagron | Naphazoline hydrochloride | b01-1966807 | 1 |
| Fagron | Naphazoline hydrochloride | B01-1966807 | 6 |
| Fagron | Naphazoline hydrochloride | B01-2155006 | 1 |
| Fagron | Naphazoline hydrochloride | NPZ3020007 | 2 |
| Fagron | Naphazoline hydrochloride | NPZ3O20007 | 2 |
| Fargon/ Phönix | Naphazoline hydrochloride | 20E29-B01-196687 | 1 |
| Fargon/Apo.am Park | Naphazoline hydrochloride | 539580002 | 1 |
| Fargon/Noweda | Naphazoline hydrochloride | 17C02-B05-346657 | 1 |
| Fargon | Naphazoline hydrochloride | 13/03-B03-295105 | 1 |
| Fargron/Noweda | Naphazoline hydrochloride | 20E29-B01-196687 | 1 |
| Fragon GmbH/ Noweda | Naphazoline hydrochloride | 15J05-B05-326850 | 1 |
| Gatt-Koller | Naphazoline hydrochloride | 1803834 | 1 |
| Gehe/EuRho | Naphazoline hydrochloride | 2008029-01 | 1 |
| Gehe/EuRo | Naphazoline hydrochloride | 1607041-01 | 1 |
| Gehe | Naphazoline hydrochloride | 15J05-B05-330834 | 1 |
| Gehe | Naphazoline hydrochloride | 17C02-B05-335313 | 1 |
| Gehe | Naphazoline hydrochloride | 19D03-B02-362717 | 2 |
| Gehe | Naphazoline hydrochloride | 20E29-B01-196687 | 1 |
| Geilenkirchen | Naphazoline hydrochloride | 18D09-B08-354882 | 1 |
| Herberata Arzneimittel | Naphazoline hydrochloride | 15223303I-02082016 | 1 |
| Jenne | Naphazoline hydrochloride | 2008029-01 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| LOBA / Gehe | Naphazoline hydrochloride | 1903006-01 | 1 |
| Loba / Gehe | Naphazoline hydrochloride | 588710001 | 1 |
| Nachprüfung | Naphazoline hydrochloride | 3318E-1885 | 1 |
| Noweda | Naphazoline hydrochloride | 1704005-02 | 1 |
| Noweda | Naphazoline hydrochloride | 1903006-01 | 1 |
| Noweda | Naphazoline hydrochloride | 2003020-01 | 1 |
| Noweda | Naphazoline hydrochloride | 23H14-B04-229156 | 1 |
| Noweda-Fragon | Naphazoline hydrochloride | 1303B03305291 | 1 |
| Otto Geilenkirchen | Naphazoline hydrochloride | 22K15-B02-223680 | 1 |
| Phoenix | Naphazoline hydrochloride | 20E29-E01-196687 | 1 |
| Phoenix | Naphazoline hydrochloride | 22K15-B02-223680 | 1 |
| Phonix | Naphazoline hydrochloride | 1704005-02 | 1 |
| Phönix | Naphazoline hydrochloride | 1704005-02 | 2 |
| Phönix | Naphazoline hydrochloride | 586550002 | 1 |
| Phönix | Naphazoline hydrochloride | B01-1966807 | 1 |

- 256 495 spectra from 1666 *Apo-Ident* customers from a total of 52 007 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Naphazoline hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Naphazoline hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 340 | 0 | 212 600 |
| **Type C** | 0 | 391 | 0 | 256 495 |

The substance/substance group *Naphazoline hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.2353 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 98.4655 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20899 | 21859 | 16.05 | 160.77 |
| 21397 | 21859 | 4.28 | 177.34 |
| 21398 | 21859 | 4.44 | 167.05 |
| 21623 | 21623 | 0.00 | 172.69 |
| 21859 | 21859 | 0.00 | 173.93 |
| 24498 | 24498 | 0.00 | 157.93 |
| 25260 | 25260 | 0.00 | 144.03 |
| 25304 | 25304 | 0.00 | 141.87 |
| 26449 | 25260 | 7.10 | 146.26 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Naphazoline nitrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20501-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Naphazoline nitrate; Naphazolini nitras

### Special notes

When selecting the *Naphazoline nitrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Naphazoline nitrate | 7 | 4 | 27 |

### Second-stage model

For differentiation of the substance/substance group *Naphazoline nitrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Naphazoline nitrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 110.97 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Naphazoline nitrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Naphazoline nitrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Naphazoline nitrate | 1512033 | 22302 | 60 | 20160126* |
| Euro OTC | Naphazoline nitrate | 1810016 | 24341 | 40 | 20181112* |
| Euro OTC | Naphazoline nitrate | 1910029 | 24940 | 40 | 20191125* |
| Euro OTC | Naphazoline nitrate | 2004011 | 25265 | 40 | 20200730* |
| Fagron | Naphazoline nitrate | 12L10-N03 | 20846 | 40 | 20121217 |
| Fagron | Naphazoline nitrate | 12J08-B40-287904 | 21808 | 60 | 20131129 |
| Fagron | Naphazoline nitrate | 22E18-B01-221068 | 26453 | 40 | 20220705 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 7 reference samples from the substance/substance group *Naphazoline nitrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 006 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 6 reference samples from the substance/substance group *Naphazoline nitrate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Naphazoline nitrate | 1512033-01 | 23275 | 40 |
| Fagron | Naphazoline nitrate | 16A14-B03-327343 | 23164 | 40 |
| Fagron | Naphazoline nitrate | 20D14-F02-370516 | 25490 | 40 |
| Fagron | Naphazoline nitrate | 24K22-B01-006897 | 27598 | 40 |
| Fagron | Naphazoline nitrate | 22E18-B01-221068 | 26453SI† | 20 |
| Fagron | Naphazoline nitrate | 24K22-B01-006897 | 27598SI | 20 |

- 212 740 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 47 spectra from 42 *Apo-Ident* customers from 28 batches from the substance/substance group *Naphazoline nitrate*.

- Among them are spectra of independent samples from 27 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Naphazoline nitrate | 2004011-03 | 4 |
| Alliance | Naphazoline nitrate | 1810016-02 | 1 |
| apomix | Naphazoline nitrate | 2004011-01 | 1 |
| Audor Pharma | Naphazoline nitrate | 12I21-N05 | 1 |
| Caelo | Naphazoline nitrate | 18K30-B02-357305 | 1 |
| eurho | Naphazoline nitrate | 2004011-01 | 1 |
| Euro OTC | Naphazoline nitrate | 1810016-01 | 1 |
| Euro OTC | Naphazoline nitrate | 191002901 | 1 |
| Euro OTC | Naphazoline nitrate | 1910029-01 | 1 |
| Euro OTC | Naphazoline nitrate | 200401101 | 1 |
| Euro OTC | Naphazoline nitrate | 2004011-01 | 8 |
| Euro OTC | Naphazoline nitrate | 4011-0001 | 1 |
| Euro OTC | Naphazoline nitrate | 740530001 | 1 |
| Euro OTC | Naphazoline nitrate | 740530002 | 2 |
| Fagron | Naphazoline nitrate | 11I05-N03 | 1 |
| Fagron | Naphazoline nitrate | 12/21-N05 | 1 |
| Fagron | Naphazoline nitrate | 12J08-B40 | 1 |
| Fagron | Naphazoline nitrate | 12J08-B40-287904 | 1 |
| Fagron | Naphazoline nitrate | 12J08B40-294166 | 1 |
| Fagron | Naphazoline nitrate | 12J08-B40-294166 | 1 |
| Fagron | Naphazoline nitrate | 12j08-b40-303401 | 1 |
| Fagron | Naphazoline nitrate | 140214N | 1 |
| Fagron | Naphazoline nitrate | 16A14-B03-322534 | 1 |
| Fagron | Naphazoline nitrate | 16A14-B03-327343 | 1 |
| Fagron | Naphazoline nitrate | 16A14-B03-333325 | 1 |
| Fagron | Naphazoline nitrate | 18K30-B02 | 1 |
| Fagron | Naphazoline nitrate | 18K30-B02-357305 | 2 |
| Fagron | Naphazoline nitrate | 20D14-F02-370516 | 3 |
| Fagron | Naphazoline nitrate | 21021304 | 1 |
| Fagron | Naphazoline nitrate | 2717M-07042 | 1 |
| Fagron | Naphazoline nitrate | 740530001 | 1 |
| Fagron | Naphazoline nitrate | D14F02-370516 | 1 |
| Noweda | Naphazoline nitrate | 2004011-03 | 1 |

- 256 839 spectra from 1666 *Apo-Ident* customers from a total of 52 125 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Naphazoline nitrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Naphazoline nitrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 45 | 2 | 256 839 |

The substance/substance group *Naphazoline nitrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 95.7447 % (> 89.3617 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20846 | 22302 | 9.82 | 232.80 |
| 21808 | 22302 | 6.69 | 236.58 |
| 22302 | 22302 | 0.00 | 241.05 |
| 24341 | 24341 | 0.00 | 253.60 |
| 24940 | 24940 | 0.00 | 237.99 |
| 25265 | 25265 | 0.00 | 233.79 |
| 26453 | 24940 | 9.24 | 240.03 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Naproxen** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22316-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Naproxen; Naproxenum

### Special notes

When selecting the *Naproxen* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Naproxen | 5 | 3 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Naproxen* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Naproxen* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 100.21 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Naproxen* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Naproxen*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Naproxen | 15F18-B03-309492 | 22316 | 45 | AR-16-FG-008486-02 |
| Fagron | Naproxen | 15F18-B03-315691 | 22327 | 45 | 20150703 |
| Fagron | Naproxen | 16B04-B09-326261 | 23105 | 40 | 20160229 |
| Fagron | Naproxen | 22H17-B03-227263 | 26542 | 40 | 20221004 |
| Fagron | Naproxen | 22H17-B03-227263 | 26542SI | 20 | 20221004 |
| Fagron | Naproxen | 23F19-B01-236106 | 27188 | 40 | 20230711 |
| Fagron | Naproxen | 23F19-B01-236106 | 27188SI | 20 | 20230711 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 250 spectra of 7 reference samples from the substance/substance group *Naproxen*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.


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- 158 076 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 130 spectra of 4 reference samples from the substance/substance group *Naproxen*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Naproxen | 17C10-B03-336472 | 23763 | 40 |
| Fagron | Naproxen | 21F15-B16-213613 | 25909 | 40 |
| Fagron | Naproxen | 24C05-B14-006038 | 27594 | 40 |
| Fagron | Naproxen | 21F15-B16-213613 | 25909SI | 10 |

- 212 810 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 27 spectra from 6 *Apo-Ident* customers from 3 batches from the substance/substance group *Naproxen*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Naproxen | 13E31-B40-287536 | 2 |
| Fagron | Naproxen | 16B04-B09-321569 | 24 |
| Fagron | Naproxen | 17C10-B03-336472 | 1 |

- 256 859 spectra from 1666 *Apo-Ident* customers from a total of 52 150 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Naproxen* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Naproxen* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 250 | 0 | 158 076 |
| **Type B** | 0 | 130 | 0 | 212 810 |
| **Type C** | 0 | 27 | 0 | 256 859 |

The substance/substance group *Naproxen* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.3846 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 77.7778 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22316 | 22316 | 0.00 | 158.37 |
| 22327 | 22316 | 1.99 | 158.88 |
| 23105 | 22316 | 5.59 | 161.21 |
| 26542 | 22316 | 7.43 | 158.69 |
| 27188 | 22316 | 7.61 | 161.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Neomycin sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20544-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Neomycin sulfate; Neomycin sulphate; Neomycini sulfas

### Special notes

When selecting the *Neomycin sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Neomycin sulfate | 12 | 5 | 236 |

### Second-stage model

For differentiation of the substance/substance group *Neomycin sulfate* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Neomycin sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Tobramycin sulfate | 34.71 | 28.62 |
| Cannabis flower, THC-dominant type | 45.94 | – |
| Sodium cromoglicate | 55.20 | – |
| ⋮ | ⋮ | ⋮ |
| Mg-Ca-K colamine phosphate | >50 | 55.44 |
| Riboflavin sodium phosphate hydrate | >50 | 63.31 |
| Zinc gluconate | >50 | 91.45 |
| Gentamicin sulfate | >50 | 101.12 |
| Carbomers | >50 | 116.09 |
| Magnesium citrate | >50 | 122.91 |
| Sodium tetraborate | >50 | 403.77 |
| Finasteride | >50 | 1347.47 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Neomycin sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Neomycin sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Neomycin sulfate | 13062923 | 21814 | 60 | AR-15-FG-016581-01 |
| Caelo | Neomycin sulfate | 13062923 | 22276 | 45 | 20130315 |
| Caelo | Neomycin sulfate | 161650 | 23856 | 30 | 20160629* |
| Caelo | Neomycin sulfate | 20002248 | 25643 | 40 | 20200923* |
| Caelo | Neomycin sulfate | 24000508 | 27222 | 40 | 20240416* |
| Euro OTC | Neomycin sulfate | 1303033-03 | 21771 | 60 | AR-15-FG-016582-01 |
| Euro OTC | Neomycin sulfate | 1601046 | 22381 | 45 | 20160212* |
| Fagron | Neomycin sulfate | 14C27-B05-302516 | 21894 | 60 | 1604527 |
| Fagron | Neomycin sulfate | 14C27-B05-302517 | 21961 | 60 | 20140418 |
| Fagron | Neomycin sulfate | 19G23-B03-364716 | 25185 | 40 | 20191007 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Neomycin sulfate | 22E11-B04-224107 | 26286 | 40 | 20220627 |
| Fagron | Neomycin sulfate | 23C10-B04-219531 | 26664 | 40 | 20230310 |
| Fagron | Neomycin sulfate | 23C10-B04-219531 | 26664SI | 20 | 20230310 |
| Fagron | Neomycin sulfate | 23G20-B10-233758 | 27052 | 40 | 20230803 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 620 spectra of 14 reference samples from the substance/substance group *Neomycin sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.

- 157 706 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 7 reference samples from the substance/substance group *Neomycin sulfate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Neomycin sulfate | 15237602 | 22389 | 40 |
| Caelo | Neomycin sulfate | 23000856 | 26894 | 40 |
| Euro OTC | Neomycin sulfate | 1802005 | 23952 | 40 |
| Euro OTC | Neomycin sulfate | 1903022 | 24642 | 40 |
| Euro OTC | Neomycin sulfate | 2003021 | 25280 | 40 |
| Caelo | Neomycin sulfate | 23000856 | 26894SI | 20 |
| Fagron | Neomycin sulfate | 22E11-B04-224107 | 26286SI† | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 700 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1287 spectra from 574 *Apo-Ident* customers from 252 batches from the substance/substance group *Neomycin sulfate*.
- Among them are spectra of independent samples from 236 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Neomycin sulfate | 1303033-03 | 1 |
| | Neomycin sulfate | 13G09-N07 | 1 |
| | Neomycin sulfate | 2003021-02 | 1 |
| | Neomycin sulfate | 2100321600 | 1 |
| | Neomycin sulfate | 21003216026 | 2 |
| | Neomycin sulfate | 22E11-B04-236817 | 2 |
| | Neomycin sulfate | 22E11-B04-236820 | 1 |
| | Neomycin sulfate | 23000856005 | 2 |
| | Neomycin sulfate | 23000856006 | 7 |
| | Neomycin sulfate | 23000856007 | 7 |
| | Neomycin sulfate | 23003478001 | 2 |
| | Neomycin sulfate | 23C10-B04-219531 | 1 |
| | Neomycin sulfate | 23C10-B04-219532 | 5 |
| | Neomycin sulfate | 23C10-B04-232371 | 3 |
| | Neomycin sulfate | 23C10-B04-219532 | 1 |
| | Neomycin sulfate | 23D14-B03-232374 | 7 |
| | Neomycin sulfate | 23D26-B03-234156 | 1 |
| | Neomycin sulfate | 24000508003 | 1 |
| | Neomycin sulfate | 24000508004 | 5 |
| | Neomycin sulfate | 24000508005 | 10 |
| | Neomycin sulfate | 24000588005 | 1 |
| | Neomycin sulfate | B03_2323704 | 1 |
| | Neomycin sulfate | GW1442 | 1 |
| | Neomycin sulfate | GY9146 | 3 |
| AHD/Euro | Neomycin sulfate | 160104602 | 1 |
| AHD/Euro | Neomycin sulfate | 1802005 | 1 |
| AHD | Neomycin sulfate | 11/19-N14 | 1 |
| AHD | Neomycin sulfate | 14A31-B02-294698 | 2 |
| AHD | Neomycin sulfate | 1802005-01 | 2 |
| Alliance healfcare | Neomycin sulfate | 1802005-01 | 1 |
| Alliance Health 13.01.204 | Neomycin sulfate | 1303033-01 | 2 |
| Alliance Healthcare | Neomycin sulfate | 1102043-03 | 1 |
| Alliance | Neomycin sulfate | 1802005-01 | 1 |
| Alliance | Neomycin sulfate | 2003021-02 | 1 |
| ApBetrO/Noweda | Neomycin sulfate | 200302-02 | 1 |
| apo-ident.;4,45EUR; Sa... | Neomycin sulfate | 1601046-01 | 1 |
| Ashland/Sanacorp | Neomycin sulfate | 1303033-02 | 1 |
| aurica/phoenix | Neomycin sulfate | 1102043-02 | 1 |
| Caelo | Neomycin sulfate | 10157505 | 3 |
| Caelo | Neomycin sulfate | 10206300 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Neomycin sulfate | 1102043-02 | 1 |
| Caelo | Neomycin sulfate | 11C21-N10 | 1 |
| Caelo | Neomycin sulfate | 12175401 | 4 |
| Caelo | Neomycin sulfate | 12276405 | 1 |
| Caelo | Neomycin sulfate | 12276410 | 2 |
| Caelo | Neomycin sulfate | 1303033-02 | 1 |
| Caelo | Neomycin sulfate | 130303303 | 3 |
| Caelo | Neomycin sulfate | 1303033-03 | 3 |
| Caelo | Neomycin sulfate | 13062905 | 4 |
| Caelo | Neomycin sulfate | 13062908 | 1 |
| Caelo | Neomycin sulfate | 13062921 | 1 |
| Caelo | Neomycin sulfate | 13062922 | 1 |
| Caelo | Neomycin sulfate | 13062923 | 6 |
| Caelo | Neomycin sulfate | 13D10N05 | 1 |
| Caelo | Neomycin sulfate | 13G09-N07 | 1 |
| Caelo | Neomycin sulfate | 14A31-B02-294696 | 1 |
| Caelo | Neomycin sulfate | 1502004-01 | 1 |
| Caelo | Neomycin sulfate | 1502004-03 | 2 |
| Caelo | Neomycin sulfate | 15237602 | 7 |
| Caelo | Neomycin sulfate | 15298902 | 2 |
| Caelo | Neomycin sulfate | 15J09-B04-314015 | 1 |
| Caelo | Neomycin sulfate | 15J27-B07-321372 | 1 |
| Caelo | Neomycin sulfate | 1601046 | 1 |
| Caelo | Neomycin sulfate | 1601046-01 | 3 |
| Caelo | Neomycin sulfate | 1601046-02 | 4 |
| Caelo | Neomycin sulfate | 16122601 | 3 |
| Caelo | Neomycin sulfate | 16122611 | 2 |
| Caelo | Neomycin sulfate | 16122612 | 8 |
| Caelo | Neomycin sulfate | 16122617 | 1 |
| Caelo | Neomycin sulfate | 16122618 | 1 |
| Caelo | Neomycin sulfate | 16122623 | 1 |
| Caelo | Neomycin sulfate | 16165004 | 4 |
| Caelo | Neomycin sulfate | 16165006 | 3 |
| Caelo | Neomycin sulfate | 16165008 | 2 |
| Caelo | Neomycin sulfate | 16165014 | 1 |
| Caelo | Neomycin sulfate | 161650145351 | 1 |
| Caelo | Neomycin sulfate | 16165015 | 1 |
| Caelo | Neomycin sulfate | 16165016 | 15 |
| Caelo | Neomycin sulfate | 16165017 | 2 |
| Caelo | Neomycin sulfate | 16165018 | 7 |
| Caelo | Neomycin sulfate | 16B10-B50-328165 | 3 |
| Caelo | Neomycin sulfate | 17F12-B04-340237 | 2 |
| Caelo | Neomycin sulfate | 18018704 | 7 |
| Caelo | Neomycin sulfate | 180200501 | 1 |
| Caelo | Neomycin sulfate | 1802005-01 | 5 |
| Caelo | Neomycin sulfate | 18161303 | 14 |
| Caelo | Neomycin sulfate | 18161304 | 4 |
| Caelo | Neomycin sulfate | 18161305 | 6 |
| Caelo | Neomycin sulfate | 18161307 | 19 |
| Caelo | Neomycin sulfate | 18161309 | 1 |
| Caelo | Neomycin sulfate | 18161310 | 8 |
| Caelo | Neomycin sulfate | 18A25-B05-346135 | 1 |
| Caelo | Neomycin sulfate | 18A25-B05-346138 | 1 |
| Caelo | Neomycin sulfate | 18G28B05352957 | 1 |
| Caelo | Neomycin sulfate | 18G28B05354472 | 1 |
| Caelo | Neomycin sulfate | 191849001 | 6 |
| Caelo | Neomycin sulfate | 191849003 | 8 |
| Caelo | Neomycin sulfate | 19184903 | 20 |
| Caelo | Neomycin sulfate | 20000391004 | 7 |
| Caelo | Neomycin sulfate | 200003914004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Neomycin sulfate | 20004305001 | 11 |
| Caelo | Neomycin sulfate | 20004305005 | 9 |
| Caelo | Neomycin sulfate | 20004305006 | 4 |
| Caelo | Neomycin sulfate | 20E13-F-03 | 1 |
| Caelo | Neomycin sulfate | 21003216005 | 14 |
| Caelo | Neomycin sulfate | 21003216006 | 7 |
| Caelo | Neomycin sulfate | 21003216022 | 2 |
| Caelo | Neomycin sulfate | 21003216023 | 1 |
| Caelo | Neomycin sulfate | 21003216025 | 1 |
| Caelo | Neomycin sulfate | 21003216026 | 1 |
| Caelo | Neomycin sulfate | 21003216027 | 5 |
| Caelo | Neomycin sulfate | 2120520043055 | 1 |
| Caelo | Neomycin sulfate | 23000856007 | 1 |
| Caelo | Neomycin sulfate | 24111203 | 1 |
| Caelo | Neomycin sulfate | 3345 | 1 |
| Caelo | Neomycin sulfate | 5/AKD35 | 1 |
| Caelo | Neomycin sulfate | 5/AKD36 | 1 |
| Caelo | Neomycin sulfate | 563313062905 | 1 |
| Caelo | Neomycin sulfate | 8718 | 1 |
| Caelo | Neomycin sulfate | 9051402 | 1 |
| Caelo | Neomycin sulfate | 9105316 | 1 |
| Caelo | Neomycin sulfate | L34419 | 1 |
| Caelo | Neomycin sulfate | N05780 | 1 |
| Caesar & Loretz GmbH... | Neomycin sulfate | 11/19-N14 | 1 |
| Caesar & Loretz GmbH... | Neomycin sulfate | 19184903 | 1 |
| Caesar & Loretz GmbH... | Neomycin sulfate | 20004305005 | 1 |
| Caesar & Loretz GmbH... | Neomycin sulfate | 20004305005 | 1 |
| Caesar & Loretz GmbH/Gehe | Neomycin sulfate | 21003216026 | 1 |
| Caesar & Loretz GmbH... | Neomycin sulfate | 19184903 | 1 |
| Caesar & Loretz GmbH... | Neomycin sulfate | 18161310 | 2 |
| Caesar & Loretz GmbH... | Neomycin sulfate | 21003216005 | 1 |
| Caesar & Loretz GmbH | Neomycin sulfate | 18018704 | 2 |
| Caesar & Loretz GmbH | Neomycin sulfate | 18161305 | 2 |
| Caesar & Loretz GmbH | Neomycin sulfate | 18161307 | 5 |
| Caesar & Loretz GmbH | Neomycin sulfate | 191849001 | 4 |
| Caesar & Loretz GmbH | Neomycin sulfate | 19184903 | 8 |
| Caesar & Loretz GmbH | Neomycin sulfate | 20000391004 | 1 |
| Caesar & Loretz GmbH | Neomycin sulfate | 20004305001 | 3 |
| Caesar & Loretz GmbH | Neomycin sulfate | 20004305005 | 6 |
| Caesar & Loretz GmbH | Neomycin sulfate | 20004305006 | 2 |
| Caesar & Loretz GmbH | Neomycin sulfate | 21003216005 | 8 |
| Caesar & Loretz GmbH | Neomycin sulfate | 21003216022 | 1 |
| Caesar & Loretz GmbH | Neomycin sulfate | 21003216026 | 2 |
| Caesar Loretz | Neomycin sulfate | 19184903 | 1 |
| Caesar&Loretz GmbH,1... | Neomycin sulfate | 16122612 | 1 |
| Caesar&loretz,AHC,05... | Neomycin sulfate | 15237602 | 1 |
| caesar&loretz,AHC,7.3.16 | Neomycin sulfate | 13062923 | 1 |
| Caesar&loretz,Phoenix | Neomycin sulfate | 12C13-N04 | 1 |
| Caesar&Loretz/Noweda | Neomycin sulfate | 15298904 | 1 |
| Cealo/AHD | Neomycin sulfate | 15J09-B04-314017 | 1 |
| Cealo | Neomycin sulfate | | 1 |
| cealo | Neomycin sulfate | 1502004-03 | 1 |
| Ebert & Jacobi | Neomycin sulfate | 1601046-01 | 1 |
| Eur Rho Gehe | Neomycin sulfate | 2003021-01 | 1 |
| EuRho / Fiebig | Neomycin sulfate | 2003021-02 | 1 |
| EuRho/Sanacorp | Neomycin sulfate | 1102043-03 | 1 |
| EuRho | Neomycin sulfate | 1102043-02 | 1 |
| EuRho | Neomycin sulfate | 1601046-01 | 1 |
| Eurho | Neomycin sulfate | 1601046-02 | 1 |
| EuRho | Neomycin sulfate | 1802005-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| euRho | Neomycin sulfate | 1903022-01 | 1 |
| EuRho | Neomycin sulfate | 2003021-01 | 2 |
| EuRho | Neomycin sulfate | 2003021-02 | 1 |
| Euro OTC | Neomycin sulfate | 1102043 | 2 |
| Euro OTC | Neomycin sulfate | 1102043-01 | 3 |
| Euro OTC | Neomycin sulfate | 1102043-02 | 7 |
| Euro OTC | Neomycin sulfate | 1102043-03 | 4 |
| Euro OTC | Neomycin sulfate | 1303001-03 | 1 |
| Euro OTC | Neomycin sulfate | 1303033-01 | 10 |
| Euro OTC | Neomycin sulfate | 1303033-02 | 17 |
| Euro OTC | Neomycin sulfate | 1303033-03 | 17 |
| Euro OTC | Neomycin sulfate | 1502004 | 1 |
| Euro OTC | Neomycin sulfate | 1502004-01 | 21 |
| Euro OTC | Neomycin sulfate | 1502004-02 | 4 |
| Euro OTC | Neomycin sulfate | 1502004-03 | 23 |
| Euro OTC | Neomycin sulfate | 151116N | 1 |
| Euro OTC | Neomycin sulfate | 1601042 | 1 |
| Euro OTC | Neomycin sulfate | 1601045-01 | 2 |
| Euro OTC | Neomycin sulfate | 1601046 | 1 |
| Euro OTC | Neomycin sulfate | 160104601 | 3 |
| Euro OTC | Neomycin sulfate | 1601046-01 | 38 |
| Euro OTC | Neomycin sulfate | 1601046-02 | 39 |
| Euro OTC | Neomycin sulfate | 1601046-1 | 1 |
| Euro OTC | Neomycin sulfate | 160146-02 | 1 |
| Euro OTC | Neomycin sulfate | 16019046-01 | 1 |
| Euro OTC | Neomycin sulfate | 18020005-01 | 2 |
| Euro OTC | Neomycin sulfate | 180200501 | 2 |
| Euro OTC | Neomycin sulfate | 1802005-01 | 141 |
| Euro OTC | Neomycin sulfate | 1802-005-01 | 1 |
| Euro OTC | Neomycin sulfate | 180205-01 | 1 |
| Euro OTC | Neomycin sulfate | 1802095 | 1 |
| Euro OTC | Neomycin sulfate | 190302-01 | 1 |
| Euro OTC | Neomycin sulfate | 1903022 | 3 |
| Euro OTC | Neomycin sulfate | 1903022-01 | 20 |
| Euro OTC | Neomycin sulfate | 191001209 | 1 |
| Euro OTC | Neomycin sulfate | 2003021 | 4 |
| Euro OTC | Neomycin sulfate | 200302101 | 1 |
| Euro OTC | Neomycin sulfate | 2003021-01 | 33 |
| Euro OTC | Neomycin sulfate | 200302102 | 1 |
| Euro OTC | Neomycin sulfate | 2003021-02 | 70 |
| Euro OTC | Neomycin sulfate | 3021-012 | 1 |
| Euro OTC | Neomycin sulfate | 3519A-01926 | 1 |
| Euro OTC | Neomycin sulfate | G73890 | 1 |
| Euro OTC | Neomycin sulfate | L34419 | 4 |
| Euro OTC | Neomycin sulfate | N05780 | 1 |
| Euro OTC | Neomycin sulfate | w13203 | 1 |
| Euro OTC | Neomycin sulfate | W13203 | 2 |
| euro//Noweda | Neomycin sulfate | 1601046-02 | 1 |
| Euro/Phönix | Neomycin sulfate | 1502004-01 | 1 |
| Euro/Phönix | Neomycin sulfate | 1502004-03 | 1 |
| Euro/Phönix | Neomycin sulfate | 2003021-01 | 1 |
| Euro/Sanacorp | Neomycin sulfate | 1601046-02 | 1 |
| Euro/Sanacorp | Neomycin sulfate | 1661046-02 | 2 |
| Euro/Sanacorp | Neomycin sulfate | 1802005-01 | 2 |
| Euro/Sanacorp | Neomycin sulfate | 2003021-01 | 1 |
| euro | Neomycin sulfate | 1502004-02 | 2 |
| Euroo/Noweda | Neomycin sulfate | 2003021-01 | 1 |
| Eurp | Neomycin sulfate | 2003021 | 1 |
| Fagron | Neomycin sulfate | 100810-112-91 | 1 |
| Fagron | Neomycin sulfate | 10121-N01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Neomycin sulfate | 11/19-N14 | 4 |
| Fagron | Neomycin sulfate | 116M-01926 | 1 |
| Fagron | Neomycin sulfate | 11C21-N10 | 3 |
| Fagron | Neomycin sulfate | 12C13-N04 | 4 |
| Fagron | Neomycin sulfate | 12H23-N04 | 6 |
| Fagron | Neomycin sulfate | 12I19-N14 | 1 |
| Fagron | Neomycin sulfate | 13D10-N05 | 5 |
| Fagron | Neomycin sulfate | 13D10-NO5 | 1 |
| Fagron | Neomycin sulfate | 13G09-N06 | 1 |
| Fagron | Neomycin sulfate | 13G09N07 | 2 |
| Fagron | Neomycin sulfate | 13G09-N07 | 16 |
| Fagron | Neomycin sulfate | 13G09-N070129/340 | 1 |
| Fagron | Neomycin sulfate | 13K15-B33-288069 | 3 |
| Fagron | Neomycin sulfate | 13K15-B33-288073 | 1 |
| Fagron | Neomycin sulfate | 14A31B02 | 2 |
| Fagron | Neomycin sulfate | 14A31-B02 | 2 |
| Fagron | Neomycin sulfate | 14A31B02294696 | 1 |
| Fagron | Neomycin sulfate | 14A31-B02-294696 | 5 |
| Fagron | Neomycin sulfate | 14A31-B02-294697 | 1 |
| Fagron | Neomycin sulfate | 14A31-B02-294698 | 1 |
| Fagron | Neomycin sulfate | 14A31-B02-296724 | 1 |
| Fagron | Neomycin sulfate | 14A31-B02-302519 | 5 |
| Fagron | Neomycin sulfate | 14C27-B05 | 1 |
| Fagron | Neomycin sulfate | 14c27-B05-302516 | 1 |
| Fagron | Neomycin sulfate | 14C27-B05-302516 | 2 |
| Fagron | Neomycin sulfate | 14C27-B05-302517 | 1 |
| Fagron | Neomycin sulfate | 15/27-B07-321372 | 2 |
| Fagron | Neomycin sulfate | 1502004-01 | 2 |
| Fagron | Neomycin sulfate | 1502004-03 | 1 |
| Fagron | Neomycin sulfate | 15i09-B04-314015 | 1 |
| Fagron | Neomycin sulfate | 15J09-B04 | 1 |
| Fagron | Neomycin sulfate | 15j09-b04-314015 | 1 |
| Fagron | Neomycin sulfate | 15J09-B04314015 | 1 |
| Fagron | Neomycin sulfate | 15J09-B04-314015 | 5 |
| Fagron | Neomycin sulfate | 15J09-B04-314017 | 5 |
| Fagron | Neomycin sulfate | 15J27-B07 | 1 |
| Fagron | Neomycin sulfate | 15J27-B07-321372 | 2 |
| Fagron | Neomycin sulfate | 15J09-B04-314017 | 1 |
| Fagron | Neomycin sulfate | 16A20-B01-327433 | 1 |
| Fagron | Neomycin sulfate | 16A20-B10 | 2 |
| Fagron | Neomycin sulfate | 16A20-B10-324346 | 2 |
| Fagron | Neomycin sulfate | 16A20-B10-327433 | 2 |
| Fagron | Neomycin sulfate | 16b10-b50 | 1 |
| Fagron | Neomycin sulfate | 16B10-B50 | 3 |
| Fagron | Neomycin sulfate | 16B10-B50-328165 | 11 |
| Fagron | Neomycin sulfate | 16B28-B05-352957 | 1 |
| Fagron | Neomycin sulfate | 17B14-B08 | 1 |
| Fagron | Neomycin sulfate | 17B14-B08-334000 | 3 |
| Fagron | Neomycin sulfate | 17F12-804 | 1 |
| Fagron | Neomycin sulfate | 17F12-B04 | 1 |
| Fagron | Neomycin sulfate | 17f12-b04-340237 | 1 |
| Fagron | Neomycin sulfate | 17F12-B04-340237 | 1 |
| Fagron | Neomycin sulfate | 17G05-B04 | 1 |
| Fagron | Neomycin sulfate | 180200501 | 1 |
| Fagron | Neomycin sulfate | 1802005-01 | 6 |
| Fagron | Neomycin sulfate | 183360-0009 | 1 |
| Fagron | Neomycin sulfate | 18A25-B05-346136 | 1 |
| Fagron | Neomycin sulfate | 18A25-B05-346138 | 4 |
| Fagron | Neomycin sulfate | 18A25-B-05-346138 | 1 |
| Fagron | Neomycin sulfate | 18G28B05 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Neomycin sulfate | 18G28-B05 | 3 |
| Fagron | Neomycin sulfate | 18g28-b05-352953 | 1 |
| Fagron | Neomycin sulfate | 18G28-B05-352953 | 5 |
| Fagron | Neomycin sulfate | 18G28-B05-352957 | 5 |
| Fagron | Neomycin sulfate | 18G28-B05-354472 | 7 |
| Fagron | Neomycin sulfate | 19G23-B03 | 1 |
| Fagron | Neomycin sulfate | 19G23-B03-364716 | 3 |
| Fagron | Neomycin sulfate | 19G23-B03-364717 | 1 |
| Fagron | Neomycin sulfate | 19G23-B03-364720 | 4 |
| Fagron | Neomycin sulfate | 19G23-BO3-364717 | 1 |
| Fagron | Neomycin sulfate | 19G23-BO3-364720 | 1 |
| Fagron | Neomycin sulfate | 19i23-b04-195473 | 1 |
| Fagron | Neomycin sulfate | 20A29-F01 | 1 |
| Fagron | Neomycin sulfate | 20A29-F01-370834 | 2 |
| Fagron | Neomycin sulfate | 20A29-F01-370836 | 6 |
| Fagron | Neomycin sulfate | 20A29F01370841 | 1 |
| Fagron | Neomycin sulfate | 20A29-F01-370841 | 3 |
| Fagron | Neomycin sulfate | 20A29-F01-370842 | 1 |
| Fagron | Neomycin sulfate | 20A29-FO1-370836 | 2 |
| Fagron | Neomycin sulfate | 20D08-B07-200574 | 1 |
| Fagron | Neomycin sulfate | 20do8-b07-200574 | 1 |
| Fagron | Neomycin sulfate | 20do8-b07-201750 | 1 |
| Fagron | Neomycin sulfate | 20E13-F03-371373 | 1 |
| Fagron | Neomycin sulfate | 21D30-F06 | 2 |
| Fagron | Neomycin sulfate | 21D30-F06-378610 | 2 |
| Fagron | Neomycin sulfate | 21D30-F06-378614 | 9 |
| Fagron | Neomycin sulfate | 21D3O-FO6-378614 | 1 |
| Fagron | Neomycin sulfate | 22E12-B10-224471 | 1 |
| Fagron | Neomycin sulfate | 23A09-B07-229452 | 1 |
| Fagron | Neomycin sulfate | 23C10-804-219532 | 1 |
| Fagron | Neomycin sulfate | 23C10-B04-219531 | 1 |
| Fagron | Neomycin sulfate | 23D14-B03-234155 | 1 |
| Fagron | Neomycin sulfate | 352954 | 1 |
| Fagron | Neomycin sulfate | 4312I-01926 | 1 |
| Fagron | Neomycin sulfate | b03-364717 | 1 |
| Fagron | Neomycin sulfate | F08469 | 1 |
| Fagron | Neomycin sulfate | FO8469 | 1 |
| Fagron | Neomycin sulfate | M71862 | 2 |
| Fagron | Neomycin sulfate | NMZ11006K | 1 |
| Fagron | Neomycin sulfate | X51344 | 1 |
| Fargon / AHD | Neomycin sulfate | 18G28-B05-354472 | 1 |
| Fargon | Neomycin sulfate | 15j27-b07-321372 | 1 |
| fargron | Neomycin sulfate | 14A31-B02-294698 | 1 |
| Fiebig | Neomycin sulfate | 1502004-03 | 2 |
| Fragon/Phoenix | Neomycin sulfate | 15J09-B04_322943 | 1 |
| Gehe 23.11.18 | Neomycin sulfate | 1802005-01 | 1 |
| GEHE | Neomycin sulfate | 1502001-03 | 1 |
| Gehe | Neomycin sulfate | 1601046-01 | 1 |
| Gehe | Neomycin sulfate | 1601046-02 | 1 |
| GEHE | Neomycin sulfate | 160104602 | 1 |
| Gehe | Neomycin sulfate | 1802005-01 | 1 |
| GEHE | Neomycin sulfate | 1802005-01 | 1 |
| gehe | Neomycin sulfate | 183360-0009 | 1 |
| Gehe | Neomycin sulfate | 183360-0009 | 1 |
| Gehe | Neomycin sulfate | 194A-01926 | 1 |
| Gehe | Neomycin sulfate | 2003021-02 | 2 |
| Gehe | Neomycin sulfate | 2100321606 | 1 |
| Gehe | Neomycin sulfate | 23D14-B03-232374 | 2 |
| GEHE | Neomycin sulfate | 250717(24000508005) | 1 |
| Geibo/EuRho | Neomycin sulfate | 180200501 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Geibo/EuRho | Neomycin sulfate | 1802005-01 | 1 |
| Hageda | Neomycin sulfate | 1802005-01 | 1 |
| HenryLamotte | Neomycin sulfate | 1502004-01 | 1 |
| Jenne | Neomycin sulfate | 15237602 | 1 |
| Jenne | Neomycin sulfate | 20004305006 | 1 |
| Jenne | Neomycin sulfate | 241007(23003478001) | 1 |
| Jenne | Neomycin sulfate | GY9146 | 1 |
| Kehr | Neomycin sulfate | 1601046-02 | 1 |
| Nachprüfung | Neomycin sulfate | 2082019-7 | 1 |
| Noweda/Euro | Neomycin sulfate | | 1 |
| Noweda | Neomycin sulfate | 10157505 | 2 |
| Noweda | Neomycin sulfate | 1102043-02 | 1 |
| Noweda | Neomycin sulfate | 1303033-03 | 1 |
| Noweda | Neomycin sulfate | 15298902 | 1 |
| Noweda | Neomycin sulfate | 160104601 | 1 |
| Noweda | Neomycin sulfate | 1601046-02 | 3 |
| Noweda | Neomycin sulfate | 16165016 | 1 |
| Noweda | Neomycin sulfate | 1802005-01 | 3 |
| Noweda | Neomycin sulfate | 191849001 | 1 |
| Noweda | Neomycin sulfate | 20004305001 | 1 |
| Noweda | Neomycin sulfate | 20A29-F01-370841 | 1 |
| Noweda | Neomycin sulfate | 21003216005 | 2 |
| Noweda | Neomycin sulfate | 22E11-B04-236820 | 2 |
| Noweda | Neomycin sulfate | 23C10-B04-219531 | 1 |
| Noweda | Neomycin sulfate | 23D14-B03-232374 | 4 |
| Pfizer USA / Phönix | Neomycin sulfate | 1303033-02 | 1 |
| Pfizer USA/ Phönix | Neomycin sulfate | DC3552 | 1 |
| Pfizer USA/Phoenix | Neomycin sulfate | 2003021-21 | 1 |
| Pfizer usa | Neomycin sulfate | 160104601 | 1 |
| Pfizer USA | Neomycin sulfate | 2003021 | 1 |
| Pfizer USA | Neomycin sulfate | DC3552 | 1 |
| Pfizer/Euro OCT Pharma | Neomycin sulfate | 1102043-02 | 2 |
| Pfizer/Noweda | Neomycin sulfate | W13203 | 1 |
| Ph/Euro | Neomycin sulfate | 18020501 | 1 |
| Pharmacia & Upjohn C... | Neomycin sulfate | 16165017 | 1 |
| Pharmacia & Upjohn C... | Neomycin sulfate | 16122623 | 1 |
| phnoix | Neomycin sulfate | 130303301 | 1 |
| phoenix 13.11.14 | Neomycin sulfate | 1303033-03 | 1 |
| Phoenix apo-ident | Neomycin sulfate | 200302102 | 2 |
| Phoenix/EuRho | Neomycin sulfate | 2003021-02 | 2 |
| Phoenix | Neomycin sulfate | 2003021-01 | 1 |
| Phoenix | Neomycin sulfate | 23000856007 | 1 |
| Phoenix | Neomycin sulfate | 2400508005 | 1 |
| Phönix Euro 23.6.21 | Neomycin sulfate | 2003021-01 | 1 |
| Phönix | Neomycin sulfate | 13D10-N05 | 1 |
| Phönix | Neomycin sulfate | 1601046-02 | 1 |
| Phönix | Neomycin sulfate | 1802005-01 | 3 |
| Phönix | Neomycin sulfate | 18A25B05-346138 | 1 |
| Sanacop/Pharma | Neomycin sulfate | 15J27B07-321372 | 1 |
| Sanacorp 05.07.2019 5,90EUR | Neomycin sulfate | 18G28-B05-354472 | 1 |
| Sanacorp/EuRho | Neomycin sulfate | 1601046-01 | 1 |
| Sanacorp | Neomycin sulfate | 15298902 | 1 |
| Sanacorp | Neomycin sulfate | 16165016 | 1 |
| Sanacorp | Neomycin sulfate | 180200501 | 1 |
| Sanacorp | Neomycin sulfate | 2003021-02 | 1 |
| Sanacorp | Neomycin sulfate | 23C10-B04-219532 | 1 |
| Sanacorp | Neomycin sulfate | 23D14-B03-232374 | 2 |
| Sichuan Long March P... | Neomycin sulfate | SC-NM-20180109 | 1 |
| Sichuan Long March P... | Neomycin sulfate | SC-NM-20190123 | 3 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sichuan/Noweda | Neomycin sulfate | SC-NM-20200410 | 1 |
| siehe WE-Prüfprotokoll | Neomycin sulfate | 19/12 | 1 |
| Taoasis/Phoenix | Neomycin sulfate | 1502004-01 | 1 |
| VDL;9.12;3,55; | Neomycin sulfate | 1303033-03 | 1 |

- 255 599 spectra from 1666 *Apo-Ident* customers from a total of 51 904 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Neomycin sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Neomycin sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 620 | 0 | 157 706 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 1278 | 9 | 255 599 |

The substance/substance group *Neomycin sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0323 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.3007 % (> 99.0676 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21771 | 21771 | 0.00 | 118.14 |
| 21814 | 21814 | 0.00 | 125.98 |

*continued on the next page*

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21894 | 21894 | 0.00 | 91.49 |
| 21961 | 21814 | 20.29 | 123.77 |
| 22276 | 21814 | 3.42 | 125.79 |
| 22381 | 22381 | 0.00 | 131.22 |
| 23856 | 23856 | 0.00 | 75.97 |
| 25185 | 22381 | 8.38 | 139.11 |
| 25643 | 25643 | 0.00 | 117.57 |
| 26286 | 21771 | 10.88 | 122.56 |
| 26664 | 22381 | 15.11 | 140.40 |
| 27052 | 22381 | 28.43 | 98.91 |
| 27222 | 27222 | 0.00 | 96.01 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Neostigmine bromide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20717-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Neostigmine bromide; Neostigmini bromidum

### Special notes

When selecting the *Neostigmine bromide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Neostigmine bromide | 5 | 3 | 13 |

### Second-stage model

For differentiation of the substance/substance group *Neostigmine bromide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Neostigmine bromide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dequalinium chloride | 113.04 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Neostigmine bromide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Neostigmine bromide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Neostigmine bromide | 10144105 | 20717 | 40 | 20100616 |
| Caelo | Neostigmine bromide | 12172304 | 20990 | 40 | 1403163 |
| Caelo | Neostigmine bromide | 14256802 | 21816 | 60 | AR-15-FG-014460-01 |
| Caelo | Neostigmine bromide | 14256802 | 21816SI | 60 | AR-15-FG-014460-01 |
| Caelo | Neostigmine bromide | 15228101 | 21919 | 60 | 20151002 |
| Caelo | Neostigmine bromide | 15228101 | 21919SI | 60 | 20151002 |
| Caelo | Neostigmine bromide | 193083001 | 25390 | 40 | 20191213 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 360 spectra of 7 reference samples from the substance/substance group *Neostigmine bromide*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.


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- 157 966 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 280 spectra of 7 reference samples from the substance/substance group *Neostigmine bromide*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Neostigmine bromide | 171319 | 23369 | 40 |
| Caelo | Neostigmine bromide | 17131901 | 23373 | 40 |
| Caelo | Neostigmine bromide | 22000195 | 26012 | 40 |
| Caelo | Neostigmine bromide | 171319 | 23369SI | 40 |
| Caelo | Neostigmine bromide | 17131901 | 23373SI | 40 |
| Caelo | Neostigmine bromide | 193083001 | 25390SI† | 40 |
| Caelo | Neostigmine bromide | 22000195 | 26012SI | 40 |

- 212 660 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 45 spectra from 19 *Apo-Ident* customers from 17 batches from the substance/substance group *Neostigmine bromide*.
- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Neostigmine bromide | 22000195001 | 2 |
| Caelo | Neostigmine bromide | 12172301 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Neostigmine bromide | 12172304 | 1 |
| Caelo | Neostigmine bromide | 13177201 | 1 |
| Caelo | Neostigmine bromide | 13177203 | 2 |
| Caelo | Neostigmine bromide | 13177206 | 6 |
| Caelo | Neostigmine bromide | 131772303A | 1 |
| Caelo | Neostigmine bromide | 131772303B | 1 |
| Caelo | Neostigmine bromide | 14256802 | 3 |
| Caelo | Neostigmine bromide | 15228101 | 3 |
| Caelo | Neostigmine bromide | 15228103 | 2 |
| Caelo | Neostigmine bromide | 17131901 | 4 |
| Caelo | Neostigmine bromide | 17131903 | 5 |
| Caelo | Neostigmine bromide | 18024902 | 4 |
| Caelo | Neostigmine bromide | 193083001 | 3 |
| Caelo | Neostigmine bromide | 20003839001 | 1 |
| Gehe | Neostigmine bromide | 12172301 | 1 |
| Gehe | Neostigmine bromide | 12172307 | 1 |
| Gehe | Neostigmine bromide | 13177201 | 1 |
| Hetterich/Noewda | Neostigmine bromide | 17131901 | 1 |
| Sanacorp | Neostigmine bromide | 18024902 | 1 |

- 256 841 spectra from 1666 *Apo-Ident* customers from a total of 52 136 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Neostigmine bromide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Neostigmine bromide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 280 | 0 | 212 660 |
| **Type C** | 0 | 45 | 0 | 256 841 |

The substance/substance group *Neostigmine bromide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.8571 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 86.6667 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20717 | 20990 | 7.22 | 152.40 |
| 20990 | 20990 | 0.00 | 154.56 |
| 21816 | 21816 | 0.00 | 185.75 |
| 21919 | 21816 | 28.05 | 173.88 |
| 25390 | 20990 | 37.59 | 165.78 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Nicotinamide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20335-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Nicotinamide; Nicotinamidum

### Special notes

When selecting the *Nicotinamide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Nicotinamide | 9 | 15 | 58 |

### Second-stage model

For differentiation of the substance/substance group *Nicotinamide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Nicotinamide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 104.38 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Nicotinamide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Nicotinamide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Nicotinamide | 13097506 | 21364 | 40 | 20130416 |
| Caelo | Nicotinamide | 163048 | 23038 | 40 | 20161123* |
| Caelo | Nicotinamide | 163048 | 23050 | 40 | 20161123* |
| Euro OTC | Nicotinamide | 1310025-01 | 21643 | 60 | 20131121 |
| Euro OTC | Nicotinamide | 1511010 | 22251 | 60 | 20151203* |
| Euro OTC | Nicotinamide | 1601045 | 22374 | 60 | 20160210* |
| Euro OTC | Nicotinamide | 1610019 | 22874 | 40 | 20161202* |
| Euro OTC | Nicotinamide | 1906027 | 24799 | 40 | 20190712* |
| Euro OTC | Nicotinamide | 2009043 | 25407 | 40 | 20201012* |
| Euro OTC | Nicotinamide | 2203037 | 26096 | 40 | 20220428* |
| Euro OTC | Nicotinamide | 2203037 | 26096SI | 20 | 20220428* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 480 spectra of 11 reference samples from the substance/substance group *Nicotinamide*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 846 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 719 spectra of 18 reference samples from the substance/substance group *Nicotinamide*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Nicotinamide | 11001809 | 20647 | 40 |
| Caelo | Nicotinamide | 161136 | 22434 | 60 |
| Caelo | Nicotinamide | 173419 | 23785 | 40 |
| Caelo | Nicotinamide | 190842 | 24525 | 40 |
| Caelo | Nicotinamide | 21003053 | 25861 | 50 |
| Caelo | Nicotinamide | 23002220 | 26960 | 40 |
| Euro OTC | Nicotinamide | 1707001 | 23555 | 40 |
| Euro OTC | Nicotinamide | 1801039 | 23957 | 40 |
| Euro OTC | Nicotinamide | 1812019 | 24493 | 40 |
| Euro OTC | Nicotinamide | 2001008 | 25071 | 40 |
| Euro OTC | Nicotinamide | 2105019 | 25704 | 50 |
| Euro OTC | Nicotinamide | 2309010 | 26931 | 40 |
| Euro OTC | Nicotinamide | 2411001 | 27508 | 40 |
| Fagron | Nicotinamide | 23A09-B01-226166 | 26906 | 40 |
| Fagron | Nicotinamide | 25A17-B10-009377 | 27648 | 39 |
| Caelo | Nicotinamide | 161136 | 22625 | 40 |
| Euro OTC | Nicotinamide | 2309010 | 26931SI | 20 |
| Fagron | Nicotinamide | 23A09-B01-226166 | 26906SI | 20 |

- 212 221 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information

provided by the customer regarding manufacturer and batch number.

- 157 spectra from 87 *Apo-Ident* customers from 62 batches from the substance/substance group *Nicotinamide*.
- Among them are spectra of independent samples from 58 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Nicotinamide | 2203037-03 | 2 |
| | Nicotinamide | 23003447003 | 1 |
| | Nicotinamide | 23003447008 | 1 |
| | Nicotinamide | op12106006 | 1 |
| AHD | Nicotinamide | 2203037-03 | 1 |
| Caelo | Nicotinamide | 12133403 | 1 |
| Caelo | Nicotinamide | 12268302 | 1 |
| Caelo | Nicotinamide | 13097504 | 1 |
| Caelo | Nicotinamide | 13097506 | 1 |
| Caelo | Nicotinamide | 13352002 | 1 |
| Caelo | Nicotinamide | 14246806 | 1 |
| Caelo | Nicotinamide | 1511010-01 | 1 |
| Caelo | Nicotinamide | 1610019-01 | 1 |
| Caelo | Nicotinamide | 16113610 | 1 |
| Caelo | Nicotinamide | 16304803 | 1 |
| Caelo | Nicotinamide | 1707001-01 | 2 |
| Caelo | Nicotinamide | 17104108 | 2 |
| Caelo | Nicotinamide | 17341907 | 1 |
| Caelo | Nicotinamide | 1801039-01 | 1 |
| Caelo | Nicotinamide | 18214803 | 2 |
| Caelo | Nicotinamide | 20004516002 | 1 |
| Caelo | Nicotinamide | 2009043-01 | 1 |
| Caelo | Nicotinamide | 21000112003 | 2 |
| Caelo | Nicotinamide | 21000112006 | 1 |
| Caelo | Nicotinamide | OP117072026 | 1 |
| Caesar & Loretz GmbH | Nicotinamide | 20004516002 | 1 |
| DSM Nutritional Prod... | Nicotinamide | 1106044-01 | 1 |
| EuRho/Sanacorp | Nicotinamide | 2001008-02 | 1 |
| EuRho/Sanacorp | Nicotinamide | 2009043-01 | 1 |
| EuRho | Nicotinamide | 200100801 | 1 |
| EuRho | Nicotinamide | 2203037-03 | 1 |
| Euro OTC | Nicotinamide | | 1 |
| Euro OTC | Nicotinamide | 1108021-01 | 1 |
| Euro OTC | Nicotinamide | 11208021 | 1 |
| Euro OTC | Nicotinamide | 11401052 | 1 |
| Euro OTC | Nicotinamide | 1211031-02 | 5 |
| Euro OTC | Nicotinamide | 131002501 | 1 |
| Euro OTC | Nicotinamide | 1310025-01 | 4 |
| Euro OTC | Nicotinamide | 1408019-01 | 2 |
| Euro OTC | Nicotinamide | 1408019-19 | 1 |
| Euro OTC | Nicotinamide | 1503024-02 | 1 |
| Euro OTC | Nicotinamide | 1511010-01 | 5 |
| Euro OTC | Nicotinamide | 160104501 | 1 |
| Euro OTC | Nicotinamide | 1601045-01 | 5 |
| Euro OTC | Nicotinamide | 1610019-01 | 8 |
| Euro OTC | Nicotinamide | 1707001-01 | 12 |
| Euro OTC | Nicotinamide | 1801038-01 | 1 |
| Euro OTC | Nicotinamide | 1801039-01 | 10 |
| Euro OTC | Nicotinamide | 1906027-01 | 7 |
| Euro OTC | Nicotinamide | 1906027-01 | 1 |
| Euro OTC | Nicotinamide | 2001008-01 | 3 |
| Euro OTC | Nicotinamide | 2001008-02 | 4 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Nicotinamide | 200904301 | 1 |
| Euro OTC | Nicotinamide | 2009043-01 | 7 |
| Euro OTC | Nicotinamide | 2009043-02 | 3 |
| Euro OTC | Nicotinamide | 2105019-01 | 1 |
| Euro OTC | Nicotinamide | 2203037-01 | 2 |
| Euro OTC | Nicotinamide | 2203037-02 | 6 |
| Euro OTC | Nicotinamide | 2203037-03 | 1 |
| Euro OTC | Nicotinamide | 2309010-01 | 1 |
| Euro OTC | Nicotinamide | 2610019-01 | 1 |
| Euro OTC | Nicotinamide | OP11708013 | 2 |
| Euro OTC | Nicotinamide | OP12106006 | 1 |
| Fagron | Nicotinamide | 12J02-B03 | 1 |
| Fagron | Nicotinamide | 1801039-01 | 1 |
| Fagron | Nicotinamide | 20D06-F05-369981 | 1 |
| Fagron | Nicotinamide | 20F03-F04-371807 | 2 |
| Fagron | Nicotinamide | 21A14-F02 | 1 |
| Fagron | Nicotinamide | L14020084 | 1 |
| Gatt-Koller | Nicotinamide | 221406112411 | 1 |
| Gatt-Koller | Nicotinamide | 4456/10104110 | 1 |
| Gehe | Nicotinamide | 2001008-02 | 1 |
| Noweda | Nicotinamide | 12133403 | 2 |
| Noweda | Nicotinamide | 22002418006 | 1 |
| Noweda | Nicotinamide | 2309010-01 | 1 |
| Phoenix | Nicotinamide | 1211031-02 | 1 |
| Phoenix | Nicotinamide | 2001008-01 | 1 |
| Sanacorp | Nicotinamide | 2009043-01 | 1 |
| Sanacorp | Nicotinamide | 22002418003 | 1 |
| sanacorp | Nicotinamide | oP12106006 | 1 |
| VDL;16.04.15;5,60EUR | Nicotinamide | 1408019-01 | 1 |

- 256 729 spectra from 1666 *Apo-Ident* customers from a total of 52 094 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Nicotinamide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Nicotinamide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 719 | 0 | 212 221 |
| **Type C** | 0 | 157 | 0 | 256 729 |

The substance/substance group *Nicotinamide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.1655 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 96.1783 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21364 | 22251 | 7.00 | 276.76 |
| 21643 | 22251 | 4.29 | 276.39 |
| 22251 | 22251 | 0.00 | 275.95 |
| 22374 | 22374 | 0.00 | 274.57 |
| 22874 | 22874 | 0.00 | 274.16 |
| 23038 | 23038 | 0.00 | 275.24 |
| 23050 | 23050 | 0.00 | 275.35 |
| 24799 | 24799 | 0.00 | 276.93 |
| 25407 | 25407 | 0.00 | 278.40 |
| 26096 | 26096 | 0.00 | 277.85 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Nicotinic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20383-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Nicotinic acid; Acidum nicotinicum

### Special notes

When selecting the *Nicotinic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Nicotinic acid | 4 | 3 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Nicotinic acid* the following second-stage model is used:

- Submodel 12

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Nicotinic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Midazolam hydrochloride | 136.79 | – |
| ⋮ | ⋮ | ⋮ |
| Mesalazine | 139.37 | 23.56 |
| Clioquinol | >50 | 50.27 |
| Miconazole nitrate | >50 | 60.84 |
| Theophylline-ethylenediamine hydrate | >50 | 214.38 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Nicotinic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Nicotinic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Nicotinic acid | 1906026 | 24805 | 40 | 20190711* |
| Fagron | Nicotinic acid | 14E01-B09-293947 | 21692 | 60 | AR-15-FG-008938-01 |
| Fagron | Nicotinic acid | 16H19-B02-330121 | 23225 | 40 | AR-17-FG-016013-01 |
| Fagron | Nicotinic acid | 21C04-B03-215782 | 27042 | 40 | 20210514 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 180 spectra of 4 reference samples from the substance/substance group *Nicotinic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

- 158 146 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 5 reference samples from the substance/substance group *Nicotinic acid*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Nicotinic acid | 1801021 | 23954 | 40 |
| Fagron | Nicotinic acid | 18B15-B07-350570 | 24592 | 40 |
| Fagron | Nicotinic acid | 23A11-B03-229438 | 26819 | 40 |
| Fagron | Nicotinic acid | 23A11-B03-229438 | 26819SI | 20 |
| Fagron | Nicotinic acid | 21C04-B03-215782 | 27042SI† | 20 |

- 212 780 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4 spectra from 2 *Apo-Ident* customers from 3 batches from the substance/substance group *Nicotinic acid*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Nicotinic acid | 1801021-01 | 2 |
| Fagron | Nicotinic acid | L17120080 | 1 |
| gonmisol | Nicotinic acid | 17-18/NCN(P)/B/008 | 1 |

- 256 882 spectra from 1666 *Apo-Ident* customers from a total of 52 151 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Nicotinic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Nicotinic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 4 | 0 | 256 882 |

The substance/substance group *Nicotinic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21692 | 21692 | 0.00 | 174.23 |
| 23225 | 23225 | 0.00 | 170.77 |
| 24805 | 24805 | 0.00 | 179.46 |
| 27042 | 23225 | 7.05 | 170.55 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Nifedipine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10003587-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Nifedipine; Nifedipinum

### Special notes

When selecting the *Nifedipine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Nifedipine | 3 | 1 | 6 |

### Second-stage model

For differentiation of the substance/substance group *Nifedipine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Nifedipine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Caffeine citrate | 168.74 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Nifedipine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Nifedipine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Nifedipine | 21B18-F02-378364 | 26067 | 40 | 20210609 |
| Fagron | Nifedipine | 22G07-B03-218877 | 26469 | 40 | 230502385 |
| Fagron | Nifedipine | 22G07-B03-218877 | 26469SI | 20 | 230502385 |
| Fagron | Nifedipine | 23F29-B05-228724 | 26900 | 40 | 20220803 |
| Fagron | Nifedipine | 23F29-B05-228724 | 26900SI | 20 | 20220803 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 160 spectra of 5 reference samples from the substance/substance group *Nifedipine*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.
- 158 166 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 2 reference samples from the substance/substance group *Nifedipine*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Nifedipine | 18K19-B02-363428 | 25056 | 40 |
| Fagron | Nifedipine | 21B18-F02-378364 | 26067SI† | 20 |

- 212 880 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 10 spectra from 9 *Apo-Ident* customers from 8 batches from the substance/substance group *Nifedipine*.
- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Nifedipine | 21829-25-4 | 1 |
| | Nifedipine | 22G07-B03 | 1 |
| | Nifedipine | 22G07-B03-218877 | 1 |
| | Nifedipine | 23005NFD1RA | 1 |
| | Nifedipine | 23F29-B05-2287204 | 1 |
| | Nifedipine | 23F29-B05-229076 | 1 |
| Alliance | Nifedipine | 23F29-B05-228724 | 1 |
| Noweda | Nifedipine | 23F29-B05-228724 | 1 |
| Sanacorp | Nifedipine | 22G07-B03 | 1 |
| Sanacorp | Nifedipine | 22G07-B03-218877 | 1 |

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 256 876 spectra from 1666 *Apo-Ident* customers from a total of 52 145 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Nifedipine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Nifedipine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 160 | 0 | 158 166 |
| **Type B** | 0 | 60 | 0 | 212 880 |
| **Type C** | 0 | 10 | 0 | 256 876 |

The substance/substance group *Nifedipine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.2500 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26067 | 26469 | 32.13 | 313.24 |
| 26469 | 26469 | 0.00 | 316.28 |
| 26900 | 26469 | 9.97 | 314.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Nitrofurantoin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20698-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Nitrofurantoin; Nitrofurantoinum

### Special notes

When selecting the *Nitrofurantoin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Nitrofurantoin | 6 | 3 | 18 |

### Second-stage model

For differentiation of the substance/substance group *Nitrofurantoin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Nitrofurantoin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 140.74 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Nitrofurantoin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Nitrofurantoin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Nitrofurantoin | 12C30-N03 | 20698 | 40 | 1401461 |
| Fagron | Nitrofurantoin | 12C30-N03 | 20837 | 40 | 20120417 |
| Fagron | Nitrofurantoin | 13B28-N07 | 21091 | 40 | 20130304 |
| Fagron | Nitrofurantoin | 15J15-B06-315225 | 22257 | 60 | AR-16-FG-003763-01 |
| Fagron | Nitrofurantoin | 15J15-B06-315225 | 22322 | 60 | 20151028 |
| Fagron | Nitrofurantoin | 21J07-B11-219876 | 26410 | 40 | 230502391 |
| Fagron | Nitrofurantoin | 21J07-B11-219876 | 26410SI | 20 | 230502391 |
| Fagron | Nitrofurantoin | 22L02-B01-227369 | 26550 | 40 | 20221227 |
| Fagron | Nitrofurantoin | 22L02-B01-227369 | 26550SI | 20 | 20221227 |
| Fagron | Nitrofurantoin | 23E23-B06-232014 | 26901 | 40 | 20230630 |
| Fagron | Nitrofurantoin | 23E23-B06-232014 | 26901SI | 20 | 20230630 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.


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- 420 spectra of 11 reference samples from the substance/substance group *Nitrofurantoin*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 906 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 3 reference samples from the substance/substance group *Nitrofurantoin*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Nitrofurantoin | 11K-21-N23 | 20836 | 40 |
| Fagron | Nitrofurantoin | 11I07-N11 | 21273 | 40 |
| Fagron | Nitrofurantoin | 23E23-B07-236326 | 27189 | 40 |

- 212 820 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 35 spectra from 28 *Apo-Ident* customers from 23 batches from the substance/substance group *Nitrofurantoin*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Nitrofurantoin | 22102-b01-227369 | 1 |
| | Nitrofurantoin | 22L02-B01-227369 | 2 |
| | Nitrofurantoin | 22L02-B01-227369 | 1 |
| | Nitrofurantoin | 23E23-B07-008297 | 2 |
| | Nitrofurantoin | 23E23-B07-239932 | 2 |
| | Nitrofurantoin | B11-2198706 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Apotheke am Lindenhof | Nitrofurantoin | 15J15-B06 | 1 |
| Fagron | Nitrofurantoin | 11/07-N11 | 1 |
| Fagron | Nitrofurantoin | 11F07-N06 | 3 |
| Fagron | Nitrofurantoin | 12C30-N03 | 1 |
| Fagron | Nitrofurantoin | 12F19-N02 | 1 |
| Fagron | Nitrofurantoin | 13A08-N01 | 1 |
| Fagron | Nitrofurantoin | 13B28-N07 | 1 |
| Fagron | Nitrofurantoin | 13D10-N03 | 1 |
| Fagron | Nitrofurantoin | 15J15-B06 | 1 |
| Fagron | Nitrofurantoin | 15J15-B06-313939 | 3 |
| Fagron | Nitrofurantoin | 15J15-B06-315225 | 3 |
| Fagron | Nitrofurantoin | 15J15-B06-317250 | 3 |
| Fagron | Nitrofurantoin | 15J15-B06-319031 | 1 |
| Fagron | Nitrofurantoin | 201203080296 | 1 |
| Fagron | Nitrofurantoin | 23E23-B07-236326 | 1 |
| Fagron | Nitrofurantoin | 2714I-03527 | 1 |
| Fagron | Nitrofurantoin | 3071403 | 1 |
| Fagron | Nitrofurantoin | 71/14 | 1 |

- 256 851 spectra from 1666 *Apo-Ident* customers from a total of 52 130 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Nitrofurantoin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Nitrofurantoin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 34 | 1 | 256 851 |

The substance/substance group *Nitrofurantoin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.1429 % (> 88.5714 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20698 | 20698 | 0.00 | 257.10 |
| 20837 | 20698 | 5.67 | 256.54 |
| 21091 | 22257 | 37.82 | 229.96 |
| 22257 | 22257 | 0.00 | 247.85 |
| 22322 | 22257 | 4.51 | 249.41 |
| 26410 | 26410 | 0.00 | 286.16 |
| 26550 | 26410 | 11.93 | 285.65 |
| 26901 | 26410 | 13.08 | 285.93 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Non-ionic emulsifying alcohol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20467-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Non-ionic emulsifying alcohol; Alcoholes emulsificantes nonionici

### Special notes

When selecting the *Non-ionic emulsifying alcohol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Non-ionic emulsifying alcohol | 9 | 4 | 26 |

### Second-stage model

For differentiation of the substance/substance group *Non-ionic emulsifying alcohol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Non-ionic emulsifying alcohol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cetomacrogol emulsifying wax 1000 NI | 22.41 | – |
| Emulsifying cetostearyl alcohol (type A) | 22.63 | – |
| Glycerol monostearate, emulsifying | 43.96 | – |
| Cetostearyl alcohol | 47.83 | – |
| Glycerol monostearate 60 | 65.77 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Non-ionic emulsifying alcohol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Non-ionic emulsifying alcohol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| apomix | Non-ionic emulsifying alcohol | NS-8350010216 | 23274 | 40 | 20160718 |
| apomix | Non-ionic emulsifying alcohol | NS-8350010618 | 24695 | 40 | 20180925 |
| apomix | Non-ionic emulsifying alcohol | NS-8350010419 | 25391 | 40 | 20190527 |
| apomix | Non-ionic emulsifying alcohol | NS-8350010720 | 26585 | 40 | 20220722 |
| apomix | Non-ionic emulsifying alcohol | NS-8350010720 | 26585SI | 20 | 20220722 |
| Bombastus | Non-ionic emulsifying alcohol | 19001210 | 24644 | 40 | 20190221 |
| Bombastus | Non-ionic emulsifying alcohol | 19001210 | 24664 | 40 | 20190221 |
| Caelo | Non-ionic emulsifying alcohol | 13413001 | 21069 | 40 | 1405257 |
| Caelo | Non-ionic emulsifying alcohol | 13413001 | 21524 | 40 | 20140116 |
| Caelo | Non-ionic emulsifying alcohol | 182021 | 24282 | 40 | 20180725* |
| Caelo | Non-ionic emulsifying alcohol | 20002375001 | 25511 | 40 | 20200731 |
| Caelo | Non-ionic emulsifying alcohol | 21001521 | 25695 | 50 | 20210518* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 470 spectra of 12 reference samples from the substance/substance group *Non-ionic emulsifying alcohol*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 856 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 7 reference samples from the substance/substance group *Non-ionic emulsifying alcohol*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Non-ionic emulsifying alcohol | 162231 | 22745 | 40 |
| Caelo | Non-ionic emulsifying alcohol | 171836 | 23576 | 40 |
| Caelo | Non-ionic emulsifying alcohol | 22003308004 | 26735 | 40 |
| Caelo | Non-ionic emulsifying alcohol | 24000497003 | 27586 | 40 |
| apomix | Non-ionic emulsifying alcohol | NS-8350010720 | 25864 | 50 |
| apomix | Non-ionic emulsifying alcohol | NS-8350010720 | 25864SI | 10 |
| Caelo | Non-ionic emulsifying alcohol | 22003308004 | 26735SI | 20 |

- 212 700 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 70 spectra from 32 *Apo-Ident* customers from 29 batches from the substance/substance group *Non-ionic emulsifying alcohol*.

- Among them are spectra of independent samples from 26 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Non-ionic emulsifying alcohol | 22003308002 | 2 |
| | Non-ionic emulsifying alcohol | 24000497002 | 1 |
| | Non-ionic emulsifying alcohol | NS-8350010720 | 1 |
| Bombastus | Non-ionic emulsifying alcohol | 18005087P-190119-2 | 1 |
| Bombastus | Non-ionic emulsifying alcohol | 18005087P-190315-2 | 1 |
| Bombastus | Non-ionic emulsifying alcohol | 19001210 | 2 |
| Bombastus | Non-ionic emulsifying alcohol | 267575 | 2 |
| Bombastus | Non-ionic emulsifying alcohol | 274059 | 1 |
| Bombastus | Non-ionic emulsifying alcohol | 278281 | 2 |
| Bombastus | Non-ionic emulsifying alcohol | 284009 | 2 |
| Bombastus | Non-ionic emulsifying alcohol | 292319 | 8 |
| Bombastus | Non-ionic emulsifying alcohol | 295568 | 6 |
| Bombastus | Non-ionic emulsifying alcohol | 2995568 | 1 |
| Bombastus | Non-ionic emulsifying alcohol | 304997 | 5 |
| Bombastus | Non-ionic emulsifying alcohol | 3066 | 1 |
| Bombastus | Non-ionic emulsifying alcohol | 306665 | 1 |
| Bombastus | Non-ionic emulsifying alcohol | 306666 | 8 |
| Bombastus | Non-ionic emulsifying alcohol | 311625 | 2 |
| Caelo | Non-ionic emulsifying alcohol | 12254402 | 1 |
| Caelo | Non-ionic emulsifying alcohol | 14241503 | 1 |
| Caelo | Non-ionic emulsifying alcohol | 15287902 | 3 |
| Caelo | Non-ionic emulsifying alcohol | 18202102 | 1 |
| Caelo | Non-ionic emulsifying alcohol | 19045201 | 1 |
| Caelo | Non-ionic emulsifying alcohol | 20002375001 | 4 |
| Caelo | Non-ionic emulsifying alcohol | 20002375003 | 2 |
| Caelo | Non-ionic emulsifying alcohol | 2002375001 | 1 |
| Caelo | Non-ionic emulsifying alcohol | 21091302 | 1 |
| Caelo | Non-ionic emulsifying alcohol | 311625 | 1 |
| Caesar & Loretz GmbH | Non-ionic emulsifying alcohol | 18202102 | 1 |
| E Plus | Non-ionic emulsifying alcohol | 17043701 | 1 |
| Euro OTC | Non-ionic emulsifying alcohol | 278281 | 2 |
| L11 | Non-ionic emulsifying alcohol | 17043701 | 1 |
| L31 | Non-ionic emulsifying alcohol | 16223104 | 1 |
| Phönix | Non-ionic emulsifying alcohol | 274059 | 1 |

- 256 816 spectra from 1666 *Apo-Ident* customers from a total of 52 125 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Non-ionic emulsifying alcohol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Non-ionic emulsifying alcohol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 470 | 0 | 157 856 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 70 | 0 | 256 816 |


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The substance/substance group *Non-ionic emulsifying alcohol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7234 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 91.4286 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21069 | 21069 | 0.00 | 45.90 |
| 21524 | 25695 | 10.90 | 37.71 |
| 23274 | 25695 | 13.49 | 46.26 |
| 24282 | 24282 | 0.00 | 54.02 |
| 24644 | 24282 | 12.38 | 47.72 |
| 24664 | 24282 | 12.50 | 52.24 |
| 24695 | 25695 | 7.56 | 44.48 |
| 25391 | 21069 | 17.88 | 31.37 |
| 25511 | 24282 | 26.92 | 59.92 |
| 25695 | 25695 | 0.00 | 48.39 |
| 26585 | 25695 | 17.28 | 37.73 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Norethisterone acetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20797-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Norethisterone acetate; Norethisteroni acetas

### Special notes

When selecting the *Norethisterone acetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Norethisterone acetate | 7 | 3 | 50 |

### Second-stage model

For differentiation of the substance/substance group *Norethisterone acetate* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Norethisterone acetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 116.00 | – |
| ⋮ | ⋮ | ⋮ |
| Prednicarbate | >50 | 90.37 |
| Capsaicin | >50 | 101.94 |
| Oxybutynin hydrochloride | >50 | 164.71 |
| Alfatradiol | >50 | 239.55 |
| Sodium citrate | >50 | 256.59 |
| Levocarnitine | >50 | 263.99 |
| Tetracaine | >50 | 267.26 |
| Cyproterone acetate | >50 | 323.63 |
| Amitriptyline hydrochloride | >50 | 532.42 |
| Pyridoxal-5-phosphate hydrate | >50 | 592.50 |
| Heparin sodium | >50 | 641.34 |
| Valine | >50 | 650.26 |
| Quinine hydrochloride dihydrate | >50 | 722.12 |
| Methoxsalen | >50 | 780.61 |
| Ciprofloxacin hydrochloride | >50 | 1058.79 |
| Amifampridine | >50 | 2049.32 |
| Sucrose | >50 | 2301.51 |
| Triclosan | >50 | 2385.04 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Norethisterone acetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Norethisterone acetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Norethisterone acetate | 15417004 | 23122 | 40 | 1711489 |
| Caelo | Norethisterone acetate | 182252 | 24395 | 40 | 20181031* |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Norethisterone acetate | 1306033-01 | 21627 | 60 | 1511684 |
| Euro OTC | Norethisterone acetate | 2401002 | 27151 | 40 | 20240321* |
| Euro OTC | Norethisterone acetate | 2401002 | 27151SI | 30 | 20240321* |
| Fagron | Norethisterone acetate | 12L14-N03 | 20797 | 40 | 1401558 |
| Fagron | Norethisterone acetate | 17B21-B01-341608 | 23918 | 40 | 20170619 |
| Fagron | Norethisterone acetate | 19I30-F02-366139 | 25364 | 40 | 20191127 |
| Fagron | Norethisterone acetate | 19I30-F02-366139 | 25364SI | 20 | 20191127 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 350 spectra of 9 reference samples from the substance/substance group *Norethisterone acetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 976 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 170 spectra of 5 reference samples from the substance/substance group *Norethisterone acetate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Norethisterone acetate | 2106015 | 25771 | 40 |
| Fagron | Norethisterone acetate | 14H29-B03-325225 | 23171 | 40 |
| Fagron | Norethisterone acetate | 23H08-B10-227915 | 27025 | 40 |
| Euro OTC | Norethisterone acetate | 2106015 | 25771SI | 20 |
| Fagron | Norethisterone acetate | 23H08-B10-227915 | 27025SI | 30 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 770 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 65 spectra from 37 *Apo-Ident* customers from 55 batches from the substance/substance group *Norethisterone acetate*.

- Among them are spectra of independent samples from 49 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Norethisterone acetate | 23H08-B10-239942 | 1 |
| Bombastus | Norethisterone acetate | 13J08-N04 | 1 |
| Caelo | Norethisterone acetate | 15417001 | 1 |
| Caelo | Norethisterone acetate | 15417008 | 1 |
| Caelo | Norethisterone acetate | 16081814 | 1 |
| Caelo | Norethisterone acetate | 17B21-B01-335383 | 1 |
| Euro OTC | Norethisterone acetate | 1306033-02 | 2 |
| Euro/Phönix | Norethisterone acetate | 1306033-01 | 1 |
| Fagron | Norethisterone acetate | | 1 |
| Fagron | Norethisterone acetate | 12C06-N10 | 2 |
| Fagron | Norethisterone acetate | 13D19-N06 | 1 |
| Fagron | Norethisterone acetate | 13J08-N04 | 1 |
| Fagron | Norethisterone acetate | 14d08-b01-292736 | 1 |
| Fagron | Norethisterone acetate | 14D08-B01-292738 | 1 |
| Fagron | Norethisterone acetate | 14H29-B03 | 1 |
| Fagron | Norethisterone acetate | 14H29-B03-299313 | 1 |
| Fagron | Norethisterone acetate | 14H29-B03-302277 | 2 |
| Fagron | Norethisterone acetate | 14h29-b03-310697 | 1 |
| Fagron | Norethisterone acetate | 14H29-B03-321322 | 1 |
| Fagron | Norethisterone acetate | 14H29-B03-325224 | 1 |
| Fagron | Norethisterone acetate | 17B21-B01 | 1 |
| Fagron | Norethisterone acetate | 17B21-B01-335384 | 1 |
| Fagron | Norethisterone acetate | 17B21-B01-341607 | 2 |
| Fagron | Norethisterone acetate | 17B21-B01-341608 | 1 |
| Fagron | Norethisterone acetate | 17B21-B01-344250 | 1 |
| Fagron | Norethisterone acetate | 18C12-B03-347998 | 1 |
| Fagron | Norethisterone acetate | 18C12-B03-349111 | 1 |
| Fagron | Norethisterone acetate | 18C12-B03-349157 | 2 |
| Fagron | Norethisterone acetate | 18C12-B03-353056 | 1 |
| Fagron | Norethisterone acetate | 18C12-B03-354813 | 1 |
| Fagron | Norethisterone acetate | 18C12-B03-354815 | 2 |
| Fagron | Norethisterone acetate | 18L14-B05 | 2 |
| Fagron | Norethisterone acetate | 18L14-B05-358972 | 1 |
| Fagron | Norethisterone acetate | 18L14-B05-358976 | 1 |
| Fagron | Norethisterone acetate | 18L14-B05-358977 | 1 |
| Fagron | Norethisterone acetate | 19/30-F02-366134 | 1 |
| Fagron | Norethisterone acetate | 19130-F02-373337 | 1 |
| Fagron | Norethisterone acetate | 19I30-F02-366134 | 1 |
| Fagron | Norethisterone acetate | 19I30-F02-366136 | 1 |
| Fagron | Norethisterone acetate | 19I30-f02-366139 | 1 |
| Fagron | Norethisterone acetate | 19I30-F02-366139 | 1 |
| Fagron | Norethisterone acetate | 19I30-F02-3688303 | 1 |
| Fagron | Norethisterone acetate | 21g12-b02-213688 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Norethisterone acetate | 21G12-B02-213688 | 1 |
| Fagron | Norethisterone acetate | 21G12-B02-213691 | 2 |
| Fagron | Norethisterone acetate | 21G12-B02 | 1 |
| Fagron | Norethisterone acetate | 22061206 | 1 |
| Fagron | Norethisterone acetate | 23071509 | 1 |
| Fagron | Norethisterone acetate | F02-3661309 | 1 |
| Fagron | Norethisterone acetate | F02-3733307 | 2 |
| Gehe | Norethisterone acetate | 14H29-B03-321324 | 1 |
| Gehe | Norethisterone acetate | 15417011 | 1 |
| GEHE | Norethisterone acetate | 18L-14B05 | 1 |
| Phoenix | Norethisterone acetate | 17B21B01335384 | 1 |
| Phönix | Norethisterone acetate | 14H29-B03-315702 | 1 |
| Phönix | Norethisterone acetate | F02-3661305 | 1 |

- 256 821 spectra from 1666 *Apo-Ident* customers from a total of 52 098 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Norethisterone acetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Norethisterone acetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 350 | 0 | 157 976 |
| **Type B** | 0 | 170 | 0 | 212 770 |
| **Type C** | 0 | 63 | 2 | 256 821 |

The substance/substance group *Norethisterone acetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2857 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.4706 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 96.9231 % (> 92.3077 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested

reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20797 | 20797 | 0.00 | 146.17 |
| 21627 | 21627 | 0.00 | 140.38 |
| 23122 | 23122 | 0.00 | 143.14 |
| 23918 | 24395 | 3.86 | 147.34 |
| 24395 | 24395 | 0.00 | 147.67 |
| 25364 | 24395 | 4.52 | 147.98 |
| 27151 | 27151 | 0.00 | 138.66 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Noscapine hydrochloride hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006312-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Noscapine hydrochloride hydrate; Noscapini hydrochloridum hydricum

### Special notes

When selecting the *Noscapine hydrochloride hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Noscapine hydrochloride hydrate | 3 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Noscapine hydrochloride hydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Noscapine hydrochloride hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Methacholine chloride | 115.58 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Noscapine hydrochloride hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Noscapine hydrochloride hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Noscapine hydrochloride h… | 23F20-B11-231036 | 26899 | 40 | 240603357 |
| Fagron | Noscapine hydrochloride h… | 24C23-B04-235324 | 27379 | 40 | 20240426 |
| Gatt-Koller | Noscapine hydrochloride h… | 23J00299 | 26675 | 35 | 240401847 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 115 spectra of 3 reference samples from the substance/substance group *Noscapine hydrochloride hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.
- 158 211 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 100 spectra of 4 reference samples from the substance/substance group *Noscapine hydrochloride hydrate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Gatt-Koller | Noscapine hydrochloride h... | 22J02175 | 26676 | 40 |
| Fagron | Noscapine hydrochloride h... | 23F20-B11-231036 | 26899SI† | 20 |
| Gatt-Koller | Noscapine hydrochloride h... | 23J00299 | 26675SI† | 20 |
| Gatt-Koller | Noscapine hydrochloride h... | 22J02175 | 26676SI | 20 |

- 212 840 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Noscapine hydrochloride hydrate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Noscapine hydrochloride hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Noscapine hydrochloride hydrate* and it was evaluated how many matches (positive) and rejections (negative) were

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 115 | 0 | 158 211 |
| **Type B** | 0 | 100 | 0 | 212 840 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Noscapine hydrochloride hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 94.7826 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 94.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26675 | 26675 | 0.00 | 204.77 |
| 26899 | 26899 | 0.00 | 185.71 |
| 27379 | 26899 | 76.64 | 198.19 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Nystatin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20116-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Nystatin; Nystatinum

### Special notes

When selecting the *Nystatin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Nystatin | 12 | 10 | 267 |

### Second-stage model

For differentiation of the substance/substance group *Nystatin* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Nystatin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 42.10 | – |
| Cannabis flower, THC-dominant type | 45.65 | – |
| Polymyxin B sulfate | 54.58 | 29.13 |
| ⋮ | ⋮ | ⋮ |
| Bacitracin | >50 | 16.62 |
| Amphotericin B | >50 | 21.36 |
| alpha-tocopheryl acetate dry concentrate | >50 | 31.84 |
| Colistin sulfate | >50 | 35.82 |
| Cyanocobalamin | >50 | 39.38 |
| Riboflavin | >50 | 52.27 |
| Calcium glycerophosphate | >50 | 55.78 |
| Estradiol hemihydrate | >50 | 64.38 |
| Estriol | >50 | 77.60 |
| Triamcinolone | >50 | 88.82 |
| Calcium pantothenate | >50 | 95.69 |
| Carmellose sodium | >50 | 101.17 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 110.18 |
| Gelatine, white | >50 | 122.01 |
| SyrSpend® SF Alka | >50 | 131.80 |
| Methylcobalamin | >50 | 146.51 |
| Hyoscine hydrobromide | >50 | 153.20 |
| Tosylchloramide sodium | >50 | 156.49 |
| Rice starch | >50 | 167.53 |
| Corn starch | >50 | 210.40 |
| Oxalic acid | >50 | 241.80 |
| SyrSpend® SF pH4 | >50 | 287.58 |
| Acacia, dried dispersion | >50 | 317.36 |
| Wheat starch | >50 | 326.95 |
| Maltodextrin | >50 | 334.71 |
| Potato starch | >50 | 345.57 |
| Fructose | >50 | 514.53 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Nystatin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Nystatin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Nystatin | AP4018717N | 23985 | 40 | 20160307 |
| Caelo | Nystatin | 16272214 | 23711 | 40 | 20160929 |
| Caelo | Nystatin | 17025110 | 23984 | 40 | 20170308 |
| Caelo | Nystatin | 21004088001 | 26305 | 30 | 20220201 |
| Caelo | Nystatin | 21004088001 | 26305SI | 20 | 20220201 |
| Euro OTC | Nystatin | 1712010-01 | 24103 | 40 | 1807445 |
| Euro OTC | Nystatin | 1905014 | 24780 | 40 | 20190709* |
| Euro OTC | Nystatin | 2006026 | 25354 | 40 | 20200907* |
| Euro OTC | Nystatin | 2111001 | 25879 | 50 | 20211210* |
| Euro OTC | Nystatin | 2301016 | 26595 | 40 | 20230214* |
| Euro OTC | Nystatin | 2301016 | 26595SI | 20 | 20230214* |
| Fagron | Nystatin | 19B28-B05-191210 | 24645 | 40 | 20190316 |
| Fagron | Nystatin | 19H08-B04-200385 | 25722 | 50 | 20190823 |
| Fagron | Nystatin | 22A18-B07-218934 | 26381 | 40 | 20220325 |
| Fagron | Nystatin | 22A18-B07-218934 | 26381SI | 20 | 20220325 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 550 spectra of 15 reference samples from the substance/substance group *Nystatin*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.
- 157 776 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 410 spectra of 11 reference samples from the substance/substance group *Nystatin*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Nystatin | 20000969005 | 25435 | 40 |
| Caelo | Nystatin | 23001392 | 26843 | 40 |
| Caelo | Nystatin | 24000661 | 27326 | 40 |
| Caelo | Nystatin | 24002366 | 27550 | 40 |
| Euro OTC | Nystatin | 1612001-03 | 23727 | 40 |
| Euro OTC | Nystatin | 2310010 | 27005 | 40 |
| Euro OTC | Nystatin | 2410014 | 27495 | 40 |
| Fagron | Nystatin | 16L21-B01-338864 | 23712 | 40 |
| Fagron | Nystatin | 22I27-B12-225522 | 26460 | 40 |
| Fagron | Nystatin | 24F20-B11-006849 | 27600 | 40 |
| Euro OTC | Nystatin | 2111001 | 25879SI[†] | 10 |

- 212 530 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2206 spectra from 860 *Apo-Ident* customers from 275 batches from the substance/substance group *Nystatin*.

- Among them are spectra of independent samples from 265 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Nystatin | | 2 |
| | Nystatin | 2006026-02 | 1 |
| | Nystatin | 21004088001 | 3 |
| | Nystatin | 21004088004 | 1 |
| | Nystatin | 21004088006 | 1 |
| | Nystatin | 211100-02 | 1 |
| | Nystatin | 2111001-02 | 2 |
| | Nystatin | 2111001-03 | 5 |
| | Nystatin | 21H13-B01-217016 | 1 |
| | Nystatin | 220002863006 | 1 |
| | Nystatin | 22002863002 | 1 |
| | Nystatin | 22002863006 | 7 |
| | Nystatin | 22002863011 | 8 |
| | Nystatin | 230000218004 | 1 |
| | Nystatin | 23000218004 | 18 |
| | Nystatin | 23000218005 | 9 |
| | Nystatin | 23000218006 | 31 |
| | Nystatin | 23000218007 | 6 |
| | Nystatin | 23001392004 | 3 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Nystatin | 23001392005 | 5 |
| | Nystatin | 23001392006 | 3 |
| | Nystatin | 2300218004 | 1 |
| | Nystatin | 230101601 | 1 |
| | Nystatin | 2301016-01 | 63 |
| | Nystatin | 2301016-02 | 2 |
| | Nystatin | 2310010-0 | 1 |
| | Nystatin | 2310010-01 | 47 |
| | Nystatin | 23164042 | 1 |
| | Nystatin | 24000661003 | 9 |
| | Nystatin | 24000661004 | 28 |
| | Nystatin | 24000661005 | 7 |
| | Nystatin | 2400066104 | 1 |
| | Nystatin | 26001021A | 1 |
| | Nystatin | 30800923 | 1 |
| | Nystatin | 3210010-01 | 1 |
| | Nystatin | 37401222 | 2 |
| 1712010-02 | Nystatin | 2164071 | 1 |
| AHC | Nystatin | 2301016-01 | 1 |
| AHD/Euro | Nystatin | 1712010-01 | 1 |
| AHD | Nystatin | 1612001-01 | 1 |
| AHD | Nystatin | 18072114 | 1 |
| AHD | Nystatin | 23000218005 | 1 |
| AHD | Nystatin | 23001392004 | 1 |
| Alliance Healthcare | Nystatin | 1905014-03 | 1 |
| Alliance Healthcare | Nystatin | 2006026-01 | 1 |
| Alliance Healthcare | Nystatin | 2006026-02 | 3 |
| Alliance Healthcare | Nystatin | 23000218005 | 1 |
| Alliance Healthcare | Nystatin | 23001392004 | 1 |
| Alliance Healthcare | Nystatin | 2310010-01 | 1 |
| Alliance/EurRho | Nystatin | 2006026-0231 | 1 |
| Alliance | Nystatin | 2111001-02 | 1 |
| Alliance | Nystatin | 2301016-01 | 1 |
| Antibiotice SA Iasi/ AHD | Nystatin | 1712010-01 | 1 |
| Antibiotice/Phoenix | Nystatin | 4019851 | 3 |
| Antibiotice | Nystatin | 1712010-01 | 2 |
| Anzag | Nystatin | 1712010-01 | 1 |
| Anzag | Nystatin | 2301016-01 | 1 |
| Anzag | Nystatin | 2310010-01 | 1 |
| Anzag | Nystatin | 24000661004 | 1 |
| Anzag | Nystatin | 2902041-02 | 1 |
| Apo Ident | Nystatin | 2006026-01 | 1 |
| Apo Ident | Nystatin | 800219 | 1 |
| apo | Nystatin | 2006026-02 | 2 |
| ApoHo 20.6.17 | Nystatin | 1722 | 1 |
| apoident/AHD | Nystatin | 1905014-01 | 3 |
| apo-ident/Alliance | Nystatin | 2006026-01 | 1 |
| apo-ident/Phoenix | Nystatin | 191220111 | 1 |
| Apo-ident | Nystatin | 1905014-02 | 1 |
| apomix | Nystatin | 2006026-01 | 1 |
| apomix | Nystatin | 2111001-02 | 1 |
| apotec / AHD | Nystatin | 1905014-01 | 1 |
| apotec | Nystatin | 1905014-01 | 1 |
| Bombastus | Nystatin | 1212024-01 | 1 |
| Caeasar & Loretz GmbH | Nystatin | 21000074004 | 2 |
| Caele/Sanacorp | Nystatin | 18072108 | 1 |
| Caelo | Nystatin | 1(18072128) | 1 |
| Caelo | Nystatin | 103034004 | 1 |
| Caelo | Nystatin | 11069704 | 1 |
| Caelo | Nystatin | 11069706 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Nystatin | 11069716 | 1 |
| Caelo | Nystatin | 11069719 | 1 |
| Caelo | Nystatin | 11069730 | 1 |
| Caelo | Nystatin | 11069731 | 1 |
| Caelo | Nystatin | 1107046-01 | 1 |
| Caelo | Nystatin | 11071894 | 1 |
| Caelo | Nystatin | 12017003 | 1 |
| Caelo | Nystatin | 12017004 | 4 |
| Caelo | Nystatin | 12017009 | 1 |
| Caelo | Nystatin | 12017010 | 1 |
| Caelo | Nystatin | 12017011 | 3 |
| Caelo | Nystatin | 12017015 | 2 |
| Caelo | Nystatin | 12138021 | 2 |
| Caelo | Nystatin | 12158004 | 3 |
| Caelo | Nystatin | 12158005 | 1 |
| Caelo | Nystatin | 12158006 | 7 |
| Caelo | Nystatin | 12158008 | 3 |
| Caelo | Nystatin | 12158009 | 1 |
| Caelo | Nystatin | 12158010 | 4 |
| Caelo | Nystatin | 12158019 | 3 |
| Caelo | Nystatin | 12158020 | 1 |
| Caelo | Nystatin | 12158021 | 2 |
| Caelo | Nystatin | 12158022 | 1 |
| Caelo | Nystatin | 121580921 | 1 |
| Caelo | Nystatin | 12158oo4 | 1 |
| Caelo | Nystatin | 13101201 | 1 |
| Caelo | Nystatin | 13101202 | 1 |
| Caelo | Nystatin | 13173401 | 8 |
| Caelo | Nystatin | 13173408 | 1 |
| Caelo | Nystatin | 14363514 | 1 |
| Caelo | Nystatin | 15335310 | 1 |
| Caelo | Nystatin | 1612001 | 1 |
| Caelo | Nystatin | 1612001-03 | 1 |
| Caelo | Nystatin | 16272203 | 2 |
| Caelo | Nystatin | 16L21-B01-338876 | 1 |
| Caelo | Nystatin | 1712010-01 | 8 |
| Caelo | Nystatin | 17400520 | 1 |
| Caelo | Nystatin | 18072014 | 1 |
| Caelo | Nystatin | 18072104 | 2 |
| Caelo | Nystatin | 18072105 | 6 |
| Caelo | Nystatin | 18072107 | 1 |
| Caelo | Nystatin | 18072108 | 8 |
| Caelo | Nystatin | 18072109 | 11 |
| Caelo | Nystatin | 18072112 | 4 |
| Caelo | Nystatin | 18072113 | 28 |
| Caelo | Nystatin | 18072114 | 18 |
| Caelo | Nystatin | 18072118 | 2 |
| Caelo | Nystatin | 18072120 | 9 |
| Caelo | Nystatin | 18072121 | 8 |
| Caelo | Nystatin | 18072123 | 18 |
| Caelo | Nystatin | 18072124 | 13 |
| Caelo | Nystatin | 18072126 | 2 |
| Caelo | Nystatin | 18072128 | 5 |
| Caelo | Nystatin | 18072128P-190709-1 | 1 |
| Caelo | Nystatin | 18072129 | 4 |
| Caelo | Nystatin | 1807213 | 2 |
| Caelo | Nystatin | 183034004 | 1 |
| Caelo | Nystatin | 19026806 | 1 |
| Caelo | Nystatin | 19028801 | 27 |
| Caelo | Nystatin | 19028803 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Nystatin | 19028805 | 1 |
| Caelo | Nystatin | 19028806 | 19 |
| Caelo | Nystatin | 19028808 | 15 |
| Caelo | Nystatin | 19028809 | 29 |
| Caelo | Nystatin | 1902881 | 1 |
| Caelo | Nystatin | 19028810 | 1 |
| Caelo | Nystatin | 19028811 | 1 |
| Caelo | Nystatin | 19028813 | 17 |
| Caelo | Nystatin | 1903034005 | 1 |
| Caelo | Nystatin | 19034004 | 1 |
| Caelo | Nystatin | 1905014-02 | 1 |
| Caelo | Nystatin | 19058809 | 1 |
| Caelo | Nystatin | 19303034009 | 1 |
| Caelo | Nystatin | 193034003 | 15 |
| Caelo | Nystatin | 193034004 | 21 |
| Caelo | Nystatin | 193034005 | 3 |
| Caelo | Nystatin | 193034009 | 15 |
| Caelo | Nystatin | 19304004 | 1 |
| Caelo | Nystatin | 19B28-B06-196732 | 1 |
| Caelo | Nystatin | 20000096006 | 1 |
| Caelo | Nystatin | 2000096006 | 1 |
| Caelo | Nystatin | 20000969002 | 4 |
| Caelo | Nystatin | 20000969005 | 27 |
| Caelo | Nystatin | 20000969006 | 14 |
| Caelo | Nystatin | 2000096902 | 1 |
| Caelo | Nystatin | 20002487001 | 1 |
| Caelo | Nystatin | 20002487004 | 1 |
| Caelo | Nystatin | 20004452001 | 3 |
| Caelo | Nystatin | 20004452002 | 15 |
| Caelo | Nystatin | 20004452003 | 20 |
| Caelo | Nystatin | 2000969005 | 1 |
| Caelo | Nystatin | 2006026-02 | 2 |
| Caelo | Nystatin | 2006026-023 | 1 |
| Caelo | Nystatin | 2091304 | 1 |
| Caelo | Nystatin | 210000740004 | 1 |
| Caelo | Nystatin | 21000074001 | 1 |
| Caelo | Nystatin | 21000074003 | 2 |
| Caelo | Nystatin | 21000074004 | 30 |
| Caelo | Nystatin | 21000074005 | 21 |
| Caelo | Nystatin | 21000074008 | 1 |
| Caelo | Nystatin | 2100074004 | 1 |
| Caelo | Nystatin | 2100074005 | 1 |
| Caelo | Nystatin | 210021650009 | 1 |
| Caelo | Nystatin | 21002165001 | 15 |
| Caelo | Nystatin | 21002165002 | 4 |
| Caelo | Nystatin | 21002165003 | 14 |
| Caelo | Nystatin | 21002165006 | 1 |
| Caelo | Nystatin | 21002165007 | 18 |
| Caelo | Nystatin | 21002165009 | 10 |
| Caelo | Nystatin | 21004088001 | 17 |
| Caelo | Nystatin | 21004088004 | 5 |
| Caelo | Nystatin | 21004088006 | 8 |
| Caelo | Nystatin | 21004088008 | 4 |
| Caelo | Nystatin | 2111001-03 | 1 |
| Caelo | Nystatin | 22002863002 | 1 |
| Caelo | Nystatin | 22002863006 | 1 |
| Caelo | Nystatin | 22002863010 | 1 |
| Caelo | Nystatin | 2202863011 | 1 |
| Caelo | Nystatin | 23000218005 | 1 |
| Caelo | Nystatin | 23000218006 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Nystatin | 2301016-01 | 2 |
| Caelo | Nystatin | 3101201 | 1 |
| Caelo | Nystatin | 3338 | 1 |
| Caelo | Nystatin | 4010914 | 1 |
| Caelo | Nystatin | 485870081652 | 1 |
| Caelo | Nystatin | 6082013B | 1 |
| Caelo | Nystatin | 81072113 | 1 |
| Caelo | Nystatin | 930340031 | 1 |
| Caelo | Nystatin | C129330 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 18072124 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 1712010-01 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028810 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21004088006 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 20000969005 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21000074004 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 22002863006 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 18072128 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028809 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028809 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21000074005 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028813 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21000074004 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21002165002 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 22002863011 | 1 |
| Caesar & Loretz GmbH/AEP | Nystatin | 23000218004 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028809 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21000074004 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 20004452003 | 1 |
| Caesar & Loretz GmbH/Gehe | Nystatin | 193034004 | 2 |
| Caesar & Loretz GmbH/Gehe | Nystatin | 20000969005 | 2 |
| Caesar & Loretz GmbH/Gehe | Nystatin | 20004452002 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 20004452001 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028808 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21002165001 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21002165001 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 193034009 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21000074004 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 24000661005 | 1 |
| Caesar & Loretz GmbH/K | Nystatin | 19028810 | 1 |
| Caesar & Loretz GmbH/K | Nystatin | 21004088001 | 1 |
| Caesar & Loretz GmbH/kehr | Nystatin | 19028813 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028813 | 3 |
| Caesar & Loretz GmbH... | Nystatin | 193034009 | 2 |
| Caesar & Loretz GmbH/N | Nystatin | 22002863011 | 2 |
| Caesar & Loretz GmbH... | Nystatin | 19028808 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 193034009 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 2006026-01 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21002165003 | 2 |
| Caesar & Loretz GmbH... | Nystatin | 21002165009 | 2 |
| Caesar & Loretz GmbH... | Nystatin | 20000969005 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21004088001 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21004088006 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 20000969006 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 210000745005 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21004088001 | 1 |
| Caesar & Loretz GmbH/Sa | Nystatin | 19028806 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 19028801 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 193034003 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 193034004 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 20000969006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Nystatin | 20004452002 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 20004452003 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21000074005 | 1 |
| Caesar & Loretz GmbH... | Nystatin | 21004088008 | 1 |
| Caesar & Loretz GmbH | Nystatin | 18072113 | 3 |
| Caesar & Loretz GmbH | Nystatin | 18072120 | 1 |
| Caesar & Loretz GmbH | Nystatin | 18072123 | 5 |
| Caesar & Loretz GmbH | Nystatin | 18072124 | 3 |
| Caesar & Loretz GmbH | Nystatin | 18072128 | 3 |
| Caesar & Loretz GmbH | Nystatin | 18072129 | 3 |
| Caesar & Loretz GmbH | Nystatin | 19028801 | 9 |
| Caesar & Loretz GmbH | Nystatin | 19028806 | 3 |
| Caesar & Loretz GmbH | Nystatin | 19028808 | 8 |
| Caesar & Loretz GmbH | Nystatin | 19028809 | 5 |
| Caesar & Loretz GmbH | Nystatin | 19028813 | 5 |
| Caesar & Loretz GmbH | Nystatin | 193034003 | 7 |
| Caesar & Loretz GmbH | Nystatin | 193034004 | 6 |
| Caesar & Loretz GmbH | Nystatin | 193034005 | 4 |
| Caesar & Loretz GmbH | Nystatin | 193034009 | 6 |
| Caesar & Loretz GmbH | Nystatin | 20000969002 | 1 |
| Caesar & Loretz GmbH | Nystatin | 20000969005 | 7 |
| Caesar & Loretz GmbH | Nystatin | 20000969006 | 11 |
| Caesar & Loretz GmbH | Nystatin | 20004452001 | 3 |
| Caesar & Loretz GmbH | Nystatin | 20004452002 | 13 |
| Caesar & Loretz GmbH | Nystatin | 20004452003 | 6 |
| Caesar & Loretz GmbH | Nystatin | 2000969006 | 2 |
| Caesar & Loretz GmbH | Nystatin | 21000074003 | 5 |
| Caesar & Loretz GmbH | Nystatin | 21000074004 | 6 |
| Caesar & Loretz GmbH | Nystatin | 21000074005 | 9 |
| Caesar & Loretz GmbH | Nystatin | 21000074008 | 1 |
| Caesar & Loretz GmbH | Nystatin | 21002165001 | 6 |
| Caesar & Loretz GmbH | Nystatin | 21002165002 | 2 |
| Caesar & Loretz GmbH | Nystatin | 21002165007 | 8 |
| Caesar & Loretz GmbH | Nystatin | 21002165009 | 3 |
| Caesar & Loretz GmbH | Nystatin | 21004088001 | 6 |
| Caesar & Loretz GmbH | Nystatin | 21004088004 | 1 |
| Caesar & Loretz GmbH | Nystatin | 21004088006 | 1 |
| Caesar & Loretz GmbH | Nystatin | 21004088008 | 3 |
| Caesar & Loretz GmbH | Nystatin | 22002863006 | 2 |
| Caesar & Loretz GmbH | Nystatin | 23000218004 | 1 |
| Caesar & Loretz Hilden | Nystatin | 18072112 | 2 |
| Caesar & Loretz Hilden | Nystatin | 18293404 | 1 |
| Caesar & Loretz Hilden | Nystatin | 19028801 | 1 |
| Caesar & Loretz/Geil... | Nystatin | 19028806 | 1 |
| Caesar & Loretz/Geil... | Nystatin | 19028809 | 2 |
| Caesar & Loretz/Geil... | Nystatin | 193034004 | 2 |
| Caesar & Loretz/Phoenix | Nystatin | 20004452002 | 1 |
| Caesar & Loretz | Nystatin | 20004452002 | 1 |
| Caesar&Lorenz / Gehe | Nystatin | 19028810 | 1 |
| Caesar&Lorenz | Nystatin | 2100074004 | 1 |
| Caesar&Lorenz | Nystatin | 21002165001 | 1 |
| Caesar&Lorenz | Nystatin | 21002165007 | 1 |
| Caesar&loretz,Anzag | Nystatin | 12158008 | 3 |
| Caesar&loretz,Phoenix | Nystatin | 1218008 | 1 |
| Caesar&loretz,Phoenix | Nystatin | 13173401 | 4 |
| Caesar&loretz,Phoenix | Nystatin | 13173408 | 1 |
| Caesar&loretz,Phoenix | Nystatin | 14196509 | 2 |
| Caesar&loretz,Phoenix | Nystatin | 14363512 | 1 |
| caewlo | Nystatin | 21004088001 | 1 |
| Canea Pharma GmbH | Nystatin | 18072121 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Cealo/ AHD | Nystatin | 19028801 | 1 |
| Cealo/Alliance Healthcare | Nystatin | 18072118 | 1 |
| DSM Caüua S.p.A | Nystatin | 1207009-01 | 1 |
| Eu Rho Pharm/ K | Nystatin | 2006026-01 | 1 |
| EuRho / Noweda | Nystatin | 1712010-01 | 2 |
| EuRho / Phönix | Nystatin | 1712010-01 | 2 |
| Eurho Phönix | Nystatin | 1905014-02 | 3 |
| Eurho Phönix | Nystatin | 2006026 | 1 |
| EuRho/Anzag | Nystatin | 1107036-01 | 1 |
| EuRho/Anzag | Nystatin | 1712010-02 | 1 |
| EuRho/Fiebig | Nystatin | 1905014-01 | 4 |
| Eurho/Fiebig | Nystatin | 8000219 | 1 |
| EuRho/Noweda | Nystatin | 2006026-02 | 1 |
| EuRho/Noweda | Nystatin | 2111001-02 | 1 |
| EuRho/Sanacorp | Nystatin | 1712010-01 | 2 |
| EuRho/Sanacorp | Nystatin | 1712010-02 | 2 |
| EuRho/Sanacorp | Nystatin | 2006026-02 | 1 |
| Eurho/Synoph | Nystatin | 200602-03 | 4 |
| Eurho/Synoph | Nystatin | 2006026-02 | 1 |
| EuRho | Nystatin | 1107046-01 | 1 |
| EuRho | Nystatin | 1207009-01 | 1 |
| EuRho | Nystatin | 1503021-02 | 2 |
| EuRho | Nystatin | 1712010-01 | 1 |
| EuRho | Nystatin | 1905014-02 | 2 |
| EuRho | Nystatin | 2006026-01 | 1 |
| EuRho | Nystatin | 2006026-02 | 2 |
| EuRho | Nystatin | 2111001-02 | 1 |
| Euro Gehe | Nystatin | 1712010-01 | 1 |
| Euro Noweda | Nystatin | 26001021A | 1 |
| Euro OTC | Nystatin | 1107036-01 | 4 |
| Euro OTC | Nystatin | 1107046-01 | 2 |
| Euro OTC | Nystatin | 1111057-01 | 8 |
| Euro OTC | Nystatin | 1207009-01 | 7 |
| Euro OTC | Nystatin | 1207009-02 | 3 |
| Euro OTC | Nystatin | 121024-01 | 1 |
| Euro OTC | Nystatin | 1212024-01 | 15 |
| Euro OTC | Nystatin | 1212024-02 | 14 |
| Euro OTC | Nystatin | 127009-02 | 1 |
| Euro OTC | Nystatin | 130705301 | 1 |
| Euro OTC | Nystatin | 1307053-01 | 5 |
| Euro OTC | Nystatin | 1307053-02 | 2 |
| Euro OTC | Nystatin | 1511020-01 | 1 |
| Euro OTC | Nystatin | 1511020-02 | 1 |
| Euro OTC | Nystatin | 16120001-02 | 1 |
| Euro OTC | Nystatin | 1612001-01 | 4 |
| Euro OTC | Nystatin | 1612001-02 | 1 |
| Euro OTC | Nystatin | 161200103 | 3 |
| Euro OTC | Nystatin | 1612001-03 | 8 |
| Euro OTC | Nystatin | 1712010 | 1 |
| Euro OTC | Nystatin | 171201001 | 1 |
| Euro OTC | Nystatin | 1712010-01 | 95 |
| Euro OTC | Nystatin | 171201002 | 4 |
| Euro OTC | Nystatin | 1712010-02 | 47 |
| Euro OTC | Nystatin | 1712010-12 | 1 |
| Euro OTC | Nystatin | 1712020-01 | 2 |
| Euro OTC | Nystatin | 17400520 | 6 |
| Euro OTC | Nystatin | 18072114 | 1 |
| Euro OTC | Nystatin | 18072124 | 2 |
| Euro OTC | Nystatin | 190501-01 | 1 |
| Euro OTC | Nystatin | 19050114-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Nystatin | 1905014 | 2 |
| Euro OTC | Nystatin | 190501401 | 2 |
| Euro OTC | Nystatin | 1905014-01 | 122 |
| Euro OTC | Nystatin | 1905014-02 | 37 |
| Euro OTC | Nystatin | 1905014-03 | 11 |
| Euro OTC | Nystatin | 190514-02 | 1 |
| Euro OTC | Nystatin | 19500711 | 1 |
| Euro OTC | Nystatin | 20006026-01 | 1 |
| Euro OTC | Nystatin | 20006026-02 | 1 |
| Euro OTC | Nystatin | 2003026-01 | 1 |
| Euro OTC | Nystatin | 2006012501 | 1 |
| Euro OTC | Nystatin | 200602302 | 1 |
| Euro OTC | Nystatin | 2006023-02 | 1 |
| Euro OTC | Nystatin | 2006025-2 | 1 |
| Euro OTC | Nystatin | 2006026 | 1 |
| Euro OTC | Nystatin | 2006026-01 | 47 |
| Euro OTC | Nystatin | 200602602 | 2 |
| Euro OTC | Nystatin | 2006026-02 | 92 |
| Euro OTC | Nystatin | 2006026-026 | 1 |
| Euro OTC | Nystatin | 2006026-03 | 1 |
| Euro OTC | Nystatin | 2006026-1 | 1 |
| Euro OTC | Nystatin | 2006026-23 | 1 |
| Euro OTC | Nystatin | 2006226-02 | 1 |
| Euro OTC | Nystatin | 200626-01 | 2 |
| Euro OTC | Nystatin | 200626-02 | 1 |
| Euro OTC | Nystatin | 21000074004 | 1 |
| Euro OTC | Nystatin | 2111001_03 | 1 |
| Euro OTC | Nystatin | 2111001-002 | 1 |
| Euro OTC | Nystatin | 2111001-01 | 14 |
| Euro OTC | Nystatin | 2111001-02 | 67 |
| Euro OTC | Nystatin | 2111001-03 | 5 |
| Euro OTC | Nystatin | 2111011-02 | 1 |
| Euro OTC | Nystatin | 2301016-01 | 15 |
| Euro OTC | Nystatin | 2310010-01 | 1 |
| Euro OTC | Nystatin | 26001021A | 2 |
| Euro OTC | Nystatin | 2811032-01 | 1 |
| Euro OTC | Nystatin | 4014991 | 1 |
| Euro OTC | Nystatin | 4019851 | 3 |
| Euro OTC | Nystatin | 6026-01 | 1 |
| Euro OTC | Nystatin | 702270 | 1 |
| Euro OTC | Nystatin | 8000219 | 7 |
| Euro OTC | Nystatin | AP200923-01 | 1 |
| Euro OTC | Nystatin | C129440 | 1 |
| Euro OTC | Nystatin | C129531 | 2 |
| Euro OTC | Nystatin | C129854 | 1 |
| Euro OTC | Nystatin | Nys011222 | 1 |
| Euro Pharma | Nystatin | 2111001-02 | 1 |
| EUro/AHD | Nystatin | 1307053-01 | 1 |
| Euro/Gehe | Nystatin | 1905014-01 | 1 |
| Euro/Gehe | Nystatin | 2006026-01 | 1 |
| Euro/Gehe | Nystatin | 2006026-02 | 1 |
| Euro/Jenne | Nystatin | 2006026-02 | 1 |
| Euro/Phoenix | Nystatin | 1905014-03 | 1 |
| Europharm/Otto | Nystatin | 1107046-01 | 1 |
| Fagron | Nystatin | | 1 |
| Fagron | Nystatin | 11000422a | 1 |
| Fagron | Nystatin | 11C21-N10 | 1 |
| Fagron | Nystatin | 11K11-No4 | 1 |
| Fagron | Nystatin | 12C29-N09 | 1 |
| Fagron | Nystatin | 12G04-N12 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Nystatin | 13C11-N08 | 1 |
| Fagron | Nystatin | 16L21-B01 | 1 |
| Fagron | Nystatin | 17B01-B11-338878 | 1 |
| Fagron | Nystatin | 17J25-B01-344221 | 1 |
| Fagron | Nystatin | 17J25-B01-348043 | 2 |
| Fagron | Nystatin | 18072112 | 1 |
| Fagron | Nystatin | 18900619B | 1 |
| Fagron | Nystatin | 1905014-01 | 1 |
| Fagron | Nystatin | 19828 | 1 |
| Fagron | Nystatin | 19B28-B05-191208 | 2 |
| Fagron | Nystatin | 19B28-B05-191210 | 2 |
| Fagron | Nystatin | 19H08-B04-200385 | 2 |
| Fagron | Nystatin | 20121202 | 1 |
| Fagron | Nystatin | 20H18-B13-201282 | 1 |
| Fagron | Nystatin | 20H18B13201991 | 1 |
| Fagron | Nystatin | 20H18-B13-201991 | 2 |
| Fagron | Nystatin | 21H13-B01-214453 | 1 |
| Fagron | Nystatin | 4014376 | 1 |
| Fagron | Nystatin | B01-2144503 | 1 |
| Fagron | Nystatin | b04-2003805 | 1 |
| Fiebig | Nystatin | 24000661005 | 1 |
| Gatt-Koller | Nystatin | 1900206 | 2 |
| Gehe amax | Nystatin | 1712010-01 | 1 |
| Gehe amax | Nystatin | 1905014-01 | 1 |
| Gehe Rostock | Nystatin | 2111001-02 | 1 |
| Gehe/EuRho | Nystatin | 1905014-02 | 1 |
| Gehe | Nystatin | 1107036-01 | 1 |
| Gehe | Nystatin | 1111057-01 | 1 |
| Gehe | Nystatin | 1207009-01 | 1 |
| Gehe | Nystatin | 12158008 | 1 |
| Gehe | Nystatin | 1307053-02 | 1 |
| Gehe | Nystatin | 1712010-01 | 1 |
| Gehe | Nystatin | 1712010-02 | 1 |
| Gehe | Nystatin | 1905014-01 | 1 |
| Gehe | Nystatin | 1905014-03 | 1 |
| Gehe | Nystatin | 20000969005 | 3 |
| Gehe | Nystatin | 200602601 | 1 |
| Gehe | Nystatin | 21000074004 | 1 |
| GEHE | Nystatin | 22002863006 | 1 |
| Gehe | Nystatin | 2301016-01 | 5 |
| GEhe | Nystatin | 230101601 | 1 |
| GEHE | Nystatin | 2301016-01 | 1 |
| Gehe | Nystatin | 2310010-01 | 3 |
| Geilenkirchen | Nystatin | 1905014-01 | 1 |
| Holdermann | Nystatin | 22002863011 | 1 |
| Holdermann | Nystatin | 2310010-01 | 1 |
| Holdermann | Nystatin | 24000661004 | 1 |
| Jenne | Nystatin | 21000074003 | 1 |
| Jenne | Nystatin | 230824(23000218006) | 1 |
| Jenne | Nystatin | 250717(24000661004) | 1 |
| Kehr | Nystatin | 1612001-02 | 1 |
| Kehr | Nystatin | 18072123 | 1 |
| Kehr | Nystatin | 23000218006 | 1 |
| kehr | Nystatin | 230101601 | 1 |
| Kehr | Nystatin | 2301016-01 | 2 |
| Kehr | Nystatin | 24000661004 | 2 |
| L10 | Nystatin | 2310010-01 | 1 |
| L12 | Nystatin | 1712010-01 | 1 |
| Nachprüfung | Nystatin | 1118E-01941 | 1 |
| Nachprüfung | Nystatin | 123456 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda Taucha | Nystatin | 2111001-01 | 1 |
| Noweda | Nystatin | 1207009-01 | 1 |
| Noweda | Nystatin | 19028801 | 1 |
| Noweda | Nystatin | 19028808 | 1 |
| Noweda | Nystatin | 21000074005 | 2 |
| Noweda | Nystatin | 2111001 | 1 |
| Noweda | Nystatin | 2111001-02 | 1 |
| noweda | Nystatin | 22002863006 | 2 |
| Noweda | Nystatin | 22002863011 | 1 |
| Noweda | Nystatin | 23000218004 | 3 |
| Noweda | Nystatin | 23000218006 | 7 |
| Noweda | Nystatin | 23001392006 | 1 |
| Noweda | Nystatin | 2301016-01 | 3 |
| Noweda | Nystatin | 2310010-01 | 5 |
| Noweda | Nystatin | 24000661004 | 1 |
| Noweda | Nystatin | 24000661005 | 1 |
| Noweda | Nystatin | 2410014-01 | 2 |
| Noweda | Nystatin | 29800924 | 1 |
| Nystatin | Nystatin | 1905014-01 | 1 |
| Otto Geilenkirchen | Nystatin | 22002863011 | 1 |
| Otto Geilenkirchen | Nystatin | 2300218004 | 1 |
| ph.Eur | Nystatin | 2111001-02 | 1 |
| Phoenix/apotec | Nystatin | 2301016-01 | 1 |
| Phoenix/Kayna | Nystatin | 2310010-01 | 1 |
| Phoenix | Nystatin | 1712010-01 | 1 |
| Phoenix | Nystatin | 1712010-02 | 1 |
| Phoenix | Nystatin | 17400520 | 1 |
| Phoenix | Nystatin | 1905014-01 | 2 |
| Phoenix | Nystatin | 20004452003 | 1 |
| Phoenix | Nystatin | 21002165003 | 1 |
| Phoenix | Nystatin | 23000218005 | 1 |
| Phoenix | Nystatin | 23000218006 | 1 |
| Phoenix | Nystatin | 2301016-01 | 2 |
| Phoenix | Nystatin | 2310010-01 | 1 |
| Phoenix | Nystatin | 3361 | 1 |
| Phoenix | Nystatin | 3410 | 1 |
| Phönix Gotha | Nystatin | 1712010-02 | 1 |
| Phönix/Euro | Nystatin | 1111057-01 | 1 |
| Phönix | Nystatin | 12017005 | 2 |
| Phönix | Nystatin | 1212024-01 | 1 |
| Phönix | Nystatin | 1212024-02 | 1 |
| Phönix | Nystatin | 12158010 | 1 |
| Phönix | Nystatin | 1712010-01 | 1 |
| Phönix | Nystatin | 18072109 | 1 |
| Phönix | Nystatin | 18072121 | 1 |
| Phönix | Nystatin | 19028813 | 1 |
| Phönix | Nystatin | 1905014-01 | 4 |
| Phönix | Nystatin | 1905014-02 | 1 |
| Phönix | Nystatin | 1930343004 | 1 |
| Phönix | Nystatin | 20000969005 | 1 |
| Phönix | Nystatin | 2006026-01 | 1 |
| Phönix | Nystatin | 2006026-02 | 2 |
| Phönix | Nystatin | 21002165001 | 2 |
| Phönix | Nystatin | 2111001-01 | 1 |
| Phönix | Nystatin | 23000218004 | 4 |
| Phönix | Nystatin | 23000218006 | 2 |
| Phönix | Nystatin | 2301016-01 | 4 |
| Phönix | Nystatin | 2310010-01 | 2 |
| Phönix | Nystatin | 37401222 | 1 |
| Sanacorp/Caesar & Lo… | Nystatin | 18072120 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp/EuRho | Nystatin | 171201001 | 1 |
| Sanacorp | Nystatin | 1107046-01 | 1 |
| Sanacorp | Nystatin | 1212024-02 | 1 |
| sanacorp | Nystatin | 19028808 | 1 |
| Sanacorp | Nystatin | 193034009 | 1 |
| Sanacorp | Nystatin | 20004452002 | 1 |
| Sanacorp | Nystatin | 2002863011 | 1 |
| Sanacorp | Nystatin | 21002165003 | 1 |
| Sanacorp | Nystatin | 21004088006 | 1 |
| Sanacorp | Nystatin | 23000218006 | 2 |
| Sanacorp | Nystatin | 23001392006 | 1 |
| Sanacorp | Nystatin | 2301016-01 | 4 |
| Sanacorp | Nystatin | 2310010-01 | 1 |
| Sanacorp | Nystatin | 24000661003 | 1 |
| Sanacorp | Nystatin | 24000661004 | 1 |
| VUAB Pharma / Gehe | Nystatin | 2006026-02 | 1 |
| VUAB Pharma | Nystatin | 17400520 | 2 |
| VUAB Pharma | Nystatin | 2111001-02 | 1 |
| VUAB/Noweda | Nystatin | 8000219 | 1 |

- 254 680 spectra from 1666 *Apo-Ident* customers from a total of 51 885 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Nystatin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Nystatin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 550 | 0 | 157 776 |
| **Type B** | 0 | 410 | 0 | 212 530 |
| **Type C** | 0 | 2077 | 129 | 254 680 |

The substance/substance group *Nystatin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9091 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5366 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 94.1523 % (> 94.0163 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23711 | 24780 | 16.86 | 94.88 |
| 23984 | 26595 | 19.62 | 102.93 |
| 23985 | 26595 | 19.46 | 105.90 |
| 24103 | 24103 | 0.00 | 100.61 |
| 24645 | 24780 | 16.84 | 103.06 |
| 24780 | 24780 | 0.00 | 103.62 |
| 25354 | 25354 | 0.00 | 87.92 |
| 25722 | 24780 | 26.64 | 92.19 |
| 25879 | 25879 | 0.00 | 79.12 |
| 26305 | 26595 | 25.29 | 97.12 |
| 26381 | 24780 | 8.30 | 100.75 |
| 26595 | 26595 | 0.00 | 106.45 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Octenidine dihydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20759-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Octenidine dihydrochloride; Octenidini dihydrochloridum

### Special notes

When selecting the *Octenidine dihydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Octenidine dihydrochloride | 10 | 5 | 293 |

### Second-stage model

For differentiation of the substance/substance group *Octenidine dihydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Octenidine dihydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 105.75 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Octenidine dihydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Octenidine dihydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Octenidine dihydrochloride | 12115202 | 20759 | 40 | 20120511 |
| Caelo | Octenidine dihydrochloride | 13071407 | 20988 | 40 | 1407345 |
| Caelo | Octenidine dihydrochloride | 13166806 | 21331 | 40 | 20130718 |
| Caelo | Octenidine dihydrochloride | 15275502 | 21888 | 60 | 20150910 |
| Caelo | Octenidine dihydrochloride | 15356601 | 21947 | 60 | 1604116 |
| Caelo | Octenidine dihydrochloride | 15356601 | 21947SI | 60 | 1604116 |
| Caelo | Octenidine dihydrochloride | 170423 | 23307 | 40 | 20170214* |
| Caelo | Octenidine dihydrochloride | 170423 | 23307SI | 40 | 20170214* |
| Caelo | Octenidine dihydrochloride | 163355 | 23309 | 40 | 20170403* |
| Caelo | Octenidine dihydrochloride | 18223413 | 24597 | 40 | 20181005 |
| Caelo | Octenidine dihydrochloride | 18223413 | 24597SI | 40 | 20181005 |
| Caelo | Octenidine dihydrochloride | 23002809 | 27110 | 40 | 20240130* |
| Caelo | Octenidine dihydrochloride | 24002081 | 27444 | 40 | 20240912* |
| Caelo | Octenidine dihydrochloride | 24002081 | 27444SI | 40 | 20240912* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 620 spectra of 14 reference samples from the substance/substance group *Octenidine dihydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 706 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 520 spectra of 12 reference samples from the substance/substance group *Octenidine dihydrochloride*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Octenidine dihydrochloride | 160330 | 22485 | 60 |
| Caelo | Octenidine dihydrochloride | 180174 | 24023 | 40 |
| Caelo | Octenidine dihydrochloride | 20000606 | 25202 | 40 |
| Caelo | Octenidine dihydrochloride | 21002272 | 26010 | 40 |
| Fagron | Octenidine dihydrochloride | 25A08-B05-006681 | 27597 | 40 |
| Caelo | Octenidine dihydrochloride | 15275502 | 21888SI† | 60 |
| Caelo | Octenidine dihydrochloride | 163355 | 23309SI† | 40 |
| Caelo | Octenidine dihydrochloride | 180174 | 24023SI | 40 |
| Caelo | Octenidine dihydrochloride | 20000606 | 25202SI | 40 |
| Caelo | Octenidine dihydrochloride | 21002272 | 26010SI | 40 |
| Caelo | Octenidine dihydrochloride | 23002809 | 27110SI† | 40 |
| Fagron | Octenidine dihydrochloride | 25A08-B05-006681 | 27597SI | 40 |

- 212 420 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3103 spectra from 998 *Apo-Ident* customers from 298 batches from the substance/substance group *Octenidine dihydrochloride*.
- Among them are spectra of independent samples from 293 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Octenidine dihydrochloride | | 1 |
| | Octenidine dihydrochloride | 191023/5 | 1 |
| | Octenidine dihydrochloride | 21002272001 | 2 |
| | Octenidine dihydrochloride | 21002272002 | 1 |
| | Octenidine dihydrochloride | 21002272008 | 1 |
| | Octenidine dihydrochloride | 21002272011 | 3 |
| | Octenidine dihydrochloride | 21002272012 | 11 |
| | Octenidine dihydrochloride | 21002272018 | 9 |
| | Octenidine dihydrochloride | 21002272020 | 2 |
| | Octenidine dihydrochloride | 21002272022 | 5 |
| | Octenidine dihydrochloride | 21002272024 | 8 |
| | Octenidine dihydrochloride | 21002272025 | 2 |
| | Octenidine dihydrochloride | 2102272024 | 1 |
| | Octenidine dihydrochloride | 22003039001 | 1 |
| | Octenidine dihydrochloride | 22003039002 | 38 |
| | Octenidine dihydrochloride | 220030390021 | 1 |
| | Octenidine dihydrochloride | 22003039003 | 15 |
| | Octenidine dihydrochloride | 22003039004 | 15 |
| | Octenidine dihydrochloride | 22003039005 | 69 |
| | Octenidine dihydrochloride | 22003039006 | 1 |
| | Octenidine dihydrochloride | 22003039008 | 13 |
| | Octenidine dihydrochloride | 22003039009 | 19 |
| | Octenidine dihydrochloride | 2203039002 | 2 |
| | Octenidine dihydrochloride | 2272012 | 1 |
| | Octenidine dihydrochloride | 230028009003 | 1 |
| | Octenidine dihydrochloride | 23002809002 | 13 |
| | Octenidine dihydrochloride | 23002809003 | 35 |
| | Octenidine dihydrochloride | 23002809004 | 39 |
| | Octenidine dihydrochloride | 23002809005 | 1 |
| | Octenidine dihydrochloride | 23002809006 | 7 |
| | Octenidine dihydrochloride | 23002809007 | 14 |
| | Octenidine dihydrochloride | 2300280900757/24P | 1 |
| | Octenidine dihydrochloride | 230028090087 | 1 |
| | Octenidine dihydrochloride | 23002809012 | 2 |
| | Octenidine dihydrochloride | 23002809017 | 4 |
| | Octenidine dihydrochloride | 2300280904 | 1 |
| | Octenidine dihydrochloride | 25A08-B05-006732 | 2 |
| | Octenidine dihydrochloride | 312122 | 1 |
| Aep | Octenidine dihydrochloride | 22003039004 | 1 |
| AEP | Octenidine dihydrochloride | 23002809003 | 1 |
| AEP | Octenidine dihydrochloride | 23002809004 | 1 |
| AHC | Octenidine dihydrochloride | 20000606005 | 1 |
| AHD | Octenidine dihydrochloride | 16335507 | 1 |
| AHD | Octenidine dihydrochloride | 18197504 | 1 |
| AHD | Octenidine dihydrochloride | 20000606009 | 1 |
| AHD | Octenidine dihydrochloride | 21002272012 | 2 |
| AHD | Octenidine dihydrochloride | 21002272024 | 2 |
| AHD | Octenidine dihydrochloride | 22003039005 | 5 |
| AHD | Octenidine dihydrochloride | 23002809003 | 1 |
| AHD | Octenidine dihydrochloride | 23002809007 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Allaince Helthcare | Octenidine dihydrochloride | 23002809003 | 1 |
| Alliance Health Care | Octenidine dihydrochloride | 21002272025 | 1 |
| Alliance Health Care | Octenidine dihydrochloride | 25A08-B05-006732 | 1 |
| Alliance Healthcare | Octenidine dihydrochloride | 18223403 | 3 |
| Alliance Healthcare | Octenidine dihydrochloride | 18223415 | 1 |
| Alliance Healthcare | Octenidine dihydrochloride | 21002272024 | 1 |
| Alliance Healthcare | Octenidine dihydrochloride | 22003039005 | 1 |
| Alliance | Octenidine dihydrochloride | 22003039002 | 2 |
| Anzag | Octenidine dihydrochloride | 17042602 | 1 |
| Anzag | Octenidine dihydrochloride | 20004187003 | 2 |
| Anzag | Octenidine dihydrochloride | 23002809004 | 1 |
| Anzag | Octenidine dihydrochloride | 230503 | 1 |
| Anzag | Octenidine dihydrochloride | 230914(22003039005) | 1 |
| Anzag | Octenidine dihydrochloride | 231025(22003039005) | 1 |
| Anzag | Octenidine dihydrochloride | 231206(22003039005) | 1 |
| Anzag | Octenidine dihydrochloride | 240118(22003039005) | 1 |
| Anzag | Octenidine dihydrochloride | 241014(23002809004) | 1 |
| Anzag | Octenidine dihydrochloride | 241128(23002809004) | 1 |
| Anzag | Octenidine dihydrochloride | 241129(23002809004) | 1 |
| Anzag | Octenidine dihydrochloride | 250130(23002809003) | 1 |
| Anzag | Octenidine dihydrochloride | 250207(23002809003) | 1 |
| Anzag | Octenidine dihydrochloride | 250313(23002809003) | 1 |
| Anzag | Octenidine dihydrochloride | 250709(23002809017) | 1 |
| apomix | Octenidine dihydrochloride | 13166813 | 1 |
| Audor Pharma | Octenidine dihydrochloride | 17042304 | 1 |
| Bombastus | Octenidine dihydrochloride | 17218506 | 1 |
| Bombastus | Octenidine dihydrochloride | 18017402 | 1 |
| Cae | Octenidine dihydrochloride | 21002272002 | 1 |
| Caelo | Octenidine dihydrochloride | | 1 |
| Caelo | Octenidine dihydrochloride | 10(20000606019) | 1 |
| Caelo | Octenidine dihydrochloride | 1000609006 | 1 |
| Caelo | Octenidine dihydrochloride | 11(20004187011) | 1 |
| Caelo | Octenidine dihydrochloride | 11071925 | 1 |
| Caelo | Octenidine dihydrochloride | 12(20004187011) | 1 |
| Caelo | Octenidine dihydrochloride | 13061801 | 1 |
| Caelo | Octenidine dihydrochloride | 13166801 | 1 |
| Caelo | Octenidine dihydrochloride | 13166808 | 2 |
| Caelo | Octenidine dihydrochloride | 13166810 | 1 |
| Caelo | Octenidine dihydrochloride | 15006202 | 3 |
| Caelo | Octenidine dihydrochloride | 15006203 | 1 |
| Caelo | Octenidine dihydrochloride | 15006207 | 5 |
| Caelo | Octenidine dihydrochloride | 1515E-03732 | 1 |
| Caelo | Octenidine dihydrochloride | 15275502 | 8 |
| Caelo | Octenidine dihydrochloride | 152755020 | 1 |
| Caelo | Octenidine dihydrochloride | 15275503 | 3 |
| Caelo | Octenidine dihydrochloride | 15275504 | 1 |
| Caelo | Octenidine dihydrochloride | 15356601 | 6 |
| Caelo | Octenidine dihydrochloride | 15356603 | 4 |
| Caelo | Octenidine dihydrochloride | 15356702 | 1 |
| Caelo | Octenidine dihydrochloride | 15356703 | 9 |
| Caelo | Octenidine dihydrochloride | 16032803 | 8 |
| Caelo | Octenidine dihydrochloride | 16032901 | 2 |
| Caelo | Octenidine dihydrochloride | 16032902 | 4 |
| Caelo | Octenidine dihydrochloride | 16032903 | 2 |
| Caelo | Octenidine dihydrochloride | 16032909 | 7 |
| Caelo | Octenidine dihydrochloride | 16032910 | 6 |
| Caelo | Octenidine dihydrochloride | 16033001 | 2 |
| Caelo | Octenidine dihydrochloride | 16033002 | 2 |
| Caelo | Octenidine dihydrochloride | 16277802 | 9 |
| Caelo | Octenidine dihydrochloride | 16302910 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Octenidine dihydrochloride | 16325202 | 1 |
| Caelo | Octenidine dihydrochloride | 16325304 | 11 |
| Caelo | Octenidine dihydrochloride | 16325305 | 15 |
| Caelo | Octenidine dihydrochloride | 16325406 | 6 |
| Caelo | Octenidine dihydrochloride | 16325408 | 2 |
| Caelo | Octenidine dihydrochloride | 16325410 | 3 |
| Caelo | Octenidine dihydrochloride | 16335502 | 3 |
| Caelo | Octenidine dihydrochloride | 16335504 | 23 |
| Caelo | Octenidine dihydrochloride | 16335505 | 5 |
| Caelo | Octenidine dihydrochloride | 16335506 | 1 |
| Caelo | Octenidine dihydrochloride | 16335507 | 11 |
| Caelo | Octenidine dihydrochloride | 16335508 | 8 |
| Caelo | Octenidine dihydrochloride | 16335509 | 20 |
| Caelo | Octenidine dihydrochloride | 16335510 | 12 |
| Caelo | Octenidine dihydrochloride | 17042302 | 8 |
| Caelo | Octenidine dihydrochloride | 17042303 | 6 |
| Caelo | Octenidine dihydrochloride | 17042304 | 13 |
| Caelo | Octenidine dihydrochloride | 17042305 | 5 |
| Caelo | Octenidine dihydrochloride | 17042501 | 1 |
| Caelo | Octenidine dihydrochloride | 17042601 | 1 |
| Caelo | Octenidine dihydrochloride | 17042602 | 9 |
| Caelo | Octenidine dihydrochloride | 17042701 | 1 |
| Caelo | Octenidine dihydrochloride | 17042903 | 22 |
| Caelo | Octenidine dihydrochloride | 171116OHC/16335509 | 1 |
| Caelo | Octenidine dihydrochloride | 172118501 | 1 |
| Caelo | Octenidine dihydrochloride | 17218051 | 1 |
| Caelo | Octenidine dihydrochloride | 17218501 | 45 |
| Caelo | Octenidine dihydrochloride | 17218503 | 15 |
| Caelo | Octenidine dihydrochloride | 172185035514 | 1 |
| Caelo | Octenidine dihydrochloride | 17218504 | 1 |
| Caelo | Octenidine dihydrochloride | 17218506 | 26 |
| Caelo | Octenidine dihydrochloride | 17218507 | 16 |
| Caelo | Octenidine dihydrochloride | 17218508 | 32 |
| Caelo | Octenidine dihydrochloride | 17218509 | 37 |
| Caelo | Octenidine dihydrochloride | 17218907 | 1 |
| Caelo | Octenidine dihydrochloride | 1728506 | 1 |
| Caelo | Octenidine dihydrochloride | 1728508 | 1 |
| Caelo | Octenidine dihydrochloride | 18017402 | 74 |
| Caelo | Octenidine dihydrochloride | 18017404 | 1 |
| Caelo | Octenidine dihydrochloride | 18197501 | 55 |
| Caelo | Octenidine dihydrochloride | 18197502 | 25 |
| Caelo | Octenidine dihydrochloride | 181975025789 | 1 |
| Caelo | Octenidine dihydrochloride | 18197503 | 1 |
| Caelo | Octenidine dihydrochloride | 18197504 | 20 |
| Caelo | Octenidine dihydrochloride | 181987504 | 1 |
| Caelo | Octenidine dihydrochloride | 18223401 | 5 |
| Caelo | Octenidine dihydrochloride | 18223403 | 66 |
| Caelo | Octenidine dihydrochloride | 18223404 | 40 |
| Caelo | Octenidine dihydrochloride | 18223407 | 8 |
| Caelo | Octenidine dihydrochloride | 18223409 | 43 |
| Caelo | Octenidine dihydrochloride | 18223410 | 7 |
| Caelo | Octenidine dihydrochloride | 18223411 | 25 |
| Caelo | Octenidine dihydrochloride | 18223413 | 50 |
| Caelo | Octenidine dihydrochloride | 18223414 | 3 |
| Caelo | Octenidine dihydrochloride | 18223415 | 34 |
| Caelo | Octenidine dihydrochloride | 18223416 | 34 |
| Caelo | Octenidine dihydrochloride | 18223418 | 4 |
| Caelo | Octenidine dihydrochloride | 18223419 | 15 |
| Caelo | Octenidine dihydrochloride | 18223420 | 4 |
| Caelo | Octenidine dihydrochloride | 18223423 | 40 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Octenidine dihydrochloride | 18223424 | 35 |
| Caelo | Octenidine dihydrochloride | 18223425 | 1 |
| Caelo | Octenidine dihydrochloride | 18223426 | 20 |
| Caelo | Octenidine dihydrochloride | 18223427 | 14 |
| Caelo | Octenidine dihydrochloride | 18223428 | 4 |
| Caelo | Octenidine dihydrochloride | 1822413 | 1 |
| Caelo | Octenidine dihydrochloride | 18233427 | 1 |
| Caelo | Octenidine dihydrochloride | 1823419 | 1 |
| Caelo | Octenidine dihydrochloride | 190118-03 | 1 |
| Caelo | Octenidine dihydrochloride | 2(18223413) | 1 |
| Caelo | Octenidine dihydrochloride | 2000006016 | 1 |
| Caelo | Octenidine dihydrochloride | 200000606001 | 1 |
| Caelo | Octenidine dihydrochloride | 200000606005 | 2 |
| Caelo | Octenidine dihydrochloride | 200000606006 | 2 |
| Caelo | Octenidine dihydrochloride | 200000606011 | 1 |
| Caelo | Octenidine dihydrochloride | 200000606012 | 2 |
| Caelo | Octenidine dihydrochloride | 200000606016 | 2 |
| Caelo | Octenidine dihydrochloride | 200004187011 | 1 |
| Caelo | Octenidine dihydrochloride | 2000060002 | 1 |
| Caelo | Octenidine dihydrochloride | 2000060060011 | 1 |
| Caelo | Octenidine dihydrochloride | 200006012 | 1 |
| Caelo | Octenidine dihydrochloride | 20000605007 | 1 |
| Caelo | Octenidine dihydrochloride | 20000606001 | 31 |
| Caelo | Octenidine dihydrochloride | 20000606002 | 42 |
| Caelo | Octenidine dihydrochloride | 20000606005 | 26 |
| Caelo | Octenidine dihydrochloride | 20000606006 | 55 |
| Caelo | Octenidine dihydrochloride | 20000606007 | 11 |
| Caelo | Octenidine dihydrochloride | 20000606008 | 2 |
| Caelo | Octenidine dihydrochloride | 20000606009 | 17 |
| Caelo | Octenidine dihydrochloride | 2000060601 | 1 |
| Caelo | Octenidine dihydrochloride | 20000606010 | 1 |
| Caelo | Octenidine dihydrochloride | 20000606011 | 29 |
| Caelo | Octenidine dihydrochloride | 20000606012 | 26 |
| Caelo | Octenidine dihydrochloride | 20000606015 | 3 |
| Caelo | Octenidine dihydrochloride | 20000606016 | 23 |
| Caelo | Octenidine dihydrochloride | 20000606017 | 1 |
| Caelo | Octenidine dihydrochloride | 20000606018 | 5 |
| Caelo | Octenidine dihydrochloride | 20000606019 | 44 |
| Caelo | Octenidine dihydrochloride | 2000060602 | 1 |
| Caelo | Octenidine dihydrochloride | 20000606022 | 5 |
| Caelo | Octenidine dihydrochloride | 2000060606 | 1 |
| Caelo | Octenidine dihydrochloride | 2000060611 | 1 |
| Caelo | Octenidine dihydrochloride | 2000060616 | 1 |
| Caelo | Octenidine dihydrochloride | 2000060619 | 1 |
| Caelo | Octenidine dihydrochloride | 20000620002 | 8 |
| Caelo | Octenidine dihydrochloride | 20004107016 | 1 |
| Caelo | Octenidine dihydrochloride | 2000418012 | 1 |
| Caelo | Octenidine dihydrochloride | 20004187001 | 25 |
| Caelo | Octenidine dihydrochloride | 20004187002 | 28 |
| Caelo | Octenidine dihydrochloride | 20004187003 | 29 |
| Caelo | Octenidine dihydrochloride | 20004187004 | 4 |
| Caelo | Octenidine dihydrochloride | 20004187006 | 6 |
| Caelo | Octenidine dihydrochloride | 20004187009 | 20 |
| Caelo | Octenidine dihydrochloride | 2000418701 | 1 |
| Caelo | Octenidine dihydrochloride | 20004187010 | 3 |
| Caelo | Octenidine dihydrochloride | 20004187011 | 27 |
| Caelo | Octenidine dihydrochloride | 20004187012 | 36 |
| Caelo | Octenidine dihydrochloride | 20004187013 | 7 |
| Caelo | Octenidine dihydrochloride | 20004187014 | 17 |
| Caelo | Octenidine dihydrochloride | 20004187015 | 26 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Octenidine dihydrochloride | 20004187015(2x) | 1 |
| Caelo | Octenidine dihydrochloride | 20004187016 | 15 |
| Caelo | Octenidine dihydrochloride | 20004187017 | 17 |
| Caelo | Octenidine dihydrochloride | 2000418704 | 1 |
| Caelo | Octenidine dihydrochloride | 200041871002 | 1 |
| Caelo | Octenidine dihydrochloride | 20004187101 | 1 |
| Caelo | Octenidine dihydrochloride | 200048187006 | 1 |
| Caelo | Octenidine dihydrochloride | 2000606001 | 1 |
| Caelo | Octenidine dihydrochloride | 2000606002 | 1 |
| Caelo | Octenidine dihydrochloride | 2000606006 | 1 |
| Caelo | Octenidine dihydrochloride | 2000606011 | 1 |
| Caelo | Octenidine dihydrochloride | 2000606012 | 1 |
| Caelo | Octenidine dihydrochloride | 2000606019 | 3 |
| Caelo | Octenidine dihydrochloride | 2000606021 | 1 |
| Caelo | Octenidine dihydrochloride | 200060612 | 1 |
| Caelo | Octenidine dihydrochloride | 2000620002 | 1 |
| Caelo | Octenidine dihydrochloride | 2004187002 | 1 |
| Caelo | Octenidine dihydrochloride | 2004187003 | 2 |
| Caelo | Octenidine dihydrochloride | 2004187006 | 1 |
| Caelo | Octenidine dihydrochloride | 2004187009 | 3 |
| Caelo | Octenidine dihydrochloride | 2004187011 | 1 |
| Caelo | Octenidine dihydrochloride | 210002272024 | 1 |
| Caelo | Octenidine dihydrochloride | 2100227003 | 1 |
| Caelo | Octenidine dihydrochloride | 2100227014 | 2 |
| Caelo | Octenidine dihydrochloride | 21002272001 | 4 |
| Caelo | Octenidine dihydrochloride | 21002272002 | 22 |
| Caelo | Octenidine dihydrochloride | 21002272003 | 28 |
| Caelo | Octenidine dihydrochloride | 21002272004 | 32 |
| Caelo | Octenidine dihydrochloride | 21002272006 | 13 |
| Caelo | Octenidine dihydrochloride | 21002272009 | 7 |
| Caelo | Octenidine dihydrochloride | 21002272011 | 1 |
| Caelo | Octenidine dihydrochloride | 21002272012 | 5 |
| Caelo | Octenidine dihydrochloride | 21002272014 | 26 |
| Caelo | Octenidine dihydrochloride | 21002272015 | 8 |
| Caelo | Octenidine dihydrochloride | 21002272018 | 17 |
| Caelo | Octenidine dihydrochloride | 21002272019 | 1 |
| Caelo | Octenidine dihydrochloride | 2100227202 | 1 |
| Caelo | Octenidine dihydrochloride | 21002272020 | 1 |
| Caelo | Octenidine dihydrochloride | 21002272022 | 16 |
| Caelo | Octenidine dihydrochloride | 21002272024 | 8 |
| Caelo | Octenidine dihydrochloride | 21002272025 | 1 |
| Caelo | Octenidine dihydrochloride | 2100227205 | 1 |
| Caelo | Octenidine dihydrochloride | 2100272020 | 1 |
| Caelo | Octenidine dihydrochloride | 2102272003 | 1 |
| Caelo | Octenidine dihydrochloride | 2102272024 | 1 |
| Caelo | Octenidine dihydrochloride | 210906(20004187011) | 1 |
| Caelo | Octenidine dihydrochloride | 211002272004 | 1 |
| Caelo | Octenidine dihydrochloride | 22003039002 | 7 |
| Caelo | Octenidine dihydrochloride | 22003039004 | 1 |
| Caelo | Octenidine dihydrochloride | 22003039005 | 5 |
| Caelo | Octenidine dihydrochloride | 2200309002 | 1 |
| Caelo | Octenidine dihydrochloride | 220516(21002272002) | 1 |
| Caelo | Octenidine dihydrochloride | 220622(21002272002) | 1 |
| Caelo | Octenidine dihydrochloride | 220930(21002272003) | 1 |
| Caelo | Octenidine dihydrochloride | 221222/5 | 1 |
| Caelo | Octenidine dihydrochloride | 23002809003 | 1 |
| Caelo | Octenidine dihydrochloride | 23002809004 | 3 |
| Caelo | Octenidine dihydrochloride | 2304187009 | 1 |
| Caelo | Octenidine dihydrochloride | 2x2004187002 | 1 |
| Caelo | Octenidine dihydrochloride | 3(18223424) | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Octenidine dihydrochloride | 300718A | 1 |
| Caelo | Octenidine dihydrochloride | 3277 | 1 |
| Caelo | Octenidine dihydrochloride | 3329 | 1 |
| Caelo | Octenidine dihydrochloride | 4(18223426) | 1 |
| Caelo | Octenidine dihydrochloride | 5(18223426) | 1 |
| Caelo | Octenidine dihydrochloride | 6(20000606005) | 1 |
| Caelo | Octenidine dihydrochloride | 606007 | 1 |
| Caelo | Octenidine dihydrochloride | 606019 | 1 |
| Caelo | Octenidine dihydrochloride | 6325305 | 1 |
| Caelo | Octenidine dihydrochloride | 7(20000606001) | 1 |
| Caelo | Octenidine dihydrochloride | 718A-03273 | 1 |
| Caelo | Octenidine dihydrochloride | 8(20000606006) | 1 |
| Caelo | Octenidine dihydrochloride | 816M-03732 | 1 |
| Caelo | Octenidine dihydrochloride | 8724 | 1 |
| Caelo | Octenidine dihydrochloride | 9(2000060611) | 1 |
| Caesar & Lorenz GmbH | Octenidine dihydrochloride | 16325410 | 1 |
| Caesar & Lorenz GmbH | Octenidine dihydrochloride | 17218503 | 1 |
| Caesar & Lorenz GmbH | Octenidine dihydrochloride | 18223416 | 2 |
| Caesar & Lorenz GmbH | Octenidine dihydrochloride | 200006006 | 1 |
| Caesar & Lorenz GmbH | Octenidine dihydrochloride | 20000606001 | 1 |
| Caesar & Lorenz GmbH | Octenidine dihydrochloride | 20000606005 | 1 |
| Caesar & Loretz / Sa... | Octenidine dihydrochloride | 18223404 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 16325305 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 18223403 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187009 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 21002272004 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187002 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 18223403 | 2 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 18223428 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 18233415 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606005 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606006 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606012 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 18223416 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 18223426 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187003 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 21002272018 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 21002272018 | 2 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606002 | 1 |
| Caesar & Loretz GmbH/ G | Octenidine dihydrochloride | 18223404 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187014 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606002 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606011 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187018 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187002 | 1 |
| Caesar & Loretz GmbH/ | Octenidine dihydrochloride | 21002272002 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187003 | 2 |
| Caesar & Loretz GmbH/AEP | Octenidine dihydrochloride | 20000606009 | 1 |
| Caesar & Loretz GmbH/AEP | Octenidine dihydrochloride | 20004187015 | 1 |
| Caesar & Loretz GmbH/AHD | Octenidine dihydrochloride | 18223427 | 2 |
| Caesar & Loretz GmbH/AHD | Octenidine dihydrochloride | 20000606012 | 1 |
| Caesar & Loretz GmbH/AHD | Octenidine dihydrochloride | 21002272003 | 1 |
| Caesar & Loretz GmbH/AHD | Octenidine dihydrochloride | 21002272018 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606011 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 18223423 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606011 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20000606012 | 1 |
| Caesar & Loretz GmbH... | Octenidine dihydrochloride | 20004187011 | 1 |
| Caesar & Loretz GmbH/G | Octenidine dihydrochloride | 20004187003 | 1 |
| Caesar & Loretz GmbH/Gehe | Octenidine dihydrochloride | 18223413 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Octenidine dihydrochloride | 20000606006 | 1 |
| Caesar & Loretz GmbH/Gehe | Octenidine dihydrochloride | 20000606009 | 1 |
| Caesar & Loretz GmbH/Gehe | Octenidine dihydrochloride | 20000606010 | 1 |
| Caesar & Loretz GmbH/Gehe | Octenidine dihydrochloride | 20000606012 | 1 |
| Caesar & Loretz GmbH/GEHE | Octenidine dihydrochloride | 20000606012 | 1 |
| Caesar & Loretz GmbH/GEHE | Octenidine dihydrochloride | 20000606018 | 1 |
| Caesar & Loretz GmbH/Gehe | Octenidine dihydrochloride | 20004187003 | 2 |
| Caesar & Loretz GmbH/Gehe | Octenidine dihydrochloride | 20004187009 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187012 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187002 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223411 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20000606002 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20000606005 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20000606016 | 2 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187001 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 21002272011 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 21002272014 | 2 |
| Caesar & Loretz GmbH/K | Octenidine dihydrochloride | 20004187013 | 1 |
| Caesar & Loretz GmbH/Kehr | Octenidine dihydrochloride | 18223418 | 1 |
| Caesar & Loretz GmbH/Kehr | Octenidine dihydrochloride | 21002272014 | 2 |
| Caesar & Loretz GmbH/Kehr | Octenidine dihydrochloride | 21002272025 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223425 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187015 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223423 | 2 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20000606006 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20000606015 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20000606019 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187002 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187016 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 21002272022 | 2 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 21002272002 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 21002272003 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 21002272004 | 2 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223416 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223423 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20000606019 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187003 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187006 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187014 | 3 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 21002272003 | 2 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 22003039002 | 1 |
| Caesar & Loretz GmbH/S | Octenidine dihydrochloride | 20004187016 | 1 |
| Caesar & Loretz GmbH/Sana | Octenidine dihydrochloride | 18223415 | 1 |
| Caesar & Loretz GmbH/Sana | Octenidine dihydrochloride | 20000606006 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223411 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223415 | 2 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 18223427 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187001 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187003 | 1 |
| Caesar & Loretz GmbH… | Octenidine dihydrochloride | 20004187016 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 15006210 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 17218509 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18017404 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 181975002 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18197502 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223403 | 3 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223404 | 3 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223409 | 3 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223411 | 4 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223413 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223415 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223416 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223419 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223420 | 3 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223423 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223424 | 7 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223426 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223427 | 4 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 18223428 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 200006001 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606001 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606002 | 9 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606005 | 9 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606006 | 13 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606007 | 3 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606009 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606010 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606011 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606012 | 10 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606015 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606016 | 3 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606019 | 19 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20000606022 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 200006066005 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187001 | 12 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187002 | 18 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187003 | 13 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187006 | 4 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187009 | 6 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187010 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187011 | 11 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187012 | 8 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187013 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187014 | 7 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187015 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187016 | 9 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 20004187017 | 9 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272002 | 12 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272003 | 10 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272004 | 10 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272006 | 4 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272009 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272011 | 3 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272012 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272014 | 7 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272018 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272020 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272022 | 8 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272024 | 5 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 21002272025 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 22003039002 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 22003039003 | 1 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 22003039004 | 2 |
| Caesar & Loretz GmbH | Octenidine dihydrochloride | 22003039005 | 5 |
| Caesar & Loretz Hild... | Octenidine dihydrochloride | 20000606005 | 2 |
| Caesar & Loretz Hild... | Octenidine dihydrochloride | 18223413 | 1 |
| Caesar & Loretz Hild... | Octenidine dihydrochloride | 183223424 | 1 |
| Caesar & Loretz Hild... | Octenidine dihydrochloride | 20000606012 | 1 |
| Caesar & Loretz Hild... | Octenidine dihydrochloride | 20000606019 | 1 |
| Caesar & Loretz Hilden | Octenidine dihydrochloride | 18223403 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz Hilden | Octenidine dihydrochloride | 18223416 | 1 |
| Caesar & Loretz Hilden | Octenidine dihydrochloride | 20000606006 | 2 |
| Caesar & Loretz/AHD | Octenidine dihydrochloride | 20000606001 | 1 |
| Caesar & Loretz/Noweda | Octenidine dihydrochloride | 20000606019 | 1 |
| Caesar & Loretz/Noweda | Octenidine dihydrochloride | 20004187002 | 1 |
| Caesar & Loretz | Octenidine dihydrochloride | 232215 | 1 |
| Caesar&Lorenz / Gehe | Octenidine dihydrochloride | 18223419 | 1 |
| Caesar&Lorenz/AHD | Octenidine dihydrochloride | 17218508 | 1 |
| Caesar&Lorenz | Octenidine dihydrochloride | 2000487017 | 1 |
| Caesar&Loretz GmbH, ... | Octenidine dihydrochloride | 17042302 | 1 |
| Caesar&Loretz GmbH | Octenidine dihydrochloride | 16335504 | 1 |
| Caesar&Loretz GmbH | Octenidine dihydrochloride | 20000606011 | 1 |
| Caesar&Loretz GmbH | Octenidine dihydrochloride | 21002272011 | 1 |
| Caleo/ Fiebig | Octenidine dihydrochloride | 17218508 | 2 |
| CALEO/Noweda | Octenidine dihydrochloride | 20000606006 | 1 |
| Caleo | Octenidine dihydrochloride | 16033001 | 1 |
| Caleo | Octenidine dihydrochloride | 18197504 | 1 |
| Caleo | Octenidine dihydrochloride | 18223409 | 1 |
| Caleo | Octenidine dihydrochloride | 20004187001 | 2 |
| Caleo | Octenidine dihydrochloride | 2000606001 | 1 |
| Calo, Hilden/ Phönix | Octenidine dihydrochloride | 20004187012 | 1 |
| Calo/Gehe | Octenidine dihydrochloride | 16335508 | 1 |
| Calo/Gehe | Octenidine dihydrochloride | 18223404 | 1 |
| carelo | Octenidine dihydrochloride | 22003039005 | 1 |
| Cealo / Anzag | Octenidine dihydrochloride | 221019(21002272003) | 1 |
| Cealo / Anzag | Octenidine dihydrochloride | 230221(21002272018) | 1 |
| Cealo/Anzag | Octenidine dihydrochloride | 211203(20004187015) | 1 |
| Cealo/Sanacorp | Octenidine dihydrochloride | 15006207 | 1 |
| Cealo/Sanacorp | Octenidine dihydrochloride | 16325305 | 1 |
| Cealo | Octenidine dihydrochloride | 17218507 | 1 |
| Cealo | Octenidine dihydrochloride | 20000606001 | 1 |
| Cealo5440 | Octenidine dihydrochloride | 17218501 | 1 |
| Ceasar & Loretz GmbH... | Octenidine dihydrochloride | 16335509 | 1 |
| Ceasar & Loretz | Octenidine dihydrochloride | 20004187012 | 3 |
| Celo | Octenidine dihydrochloride | 16277802 | 1 |
| Celo | Octenidine dihydrochloride | 20000606006 | 2 |
| Ebert & Jacobi | Octenidine dihydrochloride | 16032902 | 1 |
| Ebert & Jacobi | Octenidine dihydrochloride | 16325406 | 1 |
| EuRho/ AHD | Octenidine dihydrochloride | 17218507 | 1 |
| EuRho/Sanacorp | Octenidine dihydrochloride | 16335508 | 1 |
| Euro OTC | Octenidine dihydrochloride | 16032803 | 1 |
| Euro OTC | Octenidine dihydrochloride | 17218501 | 1 |
| Euro OTC | Octenidine dihydrochloride | 18223404 | 1 |
| Euro OTC | Octenidine dihydrochloride | 18223413 | 4 |
| Euro OTC | Octenidine dihydrochloride | 20004187014 | 1 |
| Fagron | Octenidine dihydrochloride | 15356601 | 1 |
| Fagron | Octenidine dihydrochloride | 15356703 | 1 |
| Fagron | Octenidine dihydrochloride | 16277802 | 1 |
| Fagron | Octenidine dihydrochloride | 16335507 | 1 |
| Fagron | Octenidine dihydrochloride | 16335510 | 1 |
| Fagron | Octenidine dihydrochloride | 18017402 | 1 |
| Fagron | Octenidine dihydrochloride | 18223403 | 2 |
| Fagron | Octenidine dihydrochloride | 187223403 | 1 |
| Fagron | Octenidine dihydrochloride | 18A12-B03-346964 | 1 |
| Ferak / Caesar & Lor... | Octenidine dihydrochloride | 18197502 | 1 |
| Ferak Berlin GmbH/ AHD | Octenidine dihydrochloride | 20000620002 | 1 |
| Ferak/Noweda | Octenidine dihydrochloride | 202120 | 1 |
| Ferak/Phoenix | Octenidine dihydrochloride | 62120 | 1 |
| Fiebig | Octenidine dihydrochloride | 18017402 | 1 |
| Fiebig | Octenidine dihydrochloride | 20000606009 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fresenius | Octenidine dihydrochloride | 60715101 | 1 |
| Gehe 21-01-2019 | Octenidine dihydrochloride | 18223403 | 1 |
| Gehe amax | Octenidine dihydrochloride | 15356603 | 1 |
| Gehe amax | Octenidine dihydrochloride | 15356703 | 1 |
| Gehe amax | Octenidine dihydrochloride | 16325305 | 1 |
| Gehe amax | Octenidine dihydrochloride | 17042305 | 1 |
| Gehe amax | Octenidine dihydrochloride | 17218509 | 1 |
| Gehe amax | Octenidine dihydrochloride | 18197501 | 1 |
| Gehe amax | Octenidine dihydrochloride | 20000606006 | 1 |
| Gehe Rostock | Octenidine dihydrochloride | 18223427 | 1 |
| Gehe Rostock | Octenidine dihydrochloride | 21002272022 | 1 |
| Gehe | Octenidine dihydrochloride | 16032909 | 2 |
| GEHE | Octenidine dihydrochloride | 16325304 | 1 |
| GEHE | Octenidine dihydrochloride | 16325305 | 1 |
| Gehe | Octenidine dihydrochloride | 16335502 | 1 |
| gehe | Octenidine dihydrochloride | 17042602 | 1 |
| Gehe | Octenidine dihydrochloride | 17042903 | 1 |
| Gehe | Octenidine dihydrochloride | 17218501 | 1 |
| Gehe | Octenidine dihydrochloride | 17218508 | 1 |
| GEHE | Octenidine dihydrochloride | 17218509 | 1 |
| Gehe | Octenidine dihydrochloride | 172218508 | 1 |
| Gehe | Octenidine dihydrochloride | 18017402 | 2 |
| Gehe | Octenidine dihydrochloride | 18223401 | 1 |
| Gehe | Octenidine dihydrochloride | 18223403 | 1 |
| Gehe | Octenidine dihydrochloride | 18223419 | 1 |
| Gehe | Octenidine dihydrochloride | 18223424 | 1 |
| Gehe | Octenidine dihydrochloride | 20000606018 | 1 |
| Gehe | Octenidine dihydrochloride | 20004187003 | 1 |
| Gehe | Octenidine dihydrochloride | 20004187013 | 2 |
| gehe | Octenidine dihydrochloride | 20004187016 | 1 |
| Gehe | Octenidine dihydrochloride | 20004187016 | 1 |
| Gehe | Octenidine dihydrochloride | 21002272018 | 1 |
| Gehe | Octenidine dihydrochloride | 21002272022 | 1 |
| Gehe | Octenidine dihydrochloride | 21002272024 | 1 |
| Gehe | Octenidine dihydrochloride | 22003039002 | 2 |
| Gehe | Octenidine dihydrochloride | 22003039004 | 1 |
| Gehe | Octenidine dihydrochloride | 22003039005 | 7 |
| Gehe | Octenidine dihydrochloride | 22003039006 | 1 |
| Gehe | Octenidine dihydrochloride | 22003039009 | 1 |
| Gehe | Octenidine dihydrochloride | 23002809003 | 1 |
| Gehe | Octenidine dihydrochloride | 23002809004 | 1 |
| Hepart | Octenidine dihydrochloride | 17218508 | 1 |
| Jenne | Octenidine dihydrochloride | 17218507 | 1 |
| JENNE | Octenidine dihydrochloride | 17218508 | 1 |
| Jenne | Octenidine dihydrochloride | 18223416 | 1 |
| Jenne | Octenidine dihydrochloride | 20004187009 | 1 |
| Jenne | Octenidine dihydrochloride | 22003039009 | 1 |
| Jenne | Octenidine dihydrochloride | 240321(23002809002) | 1 |
| Jenne | Octenidine dihydrochloride | 240418(23002809003) | 1 |
| Kehr | Octenidine dihydrochloride | 17218508 | 1 |
| Kehr | Octenidine dihydrochloride | 21002272014 | 1 |
| Kehr | Octenidine dihydrochloride | 21002272018 | 2 |
| Kehr | Octenidine dihydrochloride | 22003039002 | 2 |
| Kehr | Octenidine dihydrochloride | 22003039003 | 1 |
| Kehr | Octenidine dihydrochloride | 22003039004 | 1 |
| Kehr | Octenidine dihydrochloride | 22003039005 | 5 |
| Kehr | Octenidine dihydrochloride | 22003039009 | 1 |
| kehr | Octenidine dihydrochloride | 23002809002 | 1 |
| Kehr | Octenidine dihydrochloride | 23002809002 | 1 |
| Kehr | Octenidine dihydrochloride | 23002809007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Kehr-Holdermann | Octenidine dihydrochloride | 22003039008 | 1 |
| Krieger | Octenidine dihydrochloride | 20000606019 | 1 |
| Krieger | Octenidine dihydrochloride | 3132 | 1 |
| Löwen City-Apotheke ... | Octenidine dihydrochloride | 2042015 | 1 |
| Noweda /Cealo | Octenidine dihydrochloride | 20000606006 | 1 |
| Noweda | Octenidine dihydrochloride | 16335507 | 1 |
| Noweda | Octenidine dihydrochloride | 17218501 | 1 |
| Noweda | Octenidine dihydrochloride | 18197502 | 2 |
| Noweda | Octenidine dihydrochloride | 18223403 | 1 |
| Noweda | Octenidine dihydrochloride | 18223415 | 1 |
| Noweda | Octenidine dihydrochloride | 18223420 | 2 |
| Noweda | Octenidine dihydrochloride | 1822419 | 1 |
| Noweda | Octenidine dihydrochloride | 20000606019 | 1 |
| Noweda | Octenidine dihydrochloride | 20004187001 | 1 |
| Noweda | Octenidine dihydrochloride | 20004187016 | 2 |
| Noweda | Octenidine dihydrochloride | 20004187017 | 1 |
| Noweda | Octenidine dihydrochloride | 2004187009 | 1 |
| Noweda | Octenidine dihydrochloride | 21002272003no | 1 |
| Noweda | Octenidine dihydrochloride | 21002272012 | 1 |
| Noweda | Octenidine dihydrochloride | 21002272014 | 1 |
| Noweda | Octenidine dihydrochloride | 21002272024 | 2 |
| Noweda | Octenidine dihydrochloride | 220030309005 | 1 |
| Noweda | Octenidine dihydrochloride | 22003039002 | 4 |
| Noweda | Octenidine dihydrochloride | 22003039004 | 1 |
| Noweda | Octenidine dihydrochloride | 22003039005 | 10 |
| Noweda | Octenidine dihydrochloride | 22003039006 | 1 |
| noweda | Octenidine dihydrochloride | 22003039008 | 1 |
| Noweda | Octenidine dihydrochloride | 22003039008 | 1 |
| Noweda | Octenidine dihydrochloride | 22003039009 | 1 |
| Noweda | Octenidine dihydrochloride | 23002809003 | 6 |
| Noweda | Octenidine dihydrochloride | 23002809004 | 1 |
| Noweda | Octenidine dihydrochloride | 23002809007 | 1 |
| Phenix | Octenidine dihydrochloride | 23002809003 | 1 |
| Pheonix | Octenidine dihydrochloride | 17218509 | 1 |
| Phö | Octenidine dihydrochloride | 22003039005 | 1 |
| Phoenix | Octenidine dihydrochloride | 17218506 | 1 |
| Phoenix | Octenidine dihydrochloride | 18223415 | 2 |
| Phoenix | Octenidine dihydrochloride | 20000606016 | 1 |
| Phoenix | Octenidine dihydrochloride | 20004187003 | 2 |
| Phoenix | Octenidine dihydrochloride | 20004187016 | 1 |
| Phoenix | Octenidine dihydrochloride | 22003039002 | 1 |
| Phoenix | Octenidine dihydrochloride | 22003039004 | 1 |
| Phoenix | Octenidine dihydrochloride | 22003039005 | 8 |
| Phoenix | Octenidine dihydrochloride | 22003039008 | 1 |
| Phoenix | Octenidine dihydrochloride | 23002809004 | 1 |
| Phoenix | Octenidine dihydrochloride | 23002809006 | 1 |
| Phoenix | Octenidine dihydrochloride | 24002081002 | 1 |
| Phoenix | Octenidine dihydrochloride | 3033 | 1 |
| Phoenix | Octenidine dihydrochloride | 3040 | 1 |
| Phoenix | Octenidine dihydrochloride | 3107 | 1 |
| Phoenix | Octenidine dihydrochloride | 3113 | 1 |
| Phoenix | Octenidine dihydrochloride | 3221 | 1 |
| Phoenix | Octenidine dihydrochloride | 3419 | 1 |
| Phoenix | Octenidine dihydrochloride | 3423 | 1 |
| Phönix Gotha | Octenidine dihydrochloride | 17218508 | 1 |
| Phönix | Octenidine dihydrochloride | 17218506 | 1 |
| Phönix | Octenidine dihydrochloride | 20000606011 | 1 |
| Phönix | Octenidine dihydrochloride | 20004187006 | 1 |
| Phönix | Octenidine dihydrochloride | 20004187013 | 1 |
| Phönix | Octenidine dihydrochloride | 2000606019 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| PHÖNIX | Octenidine dihydrochloride | 21002272002 | 1 |
| Phönix | Octenidine dihydrochloride | 21002272006 | 1 |
| Phönix | Octenidine dihydrochloride | 21002272018 | 1 |
| Phönix | Octenidine dihydrochloride | 22003039002 | 6 |
| Phönix | Octenidine dihydrochloride | 22003039004 | 1 |
| phönix | Octenidine dihydrochloride | 22003039005 | 1 |
| Phönix | Octenidine dihydrochloride | 22003039005 | 5 |
| Phönix | Octenidine dihydrochloride | 22003039009 | 1 |
| Phönix | Octenidine dihydrochloride | 23002809002 | 3 |
| Phönix | Octenidine dihydrochloride | 23002809003 | 1 |
| Phönix | Octenidine dihydrochloride | 23002809004 | 8 |
| Phönix | Octenidine dihydrochloride | 3155 | 1 |
| sanacorb | Octenidine dihydrochloride | 18197502 | 1 |
| Sanacorb | Octenidine dihydrochloride | 22003039002 | 1 |
| Sanacorp | Octenidine dihydrochloride | 16335504 | 1 |
| Sanacorp | Octenidine dihydrochloride | 17218509 | 1 |
| Sanacorp | Octenidine dihydrochloride | 18223426 | 1 |
| Sanacorp | Octenidine dihydrochloride | 21002272012 | 1 |
| Sanacorp | Octenidine dihydrochloride | 22003039002 | 3 |
| Sanacorp | Octenidine dihydrochloride | 22003039005 | 1 |
| Sanacorp | Octenidine dihydrochloride | 23002809004 | 1 |
| Spangro | Octenidine dihydrochloride | 17042305 | 1 |

- 253 783 spectra from 1666 *Apo-Ident* customers from a total of 51 859 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Octenidine dihydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Octenidine dihydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 620 | 0 | 157 706 |
| **Type B** | 0 | 520 | 0 | 212 420 |
| **Type C** | 0 | 3072 | 31 | 253 783 |

The substance/substance group *Octenidine dihydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0323 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8462 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.0010 % (> 98.9043 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to

exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20759 | 27110 | 8.84 | 167.53 |
| 20988 | 20988 | 0.00 | 164.24 |
| 21331 | 21947 | 19.99 | 175.89 |
| 21888 | 21947 | 3.45 | 165.25 |
| 21947 | 21947 | 0.00 | 168.10 |
| 23307 | 23307 | 0.00 | 176.95 |
| 23309 | 23309 | 0.00 | 167.90 |
| 24597 | 27110 | 8.71 | 167.79 |
| 27110 | 27110 | 0.00 | 167.86 |
| 27444 | 27444 | 0.00 | 174.16 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ofloxacin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21047-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ofloxacin; Ofloxacinum

### Special notes

When selecting the *Ofloxacin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ofloxacin | 4 | 2 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Ofloxacin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ofloxacin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Calcium colamine phosphate | 79.14 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ofloxacin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ofloxacin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ofloxacin | 13A17-N01 | 21047 | 40 | 1403155 |
| Fagron | Ofloxacin | 13A17-N01 | 21052 | 40 | 20130123 |
| Fagron | Ofloxacin | 13A17-N01 | 21811 | 60 | 20130123 |
| Fagron | Ofloxacin | 15H19-B01-312926 | 21918 | 60 | 20151006 |
| Fagron | Ofloxacin | 15H19-B01-325226 | 23090 | 40 | 1707611 |
| Fagron | Ofloxacin | 18J30-B01-360431 | 24598 | 40 | 20190419 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 280 spectra of 6 reference samples from the substance/substance group *Ofloxacin*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 046 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this


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entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Ofloxacin*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Ofloxacin | 15H19-B01-337265 | 23753 | 40 |
| Fagron | Ofloxacin | 22L30-B09-218540 | 26915 | 40 |
| Fagron | Ofloxacin | 15H19-B01-337265 | 23754 | 40 |
| Fagron | Ofloxacin | 22L30-B09-218540 | 26915SI | 20 |

- 212 800 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 17 spectra from 12 *Apo-Ident* customers from 13 batches from the substance/substance group *Ofloxacin*.
- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ofloxacin | 22L30-B09-218540 | 1 |
| Caelo | Ofloxacin | 15H19-B01 | 1 |
| Fagron | Ofloxacin | 13A17-N01 | 2 |
| Fagron | Ofloxacin | 15H19-B01-314470 | 1 |
| Fagron | Ofloxacin | 15H19-B01-318532 | 1 |
| Fagron | Ofloxacin | 15H19-B01-337265 | 1 |
| Fagron | Ofloxacin | 15H1-OF-M20150401B | 1 |
| Fagron | Ofloxacin | 18J30-B01 | 2 |
| Fagron | Ofloxacin | 18J30-B01_363954 | 1 |
| Fagron | Ofloxacin | 18J30-B01-363954 | 3 |
| Fagron | Ofloxacin | B01-3619609 | 1 |
| Fagron | Ofloxacin | B01-3639504 | 1 |
| Fragon | Ofloxacin | 15H19-B01-343412 | 1 |

- 256 869 spectra from 1666 *Apo-Ident* customers from a total of 52 140 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ofloxacin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ofloxacin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 17 | 0 | 256 869 |

The substance/substance group *Ofloxacin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21047 | 21047 | 0.00 | 168.23 |
| 21052 | 21047 | 7.00 | 167.36 |
| 21811 | 23090 | 19.16 | 146.80 |
| 21918 | 23090 | 16.31 | 148.09 |
| 23090 | 23090 | 0.00 | 169.14 |
| 24598 | 23090 | 10.11 | 169.11 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at


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least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Omeprazole** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21098-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Omeprazole; Omeprazolum

### Special notes

When selecting the *Omeprazole* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Omeprazole | 6 | 3 | 148 |

### Second-stage model

For differentiation of the substance/substance group *Omeprazole* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Omeprazole* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cyproterone acetate | 97.03 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Omeprazole* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Omeprazole*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Omeprazole | 15K12-B02-314608 | 22740 | 40 | 20151124 |
| Fagron | Omeprazole | 15K12-B02-314608 | 22890 | 40 | 20151124 |
| Fagron | Omeprazole | 19F14-B01-362735 | 24768 | 40 | 1910227 |
| Fagron | Omeprazole | 20F18-F21-375443 | 25582 | 40 | 20200715 |
| Fagron | Omeprazole | 22G08-B01-221106 | 26384 | 40 | 20220714 |
| Fagron | Omeprazole | 22L08-B02-225402 | 26539 | 40 | 20221228 |
| Inresa | Omeprazole | OPFP14017 | 21787 | 60 | 1507407 |
| Inresa | Omeprazole | OPFP14017 | 21796 | 60 | 20140228 |
| Inresa | Omeprazole | OPFP14017 | 22284 | 60 | 20140528 |
| Inresa | Omeprazole | OPFP14017 | 23273 | 40 | 20150428 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 460 spectra of 10 reference samples from the substance/substance group *Omeprazole*. These samples are listed above in the *calibration samples* section. The reference samples come from 6


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different batches.

- 157 866 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 6 reference samples from the substance/substance group *Omeprazole*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Omeprazole | 16I20-B03-328940 | 23272 | 40 |
| Fagron | Omeprazole | 18K01-B03-358185 | 24583 | 40 |
| Fagron | Omeprazole | 22C31-B01-218818 | 26151 | 40 |
| Fagron | Omeprazole | 22C31-B01-218818 | 26151SI | 20 |
| Fagron | Omeprazole | 22G08-B01-221106 | 26384SI† | 20 |
| Fagron | Omeprazole | 22L08-B02-225402 | 26539SI† | 20 |

- 212 760 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 628 spectra from 225 *Apo-Ident* customers from 163 batches from the substance/substance group *Omeprazole*.

- Among them are spectra of independent samples from 148 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Omeprazole | | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Omeprazole | 20F18-F21-371963 | 1 |
| | Omeprazole | 20J27-F02-526599 | 1 |
| | Omeprazole | 21D08-F03-526980 | 2 |
| | Omeprazole | 22C31-B01-218818 | 3 |
| | Omeprazole | 22G08-B01-221106 | 3 |
| | Omeprazole | 22G-08-B01-221106 | 1 |
| | Omeprazole | 22L08_B02_225421 | 1 |
| | Omeprazole | 22L08-B02-225402 | 29 |
| | Omeprazole | 22L08-B02-22540257/23P | 1 |
| | Omeprazole | 22L08-B02-225421 | 2 |
| | Omeprazole | 23C16-B08-227714 | 2 |
| | Omeprazole | 23C16-B08-230403 | 3 |
| | Omeprazole | 23C16-B08-230663 | 1 |
| | Omeprazole | 23C16-B08-230664 | 5 |
| | Omeprazole | 23C16-B08-234655 | 3 |
| | Omeprazole | 23G31-B06-232416 | 4 |
| | Omeprazole | 23H09-B05-234459 | 2 |
| | Omeprazole | 23H09-B05-235015 | 1 |
| | Omeprazole | 24E11-B02-004834 | 1 |
| | Omeprazole | 24E11-B02-004857 | 3 |
| | Omeprazole | B01-2867002 | 1 |
| | Omeprazole | B05-2346606 | 1 |
| | Omeprazole | B06-2324106 | 1 |
| | Omeprazole | B08-2277104 | 1 |
| | Omeprazole | B08-2346505 | 8 |
| | Omeprazole | B08-234655 | 1 |
| | Omeprazole | BO8-2277104 | 1 |
| | Omeprazole | F03-5269800 | 1 |
| | Omeprazole | OPFP21008 | 1 |
| | Omeprazole | OPFP21028 | 3 |
| | Omeprazole | OZ23010 | 2 |
| AHD | Omeprazole | 22L08-B02-225402 | 4 |
| Alliance Healthcare | Omeprazole | 20F18-F21-375443 | 1 |
| Caelo | Omeprazole | 15k12b022314608 | 1 |
| Caelo | Omeprazole | 15K12B02314608 | 1 |
| Caelo | Omeprazole | 16l20-B03-329040 | 1 |
| Caelo | Omeprazole | 17H15-B03 | 1 |
| Caelo | Omeprazole | 17H15-B03-340200 | 2 |
| Caelo | Omeprazole | 17H15-B03342821 | 1 |
| Caelo | Omeprazole | 18E22-B03-353496 | 1 |
| Caelo | Omeprazole | 18K01-B03-358185 | 1 |
| Caelo | Omeprazole | 19F14-B01 | 1 |
| Caelo | Omeprazole | 20f18-f21-371963 | 1 |
| Caelo | Omeprazole | 21/01-B05-213885 | 1 |
| Caelo | Omeprazole | 21D08-F03-526829 | 1 |
| Caelo | Omeprazole | 22444 | 2 |
| Fagrin/Noweda | Omeprazole | 21D08-F03-526829 | 1 |
| Fagron | Omeprazole | | 1 |
| Fagron | Omeprazole | 15B26-B40-305669 | 2 |
| Fagron | Omeprazole | 15k12-B02 | 1 |
| Fagron | Omeprazole | 15K12-B02 | 2 |
| Fagron | Omeprazole | 15K12-B02-314608 | 7 |
| Fagron | Omeprazole | 15K12-B02-525174 | 2 |
| Fagron | Omeprazole | 16/20-B03 | 1 |
| Fagron | Omeprazole | 16/20-B03-328940 | 4 |
| Fagron | Omeprazole | 16B16-B01-52535 | 1 |
| Fagron | Omeprazole | 16I20-B03-328940 | 7 |
| Fagron | Omeprazole | 16J20-B03-328940 | 1 |
| Fagron | Omeprazole | 16l20-B03-328940 | 1 |
| Fagron | Omeprazole | 17B28-B02 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Omeprazole | 17B28-B02-525511 | 2 |
| Fagron | Omeprazole | 17-B28-B02-525511 | 1 |
| Fagron | Omeprazole | 17B28-B02-525557 | 3 |
| Fagron | Omeprazole | 17H15-B03 | 2 |
| Fagron | Omeprazole | 17H15-B03-340200 | 1 |
| Fagron | Omeprazole | 17h15-b03-342821 | 1 |
| Fagron | Omeprazole | 17H15B03342821 | 1 |
| Fagron | Omeprazole | 17H15-B03-342821 | 18 |
| Fagron | Omeprazole | 17h15b0334821 | 1 |
| Fagron | Omeprazole | 17K28-B07 | 2 |
| Fagron | Omeprazole | 17k28b07348698 | 1 |
| Fagron | Omeprazole | 17K28-B07-348698 | 22 |
| Fagron | Omeprazole | 17K28-B07-3486998 | 1 |
| Fagron | Omeprazole | 18E22-B03 | 1 |
| Fagron | Omeprazole | 18e22b03353496 | 1 |
| Fagron | Omeprazole | 18E22B03353496 | 1 |
| Fagron | Omeprazole | 18E22-B03-353496 | 12 |
| Fagron | Omeprazole | 18e22-b03-353496 | 1 |
| Fagron | Omeprazole | 18K01-B03 | 2 |
| Fagron | Omeprazole | 18K01B03358185 | 2 |
| Fagron | Omeprazole | 18K01-B03-358185 | 16 |
| Fagron | Omeprazole | 18K01-B03-358186 | 2 |
| Fagron | Omeprazole | 19F14 | 1 |
| Fagron | Omeprazole | 19F14-B01 | 4 |
| Fagron | Omeprazole | 19F14-B01-362735 | 14 |
| Fagron | Omeprazole | 19f14-B01-363425 | 1 |
| Fagron | Omeprazole | 19F14B01363425 | 1 |
| Fagron | Omeprazole | 19F14-B01-363425 | 14 |
| Fagron | Omeprazole | 19F14-B01-363427 | 1 |
| Fagron | Omeprazole | 19F14-B01-36345 | 2 |
| Fagron | Omeprazole | 19F14-B01-526150 | 4 |
| Fagron | Omeprazole | 19F14B01526150Set19L06-Ko2 | 1 |
| Fagron | Omeprazole | 19F-B01-363425 | 1 |
| Fagron | Omeprazole | 19J29-F03 | 2 |
| Fagron | Omeprazole | 19J29-F03-367825 | 13 |
| Fagron | Omeprazole | 19L09-K02 | 1 |
| Fagron | Omeprazole | 20A16-F02 | 7 |
| Fagron | Omeprazole | 20A16-F02-367834 | 3 |
| Fagron | Omeprazole | 20A16-F02-368827 | 9 |
| Fagron | Omeprazole | 20A16-F02-368828 | 2 |
| Fagron | Omeprazole | 20A16-FO2-368827 | 1 |
| Fagron | Omeprazole | 20A416-F02-368827 | 1 |
| Fagron | Omeprazole | 20F18-F21 | 5 |
| Fagron | Omeprazole | 20F18-F21-371963 | 24 |
| Fagron | Omeprazole | 20F18-F21-3754403 | 1 |
| Fagron | Omeprazole | 20F18F21375443 | 1 |
| Fagron | Omeprazole | 20F18-F21-375443 | 32 |
| Fagron | Omeprazole | 20F18-F21-526401 | 3 |
| Fagron | Omeprazole | 20J27-F02 | 3 |
| Fagron | Omeprazole | 20J27-F02-376140 | 1 |
| Fagron | Omeprazole | 20J27-F02-526487 | 2 |
| Fagron | Omeprazole | 20j27-f02-526599 | 1 |
| Fagron | Omeprazole | 20J27-F02-526599 | 5 |
| Fagron | Omeprazole | 20J27F-F02-376140 | 1 |
| Fagron | Omeprazole | 21/01-B05-213885 | 2 |
| Fagron | Omeprazole | 2101-B05-213885 | 1 |
| Fagron | Omeprazole | 21101-B05-213885 | 1 |
| Fagron | Omeprazole | 21101-BO5-213885 | 2 |
| Fagron | Omeprazole | 21C30-B03 | 1 |
| Fagron | Omeprazole | 21C30-B03-215335 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Omeprazole | 21D08-F03_526829 | 1 |
| Fagron | Omeprazole | 21D08F03526829 | 1 |
| Fagron | Omeprazole | 21D08-F03-526829 | 5 |
| Fagron | Omeprazole | 21D08-F03-526980 | 2 |
| Fagron | Omeprazole | 21H04-B12-213937 | 2 |
| Fagron | Omeprazole | 21I01-B05 | 3 |
| Fagron | Omeprazole | 21I01-B05_213885 | 1 |
| Fagron | Omeprazole | 21I01-B05-213885 | 36 |
| Fagron | Omeprazole | 21I01-B05-217276 | 3 |
| Fagron | Omeprazole | 21I1-B05 | 1 |
| Fagron | Omeprazole | 21l01-B05-21028 | 1 |
| Fagron | Omeprazole | 21l01-B05-213885 | 4 |
| Fagron | Omeprazole | 21O01-B05-213885 | 1 |
| Fagron | Omeprazole | 22C31-B01 | 1 |
| Fagron | Omeprazole | 22C31-B01_218818 | 1 |
| Fagron | Omeprazole | 22C31-B01-218672 | 2 |
| Fagron | Omeprazole | 22c31-b01-218818 | 1 |
| Fagron | Omeprazole | 22C31B01218818 | 1 |
| Fagron | Omeprazole | 22C31B-01-218818 | 1 |
| Fagron | Omeprazole | 22C31-B01-218818 | 32 |
| Fagron | Omeprazole | 22C31-B01-21888 | 1 |
| Fagron | Omeprazole | 22C31-BO1-218818 | 3 |
| Fagron | Omeprazole | 22G08-B01 | 1 |
| Fagron | Omeprazole | 22G08-B01-221106 | 19 |
| Fagron | Omeprazole | 22L08-B02_225402 | 1 |
| Fagron | Omeprazole | 22L08-B02-225402 | 8 |
| Fagron | Omeprazole | 22L08-BO2-2225402 | 1 |
| Fagron | Omeprazole | 2OF18-F21-371963 | 1 |
| Fagron | Omeprazole | 2OF18-F21-375443 | 1 |
| Fagron | Omeprazole | 70192525 | 1 |
| Fagron | Omeprazole | 73590-58-6 | 1 |
| Fagron | Omeprazole | b01-2188108 | 1 |
| Fagron | Omeprazole | B01-3634205 | 2 |
| Fagron | Omeprazole | B01-526150 | 2 |
| Fagron | Omeprazole | B05-2138805 | 3 |
| Fagron | Omeprazole | B05-213885 | 1 |
| Fagron | Omeprazole | F02-3678304 | 2 |
| Fagron | Omeprazole | F02-3688207 | 1 |
| Fagron | Omeprazole | F02-3761400 | 1 |
| Fagron | Omeprazole | F03-3678205 | 5 |
| Fagron | Omeprazole | F03-5268209 | 1 |
| Fagron | Omeprazole | F21-3719603 | 3 |
| Fagron | Omeprazole | F21-3719605 | 1 |
| Fagron | Omeprazole | F21-3754403 | 1 |
| Fagron | Omeprazole | OPFP16030 | 1 |
| Fagron | Omeprazole | OPFP17033 | 3 |
| Fagron | Omeprazole | OPFP18052 | 2 |
| Fagron | Omeprazole | OPFP18052/18K01-B03-358185 | 1 |
| Fagron | Omeprazole | OPFP19002 | 3 |
| Fagron | Omeprazole | OPFP19002/19F14-B01-526150 | 1 |
| Fagron | Omeprazole | OPFP19017 | 1 |
| Fagron | Omeprazole | OPFP20024 | 7 |
| Fagron | Omeprazole | OPFP21028 | 4 |
| Fargon/AHD | Omeprazole | 17K28-B07 | 1 |
| Fargon/AHD | Omeprazole | 18K01-B03 | 1 |
| Fargon/Fiebig | Omeprazole | 18K01-B03 | 1 |
| Fargon/Phönix | Omeprazole | 21I01-B05-213885 | 1 |
| Fargon | Omeprazole | 19J29-F03-367825 | 1 |
| Ferdinand Eimermacher | Omeprazole | 4271019 | 1 |
| Fiebig | Omeprazole | 22L08-B02-225402 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fragon | Omeprazole | 17K28-B07-348698 | 1 |
| Gehe | Omeprazole | 17H15-B03-342821 | 1 |
| Gehe | Omeprazole | 22G08-B01-221106 | 1 |
| Lee Pharma Limited/ Gehe | Omeprazole | 19F14-B01-363425 | 2 |
| Lee Pharma Ltd. | Omeprazole | 21101-B05-213885 | 1 |
| Noveda | Omeprazole | 21D08-F03-526980 | 1 |
| Noweda | Omeprazole | 15K15-B02-314608 | 1 |
| Noweda | Omeprazole | 17H15-B03-342821 | 3 |
| noweda | Omeprazole | 19j29-f03-367825 | 1 |
| Noweda | Omeprazole | 21D08-F03-526980 | 2 |
| Noweda | Omeprazole | 22G08-B01-221106 | 1 |
| Noweda | Omeprazole | 22L08-B02-225402 | 2 |
| Phoenix | Omeprazole | 18E22-B03-353496 | 4 |
| Phönix | Omeprazole | 17K28-B07-348698 | 2 |
| Phönix | Omeprazole | 20A16-F02-368827 | 1 |
| Phönix | Omeprazole | 21I01B05213885 | 1 |
| Sanacorp | Omeprazole | 17H15-B03-342821 | 1 |
| SANACORP | Omeprazole | 21I01-B05-213885 | 1 |
| Sanacorp | Omeprazole | 22L08B02225402 | 1 |

- 256 258 spectra from 1666 *Apo-Ident* customers from a total of 51 990 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Omeprazole* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Omeprazole* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 460 | 0 | 157 866 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 603 | 25 | 256 258 |

The substance/substance group *Omeprazole* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6957 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 96.0191 % (> 95.5414 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21787 | 21787 | 0.00 | 97.28 |
| 21796 | 21787 | 4.77 | 98.82 |
| 22284 | 21787 | 4.60 | 96.16 |
| 22740 | 21787 | 15.13 | 94.03 |
| 22890 | 21787 | 14.91 | 98.02 |
| 23273 | 21787 | 7.02 | 101.43 |
| 24768 | 24768 | 0.00 | 122.65 |
| 25582 | 21787 | 7.68 | 102.48 |
| 26384 | 21787 | 5.65 | 96.77 |
| 26539 | 21787 | 5.40 | 97.34 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ornithine aspartate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20842-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ornithine aspartate; Ornithini aspartas

### Special notes

When selecting the *Ornithine aspartate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ornithine aspartate | 9 | 4 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Ornithine aspartate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ornithine aspartate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 79.64 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ornithine aspartate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ornithine aspartate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Ornithine aspartate | 1312030-01 | 21710 | 60 | 1506280 |
| Euro OTC | Ornithine aspartate | 1611018 | 22924 | 40 | 20161213* |
| Euro OTC | Ornithine aspartate | 1611018-01 | 23198 | 40 | 20161213 |
| Euro OTC | Ornithine aspartate | 2301047 | 26592 | 40 | 20230307* |
| Euro OTC | Ornithine aspartate | 2307023 | 26877 | 40 | 20230804* |
| Euro OTC | Ornithine aspartate | 2404004 | 27404 | 40 | 20241104* |
| Fagron | Ornithine aspartate | 14A20-B07-296093 | 21694 | 45 | 1506279 |
| Fagron | Ornithine aspartate | 14I24-B04-307758 | 22599 | 40 | 20141110 |
| Fagron | Ornithine aspartate | 14I24-B04-307758 | 22600 | 40 | 20141110 |
| Fagron | Ornithine aspartate | 17I21-B05-342561 | 23864 | 40 | 1804455 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 425 spectra of 10 reference samples from the substance/substance group *Ornithine aspartate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 901 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 240 spectra of 7 reference samples from the substance/substance group *Ornithine aspartate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Ornithine aspartate | 1711015 | 23899 | 40 |
| Euro OTC | Ornithine aspartate | 1805026 | 24125 | 40 |
| Euro OTC | Ornithine aspartate | 1907037 | 24859 | 40 |
| Euro OTC | Ornithine aspartate | 2201011 | 25959 | 40 |
| Euro OTC | Ornithine aspartate | 2201011 | 25959SI | 40 |
| Euro OTC | Ornithine aspartate | 2301047 | 26592SI† | 20 |
| Euro OTC | Ornithine aspartate | 2307023 | 26877SI† | 20 |

- 212 700 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Ornithine aspartate*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ornithine aspartate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ornithine aspartate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 425 | 0 | 157 901 |
| **Type B** | 0 | 240 | 0 | 212 700 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Ornithine aspartate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5882 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21694 | 21694 | 0.00 | 136.58 |
| 21710 | 21710 | 0.00 | 115.24 |
| 22599 | 21694 | 6.80 | 137.35 |
| 22600 | 21710 | 11.79 | 113.45 |
| 22924 | 22924 | 0.00 | 122.02 |
| 23198 | 21694 | 11.28 | 141.28 |
| 23864 | 23864 | 0.00 | 100.33 |
| 26592 | 26592 | 0.00 | 117.56 |
| 26877 | 26877 | 0.00 | 117.55 |
| 27404 | 27404 | 0.00 | 101.03 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ornithine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20389-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ornithine hydrochloride; Ornithini hydrochloridum

### Special notes

When selecting the *Ornithine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ornithine hydrochloride | 8 | 10 | 15 |

### Second-stage model

For differentiation of the substance/substance group *Ornithine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ornithine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycine | 86.18 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ornithine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ornithine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Ornithine hydrochloride | 1307028-01 | 21622 | 120 | 20130813 |
| Euro OTC | Ornithine hydrochloride | 1605011 | 22573 | 40 | 20160601* |
| Euro OTC | Ornithine hydrochloride | 1612009 | 22923 | 40 | 20170113* |
| Euro OTC | Ornithine hydrochloride | 2001004 | 25084 | 40 | 20200123* |
| Euro OTC | Ornithine hydrochloride | 2004018 | 25271 | 40 | 20200731* |
| Euro OTC | Ornithine hydrochloride | 2305021 | 26751 | 40 | 20230616* |
| Euro OTC | Ornithine hydrochloride | 2305021 | 26751SI | 20 | 20230616* |
| Euro OTC | Ornithine hydrochloride | 2408003 | 27391 | 40 | 20241029* |
| Fagron | Ornithine hydrochloride | 13A03-N05 | 20967 | 40 | 1403094 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 9 reference samples from the substance/substance group *Ornithine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 906 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 440 spectra of 12 reference samples from the substance/substance group *Ornithine hydrochloride*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Ornithine hydrochloride | 1612009-01 | 23009 | 40 |
| Euro OTC | Ornithine hydrochloride | 1704006 | 23159 | 40 |
| Euro OTC | Ornithine hydrochloride | 1803018 | 24085 | 40 |
| Euro OTC | Ornithine hydrochloride | 1906015 | 24810 | 40 |
| Euro OTC | Ornithine hydrochloride | 2101021 | 25547 | 40 |
| Euro OTC | Ornithine hydrochloride | 2103016 | 25598 | 40 |
| Euro OTC | Ornithine hydrochloride | 2107018 | 25764 | 50 |
| Euro OTC | Ornithine hydrochloride | 2201012 | 26042 | 40 |
| Euro OTC | Ornithine hydrochloride | 2301046 | 26572 | 40 |
| Euro OTC | Ornithine hydrochloride | 2409011 | 27392 | 40 |
| Euro OTC | Ornithine hydrochloride | 2201012 | 26042SI | 10 |
| Euro OTC | Ornithine hydrochloride | 2301046 | 26572SI | 20 |

- 212 500 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 24 spectra from 5 *Apo-Ident* customers from 16 batches from the substance/substance group *Ornithine hydrochloride*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Ornithine hydrochloride | 1014I-03475 | 1 |
| Euro OTC | Ornithine hydrochloride | 1704006-01 | 1 |
| Euro OTC | Ornithine hydrochloride | 1906015-01 | 1 |
| Euro OTC | Ornithine hydrochloride | 2001004-01 | 1 |
| Euro OTC | Ornithine hydrochloride | 2004018-01 | 9 |
| Euro OTC | Ornithine hydrochloride | 2101021-01 | 1 |
| Euro OTC | Ornithine hydrochloride | 2103016-01 | 1 |
| Euro OTC | Ornithine hydrochloride | 2107018-01 | 1 |
| Euro OTC | Ornithine hydrochloride | 2201012-01 | 1 |
| Euro OTC | Ornithine hydrochloride | 2201012-02 | 1 |
| Euro OTC | Ornithine hydrochloride | 315E-03475 | 1 |
| Euro OTC | Ornithine hydrochloride | 4712A-03475 | 1 |
| Euro OTC | Ornithine hydrochloride | 516Q-03475 | 1 |
| Euro OTC | Ornithine hydrochloride | 5217M-03475 | 1 |
| Fagron | Ornithine hydrochloride | 13A03-N05 | 1 |
| Fagron | Ornithine hydrochloride | 15A13-B03 | 1 |

- 256 862 spectra from 1666 *Apo-Ident* customers from a total of 52 137 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ornithine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ornithine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 440 | 0 | 212 500 |
| **Type C** | 0 | 24 | 0 | 256 862 |

The substance/substance group *Ornithine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6364 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 75.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20967 | 20967 | 0.00 | 200.77 |
| 21622 | 22573 | 3.26 | 201.39 |
| 22573 | 22573 | 0.00 | 201.49 |
| 22923 | 22923 | 0.00 | 201.68 |
| 25084 | 25084 | 0.00 | 200.87 |
| 25271 | 25271 | 0.00 | 200.43 |
| 26751 | 26751 | 0.00 | 201.89 |
| 27391 | 27391 | 0.00 | 203.65 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Oxalic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20458-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Oxalic acid; Acidum oxalicum cryst.

### Special notes

When selecting the *Oxalic acid* substance/substance group, the following information is displayed to the user:

- Advice: Currently no longer available from major pharmaceutical manufacturers. Therefore, batch maintenance is currently not possible.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Oxalic acid | 6 | 3 | 28 |

### Second-stage model

For differentiation of the substance/substance group *Oxalic acid* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Oxalic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 65.27 | – |
| ⋮ | ⋮ | ⋮ |
| Colistin sulfate | >50 | 55.87 |
| Polymyxin B sulfate | >50 | 56.96 |
| Bacitracin | >50 | 70.04 |
| Riboflavin | >50 | 71.69 |
| Cyanocobalamin | >50 | 88.12 |
| Calcium glycerophosphate | >50 | 99.02 |
| Amphotericin B | >50 | 100.78 |
| Tosylchloramide sodium | >50 | 106.26 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 108.06 |
| Carmellose sodium | >50 | 108.61 |
| SyrSpend® SF Alka | >50 | 123.05 |
| Hyoscine hydrobromide | >50 | 131.20 |
| Nystatin | >50 | 133.20 |
| Triamcinolone | >50 | 138.97 |
| Calcium pantothenate | >50 | 139.63 |
| Wheat starch | >50 | 145.27 |
| Gelatine, white | >50 | 148.10 |
| Rice starch | >50 | 161.15 |
| Estriol | >50 | 161.55 |
| Estradiol hemihydrate | >50 | 166.27 |
| Fructose | >50 | 169.94 |
| SyrSpend® SF pH4 | >50 | 183.66 |
| Acacia, dried dispersion | >50 | 184.66 |
| Potato starch | >50 | 221.96 |
| alpha-tocopheryl acetate dry concentrate | >50 | 222.10 |
| Corn starch | >50 | 232.90 |
| Maltodextrin | >50 | 252.43 |
| Methylcobalamin | >50 | 288.27 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Oxalic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Oxalic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Oxalic acid | 13353901 | 21042 | 40 | 20131029 |
| Caelo | Oxalic acid | 12212410 | 21066 | 40 | 1403223 |
| Caelo | Oxalic acid | 13353918 | 21774 | 60 | 20131029 |
| Caelo | Oxalic acid | 171140 | 23287 | 40 | 20170426* |
| Caelo | Oxalic acid | 171140 | 23688 | 40 | 20170426* |
| Caelo | Oxalic acid | 18202403 | 24428 | 40 | 1905160 |
| Caelo | Oxalic acid | 20000475 | 25207 | 40 | 20200313* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 300 spectra of 7 reference samples from the substance/substance group *Oxalic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.
- 158 026 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 4 reference samples from the substance/substance group *Oxalic acid*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Oxalic acid | 13353905 | 21453 | 60 |
| Caelo | Oxalic acid | 20003046 | 25623 | 40 |
| Caelo | Oxalic acid | 21004224 | 26007 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Oxalic acid | 21004224 | 26007SI | 10 |

- 212 790 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 34 spectra from 28 *Apo-Ident* customers from 30 batches from the substance/substance group *Oxalic acid*.

- Among them are spectra of independent samples from 28 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Oxalic acid | 12589 | 1 |
| Caelo | Oxalic acid | 10383104 | 1 |
| Caelo | Oxalic acid | 11111703 | 1 |
| Caelo | Oxalic acid | 12147010 | 1 |
| Caelo | Oxalic acid | 12212406 | 1 |
| Caelo | Oxalic acid | 12212407 | 1 |
| Caelo | Oxalic acid | 12212411 | 1 |
| Caelo | Oxalic acid | 13195413 | 1 |
| Caelo | Oxalic acid | 13195414 | 1 |
| Caelo | Oxalic acid | 13353901 | 1 |
| Caelo | Oxalic acid | 13353905 | 3 |
| Caelo | Oxalic acid | 13353907 | 2 |
| Caelo | Oxalic acid | 13353910 | 1 |
| Caelo | Oxalic acid | 13353915 | 1 |
| Caelo | Oxalic acid | 14334703 | 1 |
| Caelo | Oxalic acid | 15399901 | 1 |
| Caelo | Oxalic acid | 16050205 | 1 |
| Caelo | Oxalic acid | 16297401 | 1 |
| Caelo | Oxalic acid | 17114003 | 1 |
| Caelo | Oxalic acid | 17344503 | 1 |
| Caelo | Oxalic acid | 18196401 | 1 |
| Caelo | Oxalic acid | 4812U-01039 | 1 |
| Caelo | Oxalic acid | 7111808 | 1 |
| Caelo | Oxalic acid | 914E-01039 | 1 |
| Caelo | Oxalic acid | Retest17111401 | 2 |
| Caesar & Loretz GmbH... | Oxalic acid | 20003046001 | 1 |
| Caesar & Loretz GmbH | Oxalic acid | 20000475004 | 1 |
| Caesar&Loretz GmbH/ ... | Oxalic acid | 13353920 | 1 |
| Nachprüfung | Oxalic acid | | 1 |
| sanacorp | Oxalic acid | 11098213 | 1 |

- 256 852 spectra from 1666 *Apo-Ident* customers from a total of 52 124 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,


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the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Oxalic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Oxalic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 34 | 0 | 256 852 |

The substance/substance group *Oxalic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 82.3529 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21042 | 21066 | 6.05 | 151.27 |
| 21066 | 21066 | 0.00 | 145.27 |
| 21774 | 21066 | 6.97 | 144.89 |
| 23287 | 23287 | 0.00 | 148.31 |
| 23688 | 23688 | 0.00 | 148.47 |
| 24428 | 24428 | 0.00 | 149.69 |
| 25207 | 25207 | 0.00 | 135.24 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,

thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Oxetacaine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 23686-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Oxetacaine; Oxetacainum

### Special notes

When selecting the *Oxetacaine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Oxetacaine | 5 | 1 | 21 |

### Second-stage model

For differentiation of the substance/substance group *Oxetacaine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Oxetacaine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Clobetasol propionate | 109.83 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Oxetacaine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Oxetacaine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Oxetacaine | APO10-160120 | 24104 | 40 | 1809415 |
| Caelo | Oxetacaine | 172498 | 23686 | 40 | 20170925* |
| Caelo | Oxetacaine | 191134 | 24757 | 40 | 20190523* |
| Euro OTC | Oxetacaine | 2002021 | 25254 | 40 | 20200612* |
| Euro OTC | Oxetacaine | 2002020-01 | 25293 | 40 | 20200714 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 5 reference samples from the substance/substance group *Oxetacaine*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 126 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 50 spectra of 1 reference samples from the substance/substance group *Oxetacaine*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Oxetacaine | 17249805 | 23916 | 50 |

- 212 890 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 101 spectra from 80 *Apo-Ident* customers from 21 batches from the substance/substance group *Oxetacaine*.
- Among them are spectra of independent samples from 21 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Oxetacaine | 2002020-03 | 1 |
| | Oxetacaine | 2002020-13 | 1 |
| | Oxetacaine | 21001626004 | 1 |
| | Oxetacaine | 21001626006 | 9 |
| | Oxetacaine | 21001626008 | 3 |
| Caelo | Oxetacaine | 17249805 | 1 |
| Caelo | Oxetacaine | 17249806 | 1 |
| Caelo | Oxetacaine | 17249808 | 1 |
| Caelo | Oxetacaine | 17249809 | 1 |
| Caelo | Oxetacaine | 17249810 | 6 |
| Caelo | Oxetacaine | 191134001 | 7 |
| Caelo | Oxetacaine | 191134002 | 7 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Oxetacaine | 191134005 | 5 |
| Caelo | Oxetacaine | 191134007 | 6 |
| Caelo | Oxetacaine | 19113401 | 8 |
| Caelo | Oxetacaine | 19113402 | 9 |
| Caelo | Oxetacaine | 21001626002 | 3 |
| Caelo | Oxetacaine | 21001626004 | 2 |
| Caelo | Oxetacaine | 91134002 | 1 |
| Caesar & Loretz GmbH… | Oxetacaine | 191134007 | 1 |
| Caesar & Loretz GmbH… | Oxetacaine | 191134005 | 1 |
| Caesar & Loretz GmbH… | Oxetacaine | 191134007 | 1 |
| Caesar & Loretz GmbH… | Oxetacaine | 19113402 | 1 |
| Caesar & Loretz GmbH… | Oxetacaine | 191134002 | 2 |
| Caesar & Loretz GmbH | Oxetacaine | 191134001 | 4 |
| CAESAR & LORETZ GMBH | Oxetacaine | 191134002 | 1 |
| Caesar & Loretz GmbH | Oxetacaine | 191134005 | 1 |
| Caesar & Loretz GmbH | Oxetacaine | 191134007 | 3 |
| Caesar&Lorenz | Oxetacaine | 191134005 | 1 |
| EuRho | Oxetacaine | 2002021-01 | 1 |
| Euro OTC | Oxetacaine | 2002020-02 | 1 |
| Euro OTC | Oxetacaine | 2002020-03 | 4 |
| Euro OTC | Oxetacaine | 2002021-01 | 2 |
| Euro OTC | Oxetacaine | 200221-01 | 1 |
| Gehe | Oxetacaine | 21001626008 | 1 |
| Kehr | Oxetacaine | 17249805 | 1 |
| Sanacorp | Oxetacaine | 21001626006 | 1 |

- 256 785 spectra from 1666 *Apo-Ident* customers from a total of 52 132 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Oxetacaine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Oxetacaine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 50 | 0 | 212 890 |
| **Type C** | 0 | 101 | 0 | 256 785 |

The substance/substance group *Oxetacaine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 88.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 94.0594 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23686 | 23686 | 0.00 | 140.33 |
| 24104 | 24104 | 0.00 | 145.81 |
| 24757 | 24757 | 0.00 | 141.13 |
| 25254 | 25254 | 0.00 | 148.01 |
| 25293 | 24104 | 10.33 | 143.84 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Oxybuprocaine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20958-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Oxybuprocaine hydrochloride; Oxybuprocaini hydrochloridum

### Special notes

When selecting the *Oxybuprocaine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Oxybuprocaine hydrochloride | 6 | 4 | 17 |

### Second-stage model

For differentiation of the substance/substance group *Oxybuprocaine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Oxybuprocaine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 111.05 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Oxybuprocaine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Oxybuprocaine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Oxybuprocaine hydrochloride | 13D16-N12 | 20958 | 40 | 1402060 |
| Fagron | Oxybuprocaine hydrochloride | 13J24-B07-295015 | 21799 | 60 | AR-15-FG-014812-02 |
| Fagron | Oxybuprocaine hydrochloride | 13J24-B07-295015 | 21799SI | 60 | AR-15-FG-014812-02 |
| Fagron | Oxybuprocaine hydrochloride | 15A26-B07-306787 | 21922 | 60 | 20150203 |
| Fagron | Oxybuprocaine hydrochloride | 15A26-B07-306787 | 21922SI | 60 | 20150203 |
| Fagron | Oxybuprocaine hydrochloride | 16L05-B06-334330 | 23719 | 40 | 20170113 |
| Fagron | Oxybuprocaine hydrochloride | 16L05-B06-334330 | 23720 | 40 | 20170113 |
| Fagron | Oxybuprocaine hydrochloride | 17G21-B03-338576 | 23745 | 40 | 20170823 |
| Fagron | Oxybuprocaine hydrochloride | 16L05-B06-334330 | 23752 | 40 | 20170113 |
| Fagron | Oxybuprocaine hydrochloride | 19K04-B04-195510 | 25581 | 40 | 20191114 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 480 spectra of 10 reference samples from the substance/substance group *Oxybuprocaine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference


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samples come from 6 different batches.

- 157 846 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 230 spectra of 6 reference samples from the substance/substance group *Oxybuprocaine hydrochloride*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Oxybuprocaine hydrochloride | 18F20-B02-355633 | 24580 | 40 |
| Fagron | Oxybuprocaine hydrochloride | 20B13-B01-197691 | 25744 | 50 |
| Fagron | Oxybuprocaine hydrochloride | 20I03-B06-202527 | 25940 | 40 |
| Fagron | Oxybuprocaine hydrochloride | 24K06-B14-008696 | 27607 | 40 |
| Fagron | Oxybuprocaine hydrochloride | 20I03-B06-202527 | 25940SI | 40 |
| Fagron | Oxybuprocaine hydrochloride | 24K06-B14-008696 | 27607SI | 20 |

- 212 710 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 24 spectra from 12 *Apo-Ident* customers from 18 batches from the substance/substance group *Oxybuprocaine hydrochloride*.

- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Oxybuprocaine hydrochloride | 14G21B02300384 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 12L19N01 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 13C01-N01 | 4 |
| Fagron | Oxybuprocaine hydrochloride | 13h13-n05 | 2 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Oxybuprocaine hydrochloride | 13J24B07295015 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 15A26-B07 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 16L05-B06 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 16L05-B06-332495 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 18F20-B02-351233 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 18F20-B02-355633 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 19K04-B04-195510 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 19K04-B04-195511 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 20B13-B01-197691 | 2 |
| Fagron | Oxybuprocaine hydrochloride | 20I03-B06-202527 | 2 |
| Fagron | Oxybuprocaine hydrochloride | 3613N-07321 | 1 |
| Fagron | Oxybuprocaine hydrochloride | 4612M-03639 | 1 |
| Klenk | Oxybuprocaine hydrochloride | 3613M-07321 | 1 |
| Phönix | Oxybuprocaine hydrochloride | 16L05-B06-329642 | 1 |

- 256 862 spectra from 1666 *Apo-Ident* customers from a total of 52 135 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Oxybuprocaine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Oxybuprocaine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 230 | 0 | 212 710 |
| **Type C** | 0 | 23 | 1 | 256 862 |

The substance/substance group *Oxybuprocaine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.3913 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 95.8333 % (> 83.3333 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20958 | 20958 | 0.00 | 141.06 |
| 21799 | 21799 | 0.00 | 119.51 |
| 21922 | 21799 | 11.52 | 135.27 |
| 23719 | 21799 | 17.94 | 141.58 |
| 23720 | 21799 | 15.79 | 139.43 |
| 23745 | 21799 | 18.19 | 141.40 |
| 23752 | 21799 | 21.13 | 143.70 |
| 25581 | 21799 | 16.50 | 139.09 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Oxybutynin hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20565-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Oxybutynin hydrochloride; Oxybutynini hydrochloridum

### Special notes

When selecting the *Oxybutynin hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Oxybutynin hydrochloride | 6 | 8 | 80 |

### Second-stage model

For differentiation of the substance/substance group *Oxybutynin hydrochloride* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Oxybutynin hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 115.46 | – |
| ⋮ | ⋮ | ⋮ |
| Prednicarbate | >50 | 61.31 |
| Levocarnitine | >50 | 99.73 |
| Cyproterone acetate | >50 | 110.24 |
| Capsaicin | >50 | 112.55 |
| Sodium citrate | >50 | 145.46 |
| Tetracaine | >50 | 202.01 |
| Norethisterone acetate | >50 | 271.25 |
| Alfatradiol | >50 | 294.02 |
| Amitriptyline hydrochloride | >50 | 312.48 |
| Quinine hydrochloride dihydrate | >50 | 328.00 |
| Valine | >50 | 432.89 |
| Methoxsalen | >50 | 464.63 |
| Pyridoxal-5-phosphate hydrate | >50 | 467.04 |
| Ciprofloxacin hydrochloride | >50 | 539.48 |
| Heparin sodium | >50 | 557.42 |
| Triclosan | >50 | 1580.84 |
| Amifampridine | >50 | 1887.63 |
| Sucrose | >50 | 1992.15 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Oxybutynin hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Oxybutynin hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Oxybutynin hydrochloride | 2005030 | 25351 | 40 | 20200911* |
| Euro OTC | Oxybutynin hydrochloride | 2010024 | 25457 | 40 | 20201201* |

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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Oxybutynin hydrochloride | 13H26-B03-290572 | 21543 | 60 | AR-15-FG-002173-01 |
| Fagron | Oxybutynin hydrochloride | 14A29-B09-293841 | 21704 | 45 | 20140227 |
| Fagron | Oxybutynin hydrochloride | 14I16-B03-312059 | 22732 | 40 | 20141007 |
| Fagron | Oxybutynin hydrochloride | 18K22-B01-359482 | 25059 | 40 | 20181217 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 265 spectra of 6 reference samples from the substance/substance group *Oxybutynin hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 061 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 380 spectra of 11 reference samples from the substance/substance group *Oxybutynin hydrochloride*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Oxybutynin hydrochloride | 2205010 | 26189 | 40 |
| Euro OTC | Oxybutynin hydrochloride | 2301024 | 26578 | 40 |
| Euro OTC | Oxybutynin hydrochloride | 2310011 | 27062 | 40 |
| Euro OTC | Oxybutynin hydrochloride | 2403009 | 27211 | 40 |
| Fagron | Oxybutynin hydrochloride | 12D24-N07 | 20565 | 40 |
| Fagron | Oxybutynin hydrochloride | 16A18-B02-321181 | 23268 | 40 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-344347 | 23995 | 40 |
| Fagron | Oxybutynin hydrochloride | 21H27-B01-220138 | 26288 | 40 |
| Euro OTC | Oxybutynin hydrochloride | 2205010 | 26189SI | 20 |
| Euro OTC | Oxybutynin hydrochloride | 2301024 | 26578SI | 20 |
| Fagron | Oxybutynin hydrochloride | 21H27-B01-220138 | 26288SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 560 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 207 spectra from 71 *Apo-Ident* customers from 85 batches from the substance/substance group *Oxybutynin hydrochloride*.

- Among them are spectra of independent samples from 80 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Oxybutynin hydrochloride | 21H27-B01-224479 | 3 |
| | Oxybutynin hydrochloride | 21H27-B01-227285 | 2 |
| | Oxybutynin hydrochloride | 23J30-B03-002489 | 1 |
| | Oxybutynin hydrochloride | B0122013008 | 1 |
| | Oxybutynin hydrochloride | CC0100362 | 2 |
| Audor Pharma | Oxybutynin hydrochloride | | 3 |
| Audor Pharma | Oxybutynin hydrochloride | APOH/043/2017-2018 | 2 |
| Audor Pharma | Oxybutynin hydrochloride | APOH/067/2018-2019 | 2 |
| Audor Pharma | Oxybutynin hydrochloride | APOH0122017201810B | 2 |
| Audor Pharma | Oxybutynin hydrochloride | APOH0122017-2018-10B | 1 |
| Caelo | Oxybutynin hydrochloride | 129099 | 1 |
| Caelo | Oxybutynin hydrochloride | 15F05-B03-318524 | 4 |
| Caelo | Oxybutynin hydrochloride | 16/23-B03-328916 | 1 |
| Caelo | Oxybutynin hydrochloride | 16/23-B03-333371 | 3 |
| Caelo | Oxybutynin hydrochloride | 16A18_B02_321181 | 2 |
| Caelo | Oxybutynin hydrochloride | 16A18-B02-326183 | 1 |
| Caelo | Oxybutynin hydrochloride | 16I23-B03-328916 | 1 |
| Caelo | Oxybutynin hydrochloride | 18A12-B03 | 2 |
| Caelo | Oxybutynin hydrochloride | 18A12-B03-344348 | 1 |
| Caelo | Oxybutynin hydrochloride | 18A12-B03-344350 | 1 |
| Caelo | Oxybutynin hydrochloride | 18A12-Bo3-344350 | 1 |
| Euro OTC | Oxybutynin hydrochloride | 18K22-B01-359482 | 2 |
| Euro OTC | Oxybutynin hydrochloride | 2010024-01 | 4 |
| Euro OTC | Oxybutynin hydrochloride | 2010024-02 | 1 |
| Fagro/Sanacorp | Oxybutynin hydrochloride | 16/23-B03-32891613 | 1 |
| Fagro/Sanacorp | Oxybutynin hydrochloride | 16A18-B02-326183 | 1 |
| Fagron | Oxybutynin hydrochloride | 127979 | 2 |
| Fagron | Oxybutynin hydrochloride | 129099 | 1 |
| Fagron | Oxybutynin hydrochloride | 130563 | 1 |
| Fagron | Oxybutynin hydrochloride | 13H26-B03 | 1 |
| Fagron | Oxybutynin hydrochloride | 13H26-B03-287325 | 1 |
| Fagron | Oxybutynin hydrochloride | 14/16_B03_300207 | 1 |
| Fagron | Oxybutynin hydrochloride | 14/16-B03-300207 | 5 |
| Fagron | Oxybutynin hydrochloride | 14/16-B03-300209 | 1 |
| Fagron | Oxybutynin hydrochloride | 14A29_B09_307322 | 2 |
| Fagron | Oxybutynin hydrochloride | 14a29-b09-307322 | 2 |
| Fagron | Oxybutynin hydrochloride | 14A29-B09-307322 | 5 |
| Fagron | Oxybutynin hydrochloride | 14I16-B03 | 1 |
| Fagron | Oxybutynin hydrochloride | 14I16-B03-300207 | 1 |
| Fagron | Oxybutynin hydrochloride | 15F05_B03_315221 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Oxybutynin hydrochloride | 15F05-b03-315220 | 1 |
| Fagron | Oxybutynin hydrochloride | 15F05-B03-315221 | 6 |
| Fagron | Oxybutynin hydrochloride | 15F05-B03-318524 | 1 |
| Fagron | Oxybutynin hydrochloride | 16/23-b03-333371 | 1 |
| Fagron | Oxybutynin hydrochloride | 1607080 | 1 |
| Fagron | Oxybutynin hydrochloride | 16A18-B02-321181 | 3 |
| Fagron | Oxybutynin hydrochloride | 16A18-B02-322538 | 3 |
| Fagron | Oxybutynin hydrochloride | 16A18-B02-326183 | 3 |
| Fagron | Oxybutynin hydrochloride | 16I23-B03-328916 | 3 |
| Fagron | Oxybutynin hydrochloride | 16I23-B03-329448 | 1 |
| Fagron | Oxybutynin hydrochloride | 16I23-B03-333371 | 2 |
| Fagron | Oxybutynin hydrochloride | 16l23-b03-328916 | 1 |
| Fagron | Oxybutynin hydrochloride | 1709250/16I23-B03-33 | 1 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03 | 2 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-344347 | 1 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-344348 | 6 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-344350 | 1 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-345554 | 2 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-346964 | 4 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-347807 | 1 |
| Fagron | Oxybutynin hydrochloride | 18A12B03349624 | 1 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-349624 | 3 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-350471 | 3 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-351262 | 2 |
| Fagron | Oxybutynin hydrochloride | 18A12B03352129 | 1 |
| Fagron | Oxybutynin hydrochloride | 18A12-B03-353049 | 1 |
| Fagron | Oxybutynin hydrochloride | 18A23-B03-351262 | 1 |
| Fagron | Oxybutynin hydrochloride | 18K22-B01 | 2 |
| Fagron | Oxybutynin hydrochloride | 18K22-B01-358358 | 2 |
| Fagron | Oxybutynin hydrochloride | 18K22-B01-359482 | 5 |
| Fagron | Oxybutynin hydrochloride | 18K22-B01-363434 | 1 |
| Fagron | Oxybutynin hydrochloride | 18K22-B01-363953 | 2 |
| Fagron | Oxybutynin hydrochloride | 20K100-F04-375776 | 1 |
| Fagron | Oxybutynin hydrochloride | 20K10-F04 | 1 |
| Fagron | Oxybutynin hydrochloride | 20K10-F04 | 1 |
| Fagron | Oxybutynin hydrochloride | 20K10-F04-3757706 | 2 |
| Fagron | Oxybutynin hydrochloride | 20K10-F04-375776 | 5 |
| Fagron | Oxybutynin hydrochloride | 20K10-F04-375777 | 15 |
| Fagron | Oxybutynin hydrochloride | 21G01-F05-379447 | 10 |
| Fagron | Oxybutynin hydrochloride | 21H27-B01-2164002 | 1 |
| Fagron | Oxybutynin hydrochloride | 21H27-B01-218125 | 3 |
| Fagron | Oxybutynin hydrochloride | 21H27-B01-220138 | 1 |
| Fagron | Oxybutynin hydrochloride | 22032E005 | 1 |
| Fagron | Oxybutynin hydrochloride | 22032F004 | 5 |
| Fagron | Oxybutynin hydrochloride | 4375777 | 1 |
| Fagron | Oxybutynin hydrochloride | 5-37944007 | 1 |
| Fagron | Oxybutynin hydrochloride | F04-3757706 | 2 |
| Fagron | Oxybutynin hydrochloride | F04-3757707 | 1 |
| Fagron | Oxybutynin hydrochloride | F04-375776 | 1 |
| Fagron | Oxybutynin hydrochloride | F05-379449 | 1 |
| Fagron | Oxybutynin hydrochloride | LCA0100105 | 1 |
| Fagron | Oxybutynin hydrochloride | OH/044/2020-2021 | 1 |
| Krieger | Oxybutynin hydrochloride | F04-3757707 | 1 |
| Noweda | Oxybutynin hydrochloride | 18A12-B03-347807 | 1 |
| Noweda | Oxybutynin hydrochloride | 18A12-B03-351262 | 1 |
| Phoenix | Oxybutynin hydrochloride | 16/23-B03-328916 | 1 |
| Phoenix | Oxybutynin hydrochloride | 18A12-B03-346964 | 1 |
| Phoenix | Oxybutynin hydrochloride | 22032E005 | 2 |
| Phönix | Oxybutynin hydrochloride | 18A12-B03-349624 | 1 |
| Sanacorp | Oxybutynin hydrochloride | 18A12-B03-353049 | 1 |

- 256 679 spectra from 1666 *Apo-Ident* customers from a total of 52 069 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Oxybutynin hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Oxybutynin hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 265 | 0 | 158 061 |
| **Type B** | 0 | 380 | 0 | 212 560 |
| **Type C** | 0 | 207 | 0 | 256 679 |

The substance/substance group *Oxybutynin hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7358 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4211 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.1014 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21543 | 21543 | 0.00 | 176.88 |
| 21704 | 25457 | 4.50 | 174.82 |
| 22732 | 21543 | 5.05 | 177.90 |
| 25059 | 25351 | 9.59 | 178.87 |
| 25351 | 25351 | 0.00 | 180.09 |
| 25457 | 25457 | 0.00 | 176.08 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at


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least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Oxytetracycline hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20090-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Oxytetracycline hydrochloride; Oxytetracyclini hydrochloridum

### Special notes

When selecting the *Oxytetracycline hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Oxytetracycline hydrochloride | 13 | 5 | 157 |

### Second-stage model

For differentiation of the substance/substance group *Oxytetracycline hydrochloride* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Oxytetracycline hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 57.79 | – |
| ⋮ | ⋮ | ⋮ |
| Dequalinium chloride | >50 | 49.57 |
| Eosin Y | >50 | 77.50 |
| Tannin | >50 | 115.48 |
| Levothyroxin sodium | >50 | 128.08 |
| Dithranol | >50 | 227.76 |
| Acetylsalicylic acid | >50 | 393.73 |
| Sodium salicylate | >50 | 430.92 |
| Benzoic acid | >50 | 496.47 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Oxytetracycline hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Oxytetracycline hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Oxytetracycline hydrochloride | 12130001 | 20847 | 40 | 20120530 |
| Caelo | Oxytetracycline hydrochloride | 12328103 | 21039 | 40 | 20121214 |
| Caelo | Oxytetracycline hydrochloride | 16077002 | 22503 | 40 | AR-16-FG-011460-01 |
| Euro OTC | Oxytetracycline hydrochloride | 1306022-02 | 21600 | 60 | 1507542 |
| Euro OTC | Oxytetracycline hydrochloride | 1506037 | 21836 | 60 | 20150721* |
| Euro OTC | Oxytetracycline hydrochloride | 1506037 | 21999 | 60 | 20150721* |
| Euro OTC | Oxytetracycline hydrochloride | 1602025 | 22546 | 40 | 20160609* |
| Euro OTC | Oxytetracycline hydrochloride | 1602025-01 | 22658 | 40 | AR-16-FG-014422-01 |
| Euro OTC | Oxytetracycline hydrochloride | 1602025 | 22669 | 40 | 20160609* |
| Euro OTC | Oxytetracycline hydrochloride | 1602025-02 | 22839 | 40 | 20161021 |
| Euro OTC | Oxytetracycline hydrochloride | 1602025-02 | 22846 | 40 | 20161021 |
| Euro OTC | Oxytetracycline hydrochloride | 1701034 | 23137 | 40 | 20170314* |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Oxytetracycline hydrochloride | 1701035-02 | 23970 | 40 | 20170314 |
| Euro OTC | Oxytetracycline hydrochloride | 2103010 | 25657 | 40 | 20210420* |
| Fagron | Oxytetracycline hydrochloride | 13D08-N11 | 20848 | 60 | 20110131 |
| Fagron | Oxytetracycline hydrochloride | 15D29-B99-309066 | 21915 | 60 | 20150522 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 740 spectra of 16 reference samples from the substance/substance group *Oxytetracycline - hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 13 different batches.

- 157 586 spectra from a total of 2944 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 300 spectra of 9 reference samples from the substance/substance group *Oxytetracycline hydrochloride*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Oxytetracycline hydrochloride | 173168 | 23786 | 40 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033 | 23971 | 40 |
| Euro OTC | Oxytetracycline hydrochloride | 2310021 | 27275 | 40 |
| Euro OTC | Oxytetracycline hydrochloride | 2503013 | 27631 | 40 |
| Fagron | Oxytetracycline hydrochloride | 15L16-B02-322908 | 23226 | 40 |
| Caelo | Oxytetracycline hydrochloride | 12130001 | 20847† | 20 |
| Euro OTC | Oxytetracycline hydrochloride | 2310021 | 27275SI | 20 |
| Euro OTC | Oxytetracycline hydrochloride | 2503013 | 27631SI | 20 |
| Fagron | Oxytetracycline hydrochloride | 15L16-B02-322908 | 23417 | 40 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 640 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1130 spectra from 476 *Apo-Ident* customers from 174 batches from the substance/substance group *Oxytetracycline hydrochloride*.

- Among them are spectra of independent samples from 156 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Oxytetracycline hydrochloride | | 1 |
| | Oxytetracycline hydrochloride | 10305038 | 1 |
| | Oxytetracycline hydrochloride | 130602202 | 1 |
| | Oxytetracycline hydrochloride | 140701201 | 1 |
| | Oxytetracycline hydrochloride | 2103010-01 | 5 |
| | Oxytetracycline hydrochloride | 2103010-03 | 22 |
| | Oxytetracycline hydrochloride | 2310021 | 2 |
| | Oxytetracycline hydrochloride | 2310021-01 | 25 |
| 049 | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| AHD | Oxytetracycline hydrochloride | 1602025-01 | 1 |
| AHD | Oxytetracycline hydrochloride | 17316805 | 1 |
| AHD | Oxytetracycline hydrochloride | 17316815 | 1 |
| AHD | Oxytetracycline hydrochloride | 1801033-02 | 1 |
| AHD | Oxytetracycline hydrochloride | 2103010-01 | 1 |
| AHD | Oxytetracycline hydrochloride | 21030-10-03 | 1 |
| Alliance Healthcare | Oxytetracycline hydrochloride | 1205028-02 | 1 |
| Alliance Healthcare | Oxytetracycline hydrochloride | 1205222-01 | 1 |
| Alliance Healthcare | Oxytetracycline hydrochloride | 2103010-01 | 2 |
| Alliance | Oxytetracycline hydrochloride | 1407012-03 | 1 |
| Anzag | Oxytetracycline hydrochloride | 12328103 | 1 |
| Anzag | Oxytetracycline hydrochloride | 1506037 | 1 |
| Anzag | Oxytetracycline hydrochloride | 1506037-02 | 1 |
| Apoident | Oxytetracycline hydrochloride | 1602025-01 | 1 |
| apomix | Oxytetracycline hydrochloride | 1602025-02 | 1 |
| apomix | Oxytetracycline hydrochloride | 16077014 | 1 |
| Bombastus | Oxytetracycline hydrochloride | 13L19-B33-290732 | 1 |
| Bombastus | Oxytetracycline hydrochloride | 17316812 | 1 |
| Bombastus | Oxytetracycline hydrochloride | 17316815 | 1 |
| Bombastus | Oxytetracycline hydrochloride | 180103301 | 1 |
| Caelo | Oxytetracycline hydrochloride | 1/01034-02 | 1 |
| Caelo | Oxytetracycline hydrochloride | 11336507 | 1 |
| Caelo | Oxytetracycline hydrochloride | 11336510 | 3 |
| Caelo | Oxytetracycline hydrochloride | 12091405 | 1 |
| Caelo | Oxytetracycline hydrochloride | 12130001 | 1 |
| Caelo | Oxytetracycline hydrochloride | 12328103 | 1 |
| Caelo | Oxytetracycline hydrochloride | 12328104 | 1 |
| Caelo | Oxytetracycline hydrochloride | 12328107 | 1 |
| Caelo | Oxytetracycline hydrochloride | 12G10-N04 | 1 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Oxytetracycline hydrochloride | 1306022-01 | 2 |
| Caelo | Oxytetracycline hydrochloride | 13L19-B33 | 1 |
| Caelo | Oxytetracycline hydrochloride | 13L19-B33-290730 | 1 |
| Caelo | Oxytetracycline hydrochloride | 1407012-01 | 1 |
| Caelo | Oxytetracycline hydrochloride | 14128003 | 1 |
| Caelo | Oxytetracycline hydrochloride | 14128004 | 1 |
| Caelo | Oxytetracycline hydrochloride | 14I22-B01-301463 | 1 |
| Caelo | Oxytetracycline hydrochloride | 15060108 | 1 |
| Caelo | Oxytetracycline hydrochloride | 15060109 | 9 |
| Caelo | Oxytetracycline hydrochloride | 1506037 | 1 |
| Caelo | Oxytetracycline hydrochloride | 1506037-01 | 7 |
| Caelo | Oxytetracycline hydrochloride | 150603702 | 1 |
| Caelo | Oxytetracycline hydrochloride | 1506037-02 | 3 |
| Caelo | Oxytetracycline hydrochloride | 1602025-01 | 1 |
| Caelo | Oxytetracycline hydrochloride | 160202502 | 3 |
| Caelo | Oxytetracycline hydrochloride | 1602025-02 | 4 |
| Caelo | Oxytetracycline hydrochloride | 16044007 | 1 |
| Caelo | Oxytetracycline hydrochloride | 16077001 | 3 |
| Caelo | Oxytetracycline hydrochloride | 16077002 | 3 |
| Caelo | Oxytetracycline hydrochloride | 16077003 | 3 |
| Caelo | Oxytetracycline hydrochloride | 16077007 | 2 |
| Caelo | Oxytetracycline hydrochloride | 16077008 | 9 |
| Caelo | Oxytetracycline hydrochloride | 16077009 | 1 |
| Caelo | Oxytetracycline hydrochloride | 16077011 | 2 |
| Caelo | Oxytetracycline hydrochloride | 16077012 | 1 |
| Caelo | Oxytetracycline hydrochloride | 16077015 | 1 |
| Caelo | Oxytetracycline hydrochloride | 16077016 | 2 |
| Caelo | Oxytetracycline hydrochloride | 16077017 | 1 |
| Caelo | Oxytetracycline hydrochloride | 1607716 | 1 |
| Caelo | Oxytetracycline hydrochloride | 163406010 | 1 |
| Caelo | Oxytetracycline hydrochloride | 16340605 | 4 |
| Caelo | Oxytetracycline hydrochloride | 16340606 | 3 |
| Caelo | Oxytetracycline hydrochloride | 16340609 | 1 |
| Caelo | Oxytetracycline hydrochloride | 16340610 | 16 |
| Caelo | Oxytetracycline hydrochloride | 16340611 | 2 |
| Caelo | Oxytetracycline hydrochloride | 16340616 | 1 |
| Caelo | Oxytetracycline hydrochloride | 1701034-01 | 1 |
| Caelo | Oxytetracycline hydrochloride | 1701034-02 | 11 |
| Caelo | Oxytetracycline hydrochloride | 1716819 | 1 |
| Caelo | Oxytetracycline hydrochloride | 17316805 | 6 |
| Caelo | Oxytetracycline hydrochloride | 17316806 | 4 |
| Caelo | Oxytetracycline hydrochloride | 17316809 | 1 |
| Caelo | Oxytetracycline hydrochloride | 17316811 | 4 |
| Caelo | Oxytetracycline hydrochloride | 17316812 | 3 |
| Caelo | Oxytetracycline hydrochloride | 17316815 | 6 |
| Caelo | Oxytetracycline hydrochloride | 17316816 | 1 |
| Caelo | Oxytetracycline hydrochloride | 17316819 | 1 |
| Caelo | Oxytetracycline hydrochloride | 17316820 | 2 |
| Caelo | Oxytetracycline hydrochloride | 1801033-01 | 3 |
| Caelo | Oxytetracycline hydrochloride | 21021305 | 1 |
| Caelo | Oxytetracycline hydrochloride | 5041402 | 1 |
| Caesar & Loretz GmbH... | Oxytetracycline hydrochloride | 17316815 | 2 |
| Caesar & Loretz GmbH | Oxytetracycline hydrochloride | 17316815 | 1 |
| Caesar & Loretz Hilden | Oxytetracycline hydrochloride | 17316815 | 1 |
| Caesar u. Loretz/Noweda | Oxytetracycline hydrochloride | 1602025-02 | 1 |
| Caesar&Loretz GmbH | Oxytetracycline hydrochloride | 15060109 | 1 |
| Caesar&Loretz | Oxytetracycline hydrochloride | 16340610 | 1 |
| Caleo/ Noweda | Oxytetracycline hydrochloride | 16340616 | 1 |
| Caleo/ Noweda | Oxytetracycline hydrochloride | 17316805 | 1 |
| Century Pharmaceutic... | Oxytetracycline hydrochloride | 10305038-OH | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Century Pharmaceuticals | Oxytetracycline hydrochloride | 2103010-01 | 1 |
| Ebert & Jacobi | Oxytetracycline hydrochloride | 1701034-01 | 2 |
| Eu Rho Pharm/G | Oxytetracycline hydrochloride | 2103010-01 | 1 |
| EuRho / Gehe | Oxytetracycline hydrochloride | 2103010-03 | 1 |
| EuRho/Alliance Healt… | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| EuRho/Alliance | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| EuRho/Gehe | Oxytetracycline hydrochloride | 1801033-02 | 1 |
| EuRho/Phönix | Oxytetracycline hydrochloride | YT170302019 | 1 |
| EuRho | Oxytetracycline hydrochloride | 1111061-01 | 1 |
| EuRho | Oxytetracycline hydrochloride | 1205028-01 | 2 |
| EuRho | Oxytetracycline hydrochloride | 1407012-01 | 1 |
| EuRho | Oxytetracycline hydrochloride | 2103010-03 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | | 2 |
| Euro OTC | Oxytetracycline hydrochloride | 1011045-01 | 3 |
| Euro OTC | Oxytetracycline hydrochloride | 10305038 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 10305038-OH | 6 |
| Euro OTC | Oxytetracycline hydrochloride | 1111061-01 | 6 |
| Euro OTC | Oxytetracycline hydrochloride | 1111061-61 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 11701034-02 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1205028 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 12050-28 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1205028-01 | 6 |
| Euro OTC | Oxytetracycline hydrochloride | 120502802 | 2 |
| Euro OTC | Oxytetracycline hydrochloride | 1205028-02 | 14 |
| Euro OTC | Oxytetracycline hydrochloride | 1306022 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 130602201 | 2 |
| Euro OTC | Oxytetracycline hydrochloride | 1306022-01 | 25 |
| Euro OTC | Oxytetracycline hydrochloride | 130602202 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1306022-02 | 17 |
| Euro OTC | Oxytetracycline hydrochloride | 1306022-03 | 5 |
| Euro OTC | Oxytetracycline hydrochloride | 1407011202 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1407012-01 | 17 |
| Euro OTC | Oxytetracycline hydrochloride | 1407012-02 | 18 |
| Euro OTC | Oxytetracycline hydrochloride | 140701203 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1407012-03 | 5 |
| Euro OTC | Oxytetracycline hydrochloride | 1407012-09 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1407012-1 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 15051507 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 15060109 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1506037 | 3 |
| Euro OTC | Oxytetracycline hydrochloride | 150603701 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1506037-01 | 31 |
| Euro OTC | Oxytetracycline hydrochloride | 1506037-02 | 30 |
| Euro OTC | Oxytetracycline hydrochloride | 1506037-03 | 19 |
| Euro OTC | Oxytetracycline hydrochloride | 15060377-01 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 16020228-02 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1602025 | 3 |
| Euro OTC | Oxytetracycline hydrochloride | 1602025_01 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 160202501 | 2 |
| Euro OTC | Oxytetracycline hydrochloride | 1602025-01 | 23 |
| Euro OTC | Oxytetracycline hydrochloride | 160202502 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1602025-02 | 57 |
| Euro OTC | Oxytetracycline hydrochloride | 1602025-1 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 162025-02 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 170034-01 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 17010301 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1701034 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 170103401 | 2 |
| Euro OTC | Oxytetracycline hydrochloride | 1701034-01 | 51 |
| Euro OTC | Oxytetracycline hydrochloride | 1701034-0104915216 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Oxytetracycline hydrochloride | 1701034-015415 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 170103402 | 3 |
| Euro OTC | Oxytetracycline hydrochloride | 1701034-02 | 57 |
| Euro OTC | Oxytetracycline hydrochloride | 170313OH/1602025-01 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 170612181 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 171034-02 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 18010322-02 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033 | 6 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033_02 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 180103301 | 5 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033-01 | 92 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033-01P-190311-2 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 180103302 | 3 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033-02 | 58 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033-1 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 1801033-22 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 181016183 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 2102010-03 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 2103010_03 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 210301001 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 2103010-01 | 59 |
| Euro OTC | Oxytetracycline hydrochloride | 210301002 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 2103010-02 | 13 |
| Euro OTC | Oxytetracycline hydrochloride | 2103010-03 | 40 |
| Euro OTC | Oxytetracycline hydrochloride | 2103010-10 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 21111815 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 213010-02 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 28011505 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 375-18 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 5015A-02865 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | 513E-02865 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | YT150502056 | 1 |
| Euro OTC | Oxytetracycline hydrochloride | YT160702059 | 2 |
| Euro OTC | Oxytetracycline hydrochloride | YT170302019 | 1 |
| Euro/ Jenne | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| Euro/Gehe | Oxytetracycline hydrochloride | 1602025-02 | 1 |
| Euro/Gehe | Oxytetracycline hydrochloride | 170103 | 1 |
| Euro/Gehe | Oxytetracycline hydrochloride | 1701034-01 | 1 |
| Euro/Gehe | Oxytetracycline hydrochloride | 181033-02 | 1 |
| Euro/Gehe | Oxytetracycline hydrochloride | 2103010-01 | 2 |
| Eurp OTG/AllianceHea... | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| Fagro/Anzag | Oxytetracycline hydrochloride | 14I22-B01-301464 | 1 |
| Fagron | Oxytetracycline hydrochloride | | 1 |
| Fagron | Oxytetracycline hydrochloride | 12A26-N05 | 3 |
| Fagron | Oxytetracycline hydrochloride | 12G10-N04 | 8 |
| Fagron | Oxytetracycline hydrochloride | 130602203 | 1 |
| Fagron | Oxytetracycline hydrochloride | 13D08-N11 | 6 |
| Fagron | Oxytetracycline hydrochloride | 13I26-N11 | 1 |
| Fagron | Oxytetracycline hydrochloride | 13L19-B33 | 4 |
| Fagron | Oxytetracycline hydrochloride | 13L19-B33-290730 | 3 |
| Fagron | Oxytetracycline hydrochloride | 13L19-B33-290731 | 2 |
| Fagron | Oxytetracycline hydrochloride | 14/22-B01-301464 | 1 |
| Fagron | Oxytetracycline hydrochloride | 14/22-B01-301465 | 1 |
| Fagron | Oxytetracycline hydrochloride | 1407012-01 | 1 |
| Fagron | Oxytetracycline hydrochloride | 14I22-B01 | 1 |
| Fagron | Oxytetracycline hydrochloride | 14I22-B01-301464 | 1 |
| Fagron | Oxytetracycline hydrochloride | 14I22-B01-301465 | 1 |
| Fagron | Oxytetracycline hydrochloride | 14l22-B01-301463 | 1 |
| Fagron | Oxytetracycline hydrochloride | 15D29-B99-308608 | 1 |
| Fagron | Oxytetracycline hydrochloride | 15D29-B99-309066 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Oxytetracycline hydrochloride | 15D29-B99-309067 | 1 |
| Fagron | Oxytetracycline hydrochloride | 15116-b02-322907 | 1 |
| Fagron | Oxytetracycline hydrochloride | 15L16-B02-322907 | 1 |
| Fagron | Oxytetracycline hydrochloride | 15L16-B02-322908 | 1 |
| Fagron | Oxytetracycline hydrochloride | 1701034-02 | 1 |
| Fagron | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| Fagron | Oxytetracycline hydrochloride | 3-45703A | 1 |
| Fagron | Oxytetracycline hydrochloride | 4-49732A-2 | 1 |
| Fagron | Oxytetracycline hydrochloride | 912A-02865 | 1 |
| Fagron | Oxytetracycline hydrochloride | C22H25CIN209 | 1 |
| Fagropn | Oxytetracycline hydrochloride | 13L19-B33-290731 | 1 |
| Fiebig | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| Gehe amax | Oxytetracycline hydrochloride | 150603737-03 | 1 |
| Gehe amax | Oxytetracycline hydrochloride | 1701034-02 | 1 |
| Gehe amax | Oxytetracycline hydrochloride | 1801033-01 | 1 |
| Gehe amax | Oxytetracycline hydrochloride | 4-48969A | 1 |
| Gehe | Oxytetracycline hydrochloride | 1205028-01 | 1 |
| Gehe | Oxytetracycline hydrochloride | 12A26-N05 | 2 |
| Gehe | Oxytetracycline hydrochloride | 12g10-n04 | 1 |
| Gehe | Oxytetracycline hydrochloride | 1306022-02 | 1 |
| Gehe | Oxytetracycline hydrochloride | 1407012-03 | 1 |
| Gehe | Oxytetracycline hydrochloride | 1506037-02 | 3 |
| Gehe | Oxytetracycline hydrochloride | 1602025-02 | 3 |
| GEHE | Oxytetracycline hydrochloride | 1602025-02 | 1 |
| GEHE | Oxytetracycline hydrochloride | 1701034-01 | 1 |
| Gehe | Oxytetracycline hydrochloride | 1701034-02 | 1 |
| Gehe | Oxytetracycline hydrochloride | 17316805 | 1 |
| Gehe | Oxytetracycline hydrochloride | 1801033-02 | 1 |
| Gehe | Oxytetracycline hydrochloride | 2103010-01 | 1 |
| Gehe | Oxytetracycline hydrochloride | 2103010-03 | 4 |
| Gehe | Oxytetracycline hydrochloride | 2310021-01 | 1 |
| Holdermann | Oxytetracycline hydrochloride | 2310021-01 | 1 |
| Kehr-Holdermann | Oxytetracycline hydrochloride | 2103010-02 | 1 |
| L12 | Oxytetracycline hydrochloride | 12328107 | 1 |
| L12 | Oxytetracycline hydrochloride | 16340610 | 1 |
| L30 | Oxytetracycline hydrochloride | 1701034-02 | 1 |
| Laborchemie Apolda/Phönix | Oxytetracycline hydrochloride | 1506037-02 | 1 |
| Nachprüfung vom 23.07. | Oxytetracycline hydrochloride | 91618269 | 1 |
| Norbrook/Gehe | Oxytetracycline hydrochloride | 140701203 | 1 |
| Noweda/Euro | Oxytetracycline hydrochloride | 2103010-01 | 1 |
| Noweda | Oxytetracycline hydrochloride | 140701202 | 1 |
| Noweda | Oxytetracycline hydrochloride | 140701203 | 1 |
| Noweda | Oxytetracycline hydrochloride | 1701034-01 | 1 |
| Noweda | Oxytetracycline hydrochloride | 1701034-02 | 1 |
| Noweda | Oxytetracycline hydrochloride | 1801033-01 | 2 |
| noweda | Oxytetracycline hydrochloride | 2103010 | 1 |
| Noweda | Oxytetracycline hydrochloride | 2103010-01 | 2 |
| Noweda | Oxytetracycline hydrochloride | 2103010-03 | 10 |
| Noweda | Oxytetracycline hydrochloride | 2310021-01 | 3 |
| Noweda | Oxytetracycline hydrochloride | 2503013-01 | 1 |
| Phoenix | Oxytetracycline hydrochloride | 1602025-02 | 1 |
| Phoenix | Oxytetracycline hydrochloride | 17316817 | 1 |
| Phoenix | Oxytetracycline hydrochloride | 1801033-01 | 3 |
| Phoenix | Oxytetracycline hydrochloride | 2310021-01 | 2 |
| Phoenix | Oxytetracycline hydrochloride | 3036 | 1 |
| Phönix Gotha | Oxytetracycline hydrochloride | 1232814 | 1 |
| Phönix Gotha | Oxytetracycline hydrochloride | 1407012-02 | 1 |
| Phönix | Oxytetracycline hydrochloride | 1205028-01 | 1 |
| Phönix | Oxytetracycline hydrochloride | 1701034-02 | 1 |
| Phönix | Oxytetracycline hydrochloride | 2103010-03 | 3 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Puren Pharma GmbH / ... | Oxytetracycline hydrochloride | 17316816 | 1 |
| Sanacorp Stralsund | Oxytetracycline hydrochloride | 2103010-02 | 1 |
| Sanacorp | Oxytetracycline hydrochloride | 1701034-01 | 1 |
| SANACORP | Oxytetracycline hydrochloride | 1801033-02 | 1 |
| Sanacorp | Oxytetracycline hydrochloride | 2310021 | 1 |
| Yangzhou Liberty Pha... | Oxytetracycline hydrochloride | 1801033-01 | 1 |

- 255 756 spectra from 1666 *Apo-Ident* customers from a total of 51 984 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Oxytetracycline hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Oxytetracycline hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 740 | 0 | 157 586 |
| **Type B** | 0 | 300 | 0 | 212 640 |
| **Type C** | 0 | 1088 | 42 | 255 756 |

The substance/substance group *Oxytetracycline hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1892 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 96.2832 % (> 96.0177 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20847 | 21999 | 28.85 | 120.25 |
| 20848 | 21836 | 26.45 | 103.50 |
| 21039 | 21600 | 15.36 | 187.43 |
| 21600 | 21600 | 0.00 | 189.03 |
| 21836 | 21836 | 0.00 | 109.45 |
| 21915 | 21836 | 63.11 | 103.92 |
| 21999 | 21999 | 0.00 | 140.80 |
| 22503 | 22503 | 0.00 | 138.47 |
| 22546 | 22546 | 0.00 | 132.35 |
| 22658 | 22658 | 0.00 | 129.70 |
| 22669 | 22669 | 0.00 | 132.61 |
| 22839 | 22669 | 35.78 | 134.65 |
| 22846 | 22669 | 14.79 | 132.30 |
| 23137 | 23137 | 0.00 | 147.22 |
| 23970 | 23137 | 37.96 | 147.15 |
| 25657 | 25657 | 0.00 | 170.69 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Papaverine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20481-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Papaverine hydrochloride; Papaverini hydrochloridum

### Special notes

When selecting the *Papaverine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Papaverine hydrochloride | 5 | 3 | 15 |

### Second-stage model

For differentiation of the substance/substance group *Papaverine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Papaverine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Doxylamine hydrogen succinate | 86.69 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Papaverine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Papaverine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Papaverine hydrochloride | 13324310 | 21735 | 60 | 20130920 |
| Caelo | Papaverine hydrochloride | 123161 | 23054 | 40 | 20121127* |
| Caelo | Papaverine hydrochloride | 180876 | 25614 | 40 | 20180328* |
| Caelo | Papaverine hydrochloride | 22003603 | 26502 | 30 | 20221216* |
| Caelo | Papaverine hydrochloride | 22003603 | 26502SI | 20 | 20221216* |
| Gatt-Koller | Papaverine hydrochloride | 21J01628 | 27096 | 30 | 20210907 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 220 spectra of 6 reference samples from the substance/substance group *Papaverine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

- 158 106 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 5 reference samples from the substance/substance group *Papaverine hydrochloride*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Papaverine hydrochloride | 163159 | 23053 | 40 |
| Caelo | Papaverine hydrochloride | 16315911 | 23928 | 40 |
| Caelo | Papaverine hydrochloride | 23001264 | 26851 | 40 |
| Caelo | Papaverine hydrochloride | 23001264 | 26851SI | 20 |
| Gatt-Koller | Papaverine hydrochloride | 21J01628 | 27096SI† | 20 |

- 212 780 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 18 spectra from 11 *Apo-Ident* customers from 16 batches from the substance/substance group *Papaverine hydrochloride*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Papaverine hydrochloride | | 1 |
| Caelo | Papaverine hydrochloride | 12166105 | 1 |
| Caelo | Papaverine hydrochloride | 12166112 | 1 |
| Caelo | Papaverine hydrochloride | 12316105 | 1 |
| Caelo | Papaverine hydrochloride | 13324307 | 1 |
| Caelo | Papaverine hydrochloride | 15160601 | 1 |
| Caelo | Papaverine hydrochloride | 15160608 | 2 |
| Caelo | Papaverine hydrochloride | 16315903 | 1 |
| Caelo | Papaverine hydrochloride | 16315907 | 1 |
| Caelo | Papaverine hydrochloride | 16315911 | 1 |
| Caelo | Papaverine hydrochloride | 17358802 | 1 |
| Caelo | Papaverine hydrochloride | 1817Q-02043 | 1 |
| Fagron | Papaverine hydrochloride | 21F07-B09 | 2 |
| GATT-KOLLER/PHOENIX | Papaverine hydrochloride | 2927/07131314 | 1 |
| Phönix Gotha | Papaverine hydrochloride | 12166101 | 1 |
| Phönix Gotha | Papaverine hydrochloride | 13324306 | 1 |

- 256 868 spectra from 1666 *Apo-Ident* customers from a total of 52 137 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Papaverine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Papaverine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 220 | 0 | 158 106 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 17 | 1 | 256 868 |

The substance/substance group *Papaverine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.2727 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21735 | 26502 | 18.12 | 136.67 |
| 23054 | 23054 | 0.00 | 136.98 |
| 25614 | 25614 | 0.00 | 135.93 |
| 26502 | 26502 | 0.00 | 135.78 |
| 27096 | 23054 | 8.37 | 138.31 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Paracetamol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20972-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Paracetamol; Paracetamolum

### Special notes

When selecting the *Paracetamol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Paracetamol | 10 | 9 | 85 |

### Second-stage model

For differentiation of the substance/substance group *Paracetamol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Paracetamol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 118.77 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Paracetamol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Paracetamol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Paracetamol | 15075706 | 22608 | 40 | 20150424 |
| Caelo | Paracetamol | 15075707 | 22822 | 40 | 20150424 |
| Caelo | Paracetamol | 191851 | 24889 | 40 | 20190827* |
| Caelo | Paracetamol | 20001174 | 25629 | 40 | 20200624* |
| Caelo | Paracetamol | 22002446 | 26370 | 40 | 20220818* |
| Caelo | Paracetamol | 22002446 | 26370SI | 20 | 20220818* |
| Euro OTC | Paracetamol | 1111024-02 | 21598 | 60 | 20120123 |
| Fagron | Paracetamol | 13D30-N03 | 20972 | 40 | 1402271 |
| Fagron | Paracetamol | 13D16-N08 | 20973 | 40 | 1402296 |
| Fagron | Paracetamol | 13G23-N03 | 20974 | 40 | 1402297 |
| Fagron | Paracetamol | 21K05-B01-223625 | 26379 | 40 | 20220307 |
| Fagron | Paracetamol | 21K05-B01-223625 | 26379SI | 20 | 20220307 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 460 spectra of 12 reference samples from the substance/substance group *Paracetamol*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 866 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 400 spectra of 11 reference samples from the substance/substance group *Paracetamol*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Paracetamol | 170284 | 23852 | 40 |
| Caelo | Paracetamol | 180830 | 24053 | 40 |
| Caelo | Paracetamol | 22003365 | 26492 | 40 |
| Caelo | Paracetamol | 22003972 | 26497 | 40 |
| Euro OTC | Paracetamol | 2003059 | 25144 | 40 |
| Euro OTC | Paracetamol | 2211002 | 26426 | 40 |
| Euro OTC | Paracetamol | 2301037 | 26588 | 40 |
| Euro OTC | Paracetamol | 2301022 | 26597 | 40 |
| Euro OTC | Paracetamol | 2401012 | 27142 | 40 |
| Caelo | Paracetamol | 22003365 | 26492SI | 20 |
| Caelo | Paracetamol | 22003972 | 26497SI | 20 |

- 212 540 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 241 spectra from 144 *Apo-Ident* customers from 88 batches from the substance/substance group *Paracetamol*.

- Among them are spectra of independent samples from 84 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Paracetamol | 20003925015 | 1 |
| | Paracetamol | 2003059-01 | 1 |
| | Paracetamol | 2003059-02 | 1 |
| | Paracetamol | 2003059-04 | 1 |
| | Paracetamol | 20F18-F02-224205 | 1 |
| | Paracetamol | 21K05-B01-223625 | 2 |
| | Paracetamol | 22002446004 | 1 |
| | Paracetamol | 22002805001 | 1 |
| | Paracetamol | 22003365004 | 1 |
| | Paracetamol | 2211002-01 | 2 |
| | Paracetamol | 230102201 | 1 |
| | Paracetamol | 2301022-01 | 3 |
| | Paracetamol | 231022-01 | 1 |
| Anzag | Paracetamol | 22003972003 | 1 |
| Atsbsx Ilsc Fabrikas... | Paracetamol | 21K05-B01-223625 | 1 |
| Caelo | Paracetamol | | 1 |
| Caelo | Paracetamol | 10065102 | 1 |
| Caelo | Paracetamol | 10325020 | 1 |
| Caelo | Paracetamol | 11300108 | 1 |
| Caelo | Paracetamol | 11300120 | 2 |
| Caelo | Paracetamol | 13082005 | 1 |
| Caelo | Paracetamol | 13082010 | 3 |
| Caelo | Paracetamol | 13082011 | 1 |
| Caelo | Paracetamol | 15075704 | 4 |
| Caelo | Paracetamol | 15075708 | 1 |
| Caelo | Paracetamol | 15217701 | 1 |
| Caelo | Paracetamol | 15217704 | 1 |
| Caelo | Paracetamol | 15217706 | 1 |
| Caelo | Paracetamol | 15217708 | 1 |
| Caelo | Paracetamol | 15217710 | 5 |
| Caelo | Paracetamol | 15217712 | 2 |
| Caelo | Paracetamol | 15245901 | 3 |
| Caelo | Paracetamol | 15245902 | 1 |
| Caelo | Paracetamol | 17028409 | 4 |
| Caelo | Paracetamol | 17028411 | 3 |
| Caelo | Paracetamol | 18018602 | 1 |
| Caelo | Paracetamol | 18018604 | 1 |
| Caelo | Paracetamol | 18083003 | 4 |
| Caelo | Paracetamol | 18083005 | 5 |
| Caelo | Paracetamol | 18083006 | 4 |
| Caelo | Paracetamol | 18083007 | 1 |
| Caelo | Paracetamol | 18083012 | 2 |
| Caelo | Paracetamol | 18083014 | 5 |
| Caelo | Paracetamol | 1814U-02045 | 1 |
| Caelo | Paracetamol | 1912M-02045 | 1 |
| Caelo | Paracetamol | 191851001 | 1 |
| Caelo | Paracetamol | 191851002 | 3 |
| Caelo | Paracetamol | 191851004 | 6 |
| Caelo | Paracetamol | 19185102 | 4 |
| Caelo | Paracetamol | 20001174002 | 3 |
| Caelo | Paracetamol | 20003925001 | 1 |
| Caelo | Paracetamol | 20003925002 | 5 |
| Caelo | Paracetamol | 20003925004 | 5 |
| Caelo | Paracetamol | 20003925005 | 2 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Paracetamol | 20003925007 | 2 |
| Caelo | Paracetamol | 20003925008 | 1 |
| Caelo | Paracetamol | 20003925009 | 1 |
| Caelo | Paracetamol | 20003925011 | 1 |
| Caelo | Paracetamol | 20003925014 | 2 |
| Caelo | Paracetamol | 20003925015 | 2 |
| Caelo | Paracetamol | 20003925016 | 2 |
| Caelo | Paracetamol | 20003925018 | 8 |
| Caelo | Paracetamol | 2000392504 | 1 |
| Caelo | Paracetamol | 2000395016 | 1 |
| Caelo | Paracetamol | 211222 | 1 |
| Caelo | Paracetamol | 22002446004 | 2 |
| Caelo | Paracetamol | 22002446005 | 5 |
| Caelo | Paracetamol | 22002805001 | 8 |
| Caelo | Paracetamol | 22002805002 | 1 |
| Caelo | Paracetamol | 22002805005 | 1 |
| Caelo | Paracetamol | 22003365002 | 3 |
| Caelo | Paracetamol | 2815I-02045 | 1 |
| Caelo | Paracetamol | 5116I-02045 | 1 |
| Caesar & Loretz GmbH... | Paracetamol | 22002805002 | 2 |
| Caesar & Loretz GmbH... | Paracetamol | 22002805001 | 1 |
| Caesar & Loretz GmbH... | Paracetamol | 18083012 | 1 |
| Caesar & Loretz GmbH/AHD | Paracetamol | 22002446002 | 1 |
| Caesar & Loretz GmbH/Gehe | Paracetamol | 20003925009 | 1 |
| Caesar & Loretz GmbH/Kehr | Paracetamol | 22002805001 | 1 |
| Caesar & Loretz GmbH... | Paracetamol | 22002805007 | 1 |
| Caesar & Loretz GmbH... | Paracetamol | 20003925005 | 2 |
| Caesar & Loretz GmbH... | Paracetamol | 22002805002 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 18083003 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 18083006 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 18083008 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 191851002 | 2 |
| Caesar & Loretz GmbH | Paracetamol | 191851004 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 20003925014 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 20003925017 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 22002446002 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 22002446004 | 3 |
| Caesar & Loretz GmbH | Paracetamol | 22002805001 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 22002805002 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 22003365002 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 22003365004 | 1 |
| Caesar & Loretz GmbH | Paracetamol | 22003365007 | 1 |
| Caesar & Loretz Hilden | Paracetamol | 18083006 | 1 |
| Euro OTC | Paracetamol | 1111024-01 | 1 |
| Euro OTC | Paracetamol | 1111024-02 | 1 |
| Euro OTC | Paracetamol | 17028409 | 1 |
| Euro OTC | Paracetamol | 2003059-01 | 6 |
| Euro OTC | Paracetamol | 2003059-02 | 3 |
| Euro OTC | Paracetamol | 2003059-03 | 3 |
| Euro OTC | Paracetamol | 200305904 | 2 |
| Euro OTC | Paracetamol | 2211002-01 | 7 |
| Euro OTC | Paracetamol | 2301022-01 | 1 |
| Euro OTC | Paracetamol | 3003059-02 | 1 |
| Fagron | Paracetamol | | 1 |
| Fagron | Paracetamol | 13L16-B02-322725 | 1 |
| Fagron | Paracetamol | 17H17-B03 | 2 |
| Fagron | Paracetamol | 17H17-B03-359484 | 1 |
| Fagron | Paracetamol | 17H17-B03-367674 | 1 |
| Fagron | Paracetamol | 17H17-B03-368809 | 1 |
| Fagron | Paracetamol | 20F18-F02-224205 | 4 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Paracetamol | 20F18-F02-374185 | 1 |
| Fagron | Paracetamol | 20F8-F02 | 1 |
| Fagron | Paracetamol | 22005356 | 1 |
| Gehe | Paracetamol | 20003925007 | 1 |
| Gehe | Paracetamol | 2301022-01 | 1 |
| Jenne | Paracetamol | 15245901 | 1 |
| Kehr | Paracetamol | 20003925005 | 1 |
| Nachprüfung | Paracetamol | 15245901 | 2 |
| Noweda | Paracetamol | 18018602 | 2 |
| Noweda | Paracetamol | 2003059-02 | 1 |
| Noweda | Paracetamol | 20F18-F02-224205 | 1 |
| Noweda | Paracetamol | 2211002-01 | 3 |
| Noweda | Paracetamol | 2301022-01 | 1 |
| Phönix | Paracetamol | 22002805001 | 1 |
| Sanacorp | Paracetamol | 22002805001 | 1 |

- 256 645 spectra from 1666 *Apo-Ident* customers from a total of 52 065 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Paracetamol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Paracetamol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 460 | 0 | 157 866 |
| **Type B** | 0 | 400 | 0 | 212 540 |
| **Type C** | 0 | 236 | 5 | 256 645 |

The substance/substance group *Paracetamol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6957 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.9253 % (> 96.6805 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20972 | 20972 | 0.00 | 202.63 |
| 20973 | 20973 | 0.00 | 201.78 |
| 20974 | 20974 | 0.00 | 216.13 |
| 21598 | 24889 | 8.99 | 201.43 |
| 22608 | 24889 | 7.55 | 199.06 |
| 22822 | 25629 | 8.21 | 202.92 |
| 24889 | 24889 | 0.00 | 207.77 |
| 25629 | 25629 | 0.00 | 205.85 |
| 26370 | 26370 | 0.00 | 203.66 |
| 26379 | 20974 | 26.70 | 216.56 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Patent blue V** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20469-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Patent blue V

### Special notes

When selecting the *Patent blue V* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Patent blue V | 6 | 2 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Patent blue V* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Patent blue V* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 55.29 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Patent blue V* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Patent blue V*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Patent blue V | 12364206 | 21384 | 40 | 1508043 |
| Caelo | Patent blue V | 12364206 | 21385 | 40 | 20130110 |
| Caelo | Patent blue V | 13351803 | 21695 | 60 | 20131114 |
| Caelo | Patent blue V | 13351807 | 22387 | 40 | 1702362 |
| Caelo | Patent blue V | 190746 | 24731 | 40 | 20190425* |
| Caelo | Patent blue V | 20000907 | 25212 | 40 | 20200604* |
| Caelo | Patent blue V | 21002827 | 26118 | 40 | 20210923* |
| Caelo | Patent blue V | 21002827 | 26118SI | 20 | 20210923* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 8 reference samples from the substance/substance group *Patent blue V*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Patent blue V*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Patent blue V | 16306902 | 23214 | 40 |
| Caelo | Patent blue V | 22002332 | 26354 | 40 |
| Caelo | Patent blue V | 16306902 | 23215 | 40 |
| Caelo | Patent blue V | 22002332 | 26354SI | 20 |

- 212 800 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 75 spectra from 64 *Apo-Ident* customers from 19 batches from the substance/substance group *Patent blue V*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Patent blue V | 22002332005 | 6 |
| | Patent blue V | 22002332008 | 1 |
| Bombastus | Patent blue V | 11305302 | 1 |
| Bombastus | Patent blue V | 17034204 | 1 |
| Caelo | Patent blue V | 11305302 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Patent blue V | 11305303 | 3 |
| Caelo | Patent blue V | 12364202 | 1 |
| Caelo | Patent blue V | 12364206 | 4 |
| Caelo | Patent blue V | 13351803 | 1 |
| Caelo | Patent blue V | 13351807 | 5 |
| Caelo | Patent blue V | 13351808 | 1 |
| Caelo | Patent blue V | 150602 | 1 |
| Caelo | Patent blue V | 15060204 | 2 |
| Caelo | Patent blue V | 16306904 | 4 |
| Caelo | Patent blue V | 17034204 | 8 |
| Caelo | Patent blue V | 17034207 | 6 |
| Caelo | Patent blue V | 17034210 | 4 |
| Caelo | Patent blue V | 19074603 | 10 |
| Caelo | Patent blue V | 20000907006 | 3 |
| Caelo | Patent blue V | 2759 | 1 |
| Caelo | Patent blue V | P-15051823/17034204 | 1 |
| Caesar & Loretz GmbH/Gehe | Patent blue V | 19074603 | 1 |
| Caesar & Loretz GmbH/Gehe | Patent blue V | 20000907006 | 1 |
| Caesar & Loretz GmbH | Patent blue V | 17034207 | 1 |
| Caesar & Loretz GmbH | Patent blue V | 19074603 | 1 |
| Caesar & Loretz GmbH | Patent blue V | 20000907006 | 4 |
| Euro OTC | Patent blue V | 17034210 | 1 |
| GEHE | Patent blue V | 17034207 | 1 |

- 256 811 spectra from 1666 *Apo-Ident* customers from a total of 52 134 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Patent blue V* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Patent blue V* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 75 | 0 | 256 811 |

The substance/substance group *Patent blue V* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)


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In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21384 | 21384 | 0.00 | 156.50 |
| 21385 | 21384 | 3.76 | 154.87 |
| 21695 | 22387 | 6.40 | 138.19 |
| 22387 | 22387 | 0.00 | 141.87 |
| 24731 | 24731 | 0.00 | 95.42 |
| 25212 | 25212 | 0.00 | 88.67 |
| 26118 | 26118 | 0.00 | 101.76 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Pectin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005975-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Pectin

### Special notes

When selecting the *Pectin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Pectin | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Pectin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Pectin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 31.71 | – |
| Cannabis flower, CBD-dominant type | 35.46 | – |
| Sodium dihydrogen phosphate dihydrate | 60.35 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Pectin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Pectin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Pectin | 21003677 | 26013 | 40 | 20220107* |
| Caelo | Pectin | 24001504 | 27318 | 40 | 20240717* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 80 spectra of 2 reference samples from the substance/substance group *Pectin*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.
- 158 246 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 90 spectra of 4 reference samples from the substance/substance group *Pectin*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Pectin | 23000147 | 27108 | 40 |
| Caelo | Pectin | 21003677 | 26013SI† | 10 |
| Caelo | Pectin | 23000147 | 27108SI | 20 |
| Caelo | Pectin | 24001504 | 27318SI† | 20 |

- 212 850 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Pectin*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Pectin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

relevant spectra of the various substances were compared with *Pectin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 80 | 0 | 158 246 |
| **Type B** | 0 | 90 | 0 | 212 850 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Pectin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 92.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 93.3333 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26013 | 26013 | 0.00 | 99.74 |
| 27318 | 27318 | 0.00 | 89.35 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Phenazone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22532-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Phenazone; Phenazonum

### Special notes

When selecting the *Phenazone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Phenazone | 7 | 4 | 4 |

### Second-stage model

For differentiation of the substance/substance group *Phenazone* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Phenazone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Midazolam hydrochloride | 100.45 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Phenazone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Phenazone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Phenazone | 15415101 | 22576 | 40 | 20151215 |
| Caelo | Phenazone | 15415107 | 22827 | 40 | 20151215 |
| Caelo | Phenazone | 181347 | 24259 | 40 | 20180629* |
| Fagron | Phenazone | 13G16-B07-287172 | 22532 | 40 | AR-16-FG-011360-01 |
| Fagron | Phenazone | 13G16-B07-287172 | 22720 | 40 | 20130814 |
| Fagron | Phenazone | 15H28-B09-322944 | 24698 | 40 | 20150916 |
| Fagron | Phenazone | 21B23-B97-210607 | 25589 | 40 | 20210301 |
| Fagron | Phenazone | 22K28-B11-226183 | 26468 | 40 | 20221214 |
| Fagron | Phenazone | 22K28-B11-226183 | 26468SI | 20 | 20221214 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 340 spectra of 9 reference samples from the substance/substance group *Phenazone*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 986 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 4 reference samples from the substance/substance group *Phenazone*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Phenazone | 170836 | 23302 | 40 |
| Caelo | Phenazone | 182565 | 24369 | 40 |
| Caelo | Phenazone | 21002059 | 25797 | 50 |
| Caelo | Phenazone | 21003237 | 25847 | 50 |

- 212 760 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4 spectra from 4 *Apo-Ident* customers from 4 batches from the substance/substance group *Phenazone*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Phenazone | 17083601 | 1 |
| Caelo | Phenazone | 18061101 | 1 |
| Caelo | Phenazone | 181347001 | 1 |
| Caelo | Phenazone | 182565002 | 1 |

- 256 882 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Phenazone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Phenazone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 340 | 0 | 157 986 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 4 | 0 | 256 882 |

The substance/substance group *Phenazone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2353 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22532 | 22532 | 0.00 | 199.70 |
| 22576 | 22532 | 10.93 | 199.06 |
| 22720 | 22532 | 3.14 | 201.05 |
| 22827 | 22532 | 9.08 | 199.12 |
| 24259 | 24259 | 0.00 | 196.81 |
| 24698 | 22532 | 17.67 | 200.57 |
| 25589 | 22532 | 16.59 | 202.56 |
| 26468 | 22532 | 15.98 | 207.92 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Pheniramine maleate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20694-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Pheniramine maleate; Pheniramini maleas

### Special notes

When selecting the *Pheniramine maleate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Pheniramine maleate | 6 | 6 | 41 |

### Second-stage model

For differentiation of the substance/substance group *Pheniramine maleate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Pheniramine maleate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Ketoprofen | 63.51 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Pheniramine maleate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Pheniramine maleate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Pheniramine maleate | 12200502 | 20694 | 40 | 1401559 |
| Caelo | Pheniramine maleate | 15172702 | 22790 | 40 | 1908273 |
| Euro OTC | Pheniramine maleate | 1910024 | 24921 | 40 | 20191122* |
| Euro OTC | Pheniramine maleate | 2209021 | 26348 | 40 | 20221018* |
| Euro OTC | Pheniramine maleate | 2209021 | 26348SI | 20 | 20221018* |
| Fagron | Pheniramine maleate | 13D24-N04 | 20928 | 40 | 20130530 |
| Fagron | Pheniramine maleate | 18C21-B02-362029 | 24948 | 40 | 20180426 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 260 spectra of 7 reference samples from the substance/substance group *Pheniramine maleate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 260 spectra of 8 reference samples from the substance/substance group *Pheniramine maleate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Pheniramine maleate | 173167 | 23821 | 40 |
| Euro OTC | Pheniramine maleate | 1109013-02 | 20756 | 40 |
| Euro OTC | Pheniramine maleate | 1701021 | 23384 | 40 |
| Euro OTC | Pheniramine maleate | 2304009 | 26640 | 40 |
| Euro OTC | Pheniramine maleate | 2501020 | 27518 | 20 |
| Fagron | Pheniramine maleate | 23B02-B03-222367 | 26668 | 40 |
| Euro OTC | Pheniramine maleate | 2304009 | 26640SI | 20 |
| Fagron | Pheniramine maleate | 23B02-B03-222367 | 26668SI | 20 |

- 212 680 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 96 spectra from 48 *Apo-Ident* customers from 42 batches from the substance/substance group *Pheniramine maleate*.

- Among them are spectra of independent samples from 41 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Pheniramine maleate | 2209021-01 | 1 |
| Alliance Healthcare | Pheniramine maleate | 12L04-N05 | 1 |
| Anzag | Pheniramine maleate | 17316706 | 2 |
| Caelo | Pheniramine maleate | 12352602 | 1 |
| Caelo | Pheniramine maleate | 12352604 | 1 |
| Caelo | Pheniramine maleate | 1235611 | 1 |
| Caelo | Pheniramine maleate | 14C25-B01-292540 | 1 |
| Caelo | Pheniramine maleate | 14C25-B01-302272 | 1 |
| Caelo | Pheniramine maleate | 14C25-B01-322989 | 1 |
| Caelo | Pheniramine maleate | 15172704 | 1 |
| Caelo | Pheniramine maleate | 15172708 | 1 |
| Caelo | Pheniramine maleate | 15172711 | 1 |
| Caelo | Pheniramine maleate | 173167001 | 1 |
| Caelo | Pheniramine maleate | 173167002 | 2 |
| Caelo | Pheniramine maleate | 173167003 | 1 |
| Caelo | Pheniramine maleate | 17316702 | 1 |
| Caelo | Pheniramine maleate | 17316705 | 1 |
| Caelo | Pheniramine maleate | 17316706 | 3 |
| Caelo | Pheniramine maleate | 17316707 | 1 |
| Caelo | Pheniramine maleate | 17316708 | 1 |
| Caelo | Pheniramine maleate | 9276210 | 1 |
| Caesar & Loretz GmbH | Pheniramine maleate | 173167002 | 6 |
| Cealo | Pheniramine maleate | 12352608 | 1 |
| EuRO 14.11.2013 Phönix | Pheniramine maleate | 1209032-01 | 1 |
| Euro OTC | Pheniramine maleate | 1109013-01 | 1 |
| Euro OTC | Pheniramine maleate | 1209032-01 | 2 |
| Euro OTC | Pheniramine maleate | 1411044-01 | 1 |
| Euro OTC | Pheniramine maleate | 1411044-02 | 3 |
| Euro OTC | Pheniramine maleate | 1701021-01 | 19 |
| Euro OTC | Pheniramine maleate | 1910024-01 | 1 |
| Euro OTC | Pheniramine maleate | 1910024-02 | 2 |
| Euro OTC | Pheniramine maleate | 2209021-01 | 2 |
| Fagron | Pheniramine maleate | 12I06-N02 | 1 |
| Fagron | Pheniramine maleate | 12L04-N05 | 3 |
| Fagron | Pheniramine maleate | 14C25-B01-292540 | 1 |
| Fagron | Pheniramine maleate | 14C25-B01-295293 | 3 |
| Fagron | Pheniramine maleate | 14c25b01307150 | 1 |
| Fagron | Pheniramine maleate | 14c25-b01-307150 | 1 |
| Fagron | Pheniramine maleate | 14C25-B01-307150 | 3 |
| Fagron | Pheniramine maleate | 14C25-B01-328732 | 2 |
| Fagron | Pheniramine maleate | 18C21-B02-351507 | 2 |
| Fagron | Pheniramine maleate | 18C21-B02-357417 | 1 |
| Fagron | Pheniramine maleate | 18C21-B02-369804 | 1 |
| Fagron | Pheniramine maleate | 18C21B02370926 | 1 |
| Noweda 28.08.2019 | Pheniramine maleate | 15172714 | 1 |
| Noweda | Pheniramine maleate | 1701021 | 1 |
| Phönix 25.4.19 | Pheniramine maleate | 1701021-01 | 7 |
| Sanacorp | Pheniramine maleate | 18C21-B02-369804 | 1 |
| Supriya LifeScience … | Pheniramine maleate | SLL/P/1213063 | 1 |
| Supriya LifeScience … | Pheniramine maleate | 14C25-B01 | 1 |

- 256 790 spectra from 1666 *Apo-Ident* customers from a total of 52 111 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Pheniramine maleate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Pheniramine maleate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 260 | 0 | 212 680 |
| **Type C** | 0 | 95 | 1 | 256 790 |

The substance/substance group *Pheniramine maleate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6923 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.9583 % (> 95.8333 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20694 | 20694 | 0.00 | 102.57 |
| 20928 | 20694 | 13.79 | 102.92 |
| 22790 | 22790 | 0.00 | 116.95 |
| 24921 | 24921 | 0.00 | 119.86 |
| 24948 | 22790 | 23.29 | 135.43 |
| 26348 | 26348 | 0.00 | 131.86 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Phenylbutazon** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20447-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Phenylbutazon; Phenylbutazonum

### Special notes

When selecting the *Phenylbutazon* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Phenylbutazon | 9 | 5 | 12 |

### Second-stage model

For differentiation of the substance/substance group *Phenylbutazon* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Phenylbutazon* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dithranol | 126.84 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Phenylbutazon* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Phenylbutazon*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Phenylbutazon | 14057202 | 21379 | 40 | 20140321 |
| Caelo | Phenylbutazon | 161121 | 22471 | 60 | 20160331* |
| Euro OTC | Phenylbutazon | 1305050-02 | 21605 | 60 | AR-15-FG-005687-01 |
| Euro OTC | Phenylbutazon | 1507023 | 21855 | 60 | 20150805* |
| Euro OTC | Phenylbutazon | 1908013 | 24861 | 40 | 20190923* |
| Euro OTC | Phenylbutazon | 2001046 | 25239 | 40 | 20200728* |
| Euro OTC | Phenylbutazon | 2101032 | 25535 | 40 | 20210218* |
| Euro OTC | Phenylbutazon | 2209001 | 26347 | 40 | 20220921* |
| Euro OTC | Phenylbutazon | 2209001 | 26347SI | 20 | 20220921* |
| Fagron | Phenylbutazon | 23H09-B02-004580 | 27483 | 40 | 20230907 |
| Fagron | Phenylbutazon | 23H09-B02-004580 | 27483SI | 20 | 20230907 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 460 spectra of 11 reference samples from the substance/substance group *Phenylbutazon*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 866 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 220 spectra of 6 reference samples from the substance/substance group *Phenylbutazon*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Phenylbutazon | 1604033 | 22563 | 40 |
| Euro OTC | Phenylbutazon | 1804018 | 24122 | 40 |
| Euro OTC | Phenylbutazon | 2107012 | 25830 | 50 |
| Fagron | Phenylbutazon | 18B21-B06-361114 | 24952 | 40 |
| Fagron | Phenylbutazon | 22G22-B03-221076 | 26451 | 40 |
| Euro OTC | Phenylbutazon | 2107012 | 25830SI | 10 |

- 212 720 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 12 spectra from 11 *Apo-Ident* customers from 12 batches from the substance/substance group *Phenylbutazon*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Phenylbutazon | 10262901 | 1 |
| Caelo | Phenylbutazon | 14099511 | 1 |
| Caelo | Phenylbutazon | 15218502 | 1 |
| Caelo | Phenylbutazon | 18063205 | 1 |
| Euro OTC | Phenylbutazon | 130505_01 | 1 |
| Euro OTC | Phenylbutazon | 170612PB/1604033-01 | 1 |
| Euro OTC | Phenylbutazon | 180401802 | 1 |
| Euro OTC | Phenylbutazon | 1804018-03 | 1 |
| Euro OTC | Phenylbutazon | 19091806 | 1 |
| Euro OTC | Phenylbutazon | 2001046-01 | 1 |
| Fagron | Phenylbutazon | 11H26-N02 | 1 |
| Fagron | Phenylbutazon | 13D30-N16 | 1 |

- 256 874 spectra from 1666 *Apo-Ident* customers from a total of 52 141 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Phenylbutazon* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Phenylbutazon* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 460 | 0 | 157 866 |
| **Type B** | 0 | 220 | 0 | 212 720 |
| **Type C** | 0 | 12 | 0 | 256 874 |

The substance/substance group *Phenylbutazon* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6957 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.2727 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21379 | 21605 | 5.14 | 219.07 |
| 21605 | 21605 | 0.00 | 213.97 |
| 21855 | 21855 | 0.00 | 217.46 |
| 22471 | 22471 | 0.00 | 216.08 |
| 24861 | 24861 | 0.00 | 223.81 |
| 25239 | 25239 | 0.00 | 223.40 |
| 25535 | 25535 | 0.00 | 225.99 |
| 26347 | 26347 | 0.00 | 225.83 |
| 27483 | 26347 | 4.48 | 226.52 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Phenylephrine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20567-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Phenylephrine hydrochloride; Phenylephrini hydrochloridum

### Special notes

When selecting the *Phenylephrine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Phenylephrine hydrochloride | 8 | 5 | 87 |

### Second-stage model

For differentiation of the substance/substance group *Phenylephrine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Phenylephrine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Caffeine citrate | 129.76 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Phenylephrine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Phenylephrine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Phenylephrine hydrochloride | 1704009 | 23394 | 40 | 20170524* |
| Euro OTC | Phenylephrine hydrochloride | 2001012 | 25102 | 40 | 20200218* |
| Euro OTC | Phenylephrine hydrochloride | 2109007 | 25823 | 50 | 20211006* |
| Euro OTC | Phenylephrine hydrochloride | 2202012 | 26039 | 40 | 20220310* |
| Fagron | Phenylephrine hydrochloride | 12J19-B40-288254 | 21051 | 40 | 20131210 |
| Fagron | Phenylephrine hydrochloride | 14H13-B02-308438 | 21960 | 60 | AR-16-FG-008920-01 |
| Fagron | Phenylephrine hydrochloride | 16A20-B07-317987 | 22388 | 40 | AR-16-FG-013385-01 |
| Fagron | Phenylephrine hydrochloride | 20D01-F06-370692 | 25366 | 40 | 20200529 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 350 spectra of 8 reference samples from the substance/substance group *Phenylephrine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 976 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 290 spectra of 8 reference samples from the substance/substance group *Phenylephrine hydrochloride*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Phenylephrine hydrochloride | 2010018 | 25455 | 40 |
| Fagron | Phenylephrine hydrochloride | 17C23-B04-333878 | 23263 | 40 |
| Fagron | Phenylephrine hydrochloride | 17C23-B04-333880 | 23267 | 40 |
| Fagron | Phenylephrine hydrochloride | 22D28-B01-218602 | 26167 | 40 |
| Fagron | Phenylephrine hydrochloride | 24I25-B06-004500 | 27480 | 40 |
| Euro OTC | Phenylephrine hydrochloride | 2109007 | 25823SI† | 10 |
| Euro OTC | Phenylephrine hydrochloride | 2202012 | 26039SI† | 40 |
| Fagron | Phenylephrine hydrochloride | 22D28-B01-218602 | 26167SI | 40 |

- 212 650 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 208 spectra from 38 *Apo-Ident* customers from 92 batches from the substance/substance group *Phenylephrine hydrochloride*.

- Among them are spectra of independent samples from 87 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Phenylephrine hydrochloride | 21C04-F02-377267 | 1 |
| | Phenylephrine hydrochloride | 21F15-B10-216432 | 1 |
| | Phenylephrine hydrochloride | 23A04-B05-226165 | 1 |
| ALH | Phenylephrine hydrochloride | 16A20-B07-322159 | 1 |
| Audor Pharma | Phenylephrine hydrochloride | APP70-16017PE | 1 |
| Audor Pharma | Phenylephrine hydrochloride | APP70-17001PE | 2 |
| Audor Pharma | Phenylephrine hydrochloride | APP70-17011PE | 1 |
| Audor Pharma | Phenylephrine hydrochloride | APP70-18008PE | 1 |
| Caelo | Phenylephrine hydrochloride | 14H13-B02-308438 | 1 |
| Caelo | Phenylephrine hydrochloride | 17C23-B04-334819 | 1 |
| Caelo | Phenylephrine hydrochloride | 17H18-B02_353092 | 1 |
| Caelo | Phenylephrine hydrochloride | 17H18-B02-349261 | 2 |
| Caelo | Phenylephrine hydrochloride | 17H18-B02-353092 | 1 |
| Caelo | Phenylephrine hydrochloride | 18026008 | 1 |
| Euro OTC | Phenylephrine hydrochloride | 1704009-01 | 1 |
| Euro OTC | Phenylephrine hydrochloride | 2001012-01 | 1 |
| Euro OTC | Phenylephrine hydrochloride | 2010018-01 | 1 |
| Euro OTC | Phenylephrine hydrochloride | 21022182 | 1 |
| Euro OTC | Phenylephrine hydrochloride | 2109007-01 | 2 |
| Fagon | Phenylephrine hydrochloride | 20D01-F06-370690 | 1 |
| Fagron | Phenylephrine hydrochloride | 10091504 | 1 |
| Fagron | Phenylephrine hydrochloride | 1021402 | 1 |
| Fagron | Phenylephrine hydrochloride | 12031801 | 1 |
| Fagron | Phenylephrine hydrochloride | 12A03-N09 | 1 |
| Fagron | Phenylephrine hydrochloride | 12C08-N17 | 1 |
| Fagron | Phenylephrine hydrochloride | 12g19-n04 | 1 |
| Fagron | Phenylephrine hydrochloride | 12G19-N04 | 1 |
| Fagron | Phenylephrine hydrochloride | 12J19-B40-288253 | 2 |
| Fagron | Phenylephrine hydrochloride | 13A03-N09 | 3 |
| Fagron | Phenylephrine hydrochloride | 13B14-N03 | 1 |
| Fagron | Phenylephrine hydrochloride | 13G10-N04 | 1 |
| Fagron | Phenylephrine hydrochloride | 13K25-B02-293844 | 3 |
| Fagron | Phenylephrine hydrochloride | 13K25-B02-293845 | 1 |
| Fagron | Phenylephrine hydrochloride | 14H13-02-309892 | 1 |
| Fagron | Phenylephrine hydrochloride | 14H13-B02 | 1 |
| Fagron | Phenylephrine hydrochloride | 14H13-B02-299814 | 1 |
| Fagron | Phenylephrine hydrochloride | 14H13-B02-299816 | 2 |
| Fagron | Phenylephrine hydrochloride | 14H13B02299817 | 1 |
| Fagron | Phenylephrine hydrochloride | 14H13B02-299817 | 1 |
| Fagron | Phenylephrine hydrochloride | 14H13B02309892 | 1 |
| Fagron | Phenylephrine hydrochloride | 14H13-B02-309892 | 4 |
| Fagron | Phenylephrine hydrochloride | 15F09-B08-316796 | 2 |
| Fagron | Phenylephrine hydrochloride | 16A20-B07-233159 | 1 |
| Fagron | Phenylephrine hydrochloride | 16A20-B07-317987 | 2 |
| Fagron | Phenylephrine hydrochloride | 16A20B07322159 | 1 |
| Fagron | Phenylephrine hydrochloride | 16A20-B07-323398 | 3 |
| Fagron | Phenylephrine hydrochloride | 16A-B07-317987 | 1 |
| Fagron | Phenylephrine hydrochloride | 17C23-B04-333878 | 3 |
| Fagron | Phenylephrine hydrochloride | 17C23-B04-333879 | 1 |
| Fagron | Phenylephrine hydrochloride | 17c23-b04-333880 | 1 |
| Fagron | Phenylephrine hydrochloride | 17C23-B04-333880 | 1 |
| Fagron | Phenylephrine hydrochloride | 17C23-B04-334819 | 7 |
| Fagron | Phenylephrine hydrochloride | 17H18-B02 | 1 |
| Fagron | Phenylephrine hydrochloride | 17-H18-B02 | 1 |
| Fagron | Phenylephrine hydrochloride | 17H18-B02-345401 | 3 |
| Fagron | Phenylephrine hydrochloride | 17H18-B02-348065 | 1 |
| Fagron | Phenylephrine hydrochloride | 17H18-B02-349261 | 2 |
| Fagron | Phenylephrine hydrochloride | 17H18-B02-349262 | 4 |
| Fagron | Phenylephrine hydrochloride | 17H18-B02-353092 | 2 |
| Fagron | Phenylephrine hydrochloride | 17H-18-B02-353092 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Phenylephrine hydrochloride | 17-H18-B02-353092 | 1 |
| Fagron | Phenylephrine hydrochloride | 17H18-B02-353093 | 1 |
| Fagron | Phenylephrine hydrochloride | 18L06-B02 | 8 |
| Fagron | Phenylephrine hydrochloride | 18L06-B02-360768 | 15 |
| Fagron | Phenylephrine hydrochloride | 18L06-B02-363037 | 2 |
| Fagron | Phenylephrine hydrochloride | 18L06-B02-367069 | 4 |
| Fagron | Phenylephrine hydrochloride | 18L06-B02-367673 | 11 |
| Fagron | Phenylephrine hydrochloride | 198099-0004 | 1 |
| Fagron | Phenylephrine hydrochloride | 19L06-B02-360768 | 1 |
| Fagron | Phenylephrine hydrochloride | 19L06-B02-367069 | 1 |
| Fagron | Phenylephrine hydrochloride | 20D01-F06 | 4 |
| Fagron | Phenylephrine hydrochloride | 20D01-F06-0003 | 1 |
| Fagron | Phenylephrine hydrochloride | 20D01-F06-370691 | 8 |
| Fagron | Phenylephrine hydrochloride | 20D01-F06-370692 | 1 |
| Fagron | Phenylephrine hydrochloride | 20D01-F06-373487 | 7 |
| Fagron | Phenylephrine hydrochloride | 20G10-F09 | 2 |
| Fagron | Phenylephrine hydrochloride | 20G10-F09-373759 | 1 |
| Fagron | Phenylephrine hydrochloride | 21C04-F02 | 1 |
| Fagron | Phenylephrine hydrochloride | 21C04-F02-377267 | 1 |
| Fagron | Phenylephrine hydrochloride | 21F15-B10 | 2 |
| Fagron | Phenylephrine hydrochloride | 21F15-B10-216432 | 1 |
| Fagron | Phenylephrine hydrochloride | 21F15-B10-217523 | 6 |
| Fagron | Phenylephrine hydrochloride | 2-IL-D-0080117 | 1 |
| Fagron | Phenylephrine hydrochloride | B02-3670609 | 1 |
| Fagron | Phenylephrine hydrochloride | B02-3676703 | 2 |
| Fagron | Phenylephrine hydrochloride | F06-3706900 | 2 |
| Fagron | Phenylephrine hydrochloride | F06-3706901 | 2 |
| Fagron | Phenylephrine hydrochloride | F06-3706902 | 1 |
| Fagron | Phenylephrine hydrochloride | PEH-170717 | 3 |
| Fagron | Phenylephrine hydrochloride | PEH-200305 | 1 |
| Gatt-Koller | Phenylephrine hydrochloride | 330010164116 | 1 |
| GEHE | Phenylephrine hydrochloride | 17H18-B02 | 6 |
| GEHE | Phenylephrine hydrochloride | 17H18-B02-345401 | 2 |
| Jenne | Phenylephrine hydrochloride | 14H13-B02 | 2 |
| JENNE | Phenylephrine hydrochloride | 17H18-B02-339756 | 1 |
| Nachprüfung | Phenylephrine hydrochloride | 123456 | 1 |
| Noweda/Fargon | Phenylephrine hydrochloride | 17C23-B04-336301 | 4 |
| Noweda | Phenylephrine hydrochloride | 12F01-N20 | 2 |
| Phoenix | Phenylephrine hydrochloride | 15F09-B08 | 1 |
| PHÖNIX | Phenylephrine hydrochloride | 17C23-B04-334819 | 1 |
| PHÖNIX | Phenylephrine hydrochloride | 18L06-B02 | 3 |

- 256 678 spectra from 1666 *Apo-Ident* customers from a total of 52 064 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Phenylephrine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Phenylephrine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 350 | 0 | 157 976 |
| **Type B** | 0 | 290 | 0 | 212 650 |
| **Type C** | 0 | 208 | 0 | 256 678 |

The substance/substance group *Phenylephrine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.2857 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.9310 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.1154 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21051 | 21960 | 5.19 | 280.90 |
| 21960 | 21960 | 0.00 | 283.01 |
| 22388 | 22388 | 0.00 | 283.22 |
| 23394 | 23394 | 0.00 | 280.57 |
| 25102 | 25102 | 0.00 | 286.68 |
| 25366 | 21960 | 5.82 | 281.99 |
| 25823 | 25823 | 0.00 | 273.19 |
| 26039 | 26039 | 0.00 | 272.01 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Phenytoin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20949-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Phenytoin; Phenytoinum

### Special notes

When selecting the *Phenytoin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Phenytoin | 6 | 3 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Phenytoin* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Phenytoin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 106.83 | – |
| ⋮ | ⋮ | ⋮ |
| Saccharin sodium | >50 | 86.84 |
| Propranolol hydrochloride | >50 | 110.85 |
| Quinoline yellow | >50 | 145.79 |
| Atropine sulfate | >50 | 162.54 |
| Mometasone furoate | >50 | 186.38 |
| Magnesium hydrogen citrate | >50 | 258.74 |
| Calcium orotate dihydrate | >50 | 264.61 |
| Potassium sorbate | >50 | 367.20 |
| Hydrocortisone | >50 | 375.08 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Phenytoin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Phenytoin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Phenytoin | 13G26-N02 | 20949 | 40 | 1401380 |
| Fagron | Phenytoin | 15E12-B05-312661 | 22271 | 45 | 20150519 |
| Fagron | Phenytoin | 18F01-B02-350492 | 24438 | 40 | 20180705 |
| Fagron | Phenytoin | 18F01-B02-350492 | 24693 | 40 | 20180705 |
| Fagron | Phenytoin | 19E14-B02 | 24818 | 40 | 20190722 |
| Fagron | Phenytoin | 22A17-F03-381312 | 27041 | 40 | 20220301 |
| Fagron | Phenytoin | 25B05-B17-007513 | 27638 | 40 | 20250320 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 285 spectra of 7 reference samples from the substance/substance group *Phenytoin*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 041 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 6 reference samples from the substance/substance group *Phenytoin*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Phenytoin | 12I07-N02 | 20678 | 40 |
| Fagron | Phenytoin | 16C14-B06-325086 | 23110 | 40 |
| Fagron | Phenytoin | 17L22-B04-345861 | 23994 | 40 |
| Fagron | Phenytoin | 16C14-B06-325086 | 23377 | 40 |
| Fagron | Phenytoin | 22A17-F03-381312 | 27041SI† | 20 |
| Fagron | Phenytoin | 25B05-B17-007513 | 27638SI† | 20 |

- 212 740 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 8 spectra from 7 *Apo-Ident* customers from 5 batches from the substance/substance group *Phenytoin*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Phenytoin | 22A17-F03-381312 | 3 |
| Caelo | Phenytoin | 17L22-B04-345861 | 1 |
| Fagron | Phenytoin | 12C27N13 | 1 |
| Fagron | Phenytoin | 12I07-N02 | 1 |
| Fagron | Phenytoin | 13G26-N02 | 1 |
| Fagron | Phenytoin | 22A17-F03-381312 | 1 |

- 256 878 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Phenytoin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Phenytoin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 285 | 0 | 158 041 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 8 | 0 | 256 878 |

The substance/substance group *Phenytoin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8947 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20949 | 20949 | 0.00 | 317.65 |
| 22271 | 20949 | 17.83 | 317.82 |
| 24438 | 20949 | 7.82 | 317.22 |
| 24693 | 20949 | 5.31 | 318.88 |
| 24818 | 20949 | 6.79 | 317.67 |
| 27041 | 20949 | 24.75 | 311.05 |
| 27638 | 20949 | 9.09 | 316.17 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Pilocarpine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21519-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Pilocarpine hydrochloride; Pilocarpini hydrochloridum

### Special notes

When selecting the *Pilocarpine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Pilocarpine hydrochloride | 7 | 6 | 57 |

### Second-stage model

For differentiation of the substance/substance group *Pilocarpine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Pilocarpine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Ofloxacin | 52.03 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Pilocarpine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Pilocarpine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Pilocarpine hydrochloride | 12217319 | 21518 | 60 | 20120806 |
| Caelo | Pilocarpine hydrochloride | 12217319 | 21519 | 60 | 1501660 |
| Caelo | Pilocarpine hydrochloride | 171595 | 23337 | 40 | 20170606* |
| Caelo | Pilocarpine hydrochloride | 17124208 | 23371 | 40 | 20170607 |
| Euro OTC | Pilocarpine hydrochloride | 1305044-01 | 21629 | 60 | 20130725 |
| Euro OTC | Pilocarpine hydrochloride | 1305044-01 | 21629SI | 60 | 20130725 |
| Euro OTC | Pilocarpine hydrochloride | 1603047 | 22553 | 40 | 20160429* |
| Euro OTC | Pilocarpine hydrochloride | 1603047 | 22553SI | 40 | 20160429* |
| Euro OTC | Pilocarpine hydrochloride | 1908008 | 24845 | 40 | 20190830* |
| Fagron | Pilocarpine hydrochloride | 22H16-B10-221817 | 26386 | 40 | 20220912 |
| Fagron | Pilocarpine hydrochloride | 22H16-B10-221817 | 26386SI | 40 | 20220912 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 520 spectra of 11 reference samples from the substance/substance group *Pilocarpine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 806 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 660 spectra of 16 reference samples from the substance/substance group *Pilocarpine hydrochloride*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Pilocarpine hydrochloride | 171242 | 23338 | 40 |
| Caelo | Pilocarpine hydrochloride | 191220 | 24762 | 40 |
| Caelo | Pilocarpine hydrochloride | 23000207 | 26727 | 40 |
| Euro OTC | Pilocarpine hydrochloride | 1806012 | 24140 | 40 |
| Euro OTC | Pilocarpine hydrochloride | 2010012 | 25478 | 40 |
| Euro OTC | Pilocarpine hydrochloride | 2208009 | 26270 | 40 |
| Caelo | Pilocarpine hydrochloride | 12217319 | 21518SI† | 60 |
| Caelo | Pilocarpine hydrochloride | 171595 | 23337SI† | 40 |
| Caelo | Pilocarpine hydrochloride | 171242 | 23338SI | 40 |
| Caelo | Pilocarpine hydrochloride | 17124208 | 23371SI† | 40 |
| Caelo | Pilocarpine hydrochloride | 191220 | 24762SI | 40 |
| Caelo | Pilocarpine hydrochloride | 23000207 | 26727SI | 40 |
| Euro OTC | Pilocarpine hydrochloride | 1806012 | 24140SI | 40 |
| Euro OTC | Pilocarpine hydrochloride | 1908008 | 24845SI† | 40 |
| Euro OTC | Pilocarpine hydrochloride | 2010012 | 25478SI | 40 |
| Euro OTC | Pilocarpine hydrochloride | 2208009 | 26270SI | 40 |

- 212 280 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 193 spectra from 110 *Apo-Ident* customers from 61 batches from the substance/substance group *Pilocarpine hydrochloride*.
- Among them are spectra of independent samples from 57 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Pilocarpine hydrochloride | 2208009-01 | 3 |
| | Pilocarpine hydrochloride | 23000207002 | 2 |
| | Pilocarpine hydrochloride | 23003455003 | 1 |
| | Pilocarpine hydrochloride | 24001858003 | 1 |
| 1806012-01 | Pilocarpine hydrochloride | 15198603 | 1 |
| 1Caesar & Loretz GmbH | Pilocarpine hydrochloride | 21001750010 | 1 |
| Caelo | Pilocarpine hydrochloride | 11161903 | 1 |
| Caelo | Pilocarpine hydrochloride | 12217302 | 1 |
| Caelo | Pilocarpine hydrochloride | 12217307 | 1 |
| Caelo | Pilocarpine hydrochloride | 12217316 | 1 |
| Caelo | Pilocarpine hydrochloride | 12K07-N09 | 1 |
| Caelo | Pilocarpine hydrochloride | 130504401 | 1 |
| Caelo | Pilocarpine hydrochloride | 1305044-03 | 1 |
| Caelo | Pilocarpine hydrochloride | 14239402 | 1 |
| Caelo | Pilocarpine hydrochloride | 15198610 | 2 |
| Caelo | Pilocarpine hydrochloride | 15198701 | 2 |
| Caelo | Pilocarpine hydrochloride | 1603047-02 | 3 |
| Caelo | Pilocarpine hydrochloride | 17124208 | 4 |
| Caelo | Pilocarpine hydrochloride | 17159510 | 1 |
| Caelo | Pilocarpine hydrochloride | 17236401 | 1 |
| Caelo | Pilocarpine hydrochloride | 17332002 | 4 |
| Caelo | Pilocarpine hydrochloride | 18138704 | 6 |
| Caelo | Pilocarpine hydrochloride | 18138709 | 1 |
| Caelo | Pilocarpine hydrochloride | 191220001 | 5 |
| Caelo | Pilocarpine hydrochloride | 19122001 | 1 |
| Caelo | Pilocarpine hydrochloride | 21000139001 | 2 |
| Caelo | Pilocarpine hydrochloride | 21001750003 | 4 |
| Caelo | Pilocarpine hydrochloride | 2211112032607 | 1 |
| Caelo | Pilocarpine hydrochloride | 25051303 | 1 |
| Caesar & Loretz GmbH... | Pilocarpine hydrochloride | 191220001 | 1 |
| Caesar & Loretz GmbH... | Pilocarpine hydrochloride | 191220001 | 1 |
| Caesar & Loretz GmbH... | Pilocarpine hydrochloride | 191220009 | 4 |
| Caesar & Loretz GmbH... | Pilocarpine hydrochloride | 191220001 | 1 |
| Caesar & Loretz GmbH | Pilocarpine hydrochloride | 191220001 | 1 |
| Caesar & Loretz GmbH | Pilocarpine hydrochloride | 191220003 | 1 |
| Caesar & Loretz GmbH | Pilocarpine hydrochloride | 19122001 | 1 |
| Caesar & Loretz GmbH | Pilocarpine hydrochloride | 21000139001 | 1 |
| Caesar & Loretz GmbH | Pilocarpine hydrochloride | 21000139002 | 3 |
| Caesar & Loretz GmbH | Pilocarpine hydrochloride | 21000139005 | 4 |
| Caesar & Loretz GmbH | Pilocarpine hydrochloride | 21001750003 | 4 |
| EuRho/Noweda | Pilocarpine hydrochloride | 18060012-01 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 1202031-01 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 1202031-02 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 13050-14-01 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 130504401 | 2 |
| Euro OTC | Pilocarpine hydrochloride | 1305044-01 | 6 |
| Euro OTC | Pilocarpine hydrochloride | 1305044-03 | 2 |
| Euro OTC | Pilocarpine hydrochloride | 1603047 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 1603047-01 | 6 |
| Euro OTC | Pilocarpine hydrochloride | 160304702 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Pilocarpine hydrochloride | 1603047-02 | 28 |
| Euro OTC | Pilocarpine hydrochloride | 1806012-01 | 12 |
| Euro OTC | Pilocarpine hydrochloride | 1806012-02 | 4 |
| Euro OTC | Pilocarpine hydrochloride | 18A31-B05-350799 | 5 |
| Euro OTC | Pilocarpine hydrochloride | 18CB02 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 19008008-01 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 190800 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 1908008-01 | 16 |
| Euro OTC | Pilocarpine hydrochloride | 19CC02 | 1 |
| Euro OTC | Pilocarpine hydrochloride | 2010012-01 | 4 |
| Euro OTC | Pilocarpine hydrochloride | Euroo | 1 |
| Euro OTG | Pilocarpine hydrochloride | 1305044-01 | 1 |
| Fagron | Pilocarpine hydrochloride | 13H24-N03 | 1 |
| Fagron | Pilocarpine hydrochloride | 15B27-B03-309493 | 1 |
| Fagron | Pilocarpine hydrochloride | 18A31-B05-346072 | 1 |
| Fagron | Pilocarpine hydrochloride | 18A31-B05350799 | 1 |
| Fagron | Pilocarpine hydrochloride | 18A31-B05-350799 | 1 |
| Fagron | Pilocarpine hydrochloride | 19E20-B13-191235 | 1 |
| Fagron | Pilocarpine hydrochloride | 20D14-B05-196754 | 2 |
| Fagron | Pilocarpine hydrochloride | 20H18-B06-203134 | 1 |
| Fagron | Pilocarpine hydrochloride | 350799 | 1 |
| Gehe | Pilocarpine hydrochloride | 15198610 | 1 |
| Gehe | Pilocarpine hydrochloride | 17124209 | 1 |
| Gehe | Pilocarpine hydrochloride | 1806012-02 | 1 |
| GEHE | Pilocarpine hydrochloride | 18138704 | 1 |
| Leyhs | Pilocarpine hydrochloride | 15198701 | 1 |
| Noweda | Pilocarpine hydrochloride | 23003455003 | 1 |
| Phönix | Pilocarpine hydrochloride | 1603047-02 | 1 |
| Sanacorp | Pilocarpine hydrochloride | 12217302 | 1 |
| SourcetechQuimica/Noweda | Pilocarpine hydrochloride | | 1 |

- 256 693 spectra from 1666 *Apo-Ident* customers from a total of 52 093 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Pilocarpine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Pilocarpine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 520 | 0 | 157 806 |
| **Type B** | 0 | 660 | 0 | 212 280 |
| **Type C** | 0 | 193 | 0 | 256 693 |

The substance/substance group *Pilocarpine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8462 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0909 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 96.8912 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21518 | 24845 | 23.59 | 57.39 |
| 21519 | 21519 | 0.00 | 61.98 |
| 21629 | 24845 | 6.41 | 61.30 |
| 22553 | 22553 | 0.00 | 65.18 |
| 23337 | 23337 | 0.00 | 67.07 |
| 23371 | 21519 | 7.11 | 61.29 |
| 24845 | 24845 | 0.00 | 61.63 |
| 26386 | 21519 | 30.47 | 72.52 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Poloxamers** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20540-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Poloxamers; Poloxamera

### Special notes

When selecting the *Poloxamers* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Poloxamers | 6 | 7 | 51 |

### Second-stage model

For differentiation of the substance/substance group *Poloxamers* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Poloxamers* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycerol monostearate, emulsifying | 97.08 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Poloxamers* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Poloxamers*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Poloxamers | 14196101 | 21652 | 60 | AR-14-FG-013090-01 |
| Caelo | Poloxamers | 16242605 | 23257 | 40 | 20160915 |
| Caelo | Poloxamers | 20003669003 | 25509 | 40 | 20201117 |
| Caelo | Poloxamers | 22003362006 | 26746 | 40 | 20230208 |
| Caelo | Poloxamers | 22003362006 | 26746SI | 20 | 20230208 |
| Caelo | Poloxamers | 23001663 | 27115 | 40 | 20231207* |
| Caelo | Poloxamers | 23001663 | 27115SI | 20 | 20231207* |
| Fagron | Poloxamers | 14G17-B03-296866 | 21726 | 60 | 20140806 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 8 reference samples from the substance/substance group *Poloxamers*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 290 spectra of 8 reference samples from the substance/substance group *Poloxamers*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Poloxamers | 170486 | 23311 | 40 |
| Caelo | Poloxamers | 172921 | 23810 | 40 |
| Caelo | Poloxamers | 181607 | 24219 | 40 |
| Caelo | Poloxamers | 182636 | 24358 | 40 |
| Caelo | Poloxamers | 21001523004 | 25980 | 40 |
| Caelo | Poloxamers | 24002242 | 27437 | 40 |
| Caelo | Poloxamers | 25000580 | 27662 | 40 |
| Caelo | Poloxamers | 21001523004 | 25980SI | 10 |

- 212 650 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 152 spectra from 102 *Apo-Ident* customers from 55 batches from the substance/substance group *Poloxamers*.

- Among them are spectra of independent samples from 51 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Poloxamers | 22003362002 | 1 |
| | Poloxamers | 22003362006 | 6 |
| | Poloxamers | 22003362007 | 3 |
| | Poloxamers | 22003362010 | 3 |
| | Poloxamers | 24002242001 | 1 |
| | Poloxamers | 24002242009 | 1 |
| Anzag | Poloxamers | 22003362006 | 1 |
| Caelo | Poloxamers | 11B22-N04 | 1 |
| Caelo | Poloxamers | 12286801 | 2 |
| Caelo | Poloxamers | 12286805 | 1 |
| Caelo | Poloxamers | 12286806 | 1 |
| Caelo | Poloxamers | 13133201 | 1 |
| Caelo | Poloxamers | 13133203 | 2 |
| Caelo | Poloxamers | 13133207 | 1 |
| Caelo | Poloxamers | 14196101 | 2 |
| Caelo | Poloxamers | 14196104 | 1 |
| Caelo | Poloxamers | 14196105 | 1 |
| Caelo | Poloxamers | 14196108 | 2 |
| Caelo | Poloxamers | 14359501 | 1 |
| Caelo | Poloxamers | 15183102 | 2 |
| Caelo | Poloxamers | 15397802 | 5 |
| Caelo | Poloxamers | 16189301 | 1 |
| Caelo | Poloxamers | 16189302 | 4 |
| Caelo | Poloxamers | 16242601 | 3 |
| Caelo | Poloxamers | 16242605 | 3 |
| Caelo | Poloxamers | 162426056 | 1 |
| Caelo | Poloxamers | 17048601 | 4 |
| Caelo | Poloxamers | 17048606 | 2 |
| Caelo | Poloxamers | 17292101 | 2 |
| Caelo | Poloxamers | 18025101 | 13 |
| Caelo | Poloxamers | 18160702 | 10 |
| Caelo | Poloxamers | 18160704 | 4 |
| Caelo | Poloxamers | 182636001 | 3 |
| Caelo | Poloxamers | 18263601 | 4 |
| Caelo | Poloxamers | 18263605 | 3 |
| Caelo | Poloxamers | 18263607 | 4 |
| Caelo | Poloxamers | 20000294001 | 3 |
| Caelo | Poloxamers | 20003669003 | 8 |
| Caelo | Poloxamers | 21001523001 | 5 |
| Caelo | Poloxamers | 21001523004 | 1 |
| Caelo | Poloxamers | 21001523009 | 2 |
| Caelo | Poloxamers | 22003362002 | 1 |
| Caesar & Loretz GmbH… | Poloxamers | 18263601 | 1 |
| Caesar & Loretz GmbH/Gehe | Poloxamers | 18263607 | 1 |
| Caesar & Loretz GmbH… | Poloxamers | 182636 | 1 |
| Caesar & Loretz GmbH | Poloxamers | 15183102 | 1 |
| Caesar & Loretz GmbH | Poloxamers | 182636002 | 3 |
| Caesar & Loretz GmbH | Poloxamers | 18263601 | 1 |
| Caesar & Loretz GmbH | Poloxamers | 18263607 | 1 |
| Caesar & Loretz GmbH | Poloxamers | 20000294001 | 1 |
| Caesar & Loretz GmbH | Poloxamers | 20003669003 | 2 |
| Caesar & Loretz GmbH | Poloxamers | 21001523001 | 1 |
| Caesar & Loretz GmbH | Poloxamers | 21001523004 | 2 |
| Euro OTC | Poloxamers | 15397802 | 1 |
| Fagron | Poloxamers | 12K23-N03 | 1 |
| Fagron | Poloxamers | 13G29-N01 | 1 |
| Fagron | Poloxamers | 13G29-NO1 | 1 |
| Fagron | Poloxamers | 15A26-B03-303503 | 1 |
| Fagron | Poloxamers | 315E-07027 | 1 |
| Fagron | Poloxamers | 318A-07027 | 1 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Poloxamers | 5211Q-07027 | 1 |
| Fagron | Poloxamers | 5315I-07027 | 1 |
| Fagron | Poloxamers | 914I-07027 | 1 |
| Fagron | Poloxamers | WPIH605B | 1 |
| Fagron | Poloxamers | WPWI610C | 1 |
| Noweda | Poloxamers | 18263607 | 1 |
| Phonix | Poloxamers | 12/13-N10 | 1 |
| Sanacorp | Poloxamers | 14196101 | 2 |
| Sigma-Aldrich | Poloxamers | BCBW9875 | 1 |

- 256 734 spectra from 1666 *Apo-Ident* customers from a total of 52 098 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Poloxamers* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Poloxamers* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 290 | 0 | 212 650 |
| **Type C** | 0 | 151 | 1 | 256 734 |

The substance/substance group *Poloxamers* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.9310 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.3421 % (> 97.3684 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21652 | 21652 | 0.00 | 127.14 |
| 21726 | 21652 | 6.55 | 127.01 |
| 23257 | 21652 | 8.77 | 128.21 |
| 25509 | 27115 | 11.86 | 129.25 |
| 26746 | 27115 | 16.87 | 129.57 |
| 27115 | 27115 | 0.00 | 129.00 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Polymyxin B sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20853-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Polymyxin B sulfate; Polymyxin B sulphate; Polymyxini B sulfas

### Special notes

When selecting the *Polymyxin B sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Polymyxin B sulfate | 14 | 14 | 85 |

### Second-stage model

For differentiation of the substance/substance group *Polymyxin B sulfate* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Polymyxin B sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 33.90 | – |
| Colistin sulfate | 40.71 | 19.36 |
| Bacitracin | 46.83 | 19.37 |
| Cannabis flower, THC-dominant type | 57.52 | – |
| ⋮ | ⋮ | ⋮ |
| Calcium pantothenate | 60.08 | 19.60 |
| Riboflavin | >50 | 33.60 |
| Amphotericin B | >50 | 46.90 |
| Nystatin | >50 | 51.06 |
| Cyanocobalamin | >50 | 58.15 |
| Triamcinolone | >50 | 61.90 |
| Methylcobalamin | >50 | 65.02 |
| Calcium glycerophosphate | >50 | 70.38 |
| alpha-tocopheryl acetate dry concentrate | >50 | 72.35 |
| Gelatine, white | >50 | 77.03 |
| Estradiol hemihydrate | >50 | 88.72 |
| Estriol | >50 | 90.82 |
| Hyoscine hydrobromide | >50 | 101.25 |
| Carmellose sodium | >50 | 118.31 |
| Tosylchloramide sodium | >50 | 121.42 |
| SyrSpend® SF Alka | >50 | 130.88 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 156.73 |
| Rice starch | >50 | 162.97 |
| Corn starch | >50 | 234.00 |
| Oxalic acid | >50 | 237.16 |
| Acacia, dried dispersion | >50 | 256.75 |
| SyrSpend® SF pH4 | >50 | 284.39 |
| Potato starch | >50 | 329.92 |
| Wheat starch | >50 | 340.74 |
| Maltodextrin | >50 | 370.04 |
| Fructose | >50 | 390.49 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Polymyxin B sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Polymyxin B sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Polymyxin B sulfate | 153501 | 22451 | 60 | 20160318* |
| Caelo | Polymyxin B sulfate | 181154 | 24407 | 40 | 20180507* |
| Euro OTC | Polymyxin B sulfate | 1304033-01 | 21094 | 40 | 20130829 |
| Euro OTC | Polymyxin B sulfate | 1202039-02 | 21329 | 40 | 1411033 |
| Euro OTC | Polymyxin B sulfate | 1304033-02 | 21584 | 60 | 20130612 |
| Euro OTC | Polymyxin B sulfate | 1505005-01 | 21980 | 60 | AR-16-FG-005387-01 |
| Euro OTC | Polymyxin B sulfate | 1604016 | 22542 | 40 | 20160509* |
| Euro OTC | Polymyxin B sulfate | 2101014 | 25597 | 40 | 20210331* |
| Euro OTC | Polymyxin B sulfate | 2303014 | 26763 | 40 | 20230525* |
| Fagron | Polymyxin B sulfate | 13C12-N02 | 20853 | 40 | 1402691 |
| Fagron | Polymyxin B sulfate | 12G13-N05 | 21258 | 40 | 1410347 |
| Fagron | Polymyxin B sulfate | 13I13-N05 | 21595 | 45 | AR-15-FG-001516-01 |
| Fagron | Polymyxin B sulfate | 14F04-B03-296722 | 21957 | 60 | 20140708 |
| Fagron | Polymyxin B sulfate | 15H14-B01-314364 | 22323 | 60 | 20150902 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 665 spectra of 14 reference samples from the substance/substance group *Polymyxin B sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 14 different batches.

- 157 661 spectra from a total of 2943 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 660 spectra of 18 reference samples from the substance/substance group *Polymyxin B sulfate*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Polymyxin B sulfate | 191131 | 24752 | 40 |
| Caelo | Polymyxin B sulfate | 22001497 | 26255 | 40 |
| Caelo | Polymyxin B sulfate | 23001927 | 26970 | 40 |
| Euro OTC | Polymyxin B sulfate | 1701010 | 23012 | 40 |
| Euro OTC | Polymyxin B sulfate | 1707013 | 23554 | 40 |
| Euro OTC | Polymyxin B sulfate | 1802006 | 23953 | 40 |
| Euro OTC | Polymyxin B sulfate | 1807004 | 24143 | 40 |
| Euro OTC | Polymyxin B sulfate | 1811022 | 24494 | 40 |
| Euro OTC | Polymyxin B sulfate | 1906002 | 24779 | 40 |
| Euro OTC | Polymyxin B sulfate | 1911021 | 25088 | 40 |
| Euro OTC | Polymyxin B sulfate | 2006009 | 25317 | 40 |
| Euro OTC | Polymyxin B sulfate | 2205005 | 26226 | 40 |
| Fagron | Polymyxin B sulfate | 13E06-N12 | 20912 | 40 |
| Fagron | Polymyxin B sulfate | 22A21-B03-218149 | 26144 | 40 |
| Caelo | Polymyxin B sulfate | 22001497 | 26255SI | 20 |
| Euro OTC | Polymyxin B sulfate | 1202039-02 | 20904 | 40 |
| Euro OTC | Polymyxin B sulfate | 2205005 | 26226SI | 20 |
| Fagron | Polymyxin B sulfate | 22A21-B03-218149 | 26144SI | 20 |

- 212 280 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 272 spectra from 178 *Apo-Ident* customers from 91 batches from the substance/substance group *Polymyxin B sulfate*.

- Among them are spectra of independent samples from 85 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Polymyxin B sulfate | 2101014-01 | 2 |
| | Polymyxin B sulfate | 22K22-B02-224472 | 2 |
| | Polymyxin B sulfate | 22K22-B02-2244702 | 1 |
| | Polymyxin B sulfate | 230035622001 | 1 |
| | Polymyxin B sulfate | 2303014-01 | 12 |
| | Polymyxin B sulfate | 230314-01 | 1 |
| | Polymyxin B sulfate | 23A12-B07-227270 | 1 |
| Alliance Healthcare | Polymyxin B sulfate | 1202039-02 | 1 |
| apo-ident/Gehe/24,50 | Polymyxin B sulfate | 1807004-01 | 1 |
| Biotika / Ebert | Polymyxin B sulfate | 15011 | 1 |
| Biotika a.s./Phoenix | Polymyxin B sulfate | 2101014-01 | 1 |
| Biotika/Noweda | Polymyxin B sulfate | 200317 | 1 |
| Biotika | Polymyxin B sulfate | 150828 | 1 |
| Bombastus | Polymyxin B sulfate | 1604016-02 | 1 |
| Caelo | Polymyxin B sulfate | 1102013-01 | 1 |
| Caelo | Polymyxin B sulfate | 13H28-B02-287953 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Polymyxin B sulfate | 150725 | 1 |
| Caelo | Polymyxin B sulfate | 15350101 | 8 |
| Caelo | Polymyxin B sulfate | 15350101P-190311-3 | 1 |
| Caelo | Polymyxin B sulfate | 1604016-01 | 3 |
| Caelo | Polymyxin B sulfate | 16C01-B04-319432 | 1 |
| Caelo | Polymyxin B sulfate | 170101001 | 3 |
| Caelo | Polymyxin B sulfate | 1701010-01 | 1 |
| Caelo | Polymyxin B sulfate | 1707013-01 | 1 |
| Caelo | Polymyxin B sulfate | 1802006-01 | 2 |
| Caelo | Polymyxin B sulfate | 1802006-011 | 1 |
| Caelo | Polymyxin B sulfate | 18115406 | 2 |
| Caelo | Polymyxin B sulfate | 18115410 | 2 |
| Caelo | Polymyxin B sulfate | 19113102 | 1 |
| Caelo | Polymyxin B sulfate | 19113103 | 1 |
| Caelo | Polymyxin B sulfate | 20003057003 | 4 |
| Caesar & Loretz GmbH | Polymyxin B sulfate | 20003057003 | 2 |
| cealo | Polymyxin B sulfate | 16c01-b04-319432 | 1 |
| EuRho/Phoenix | Polymyxin B sulfate | 2006009-01 | 1 |
| EuRho | Polymyxin B sulfate | 1202039-01 | 1 |
| EuRho | Polymyxin B sulfate | 1807004-01 | 1 |
| EuRho | Polymyxin B sulfate | 2006008-01 | 1 |
| EuRho | Polymyxin B sulfate | 2006009 | 1 |
| Euro OTC | Polymyxin B sulfate | 11091419 | 1 |
| Euro OTC | Polymyxin B sulfate | 1202039-01 | 1 |
| Euro OTC | Polymyxin B sulfate | 1202039-02 | 4 |
| Euro OTC | Polymyxin B sulfate | 1304033-01 | 1 |
| Euro OTC | Polymyxin B sulfate | 1304033-02 | 1 |
| Euro OTC | Polymyxin B sulfate | 1304033-03 | 2 |
| Euro OTC | Polymyxin B sulfate | 1406012-01 | 3 |
| Euro OTC | Polymyxin B sulfate | 140601202 | 3 |
| Euro OTC | Polymyxin B sulfate | 1406012-02 | 5 |
| Euro OTC | Polymyxin B sulfate | 150500501 | 1 |
| Euro OTC | Polymyxin B sulfate | 1505005-01 | 6 |
| Euro OTC | Polymyxin B sulfate | 1505505-01 | 1 |
| Euro OTC | Polymyxin B sulfate | 1604016-01 | 2 |
| Euro OTC | Polymyxin B sulfate | 1604016-02 | 6 |
| Euro OTC | Polymyxin B sulfate | 170101001 | 1 |
| Euro OTC | Polymyxin B sulfate | 1701010-01 | 13 |
| Euro OTC | Polymyxin B sulfate | 1707013-01 | 10 |
| Euro OTC | Polymyxin B sulfate | 180200601 | 1 |
| Euro OTC | Polymyxin B sulfate | 1802006-01 | 8 |
| Euro OTC | Polymyxin B sulfate | 1807004-01 | 6 |
| Euro OTC | Polymyxin B sulfate | 1811022-01 | 8 |
| Euro OTC | Polymyxin B sulfate | 1906002-01 | 7 |
| Euro OTC | Polymyxin B sulfate | 1911021-01 | 5 |
| Euro OTC | Polymyxin B sulfate | 20060001 | 1 |
| Euro OTC | Polymyxin B sulfate | 2006009-01 | 15 |
| Euro OTC | Polymyxin B sulfate | 2101014-01 | 23 |
| Euro OTC | Polymyxin B sulfate | 2205005-01 | 1 |
| Euro OTC | Polymyxin B sulfate | 23051502 | 1 |
| Euro OTC | Polymyxin B sulfate | 25101201 | 1 |
| Euro OTC | Polymyxin B sulfate | 28041730 | 1 |
| Euroo/Phoenix | Polymyxin B sulfate | 1304033-02 | 1 |
| Fagron | Polymyxin B sulfate | 12G13N05 | 1 |
| Fagron | Polymyxin B sulfate | 12G13-N05 | 4 |
| Fagron | Polymyxin B sulfate | 13/13-N05 | 1 |
| Fagron | Polymyxin B sulfate | 13G05-N06 | 2 |
| Fagron | Polymyxin B sulfate | 13H28-B02-287954 | 1 |
| Fagron | Polymyxin B sulfate | 13H28-B02-293470 | 1 |
| Fagron | Polymyxin B sulfate | 140822 | 1 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Polymyxin B sulfate | 14F04-B03-296721 | 1 |
| Fagron | Polymyxin B sulfate | 14H12-B06-304727 | 1 |
| Fagron | Polymyxin B sulfate | 15H14-B01-315692 | 1 |
| Fagron | Polymyxin B sulfate | 16C01-B04 | 1 |
| Fagron | Polymyxin B sulfate | 16C01-B04-319432 | 1 |
| Fagron | Polymyxin B sulfate | 16c01b04322012 | 1 |
| Fagron | Polymyxin B sulfate | 16C01-B04-322012 | 3 |
| Fagron | Polymyxin B sulfate | 16G21-B03-333808 | 1 |
| Fagron | Polymyxin B sulfate | 170621 | 1 |
| Fagron | Polymyxin B sulfate | 17H23-B01-344840 | 2 |
| Fagron | Polymyxin B sulfate | 18B28B04351511 | 1 |
| Fagron | Polymyxin B sulfate | 18B28-B04-355722 | 2 |
| Fagron | Polymyxin B sulfate | 19/11-F01-368351 | 1 |
| Fagron | Polymyxin B sulfate | 191057 | 1 |
| Fagron | Polymyxin B sulfate | 19A23-B01-361158 | 4 |
| Fagron | Polymyxin B sulfate | 19A23-B01-3621201 | 1 |
| Fagron | Polymyxin B sulfate | 19A23-B01-362121 | 2 |
| Fagron | Polymyxin B sulfate | 19I11-F01-3683501 | 1 |
| Fagron | Polymyxin B sulfate | 20B21-F08-373930 | 1 |
| Fagron | Polymyxin B sulfate | 20F23-F01 | 1 |
| Fagron | Polymyxin B sulfate | 21K09-B10-213615 | 1 |
| Fagron | Polymyxin B sulfate | 22A21-B03-218149 | 1 |
| Fagron | Polymyxin B sulfate | 22K22-B0-224472 | 1 |
| Fagron | Polymyxin B sulfate | 2517M-03315 | 1 |
| Fagron | Polymyxin B sulfate | 3518A-03315 | 1 |
| Fagron | Polymyxin B sulfate | 912A-03315 | 1 |
| Fagron | Polymyxin B sulfate | F08-3739300 | 1 |
| Fargon/Phoenix | Polymyxin B sulfate | 17H23-B01-344840 | 1 |
| Fiebig | Polymyxin B sulfate | 1807004-01 | 1 |
| Gatt-Koller | Polymyxin B sulfate | 17H23B01344840 | 1 |
| Gehe | Polymyxin B sulfate | 170101001 | 1 |
| GEHE | Polymyxin B sulfate | 1701010-01 | 1 |
| Gehe | Polymyxin B sulfate | 2101014-01 | 1 |
| Kehr | Polymyxin B sulfate | 2303014-01 | 1 |
| Noweda 03.08.2019 | Polymyxin B sulfate | 18115406 | 1 |
| Phoenix | Polymyxin B sulfate | 1807004-01 | 1 |
| Phoenix | Polymyxin B sulfate | 2006009-01 | 1 |
| Phönix/Euro | Polymyxin B sulfate | 1505005-010 | 1 |
| Phönix | Polymyxin B sulfate | 1202039-01 | 1 |
| Phönix | Polymyxin B sulfate | 1701010-01 | 1 |
| Phönix | Polymyxin B sulfate | 1707013 | 1 |
| Rondell Apotheke | Polymyxin B sulfate | 121161 | 1 |
| Sanacorp | Polymyxin B sulfate | 1707013-01 | 1 |
| Sanacorp | Polymyxin B sulfate | 2101014-01 | 1 |

- 256 614 spectra from 1666 *Apo-Ident* customers from a total of 52 064 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Polymyxin B sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Polymyxin B sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The


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following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 665 | 0 | 157 661 |
| **Type B** | 0 | 660 | 0 | 212 280 |
| **Type C** | 0 | 266 | 6 | 256 614 |

The substance/substance group *Polymyxin B sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0977 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0909 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.7941 % (> 96.6912 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20853 | 20853 | 0.00 | 49.46 |
| 21094 | 21980 | 6.93 | 55.96 |
| 21258 | 21258 | 0.00 | 48.82 |
| 21329 | 21329 | 0.00 | 52.09 |
| 21584 | 21980 | 13.38 | 58.17 |
| 21595 | 21595 | 0.00 | 66.56 |
| 21957 | 22451 | 4.64 | 63.46 |
| 21980 | 21980 | 0.00 | 58.05 |
| 22323 | 25597 | 8.27 | 61.45 |
| 22451 | 22451 | 0.00 | 67.03 |
| 22542 | 22542 | 0.00 | 49.60 |
| 24407 | 24407 | 0.00 | 46.83 |
| 25597 | 25597 | 0.00 | 60.06 |
| 26763 | 26763 | 0.00 | 55.78 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Potassium citrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20021-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Potassium citrate; Kalii citras

### Special notes

When selecting the *Potassium citrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Potassium citrate | 13 | 15 | 176 |

### Second-stage model

For differentiation of the substance/substance group *Potassium citrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Potassium citrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 72.57 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Potassium citrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Potassium citrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Potassium citrate | 11320212 | 20655 | 40 | 20111201 |
| Caelo | Potassium citrate | 13317618 | 21452 | 60 | 20130926 |
| Caelo | Potassium citrate | 15123103 | 21775 | 60 | 20150414 |
| Caelo | Potassium citrate | 161130 | 22476 | 60 | 20160602* |
| Caelo | Potassium citrate | 21000107 | 25558 | 40 | 20210113* |
| Caelo | Potassium citrate | 22002808 | 26481 | 40 | 20221104* |
| Caelo | Potassium citrate | 22002808 | 26481SI | 20 | 20221104* |
| Euro OTC | Potassium citrate | 1509044 | 21936 | 60 | 20151013* |
| Euro OTC | Potassium citrate | 1611017 | 22921 | 40 | 20161207* |
| Euro OTC | Potassium citrate | 1912008 | 25090 | 40 | 20200115* |
| Euro OTC | Potassium citrate | 2101026 | 25607 | 40 | 20210126* |
| Euro OTC | Potassium citrate | 2105012 | 25703 | 50 | 20210630* |
| Fagron | Potassium citrate monohydrate | 24J23-B006 | BR20058 | 40 | 20241227* |
| Fagron | Potassium citrate monohydrate | 24I06-B040 | BR20060 | 40 | 20241007* |
| Fagron | Potassium citrate monohydrate | 24I06-B040 | BR20060SI | 20 | 20241007* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 650 spectra of 15 reference samples from the substance/substance group *Potassium citrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 13 different batches.

- 157 676 spectra from a total of 2944 batches from further 495 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 680 spectra of 19 reference samples from the substance/substance group *Potassium citrate*.

- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Potassium citrate | 170929 | 23290 | 40 |
| Caelo | Potassium citrate | 180385 | 24046 | 40 |
| Caelo | Potassium citrate | 191804 | 24736 | 40 |
| Euro OTC | Potassium citrate | 1603040 | 22521 | 40 |
| Euro OTC | Potassium citrate | 1606041 | 22676 | 40 |
| Euro OTC | Potassium citrate | 1705024 | 23428 | 40 |
| Euro OTC | Potassium citrate | 1803003 | 24084 | 40 |
| Euro OTC | Potassium citrate | 1807034 | 24160 | 40 |
| Euro OTC | Potassium citrate | 1902027 | 24485 | 40 |
| Euro OTC | Potassium citrate | 1907016 | 24785 | 40 |
| Euro OTC | Potassium citrate | 2008015 | 25346 | 40 |
| Euro OTC | Potassium citrate | 2109025 | 25881 | 50 |
| Euro OTC | Potassium citrate | 2212005 | 26535 | 40 |
| Euro OTC | Potassium citrate | 2311001 | 27006 | 40 |
| Fagron | Potassium citrate monohydrate | 24I06-B039 | BR20059 | 40 |
| Euro OTC | Potassium citrate | 2109025 | 25881SI | 10 |
| Euro OTC | Potassium citrate | 2212005 | 26535SI | 20 |
| Fagron | Potassium citrate monohydrate | 24J23-B006 | BR20058SI† | 20 |
| Fagron | Potassium citrate monohydrate | 24I06-B039 | BR20059SI | 20 |

- 212 260 spectra from a total of 4271 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this

entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 545 spectra from 246 *Apo-Ident* customers from 182 batches from the substance/substance group *Potassium citrate*.
- Among them are spectra of independent samples from 176 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Potassium citrate | | 1 |
| | Potassium citrate | 123345 | 1 |
| | Potassium citrate | 12345 | 1 |
| | Potassium citrate | 21000107023 | 2 |
| | Potassium citrate | 22002808006 | 2 |
| | Potassium citrate | 22002808012 | 2 |
| | Potassium citrate | 2212005-01 | 6 |
| | Potassium citrate | 2212005-02 | 2 |
| | Potassium citrate | 24000093002 | 3 |
| | Potassium citrate | 24000093005 | 2 |
| | Potassium citrate | 3126221 | 1 |
| | Potassium citrate | hfdf5545 | 1 |
| ACM | Potassium citrate | KNC0196J15 | 4 |
| AHD | Potassium citrate | 24000093005 | 1 |
| Alliance/EurRho | Potassium citrate | 3055187 | 1 |
| Alliance | Potassium citrate | 1611017-01 | 1 |
| Caelo | Potassium citrate | | 9 |
| Caelo | Potassium citrate | 11102201 | 1 |
| Caelo | Potassium citrate | 1112008-01 | 1 |
| Caelo | Potassium citrate | 11320201 | 1 |
| Caelo | Potassium citrate | 11320212 | 3 |
| Caelo | Potassium citrate | 116I-01737 | 1 |
| Caelo | Potassium citrate | 1204016-01 | 1 |
| Caelo | Potassium citrate | 12135302 | 6 |
| Caelo | Potassium citrate | 12135303 | 2 |
| Caelo | Potassium citrate | 12135309 | 2 |
| Caelo | Potassium citrate | 12135311 | 3 |
| Caelo | Potassium citrate | 1215309 | 1 |
| Caelo | Potassium citrate | 12299201 | 5 |
| Caelo | Potassium citrate | 12299202 | 1 |
| Caelo | Potassium citrate | 12299203 | 4 |
| Caelo | Potassium citrate | 12334 | 1 |
| Caelo | Potassium citrate | 1234 | 4 |
| Caelo | Potassium citrate | 12345 | 3 |
| Caelo | Potassium citrate | 12345678 | 1 |
| Caelo | Potassium citrate | 123654879 | 1 |
| Caelo | Potassium citrate | 123test | 2 |
| Caelo | Potassium citrate | 123Test | 4 |
| Caelo | Potassium citrate | 123Testmessung | 1 |
| Caelo | Potassium citrate | 12456 | 1 |
| Caelo | Potassium citrate | 1256369 | 1 |
| Caelo | Potassium citrate | 12648 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Potassium citrate | 13080602 | 8 |
| Caelo | Potassium citrate | 13080603 | 1 |
| Caelo | Potassium citrate | 13135902 | 2 |
| Caelo | Potassium citrate | 13135904 | 1 |
| Caelo | Potassium citrate | 13135907 | 5 |
| Caelo | Potassium citrate | 13135908 | 1 |
| Caelo | Potassium citrate | 1314M-01737 | 1 |
| Caelo | Potassium citrate | 13317602 | 2 |
| Caelo | Potassium citrate | 13317603 | 2 |
| Caelo | Potassium citrate | 13317604 | 2 |
| Caelo | Potassium citrate | 13317613 | 3 |
| Caelo | Potassium citrate | 13317618 | 2 |
| Caelo | Potassium citrate | 14138105 | 8 |
| Caelo | Potassium citrate | 14138107 | 1 |
| Caelo | Potassium citrate | 14138112 | 1 |
| Caelo | Potassium citrate | 14138118 | 3 |
| Caelo | Potassium citrate | 14138119 | 1 |
| Caelo | Potassium citrate | 151231 | 1 |
| Caelo | Potassium citrate | 15123102 | 2 |
| Caelo | Potassium citrate | 15123103 | 4 |
| Caelo | Potassium citrate | 15148701 | 7 |
| Caelo | Potassium citrate | 15148702 | 1 |
| Caelo | Potassium citrate | 15148706 | 11 |
| Caelo | Potassium citrate | 15148707 | 4 |
| Caelo | Potassium citrate | 15148708 | 2 |
| Caelo | Potassium citrate | 15158706 | 1 |
| Caelo | Potassium citrate | 15434709 | 1 |
| Caelo | Potassium citrate | 154357 | 3 |
| Caelo | Potassium citrate | 15435701 | 7 |
| Caelo | Potassium citrate | 15435702 | 1 |
| Caelo | Potassium citrate | 154357025 | 1 |
| Caelo | Potassium citrate | 15435703 | 5 |
| Caelo | Potassium citrate | 15435709 | 4 |
| Caelo | Potassium citrate | 15435710 | 5 |
| Caelo | Potassium citrate | 15435711 | 1 |
| Caelo | Potassium citrate | 1543702 | 1 |
| Caelo | Potassium citrate | 15896 | 1 |
| Caelo | Potassium citrate | 16113002 | 3 |
| Caelo | Potassium citrate | 16113003 | 2 |
| Caelo | Potassium citrate | 16113006 | 5 |
| Caelo | Potassium citrate | 16113007 | 3 |
| Caelo | Potassium citrate | 16113008 | 2 |
| Caelo | Potassium citrate | 16113012 | 10 |
| Caelo | Potassium citrate | 17061402 | 1 |
| Caelo | Potassium citrate | 170922904 | 1 |
| Caelo | Potassium citrate | 17092903 | 8 |
| Caelo | Potassium citrate | 17092904 | 5 |
| Caelo | Potassium citrate | 18007603 | 3 |
| Caelo | Potassium citrate | 18007604 | 2 |
| Caelo | Potassium citrate | 18007607 | 2 |
| Caelo | Potassium citrate | 18038502 | 3 |
| Caelo | Potassium citrate | 18038506 | 11 |
| Caelo | Potassium citrate | 18038507 | 2 |
| Caelo | Potassium citrate | 18038509 | 1 |
| Caelo | Potassium citrate | 18038512 | 2 |
| Caelo | Potassium citrate | 18038514 | 5 |
| Caelo | Potassium citrate | 18038517 | 3 |
| Caelo | Potassium citrate | 18038519 | 4 |
| Caelo | Potassium citrate | 18038523 | 1 |
| Caelo | Potassium citrate | 1807034-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Potassium citrate | 189645 | 1 |
| Caelo | Potassium citrate | 191804001 | 5 |
| Caelo | Potassium citrate | 191804006 | 6 |
| Caelo | Potassium citrate | 191804008 | 1 |
| Caelo | Potassium citrate | 191804009 | 2 |
| Caelo | Potassium citrate | 191804011 | 1 |
| Caelo | Potassium citrate | 19180402 | 2 |
| Caelo | Potassium citrate | 20004139002 | 2 |
| Caelo | Potassium citrate | 20004139003 | 4 |
| Caelo | Potassium citrate | 21000107002 | 2 |
| Caelo | Potassium citrate | 21000107005 | 1 |
| Caelo | Potassium citrate | 21000107010 | 4 |
| Caelo | Potassium citrate | 21000107015 | 3 |
| Caelo | Potassium citrate | 2114M1737 | 1 |
| Caelo | Potassium citrate | 232262310107 | 1 |
| Caelo | Potassium citrate | 24000093002 | 2 |
| Caelo | Potassium citrate | 26113006 | 1 |
| Caelo | Potassium citrate | 28021402 | 1 |
| Caelo | Potassium citrate | 3012Q-01737 | 1 |
| Caelo | Potassium citrate | 3094247 | 1 |
| Caelo | Potassium citrate | 3112M01737 | 1 |
| Caelo | Potassium citrate | 3456 | 1 |
| Caelo | Potassium citrate | 3618E-01737 | 1 |
| Caelo | Potassium citrate | 411025-1-P | 1 |
| Caelo | Potassium citrate | 5021509 | 1 |
| Caelo | Potassium citrate | 5555 | 1 |
| Caelo | Potassium citrate | 71730128 | 2 |
| Caelo | Potassium citrate | 71730367 | 1 |
| Caelo | Potassium citrate | 9259107 | 1 |
| Caelo | Potassium citrate | 9259120 | 1 |
| Caelo | Potassium citrate | Caelo | 1 |
| Caelo | Potassium citrate | gfte | 1 |
| Caelo | Potassium citrate | RT115113 | 1 |
| Caesar & Loretz GmbH... | Potassium citrate | 19180402 | 1 |
| Caesar & Loretz GmbH... | Potassium citrate | 18038519 | 1 |
| Caesar & Loretz GmbH... | Potassium citrate | 19180402 | 1 |
| Caesar & Loretz GmbH... | Potassium citrate | 191804006 | 1 |
| Caesar & Loretz GmbH/Gehe | Potassium citrate | 191804011 | 1 |
| Caesar & Loretz GmbH... | Potassium citrate | 191804009 | 1 |
| Caesar & Loretz GmbH... | Potassium citrate | 21000107001 | 1 |
| Caesar & Loretz GmbH... | Potassium citrate | 21000107003 | 1 |
| Caesar & Loretz GmbH/Ph | Potassium citrate | 191804006 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 18007607 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 18038509 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 18038514 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 191804006 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 191804007 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 191804008 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 19180401 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 191804011 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 19180402 | 7 |
| Caesar & Loretz GmbH | Potassium citrate | 20004139002 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 20004139003 | 1 |
| Caesar & Loretz GmbH | Potassium citrate | 21000107024 | 1 |
| EuRho/Phoenix | Potassium citrate | 2105012-01 | 1 |
| EuRho/Phönix | Potassium citrate | 1311036-01 | 1 |
| EuRho | Potassium citrate | 1211006-01 | 2 |
| EuRho | Potassium citrate | 1603040-01 | 1 |
| Eurho | Potassium citrate | 2101026-01 | 1 |
| Euro OT/Phönix | Potassium citrate | 3036325 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Potassium citrate | 1306032-01 | 1 |
| Euro OTC | Potassium citrate | 1311036-01 | 9 |
| Euro OTC | Potassium citrate | 1406025-01 | 1 |
| Euro OTC | Potassium citrate | 1410014-01 | 2 |
| Euro OTC | Potassium citrate | 1504024-01 | 2 |
| Euro OTC | Potassium citrate | 1509044-01 | 6 |
| Euro OTC | Potassium citrate | 1603040-01 | 12 |
| Euro OTC | Potassium citrate | 160601-01 | 1 |
| Euro OTC | Potassium citrate | 160604-01 | 1 |
| Euro OTC | Potassium citrate | 160604101 | 1 |
| Euro OTC | Potassium citrate | 1606041-01 | 4 |
| Euro OTC | Potassium citrate | 1611017 | 1 |
| Euro OTC | Potassium citrate | 1611017-01 | 8 |
| Euro OTC | Potassium citrate | 16113006 | 2 |
| Euro OTC | Potassium citrate | 16113012 | 1 |
| Euro OTC | Potassium citrate | 1705024-01 | 7 |
| Euro OTC | Potassium citrate | 1803003-01 | 2 |
| Euro OTC | Potassium citrate | 180703401 | 1 |
| Euro OTC | Potassium citrate | 1807034-01 | 8 |
| Euro OTC | Potassium citrate | 1902027 | 1 |
| Euro OTC | Potassium citrate | 1902027-01 | 7 |
| Euro OTC | Potassium citrate | 190227-01 | 1 |
| Euro OTC | Potassium citrate | 190701601 | 2 |
| Euro OTC | Potassium citrate | 1907016-01 | 2 |
| Euro OTC | Potassium citrate | 191200-01 | 1 |
| Euro OTC | Potassium citrate | 1912008-01 | 9 |
| Euro OTC | Potassium citrate | 1912008-02 | 4 |
| Euro OTC | Potassium citrate | 1915A-01737 | 1 |
| Euro OTC | Potassium citrate | 192027-01 | 1 |
| Euro OTC | Potassium citrate | 20004139003 | 1 |
| Euro OTC | Potassium citrate | 2008015-01 | 7 |
| Euro OTC | Potassium citrate | 2008015-02 | 4 |
| Euro OTC | Potassium citrate | 2008015-15 | 1 |
| Euro OTC | Potassium citrate | 2101026-01 | 6 |
| Euro OTC | Potassium citrate | 2105012-01 | 6 |
| Euro OTC | Potassium citrate | 2109025-01 | 9 |
| Euro OTC | Potassium citrate | 2109025-02 | 2 |
| Euro OTC | Potassium citrate | 22101303 | 1 |
| Euro OTC | Potassium citrate | 2212005-01 | 2 |
| Euro OTC | Potassium citrate | 3126221 | 1 |
| EuRoh/Noweda | Potassium citrate | 1807034-01 | 1 |
| Fagron | Potassium citrate | | 1 |
| Fagron | Potassium citrate | 123456 | 6 |
| Fagron | Potassium citrate | 1234567 | 1 |
| Fagron | Potassium citrate | A35405 | 1 |
| Fragon/ Gehe | Potassium citrate | 3055187 | 1 |
| Gatt-Koller | Potassium citrate | 1800758 | 1 |
| Gehe | Potassium citrate | 19180402 | 1 |
| ghfgh | Potassium citrate | 3654645 | 1 |
| Gutenberg-Apotheke | Potassium citrate | 13135907 | 1 |
| Hiperscan | Potassium citrate | | 1 |
| HiperScan | Potassium citrate | | 1 |
| L12 | Potassium citrate | 15435709 | 1 |
| Labor | Potassium citrate | 1234 | 2 |
| lohmann | Potassium citrate | 1051470 | 1 |
| Nachprüfung | Potassium citrate | 111112 | 1 |
| Nachprüfung | Potassium citrate | 123456 | 1 |
| Noweda 10.12.2019 | Potassium citrate | 18007607 | 1 |
| Noweda | Potassium citrate | 18038506 | 1 |
| Noweda | Potassium citrate | 21000107014 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix 08.07.2014 | Potassium citrate | 13317624 | 1 |
| Phoenix Goettin | Potassium citrate | 13317613 | 1 |
| Phoenix | Potassium citrate | 1326PLV-1739 | 1 |
| Phoenix | Potassium citrate | 15148708 | 1 |
| Phönix | Potassium citrate | 15123103 | 1 |
| Sanacorp/ euRho | Potassium citrate | 1204016-01 | 1 |
| Sanacorp | Potassium citrate | 14138105 | 1 |
| Sanacorp | Potassium citrate | 160604101 | 1 |
| Sanacorp | Potassium citrate | 191804006 | 1 |
| Test | Potassium citrate | 12345 | 1 |
| Testsubstanz | Potassium citrate | | 1 |

- 256 341 spectra from 1666 *Apo-Ident* customers from a total of 51 984 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Potassium citrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Potassium citrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 650 | 0 | 157 676 |
| **Type B** | 0 | 659 | 21 | 212 260 |
| **Type C** | 0 | 539 | 6 | 256 341 |

The substance/substance group *Potassium citrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0769 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 96.9118 % (> 96.4706 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8991 % (> 98.3486 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20655 | 21936 | 5.41 | 265.93 |
| 21452 | 22476 | 8.34 | 264.12 |
| 21775 | 21936 | 5.41 | 266.28 |
| 21936 | 21936 | 0.00 | 262.57 |
| 22476 | 22476 | 0.00 | 265.40 |
| 22921 | 22921 | 0.00 | 261.02 |
| 25090 | 25090 | 0.00 | 265.75 |
| 25558 | 25558 | 0.00 | 268.92 |
| 25607 | 25607 | 0.00 | 260.58 |
| 25703 | 25703 | 0.00 | 260.50 |
| 26481 | 26481 | 0.00 | 270.38 |
| BR20058 | BR20058 | 0.00 | 175.91 |
| BR20060 | BR20060 | 0.00 | 178.45 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **potassium dihydrogen phosphate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006389-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

potassium dihydrogen phosphate; Kalii dihydrogenophosphas

### Special notes

When selecting the *potassium dihydrogen phosphate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| potassium dihydrogen phosphate | 4 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *potassium dihydrogen phosphate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *potassium dihydrogen phosphate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Silver protein | 39.42 | – |
| Carbomers | 57.24 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *potassium dihydrogen phosphate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *potassium dihydrogen phosphate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | potassium dihydrogen phosphate | 22001752 | 26567 | 40 | 20220615* |
| Caelo | potassium dihydrogen phosphate | 22001752 | 26567SI | 20 | 20220615* |
| Caelo | potassium dihydrogen phosphate | 23003147 | 27113 | 40 | 20240118* |
| Caelo | potassium dihydrogen phosphate | 23003147 | 27113SI | 20 | 20240118* |
| Caelo | potassium dihydrogen phosphate | 24002258 | 27446 | 40 | 20241014* |
| Caelo | potassium dihydrogen phosphate | 24002258 | 27446SI | 20 | 20241014* |
| Caelo | potassium dihydrogen phosphate | 25000001 | 27553 | 40 | 20250110* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 220 spectra of 7 reference samples from the substance/substance group *potassium dihydrogen phosphate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

- 158 106 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *potassium dihydrogen phosphate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | potassium dihydrogen phosphate | 172493 | 23689 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *potassium dihydrogen phosphate*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *potassium dihydrogen phosphate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For

this purpose, all relevant spectra of the various substances were compared with *potassium dihydrogen phosphate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 220 | 0 | 158 106 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *potassium dihydrogen phosphate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.2727 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26567 | 26567 | 0.00 | 59.85 |
| 27113 | 27113 | 0.00 | 57.14 |
| 27446 | 27446 | 0.00 | 57.89 |
| 27553 | 27553 | 0.00 | 54.33 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Potassium hydrocarbonate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20193-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Potassium hydrocarbonate; Kalii hydrogencarbonas

### Special notes

When selecting the *Potassium hydrocarbonate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Potassium hydrocarbonate | 6 | 3 | 53 |

### Second-stage model

For differentiation of the substance/substance group *Potassium hydrocarbonate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Potassium hydrocarbonate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 61.34 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Potassium hydrocarbonate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Potassium hydrocarbonate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Potassium hydrocarbonate | 23003573 | 27101 | 40 | 20240119* |
| Euro OTC | Potassium hydrocarbonate | 1805027-01 | 24271 | 40 | 20180606 |
| Euro OTC | Potassium hydrocarbonate | 2204004 | 26563 | 40 | 20220520* |
| Euro OTC | Potassium hydrocarbonate | 2208022 | 26564 | 40 | 20220902* |
| Euro OTC | Potassium hydrocarbonate | 2208022 | 26564SI | 20 | 20220902* |
| Euro OTC | Potassium hydrocarbonate | 2303001 | 26637 | 40 | 20230314* |
| Euro OTC | Potassium hydrocarbonate | 2401021 | 27165 | 40 | 20240227* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 260 spectra of 7 reference samples from the substance/substance group *Potassium hydrocarbonate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 066 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 170 spectra of 5 reference samples from the substance/substance group *Potassium hydrocarbonate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Potassium hydrocarbonate | 2107027 | 25791 | 50 |
| Euro OTC | Potassium hydrocarbonate | 2408009 | 27454 | 40 |
| Euro OTC | Potassium hydrocarbonate | 2505007 | 27670 | 40 |
| Euro OTC | Potassium hydrocarbonate | 2204004 | 26563SI† | 20 |
| Euro OTC | Potassium hydrocarbonate | 2303001 | 26637SI† | 20 |

- 212 770 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 93 spectra from 59 *Apo-Ident* customers from 54 batches from the substance/substance group *Potassium hydrocarbonate*.

- Among them are spectra of independent samples from 53 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Potassium hydrocarbonate | 21004124004 | 1 |
| | Potassium hydrocarbonate | 21004124011 | 1 |
| | Potassium hydrocarbonate | 21004124012 | 2 |
| | Potassium hydrocarbonate | 2208022-01 | 1 |
| | Potassium hydrocarbonate | 23003573002 | 1 |
| | Potassium hydrocarbonate | 23003573003 | 2 |
| | Potassium hydrocarbonate | 2303001-01 | 1 |
| | Potassium hydrocarbonate | 24002515004 | 2 |
| | Potassium hydrocarbonate | 2401021-01 | 1 |
| | Potassium hydrocarbonate | 3143875 | 2 |
| Caelo | Potassium hydrocarbonate | | 1 |
| Caelo | Potassium hydrocarbonate | 10052610 | 1 |
| Caelo | Potassium hydrocarbonate | 10052622 | 1 |
| Caelo | Potassium hydrocarbonate | 10052629 | 1 |
| Caelo | Potassium hydrocarbonate | 1011M-01728 | 1 |
| Caelo | Potassium hydrocarbonate | 11105804 | 1 |
| Caelo | Potassium hydrocarbonate | 11105808 | 1 |
| Caelo | Potassium hydrocarbonate | 11105811 | 3 |
| Caelo | Potassium hydrocarbonate | 11105812 | 1 |
| Caelo | Potassium hydrocarbonate | 11105818 | 1 |
| Caelo | Potassium hydrocarbonate | 11105822 | 1 |
| Caelo | Potassium hydrocarbonate | 1214190 | 1 |
| Caelo | Potassium hydrocarbonate | 12141905 | 3 |
| Caelo | Potassium hydrocarbonate | 12141910 | 8 |
| Caelo | Potassium hydrocarbonate | 12141912 | 3 |
| Caelo | Potassium hydrocarbonate | 12141915 | 3 |
| Caelo | Potassium hydrocarbonate | 12141919 | 5 |
| Caelo | Potassium hydrocarbonate | 12141920 | 1 |
| Caelo | Potassium hydrocarbonate | 12141924 | 3 |
| Caelo | Potassium hydrocarbonate | 12141930 | 2 |
| Caelo | Potassium hydrocarbonate | 1214924 | 1 |
| Caelo | Potassium hydrocarbonate | 12239701 | 3 |
| Caelo | Potassium hydrocarbonate | 12239702 | 2 |
| Caelo | Potassium hydrocarbonate | 12239703 | 3 |
| Caelo | Potassium hydrocarbonate | 1303002-01 | 1 |
| Caelo | Potassium hydrocarbonate | 13141926 | 1 |
| Caelo | Potassium hydrocarbonate | 13390303 | 1 |
| Caelo | Potassium hydrocarbonate | 13390307 | 1 |
| Caelo | Potassium hydrocarbonate | 20080410-3 | 1 |
| Caelo | Potassium hydrocarbonate | 24051301 | 1 |
| Caelo | Potassium hydrocarbonate | 3812Q-01728 | 1 |
| Caelo | Potassium hydrocarbonate | 6011405 | 1 |
| Caelo | Potassium hydrocarbonate | 700544 | 1 |
| Caelo | Potassium hydrocarbonate | 8101202 | 1 |
| Euro OTC | Potassium hydrocarbonate | 1202013-01 | 1 |
| Euro OTC | Potassium hydrocarbonate | 1204038-01 | 1 |
| Euro OTC | Potassium hydrocarbonate | 1208010-01 | 3 |
| Euro OTC | Potassium hydrocarbonate | 1303002-01 | 3 |
| Euro OTC | Potassium hydrocarbonate | 2809033-01 | 1 |
| Euro OTC | Potassium hydrocarbonate | 4413I1728 | 1 |
| Fagron | Potassium hydrocarbonate | 120801001 | 1 |
| Fagron | Potassium hydrocarbonate | 12141911 | 1 |
| Fagron | Potassium hydrocarbonate | 12K27-N06 | 1 |
| Fagron | Potassium hydrocarbonate | 13031205 | 1 |
| holdermann euro | Potassium hydrocarbonate | 1303002-01 | 1 |
| Noweda | Potassium hydrocarbonate | 1004019-01 | 1 |
| Phoenix | Potassium hydrocarbonate | 12141915 | 1 |
| Stumpf | Potassium hydrocarbonate | 1204038-01 | 1 |

- 256 793 spectra from 1666 *Apo-Ident* customers from a total of 52 099 batches from a further


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724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Potassium hydrocarbonate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Potassium hydrocarbonate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 260 | 0 | 158 066 |
| **Type B** | 0 | 170 | 0 | 212 770 |
| **Type C** | 0 | 91 | 2 | 256 793 |

The substance/substance group *Potassium hydrocarbonate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6923 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.4706 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.8495 % (> 94.6237 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24271 | 27101 | 9.98 | 72.92 |
| 26563 | 26563 | 0.00 | 74.03 |
| 26564 | 26564 | 0.00 | 75.45 |
| 26637 | 26637 | 0.00 | 75.94 |
| 27101 | 27101 | 0.00 | 73.95 |
| 27165 | 27165 | 0.00 | 74.70 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,

thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Potassium sorbate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20020-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Potassium sorbate; Kalii sorbas

### Special notes

When selecting the *Potassium sorbate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Potassium sorbate | 9 | 12 | 234 |

### Second-stage model

For differentiation of the substance/substance group *Potassium sorbate* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Potassium sorbate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 118.32 | – |
| ⋮ | ⋮ | ⋮ |
| Mometasone furoate | >50 | 39.28 |
| Atropine sulfate | >50 | 102.79 |
| Hydrocortisone | >50 | 156.46 |
| Magnesium hydrogen citrate | >50 | 200.64 |
| Propranolol hydrochloride | >50 | 292.43 |
| Quinoline yellow | >50 | 392.34 |
| Phenytoin | >50 | 490.20 |
| Saccharin sodium | >50 | 595.20 |
| Calcium orotate dihydrate | >50 | 656.34 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Potassium sorbate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Potassium sorbate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Potassium sorbate | 13224604 | 21444 | 60 | 20130813 |
| Caelo | Potassium sorbate | 163266 | 23059 | 40 | 20170105* |
| Caelo | Potassium sorbate | 17170008 | 23585 | 30 | 20170711 |
| Caelo | Potassium sorbate | 20001879 | 25556 | 40 | 20200714* |
| Caelo | Potassium sorbate | 20001880 | 25630 | 40 | 20200714* |
| Caelo | Potassium sorbate | 23001012 | 26713 | 40 | 20230516* |
| Caelo | Potassium sorbate | 23001012 | 26713SI | 20 | 20230516* |
| Euro OTC | Potassium sorbate | 1508025 | 21892 | 60 | 20150902* |
| Euro OTC | Potassium sorbate | 1608013 | 22786 | 40 | 20160819* |
| Euro OTC | Potassium sorbate | 1907023 | 24764 | 40 | 20190802* |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 410 spectra of 10 reference samples from the substance/substance group *Potassium sorbate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 916 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 530 spectra of 14 reference samples from the substance/substance group *Potassium sorbate*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Potassium sorbate | 171700 | 23638 | 40 |
| Caelo | Potassium sorbate | 173451 | 23830 | 40 |
| Caelo | Potassium sorbate | 181650 | 24224 | 40 |
| Caelo | Potassium sorbate | 191072 | 24539 | 40 |
| Caelo | Potassium sorbate | 21001391 | 25700 | 50 |
| Caelo | Potassium sorbate | 22002065 | 26244 | 40 |
| Caelo | Potassium sorbate | 23002441 | 26944 | 40 |
| Caelo | Potassium sorbate | 23002442 | 26961 | 40 |
| Euro OTC | Potassium sorbate | 1703034 | 23176 | 40 |
| Euro OTC | Potassium sorbate | 1710015 | 23772 | 40 |
| Euro OTC | Potassium sorbate | 1805029 | 24126 | 40 |
| Euro OTC | Potassium sorbate | 1901020 | 24464 | 40 |
| Caelo | Potassium sorbate | 22002065 | 26244SI | 20 |
| Caelo | Potassium sorbate | 23002441 | 26944SI | 20 |

- 212 410 spectra from a total of 4275 batches from further 872 substances. These spectra were

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2065 spectra from 1065 *Apo-Ident* customers from 239 batches from the substance/substance group *Potassium sorbate*.
- Among them are spectra of independent samples from 234 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Potassium sorbate | | 1 |
| | Potassium sorbate | 10012203 | 1 |
| | Potassium sorbate | 12211101 | 2 |
| | Potassium sorbate | 17170017 | 1 |
| | Potassium sorbate | 181023/3 | 1 |
| | Potassium sorbate | 19000555010 | 1 |
| | Potassium sorbate | 191023/2 | 1 |
| | Potassium sorbate | 20004207005 | 1 |
| | Potassium sorbate | 20004356001 | 1 |
| | Potassium sorbate | 22002065002 | 1 |
| | Potassium sorbate | 220034009014 | 1 |
| | Potassium sorbate | 220034013 | 1 |
| | Potassium sorbate | 22003409002 | 1 |
| | Potassium sorbate | 22003409004 | 4 |
| | Potassium sorbate | 22003409006 | 1 |
| | Potassium sorbate | 22003409007 | 17 |
| | Potassium sorbate | 22003409010 | 3 |
| | Potassium sorbate | 22003409013 | 14 |
| | Potassium sorbate | 22003409014 | 22 |
| | Potassium sorbate | 23001012004 | 53 |
| | Potassium sorbate | 23001012010 | 1 |
| | Potassium sorbate | 922331021 | 2 |
| /Alliance | Potassium sorbate | 18165010 | 1 |
| AEP | Potassium sorbate | 23001012004 | 1 |
| AHD | Potassium sorbate | 13065216 | 1 |
| AHD | Potassium sorbate | 17170007 | 1 |
| AHD | Potassium sorbate | 17345116 | 1 |
| AHD | Potassium sorbate | 216331021 | 1 |
| AHD | Potassium sorbate | 22003409004 | 1 |
| AHD | Potassium sorbate | 22003409013 | 1 |
| AHD | Potassium sorbate | 23001012004 | 1 |
| Alliance Healthcare | Potassium sorbate | 15382115 | 1 |
| Alliance Healthcare | Potassium sorbate | 20004207002 | 1 |
| Alliance Healthcare | Potassium sorbate | 22003409013 | 1 |
| Alliance Healthcare | Potassium sorbate | 23001012004 | 1 |
| Alliance | Potassium sorbate | 22003409007 | 2 |
| Allianz | Potassium sorbate | 17170006 | 1 |
| Anzag 12.01.15 | Potassium sorbate | 13224611 | 1 |
| Anzag | Potassium sorbate | 12211107 | 1 |
| Anzag | Potassium sorbate | 15382114 | 2 |
| Anzag | Potassium sorbate | 20004207005 | 1 |
| Anzag | Potassium sorbate | 23001012004 | 1 |
| apomix | Potassium sorbate | 13065217 | 1 |
| apomix | Potassium sorbate | 13224611 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| apomix | Potassium sorbate | 17345104 | 1 |
| Bombastus | Potassium sorbate | 1117331022 | 1 |
| Bombastus | Potassium sorbate | 14380632 | 1 |
| Caeleo/ Kehr | Potassium sorbate | 20004207002 | 1 |
| Caelo | Potassium sorbate | | 2 |
| Caelo | Potassium sorbate | 1/1/0017 | 1 |
| Caelo | Potassium sorbate | 10012210 | 1 |
| Caelo | Potassium sorbate | 10199505 | 1 |
| Caelo | Potassium sorbate | 111033102 | 1 |
| Caelo | Potassium sorbate | 1112331024 | 1 |
| Caelo | Potassium sorbate | 1118331022 | 1 |
| Caelo | Potassium sorbate | 11192305 | 3 |
| Caelo | Potassium sorbate | 11214207 | 1 |
| Caelo | Potassium sorbate | 11261304 | 3 |
| Caelo | Potassium sorbate | 12059902 | 1 |
| Caelo | Potassium sorbate | 12059905 | 2 |
| Caelo | Potassium sorbate | 12059908 | 2 |
| Caelo | Potassium sorbate | 12059909 | 4 |
| Caelo | Potassium sorbate | 12059914 | 2 |
| Caelo | Potassium sorbate | 1205999 | 1 |
| Caelo | Potassium sorbate | 12211101 | 8 |
| Caelo | Potassium sorbate | 12211102 | 4 |
| Caelo | Potassium sorbate | 12211107 | 16 |
| Caelo | Potassium sorbate | 12211108 | 2 |
| Caelo | Potassium sorbate | 12211121 | 4 |
| Caelo | Potassium sorbate | 12211123 | 1 |
| Caelo | Potassium sorbate | 12345 | 1 |
| Caelo | Potassium sorbate | 13065204 | 11 |
| Caelo | Potassium sorbate | 13065205 | 12 |
| Caelo | Potassium sorbate | 13065211 | 1 |
| Caelo | Potassium sorbate | 13065216 | 11 |
| Caelo | Potassium sorbate | 13065217 | 11 |
| Caelo | Potassium sorbate | 13065222 | 1 |
| Caelo | Potassium sorbate | 13111409 | 1 |
| Caelo | Potassium sorbate | 1312024-01 | 2 |
| Caelo | Potassium sorbate | 13224604 | 17 |
| Caelo | Potassium sorbate | 13224608 | 2 |
| Caelo | Potassium sorbate | 13224610 | 1 |
| Caelo | Potassium sorbate | 13224611 | 12 |
| Caelo | Potassium sorbate | 13224612 | 18 |
| Caelo | Potassium sorbate | 13277804 | 1 |
| Caelo | Potassium sorbate | 1397235 | 1 |
| Caelo | Potassium sorbate | 14140007 | 1 |
| Caelo | Potassium sorbate | 14192605 | 2 |
| Caelo | Potassium sorbate | 143806 | 1 |
| Caelo | Potassium sorbate | 1438060 | 2 |
| Caelo | Potassium sorbate | 14380601 | 18 |
| Caelo | Potassium sorbate | 14380602 | 2 |
| Caelo | Potassium sorbate | 14380606 | 9 |
| Caelo | Potassium sorbate | 14380607 | 7 |
| Caelo | Potassium sorbate | 14380610 | 13 |
| Caelo | Potassium sorbate | 14380612 | 2 |
| Caelo | Potassium sorbate | 14380613 | 1 |
| Caelo | Potassium sorbate | 14380618 | 1 |
| Caelo | Potassium sorbate | 14380620 | 6 |
| Caelo | Potassium sorbate | 14380621 | 11 |
| Caelo | Potassium sorbate | 14380622 | 12 |
| Caelo | Potassium sorbate | 14380627 | 10 |
| Caelo | Potassium sorbate | 14380631 | 1 |
| Caelo | Potassium sorbate | 14380632 | 23 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Potassium sorbate | 14380633 | 16 |
| Caelo | Potassium sorbate | 14380635 | 8 |
| Caelo | Potassium sorbate | 14382606 | 1 |
| Caelo | Potassium sorbate | 1438633 | 1 |
| Caelo | Potassium sorbate | 1508025-01 | 1 |
| Caelo | Potassium sorbate | 15248203 | 3 |
| Caelo | Potassium sorbate | 15248204 | 20 |
| Caelo | Potassium sorbate | 15248205 | 11 |
| Caelo | Potassium sorbate | 15382103 | 1 |
| Caelo | Potassium sorbate | 15382105 | 16 |
| Caelo | Potassium sorbate | 15382106 | 1 |
| Caelo | Potassium sorbate | 15382114 | 13 |
| Caelo | Potassium sorbate | 15382115 | 11 |
| Caelo | Potassium sorbate | 1608013-01 | 1 |
| Caelo | Potassium sorbate | 16156505 | 4 |
| Caelo | Potassium sorbate | 16326602 | 4 |
| Caelo | Potassium sorbate | 16326606 | 20 |
| Caelo | Potassium sorbate | 16326607 | 17 |
| Caelo | Potassium sorbate | 16326608 | 21 |
| Caelo | Potassium sorbate | 16326609 | 20 |
| Caelo | Potassium sorbate | 16326615 | 1 |
| Caelo | Potassium sorbate | 17(18165014) | 1 |
| Caelo | Potassium sorbate | 17170002 | 4 |
| Caelo | Potassium sorbate | 17170005 | 1 |
| Caelo | Potassium sorbate | 17170006 | 13 |
| Caelo | Potassium sorbate | 17170007 | 28 |
| Caelo | Potassium sorbate | 17170007-20171106Ma1 | 1 |
| Caelo | Potassium sorbate | 17170008 | 25 |
| Caelo | Potassium sorbate | 17170012 | 5 |
| Caelo | Potassium sorbate | 17170013 | 34 |
| Caelo | Potassium sorbate | 17170014 | 34 |
| Caelo | Potassium sorbate | 17170015 | 2 |
| Caelo | Potassium sorbate | 17170016 | 3 |
| Caelo | Potassium sorbate | 17170016P-190225-3 | 1 |
| Caelo | Potassium sorbate | 17170017 | 19 |
| Caelo | Potassium sorbate | 17170018 | 1 |
| Caelo | Potassium sorbate | 1717008 | 1 |
| Caelo | Potassium sorbate | 17345103 | 31 |
| Caelo | Potassium sorbate | 17345104 | 59 |
| Caelo | Potassium sorbate | 17345105 | 1 |
| Caelo | Potassium sorbate | 17345113 | 3 |
| Caelo | Potassium sorbate | 17345116 | 34 |
| Caelo | Potassium sorbate | 18(19000555006) | 1 |
| Caelo | Potassium sorbate | 18165006 | 32 |
| Caelo | Potassium sorbate | 18165010 | 56 |
| Caelo | Potassium sorbate | 18165014 | 25 |
| Caelo | Potassium sorbate | 18165015 | 31 |
| Caelo | Potassium sorbate | 18165016 | 2 |
| Caelo | Potassium sorbate | 18165016P-190923-1 | 1 |
| Caelo | Potassium sorbate | 1816510 | 1 |
| Caelo | Potassium sorbate | 190000555006 | 1 |
| Caelo | Potassium sorbate | 190000555010 | 1 |
| Caelo | Potassium sorbate | 190000555011 | 2 |
| Caelo | Potassium sorbate | 1900055006 | 2 |
| Caelo | Potassium sorbate | 1900055011 | 4 |
| Caelo | Potassium sorbate | 19000555005 | 4 |
| Caelo | Potassium sorbate | 19000555006 | 59 |
| Caelo | Potassium sorbate | 190005550066 | 1 |
| Caelo | Potassium sorbate | 19000555009 | 1 |
| Caelo | Potassium sorbate | 19000555010 | 37 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Potassium sorbate | 19000555011 | 38 |
| Caelo | Potassium sorbate | 1900055505 | 2 |
| Caelo | Potassium sorbate | 1900055506 | 3 |
| Caelo | Potassium sorbate | 1900055510 | 1 |
| Caelo | Potassium sorbate | 1900555010 | 1 |
| Caelo | Potassium sorbate | 191072008 | 1 |
| Caelo | Potassium sorbate | 19107203 | 3 |
| Caelo | Potassium sorbate | 19107203P-200518-1 | 1 |
| Caelo | Potassium sorbate | 19107206 | 1 |
| Caelo | Potassium sorbate | 19107207 | 2 |
| Caelo | Potassium sorbate | 19107208 | 42 |
| Caelo | Potassium sorbate | 19107280 | 1 |
| Caelo | Potassium sorbate | 198000555006 | 1 |
| Caelo | Potassium sorbate | 200004207002 | 1 |
| Caelo | Potassium sorbate | 200004207005 | 1 |
| Caelo | Potassium sorbate | 200004356006 | 1 |
| Caelo | Potassium sorbate | 20004207002 | 44 |
| Caelo | Potassium sorbate | 20004207005 | 45 |
| Caelo | Potassium sorbate | 20004356001 | 41 |
| Caelo | Potassium sorbate | 20004356011 | 20 |
| Caelo | Potassium sorbate | 2000435611 | 1 |
| Caelo | Potassium sorbate | 20021112-2 | 1 |
| Caelo | Potassium sorbate | 2004207002 | 1 |
| Caelo | Potassium sorbate | 2004207005 | 3 |
| Caelo | Potassium sorbate | 2004356001 | 1 |
| Caelo | Potassium sorbate | 2004356006 | 1 |
| Caelo | Potassium sorbate | 200613K1 | 1 |
| Caelo | Potassium sorbate | 20082001 | 1 |
| Caelo | Potassium sorbate | 2041402 | 1 |
| Caelo | Potassium sorbate | 21001391008 | 2 |
| Caelo | Potassium sorbate | 22002065002 | 13 |
| Caelo | Potassium sorbate | 22003409001 | 1 |
| Caelo | Potassium sorbate | 22003409002 | 2 |
| Caelo | Potassium sorbate | 22003409003 | 2 |
| Caelo | Potassium sorbate | 22003409004 | 18 |
| Caelo | Potassium sorbate | 22003409007 | 15 |
| Caelo | Potassium sorbate | 22003409013 | 2 |
| Caelo | Potassium sorbate | 22003409014 | 3 |
| Caelo | Potassium sorbate | 220905(22002065002) | 1 |
| Caelo | Potassium sorbate | 23001012004 | 1 |
| Caelo | Potassium sorbate | 27101705 | 1 |
| Caelo | Potassium sorbate | 317331021 | 2 |
| Caelo | Potassium sorbate | 3354 | 1 |
| Caelo | Potassium sorbate | 3512M-01748 | 1 |
| Caelo | Potassium sorbate | 7111805 | 1 |
| Caelo | Potassium sorbate | 8165015 | 1 |
| Caelo | Potassium sorbate | 90318101 | 1 |
| Caelo | Potassium sorbate | 9061806 | 1 |
| Caelo | Potassium sorbate | 912331023 | 1 |
| Caelo | Potassium sorbate | 91623299 | 2 |
| Caelo | Potassium sorbate | 9305601 | 2 |
| Caelo | Potassium sorbate | AKD10 | 1 |
| Caelo | Potassium sorbate | K-010213-1 | 1 |
| Caelo | Potassium sorbate | RT287 | 1 |
| Caelo | Potassium sorbate | RT5324 | 1 |
| Caesar & Lorenz GmbH | Potassium sorbate | 19000555006 | 1 |
| Caesar & Lorenz/Noweda | Potassium sorbate | 20004356001 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207002 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 171700006 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19107208 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Potassium sorbate | 22003409013 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 15382114 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 17345103 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 17345116 | 2 |
| Caesar & Loretz GmbH... | Potassium sorbate | 18165015 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207005 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004356001 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004356011 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207005 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 13065217 | 2 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19000555010 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004356011 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 22003409004 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19000555010 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 17170017 | 1 |
| Caesar & Loretz GmbH/AHD | Potassium sorbate | 19107203 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19000555010 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 18165015 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207002 | 1 |
| Caesar & Loretz GmbH/G | Potassium sorbate | 20004356001 | 2 |
| Caesar & Loretz GmbH... | Potassium sorbate | 1900055510 | 1 |
| Caesar & Loretz GmbH/Gehe | Potassium sorbate | 18165014 | 1 |
| Caesar & Loretz GmbH/Gehe | Potassium sorbate | 190000555006 | 1 |
| Caesar & Loretz GmbH/Gehe | Potassium sorbate | 19000555006 | 1 |
| Caesar & Loretz GmbH/Gehe | Potassium sorbate | 20004207002 | 1 |
| Caesar & Loretz GmbH/Gehe | Potassium sorbate | 20004207005 | 2 |
| Caesar & Loretz GmbH/Gehe | Potassium sorbate | 22003409014 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207002 | 1 |
| Caesar & Loretz GmbH/K | Potassium sorbate | 19107208 | 1 |
| Caesar & Loretz GmbH/Kehr | Potassium sorbate | 19000555010 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19107208 | 1 |
| Caesar & Loretz GmbH/Now | Potassium sorbate | 20004207005 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19000555006 | 2 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207002 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207005 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004356011 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19000555011 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207002 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004356001 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 22003409003 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 17345104 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 18165014 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19000555008 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 19107208 | 2 |
| Caesar & Loretz GmbH... | Potassium sorbate | 20004207002 | 1 |
| Caesar & Loretz GmbH... | Potassium sorbate | 22003409002 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 11261303 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 14380627 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 17170006 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 17345103 | 1 |
| Caesar & Loretz GmbH' | Potassium sorbate | 17345109 | 2 |
| Caesar & Loretz GmbH | Potassium sorbate | 18165002 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 18165004 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 18165006 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 18165010 | 12 |
| Caesar & Loretz GmbH | Potassium sorbate | 18165014 | 4 |
| Caesar & Loretz GmbH | Potassium sorbate | 18165015 | 6 |
| Caesar & Loretz GmbH | Potassium sorbate | 19000555005 | 3 |
| Caesar & Loretz GmbH | Potassium sorbate | 19000555006 | 17 |
| Caesar & Loretz GmbH | Potassium sorbate | 19000555008 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Potassium sorbate | 19000555009 | 3 |
| Caesar & Loretz GmbH | Potassium sorbate | 19000555010 | 11 |
| Caesar & Loretz GmbH | Potassium sorbate | 19000555011 | 6 |
| Caesar & Loretz GmbH | Potassium sorbate | 19107203 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 19107208 | 15 |
| Caesar & Loretz GmbH | Potassium sorbate | 20001879002 | 2 |
| Caesar & Loretz GmbH | Potassium sorbate | 20004207002 | 24 |
| Caesar & Loretz GmbH | Potassium sorbate | 20004207005 | 11 |
| Caesar & Loretz GmbH | Potassium sorbate | 20004207006 | 2 |
| Caesar & Loretz GmbH | Potassium sorbate | 20004356001 | 16 |
| Caesar & Loretz GmbH | Potassium sorbate | 20004356003 | 2 |
| Caesar & Loretz GmbH | Potassium sorbate | 20004356011 | 6 |
| Caesar & Loretz GmbH | Potassium sorbate | 20004498001 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 22002065002 | 6 |
| Caesar & Loretz GmbH | Potassium sorbate | 22002065003 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 22003409002 | 5 |
| Caesar & Loretz GmbH | Potassium sorbate | 22003409004 | 5 |
| Caesar & Loretz GmbH | Potassium sorbate | 22003409007 | 4 |
| Caesar & Loretz GmbH | Potassium sorbate | 22003409013 | 1 |
| Caesar & Loretz GmbH | Potassium sorbate | 22003409014 | 1 |
| Caesar & Loretz GmbH… | Potassium sorbate | 19000555011 | 1 |
| Caesar & Loretz GmbH… | Potassium sorbate | 22002065002 | 1 |
| Caesar & Loretz/Geil… | Potassium sorbate | 19000555006 | 1 |
| Caesar & Loretz/Noweda | Potassium sorbate | 14380621 | 1 |
| Caesar & Loretz/Noweda | Potassium sorbate | 19000555010 | 1 |
| Caesar & Loretz/Sanacorp | Potassium sorbate | 17345104 | 1 |
| Caesar & Loretz | Potassium sorbate | 14380606 | 2 |
| Caesar & Loretz | Potassium sorbate | 14380633 | 1 |
| Caesar & Loretz | Potassium sorbate | 17345103 | 1 |
| Caesar & Loretz | Potassium sorbate | 19000555010 | 1 |
| Caesar / Gehe | Potassium sorbate | 14380622 | 1 |
| Caesar und Loretz | Potassium sorbate | 18165010 | 1 |
| Caesar&Loretz GmbH/S… | Potassium sorbate | 14380607 | 1 |
| Caesar&Loretz GmbH | Potassium sorbate | 14380622 | 1 |
| Caesar&Loretz GmbH | Potassium sorbate | 17170014 | 1 |
| Caesar/Gehe | Potassium sorbate | 19107208 | 1 |
| Caesar/Lorenz | Potassium sorbate | 13065204 | 1 |
| Caleo/Krieger | Potassium sorbate | 20004356001 | 1 |
| canea, gehe | Potassium sorbate | 13065215 | 1 |
| Cealo/ Noweda | Potassium sorbate | 17345103 | 1 |
| cealo | Potassium sorbate | 16326607 | 1 |
| Cealo | Potassium sorbate | 16326609 | 1 |
| Cealo | Potassium sorbate | 1710013 | 1 |
| Euro OTC | Potassium sorbate | 1111038-01 | 1 |
| Euro OTC | Potassium sorbate | 111103802 | 1 |
| Euro OTC | Potassium sorbate | 1111038-02 | 2 |
| Euro OTC | Potassium sorbate | 1312024-01 | 3 |
| Euro OTC | Potassium sorbate | 13224612 | 1 |
| Euro OTC | Potassium sorbate | 14380622 | 1 |
| Euro OTC | Potassium sorbate | 14380632 | 2 |
| Euro OTC | Potassium sorbate | 1508025-01 | 7 |
| Euro OTC | Potassium sorbate | 15382115 | 1 |
| Euro OTC | Potassium sorbate | 1608013-01 | 8 |
| Euro OTC | Potassium sorbate | 1710012-01 | 1 |
| Euro OTC | Potassium sorbate | 1710015-01 | 1 |
| Euro OTC | Potassium sorbate | 17170008 | 1 |
| Euro OTC | Potassium sorbate | 17170013 | 1 |
| Euro OTC | Potassium sorbate | 1805029-01 | 1 |
| Euro OTC | Potassium sorbate | 180529-01 | 1 |
| Euro OTC | Potassium sorbate | 1901020-01 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Potassium sorbate | 1907023-01 | 1 |
| Euro OTC | Potassium sorbate | 1907023-02 | 1 |
| Euro OTC | Potassium sorbate | 1991020-01 | 1 |
| Euro OTC | Potassium sorbate | 216331021 | 1 |
| Euro OTC | Potassium sorbate | PS20180905 | 1 |
| Fa.Phönix | Potassium sorbate | 16326607 | 1 |
| Fa.Phönix | Potassium sorbate | 17170014 | 1 |
| Fagron | Potassium sorbate | 1114331022 | 1 |
| Fagron | Potassium sorbate | 13065217 | 1 |
| Fagron | Potassium sorbate | 14380622 | 1 |
| Fagron | Potassium sorbate | 16326609 | 1 |
| Fagron | Potassium sorbate | 17170008 | 1 |
| Fagron | Potassium sorbate | 17170014 | 1 |
| Fagron | Potassium sorbate | 2717M-01748 | 1 |
| Fagron | Potassium sorbate | 3115M-01748 | 1 |
| Fagron | Potassium sorbate | 3518A-01748 | 1 |
| Fagron | Potassium sorbate | 3912A-01748 | 1 |
| Fagron | Potassium sorbate | 4314U-01748 | 1 |
| Fresenius | Potassium sorbate | 220214221 | 1 |
| Gehe / Spinnrad | Potassium sorbate | 216331021 | 1 |
| Gehe | Potassium sorbate | 11261304 | 1 |
| Gehe | Potassium sorbate | 123331021 | 1 |
| Gehe | Potassium sorbate | 13065205 | 1 |
| Gehe | Potassium sorbate | 13065216 | 1 |
| Gehe | Potassium sorbate | 14380601 | 1 |
| Gehe | Potassium sorbate | 14380607 | 1 |
| Gehe | Potassium sorbate | 14380632 | 1 |
| Gehe | Potassium sorbate | 16326606 | 1 |
| Gehe | Potassium sorbate | 17170007 | 2 |
| GEHE | Potassium sorbate | 17170008 | 1 |
| Gehe | Potassium sorbate | 17170013 | 1 |
| gehe | Potassium sorbate | 17170014 | 1 |
| Gehe | Potassium sorbate | 17345116 | 1 |
| Gehe | Potassium sorbate | 18165010 | 1 |
| Gehe | Potassium sorbate | 18165014 | 1 |
| Gehe | Potassium sorbate | 19000555006 | 1 |
| Gehe | Potassium sorbate | 200004207005 | 1 |
| Gehe | Potassium sorbate | 20004207005 | 2 |
| Gehe | Potassium sorbate | 22003409004 | 1 |
| Gehe | Potassium sorbate | 22003409007 | 1 |
| GEHE | Potassium sorbate | 22003409007 | 1 |
| Gehe | Potassium sorbate | 22003409014 | 1 |
| Gehe | Potassium sorbate | 23001012004 | 2 |
| GEHE | Potassium sorbate | 23001012004 | 2 |
| Geibo | Potassium sorbate | 17170013 | 1 |
| Ichthyol/Noweda | Potassium sorbate | 13224604 | 1 |
| Ichthyol-Gesellschaf... | Potassium sorbate | 18165014 | 1 |
| Jenne | Potassium sorbate | 123331021 | 1 |
| Jenne | Potassium sorbate | 17170007 | 1 |
| Jenne | Potassium sorbate | 22003409013 | 1 |
| jenne | Potassium sorbate | 922331021 | 1 |
| Kehr/Spinnrad | Potassium sorbate | 317331021 | 1 |
| Kehr | Potassium sorbate | 16326607 | 1 |
| Kehr | Potassium sorbate | 18165006 | 1 |
| Kehr | Potassium sorbate | 22003409013 | 1 |
| Kehr | Potassium sorbate | 23001012004 | 1 |
| Noweda / Spinnrad | Potassium sorbate | 216331021 | 1 |
| Noweda/ Spinnrad | Potassium sorbate | 218331021 | 1 |
| Noweda/Caesar & Lore... | Potassium sorbate | 22003409004 | 1 |
| Noweda/Spinnrad GmbH | Potassium sorbate | 322331021 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda/Spinnrad | Potassium sorbate | 19170208 | 1 |
| Noweda | Potassium sorbate | 12211101 | 1 |
| Noweda | Potassium sorbate | 13065222 | 1 |
| Noweda | Potassium sorbate | 15382115 | 1 |
| Noweda | Potassium sorbate | 16326606 | 1 |
| Noweda | Potassium sorbate | 17170014 | 1 |
| Noweda | Potassium sorbate | 17170017 | 1 |
| Noweda | Potassium sorbate | 17345103 | 3 |
| Noweda | Potassium sorbate | 17345116 | 1 |
| Noweda | Potassium sorbate | 18165010 | 4 |
| Noweda | Potassium sorbate | 20004207005 | 3 |
| Noweda | Potassium sorbate | 20004356001 | 1 |
| Noweda | Potassium sorbate | 20004356011 | 1 |
| Noweda | Potassium sorbate | 22003409007 | 1 |
| Noweda | Potassium sorbate | 22003409014 | 4 |
| Noweda | Potassium sorbate | 2203409014 | 1 |
| Noweda | Potassium sorbate | 23001012004 | 5 |
| Noweda | Potassium sorbate | 24000116001 | 1 |
| p&m cosmetics/gehe | Potassium sorbate | 17170014 | 1 |
| Pala | Potassium sorbate | 14380607 | 3 |
| Phoenix | Potassium sorbate | 1117331022 | 1 |
| Phoenix | Potassium sorbate | 1397235 | 1 |
| Phoenix | Potassium sorbate | 14380627 | 1 |
| Phoenix | Potassium sorbate | 17170012 | 1 |
| Phoenix | Potassium sorbate | 17170017 | 1 |
| Phoenix | Potassium sorbate | 17345104 | 1 |
| Phoenix | Potassium sorbate | 20004207002 | 1 |
| Phoenix | Potassium sorbate | 20004207005 | 1 |
| Phoenix | Potassium sorbate | 216331021 | 1 |
| Phoenix | Potassium sorbate | 22002065002 | 1 |
| Phoenix | Potassium sorbate | 22003409013 | 1 |
| Phoenix | Potassium sorbate | 23001012004 | 1 |
| Phönix/Spinnrad | Potassium sorbate | 1117331022 | 2 |
| Phönix | Potassium sorbate | 12211101 | 2 |
| phönix | Potassium sorbate | 14380632 | 1 |
| Phönix | Potassium sorbate | 16326607 | 1 |
| phönix | Potassium sorbate | 16326608 | 1 |
| Phönix | Potassium sorbate | 17345116 | 1 |
| PHÖNIX | Potassium sorbate | 19000555006 | 1 |
| Phönix | Potassium sorbate | 19000555011 | 1 |
| Phönix | Potassium sorbate | 20004207002 | 1 |
| Phönix | Potassium sorbate | 201103010 | 1 |
| Phönix | Potassium sorbate | 22003409013 | 1 |
| Phönix | Potassium sorbate | 22003409014 | 1 |
| Phönix | Potassium sorbate | 2203409007 | 1 |
| phönix | Potassium sorbate | 23001012204 | 1 |
| s.Prüfprotokoll | Potassium sorbate | | 1 |
| sana | Potassium sorbate | 13224612 | 1 |
| Sanacorp 29.10.18 EK 4,30 | Potassium sorbate | 17345104 | 1 |
| Sanacorp | Potassium sorbate | 1118331022 | 1 |
| Sanacorp | Potassium sorbate | 12211101 | 1 |
| Sanacorp | Potassium sorbate | 13065217 | 1 |
| Sanacorp | Potassium sorbate | 13224611 | 1 |
| Sanacorp | Potassium sorbate | 14380610 | 1 |
| Sanacorp | Potassium sorbate | 17170007 | 1 |
| Sanacorp | Potassium sorbate | 17170014 | 1 |
| Sanacorp | Potassium sorbate | 19107208 | 3 |
| Sanacorp | Potassium sorbate | 20004207005 | 1 |
| Sanacorp | Potassium sorbate | 22003409014 | 1 |
| Sanacorp | Potassium sorbate | 23001012004 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| sanacorp | Potassium sorbate | 2300102004 | 1 |
| Sanacorp | Potassium sorbate | 322331021 | 1 |
| siehe WE-Prüfprotokoll | Potassium sorbate | 61/11 | 1 |
| Sonnenberg-Apotheke | Potassium sorbate | 13224604 | 1 |
| Spinnrad - Noweda | Potassium sorbate | 315331021 | 1 |
| Spinnrad / Gehe | Potassium sorbate | 317331021 | 2 |
| Spinnrad / Gehe | Potassium sorbate | 616331022 | 1 |
| Spinnrad GmbH / Nowe... | Potassium sorbate | 1117331022 | 1 |
| Spinnrad GmbH Bad Se... | Potassium sorbate | 1019331022 | 1 |
| Spinnrad GmbH Bad Se... | Potassium sorbate | 1118331022 | 1 |
| Spinnrad GmbH | Potassium sorbate | 111033102 | 1 |
| Spinnrad GmbH | Potassium sorbate | 1114331022 | 1 |
| Spinnrad GmbH | Potassium sorbate | 214331021 | 1 |
| spinnrad GmbH | Potassium sorbate | 616331022 | 1 |
| Spinnrad GmbH | Potassium sorbate | 912331023 | 2 |
| Spinnrad Noweda | Potassium sorbate | 520331021 | 1 |
| Spinnrad Noweda | Potassium sorbate | 7203311027 | 1 |
| Spinnrad/ Gehe 18.01.19 | Potassium sorbate | 317331021 | 1 |
| Spinnrad/ Noweda/ 26... | Potassium sorbate | 319331021 | 1 |
| Spinnrad/ Phönix | Potassium sorbate | 322331021 | 1 |
| spinnrad/gehe | Potassium sorbate | 216331021 | 1 |
| Spinnrad/Gehe | Potassium sorbate | 315331021 | 1 |
| spinnrad/Noweda | Potassium sorbate | 1019331022 | 1 |
| Spinnrad/Noweda | Potassium sorbate | 1117331022 | 2 |
| Spinnrad/Noweda | Potassium sorbate | 1118331022 | 2 |
| Spinnrad/Noweda | Potassium sorbate | 218331021 | 1 |
| Spinnrad/Noweda | Potassium sorbate | 520331021 | 1 |
| Spinnrad/Noweda | Potassium sorbate | 720331022 | 1 |
| Spinnrad/Noweda | Potassium sorbate | 922331021 | 1 |
| Spinnrad/Phoenix | Potassium sorbate | 1019331022 | 1 |
| Spinnrad/Phoenix | Potassium sorbate | 317331021 | 1 |
| Spinnrad/Phönix | Potassium sorbate | 1019331022 | 1 |
| Spinnrad/Phönix | Potassium sorbate | 1118331022 | 1 |
| Spinnrad/Phönix | Potassium sorbate | 218331021 | 1 |
| Spinnrad/Phönix | Potassium sorbate | 319331021 | 1 |
| Spinnrad/Sanacorp | Potassium sorbate | 218331021 | 1 |
| Spinnrad/Sanacorp | Potassium sorbate | 720331022 | 1 |
| Spinnrad/Sannacorp | Potassium sorbate | 616331022 | 1 |
| Spinnrad | Potassium sorbate | 111033102 | 1 |
| spinnrad | Potassium sorbate | 1114331022 | 1 |
| Spinnrad | Potassium sorbate | 1114331022 | 3 |
| spinnrad | Potassium sorbate | 1117331022 | 1 |
| Spinnrad | Potassium sorbate | 1117331022 | 2 |
| spinnrad | Potassium sorbate | 1118331022 | 1 |
| Spinnrad | Potassium sorbate | 1118331022 | 1 |
| Spinnrad | Potassium sorbate | 214331021 | 1 |
| spinnrad | Potassium sorbate | 216331021 | 1 |
| Spinnrad | Potassium sorbate | 216331021 | 2 |
| spinnrad | Potassium sorbate | 2233102 | 1 |
| Spinnrad | Potassium sorbate | 312331021 | 2 |
| Spinnrad | Potassium sorbate | 315331021 | 2 |
| spinnrad | Potassium sorbate | 317331021 | 1 |
| Spinnrad | Potassium sorbate | 317331021 | 3 |
| spinnrad | Potassium sorbate | 520331021 | 1 |
| Spinnrad | Potassium sorbate | 520331021 | 3 |
| spinnrad | Potassium sorbate | 616331022 | 1 |
| Spinnrad | Potassium sorbate | 616331022 | 2 |
| spinnrad | Potassium sorbate | 720331022 | 2 |
| Spinnrad | Potassium sorbate | 720331022 | 1 |
| Spinnrad | Potassium sorbate | 815331022 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spinnrad | Potassium sorbate | 912331023 | 4 |
| Spinrad/Phönix | Potassium sorbate | 218331021 | 1 |
| WE: über Eyach 5g/2,... | Potassium sorbate | 14380601 | 1 |
| wie gehbat | Potassium sorbate | wiegehabt | 1 |

- 254 821 spectra from 1666 *Apo-Ident* customers from a total of 51 918 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Potassium sorbate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Potassium sorbate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 410 | 0 | 157 916 |
| **Type B** | 0 | 530 | 0 | 212 410 |
| **Type C** | 0 | 2063 | 2 | 254 821 |

The substance/substance group *Potassium sorbate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5366 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8679 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.9031 % (> 99.7579 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21444 | 21892 | 15.30 | 201.08 |
| 21892 | 21892 | 0.00 | 199.61 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22786 | 22786 | 0.00 | 197.59 |
| 23059 | 23059 | 0.00 | 205.93 |
| 23585 | 25630 | 19.17 | 206.27 |
| 24764 | 24764 | 0.00 | 198.90 |
| 25556 | 25556 | 0.00 | 205.00 |
| 25630 | 25630 | 0.00 | 205.48 |
| 26713 | 26713 | 0.00 | 204.15 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Povidone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20684-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Povidone; Povidonum

### Special notes

When selecting the *Povidone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Povidone | 15 | 8 | 57 |

### Second-stage model

For differentiation of the substance/substance group *Povidone* the following second-stage model is used:

- Submodel 05

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Povidone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Povidone iodine | 27.59 | 11.24 |
| Fusidic acid | 56.72 | 49.28 |
| ⋮ | ⋮ | ⋮ |
| Spironolactone | >50 | 46.14 |
| Progesterone | 69.85 | 53.81 |
| Testosterone propionate | >50 | 73.02 |
| Ubidecarenone | >50 | 125.85 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Povidone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Povidone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Povidone | 12032714 | 20684 | 40 | 1402437 |
| Caelo | Povidone | 14142103 | 21378 | 40 | AR-15-FG-000596-01 |
| Caelo | Povidone | 16307808 | 23255 | 40 | AR-17-FG-015299-02 |
| Caelo | Povidone | 180276 | 24044 | 40 | 20180202* |
| Caelo | Povidone | 191752 | 24746 | 40 | 20190717* |
| Caelo | Povidone | 191276 | 24754 | 40 | 20190517* |
| Caelo | Povidone | 20000212 | 25194 | 40 | 20200313* |
| Caelo | Povidone | 20003415 | 25624 | 40 | 20201116* |
| Caelo | Povidone | 21003749 | 26003 | 40 | 20220203* |
| Caelo | Povidone | 23001270 | 26831 | 40 | 20230627* |
| Caelo | Povidone | 24000976 | 27335 | 40 | 20240826* |
| Fagron | Povidone | 12E22-N05 | 20770 | 40 | 1411537 |
| Fagron | Povidone | 13J21-N02 | 22731 | 40 | AR-16-FG-019116-01 |
| Fagron | Povidone | 15C12-B02-323006 | 23265 | 40 | 1710348 |
| Fagron | Povidone | 21I30-B03-219629 | 26287 | 40 | 20220510 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 600 spectra of 15 reference samples from the substance/substance group *Povidone*. These samples are listed above in the *calibration samples* section. The reference samples come from 15 different batches.

- 157 726 spectra from a total of 2942 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 380 spectra of 11 reference samples from the substance/substance group *Povidone*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Povidone | 172091 | 23619 | 40 |
| Caelo | Povidone | 180766 | 24245 | 40 |
| Caelo | Povidone | 181820 | 24246 | 40 |
| Caelo | Povidone | 182383 | 24291 | 40 |
| Caelo | Povidone | 183000 | 24396 | 40 |
| Caelo | Povidone | 192500 | 24899 | 40 |
| Caelo | Povidone | 23002064 | 26953 | 40 |
| Fagron | Povidone | 23E05-B03-228683 | 26917 | 40 |
| Caelo | Povidone | 21003749 | 26003SI† | 20 |
| Caelo | Povidone | 23001270 | 26831SI† | 20 |
| Fagron | Povidone | 21I30-B03-219629 | 26287SI† | 20 |

- 212 560 spectra from a total of 4276 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 188 spectra from 75 *Apo-Ident* customers from 61 batches from the substance/substance group *Povidone*.
- Among them are spectra of independent samples from 57 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Povidone | 23001270003 | 3 |
| 21001192005 | Povidone | 21001192005 | 1 |
| Alliance | Povidone | 16307808 | 1 |
| Alliance | Povidone | 17209106 | 1 |
| Alliance | Povidone | 18112201 | 1 |
| Audor Pharma | Povidone | 18112201 | 1 |
| Caelo | Povidone | 12032714 | 1 |
| Caelo | Povidone | 12376301 | 1 |
| Caelo | Povidone | 13323407 | 2 |
| Caelo | Povidone | 14142103 | 1 |
| Caelo | Povidone | 14142109 | 3 |
| Caelo | Povidone | 14207508 | 3 |
| Caelo | Povidone | 14207511 | 4 |
| Caelo | Povidone | 14207515 | 1 |
| Caelo | Povidone | 14207517 | 1 |
| Caelo | Povidone | 15013721 | 1 |
| Caelo | Povidone | 15383101 | 3 |
| Caelo | Povidone | 15383102 | 1 |
| Caelo | Povidone | 15383103 | 2 |
| Caelo | Povidone | 16051101 | 2 |
| Caelo | Povidone | 16051102 | 1 |
| Caelo | Povidone | 16051103 | 1 |
| Caelo | Povidone | 16051104 | 1 |
| Caelo | Povidone | 16051108 | 2 |
| Caelo | Povidone | 16051110 | 1 |
| Caelo | Povidone | 16307802 | 1 |
| Caelo | Povidone | 16307808 | 1 |
| Caelo | Povidone | 163078085328 | 1 |
| Caelo | Povidone | 16307809 | 5 |
| Caelo | Povidone | 16307811 | 3 |
| Caelo | Povidone | 16307812 | 1 |
| Caelo | Povidone | 17209103 | 2 |
| Caelo | Povidone | 17209104 | 3 |
| Caelo | Povidone | 17209110 | 1 |
| Caelo | Povidone | 18024602 | 1 |
| Caelo | Povidone | 18027602 | 5 |
| Caelo | Povidone | 18112201 | 4 |
| Caelo | Povidone | 18182002 | 2 |
| Caelo | Povidone | 18238302 | 1 |
| Caelo | Povidone | 18300002 | 3 |
| Caelo | Povidone | 18300003 | 1 |
| Caelo | Povidone | 18300006 | 1 |
| Caelo | Povidone | 19127604 | 1 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Povidone | 19175202 | 5 |
| Caelo | Povidone | 19175204 | 2 |
| Caelo | Povidone | 192500001 | 1 |
| Caelo | Povidone | 19500001 | 1 |
| Caelo | Povidone | 20000212001 | 10 |
| Caelo | Povidone | 20000212005 | 3 |
| Caelo | Povidone | 20001927003 | 1 |
| Caelo | Povidone | 20003415 | 1 |
| Caelo | Povidone | 20003415001 | 2 |
| Caelo | Povidone | 20003415004 | 1 |
| Caelo | Povidone | 20003415005 | 2 |
| Caelo | Povidone | 20003606003 | 1 |
| Caelo | Povidone | 21001192003 | 4 |
| Caelo | Povidone | 21001192005 | 1 |
| Caelo | Povidone | 21003749002 | 4 |
| Caelo | Povidone | 22001357001 | 4 |
| Caesar & Loretz GmbH… | Povidone | 20000212005 | 1 |
| Caesar & Loretz GmbH… | Povidone | 20003415005 | 1 |
| Caesar & Loretz GmbH… | Povidone | 20001927003 | 2 |
| Caesar & Loretz GmbH… | Povidone | 20003415001 | 1 |
| Caesar & Loretz GmbH… | Povidone | 20000212001 | 1 |
| Caesar & Loretz GmbH… | Povidone | 20003415001 | 4 |
| Caesar & Loretz GmbH… | Povidone | 20003415004 | 1 |
| Caesar & Loretz GmbH… | Povidone | 21001192003 | 1 |
| Caesar & Loretz GmbH… | Povidone | 21003749002 | 1 |
| Caesar & Loretz GmbH/Sa | Povidone | 20000212005 | 1 |
| Caesar & Loretz GmbH… | Povidone | 22001357001 | 4 |
| Caesar & Loretz GmbH | Povidone | 18112201 | 1 |
| Caesar & Loretz GmbH | Povidone | 18238302 | 1 |
| Caesar & Loretz GmbH | Povidone | 18300002 | 2 |
| Caesar & Loretz GmbH | Povidone | 18300006 | 1 |
| Caesar & Loretz GmbH | Povidone | 19127604 | 1 |
| Caesar & Loretz GmbH | Povidone | 19175202 | 1 |
| Caesar & Loretz GmbH | Povidone | 20000212001 | 1 |
| Caesar & Loretz GmbH | Povidone | 20000212005 | 2 |
| Caesar & Loretz GmbH | Povidone | 20001927003 | 4 |
| Caesar & Loretz GmbH | Povidone | 20003415001 | 3 |
| Caesar & Loretz GmbH | Povidone | 20003415004 | 3 |
| Caesar & Loretz GmbH | Povidone | 20003415005 | 3 |
| Caesar & Loretz GmbH | Povidone | 20003606001 | 1 |
| Caesar & Loretz GmbH | Povidone | 21001192003 | 1 |
| Caesar & Loretz GmbH | Povidone | 21001192005 | 5 |
| Caesar & Loretz GmbH | Povidone | 21003749002 | 5 |
| Caesar & Loretz GmbH | Povidone | 22001357001 | 3 |
| Caesar & Loretz Hild… | Povidone | 18300002 | 1 |
| Caesar / Ebert | Povidone | 15383101 | 2 |
| Cealo | Povidone | 4369127 | 1 |
| Fagron | Povidone | 11276509T0 | 1 |
| Fagron | Povidone | 15C12-B02-327866 | 1 |
| Fagron | Povidone | 24701988Q0 | 1 |
| GEHE | Povidone | 18112201 | 1 |
| Gehe | Povidone | 18300002 | 1 |
| Noweda | Povidone | 20003415005 | 1 |
| Phönix | Povidone | 192500001 | 1 |
| Sanacorp | Povidone | 32470709T0 | 1 |

- 256 698 spectra from 1666 *Apo-Ident* customers from a total of 52 093 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Povidone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Povidone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 600 | 0 | 157 726 |
| **Type B** | 0 | 380 | 0 | 212 560 |
| **Type C** | 0 | 168 | 20 | 256 698 |

The substance/substance group *Povidone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4211 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 89.3617 % (> 87.7660 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20684 | 20684 | 0.00 | 30.92 |
| 20770 | 20770 | 0.00 | 52.59 |
| 21378 | 21378 | 0.00 | 29.42 |
| 22731 | 22731 | 0.00 | 84.41 |
| 23255 | 23255 | 0.00 | 31.52 |
| 23265 | 23265 | 0.00 | 74.16 |
| 24044 | 24044 | 0.00 | 36.02 |
| 24746 | 24746 | 0.00 | 118.59 |
| 24754 | 24754 | 0.00 | 123.90 |
| 25194 | 25194 | 0.00 | 146.18 |
| 25624 | 25624 | 0.00 | 78.13 |
| 26003 | 26003 | 0.00 | 77.06 |
| 26287 | 26831 | 17.69 | 51.47 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26831 | 26831 | 0.00 | 54.13 |
| 27335 | 27335 | 0.00 | 98.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Povidone iodine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20472-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Povidone iodine; Povidonum iodinatum

### Special notes

When selecting the *Povidone iodine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Povidone iodine | 17 | 7 | 59 |

### Second-stage model

For differentiation of the substance/substance group *Povidone iodine* the following second-stage model is used:

- Submodel 05

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Povidone iodine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Povidone | 21.27 | 16.46 |
| Fusidic acid | 53.26 | 45.32 |
| ⋮ | ⋮ | ⋮ |
| Progesterone | >50 | 52.51 |
| Spironolactone | >50 | 54.09 |
| Testosterone propionate | >50 | 78.18 |
| Ubidecarenone | >50 | 137.63 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Povidone iodine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Povidone iodine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Povidone iodine | 13337205 | 21466 | 60 | 20131021 |
| Caelo | Povidone iodine | 15234101 | 23252 | 40 | AR-17-FG-015433-02 |
| Caelo | Povidone iodine | 15234109 | 23256 | 40 | 20150717 |
| Caelo | Povidone iodine | 182385 | 24234 | 40 | 20180917* |
| Caelo | Povidone iodine | 20003244 | 25659 | 40 | 20210106* |
| Caelo | Povidone iodine | 22001868 | 26238 | 40 | 20220720* |
| Caelo | Povidone iodine | 23000265 | 26725 | 40 | 20230331* |
| Euro OTC | Povidone iodine | 1501029-01 | 21777 | 60 | 20150211 |
| Euro OTC | Povidone iodine | 1509009 | 21908 | 60 | 20150918* |
| Euro OTC | Povidone iodine | 1606026-02 | 23906 | 40 | 20160708 |
| Euro OTC | Povidone iodine | 1805007 | 24118 | 40 | 20180525* |
| Euro OTC | Povidone iodine | 1905008 | 24770 | 40 | 20190628* |
| Euro OTC | Povidone iodine | 2001048 | 25122 | 40 | 20200320* |
| Euro OTC | Povidone iodine | 2003030 | 25240 | 40 | 20200707* |
| Euro OTC | Povidone iodine | 2009042 | 25433 | 40 | 20201022* |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Povidone iodine | 2206025 | 26225 | 40 | 20220721* |
| Euro OTC | Povidone iodine | 2206025 | 26225SI | 20 | 20220721* |
| Euro OTC | Povidone iodine | 2305022 | 26750 | 40 | 20230705* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 760 spectra of 18 reference samples from the substance/substance group *Povidone iodine*. These samples are listed above in the *calibration samples* section. The reference samples come from 17 different batches.
- 157 566 spectra from a total of 2940 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 310 spectra of 9 reference samples from the substance/substance group *Povidone iodine*.
- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Povidone iodine | 180763 | 24261 | 40 |
| Caelo | Povidone iodine | 192297 | 24879 | 40 |
| Caelo | Povidone iodine | 24001530003 | 27572 | 40 |
| Euro OTC | Povidone iodine | 1606026 | 22675 | 40 |
| Euro OTC | Povidone iodine | 1704007 | 23435 | 40 |
| Euro OTC | Povidone iodine | 2202017 | 26044 | 40 |
| Euro OTC | Povidone iodine | 2406008 | 27295 | 40 |
| Caelo | Povidone iodine | 22001868 | 26238SI† | 20 |
| Euro OTC | Povidone iodine | 2202017 | 26044SI | 10 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 630 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 204 spectra from 78 *Apo-Ident* customers from 65 batches from the substance/substance group *Povidone iodine*.
- Among them are spectra of independent samples from 59 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Povidone iodine | 22001868001 | 3 |
| | Povidone iodine | 22001868004 | 2 |
| | Povidone iodine | 2200186800875/23P | 1 |
| | Povidone iodine | 2206025 | 1 |
| | Povidone iodine | 2206025-01 | 2 |
| | Povidone iodine | 24001530003 | 1 |
| apo-ident | Povidone iodine | 1606026-02 | 1 |
| apo-ident | Povidone iodine | 190500801 | 1 |
| Audor Pharma | Povidone iodine | 2009042-01 | 1 |
| BASF, Noweda | Povidone iodine | 1110013-02 | 1 |
| BASF/Phönix | Povidone iodine | 1501029-01 | 3 |
| Basf/Sanacorp | Povidone iodine | 180500701 | 1 |
| Basf/Sanacorp | Povidone iodine | 2009042-01 | 1 |
| Caelo | Povidone iodine | 1110013-02 | 1 |
| Caelo | Povidone iodine | 11168607 | 1 |
| Caelo | Povidone iodine | 11168612 | 1 |
| Caelo | Povidone iodine | 12072605 | 1 |
| Caelo | Povidone iodine | 12153106 | 2 |
| Caelo | Povidone iodine | 12153110 | 2 |
| Caelo | Povidone iodine | 12153116 | 2 |
| Caelo | Povidone iodine | 12153119 | 2 |
| Caelo | Povidone iodine | 1407032-01 | 1 |
| Caelo | Povidone iodine | 14195810 | 2 |
| Caelo | Povidone iodine | 15121402 | 1 |
| Caelo | Povidone iodine | 15234101 | 1 |
| Caelo | Povidone iodine | 15234109 | 1 |
| Caelo | Povidone iodine | 15442405 | 1 |
| Caelo | Povidone iodine | 17028102 | 2 |
| Caelo | Povidone iodine | 18025301 | 1 |
| Caelo | Povidone iodine | 1805007-01 | 1 |
| Caelo | Povidone iodine | 18076308 | 1 |
| Caelo | Povidone iodine | 1905008-01 | 1 |
| Caelo | Povidone iodine | 19061302 | 1 |
| Caelo | Povidone iodine | 192297004 | 6 |
| Caelo | Povidone iodine | 20003244001 | 4 |
| Caelo | Povidone iodine | 20003244004 | 2 |
| Caelo | Povidone iodine | 20003244006 | 1 |
| Caelo | Povidone iodine | 21001575002 | 2 |
| Caelo | Povidone iodine | 21001575004 | 1 |
| Caelo | Povidone iodine | 22001868004 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Povidone iodine | 19075002 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 18076308 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 19075003 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 192297002 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 192297003 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 20003244001 | 4 |
| Caesar & Loretz GmbH | Povidone iodine | 20003244006 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 20004050001 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 2003244001 | 1 |
| Caesar & Loretz GmbH | Povidone iodine | 21001575002 | 1 |
| EuRho/Noweda | Povidone iodine | 2009042-02 | 1 |
| EuRho | Povidone iodine | 2003030-01 | 2 |
| Euro OTC | Povidone iodine | 110013-02 | 1 |
| Euro OTC | Povidone iodine | 111001302 | 1 |
| Euro OTC | Povidone iodine | 1110013-02 | 4 |
| Euro OTC | Povidone iodine | 130901001 | 1 |
| Euro OTC | Povidone iodine | 1401029-01 | 1 |
| Euro OTC | Povidone iodine | 1407032-01 | 5 |
| Euro OTC | Povidone iodine | 1509009-01 | 2 |
| Euro OTC | Povidone iodine | 1509009-02 | 2 |
| Euro OTC | Povidone iodine | 1603023-01 | 2 |
| Euro OTC | Povidone iodine | 1606026 | 1 |
| Euro OTC | Povidone iodine | 1606026-02 | 21 |
| Euro OTC | Povidone iodine | 1704007-01 | 2 |
| Euro OTC | Povidone iodine | 1704007-02 | 2 |
| Euro OTC | Povidone iodine | 180500701 | 1 |
| Euro OTC | Povidone iodine | 1805007-01 | 7 |
| Euro OTC | Povidone iodine | 1805007-02 | 8 |
| Euro OTC | Povidone iodine | 1905008 | 1 |
| Euro OTC | Povidone iodine | 190500801 | 1 |
| Euro OTC | Povidone iodine | 1905008-01 | 23 |
| Euro OTC | Povidone iodine | 2001048-01 | 1 |
| Euro OTC | Povidone iodine | 2003030-01 | 10 |
| Euro OTC | Povidone iodine | 2009042-01 | 7 |
| Euro OTC | Povidone iodine | 2009042-02 | 5 |
| Euro OTC | Povidone iodine | 2202017-01 | 1 |
| Euro OTC | Povidone iodine | 2206025-01 | 1 |
| Euro OTC | Povidone iodine | 8051808 | 1 |
| Euro OTC | Povidone iodine | G4208BPZ0 | 2 |
| Euroo/Phoenix | Povidone iodine | G3115BPZ0 | 1 |
| Fagron | Povidone iodine | 1110013-02 | 1 |
| Fagron | Povidone iodine | 1905008-01 | 3 |
| Noweda | Povidone iodine | G0354BPZ0 | 1 |
| ph euro | Povidone iodine | 19050080-01 | 1 |
| Phoenix | Povidone iodine | 2003030-01 | 1 |
| Phönix | Povidone iodine | 1110013-02 | 1 |
| Sanacorp | Povidone iodine | 2202017-01 | 1 |
| Sanacorp | Povidone iodine | 2406008-01 | 1 |
| Stumpf | Povidone iodine | 11168612 | 1 |

- 256 682 spectra from 1666 *Apo-Ident* customers from a total of 52 090 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Povidone iodine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Povidone iodine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 760 | 0 | 157 566 |
| **Type B** | 0 | 305 | 5 | 212 630 |
| **Type C** | 0 | 192 | 12 | 256 682 |

The substance/substance group *Povidone iodine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.2105 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 98.3871 % (> 97.4194 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 94.1176 % (> 92.6471 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21466 | 21908 | 7.77 | 49.88 |
| 21777 | 21908 | 6.60 | 52.09 |
| 21908 | 21908 | 0.00 | 59.67 |
| 23252 | 23252 | 0.00 | 56.98 |
| 23256 | 23252 | 14.16 | 53.47 |
| 23906 | 21908 | 11.88 | 46.95 |
| 24118 | 24118 | 0.00 | 158.00 |
| 24234 | 24234 | 0.00 | 49.89 |
| 24770 | 24770 | 0.00 | 52.61 |
| 25122 | 25122 | 0.00 | 46.81 |
| 25240 | 25240 | 0.00 | 49.28 |
| 25433 | 25433 | 0.00 | 49.61 |
| 25659 | 25659 | 0.00 | 48.09 |
| 26225 | 26225 | 0.00 | 55.61 |
| 26238 | 26238 | 0.00 | 150.60 |
| 26725 | 26725 | 0.00 | 138.26 |
| 26750 | 26750 | 0.00 | 26.50 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prasterone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20703-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prasterone; Prasteronum

### Special notes

When selecting the *Prasterone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prasterone | 21 | 18 | 128 |

### Second-stage model

For differentiation of the substance/substance group *Prasterone* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prasterone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Testosterone | 56.08 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prasterone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prasterone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Prasterone | APZDHA16003-M | 23931 | 40 | 1805404 |
| Audor Pharma | Prasterone | APZDHAC17003MD | 24412 | 40 | 20180119 |
| Audor Pharma | Prasterone | APZDHAC18004D | 24430 | 40 | 1906523 |
| Euro OTC | Prasterone | 1102036-01 | 20703 | 40 | 1404310 |
| Euro OTC | Prasterone | 1506011 | 21824 | 60 | 20150629* |
| Euro OTC | Prasterone | 1602018 | 22506 | 30 | 20160301* |
| Euro OTC | Prasterone | 1704012 | 23389 | 40 | 20170529* |
| Euro OTC | Prasterone | 1707014 | 23695 | 40 | 20170829* |
| Euro OTC | Prasterone | 1710035 | 23868 | 40 | 20171212* |
| Euro OTC | Prasterone | 1712014 | 23893 | 40 | 20180115* |
| Euro OTC | Prasterone | 1809009 | 24323 | 40 | 20181010* |
| Euro OTC | Prasterone | 1907045 | 24853 | 40 | 20190905* |
| Euro OTC | Prasterone | 1809009 | 24966 | 40 | 20191111* |
| Euro OTC | Prasterone | 1910025 | 24967 | 40 | 20191111* |
| Euro OTC | Prasterone | 2001038 | 25091 | 40 | 20200302* |
| Euro OTC | Prasterone | 2102004 | 25537 | 40 | 20210224* |
| Euro OTC | Prasterone | 2101011 | 25568 | 40 | 20210224* |
| Euro OTC | Prasterone | 2301032 | 26513 | 39 | 20230202* |
| Fagron | Prasterone | 13J10-B02-287175 | 20960 | 40 | 1404309 |
| Fagron | Prasterone | 15G14-B07-310827 | 21917 | 60 | 20150814 |
| Fagron | Prasterone | 16L13-B01-330724 | 23865 | 40 | 20161228 |
| Fagron | Prasterone | 22E25-F01-382686 | 26408 | 40 | 20220720 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 909 spectra of 22 reference samples from the substance/substance group *Prasterone*. These samples are listed above in the *calibration samples* section. The reference samples come from 21 different batches.

- 157 417 spectra from a total of 2936 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 800 spectra of 23 reference samples from the substance/substance group *Prasterone*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Audor Pharma | Prasterone | APZDHA16003-1MD | 23932 | 40 |
| Euro OTC | Prasterone | 1702025 | 23147 | 40 |
| Euro OTC | Prasterone | 1805018 | 24137 | 40 |
| Euro OTC | Prasterone | 1809010 | 24318 | 40 |
| Euro OTC | Prasterone | 1901030 | 24453 | 40 |
| Euro OTC | Prasterone | 1901031 | 24454 | 40 |
| Euro OTC | Prasterone | 2005008 | 25152 | 40 |
| Euro OTC | Prasterone | 2005007 | 25153 | 40 |
| Euro OTC | Prasterone | 2201038 | 25955 | 40 |
| Euro OTC | Prasterone | 2203004 | 26100 | 30 |
| Euro OTC | Prasterone | 2206014 | 26216 | 40 |
| Euro OTC | Prasterone | 2209007 | 26344 | 40 |
| Euro OTC | Prasterone | 2301031 | 26594 | 40 |
| Euro OTC | Prasterone | 2311028 | 27003 | 40 |
| Euro OTC | Prasterone | 2408001 | 27393 | 40 |
| Euro OTC | Prasterone | 2408002 | 27394 | 40 |
| Fagron | Prasterone | 18C12-B01-347633 | 23990 | 40 |
| Fagron | Prasterone | 23K03-B04-231722 | 27033 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Prasterone | 2201038 | 25955SI | 10 |
| Euro OTC | Prasterone | 2203004 | 26100SI | 20 |
| Euro OTC | Prasterone | 2206014 | 26216SI | 20 |
| Euro OTC | Prasterone | 2209007 | 26344SI | 20 |
| Fagron | Prasterone | 22E25-F01-382686 | 26408SI[†] | 20 |

- 212 140 spectra from a total of 4268 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 270 spectra from 72 *Apo-Ident* customers from 131 batches from the substance/substance group *Prasterone*.

- Among them are spectra of independent samples from 128 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prasterone | 2203004-01 | 1 |
| | Prasterone | 2206014-01 | 1 |
| | Prasterone | 22A17-F01-381261 | 1 |
| | Prasterone | 22E25-F01-382686 | 1 |
| | Prasterone | 2301031 | 1 |
| | Prasterone | 2301031-01 | 1 |
| | Prasterone | 2301032-01 | 2 |
| | Prasterone | 2301032-02 | 5 |
| | Prasterone | 2311028-01 | 2 |
| | Prasterone | 23K03-B04-231723 | 1 |
| | Prasterone | 23L01-B05-231787 | 1 |
| | Prasterone | 23L01-B05-238894 | 1 |
| | Prasterone | 24J29B02005311 | 1 |
| Audor Pharma | Prasterone | 10050051/1P | 1 |
| Audor Pharma | Prasterone | AP11040002P | 2 |
| Audor Pharma | Prasterone | AP5103540P | 1 |
| Audor Pharma | Prasterone | APTDHAC17003-MD | 3 |
| Audor Pharma | Prasterone | APZDHA16003-M | 1 |
| Audor Pharma | Prasterone | APZDHAC17003-MD | 3 |
| Caelo | Prasterone | 1412028-01 | 1 |
| Caelo | Prasterone | 15A15-B40-307323 | 1 |
| Caelo | Prasterone | 16B19-B04-318665 | 1 |
| Caelo | Prasterone | 16I02-B02-326485 | 1 |
| Caelo | Prasterone | 16l02-B02-326485 | 2 |
| EU/AHD | Prasterone | 2005007-01 | 3 |
| EuRho/Gehe | Prasterone | 2005007-01 | 1 |
| EuRho/Noweda | Prasterone | 2101011-02 | 1 |
| EuRho | Prasterone | 1311002-01 | 1 |
| Euro OTC | Prasterone | 1203010-01 | 1 |
| Euro OTC | Prasterone | 1306021-01 | 3 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Prasterone | 1311002-01 | 2 |
| Euro OTC | Prasterone | 1401040-01 | 1 |
| Euro OTC | Prasterone | 1409004-01 | 4 |
| Euro OTC | Prasterone | 1412028 | 1 |
| Euro OTC | Prasterone | 1412028-01 | 4 |
| Euro OTC | Prasterone | 1506011-01 | 4 |
| Euro OTC | Prasterone | 1602018-01 | 5 |
| Euro OTC | Prasterone | 1602018-02 | 2 |
| Euro OTC | Prasterone | 1702025 | 3 |
| Euro OTC | Prasterone | 170202501 | 1 |
| Euro OTC | Prasterone | 1702025-01 | 7 |
| Euro OTC | Prasterone | 1704012-01 | 1 |
| Euro OTC | Prasterone | 18050118-01 | 1 |
| Euro OTC | Prasterone | 1805018-01 | 4 |
| Euro OTC | Prasterone | 1809009-01 | 1 |
| Euro OTC | Prasterone | 1809009-03 | 6 |
| Euro OTC | Prasterone | 180901001 | 1 |
| Euro OTC | Prasterone | 1809010-01 | 4 |
| Euro OTC | Prasterone | 1901030-01 | 1 |
| Euro OTC | Prasterone | 1901030-02 | 1 |
| Euro OTC | Prasterone | 190103101 | 1 |
| Euro OTC | Prasterone | 1901031-01 | 3 |
| Euro OTC | Prasterone | 1901031-02 | 1 |
| Euro OTC | Prasterone | 1910025-01 | 3 |
| Euro OTC | Prasterone | 2001038-01 | 6 |
| Euro OTC | Prasterone | 200500701 | 1 |
| Euro OTC | Prasterone | 2005007-01 | 4 |
| Euro OTC | Prasterone | 2005008-01 | 11 |
| Euro OTC | Prasterone | 201101 | 2 |
| Euro OTC | Prasterone | 2081302 | 1 |
| Euro OTC | Prasterone | 2101011-02 | 7 |
| Euro OTC | Prasterone | 2101011-03 | 6 |
| Euro OTC | Prasterone | 2102004-02 | 4 |
| Euro OTC | Prasterone | 2102004-03 | 4 |
| Euro OTC | Prasterone | 2102004-04 | 5 |
| Euro OTC | Prasterone | 220103801 | 1 |
| Euro OTC | Prasterone | 2201038-01 | 7 |
| Euro OTC | Prasterone | 22021306 | 1 |
| Euro OTC | Prasterone | 2203004-01 | 1 |
| Euro OTC | Prasterone | 2206014-01 | 1 |
| Euro OTC | Prasterone | 220900701 | 1 |
| Euro OTC | Prasterone | 2209007-01 | 1 |
| Euro OTC | Prasterone | 23021711 | 1 |
| Euro OTC | Prasterone | 26031506 | 1 |
| Euro OTC | Prasterone | 30041509 | 1 |
| Euro OTC | Prasterone | 4091511 | 1 |
| Euro OTC | Prasterone | 5101849 | 1 |
| Euro OTC | Prasterone | 9215-4/09 | 1 |
| Euro OTC | Prasterone | DHEA150801-1 | 1 |
| Euro OTC | Prasterone | T03-04/1412028-01 | 1 |
| Euro OTC | Prasterone | XPC0263 | 1 |
| Euro OTC | Prasterone | ZDHAC18002 | 1 |
| Euro/AHD | Prasterone | 2102004-04 | 1 |
| Fagron | Prasterone | 12C26-N09 | 1 |
| Fagron | Prasterone | 12G04-N19 | 2 |
| Fagron | Prasterone | 12K30-N06 | 3 |
| Fagron | Prasterone | 13J10-B02 | 1 |
| Fagron | Prasterone | 13J10-B02-287177 | 1 |
| Fagron | Prasterone | 1421-B03-300211 | 1 |
| Fagron | Prasterone | 14C18-B02 | 1 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prasterone | 14c18b02293602 | 1 |
| Fagron | Prasterone | 14C18-B02-293602 | 2 |
| Fagron | Prasterone | 14C18-B02-293606 | 1 |
| Fagron | Prasterone | 14C18-Bo2-293603 | 1 |
| Fagron | Prasterone | 14h12b05-297723 | 1 |
| Fagron | Prasterone | 14H12-B05-297727 | 2 |
| Fagron | Prasterone | 15A15-B40-307323 | 1 |
| Fagron | Prasterone | 15G14-B07-310827 | 1 |
| Fagron | Prasterone | 15I18-B09-316798 | 1 |
| Fagron | Prasterone | 16B19-B04-318665 | 2 |
| Fagron | Prasterone | 16B19-B04-322246 | 2 |
| Fagron | Prasterone | 16IO2-B02-326485 | 2 |
| Fagron | Prasterone | 16J26-B03-327602 | 1 |
| Fagron | Prasterone | 16L13-B01-332104 | 1 |
| Fagron | Prasterone | 17D11-B10-336395 | 1 |
| Fagron | Prasterone | 18B02-B02-345147 | 1 |
| Fagron | Prasterone | 18B13-B09_346424 | 1 |
| Fagron | Prasterone | 18C12 | 1 |
| Fagron | Prasterone | 18E15-B03-350802 | 2 |
| Fagron | Prasterone | 19061304 | 1 |
| Fagron | Prasterone | 19G10-B02-365017 | 2 |
| Fagron | Prasterone | 19G10-B02-365018 | 1 |
| Fagron | Prasterone | 19G10-B02-365154 | 2 |
| Fagron | Prasterone | 19G10-B02-365155 | 1 |
| Fagron | Prasterone | 20123-F03-374815 | 2 |
| Fagron | Prasterone | 20C25-U03-005782 | 1 |
| Fagron | Prasterone | 20I23-F03-374815 | 1 |
| Fagron | Prasterone | 20l23-F03-374815 | 1 |
| Fagron | Prasterone | 21G13-F03-380169 | 6 |
| Fagron | Prasterone | 21G13-FO3-380169 | 1 |
| Fagron | Prasterone | 22A17-F01-381262 | 1 |
| Fagron | Prasterone | 22H22-B04-223769 | 1 |
| Fagron | Prasterone | 22K21-B05-225380 | 1 |
| Fagron | Prasterone | 23L01-B05-233115 | 1 |
| Fagron | Prasterone | 27071705 | 1 |
| Fagron | Prasterone | 7013260004 | 1 |
| Fagron | Prasterone | 701326-0005 | 1 |
| Fagron | Prasterone | C04-140804(M) | 1 |
| Fagron | Prasterone | DHEA160802 | 1 |
| Fagron | Prasterone | DHEA190504 | 2 |
| Fagron | Prasterone | DHEAA150401-1 | 1 |
| Fagron | Prasterone | DHEAH200604W | 2 |
| Fagron | Prasterone | F02-3779709 | 1 |
| Fargon | Prasterone | 16B19-B04-318665 | 1 |
| Fragon | Prasterone | 12G04-N19 | 1 |
| Gall Pharma | Prasterone | 16/02-B02 | 1 |
| Gehe | Prasterone | 2005007-01 | 2 |
| Haihang Industry | Prasterone | 20130816 | 4 |
| Haihang | Prasterone | 20130507 | 1 |
| Jacoby Gatt-Koller | Prasterone | 20J02359 | 1 |
| Kögl | Prasterone | 1803108 | 1 |
| Nachprüfung | Prasterone | 120022 | 1 |
| NWM Shandong Northwe… | Prasterone | PST151207 | 1 |
| Ph.Eur/AHD | Prasterone | 1809009-03 | 1 |
| PROQUINA | Prasterone | 1602018_02 | 1 |
| Sanacorp | Prasterone | 1805018-01 | 1 |
| Sanacorp | Prasterone | 2203004-01 | 1 |

- 256 616 spectra from 1666 *Apo-Ident* customers from a total of 52 023 batches from a further


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724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Prasterone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prasterone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 909 | 0 | 157 417 |
| **Type B** | 0 | 800 | 0 | 212 140 |
| **Type C** | 0 | 270 | 0 | 256 616 |

The substance/substance group *Prasterone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.3399 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.7778 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20703 | 20703 | 0.00 | 148.44 |
| 20960 | 20960 | 0.00 | 148.69 |
| 21824 | 21824 | 0.00 | 141.80 |
| 21917 | 25091 | 25.82 | 141.93 |
| 22506 | 22506 | 0.00 | 151.29 |
| 23389 | 23389 | 0.00 | 108.40 |
| 23695 | 23695 | 0.00 | 122.37 |
| 23865 | 23695 | 43.67 | 137.70 |
| 23868 | 23868 | 0.00 | 111.68 |
| 23893 | 23893 | 0.00 | 133.31 |
| 23931 | 23931 | 0.00 | 137.77 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24323 | 24323 | 0.00 | 136.84 |
| 24412 | 23893 | 6.92 | 133.77 |
| 24430 | 24430 | 0.00 | 116.35 |
| 24853 | 24853 | 0.00 | 139.08 |
| 24966 | 24966 | 0.00 | 151.54 |
| 24967 | 24967 | 0.00 | 146.25 |
| 25091 | 25091 | 0.00 | 145.56 |
| 25537 | 25537 | 0.00 | 148.44 |
| 25568 | 25568 | 0.00 | 146.96 |
| 26408 | 25091 | 15.53 | 149.16 |
| 26513 | 26513 | 0.00 | 144.61 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Praziquantel** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24840-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Praziquantel; Praziquantelum

### Special notes

When selecting the *Praziquantel* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Praziquantel | 4 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Praziquantel* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Praziquantel* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 57.46 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Praziquantel* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Praziquantel*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Praziquantel | 2205031 | 26185 | 40 | 20220620* |
| Euro OTC | Praziquantel | 2205031 | 26185SI | 20 | 20220620* |
| Euro OTC | Praziquantel | 2401015 | 27159 | 30 | 20240227* |
| Euro OTC | Praziquantel | 2402035 | 27162 | 40 | 20240313* |
| Euro OTC | Praziquantel | 2501012 | 27632 | 40 | 20250409* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 170 spectra of 5 reference samples from the substance/substance group *Praziquantel*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 156 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Praziquantel*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Praziquantel | 1908004 | 24840 | 40 |
| Euro OTC | Praziquantel | 2401015 | 27159SI† | 20 |
| Euro OTC | Praziquantel | 2402035 | 27162SI† | 20 |

- 212 860 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Praziquantel*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

### Validation results

The validation runs checked whether the substance/substance group *Praziquantel* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Praziquantel* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 170 | 0 | 158 156 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Praziquantel* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.4706 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26185 | 26185 | 0.00 | 104.44 |
| 27159 | 27159 | 0.00 | 104.13 |
| 27162 | 27162 | 0.00 | 102.54 |
| 27632 | 27632 | 0.00 | 104.96 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prednicarbate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20196-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prednicarbate; Prednicarbatum

### Special notes

When selecting the *Prednicarbate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prednicarbate | 13 | 18 | 546 |

### Second-stage model

For differentiation of the substance/substance group *Prednicarbate* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prednicarbate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 48.59 | – |
| Ciclosporin | 111.56 | – |
| ⋮ | ⋮ | ⋮ |
| Oxybutynin hydrochloride | >50 | 64.21 |
| Levocarnitine | >50 | 149.62 |
| Capsaicin | >50 | 153.02 |
| Sodium citrate | >50 | 160.09 |
| Cyproterone acetate | >50 | 191.51 |
| Tetracaine | >50 | 215.03 |
| Norethisterone acetate | >50 | 235.71 |
| Amitriptyline hydrochloride | >50 | 318.77 |
| Quinine hydrochloride dihydrate | >50 | 413.34 |
| Heparin sodium | >50 | 433.32 |
| Alfatradiol | >50 | 529.02 |
| Valine | >50 | 605.98 |
| Ciprofloxacin hydrochloride | >50 | 619.77 |
| Pyridoxal-5-phosphate hydrate | >50 | 622.71 |
| Methoxsalen | >50 | 623.55 |
| Sucrose | >50 | 1972.27 |
| Amifampridine | >50 | 2026.89 |
| Triclosan | >50 | 2045.51 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prednicarbate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prednicarbate*:


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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Prednicarbate | 13119402 | 20832 | 60 | 1501576 |
| Caelo | Prednicarbate | 13119402 | 20833 | 60 | 20130517 |
| Caelo | Prednicarbate | 13119402 | 20833SI | 30 | 20130517 |
| Caelo | Prednicarbate | 13372404 | 21368 | 50 | AR-15-FG-007941-02 |
| Caelo | Prednicarbate | 13372404 | 21369 | 49 | 20131119 |
| Caelo | Prednicarbate | 13372404 | 21369SI | 33 | 20131119 |
| Euro OTC | Prednicarbate | 1302033-02 | 21610 | 60 | 1509286 |
| Euro OTC | Prednicarbate | 1507011 | 21858 | 60 | 20150730* |
| Euro OTC | Prednicarbate | 1601058 | 22366 | 45 | 20160223* |
| Euro OTC | Prednicarbate | 1601058 | 22366SI | 31 | 20160223* |
| Euro OTC | Prednicarbate | 2001031 | 25119 | 40 | 20200331* |
| Euro OTC | Prednicarbate | 2009018 | 25401 | 40 | 20200930* |
| Euro OTC | Prednicarbate | 2103017 | 25609 | 40 | 20210408* |
| Euro OTC | Prednicarbate | 2103017 | 25609SI | 38 | 20210408* |
| Euro OTC | Prednicarbate | 2204014 | 26084 | 40 | 20220511* |
| Euro OTC | Prednicarbate | 2405019 | 27277 | 40 | 20240704* |
| Euro OTC | Prednicarbate | 2405019 | 27277SI | 30 | 20240704* |
| Fagron | Prednicarbate | 12D27-N04 | 20700 | 40 | 20120509 |
| Fagron | Prednicarbate | 12D27-N04 | 20700SI | 48 | 20120509 |
| Fagron | Prednicarbate | 14A27-B02-291256 | 21572 | 60 | AR-16-FG-011442-01 |
| Fagron | Prednicarbate | 22F03-B02-223103 | 26393 | 40 | 20220930 |
| Fagron | Prednicarbate | 22F03-B02-223103 | 26393SI | 30 | 20220930 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 964 spectra of 22 reference samples from the substance/substance group *Prednicarbate*. These samples are listed above in the *calibration samples* section. The reference samples come from 13 different batches.

- 157 362 spectra from a total of 2944 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1297 spectra of 41 reference samples from the substance/substance group *Prednicarbate*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Prednicarbate | 160874 | 22447 | 60 |
| Caelo | Prednicarbate | 170138 | 23040 | 40 |
| Caelo | Prednicarbate | 173156 | 23845 | 40 |
| Caelo | Prednicarbate | 172204 | 23848 | 40 |
| Caelo | Prednicarbate | 21001161001 | 25928 | 40 |
| Caelo | Prednicarbate | 22000755 | 26130 | 40 |
| Caelo | Prednicarbate | 23001025 | 26847 | 40 |
| Caelo | Prednicarbate | 23001026 | 26848 | 40 |
| Euro OTC | Prednicarbate | 1605001 | 22558 | 30 |
| Euro OTC | Prednicarbate | 1607012 | 22703 | 40 |
| Euro OTC | Prednicarbate | 1609022 | 22860 | 40 |
| Euro OTC | Prednicarbate | 1707022 | 23540 | 40 |
| Euro OTC | Prednicarbate | 1801013 | 23887 | 40 |
| Euro OTC | Prednicarbate | 1805005 | 24134 | 40 |
| Euro OTC | Prednicarbate | 1809015 | 24320 | 40 |
| Euro OTC | Prednicarbate | 1903023 | 24633 | 40 |
| Euro OTC | Prednicarbate | 2304020 | 26922 | 40 |
| Euro OTC | Prednicarbate | 2411003 | 27458 | 30 |
| Caelo | Prednicarbate | 160874 | 22447SI | 30 |
| Caelo | Prednicarbate | 170138 | 23040SI | 20 |
| Caelo | Prednicarbate | 173156 | 23845SI | 20 |
| Caelo | Prednicarbate | 172204 | 23848SI | 20 |
| Caelo | Prednicarbate | 21001161001 | 25928SI | 36 |
| Caelo | Prednicarbate | 22000755 | 26130SI | 30 |
| Caelo | Prednicarbate | 23001025 | 26847SI | 30 |
| Caelo | Prednicarbate | 23001026 | 26848SI | 30 |
| Euro OTC | Prednicarbate | 1507011 | 21858SI† | 15 |
| Euro OTC | Prednicarbate | 1605001 | 22558SI | 25 |
| Euro OTC | Prednicarbate | 1607012 | 22703SI | 28 |
| Euro OTC | Prednicarbate | 1609022 | 22860SI | 27 |
| Euro OTC | Prednicarbate | 1707022 | 23540SI | 19 |
| Euro OTC | Prednicarbate | 1801013 | 23887SI | 20 |
| Euro OTC | Prednicarbate | 1805005 | 24134SI | 20 |
| Euro OTC | Prednicarbate | 1809015 | 24320SI | 20 |
| Euro OTC | Prednicarbate | 1903023 | 24633SI | 32 |
| Euro OTC | Prednicarbate | 2001031 | 25119SI† | 27 |
| Euro OTC | Prednicarbate | 2009018 | 25401SI† | 25 |
| Euro OTC | Prednicarbate | 2204014 | 26084SI† | 10 |
| Euro OTC | Prednicarbate | 2304020 | 26922SI | 37 |
| Euro OTC | Prednicarbate | 2411003 | 27458SI | 20 |
| Fagron | Prednicarbate | 14A27-B02-291256 | 21572SI† | 36 |

- 211 643 spectra from a total of 4264 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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provided by the customer regarding manufacturer and batch number.

- 4540 spectra from 1192 *Apo-Ident* customers from 568 batches from the substance/substance group *Prednicarbate*.
- Among them are spectra of independent samples from 544 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednicarbate | 1/0442 | 1 |
| | Prednicarbate | 191023/3 | 1 |
| | Prednicarbate | 19122604 | 1 |
| | Prednicarbate | 20003660008 | 1 |
| | Prednicarbate | 2001031-01 | 1 |
| | Prednicarbate | 21000991002 | 1 |
| | Prednicarbate | 21001161004 | 1 |
| | Prednicarbate | 21001161006 | 1 |
| | Prednicarbate | 21001161010 | 1 |
| | Prednicarbate | 21001161011 | 1 |
| | Prednicarbate | 2103017-01 | 3 |
| | Prednicarbate | 21F07-B17-216553 | 1 |
| | Prednicarbate | 220000755001 | 1 |
| | Prednicarbate | 22000755001 | 12 |
| | Prednicarbate | 22000755002 | 5 |
| | Prednicarbate | 22000755003 | 3 |
| | Prednicarbate | 22000755004 | 1 |
| | Prednicarbate | 22000755005 | 8 |
| | Prednicarbate | 22000755006 | 3 |
| | Prednicarbate | 22000755007 | 13 |
| | Prednicarbate | 22000755008 | 6 |
| | Prednicarbate | 22000755009 | 15 |
| | Prednicarbate | 22000755010 | 9 |
| | Prednicarbate | 220007755005 | 1 |
| | Prednicarbate | 2200755002 | 2 |
| | Prednicarbate | 220401401 | 2 |
| | Prednicarbate | 2204014-01 | 14 |
| | Prednicarbate | 2204014-02 | 1 |
| | Prednicarbate | 22F03-B02 | 1 |
| | Prednicarbate | 22F03-B02_223103 | 1 |
| | Prednicarbate | 22F03-B02-218938 | 2 |
| | Prednicarbate | 22F03-B02-223102 | 5 |
| | Prednicarbate | 22F03-B02-223103 | 2 |
| | Prednicarbate | 22F03-B02-223104 | 1 |
| | Prednicarbate | 22F03-B02-223105 | 1 |
| | Prednicarbate | 22F03-B02-2277918 | 1 |
| | Prednicarbate | 22F03-B02-227918 | 11 |
| | Prednicarbate | 22F03-B02-227919 | 3 |
| | Prednicarbate | 22F03-B02-232393 | 7 |
| | Prednicarbate | 22F03-B02-232393 | 1 |
| | Prednicarbate | 23001023001 | 2 |
| | Prednicarbate | 23001023002 | 1 |
| | Prednicarbate | 23001025003 | 9 |
| | Prednicarbate | 230010260002 | 1 |
| | Prednicarbate | 23001026001 | 48 |
| | Prednicarbate | 23001026002 | 57 |
| | Prednicarbate | 23001026003 | 11 |
| | Prednicarbate | 230010262 | 1 |
| | Prednicarbate | 2300126001 | 1 |
| | Prednicarbate | 23003318001 | 46 |
| | Prednicarbate | 23003318002 | 11 |
| | Prednicarbate | 23003318003 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednicarbate | 23003318005 | 5 |
| | Prednicarbate | 23003318006 | 24 |
| | Prednicarbate | 2304020 | 1 |
| | Prednicarbate | 2304020_01 | 1 |
| | Prednicarbate | 2304020-01 | 40 |
| | Prednicarbate | 2304040-01 | 1 |
| | Prednicarbate | 23H24-B06-232394 | 2 |
| | Prednicarbate | 2405019-01 | 15 |
| | Prednicarbate | 240519-01 | 1 |
| | Prednicarbate | 2411003-01 | 1 |
| | Prednicarbate | 24E16-B03-000864 | 2 |
| | Prednicarbate | 24E16-B03-000868 | 1 |
| | Prednicarbate | 24E16-B03-000867 | 1 |
| | Prednicarbate | B06-2323904 | 1 |
| | Prednicarbate | PNC001/0422 | 1 |
| 19Caesar & Loretz GmbH | Prednicarbate | 22000755001 | 1 |
| AEP | Prednicarbate | 19E14-B01-191430 | 3 |
| AEP | Prednicarbate | 21000991003 | 1 |
| AEP | Prednicarbate | 22000755003 | 1 |
| AEP | Prednicarbate | 22F03-B02-227918 | 1 |
| AEP | Prednicarbate | 23001026001 | 3 |
| AEP | Prednicarbate | 23001026003 | 1 |
| AHC | Prednicarbate | 20000609004 | 1 |
| AHC | Prednicarbate | 20000609009 | 1 |
| AHC | Prednicarbate | 2009018-01 | 1 |
| AHD | Prednicarbate | 17220408 | 1 |
| AHD | Prednicarbate | 1801013-01 | 1 |
| AHD | Prednicarbate | 1809015-01 | 1 |
| AHD | Prednicarbate | 21001161001 | 1 |
| AHD | Prednicarbate | 21001161006 | 1 |
| AHD | Prednicarbate | 21K24-B03-213699 | 1 |
| AHD | Prednicarbate | 22000755009 | 1 |
| AHD | Prednicarbate | 2204014-01 | 1 |
| AHD | Prednicarbate | 23001026001 | 1 |
| AHD | Prednicarbate | 23001026002 | 1 |
| AHD | Prednicarbate | 23001026003 | 2 |
| AHD | Prednicarbate | 23003318001 | 4 |
| AHD | Prednicarbate | 23003318006 | 1 |
| AHD | Prednicarbate | 2304020-01 | 1 |
| ALH | Prednicarbate | 16087408 | 2 |
| Alliance Healthcare | Prednicarbate | 19122602 | 1 |
| Alliance Healthcare | Prednicarbate | 21001161010 | 1 |
| Alliance Healthcare | Prednicarbate | 22000755002 | 1 |
| Alliance Healthcare | Prednicarbate | 22000755003 | 1 |
| Alliance Healthcare | Prednicarbate | 2204014-01 | 1 |
| Alliance Healthcare | Prednicarbate | 23001026002 | 1 |
| Alliance Healthcare | Prednicarbate | 23003318001 | 1 |
| Alliance | Prednicarbate | 22000755002 | 1 |
| Alliance | Prednicarbate | 22000755009 | 1 |
| Alliance | Prednicarbate | 22000755010 | 1 |
| Anzag | Prednicarbate | 17220408 | 1 |
| Anzag | Prednicarbate | 230427(22000755009) | 1 |
| Anzag | Prednicarbate | 230727(22000755005) | 1 |
| Anzag | Prednicarbate | 231025(22000755005) | 1 |
| Anzag | Prednicarbate | 240222(23001026003) | 1 |
| Anzag | Prednicarbate | 241101(23003318002) | 1 |
| Anzag | Prednicarbate | 250130(23003318005) | 1 |
| Apo-ident/Phoenix | Prednicarbate | 1903023-01 | 1 |
| apo-ident | Prednicarbate | 1607012-01 | 1 |
| apomix | Prednicarbate | 13372410 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| apomix | Prednicarbate | 1609022-01 | 2 |
| Bombastus | Prednicarbate | 15446306 | 1 |
| Bombastus | Prednicarbate | 17220408 | 1 |
| Bombastus | Prednicarbate | 17315605 | 1 |
| Bombastus | Prednicarbate | 180901501 | 2 |
| Caelo | Prednicarbate | | 3 |
| Caelo | Prednicarbate | 10(20000609009) | 1 |
| Caelo | Prednicarbate | 11(20000609009) | 1 |
| Caelo | Prednicarbate | 118194105 | 1 |
| Caelo | Prednicarbate | 12(20000609009) | 1 |
| Caelo | Prednicarbate | 121223613 | 1 |
| Caelo | Prednicarbate | 12123610 | 1 |
| Caelo | Prednicarbate | 1213608 | 1 |
| Caelo | Prednicarbate | 1220218/17220407 | 1 |
| Caelo | Prednicarbate | 12383301 | 1 |
| Caelo | Prednicarbate | 12383309 | 1 |
| Caelo | Prednicarbate | 13(20003660005) | 1 |
| Caelo | Prednicarbate | 13/23-N04 | 1 |
| Caelo | Prednicarbate | 13119401 | 1 |
| Caelo | Prednicarbate | 13119402 | 2 |
| Caelo | Prednicarbate | 13224401 | 5 |
| Caelo | Prednicarbate | 13224406 | 2 |
| Caelo | Prednicarbate | 13372403 | 9 |
| Caelo | Prednicarbate | 13372408 | 1 |
| Caelo | Prednicarbate | 13372410 | 6 |
| Caelo | Prednicarbate | 13372411 | 1 |
| Caelo | Prednicarbate | 13372419 | 6 |
| Caelo | Prednicarbate | 14(20003660008) | 1 |
| Caelo | Prednicarbate | 14A27-B02-295796 | 1 |
| Caelo | Prednicarbate | 14A27-B02-295797 | 1 |
| Caelo | Prednicarbate | 14J16-B06 | 3 |
| Caelo | Prednicarbate | 15(21000991002) | 1 |
| Caelo | Prednicarbate | 1507011-01 | 1 |
| Caelo | Prednicarbate | 1517E-03595 | 1 |
| Caelo | Prednicarbate | 15181403 | 13 |
| Caelo | Prednicarbate | 15181404 | 3 |
| Caelo | Prednicarbate | 15181408 | 1 |
| Caelo | Prednicarbate | 15181409 | 4 |
| Caelo | Prednicarbate | 15181411 | 2 |
| Caelo | Prednicarbate | 15446301 | 22 |
| Caelo | Prednicarbate | 15446302 | 13 |
| Caelo | Prednicarbate | 15446303 | 3 |
| Caelo | Prednicarbate | 1544630306 | 1 |
| Caelo | Prednicarbate | 15446304 | 1 |
| Caelo | Prednicarbate | 15446305 | 6 |
| Caelo | Prednicarbate | 15446306 | 14 |
| Caelo | Prednicarbate | 15D15-B03 | 1 |
| Caelo | Prednicarbate | 15D15-B03-308161 | 1 |
| Caelo | Prednicarbate | 15D15-B03-310847 | 2 |
| Caelo | Prednicarbate | 15G10-B02-314082 | 1 |
| Caelo | Prednicarbate | 15J22-B04-318528 | 1 |
| Caelo | Prednicarbate | 15J22-B-321005 | 1 |
| Caelo | Prednicarbate | 1601058-01 | 1 |
| Caelo | Prednicarbate | 160500 | 1 |
| Caelo | Prednicarbate | 1605001 | 1 |
| Caelo | Prednicarbate | 160701201 | 1 |
| Caelo | Prednicarbate | 1607012-01 | 2 |
| Caelo | Prednicarbate | 1608710 | 1 |
| Caelo | Prednicarbate | 16087401 | 13 |
| Caelo | Prednicarbate | 16087408 | 22 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednicarbate | 16087410 | 22 |
| Caelo | Prednicarbate | 16087411 | 3 |
| Caelo | Prednicarbate | 16087412 | 6 |
| Caelo | Prednicarbate | 168087410 | 1 |
| Caelo | Prednicarbate | 16987410 | 1 |
| Caelo | Prednicarbate | 16A18-B01-322732 | 1 |
| Caelo | Prednicarbate | 16E12-B01 | 1 |
| Caelo | Prednicarbate | 16E12-B01-325758 | 1 |
| Caelo | Prednicarbate | 16J27-B01 | 1 |
| Caelo | Prednicarbate | 16J27-B01-330976 | 5 |
| Caelo | Prednicarbate | 16J27-B01-330977 | 1 |
| Caelo | Prednicarbate | 16J27-B01-332958 | 4 |
| Caelo | Prednicarbate | 17013804 | 14 |
| Caelo | Prednicarbate | 17013805 | 11 |
| Caelo | Prednicarbate | 17014001 | 3 |
| Caelo | Prednicarbate | 17014003 | 29 |
| Caelo | Prednicarbate | 17014005 | 20 |
| Caelo | Prednicarbate | 17014006 | 2 |
| Caelo | Prednicarbate | 1704003 | 1 |
| Caelo | Prednicarbate | 1704005 | 1 |
| Caelo | Prednicarbate | 1707022-01 | 3 |
| Caelo | Prednicarbate | 17220401 | 6 |
| Caelo | Prednicarbate | 17220406 | 4 |
| Caelo | Prednicarbate | 17220407 | 49 |
| Caelo | Prednicarbate | 1722040716J27-B01-33 | 1 |
| Caelo | Prednicarbate | 172204075515 | 1 |
| Caelo | Prednicarbate | 17220408 | 50 |
| Caelo | Prednicarbate | 17220410 | 2 |
| Caelo | Prednicarbate | 1722401 | 1 |
| Caelo | Prednicarbate | 173156 | 1 |
| Caelo | Prednicarbate | 17315603 | 7 |
| Caelo | Prednicarbate | 17315604 | 40 |
| Caelo | Prednicarbate | 17315605 | 28 |
| Caelo | Prednicarbate | 17315606 | 1 |
| Caelo | Prednicarbate | 17315607 | 2 |
| Caelo | Prednicarbate | 17315609 | 48 |
| Caelo | Prednicarbate | 17315611 | 3 |
| Caelo | Prednicarbate | 177220407 | 1 |
| Caelo | Prednicarbate | 17C27-B01-339079 | 1 |
| Caelo | Prednicarbate | 17J04-B05-343934 | 1 |
| Caelo | Prednicarbate | 17j04B05346113 | 1 |
| Caelo | Prednicarbate | 17J04-B05-346113 | 1 |
| Caelo | Prednicarbate | 180101301 | 1 |
| Caelo | Prednicarbate | 1801013-01 | 9 |
| Caelo | Prednicarbate | 1805005-01 | 1 |
| Caelo | Prednicarbate | 1814112 | 1 |
| Caelo | Prednicarbate | 1819104 | 1 |
| Caelo | Prednicarbate | 18194101 | 1 |
| Caelo | Prednicarbate | 18194103 | 10 |
| Caelo | Prednicarbate | 18194104 | 61 |
| Caelo | Prednicarbate | 18194105 | 77 |
| Caelo | Prednicarbate | 18194112 | 9 |
| Caelo | Prednicarbate | 18194115 | 49 |
| Caelo | Prednicarbate | 18194116 | 5 |
| Caelo | Prednicarbate | 18194117 | 21 |
| Caelo | Prednicarbate | 18194194 | 1 |
| Caelo | Prednicarbate | 18197115 | 1 |
| Caelo | Prednicarbate | 18294103 | 1 |
| Caelo | Prednicarbate | 18B27-B01-347486 | 5 |
| Caelo | Prednicarbate | 18B27-B01-350264 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednicarbate | 18E14-B03-352560 | 2 |
| Caelo | Prednicarbate | 18E14-B03-355726 | 1 |
| Caelo | Prednicarbate | 18E14-B03-355727 | 1 |
| Caelo | Prednicarbate | 19051601 | 58 |
| Caelo | Prednicarbate | 19051602 | 46 |
| Caelo | Prednicarbate | 1905-1602 | 1 |
| Caelo | Prednicarbate | 19051603 | 1 |
| Caelo | Prednicarbate | 19051604 | 9 |
| Caelo | Prednicarbate | 191122608 | 1 |
| Caelo | Prednicarbate | 19122602 | 18 |
| Caelo | Prednicarbate | 19122604 | 53 |
| Caelo | Prednicarbate | 19122608 | 56 |
| Caelo | Prednicarbate | 1922604 | 2 |
| Caelo | Prednicarbate | 1922608 | 1 |
| Caelo | Prednicarbate | 19G09-B01-194722 | 2 |
| Caelo | Prednicarbate | 2(18194104) | 1 |
| Caelo | Prednicarbate | 200000609004 | 2 |
| Caelo | Prednicarbate | 20000360007 | 1 |
| Caelo | Prednicarbate | 200003660006 | 2 |
| Caelo | Prednicarbate | 200003660007 | 3 |
| Caelo | Prednicarbate | 20000609001 | 14 |
| Caelo | Prednicarbate | 20000609003 | 1 |
| Caelo | Prednicarbate | 20000609004 | 57 |
| Caelo | Prednicarbate | 20000609006 | 12 |
| Caelo | Prednicarbate | 20000609008 | 1 |
| Caelo | Prednicarbate | 20000609009 | 37 |
| Caelo | Prednicarbate | 2000060904 | 1 |
| Caelo | Prednicarbate | 20000609606 | 1 |
| Caelo | Prednicarbate | 2000360009 | 1 |
| Caelo | Prednicarbate | 20003660002 | 1 |
| Caelo | Prednicarbate | 20003660004 | 10 |
| Caelo | Prednicarbate | 20003660005 | 12 |
| Caelo | Prednicarbate | 20003660006 | 22 |
| Caelo | Prednicarbate | 20003660007 | 30 |
| Caelo | Prednicarbate | 200036600078 | 1 |
| Caelo | Prednicarbate | 20003660008 | 36 |
| Caelo | Prednicarbate | 20003660008mul | 1 |
| Caelo | Prednicarbate | 20003660009 | 31 |
| Caelo | Prednicarbate | 2000366005 | 1 |
| Caelo | Prednicarbate | 2000366006 | 1 |
| Caelo | Prednicarbate | 2000366007 | 3 |
| Caelo | Prednicarbate | 2000366008 | 3 |
| Caelo | Prednicarbate | 2000366009 | 1 |
| Caelo | Prednicarbate | 200036660008 | 1 |
| Caelo | Prednicarbate | 20006069006 | 1 |
| Caelo | Prednicarbate | 2000609004 | 1 |
| Caelo | Prednicarbate | 2001031-01 | 5 |
| Caelo | Prednicarbate | 2003660007 | 1 |
| Caelo | Prednicarbate | 2003660008 | 2 |
| Caelo | Prednicarbate | 2003666009 | 1 |
| Caelo | Prednicarbate | 2009018-01 | 8 |
| Caelo | Prednicarbate | 2009018-02 | 1 |
| Caelo | Prednicarbate | 201372 | 1 |
| Caelo | Prednicarbate | 2018821009912 | 1 |
| Caelo | Prednicarbate | 20A21-B12 | 1 |
| Caelo | Prednicarbate | 2100091003 | 2 |
| Caelo | Prednicarbate | 21000991001 | 2 |
| Caelo | Prednicarbate | 21000991002 | 48 |
| Caelo | Prednicarbate | 21000991003 | 36 |
| Caelo | Prednicarbate | 21000991004 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednicarbate | 21000991005 | 10 |
| Caelo | Prednicarbate | 2100116007 | 2 |
| Caelo | Prednicarbate | 21001161001 | 52 |
| Caelo | Prednicarbate | 21001161003 | 3 |
| Caelo | Prednicarbate | 21001161004 | 4 |
| Caelo | Prednicarbate | 21001161006 | 38 |
| Caelo | Prednicarbate | 21001161007 | 31 |
| Caelo | Prednicarbate | 21001161008 | 5 |
| Caelo | Prednicarbate | 21001161009 | 2 |
| Caelo | Prednicarbate | 21001161010 | 22 |
| Caelo | Prednicarbate | 21001161011 | 27 |
| Caelo | Prednicarbate | 21001161013 | 7 |
| Caelo | Prednicarbate | 2100161001 | 3 |
| Caelo | Prednicarbate | 2100161006 | 1 |
| Caelo | Prednicarbate | 2100161007 | 4 |
| Caelo | Prednicarbate | 210061009 | 1 |
| Caelo | Prednicarbate | 2100991003 | 3 |
| Caelo | Prednicarbate | 2101161011 | 1 |
| Caelo | Prednicarbate | 2103017-01 | 6 |
| Caelo | Prednicarbate | 210906(21000991002) | 1 |
| Caelo | Prednicarbate | 211001161011 | 1 |
| Caelo | Prednicarbate | 211007 | 1 |
| Caelo | Prednicarbate | 21990000022000 | 1 |
| Caelo | Prednicarbate | 21F07-817-216553 | 1 |
| Caelo | Prednicarbate | 21F07-B17-216554 | 1 |
| Caelo | Prednicarbate | 2200055003 | 1 |
| Caelo | Prednicarbate | 22000755001 | 16 |
| Caelo | Prednicarbate | 22000755002 | 16 |
| Caelo | Prednicarbate | 22000755003 | 19 |
| Caelo | Prednicarbate | 22000755005 | 5 |
| Caelo | Prednicarbate | 22000755006 | 2 |
| Caelo | Prednicarbate | 22000755007 | 13 |
| Caelo | Prednicarbate | 22000755009 | 2 |
| Caelo | Prednicarbate | 22000755010 | 1 |
| Caelo | Prednicarbate | 2200075509 | 2 |
| Caelo | Prednicarbate | 220075507 | 1 |
| Caelo | Prednicarbate | 22007553003 | 1 |
| Caelo | Prednicarbate | 220516(21001161010) | 1 |
| Caelo | Prednicarbate | 220928 | 1 |
| Caelo | Prednicarbate | 221228(22000755003) | 1 |
| Caelo | Prednicarbate | 23001026001 | 8 |
| Caelo | Prednicarbate | 23003318006 | 1 |
| Caelo | Prednicarbate | 230123(22000755003) | 1 |
| Caelo | Prednicarbate | 230213(22000755003) | 1 |
| Caelo | Prednicarbate | 230315(2200055007) | 1 |
| Caelo | Prednicarbate | 23051819 | 1 |
| Caelo | Prednicarbate | 23082013A | 1 |
| Caelo | Prednicarbate | 2748 | 1 |
| Caelo | Prednicarbate | 2790 | 1 |
| Caelo | Prednicarbate | 2x21001161001 | 1 |
| Caelo | Prednicarbate | 3(19051602) | 1 |
| Caelo | Prednicarbate | 3267 | 1 |
| Caelo | Prednicarbate | 3272 | 1 |
| Caelo | Prednicarbate | 3302 | 1 |
| Caelo | Prednicarbate | 3438 | 1 |
| Caelo | Prednicarbate | 4(19122608) | 1 |
| Caelo | Prednicarbate | 5(19122608) | 1 |
| Caelo | Prednicarbate | 6(19122608) | 1 |
| Caelo | Prednicarbate | 6090092 | 1 |
| Caelo | Prednicarbate | 7(19122608) | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednicarbate | 718A-03595 | 1 |
| Caelo | Prednicarbate | 8(19122608) | 1 |
| Caelo | Prednicarbate | 9(20000609004) | 1 |
| Caelo | Prednicarbate | 9764897 | 1 |
| Caelo | Prednicarbate | C0333/1111070 | 2 |
| Caelo | Prednicarbate | PNC101/0720 | 1 |
| Caeol/Noweda | Prednicarbate | 16A18-B01-322732 | 1 |
| Caeol/Noweda | Prednicarbate | 17315609 | 1 |
| Caeol/Phornix | Prednicarbate | 17315604 | 1 |
| Caersar & Loretz | Prednicarbate | 21000991002 | 1 |
| Caesar & Lorenz GmbH | Prednicarbate | 19051601 | 1 |
| Caesar & Lorenz GmbH | Prednicarbate | 19051602 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 19051601 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161004 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 18194112 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21000991002 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161010 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 9764897 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20003660009 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161007 | 3 |
| Caesar & Loretz GmbH... | Prednicarbate | 20000609009 | 1 |
| Caesar & Loretz GmbH/ AHD | Prednicarbate | 22000755003 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20000609004 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161007 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161010 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20003660005 | 2 |
| Caesar & Loretz GmbH... | Prednicarbate | 21000991003 | 2 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161011 | 1 |
| Caesar & Loretz GmbH/AHD | Prednicarbate | 20000609004 | 1 |
| Caesar & Loretz GmbH/AHD | Prednicarbate | 21001161010 | 1 |
| Caesar & Loretz GmbH/E | Prednicarbate | 21000991003 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 1203584 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 19122608 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161007 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | B12-1975501 | 1 |
| Caesar & Loretz GmbH/G | Prednicarbate | 20003660009 | 1 |
| Caesar & Loretz GmbH/G | Prednicarbate | 21001161006 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 18194115 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 191226 | 1 |
| Caesar & Loretz GmbH/GEHE | Prednicarbate | 19122602 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 19122604 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 20000609004 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 20000609006 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 20000609009 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 21000991003 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 21001161006 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 22000755007 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednicarbate | 23003318002 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21000991002 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161006 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 18194117 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20003660009 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161006 | 2 |
| Caesar & Loretz GmbH... | Prednicarbate | 19122604 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20000609004 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20003660004 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161007 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161011 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 22000755002 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 19051602 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Prednicarbate | 20003660005 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21000991002 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161001 | 4 |
| Caesar & Loretz GmbH... | Prednicarbate | 21000991003 | 2 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161006 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 19122602 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20000609009 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20003660008 | 1 |
| Caesar & Loretz GmbH/sa | Prednicarbate | 22000755001 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 19122604 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 20003660007 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | 21001161001 | 1 |
| Caesar & Loretz GmbH... | Prednicarbate | AP221018-02 | 1 |
| Caesar & Loretz GmbH | Prednicarbate | 16087410 | 1 |
| Caesar & Loretz GmbH | Prednicarbate | 18194103 | 1 |
| Caesar & Loretz GmbH | Prednicarbate | 18194104 | 1 |
| Caesar & Loretz GmbH | Prednicarbate | 18194105 | 16 |
| Caesar & Loretz GmbH | Prednicarbate | 18194115 | 10 |
| Caesar & Loretz GmbH | Prednicarbate | 18194117 | 1 |
| Caesar & Loretz GmbH | Prednicarbate | 19051601 | 1 |
| Caesar & Loretz GmbH | Prednicarbate | 19051602 | 10 |
| Caesar & Loretz GmbH | Prednicarbate | 19122602 | 4 |
| Caesar & Loretz GmbH | Prednicarbate | 19122604 | 6 |
| Caesar & Loretz GmbH | Prednicarbate | 19122608 | 7 |
| Caesar & Loretz GmbH | Prednicarbate | 20000609004 | 16 |
| Caesar & Loretz GmbH | Prednicarbate | 20000609006 | 6 |
| Caesar & Loretz GmbH | Prednicarbate | 20000609009 | 14 |
| Caesar & Loretz GmbH | Prednicarbate | 20003660004 | 5 |
| Caesar & Loretz GmbH | Prednicarbate | 20003660005 | 4 |
| Caesar & Loretz GmbH | Prednicarbate | 20003660006 | 5 |
| Caesar & Loretz GmbH | Prednicarbate | 20003660007 | 10 |
| Caesar & Loretz GmbH | Prednicarbate | 20003660008 | 13 |
| Caesar & Loretz GmbH | Prednicarbate | 20003660009 | 4 |
| Caesar & Loretz GmbH | Prednicarbate | 21000991002 | 8 |
| Caesar & Loretz GmbH | Prednicarbate | 21000991003 | 9 |
| Caesar & Loretz GmbH | Prednicarbate | 21000991005 | 9 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161001 | 16 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161004 | 5 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161006 | 11 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161007 | 10 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161008 | 5 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161010 | 9 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161011 | 9 |
| Caesar & Loretz GmbH | Prednicarbate | 21001161013 | 4 |
| Caesar & Loretz GmbH | Prednicarbate | 21A11-B01-2035804 | 1 |
| Caesar & Loretz GmbH | Prednicarbate | 22000755001 | 7 |
| Caesar & Loretz GmbH | Prednicarbate | 22000755002 | 4 |
| Caesar & Loretz GmbH | Prednicarbate | 22000755003 | 6 |
| Caesar & Loretz GmbH | Prednicarbate | 22000755005 | 3 |
| Caesar & Loretz GmbH | Prednicarbate | 22000755007 | 8 |
| Caesar & Loretz GmbH | Prednicarbate | 22000755009 | 2 |
| Caesar & Loretz GmbH | Prednicarbate | 22000755010 | 2 |
| Caesar & Loretz GmbH | Prednicarbate | 23001026001 | 3 |
| Caesar & Loretz GmbH | Prednicarbate | 23001026002 | 1 |
| Caesar & Loretz Hild... | Prednicarbate | 20000609004 | 1 |
| Caesar & Loretz Hilden | Prednicarbate | 18194104 | 1 |
| Caesar & Loretz Hilden | Prednicarbate | 19051602 | 2 |
| Caesar & Loretz Hilden | Prednicarbate | 19122608 | 2 |
| Caesar & Loretz Hilden | Prednicarbate | 20000609009 | 2 |
| Caesar & Loretz Hilden | Prednicarbate | 2009018-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz/Geil... | Prednicarbate | 19051602 | 1 |
| Caesar & Loretz/Noweda | Prednicarbate | 20000609004 | 1 |
| Caesar & Loretz/Noweda | Prednicarbate | 20003660005 | 1 |
| Caesar Loretz | Prednicarbate | 20003660007 | 1 |
| Caesar und Loretz GmbH | Prednicarbate | 17220406 | 1 |
| caesar&loretz GmbH,A... | Prednicarbate | 16087408 | 1 |
| Caesar&Loretz GmbH/ ... | Prednicarbate | 19122604 | 1 |
| Caesar&Loretz GmbH | Prednicarbate | 20003660006 | 1 |
| Caesar&Loretz GmbH | Prednicarbate | 22000755003 | 1 |
| caesar&loretz,Phönix | Prednicarbate | 15181411 | 1 |
| caesar&loretz | Prednicarbate | 18149103 | 1 |
| Caesar/Ebert | Prednicarbate | 18194105 | 1 |
| Caleo/ Fiebig | Prednicarbate | 17J04-B05-341872 | 1 |
| Caleo/Krieger | Prednicarbate | 21001161007 | 1 |
| Cealo / Anzag | Prednicarbate | 230221(22000755003) | 1 |
| Cealo/GEHE | Prednicarbate | 17315609 | 1 |
| Cealo/Jenne | Prednicarbate | 220306(21001161006) | 1 |
| Cealo/Phönix | Prednicarbate | 20000609004 | 1 |
| Cealo/Sanacorp | Prednicarbate | 15546306 | 1 |
| cealo | Prednicarbate | 14J16-B06-303465 | 1 |
| Celo | Prednicarbate | 1687408 | 1 |
| Defektur | Prednicarbate | 12D27-N04 | 1 |
| E und J, 22.07.2016 | Prednicarbate | 15446306 | 2 |
| Eu Rho | Prednicarbate | 2103017-01 | 1 |
| Eurho / Alliance | Prednicarbate | 2103017-01 | 2 |
| EuRho/ AHD | Prednicarbate | 1801013-01 | 1 |
| EuRho/ AHD | Prednicarbate | 1805005 | 1 |
| EuRho/ NOWEDA | Prednicarbate | 1903023-01 | 1 |
| EuRho/ NOWEDA | Prednicarbate | 2001031-01 | 1 |
| eurho/gehe | Prednicarbate | 2009018-01 | 1 |
| EuRho/Noweda | Prednicarbate | 1805005-01 | 1 |
| EuRho/Noweda | Prednicarbate | 200901801 | 1 |
| Eurho/noweda | Prednicarbate | 210301701 | 1 |
| EuRho/Phoenix | Prednicarbate | 2009018-01 | 1 |
| EuRho/Phönix | Prednicarbate | 1805005-01 | 2 |
| EuRho/Phönix | Prednicarbate | 2001031-01 | 1 |
| EuRho | Prednicarbate | 1801013-01 | 1 |
| Eurho | Prednicarbate | 2103017-01 | 2 |
| EuRho | Prednicarbate | 2103017-01 | 1 |
| Euro OCT / Krieger | Prednicarbate | 2009018-01 | 6 |
| Euro OTC | Prednicarbate | | 3 |
| Euro OTC | Prednicarbate | 1302033-01 | 1 |
| Euro OTC | Prednicarbate | 1302033-02 | 3 |
| Euro OTC | Prednicarbate | 13224402 | 1 |
| Euro OTC | Prednicarbate | 13372403 | 1 |
| Euro OTC | Prednicarbate | 1501033-01 | 2 |
| Euro OTC | Prednicarbate | 1501033-02 | 4 |
| Euro OTC | Prednicarbate | 1507011-01 | 2 |
| Euro OTC | Prednicarbate | 1507011-02 | 4 |
| Euro OTC | Prednicarbate | 1601058-01 | 5 |
| Euro OTC | Prednicarbate | 1605001 | 1 |
| Euro OTC | Prednicarbate | 1605001-01 | 10 |
| Euro OTC | Prednicarbate | 1607012-01 | 9 |
| Euro OTC | Prednicarbate | 1609011-01 | 1 |
| Euro OTC | Prednicarbate | 160902 | 1 |
| Euro OTC | Prednicarbate | 160902201 | 3 |
| Euro OTC | Prednicarbate | 1609022-01 | 24 |
| Euro OTC | Prednicarbate | 170702201 | 1 |
| Euro OTC | Prednicarbate | 1707022-01 | 40 |
| Euro OTC | Prednicarbate | 1707022201 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Prednicarbate | 1801013 | 1 |
| Euro OTC | Prednicarbate | 180101301 | 1 |
| Euro OTC | Prednicarbate | 1801013-01 | 36 |
| Euro OTC | Prednicarbate | 1805001-01 | 2 |
| Euro OTC | Prednicarbate | 180500501 | 1 |
| Euro OTC | Prednicarbate | 1805005-01 | 27 |
| Euro OTC | Prednicarbate | 1805005-02 | 2 |
| Euro OTC | Prednicarbate | 1809015001 | 1 |
| Euro OTC | Prednicarbate | 180901501 | 2 |
| Euro OTC | Prednicarbate | 1809015-01 | 37 |
| Euro OTC | Prednicarbate | 1809015-02 | 2 |
| Euro OTC | Prednicarbate | 18194103 | 2 |
| Euro OTC | Prednicarbate | 18E14-B03-355726 | 1 |
| Euro OTC | Prednicarbate | 190023-01 | 1 |
| Euro OTC | Prednicarbate | 1902012-01 | 1 |
| Euro OTC | Prednicarbate | 1903023 | 2 |
| Euro OTC | Prednicarbate | 190302301 | 3 |
| Euro OTC | Prednicarbate | 1903023-01 | 81 |
| Euro OTC | Prednicarbate | 1903023-02 | 1 |
| Euro OTC | Prednicarbate | 19032023-01 | 1 |
| Euro OTC | Prednicarbate | 190741607 | 1 |
| Euro OTC | Prednicarbate | 20001031-01 | 1 |
| Euro OTC | Prednicarbate | 20009018-01 | 2 |
| Euro OTC | Prednicarbate | 200103101 | 6 |
| Euro OTC | Prednicarbate | 2001031-01 | 83 |
| Euro OTC | Prednicarbate | 20090018-01 | 1 |
| Euro OTC | Prednicarbate | 200901-01 | 1 |
| Euro OTC | Prednicarbate | 200901801 | 3 |
| Euro OTC | Prednicarbate | 2009018-01 | 149 |
| Euro OTC | Prednicarbate | 2009018-012x | 1 |
| Euro OTC | Prednicarbate | 2009018-02 | 22 |
| Euro OTC | Prednicarbate | 200918-01 | 2 |
| Euro OTC | Prednicarbate | 209018-01 | 1 |
| Euro OTC | Prednicarbate | 210301701 | 3 |
| Euro OTC | Prednicarbate | 2103017-01 | 75 |
| Euro OTC | Prednicarbate | 2103017-02 | 7 |
| Euro OTC | Prednicarbate | 210317-01 | 1 |
| Euro OTC | Prednicarbate | 2204014_01 | 1 |
| Euro OTC | Prednicarbate | 2204014-01 | 20 |
| Euro OTC | Prednicarbate | 220414-01 | 1 |
| Euro OTC | Prednicarbate | 23001026001 | 1 |
| Euro OTC | Prednicarbate | 2304020-01 | 1 |
| Euro OTC | Prednicarbate | 3103017-01 | 1 |
| Euro OTC | Prednicarbate | B01-2035804 | 1 |
| Euro OTC | Prednicarbate | B05-2016409 | 1 |
| Euro OTC | Prednicarbate | PNC101/0720 | 1 |
| Euro Pharma/Gehe | Prednicarbate | 1801013-01 | 1 |
| Euro/Gehe | Prednicarbate | 1609022-01 | 1 |
| Euro/Gehe | Prednicarbate | 1805005-01 | 1 |
| Euro/Phönix | Prednicarbate | 1607012-01 | 1 |
| Euro/Phönix | Prednicarbate | 1903023-01 | 1 |
| Euro/Phönix | Prednicarbate | 2204014-01 | 1 |
| Euro | Prednicarbate | 1507011-01 | 1 |
| EuRoh/ Gehe | Prednicarbate | 18E14-B03-355726 | 2 |
| Fagr | Prednicarbate | 18E14-B03-352560 | 2 |
| Fagro/Gehe | Prednicarbate | 15D15-B03-308161 | 1 |
| Fagro/Sanacorp | Prednicarbate | 19G09-B01-194724 | 1 |
| Fagron | Prednicarbate | | 1 |
| Fagron | Prednicarbate | 10J04-N10 | 1 |
| Fagron | Prednicarbate | 11L23-N07 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednicarbate | 12B20-N06 | 3 |
| Fagron | Prednicarbate | 12D27-N04 | 3 |
| Fagron | Prednicarbate | 12H20-N07 | 1 |
| Fagron | Prednicarbate | 13/23-N04 | 3 |
| Fagron | Prednicarbate | 13372408 | 1 |
| Fagron | Prednicarbate | 13C25-N02 | 1 |
| Fagron | Prednicarbate | 13C25-N06 | 7 |
| Fagron | Prednicarbate | 13c25-no6 | 1 |
| Fagron | Prednicarbate | 13F11-N01 | 4 |
| Fagron | Prednicarbate | 13F11-No1 | 1 |
| Fagron | Prednicarbate | 13F11-NO1 | 1 |
| Fagron | Prednicarbate | 13G05-N03 | 5 |
| Fagron | Prednicarbate | 13I23-N04 | 8 |
| Fagron | Prednicarbate | 13l23-N04 | 1 |
| Fagron | Prednicarbate | 14A27-B02 | 2 |
| Fagron | Prednicarbate | 14a27-b02-291256 | 2 |
| Fagron | Prednicarbate | 14A27-B02-291256 | 17 |
| Fagron | Prednicarbate | 14A27-B02-291258 | 2 |
| Fagron | Prednicarbate | 14A27-B02-295793 | 1 |
| Fagron | Prednicarbate | 14A27-B02-295796 | 6 |
| Fagron | Prednicarbate | 14A27-B02-295797 | 7 |
| Fagron | Prednicarbate | 14B13-B31-291255 | 1 |
| Fagron | Prednicarbate | 14J16B06 | 1 |
| Fagron | Prednicarbate | 14J16-B06_303465 | 1 |
| Fagron | Prednicarbate | 14J16-B06-303465 | 14 |
| Fagron | Prednicarbate | 14J16B06303466 | 1 |
| Fagron | Prednicarbate | 15/22-B04-316799 | 1 |
| Fagron | Prednicarbate | 15D15-B03-30816 | 1 |
| Fagron | Prednicarbate | 15D15-B03308161 | 1 |
| Fagron | Prednicarbate | 15D15-B03-308161 | 9 |
| Fagron | Prednicarbate | 15D15-B03-308162 | 1 |
| Fagron | Prednicarbate | 15D15-B03-309682 | 1 |
| Fagron | Prednicarbate | 15E14-B03-355726 | 1 |
| Fagron | Prednicarbate | 15G10-B02 | 1 |
| Fagron | Prednicarbate | 15g10-b02-310848 | 1 |
| Fagron | Prednicarbate | 15G10-B02-310848 | 9 |
| Fagron | Prednicarbate | 15G10-B02-311819 | 1 |
| Fagron | Prednicarbate | 15G10-B02-314082 | 6 |
| Fagron | Prednicarbate | 15J22-B04 | 1 |
| Fagron | Prednicarbate | 15J22-B04-316799 | 6 |
| Fagron | Prednicarbate | 15J22-B04-318528 | 3 |
| Fagron | Prednicarbate | 15J22-B04-318930 | 6 |
| Fagron | Prednicarbate | 15J22-B04-321005 | 1 |
| Fagron | Prednicarbate | 15J22-B04-316799 | 1 |
| Fagron | Prednicarbate | 15J-B04-316799 | 1 |
| Fagron | Prednicarbate | 16/27B01-332958 | 1 |
| Fagron | Prednicarbate | 16/27-B01-332958 | 2 |
| Fagron | Prednicarbate | 160314PC | 1 |
| Fagron | Prednicarbate | 160518P | 1 |
| Fagron | Prednicarbate | 16087410 | 1 |
| Fagron | Prednicarbate | 160902201 | 1 |
| Fagron | Prednicarbate | 1612-B01-325758 | 1 |
| Fagron | Prednicarbate | 16A18/B01 | 1 |
| Fagron | Prednicarbate | 16A18-B01-322732 | 7 |
| Fagron | Prednicarbate | 16A18-B01-322733 | 2 |
| Fagron | Prednicarbate | 16E12-B01 | 2 |
| Fagron | Prednicarbate | 16E12-B01-325758 | 6 |
| Fagron | Prednicarbate | 16E12-B01-327344 | 3 |
| Fagron | Prednicarbate | 16E12-B01-32827 | 1 |
| Fagron | Prednicarbate | 16E12-B01-328270 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednicarbate | 16E12-B01-330093 | 2 |
| Fagron | Prednicarbate | 16G09-B01-194722 | 2 |
| Fagron | Prednicarbate | 16J27-B01 | 2 |
| Fagron | Prednicarbate | 16j27b01330976 | 1 |
| Fagron | Prednicarbate | 16j27-b01-330976 | 1 |
| Fagron | Prednicarbate | 16J27-b01-330976 | 1 |
| Fagron | Prednicarbate | 16J27-B01-330976 | 13 |
| Fagron | Prednicarbate | 16J27-B01-330977 | 1 |
| Fagron | Prednicarbate | 16J27-B01-332958 | 11 |
| Fagron | Prednicarbate | 16J28-B01-330976 | 1 |
| Fagron | Prednicarbate | 17013804 | 1 |
| Fagron | Prednicarbate | 17104-805-343934 | 1 |
| Fagron | Prednicarbate | 174J04-B05-343935 | 1 |
| Fagron | Prednicarbate | 17C27-B01 | 1 |
| Fagron | Prednicarbate | 17C27-B01-335530 | 10 |
| Fagron | Prednicarbate | 17C27-B01-335531 | 1 |
| Fagron | Prednicarbate | 17c27-b01-339079 | 1 |
| Fagron | Prednicarbate | 17C27-B01-339079 | 8 |
| Fagron | Prednicarbate | 17J04-B05 | 4 |
| Fagron | Prednicarbate | 17J04-B05-326113 | 1 |
| Fagron | Prednicarbate | 17J04-B05-340570 | 2 |
| Fagron | Prednicarbate | 17J04-B05-341872 | 9 |
| Fagron | Prednicarbate | 17j04-b05-343934 | 1 |
| Fagron | Prednicarbate | 17J04-B05-343934 | 9 |
| Fagron | Prednicarbate | 17J04-B05-343935 | 1 |
| Fagron | Prednicarbate | 17J04b05-346113 | 1 |
| Fagron | Prednicarbate | 17J04-B05-346113 | 10 |
| Fagron | Prednicarbate | 17Jo4B05343934 | 1 |
| Fagron | Prednicarbate | 18194104 | 1 |
| Fagron | Prednicarbate | 18194105 | 1 |
| Fagron | Prednicarbate | 18194115 | 1 |
| Fagron | Prednicarbate | 18B17-B01-347486 | 1 |
| Fagron | Prednicarbate | 18B27-01-347486 | 1 |
| Fagron | Prednicarbate | 18B27-01-350264 | 1 |
| Fagron | Prednicarbate | 18B27-B01 | 2 |
| Fagron | Prednicarbate | 18B27-B01_347486 | 1 |
| Fagron | Prednicarbate | 18B27-B01-0001 | 1 |
| Fagron | Prednicarbate | 18B27-B01-346748 | 2 |
| Fagron | Prednicarbate | 18B27-B01-347486 | 15 |
| Fagron | Prednicarbate | 18B27-B01-350264 | 12 |
| Fagron | Prednicarbate | 18B27-B01-351177 | 3 |
| Fagron | Prednicarbate | 18E14-03-352631 | 1 |
| Fagron | Prednicarbate | 18E14-B03 | 5 |
| Fagron | Prednicarbate | 18E14B03-352560 | 1 |
| Fagron | Prednicarbate | 18E14-B03-352560 | 7 |
| Fagron | Prednicarbate | 18E14-B03-35260 | 1 |
| Fagron | Prednicarbate | 18E14-B03-352631 | 10 |
| Fagron | Prednicarbate | 18E14-B03-3555726 | 1 |
| Fagron | Prednicarbate | 18e14-b03-355726 | 1 |
| Fagron | Prednicarbate | 18E14-B03-355726 | 11 |
| Fagron | Prednicarbate | 18E-14-B03-355726 | 1 |
| Fagron | Prednicarbate | 18E14-B03-355727 | 3 |
| Fagron | Prednicarbate | 18J27-B01-332958 | 1 |
| Fagron | Prednicarbate | 194722 | 1 |
| Fagron | Prednicarbate | 19E14 | 1 |
| Fagron | Prednicarbate | 19E14-B01 | 1 |
| Fagron | Prednicarbate | 19E14-B01-191430 | 19 |
| Fagron | Prednicarbate | 19E14-B01-191431 | 3 |
| Fagron | Prednicarbate | 19G09-B01 | 4 |
| Fagron | Prednicarbate | 19G09-B01-194722 | 19 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednicarbate | 19G09-B01-194724 | 3 |
| Fagron | Prednicarbate | 19J16-B04-197550 | 1 |
| Fagron | Prednicarbate | 19J16-B07 | 6 |
| Fagron | Prednicarbate | 19J16B07197550 | 1 |
| Fagron | Prednicarbate | 19J16-B07197550 | 1 |
| Fagron | Prednicarbate | 19J16-B07-197550 | 15 |
| Fagron | Prednicarbate | 19J16-B07-197552 | 3 |
| Fagron | Prednicarbate | 19J16-B07-197555 | 1 |
| Fagron | Prednicarbate | 19J16-B07-20137002 | 1 |
| Fagron | Prednicarbate | 19J16-B07-201371 | 1 |
| Fagron | Prednicarbate | 19J16-B07-201372 | 15 |
| Fagron | Prednicarbate | 19J16-B07-197550 | 1 |
| Fagron | Prednicarbate | 19J16-B07-197552 | 1 |
| Fagron | Prednicarbate | 19J16-B07-201372 | 1 |
| Fagron | Prednicarbate | 19J19-B07-197550 | 1 |
| Fagron | Prednicarbate | 20/18-B05-201649 | 1 |
| Fagron | Prednicarbate | 20003660007 | 1 |
| Fagron | Prednicarbate | 2001031-01 | 1 |
| Fagron | Prednicarbate | 20A21-B12 | 8 |
| Fagron | Prednicarbate | 20A21-B12-196767 | 1 |
| Fagron | Prednicarbate | 20A21-B12-1975501 | 2 |
| Fagron | Prednicarbate | 20A21-B12-197551 | 9 |
| Fagron | Prednicarbate | 20A21-B12-197553 | 3 |
| Fagron | Prednicarbate | 20A21-B12-197556 | 1 |
| Fagron | Prednicarbate | 20G23-B06 | 1 |
| Fagron | Prednicarbate | 20G23-B06-200074 | 1 |
| Fagron | Prednicarbate | 20g23-b06-200202 | 1 |
| Fagron | Prednicarbate | 20G23-B06-200202 | 3 |
| Fagron | Prednicarbate | 20I18-B05 | 3 |
| Fagron | Prednicarbate | 20I18-B05-2016409 | 1 |
| Fagron | Prednicarbate | 20I18-B05-201649 | 10 |
| Fagron | Prednicarbate | 20I8-B05-201649 | 1 |
| Fagron | Prednicarbate | 21a11-801-203584 | 1 |
| Fagron | Prednicarbate | 21A11-B01 | 6 |
| Fagron | Prednicarbate | 21A11-B01-201650 | 11 |
| Fagron | Prednicarbate | 21A11-B01-201651 | 1 |
| Fagron | Prednicarbate | 21A11-B01-2035804 | 2 |
| Fagron | Prednicarbate | 21A11B01203584 | 1 |
| Fagron | Prednicarbate | 21A11-B01-203584 | 31 |
| Fagron | Prednicarbate | 21A11-BO1-203584 | 1 |
| Fagron | Prednicarbate | 21F07-B17 | 3 |
| Fagron | Prednicarbate | 21F07-B17-216553 | 46 |
| Fagron | Prednicarbate | 21-F07-B17-216553 | 1 |
| Fagron | Prednicarbate | 21F07-B17-216554 | 5 |
| Fagron | Prednicarbate | 21FO7-0001 | 1 |
| Fagron | Prednicarbate | 21FO7-B17-216553 | 1 |
| Fagron | Prednicarbate | 21K24-B03-213700 | 2 |
| Fagron | Prednicarbate | 21K24-Bo3-213700 | 1 |
| Fagron | Prednicarbate | 22F03-B02-223102 | 2 |
| Fagron | Prednicarbate | 22F03-B02-227918 | 3 |
| Fagron | Prednicarbate | 22F03-B02-227919 | 1 |
| Fagron | Prednicarbate | 2762 | 1 |
| Fagron | Prednicarbate | 29091807 | 1 |
| Fagron | Prednicarbate | 2OG23-B06-200074 | 1 |
| Fagron | Prednicarbate | 3251 | 1 |
| Fagron | Prednicarbate | 4111706 | 1 |
| Fagron | Prednicarbate | 701867 | 1 |
| Fagron | Prednicarbate | 701867-0001 | 2 |
| Fagron | Prednicarbate | 7061303 | 1 |
| Fagron | Prednicarbate | 8081403 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednicarbate | 9E04-N02 | 1 |
| Fagron | Prednicarbate | 9G14-N06 | 1 |
| Fagron | Prednicarbate | B01-2016500 | 1 |
| Fagron | Prednicarbate | b01-2035804 | 1 |
| Fagron | Prednicarbate | B01-2035804 | 9 |
| Fagron | Prednicarbate | B01-203584 | 1 |
| Fagron | Prednicarbate | B03-3557206 | 1 |
| Fagron | Prednicarbate | B05-2016409 | 5 |
| Fagron | Prednicarbate | B06-2002002 | 1 |
| Fagron | Prednicarbate | B07-2013702 | 1 |
| Fagron | Prednicarbate | B12-1975501 | 5 |
| Fagron | Prednicarbate | BO1-2035804 | 1 |
| Fagron | Prednicarbate | htzthh | 1 |
| Fagron | Prednicarbate | na1668m | 1 |
| Fagron | Prednicarbate | NA2374M | 2 |
| Fagron | Prednicarbate | NT0555M13I23-N04 | 1 |
| Fagron | Prednicarbate | NT0780M | 2 |
| Fagron | Prednicarbate | NU0823M | 1 |
| Fagron | Prednicarbate | NUO823M | 1 |
| Fagron | Prednicarbate | NV2209M | 1 |
| Fagron | Prednicarbate | NW0396M | 1 |
| Fagron | Prednicarbate | NX1422M | 3 |
| Fagron | Prednicarbate | NX1925M | 3 |
| Fagron | Prednicarbate | NX2297M | 6 |
| Fagron | Prednicarbate | NZ1045M | 5 |
| Fagron | Prednicarbate | PNC102/1020 | 6 |
| Fargon / AHD | Prednicarbate | 21A11-BO1-203584 | 1 |
| Fargon/Phoenix 05.06.18 | Prednicarbate | 17J04-B05-343934 | 1 |
| Fargon/Phönix | Prednicarbate | 19J16-B07 | 1 |
| Fargon | Prednicarbate | 15J22-B04-318930 | 1 |
| Fargon | Prednicarbate | 16E12-B01_325758 | 1 |
| Fargon | Prednicarbate | 19G09-B01 | 1 |
| Fargon | Prednicarbate | 21A11-B01-203584 | 2 |
| Farmabios S.p.A. | Prednicarbate | 20003660009 | 1 |
| Farmabios S.p.A/AHD | Prednicarbate | 20000609006 | 1 |
| Fiebig Palapharm | Prednicarbate | 20000609004 | 1 |
| Fiebig | Prednicarbate | 17013804 | 1 |
| Fiebig | Prednicarbate | 17220408 | 1 |
| Fiebig | Prednicarbate | 18194105 | 1 |
| Fiebig | Prednicarbate | 20003660009 | 1 |
| Fischar GmbH & Co.KG | Prednicarbate | 21F07-B17-216553 | 1 |
| Fischar/ Noweda | Prednicarbate | 21F07-B17-216553 | 1 |
| Fragon/Sanacorp | Prednicarbate | NZ1845M | 1 |
| Fragron | Prednicarbate | NV0485M | 1 |
| Gehe amax | Prednicarbate | 1507011-01 | 1 |
| Gehe amax | Prednicarbate | 15G10-B02-314082 | 1 |
| Gehe amax | Prednicarbate | 15J22-B04-316799 | 1 |
| Gehe amax | Prednicarbate | 1607012-01 | 1 |
| Gehe amax | Prednicarbate | 16J27-B01-330976 | 1 |
| Gehe amax | Prednicarbate | 18B27-B01-350264 | 1 |
| Gehe amax | Prednicarbate | 20003660005 | 1 |
| Gehe Rostock | Prednicarbate | 19J16-B07-197550 | 1 |
| Gehe Rostock | Prednicarbate | 19J16-B07-201372 | 1 |
| Gehe | Prednicarbate | 12B14-N02 | 1 |
| Gehe | Prednicarbate | 13372403 | 2 |
| Gehe | Prednicarbate | 13G05-n03 | 1 |
| Gehe | Prednicarbate | 13123-N04 | 1 |
| Gehe | Prednicarbate | 15446302 | 1 |
| Gehe | Prednicarbate | 15J22-B04-318930 | 1 |
| Gehe | Prednicarbate | 15J22-B04-321005 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Prednicarbate | 1601058-01 | 1 |
| Gehe | Prednicarbate | 1605001-01 | 2 |
| Gehe | Prednicarbate | 1707022-01 | 5 |
| GEHE | Prednicarbate | 17315607 | 2 |
| Gehe | Prednicarbate | 1801013-01 | 5 |
| Gehe | Prednicarbate | 1805005-01 | 1 |
| Gehe | Prednicarbate | 1809015-01 | 4 |
| GEHE | Prednicarbate | 18194103 | 4 |
| Gehe | Prednicarbate | 18194105 | 1 |
| GEHE | Prednicarbate | 18194116 | 1 |
| Gehe | Prednicarbate | 18E14-B03 | 1 |
| Gehe | Prednicarbate | 1903023-01 | 3 |
| Gehe | Prednicarbate | 19032301 | 1 |
| Gehe | Prednicarbate | 19051601 | 1 |
| Gehe | Prednicarbate | 19122604 | 2 |
| Gehe | Prednicarbate | 19G09-B01 | 1 |
| Gehe | Prednicarbate | 19J16-B07 | 1 |
| Gehe | Prednicarbate | 20003660004 | 1 |
| Gehe | Prednicarbate | 2009018-01 | 2 |
| Gehe | Prednicarbate | 20G23-B06 | 2 |
| Gehe | Prednicarbate | 21000991005 | 3 |
| Gehe | Prednicarbate | 21001161001 | 2 |
| Gehe | Prednicarbate | 21001161011 | 1 |
| Gehe | Prednicarbate | 21A11-B01 | 3 |
| Gehe | Prednicarbate | 21A11B01203584 | 1 |
| Gehe | Prednicarbate | 21F07-B17 | 1 |
| Gehe | Prednicarbate | 21F07-B17-216553 | 5 |
| Gehe | Prednicarbate | 22000755002 | 2 |
| Gehe | Prednicarbate | 22000755007 | 1 |
| Gehe | Prednicarbate | 2204014-01 | 3 |
| Gehe | Prednicarbate | 22F03-B02-218938 | 1 |
| Gehe | Prednicarbate | 22F03-B02-223102 | 1 |
| Gehe | Prednicarbate | 22F03-B02-227918 | 2 |
| Gehe | Prednicarbate | 22F03-B02-232393 | 1 |
| Gehe | Prednicarbate | 23001026001 | 5 |
| Gehe | Prednicarbate | 23001026002 | 2 |
| Gehe | Prednicarbate | 23003318001 | 1 |
| Gehe | Prednicarbate | 2304020-01 | 4 |
| Gehe | Prednicarbate | 20G23-B06-200202 | 1 |
| GEHE | Prednicarbate | 7529666 | 1 |
| Gehe | Prednicarbate | B01-2016500 | 1 |
| Gehe | Prednicarbate | C0333/1170101 | 1 |
| Gehr | Prednicarbate | 23001026001 | 1 |
| Hedinger/ Sanacorp | Prednicarbate | 15181403 | 1 |
| Henry Lamotte | Prednicarbate | 15D15-B03-308161 | 1 |
| Hepart | Prednicarbate | 17C27-B01-335530 | 1 |
| JENNE | Prednicarbate | 17220406 | 2 |
| JENNE | Prednicarbate | 17315603 | 1 |
| Jenne | Prednicarbate | 17J04-B05-346113 | 1 |
| Jenne | Prednicarbate | 18194105 | 1 |
| Jenne | Prednicarbate | 18194115 | 2 |
| Jenne | Prednicarbate | 1903023-01 | 1 |
| Jenne | Prednicarbate | 19J16-B07-197552 | 1 |
| JENNE | Prednicarbate | 22000755009 | 1 |
| Jenne | Prednicarbate | 22F03-B02-227919 | 1 |
| jenne | Prednicarbate | 23001025003 | 1 |
| Jenne | Prednicarbate | 23001026001 | 2 |
| Jenne | Prednicarbate | 230627(22000755009) | 1 |
| Jenne | Prednicarbate | 240703(23003318002) | 1 |
| Jenne | Prednicarbate | P2019/91 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Kehr Holdermann | Prednicarbate | 23001026003 | 1 |
| Kehr/Fargon | Prednicarbate | 17J04-B05-346113 | 1 |
| Kehr/Fargon | Prednicarbate | 18B27-B01-350264 | 2 |
| Kehr | Prednicarbate | 16J27-B01-330976 | 1 |
| Kehr | Prednicarbate | 22000755006 | 1 |
| Kehr | Prednicarbate | 22000755010 | 3 |
| Kehr | Prednicarbate | 23001026001 | 1 |
| Kehr | Prednicarbate | 23001026002 | 1 |
| Kehr | Prednicarbate | 23003318006 | 1 |
| Kehr-Holdermann | Prednicarbate | 23001026001 | 1 |
| Klenk | Prednicarbate | 17014003 | 1 |
| Krieger | Prednicarbate | 2009018-01 | 1 |
| Kriegeram 29.06.2018 | Prednicarbate | 17315605 | 1 |
| L10 | Prednicarbate | 2304020-01 | 2 |
| Newchem / Gehe | Prednicarbate | 18E14-B03-355726 | 1 |
| Newchem / Gehe | Prednicarbate | 19E14-B01-191430 | 1 |
| Newchem / Gehe | Prednicarbate | B07-2013702 | 1 |
| Newchem spa/Noweda | Prednicarbate | 14A27-B02-291256 | 1 |
| Newchem Spa/Sanacorp | Prednicarbate | 16E12-B01 | 1 |
| Newchem/ AHD | Prednicarbate | 19122602 | 1 |
| Newchem/Phoenix | Prednicarbate | 20I18-B05 | 1 |
| NEWCHEM | Prednicarbate | 19E14-B01-191430 | 2 |
| Noveda | Prednicarbate | 21A11-B01-203584 | 1 |
| Noveda | Prednicarbate | 22F03-B02-227918 | 1 |
| Noweda 17.11.17 | Prednicarbate | 17220407 | 1 |
| Noweda Taucha | Prednicarbate | 21001161010 | 1 |
| Noweda | Prednicarbate | 1161010 | 1 |
| Noweda | Prednicarbate | 15446301 | 1 |
| Noweda | Prednicarbate | 161001 | 1 |
| Noweda | Prednicarbate | 17013804 | 2 |
| Noweda | Prednicarbate | 17315604 | 1 |
| Noweda | Prednicarbate | 17315605 | 1 |
| Noweda | Prednicarbate | 17315609 | 1 |
| Noweda | Prednicarbate | 17J04-B05-346113 | 1 |
| Noweda | Prednicarbate | 1801013-01 | 1 |
| Noweda | Prednicarbate | 1805005-01 | 1 |
| Noweda | Prednicarbate | 19051602 | 2 |
| Noweda | Prednicarbate | 19122608 | 1 |
| Noweda | Prednicarbate | 20000366007 | 1 |
| Noweda | Prednicarbate | 20003660007 | 1 |
| Noweda | Prednicarbate | 21001161001 | 1 |
| Noweda | Prednicarbate | 2103017-01 | 4 |
| Noweda | Prednicarbate | 211867001 | 1 |
| Noweda | Prednicarbate | 21a11b01203584no | 1 |
| Noweda | Prednicarbate | 21F07b17 | 1 |
| Noweda | Prednicarbate | 21F07-B17-216553 | 2 |
| Noweda | Prednicarbate | 21K24-B03-2136699 | 1 |
| Noweda | Prednicarbate | 21K24-B03-213699 | 4 |
| Noweda | Prednicarbate | 22000755001 | 1 |
| Noweda | Prednicarbate | 2200755007 | 1 |
| noweda | Prednicarbate | 2204014-01 | 2 |
| Noweda | Prednicarbate | 2204014-01 | 2 |
| Noweda | Prednicarbate | 22F03-B02-223102 | 2 |
| noweda | Prednicarbate | 22F03-B02-227918 | 1 |
| Noweda | Prednicarbate | 22F03-B02-227918 | 3 |
| Noweda | Prednicarbate | 22F03-B02-227919 | 2 |
| Noweda | Prednicarbate | 22F03-B02-232393 | 1 |
| Noweda | Prednicarbate | 23001025003 | 2 |
| Noweda | Prednicarbate | 23001026001 | 7 |
| Noweda | Prednicarbate | 23001026002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Prednicarbate | 23003318001 | 2 |
| Noweda | Prednicarbate | 23003318006 | 4 |
| Noweda | Prednicarbate | 2304020-01 | 5 |
| noweda | Prednicarbate | 231001026003 | 1 |
| noweda | Prednicarbate | 240501901 | 1 |
| noweda | Prednicarbate | 2405019-01 | 5 |
| Noweda | Prednicarbate | 2405019-01 | 4 |
| Nowedy | Prednicarbate | 23001025003 | 1 |
| Nowerda | Prednicarbate | 17J04-B05-343934 | 1 |
| Nowerda | Prednicarbate | 18B27-B01-347486 | 1 |
| Nowerda | Prednicarbate | 18E14-B03-352560 | 1 |
| Pharma S.A.U/Phönix | Prednicarbate | 1607012-01 | 2 |
| Phoenix 7.02.2020 | Prednicarbate | 1903023-01 | 1 |
| phoenix | Prednicarbate | 1323N04 | 1 |
| Phoenix | Prednicarbate | 16J27-b01-332958 | 1 |
| Phoenix | Prednicarbate | 17315604 | 1 |
| Phoenix | Prednicarbate | 17315605 | 1 |
| Phoenix | Prednicarbate | 17C27-B01-335530 | 1 |
| Phoenix | Prednicarbate | 1903023-02 | 1 |
| Phoenix | Prednicarbate | 19122602 | 1 |
| Phoenix | Prednicarbate | 20000609009 | 2 |
| Phoenix | Prednicarbate | 20003660007 | 1 |
| Phoenix | Prednicarbate | 22000755010 | 2 |
| Phoenix | Prednicarbate | 23001025003 | 1 |
| Phoenix | Prednicarbate | 23001026002 | 4 |
| Phoenix | Prednicarbate | 23003318001 | 4 |
| Phoenix | Prednicarbate | 23003318006 | 2 |
| phoenix | Prednicarbate | 2304020-01 | 1 |
| Phoenix | Prednicarbate | 2304020-01 | 4 |
| Phoenix | Prednicarbate | 2411003-01 | 1 |
| Phoenix | Prednicarbate | 3070 | 1 |
| Phoenix | Prednicarbate | 3089 | 1 |
| Phoenix | Prednicarbate | 3097 | 1 |
| Phoenix | Prednicarbate | 3106 | 1 |
| Phoenix | Prednicarbate | 3119 | 1 |
| Phoenix | Prednicarbate | 3208 | 1 |
| Phoenix | Prednicarbate | 3239 | 1 |
| Phoenix | Prednicarbate | 3363 | 1 |
| Phoenix | Prednicarbate | 3408 | 1 |
| Phoenix | Prednicarbate | B05-2016409 | 1 |
| Phönix Gotha | Prednicarbate | 17220408 | 1 |
| Phönix/Euro | Prednicarbate | 1809015-01 | 2 |
| Phönix | Prednicarbate | 15J22-B04-318528 | 1 |
| Phönix | Prednicarbate | 16J27-B01-330976 | 1 |
| Phönix | Prednicarbate | 1707022-01 | 1 |
| Phönix | Prednicarbate | 18194104 | 2 |
| PHÖNIX | Prednicarbate | 18194105 | 1 |
| Phönix | Prednicarbate | 1903023-01 | 1 |
| PHÖNIX | Prednicarbate | 1903023-01 | 1 |
| Phönix | Prednicarbate | 20003660005 | 2 |
| Phönix | Prednicarbate | 20003660007 | 2 |
| Phönix | Prednicarbate | 2001031-01 | 4 |
| Phönix | Prednicarbate | 2009018-01 | 1 |
| Phönix | Prednicarbate | 20D07-F01370645 | 1 |
| PHÖNIX | Prednicarbate | 21001161001 | 1 |
| Phönix | Prednicarbate | 210301701 | 1 |
| Phönix | Prednicarbate | 2103017-01 | 2 |
| phönix | Prednicarbate | 21F07-B17-216553 | 1 |
| Phönix | Prednicarbate | 2200075500 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Prednicarbate | 22000755002 | 1 |
| Phönix | Prednicarbate | 2204014-01 | 1 |
| Phönix | Prednicarbate | 22F03-B02 | 1 |
| phönix | Prednicarbate | 22F03-B02-223102 | 1 |
| Phönix | Prednicarbate | 22F03-B02-223102 | 1 |
| Phönix | Prednicarbate | 22F03-B02-227918 | 1 |
| Phönix | Prednicarbate | 23001025003 | 1 |
| phönix | Prednicarbate | 23001026001 | 1 |
| Phönix | Prednicarbate | 23001026001 | 2 |
| Phönix | Prednicarbate | 23001026002 | 7 |
| Phönix | Prednicarbate | 23003318001 | 3 |
| Phönix | Prednicarbate | 23003318002 | 2 |
| Phönix | Prednicarbate | 23003318006 | 1 |
| Phönix | Prednicarbate | 24E16-B03-000868 | 1 |
| Phönix | Prednicarbate | 3134 | 1 |
| Phönix | Prednicarbate | 3154 | 1 |
| Phönix | Prednicarbate | 3185 | 1 |
| Sanacop | Prednicarbate | | 3 |
| Sanacorp, 01.03.17, ... | Prednicarbate | 1687410 | 1 |
| Sanacorp | Prednicarbate | 11L23-N07 | 1 |
| Sanacorp | Prednicarbate | 17013804 | 1 |
| Sanacorp | Prednicarbate | 1707022-01 | 1 |
| Sanacorp | Prednicarbate | 17315604 | 2 |
| Sanacorp | Prednicarbate | 17315605 | 1 |
| Sanacorp | Prednicarbate | 18194105 | 1 |
| Sanacorp | Prednicarbate | 18194115 | 1 |
| Sanacorp | Prednicarbate | 1903023 | 1 |
| sanacorp | Prednicarbate | 1903023-01 | 1 |
| Sanacorp | Prednicarbate | 20000609009 | 1 |
| Sanacorp | Prednicarbate | 20A-21-B12-197551 | 1 |
| Sanacorp | Prednicarbate | 20A21-B12-197553 | 1 |
| Sanacorp | Prednicarbate | 21A11-B01-203584 | 1 |
| Sanacorp | Prednicarbate | 22000755009 | 3 |
| Sanacorp | Prednicarbate | 2204014-01 | 1 |
| Sanacorp | Prednicarbate | 22F03-B02-223103 | 1 |
| Sanacorp | Prednicarbate | 23001025003 | 1 |
| Sanacorp | Prednicarbate | 23001026001 | 4 |
| Sanacorp | Prednicarbate | 23001026002 | 1 |
| Sanacorp | Prednicarbate | 23003318001 | 2 |
| Sanacorp | Prednicarbate | B05-2016409 | 1 |
| Sanascorp | Prednicarbate | 23001026002 | 1 |
| Sino Phyto | Prednicarbate | 13224401 | 1 |
| Sonnenberg-Apotheke | Prednicarbate | 1607012-01 | 1 |
| Symbiotica | Prednicarbate | 2103017-01 | 1 |
| Symbiotika | Prednicarbate | 2009018-01 | 1 |

- 252 346 spectra from 1666 *Apo-Ident* customers from a total of 51 590 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Prednicarbate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prednicarbate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following


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table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 964 | 0 | 157 362 |
| **Type B** | 0 | 1297 | 0 | 211 643 |
| **Type C** | 0 | 4522 | 18 | 252 346 |

The substance/substance group *Prednicarbate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.3776 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.5374 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6035 % (> 99.5374 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20700 | 21572 | 29.86 | 206.62 |
| 20832 | 20832 | 0.00 | 186.48 |
| 20833 | 20832 | 2.37 | 185.61 |
| 21368 | 21368 | 0.00 | 154.03 |
| 21369 | 21368 | 2.82 | 154.44 |
| 21572 | 21572 | 0.00 | 203.87 |
| 21610 | 21610 | 0.00 | 164.22 |
| 21858 | 21858 | 0.00 | 193.24 |
| 22366 | 22366 | 0.00 | 146.82 |
| 25119 | 25119 | 0.00 | 215.17 |
| 25401 | 25401 | 0.00 | 212.70 |
| 25609 | 25609 | 0.00 | 212.68 |
| 26084 | 26084 | 0.00 | 207.74 |
| 26393 | 26084 | 23.81 | 203.95 |
| 27277 | 27277 | 0.00 | 213.84 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical

variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prednisolon dihydrogen phosphate dinatrium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20212-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prednisolon dihydrogen phosphate dinatrium; Prednisoloni natrii phosphas

### Special notes

When selecting the *Prednisolon dihydrogen phosphate dinatrium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prednisolon dihydrogen phosphate dinatrium | 9 | 4 | 124 |

### Second-stage model

For differentiation of the substance/substance group *Prednisolon dihydrogen phosphate dinatrium* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prednisolon dihydrogen phosphate dinatrium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 67.17 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prednisolon dihydrogen phosphate dinatrium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prednisolon dihydrogen phosphate dinatrium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Prednisolon dihydrogen ph… | 13304703 | 20923 | 40 | 20130904 |
| Caelo | Prednisolon dihydrogen ph… | 13304704 | 21412 | 60 | 1411052 |
| Caelo | Prednisolon dihydrogen ph… | 16174715 | 23271 | 40 | 20160930 |
| Caelo | Prednisolon dihydrogen ph… | 20002455003 | 25393 | 40 | 20200824 |
| Caelo | Prednisolon dihydrogen ph… | 20002455003 | 25393SI | 40 | 20200824 |
| Fagron | Prednisolon dihydrogen ph… | 14E07-B06-295251 | 21571 | 60 | 20140623 |
| Fagron | Prednisolon dihydrogen ph… | 18D23-B08-351348 | 24293 | 40 | 1812421 |
| Fagron | Prednisolon dihydrogen ph… | 18K27-B04-363613 | 25375 | 40 | 20190828 |
| Fagron | Prednisolon dihydrogen ph… | 21E25-F03-378586 | 25912 | 40 | 2204384 |
| Fagron | Prednisolon dihydrogen ph… | 21E25-F03-378586 | 25912SI | 30 | 2204384 |
| Fagron | Prednisolon dihydrogen ph… | 24A29-B02-233778 | 27175 | 40 | 20240219 |
| Fagron | Prednisolon dihydrogen ph… | 24A29-B02-233778 | 27175SI | 40 | 20240219 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.


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- 510 spectra of 12 reference samples from the substance/substance group *Prednisolon dihydrogen phosphate dinatrium*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 816 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 280 spectra of 7 reference samples from the substance/substance group *Prednisolon dihydrogen phosphate dinatrium*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Prednisolon dihydrogen ph… | 181940 | 24905 | 40 |
| Caelo | Prednisolon dihydrogen ph… | 21003179007 | 25987 | 40 |
| Caelo | Prednisolon dihydrogen ph… | 24001427004 | 27652 | 40 |
| Fagron | Prednisolon dihydrogen ph… | 16I14-B03-328918 | 23270 | 40 |
| Caelo | Prednisolon dihydrogen ph… | 21003179007 | 25987SI | 40 |
| Caelo | Prednisolon dihydrogen ph… | 24001427004 | 27652SI | 40 |
| Fagron | Prednisolon dihydrogen ph… | 18K27-B04-363613 | 25375SI† | 40 |

- 212 660 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 334 spectra from 135 *Apo-Ident* customers from 132 batches from the substance/substance group *Prednisolon dihydrogen phosphate dinatrium*.

- Among them are spectra of independent samples from 124 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednisolon dihydrogen ph… | 21E25-F03-378592 | 5 |
| | Prednisolon dihydrogen ph… | 21K16-B16-226142 | 4 |
| | Prednisolon dihydrogen ph… | 22002348005 | 1 |
| | Prednisolon dihydrogen ph… | 23001195002 | 2 |
| | Prednisolon dihydrogen ph… | 23001195003 | 5 |
| | Prednisolon dihydrogen ph… | 23001195004 | 1 |
| | Prednisolon dihydrogen ph… | 23001195006 | 1 |
| | Prednisolon dihydrogen ph… | 23003063002 | 1 |
| | Prednisolon dihydrogen ph… | 23003063003 | 3 |
| | Prednisolon dihydrogen ph… | 23003063004 | 4 |
| | Prednisolon dihydrogen ph… | 24001427003 | 5 |
| | Prednisolon dihydrogen ph… | 24001427005 | 7 |
| | Prednisolon dihydrogen ph… | 24A29-B02-233778 | 2 |
| | Prednisolon dihydrogen ph… | 24C11-B02-238772 | 1 |
| | Prednisolon dihydrogen ph… | 24c11-bo2-bo2-238772 | 1 |
| | Prednisolon dihydrogen ph… | 24F12-B03-004703 | 1 |
| Alte Apotheke | Prednisolon dihydrogen ph… | 15K27B09-318738 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 14196602 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 14E07-B06-295251 | 3 |
| Caelo | Prednisolon dihydrogen ph… | 15199602 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 15199603 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 16174701 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 16174702 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 16174706 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 16174710 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 17077502 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 17077503 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 17077508 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 18024602 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 18024604 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 18194001 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 18194002 | 6 |
| Caelo | Prednisolon dihydrogen ph… | 18194003 | 3 |
| Caelo | Prednisolon dihydrogen ph… | 18194006 | 9 |
| Caelo | Prednisolon dihydrogen ph… | 18194007 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 18194010 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 18194011 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 19129302 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 19129304 | 9 |
| Caelo | Prednisolon dihydrogen ph… | 19129306 | 4 |
| Caelo | Prednisolon dihydrogen ph… | 192754002 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 19275402 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 19275403 | 3 |
| Caelo | Prednisolon dihydrogen ph… | 20001707001 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 20001707002 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 20001707003 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 20001707008 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 20002455002 | 3 |
| Caelo | Prednisolon dihydrogen ph… | 20002455003 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 20003761001 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 20003761002 | 4 |
| Caelo | Prednisolon dihydrogen ph… | 20003761003 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 2001707001 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 21000431001 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 21000431002 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 21000431003 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 21000431006 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 21001330002 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 21001330003 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 2100317009 | 1 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolon dihydrogen ph… | 21003179002 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 21003179003 | 2 |
| Caelo | Prednisolon dihydrogen ph… | 21003179004 | 4 |
| Caelo | Prednisolon dihydrogen ph… | 21003179007 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 21003179008 | 4 |
| Caelo | Prednisolon dihydrogen ph… | 21003179009 | 5 |
| Caelo | Prednisolon dihydrogen ph… | 22000048001 | 4 |
| Caelo | Prednisolon dihydrogen ph… | 22000048005 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 2200048002 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 2200048003 | 1 |
| Caelo | Prednisolon dihydrogen ph… | 23001195001 | 1 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 19129302 | 1 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 19275402 | 1 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 19129306 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednisolon dihydrogen ph… | 22000048003 | 1 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 21000431001 | 2 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 21003179004 | 1 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 21003179009 | 1 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 21000431001 | 2 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 21003179004 | 1 |
| Caesar & Loretz GmbH… | Prednisolon dihydrogen ph… | 22000048003 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 18194006 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 19129302 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 19129304 | 4 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 19275402 | 2 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 19275403 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 20001707002 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 20002455002 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 20003761002 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 21000431001 | 2 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 21000431002 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 21000431006 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 21003179003 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 21003179007 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 21003179008 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 22000048002 | 1 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 22000048003 | 2 |
| Caesar & Loretz GmbH | Prednisolon dihydrogen ph… | 23001195003 | 1 |
| Caesar & Loretz/Gehe… | Prednisolon dihydrogen ph… | 20001707001 | 1 |
| Caesar & Loretz/Gehe | Prednisolon dihydrogen ph… | 18194001 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 11C18-N11 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 11K11-N11 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 12H30-N08 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 13/27-N01 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 13A10-N04 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 13C26N06 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 13H19N04 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 13I27-N01 | 4 |
| Fagron | Prednisolon dihydrogen ph… | 14E07-B06-295251 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 14E07-B06-295253 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 14G30-B09 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 14G30-B09-303012 | 7 |
| Fagron | Prednisolon dihydrogen ph… | 14g30-b09-303014 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 14G30-B09-303014 | 4 |
| Fagron | Prednisolon dihydrogen ph… | 15f29-b11-309694 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 15F29-B11-309694 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 15J01-B02 | 4 |
| Fagron | Prednisolon dihydrogen ph… | 15J01-B02-312722 | 5 |
| Fagron | Prednisolon dihydrogen ph… | 15J01-B02-313610 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 15J01-B02-317180 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednisolon dihydrogen ph… | 15K27-B09 | 4 |
| Fagron | Prednisolon dihydrogen ph… | 15k27-b09-318738 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 15K27-B09-318738 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 15K27-B09-322162 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 15K27-B09-322163 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 15K27B09-326263 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 15K27-B09-326263 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 16/14-B03-328169 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 16I14-B03 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 16I14-B03-328169 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 16I14-B03-328918 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 17/27-b03-342560 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17/27-B03-345405 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17B08-B05 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17B08B05337466 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17B08-B05-337466 | 4 |
| Fagron | Prednisolon dihydrogen ph… | 17B08-B05-340336 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 17I12-B03-354549 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17I27-B03 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 17I27-B03-342560 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17I27-B03-344246 | 3 |
| Fagron | Prednisolon dihydrogen ph… | 17I27-B03-345405 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17I27-B03-348462 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 17I27-B03-354549 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 18B02-B04-352053 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 18D23-B08-350207 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 18D23-B08-351348 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 18D23-B08-352211 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 18K27-B04 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 18K27-B04-363611 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 18K27-B04-363613 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 19118D23-B08-350207 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 21E25-F03-378585 | 2 |
| Fagron | Prednisolon dihydrogen ph… | 21E25-F03-378591 | 1 |
| Fagron | Prednisolon dihydrogen ph… | 21K16-B16-226142 | 1 |
| Fagron | Prednisolon dihydrogen ph… | NU1356 | 1 |
| Fagron | Prednisolon dihydrogen ph… | PSP002/0816 | 2 |
| Fagron | Prednisolon dihydrogen ph… | PSP004/0117 | 1 |
| Gehe | Prednisolon dihydrogen ph… | 22002348005 | 1 |
| Gehe | Prednisolon dihydrogen ph… | 23003063004 | 1 |
| L10 | Prednisolon dihydrogen ph… | 24001427005 | 1 |
| Newchem spa | Prednisolon dihydrogen ph… | 15J01-B02-313610 | 2 |
| Noweda | Prednisolon dihydrogen ph… | 22002348005 | 1 |
| Noweda | Prednisolon dihydrogen ph… | 23001195002 | 1 |
| Noweda | Prednisolon dihydrogen ph… | 23001195003 | 2 |
| Phoenix | Prednisolon dihydrogen ph… | 192754004 | 1 |
| Sanacorp | Prednisolon dihydrogen ph… | 19129304 | 1 |
| Sanacorp | Prednisolon dihydrogen ph… | 21000431002 | 1 |
| Sidonia | Prednisolon dihydrogen ph… | 17I27-B03-342560 | 1 |
| Sidonia | Prednisolon dihydrogen ph… | 17I27-B03-344246 | 1 |
| Sidonia | Prednisolon dihydrogen ph… | 17I27-B03-345405 | 6 |
| Symbiotica / Noweda | Prednisolon dihydrogen ph… | 18K27-B04-3636101 | 1 |
| Symbiotica / Noweda | Prednisolon dihydrogen ph… | B04-3636101 | 1 |

- 256 552 spectra from 1666 *Apo-Ident* customers from a total of 52 022 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Prednisolon dihydrogen phosphate dinatrium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prednisolon dihydrogen phosphate dinatrium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 510 | 0 | 157 816 |
| **Type B** | 0 | 280 | 0 | 212 660 |
| **Type C** | 0 | 330 | 4 | 256 552 |

The substance/substance group *Prednisolon dihydrogen phosphate dinatrium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8235 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.8571 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8024 % (> 97.9042 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20923 | 21412 | 17.01 | 153.31 |
| 21412 | 21412 | 0.00 | 146.82 |
| 21571 | 21412 | 21.20 | 143.27 |
| 23271 | 21412 | 15.11 | 159.95 |
| 24293 | 24293 | 0.00 | 131.62 |
| 25375 | 24293 | 81.64 | 150.98 |
| 25393 | 21412 | 13.95 | 147.88 |
| 25912 | 25912 | 0.00 | 161.46 |
| 27175 | 21412 | 50.93 | 162.82 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,

thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prednisolone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20773-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prednisolone; Prednisolonum

### Special notes

When selecting the *Prednisolone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prednisolone | 14 | 13 | 479 |

### Second-stage model

For differentiation of the substance/substance group *Prednisolone* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prednisolone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 44.65 | – |
| Polymyxin B sulfate | 107.24 | – |
| ⋮ | ⋮ | ⋮ |
| Methylprednisolone | >50 | 45.50 |
| Triamcinolone acetonide | >50 | 67.78 |
| Fluocinolone acetonide | >50 | 86.57 |
| Betamethasone | >50 | 95.18 |
| Dexamethasone | >50 | 96.60 |
| Tyrothricin | >50 | 130.84 |
| Gramicidin | >50 | 157.31 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prednisolone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prednisolone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Prednisolone | 12324202 | 20773 | 40 | 20121113 |
| Caelo | Prednisolone | 12324226 | 21303 | 39 | 1411271 |
| Caelo | Prednisolone | 13343105 | 21449 | 60 | 1411232 |
| Caelo | Prednisolone | 154000 | 22435 | 60 | 20160225* |
| Caelo | Prednisolone | 154000 | 22435SI | 59 | 20160225* |
| Caelo | Prednisolone | 161343 | 22467 | 60 | 20160601* |
| Caelo | Prednisolone | 161343 | 22467SI | 44 | 20160601* |
| Caelo | Prednisolone | 15400002 | 22783 | 40 | 20160225 |
| Caelo | Prednisolone | 15400002 | 22783SI | 40 | 20160225 |
| Caelo | Prednisolone | 20001355 | 25192 | 40 | 20200528* |
| Caelo | Prednisolone | 20001355 | 25192SI | 40 | 20200528* |
| Euro OTC | Prednisolone | 1212021-02 | 21604 | 60 | 1411270 |

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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Prednisolone | 1212021-02 | 21604SI | 48 | 1411270 |
| Euro OTC | Prednisolone | 1501047-01 | 21849 | 60 | AR-15-FG-015509-01 |
| Euro OTC | Prednisolone | 1501047-01 | 21849SI | 30 | AR-15-FG-015509-01 |
| Euro OTC | Prednisolone | 1607011 | 22709 | 40 | 20160818* |
| Euro OTC | Prednisolone | 1607011 | 22709SI | 40 | 20160818* |
| Euro OTC | Prednisolone | 2104012 | 25688 | 50 | 20210504* |
| Euro OTC | Prednisolone | 2104012 | 25688SI | 50 | 20210504* |
| Fagron | Prednisolone | 13H07-B02-285592 | 21660 | 60 | 20130909 |
| Fagron | Prednisolone | 13H07-B02-285592 | 21660SI | 60 | 20130909 |
| Fagron | Prednisolone | 14I10-B03-302263 | 22651 | 40 | 20141020 |
| Fagron | Prednisolone | 14I10-B03-302263 | 22651SI | 40 | 20141020 |
| Fagron | Prednisolone | 16C15-B01-320761 | 22803 | 40 | 20160407 |
| Fagron | Prednisolone | 16C15-B01-320761 | 22803SI | 36 | 20160407 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 1176 spectra of 25 reference samples from the substance/substance group *Prednisolone*. These samples are listed above in the *calibration samples* section. The reference samples come from 14 different batches.
- 157 150 spectra from a total of 2943 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1012 spectra of 27 reference samples from the substance/substance group *Prednisolone*.
- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Prednisolone | 172777 | 23846 | 40 |
| Caelo | Prednisolone | 21003654002 | 26414 | 40 |
| Caelo | Prednisolone | 23002419002 | 27578 | 40 |
| Euro OTC | Prednisolone | 1702020 | 23180 | 40 |
| Euro OTC | Prednisolone | 1905005 | 24602 | 40 |
| Euro OTC | Prednisolone | 2003019 | 25243 | 40 |
| Euro OTC | Prednisolone | 2205002 | 26208 | 40 |
| Euro OTC | Prednisolone | 2401004 | 27090 | 40 |
| Euro OTC | Prednisolone | 2410003 | 27523 | 40 |
| Fagron | Prednisolone | 1108055-04 | 20855 | 40 |
| Fagron | Prednisolone | 16E09-B07-328220 | 23260 | 40 |
| Fagron | Prednisolone | 22B07-B20-220068 | 26289 | 30 |
| Fagron | Prednisolone | 24C07-B05-238310 | 27264 | 40 |
| Caelo | Prednisolone | 13343105 | 21451SI | 60 |
| Caelo | Prednisolone | 161343 | 22467SI† | 3 |
| Caelo | Prednisolone | 172777 | 23846SI | 38 |
| Caelo | Prednisolone | 21003654002 | 26414SI | 40 |
| Caelo | Prednisolone | 23002419002 | 27578SI | 40 |
| Euro OTC | Prednisolone | 1702020 | 23180SI | 21 |
| Euro OTC | Prednisolone | 1905005 | 24602SI | 40 |
| Euro OTC | Prednisolone | 2003019 | 25243SI | 40 |
| Euro OTC | Prednisolone | 2205002 | 26208SI | 40 |
| Euro OTC | Prednisolone | 2401004 | 27090SI | 40 |
| Euro OTC | Prednisolone | 2410003 | 27523SI | 40 |
| Fagron | Prednisolone | 16E09-B07-328220 | 23260SI | 20 |
| Fagron | Prednisolone | 22B07-B20-220068 | 26289SI | 40 |
| Fagron | Prednisolone | 24C07-B05-238310 | 27264SI | 40 |

- 211 928 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3005 spectra from 1020 *Apo-Ident* customers from 506 batches from the substance/substance group *Prednisolone*.
- Among them are spectra of independent samples from 478 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednisolone | 1702020-02 | 1 |
| | Prednisolone | 21003654002 | 1 |
| | Prednisolone | 21003654007 | 2 |
| | Prednisolone | 21003654010 | 1 |
| | Prednisolone | 21003654012 | 1 |
| | Prednisolone | 21003654014 | 3 |
| | Prednisolone | 21003654016 | 2 |
| | Prednisolone | 21003654017 | 2 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednisolone | 21003654021 | 7 |
| | Prednisolone | 2104012/01 | 1 |
| | Prednisolone | 2104012-01 | 2 |
| | Prednisolone | 21K27B04216441 | 1 |
| | Prednisolone | 220500201 | 1 |
| | Prednisolone | 2205002-01 | 27 |
| | Prednisolone | 2205002-0110/24P | 1 |
| | Prednisolone | 22050020176/23P | 1 |
| | Prednisolone | 22B07-B20_220050 | 1 |
| | Prednisolone | 22B07-B20-220050 | 2 |
| | Prednisolone | 22B07-B20-220068 | 1 |
| | Prednisolone | 22B07-B21 | 1 |
| | Prednisolone | 22B07-B21-22188 | 1 |
| | Prednisolone | 22B07-B21-222188 | 5 |
| | Prednisolone | 22B07-B21-222189 | 2 |
| | Prednisolone | 22B07-B21-224304 | 1 |
| | Prednisolone | 22B07-B21-224306 | 1 |
| | Prednisolone | 23002419002 | 6 |
| | Prednisolone | 23002419003 | 12 |
| | Prednisolone | 23002419006 | 11 |
| | Prednisolone | 23002419007 | 1 |
| | Prednisolone | 238309 | 1 |
| | Prednisolone | 23D24-B06-227228 | 5 |
| | Prednisolone | 23D24-B06-227230 | 2 |
| | Prednisolone | 23D24-B06-233604 | 2 |
| | Prednisolone | 23E30-B04-235950 | 4 |
| | Prednisolone | 23E30-B04-238327 | 1 |
| | Prednisolone | 23E30-B04-235950 | 1 |
| | Prednisolone | 2401004-01 | 18 |
| | Prednisolone | 2401004-0115/25P | 1 |
| | Prednisolone | 2401004-0140/24P | 1 |
| | Prednisolone | 2401004-0166/24P | 1 |
| | Prednisolone | 24100030122/25P | 1 |
| | Prednisolone | 24100030141/25P | 1 |
| | Prednisolone | 24C07-B05-005687 | 3 |
| | Prednisolone | 24C07-B05-238309 | 6 |
| | Prednisolone | B04-2336002 | 5 |
| | Prednisolone | Ko4/2011110 | 1 |
| | Prednisolone | NEPL230411 | 1 |
| A.H. 05.03.13 ek: 14,08EUR | Prednisolone | 12D30-N04 | 1 |
| Aep | Prednisolone | 21003654017 | 1 |
| AEP | Prednisolone | 21003654017 | 1 |
| AEP | Prednisolone | 21003654021 | 1 |
| AHD/EuRho | Prednisolone | 1905005-01 | 1 |
| AHD | Prednisolone | 121202103 | 1 |
| AHD | Prednisolone | 1212021-03 | 1 |
| AHD | Prednisolone | 160711-01 | 1 |
| AHD | Prednisolone | 16134308 | 1 |
| AHD | Prednisolone | 16134316 | 1 |
| AHD | Prednisolone | 1702020-01 | 1 |
| AHD | Prednisolone | 17277706 | 1 |
| AHD | Prednisolone | 21K27-B04-216441 | 2 |
| AHD | Prednisolone | 22B07-B21-222189 | 1 |
| AHD | Prednisolone | 23002419003 | 2 |
| AHD | Prednisolone | 24C07-B05-238309 | 1 |
| Alliance Healtcare | Prednisolone | 21003654002 | 1 |
| Alliance Healthcare | Prednisolone | 172777004 | 1 |
| Alliance Healthcare | Prednisolone | 17277723 | 1 |
| Alliance Healthcare | Prednisolone | 20001355002 | 1 |
| Alliance Healthcare | Prednisolone | 20004564006 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Healthcare | Prednisolone | 21003654004 | 2 |
| Alliance Healthcare | Prednisolone | 21003654012 | 1 |
| Alliance Healthcare | Prednisolone | 2401004-01 | 1 |
| anzag | Prednisolone | 14B18-B05-294966 | 1 |
| Anzag | Prednisolone | 20004564003 | 1 |
| Anzag | Prednisolone | 23002419007 | 1 |
| apo-Ident/ Sanacorp | Prednisolone | K04120190707 | 1 |
| apomix | Prednisolone | 16H04-B03-332930 | 1 |
| Apotheke Mildenau | Prednisolone | 1108055-04 | 3 |
| Beiersdorf | Prednisolone | 20004564003 | 1 |
| Berkel AHK | Prednisolone | 13343115 | 1 |
| Bomastus / Alliance ... | Prednisolone | 16134305 | 1 |
| Bombastus | Prednisolone | 1501047-02 | 1 |
| Caelo | Prednisolone | | 2 |
| Caelo | Prednisolone | 10196604 | 1 |
| Caelo | Prednisolone | 10196606 | 1 |
| Caelo | Prednisolone | 10196611 | 3 |
| Caelo | Prednisolone | 10196622 | 2 |
| Caelo | Prednisolone | 10196625 | 1 |
| Caelo | Prednisolone | 10196626 | 8 |
| Caelo | Prednisolone | 10196627 | 7 |
| Caelo | Prednisolone | 11/26-N04 | 1 |
| Caelo | Prednisolone | 1108055-04 | 2 |
| Caelo | Prednisolone | 1212021-01 | 1 |
| Caelo | Prednisolone | 121202102 | 1 |
| Caelo | Prednisolone | 1212021-03 | 6 |
| Caelo | Prednisolone | 12171301 | 6 |
| Caelo | Prednisolone | 12171302 | 1 |
| Caelo | Prednisolone | 12171303 | 2 |
| Caelo | Prednisolone | 12171306 | 2 |
| Caelo | Prednisolone | 12185702 | 2 |
| Caelo | Prednisolone | 1232417 | 1 |
| Caelo | Prednisolone | 12324202 | 11 |
| Caelo | Prednisolone | 12324203 | 3 |
| Caelo | Prednisolone | 12324204 | 4 |
| Caelo | Prednisolone | 12324205 | 13 |
| Caelo | Prednisolone | 12324207 | 4 |
| Caelo | Prednisolone | 12324213 | 7 |
| Caelo | Prednisolone | 12324216 | 9 |
| Caelo | Prednisolone | 12324217 | 5 |
| Caelo | Prednisolone | 12324219 | 7 |
| Caelo | Prednisolone | 12324220 | 2 |
| Caelo | Prednisolone | 12324221 | 2 |
| Caelo | Prednisolone | 12324226 | 7 |
| Caelo | Prednisolone | 1234205 | 1 |
| Caelo | Prednisolone | 1234556 | 1 |
| Caelo | Prednisolone | 1250216 | 1 |
| Caelo | Prednisolone | 133414 | 1 |
| Caelo | Prednisolone | 13343101 | 1 |
| Caelo | Prednisolone | 13343104 | 11 |
| Caelo | Prednisolone | 13343105 | 4 |
| Caelo | Prednisolone | 13343106 | 8 |
| Caelo | Prednisolone | 13343107 | 1 |
| Caelo | Prednisolone | 13343111 | 4 |
| Caelo | Prednisolone | 13343112 | 4 |
| Caelo | Prednisolone | 13343113 | 1 |
| Caelo | Prednisolone | 13343114 | 5 |
| Caelo | Prednisolone | 13343115 | 9 |
| Caelo | Prednisolone | 13343116 | 4 |
| Caelo | Prednisolone | 13A07-N14 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolone | 13E15-N06 | 4 |
| Caelo | Prednisolone | 14/10B03302265 | 1 |
| Caelo | Prednisolone | 14/10-B03-302266 | 1 |
| Caelo | Prednisolone | 1410B03302265 | 1 |
| Caelo | Prednisolone | 14A30-B02-294968 | 1 |
| Caelo | Prednisolone | 14B18-B05-294966 | 2 |
| Caelo | Prednisolone | 14G30-B14-302262 | 2 |
| Caelo | Prednisolone | 150104701 | 2 |
| Caelo | Prednisolone | 1501047-01 | 3 |
| Caelo | Prednisolone | 1501047-02 | 3 |
| Caelo | Prednisolone | 15055101 | 7 |
| Caelo | Prednisolone | 15055102 | 6 |
| Caelo | Prednisolone | 15055105 | 1 |
| Caelo | Prednisolone | 1511011 | 1 |
| Caelo | Prednisolone | 152006105 | 1 |
| Caelo | Prednisolone | 15206101 | 9 |
| Caelo | Prednisolone | 15206102 | 19 |
| Caelo | Prednisolone | 15206103 | 12 |
| Caelo | Prednisolone | 15206105 | 8 |
| Caelo | Prednisolone | 15206106 | 1 |
| Caelo | Prednisolone | 15206108 | 14 |
| Caelo | Prednisolone | 15400001 | 5 |
| Caelo | Prednisolone | 15400002 | 21 |
| Caelo | Prednisolone | 15400003 | 28 |
| Caelo | Prednisolone | 15400004 | 27 |
| Caelo | Prednisolone | 15400010 | 8 |
| Caelo | Prednisolone | 1540003 | 1 |
| Caelo | Prednisolone | 15K03-B04-314358 | 1 |
| Caelo | Prednisolone | 16034301 | 2 |
| Caelo | Prednisolone | 1607011-01 | 2 |
| Caelo | Prednisolone | 1613414 | 1 |
| Caelo | Prednisolone | 161343001 | 1 |
| Caelo | Prednisolone | 16134301 | 11 |
| Caelo | Prednisolone | 16134302 | 20 |
| Caelo | Prednisolone | 16134303 | 2 |
| Caelo | Prednisolone | 161343032 | 1 |
| Caelo | Prednisolone | 16134305 | 23 |
| Caelo | Prednisolone | 16134306 | 4 |
| Caelo | Prednisolone | 16134308 | 17 |
| Caelo | Prednisolone | 16134310 | 34 |
| Caelo | Prednisolone | 16134310-28122017/1 | 1 |
| Caelo | Prednisolone | 16134314 | 25 |
| Caelo | Prednisolone | 16134314/2120418 | 1 |
| Caelo | Prednisolone | 16134315 | 26 |
| Caelo | Prednisolone | 16134316 | 23 |
| Caelo | Prednisolone | 161343215 | 1 |
| Caelo | Prednisolone | 16A20-B03-316421 | 1 |
| Caelo | Prednisolone | 16C15-B01_320761 | 1 |
| Caelo | Prednisolone | 16C15-B01-320761 | 1 |
| Caelo | Prednisolone | 16C15-B01-321979 | 2 |
| Caelo | Prednisolone | 16C15-B01-324942 | 1 |
| Caelo | Prednisolone | 16C15-B02-324943 | 1 |
| Caelo | Prednisolone | 16E09-B07-328150 | 1 |
| Caelo | Prednisolone | 16E09-B07-328220 | 1 |
| Caelo | Prednisolone | 16H04-B03-332930 | 2 |
| Caelo | Prednisolone | 17020-01 | 1 |
| Caelo | Prednisolone | 1702020-01 | 3 |
| Caelo | Prednisolone | 1702020-02 | 3 |
| Caelo | Prednisolone | 1702020-03 | 1 |
| Caelo | Prednisolone | 172277710 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolone | 17277004 | 1 |
| Caelo | Prednisolone | 1727702 | 2 |
| Caelo | Prednisolone | 1727704 | 2 |
| Caelo | Prednisolone | 1727710 | 1 |
| Caelo | Prednisolone | 1727716 | 2 |
| Caelo | Prednisolone | 1727718 | 1 |
| Caelo | Prednisolone | 1727720 | 1 |
| Caelo | Prednisolone | 1727723 | 1 |
| Caelo | Prednisolone | 1727770 | 1 |
| Caelo | Prednisolone | 172777002 | 35 |
| Caelo | Prednisolone | 17277702 | 13 |
| Caelo | Prednisolone | 17277703 | 15 |
| Caelo | Prednisolone | 17277704 | 42 |
| Caelo | Prednisolone | 17277706 | 18 |
| Caelo | Prednisolone | 17277710 | 14 |
| Caelo | Prednisolone | 17277711 | 24 |
| Caelo | Prednisolone | 17277714 | 1 |
| Caelo | Prednisolone | 17277716 | 45 |
| Caelo | Prednisolone | 17277718 | 3 |
| Caelo | Prednisolone | 17277719 | 1 |
| Caelo | Prednisolone | 17277720 | 31 |
| Caelo | Prednisolone | 17277723 | 16 |
| Caelo | Prednisolone | 1727777723 | 1 |
| Caelo | Prednisolone | 177277703 | 1 |
| Caelo | Prednisolone | 17f07-b05 | 1 |
| Caelo | Prednisolone | 17F07B05341574 | 1 |
| Caelo | Prednisolone | 17F07-B05-341574 | 2 |
| Caelo | Prednisolone | 17F07-B05-341578 | 3 |
| Caelo | Prednisolone | 18138113 | 1 |
| Caelo | Prednisolone | 18A29-B02-348041 | 1 |
| Caelo | Prednisolone | 18H07-B04-354523 | 1 |
| Caelo | Prednisolone | 18H07-B04-355631 | 2 |
| Caelo | Prednisolone | 1905005-01 | 2 |
| Caelo | Prednisolone | 1905005-02 | 1 |
| Caelo | Prednisolone | 19081504 | 1 |
| Caelo | Prednisolone | 20001355001 | 4 |
| Caelo | Prednisolone | 20001355002 | 13 |
| Caelo | Prednisolone | 20001355003 | 17 |
| Caelo | Prednisolone | 200013555002 | 1 |
| Caelo | Prednisolone | 20004564001 | 1 |
| Caelo | Prednisolone | 20004564002 | 6 |
| Caelo | Prednisolone | 20004564003 | 30 |
| Caelo | Prednisolone | 20004564005 | 25 |
| Caelo | Prednisolone | 20004564006 | 11 |
| Caelo | Prednisolone | 20004564008 | 7 |
| Caelo | Prednisolone | 20004564009 | 18 |
| Caelo | Prednisolone | 20021303 | 1 |
| Caelo | Prednisolone | 2004564002 | 1 |
| Caelo | Prednisolone | 20H20-B01-200829 | 1 |
| Caelo | Prednisolone | 21003645002 | 1 |
| Caelo | Prednisolone | 21003654002 | 24 |
| Caelo | Prednisolone | 21003654004 | 13 |
| Caelo | Prednisolone | 21003654006 | 1 |
| Caelo | Prednisolone | 21003654007 | 4 |
| Caelo | Prednisolone | 21003654010 | 9 |
| Caelo | Prednisolone | 21003654012 | 4 |
| Caelo | Prednisolone | 21003654014 | 3 |
| Caelo | Prednisolone | 21003654016 | 1 |
| Caelo | Prednisolone | 21003654017 | 3 |
| Caelo | Prednisolone | 21E04-B02-215330 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolone | 21E04-B02-215330 | 1 |
| Caelo | Prednisolone | 22B07-B20-220068 | 1 |
| Caelo | Prednisolone | 23002419002 | 1 |
| Caelo | Prednisolone | 23002419003 | 2 |
| Caelo | Prednisolone | 2413Q02105 | 1 |
| Caelo | Prednisolone | 3344 | 1 |
| Caelo | Prednisolone | 411092-1-P | 1 |
| Caelo | Prednisolone | 4513U2105 | 1 |
| Caelo | Prednisolone | 4712I-02105 | 1 |
| Caelo | Prednisolone | 60367086 | 2 |
| Caelo | Prednisolone | 702020-01 | 1 |
| Caelo | Prednisolone | 9193501 | 1 |
| Caelo | Prednisolone | AP201025-04 | 1 |
| Caelo | Prednisolone | I-180716-15400003 | 1 |
| Caelo | Prednisolone | I220216/2 | 1 |
| Caelo | Prednisolone | k04c20121219 | 1 |
| Caelo | Prednisolone | NEPL160202 | 1 |
| Caelo | Prednisolone | NEPL180603 | 1 |
| Caesar & Lorenz GmbH | Prednisolone | 172777002 | 1 |
| Caesar & Lorenz | Prednisolone | 21003654012 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 172777002 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277720 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20001355003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277720 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20004564005 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277720 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 21003654010 | 1 |
| Caesar & Loretz GmbH, Now | Prednisolone | 21003654012 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277720 | 1 |
| Caesar & Loretz GmbH/GEHE | Prednisolone | 172777002 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednisolone | 17277710 | 3 |
| Caesar & Loretz GmbH/Gehe | Prednisolone | 21003654017 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277711 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20004564005 | 1 |
| Caesar & Loretz GmbH/Kehr | Prednisolone | 17277710 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277711 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20001355002 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 21003654002 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20004564005 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277720 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20001355003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20004564009 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | B09-1977207 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 17277723 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 1905005-01 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20001355002 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20004564003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone | 20001355002 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 12324205 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 12324219 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 15206101 | 2 |
| Caesar & Loretz GmbH | Prednisolone | 172777002 | 14 |
| Caesar & Loretz GmbH | Prednisolone | 172777004 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 17277702 | 2 |
| Caesar & Loretz GmbH | Prednisolone | 17277704 | 4 |
| Caesar & Loretz GmbH | Prednisolone | 17277706 | 2 |
| Caesar & Loretz GmbH | Prednisolone | 17277710 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 17277711 | 8 |
| Caesar & Loretz GmbH | Prednisolone | 17277716 | 8 |
| Caesar & Loretz GmbH | Prednisolone | 17277718 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Prednisolone | 17277720 | 14 |
| Caesar & Loretz GmbH | Prednisolone | 17277723 | 9 |
| Caesar & Loretz GmbH | Prednisolone | 190500502 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 20001355002 | 6 |
| Caesar & Loretz GmbH | Prednisolone | 20001355003 | 6 |
| Caesar & Loretz GmbH | Prednisolone | 20004564002 | 7 |
| Caesar & Loretz GmbH | Prednisolone | 20004564003 | 10 |
| Caesar & Loretz GmbH | Prednisolone | 20004564005 | 11 |
| Caesar & Loretz GmbH | Prednisolone | 20004564006 | 7 |
| Caesar & Loretz GmbH | Prednisolone | 20004564008 | 5 |
| Caesar & Loretz GmbH | Prednisolone | 20004564009 | 10 |
| Caesar & Loretz GmbH | Prednisolone | 21003654002 | 9 |
| Caesar & Loretz GmbH | Prednisolone | 21003654004 | 6 |
| Caesar & Loretz GmbH | Prednisolone | 21003654007 | 2 |
| Caesar & Loretz GmbH | Prednisolone | 21003654010 | 6 |
| Caesar & Loretz GmbH | Prednisolone | 21003654012 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 21003654014 | 2 |
| Caesar & Loretz GmbH | Prednisolone | 21003654021 | 1 |
| Caesar & Loretz GmbH | Prednisolone | 23002419003 | 1 |
| Caesar & Loretz Hild... | Prednisolone | 17277723 | 1 |
| Caesar & Loretz Hilden | Prednisolone | 17277711 | 1 |
| Caesar & Loretz Hilden | Prednisolone | 17277716 | 1 |
| Caesar & Loretz Hilden | Prednisolone | 20001355003 | 1 |
| Caesar & Loretz | Prednisolone | 20001355002 | 2 |
| Caesar u. Loretz/Noweda | Prednisolone | 16134301 | 1 |
| Caesar&Loretz GmbH/Anzag | Prednisolone | 13343112 | 1 |
| Caesar/Lorenz | Prednisolone | 12324204 | 1 |
| Caesar+ Loretz GmbH | Prednisolone | 20004564003 | 1 |
| Caleo/Jenne 28.04.22... | Prednisolone | 20004564006 | 1 |
| Caolo- Noweda | Prednisolone | 15206103 | 1 |
| Cealo/Noweda | Prednisolone | 1526108 | 1 |
| Cealo | Prednisolone | 16134305 | 2 |
| Cealo | Prednisolone | 17277703 | 1 |
| Cealo | Prednisolone | 2001355002 | 1 |
| Cealo | Prednisolone | 21003654002 | 1 |
| Celo/Noweda | Prednisolone | 1727703 | 1 |
| CVH/Jenne | Prednisolone | 19K27-B09 | 1 |
| Ebert & Jacobi | Prednisolone | 1212021-03 | 2 |
| Ebert & Jacobi | Prednisolone | 1607011-01 | 2 |
| EU.RHO.Pharm | Prednisolone | K04120190707 | 1 |
| EuRho/AHD | Prednisolone | 1702020-03 | 1 |
| EuRho/Noweda | Prednisolone | 1702020-01 | 1 |
| EuRho/Phönix | Prednisolone | 2104012-01 | 1 |
| EuRho | Prednisolone | 1012012-01 | 1 |
| EuRho | Prednisolone | 1012012-02 | 2 |
| EuRho | Prednisolone | 1212021-02 | 1 |
| EuRho | Prednisolone | 1702020-01 | 1 |
| EuRho | Prednisolone | 1702020-02 | 1 |
| EuRho | Prednisolone | 1702020-03 | 2 |
| euRho | Prednisolone | 1905005-01 | 1 |
| EuRho | Prednisolone | 190500501 | 1 |
| EuRho | Prednisolone | 1905005-01 | 1 |
| euRho | Prednisolone | 2003019-01 | 1 |
| EuRho | Prednisolone | 2003019-01 | 1 |
| EuRho | Prednisolone | 2104012-01 | 1 |
| Euro Gehe | Prednisolone | 1702020-03 | 1 |
| Euro OCT/Noweda | Prednisolone | 1501047-02 | 1 |
| Euro OTC | Prednisolone | | 2 |
| Euro OTC | Prednisolone | 1012012-02 | 2 |
| Euro OTC | Prednisolone | 1108055-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Prednisolone | 1108055-02 | 2 |
| Euro OTC | Prednisolone | 1108055-03 | 13 |
| Euro OTC | Prednisolone | 110805504 | 4 |
| Euro OTC | Prednisolone | 1108055-04 | 17 |
| Euro OTC | Prednisolone | 118055-04 | 1 |
| Euro OTC | Prednisolone | 12021-03 | 1 |
| Euro OTC | Prednisolone | 121021-01 | 2 |
| Euro OTC | Prednisolone | 1212021 | 1 |
| Euro OTC | Prednisolone | 121202101 | 1 |
| Euro OTC | Prednisolone | 1212021-01 | 33 |
| Euro OTC | Prednisolone | 121202102 | 2 |
| Euro OTC | Prednisolone | 1212021-02 | 28 |
| Euro OTC | Prednisolone | 1212021-03 | 40 |
| Euro OTC | Prednisolone | 121221-03 | 1 |
| Euro OTC | Prednisolone | 1314Q2105 | 1 |
| Euro OTC | Prednisolone | 13343104 | 1 |
| Euro OTC | Prednisolone | 14/10-B03-302263 | 1 |
| Euro OTC | Prednisolone | 1501047 | 1 |
| Euro OTC | Prednisolone | 150104701 | 3 |
| Euro OTC | Prednisolone | 1501047-01 | 28 |
| Euro OTC | Prednisolone | 1501047-02 | 18 |
| Euro OTC | Prednisolone | 1501047-03 | 6 |
| Euro OTC | Prednisolone | 150104743 | 1 |
| Euro OTC | Prednisolone | 150104747-01 | 1 |
| Euro OTC | Prednisolone | 15010477-01 | 1 |
| Euro OTC | Prednisolone | 1501074-02 | 1 |
| Euro OTC | Prednisolone | 15014047-02 | 1 |
| Euro OTC | Prednisolone | 15206108 | 1 |
| Euro OTC | Prednisolone | 15400010 | 1 |
| Euro OTC | Prednisolone | 15K03-B04-314226 | 1 |
| Euro OTC | Prednisolone | 1607011-01 | 42 |
| Euro OTC | Prednisolone | 16134316 | 2 |
| Euro OTC | Prednisolone | 16E09-B07-329686 | 2 |
| Euro OTC | Prednisolone | 170202001 | 2 |
| Euro OTC | Prednisolone | 1702020-01 | 56 |
| Euro OTC | Prednisolone | 170202002 | 3 |
| Euro OTC | Prednisolone | 1702020-02 | 52 |
| Euro OTC | Prednisolone | 1702020-03 | 25 |
| Euro OTC | Prednisolone | 170202-03 | 3 |
| Euro OTC | Prednisolone | 1702020-30 | 1 |
| Euro OTC | Prednisolone | 170202201 | 1 |
| Euro OTC | Prednisolone | 172020-03 | 1 |
| Euro OTC | Prednisolone | 18A29-B02-348044 | 1 |
| Euro OTC | Prednisolone | 18H07-B04 | 1 |
| Euro OTC | Prednisolone | 190500-01 | 2 |
| Euro OTC | Prednisolone | 19050005-01 | 1 |
| Euro OTC | Prednisolone | 1905005 | 1 |
| Euro OTC | Prednisolone | 1905005_01 | 1 |
| Euro OTC | Prednisolone | 190500501 | 6 |
| Euro OTC | Prednisolone | 1905005-01 | 87 |
| Euro OTC | Prednisolone | 1905005-02 | 31 |
| Euro OTC | Prednisolone | 1905005-0P-191223-5 | 1 |
| Euro OTC | Prednisolone | 190500t-02 | 1 |
| Euro OTC | Prednisolone | 200301901 | 2 |
| Euro OTC | Prednisolone | 2003019-01 | 44 |
| Euro OTC | Prednisolone | 200560 | 1 |
| Euro OTC | Prednisolone | 210401201 | 1 |
| Euro OTC | Prednisolone | 2104012-01 | 26 |
| Euro OTC | Prednisolone | 2401004-01 | 1 |
| Euro OTC | Prednisolone | 30042014B | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Prednisolone | 501047-01 | 1 |
| Euro OTC | Prednisolone | NEPL110103 | 1 |
| Euro/ Sanacorp | Prednisolone | 121202103 | 1 |
| Euro/Gehe | Prednisolone | 1702020-01 | 1 |
| Euro/Phoenix | Prednisolone | 190500501 | 1 |
| Euro/Phoenix | Prednisolone | 190500502 | 1 |
| Euro/Phönix | Prednisolone | 1702020-01 | 1 |
| Euro/Phönix | Prednisolone | 1905005-01 | 1 |
| euroct/gehe | Prednisolone | 1212021-01 | 1 |
| euroct/Gehe | Prednisolone | 1212021-01 | 1 |
| Europh/Ph | Prednisolone | 1702020-02 | 1 |
| Europharm/Otto | Prednisolone | 1108055-03 | 1 |
| Europharm/Otto | Prednisolone | 1108055-04 | 5 |
| Europharm | Prednisolone | 1607011-01 | 1 |
| europharma | Prednisolone | 1002001240 | 1 |
| Fa.Phönix | Prednisolone | 19k27-b09 | 1 |
| Fagron | Prednisolone | | 1 |
| Fagron | Prednisolone | 10J04-N06 | 1 |
| Fagron | Prednisolone | 11D13-N05 | 2 |
| Fagron | Prednisolone | 11G22-N08 | 1 |
| Fagron | Prednisolone | 11J26-N04 | 2 |
| Fagron | Prednisolone | 12324216 | 1 |
| Fagron | Prednisolone | 12c22-N05 | 1 |
| Fagron | Prednisolone | 12C22-N05 | 7 |
| Fagron | Prednisolone | 12D30-N04 | 7 |
| Fagron | Prednisolone | 12D30-NO4 | 1 |
| Fagron | Prednisolone | 12K14-N03 | 10 |
| Fagron | Prednisolone | 12K14-NO3 | 1 |
| Fagron | Prednisolone | 13OF-N04 | 1 |
| Fagron | Prednisolone | 13343106 | 1 |
| Fagron | Prednisolone | 13A07N14 | 1 |
| Fagron | Prednisolone | 13A07-N14 | 6 |
| Fagron | Prednisolone | 13DE15-N06 | 1 |
| Fagron | Prednisolone | 13E13-N06 | 1 |
| Fagron | Prednisolone | 13E15-N06 | 17 |
| Fagron | Prednisolone | 13E15-NO6 | 1 |
| Fagron | Prednisolone | 13G03-B09 | 1 |
| Fagron | Prednisolone | 13H07-B02 | 2 |
| Fagron | Prednisolone | 13H07-B020 | 1 |
| Fagron | Prednisolone | 13H07-B02-285590 | 3 |
| Fagron | Prednisolone | 13H07-B02-285592 | 4 |
| Fagron | Prednisolone | 13H07-B02-285593 | 4 |
| Fagron | Prednisolone | 13H07-B02-285593 | 1 |
| Fagron | Prednisolone | 13H7-B02-285590 | 1 |
| Fagron | Prednisolone | 13J28-B06 | 2 |
| Fagron | Prednisolone | 13J28-B06-289670 | 3 |
| Fagron | Prednisolone | 14/10-B03 | 1 |
| Fagron | Prednisolone | 14/10-B03-302263 | 2 |
| Fagron | Prednisolone | 14/10B03302265 | 1 |
| Fagron | Prednisolone | 14/10-B03-302265 | 4 |
| Fagron | Prednisolone | 14/10-B03-302266 | 2 |
| Fagron | Prednisolone | 14/10-B03-302269 | 1 |
| Fagron | Prednisolone | 14/10-B03-302271 | 1 |
| Fagron | Prednisolone | 1410-B03 | 1 |
| Fagron | Prednisolone | 1410-B03-302269 | 2 |
| Fagron | Prednisolone | 14818-B05-294966 | 1 |
| Fagron | Prednisolone | 14A30-B02-294968 | 5 |
| Fagron | Prednisolone | 14B18-B05 | 1 |
| Fagron | Prednisolone | 14B18B05294966 | 2 |
| Fagron | Prednisolone | 14B18-B05294966 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednisolone | 14B18-B05-294966 | 11 |
| Fagron | Prednisolone | 14B18-B05-294969 | 2 |
| Fagron | Prednisolone | 14B18-Bo5-294966 | 1 |
| Fagron | Prednisolone | 14G30-B14 | 1 |
| Fagron | Prednisolone | 14G30-B14-302262 | 4 |
| Fagron | Prednisolone | 14I10-B03 | 1 |
| Fagron | Prednisolone | 14I10-B03-302265 | 2 |
| Fagron | Prednisolone | 14I10-B03-302266 | 1 |
| Fagron | Prednisolone | 14i10-b03-302269 | 1 |
| Fagron | Prednisolone | 14I10-B03-302269 | 3 |
| Fagron | Prednisolone | 14l10-B03302265 | 1 |
| Fagron | Prednisolone | 14L10-B03-302269 | 1 |
| Fagron | Prednisolone | 1501047-02 | 1 |
| Fagron | Prednisolone | 150528P | 1 |
| Fagron | Prednisolone | 15206103 | 1 |
| Fagron | Prednisolone | 15B18-B05-294969 | 1 |
| Fagron | Prednisolone | 15D14-B01 | 1 |
| Fagron | Prednisolone | 15D14-B01-308425 | 3 |
| Fagron | Prednisolone | 15K03_B04_314226 | 1 |
| Fagron | Prednisolone | 15K03-B04 | 1 |
| Fagron | Prednisolone | 15k03-b04-314226 | 1 |
| Fagron | Prednisolone | 15K03B04314226 | 1 |
| Fagron | Prednisolone | 15K03-B04-314226 | 13 |
| Fagron | Prednisolone | 15K03-B04-314357 | 2 |
| Fagron | Prednisolone | 15K03-B04-314358 | 6 |
| Fagron | Prednisolone | 15K03-B04-314869 | 2 |
| Fagron | Prednisolone | 15KO3-B04-314226 | 1 |
| Fagron | Prednisolone | 1607011-01 | 2 |
| Fagron | Prednisolone | 16134310 | 1 |
| Fagron | Prednisolone | 16A20-B03 | 4 |
| Fagron | Prednisolone | 16A20-B03-316420 | 7 |
| Fagron | Prednisolone | 16A20-B03-316421 | 1 |
| Fagron | Prednisolone | 16A20-B03-319015 | 7 |
| Fagron | Prednisolone | 16c15-802 | 1 |
| Fagron | Prednisolone | 16C15-B01 | 1 |
| Fagron | Prednisolone | 16C15-B01-319992 | 2 |
| Fagron | Prednisolone | 16c15-B01-320761 | 2 |
| Fagron | Prednisolone | 16C15B01320761 | 2 |
| Fagron | Prednisolone | 16C15-B01-320761 | 4 |
| Fagron | Prednisolone | 16c15-b01-321979 | 1 |
| Fagron | Prednisolone | 16C15B01321979 | 1 |
| Fagron | Prednisolone | 16C15-B01-321979 | 15 |
| Fagron | Prednisolone | 16C15-B01-324942 | 6 |
| Fagron | Prednisolone | 16c15-b02 | 1 |
| Fagron | Prednisolone | 16C15-B02 | 1 |
| Fagron | Prednisolone | 16C15-B02-324943 | 6 |
| Fagron | Prednisolone | 16C15-B02-324945 | 1 |
| Fagron | Prednisolone | 16C15-BO1-321979 | 1 |
| Fagron | Prednisolone | 16C19-B07-353242 | 1 |
| Fagron | Prednisolone | 16E09/B07/328220 | 1 |
| Fagron | Prednisolone | 16E09-B07_328220 | 1 |
| Fagron | Prednisolone | 16E09-B07-328150 | 19 |
| Fagron | Prednisolone | 16E09-B07-328220 | 7 |
| Fagron | Prednisolone | 16e09-B07-329686 | 1 |
| Fagron | Prednisolone | 16E09-B07-329686 | 1 |
| Fagron | Prednisolone | 16E09-B075411 | 1 |
| Fagron | Prednisolone | 16H04b03332929 | 1 |
| Fagron | Prednisolone | 16H04-B03-332929 | 15 |
| Fagron | Prednisolone | 16H04-B03-332930 | 6 |
| Fagron | Prednisolone | 16K27-BO9-200489 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednisolone | 17014-801-340448 | 1 |
| Fagron | Prednisolone | 17020201 | 1 |
| Fagron | Prednisolone | 1711021A | 1 |
| Fagron | Prednisolone | 1717M-02105 | 1 |
| Fagron | Prednisolone | 17D14-B01 | 1 |
| Fagron | Prednisolone | 17D14b01338573 | 1 |
| Fagron | Prednisolone | 17D14-B01-338573 | 5 |
| Fagron | Prednisolone | 17D14-Bo1-338573 | 1 |
| Fagron | Prednisolone | 17F07-B05 | 3 |
| Fagron | Prednisolone | 17F07-B05_341574 | 1 |
| Fagron | Prednisolone | 17F07-B05-341574 | 8 |
| Fagron | Prednisolone | 17F07-B05-341575 | 5 |
| Fagron | Prednisolone | 17F07-B05-341578 | 2 |
| Fagron | Prednisolone | 17g2828-b03-345539 | 1 |
| Fagron | Prednisolone | 17G28-B03 | 3 |
| Fagron | Prednisolone | 17G28-B03-345538 | 10 |
| Fagron | Prednisolone | 17G28-B03-345539 | 4 |
| Fagron | Prednisolone | 17G2B03-345538 | 1 |
| Fagron | Prednisolone | 18A29-B02 | 2 |
| Fagron | Prednisolone | 18A29-B02-348041 | 2 |
| Fagron | Prednisolone | 18A29-B02-348044 | 1 |
| Fagron | Prednisolone | 18A29-B02-348540 | 6 |
| Fagron | Prednisolone | 18C19-B07 | 2 |
| Fagron | Prednisolone | 18C19-B07-351225 | 5 |
| Fagron | Prednisolone | 18C19B07351226 | 1 |
| Fagron | Prednisolone | 18C19-B07-351226 | 4 |
| Fagron | Prednisolone | 18C19-B07-353242 | 5 |
| Fagron | Prednisolone | 18H07-804 | 1 |
| Fagron | Prednisolone | 18H07-B04 | 3 |
| Fagron | Prednisolone | 18H07-B04_355630 | 1 |
| Fagron | Prednisolone | 18h07-b04-353326 | 1 |
| Fagron | Prednisolone | 18H07-B04-353326 | 4 |
| Fagron | Prednisolone | 18H07-B04-354523 | 10 |
| Fagron | Prednisolone | 18H07-B04-355630 | 7 |
| Fagron | Prednisolone | 18H07B04355631 | 1 |
| Fagron | Prednisolone | 18H07-B04-355631 | 6 |
| Fagron | Prednisolone | 18H7-B04-355631 | 1 |
| Fagron | Prednisolone | 1905005-01 | 3 |
| Fagron | Prednisolone | 194548 | 1 |
| Fagron | Prednisolone | 19-B07-351226 | 1 |
| Fagron | Prednisolone | 19E28-814-191220 | 1 |
| Fagron | Prednisolone | 19e28-B13 | 1 |
| Fagron | Prednisolone | 19E28-B13 | 1 |
| Fagron | Prednisolone | 19E28B13191224 | 1 |
| Fagron | Prednisolone | 19E28-B13-191224 | 9 |
| Fagron | Prednisolone | 19E28-B14 | 3 |
| Fagron | Prednisolone | 19E28-B14-1911225 | 1 |
| Fagron | Prednisolone | 19E28-B14-191220 | 19 |
| Fagron | Prednisolone | 19E28-B14-1912220 | 1 |
| Fagron | Prednisolone | 19H19-302 | 1 |
| Fagron | Prednisolone | 19H19-B02 | 3 |
| Fagron | Prednisolone | 19H19-B02-194547 | 1 |
| Fagron | Prednisolone | 19H19-B02-194548 | 10 |
| Fagron | Prednisolone | 19H19-B02-194549 | 2 |
| Fagron | Prednisolone | 19H19-BO2-194548 | 2 |
| Fagron | Prednisolone | 19K27-809 | 1 |
| Fagron | Prednisolone | 19K27-B09 | 2 |
| Fagron | Prednisolone | 19K27-B09-1977207 | 1 |
| Fagron | Prednisolone | 19k27b09197727 | 1 |
| Fagron | Prednisolone | 19K27-B09-197727 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednisolone | 19k27-b09-200489 | 1 |
| Fagron | Prednisolone | 19K27B09-200489 | 1 |
| Fagron | Prednisolone | 19K27-B09-200489 | 10 |
| Fagron | Prednisolone | 19K27B09200517 | 2 |
| Fagron | Prednisolone | 19K27-B09-200517 | 6 |
| Fagron | Prednisolone | 20004564003 | 1 |
| Fagron | Prednisolone | 200738 | 1 |
| Fagron | Prednisolone | 20H20-B01 | 2 |
| Fagron | Prednisolone | 20H20-B01_202715 | 1 |
| Fagron | Prednisolone | 20H20B01200714 | 1 |
| Fagron | Prednisolone | 20H20-B01-200736 | 1 |
| Fagron | Prednisolone | 20H20-B01-200738 | 7 |
| Fagron | Prednisolone | 20h20B01-200829 | 1 |
| Fagron | Prednisolone | 20H20-B01-200829 | 3 |
| Fagron | Prednisolone | 20H20-B01-202715 | 6 |
| Fagron | Prednisolone | 20H20-B01-204241 | 2 |
| Fagron | Prednisolone | 20H20-B01-200829 | 1 |
| Fagron | Prednisolone | 21/07-B03-213752 | 1 |
| Fagron | Prednisolone | 21107-B03 | 1 |
| Fagron | Prednisolone | 211217(19519-B02-194548) | 1 |
| Fagron | Prednisolone | 21E04-B02 | 1 |
| Fagron | Prednisolone | 21E04-B02215330 | 2 |
| Fagron | Prednisolone | 21E04-B02-215330 | 10 |
| Fagron | Prednisolone | 21I07B03213148 | 1 |
| Fagron | Prednisolone | 21I07-B03-213148 | 1 |
| Fagron | Prednisolone | 21I07-B03-213752 | 5 |
| Fagron | Prednisolone | 21k27-b04-216439 | 1 |
| Fagron | Prednisolone | 21K27-B04-216439 | 5 |
| Fagron | Prednisolone | 21K27-B04-216439 | 3 |
| Fagron | Prednisolone | 21K27-B04-216441 | 1 |
| Fagron | Prednisolone | 22807-820-220050 | 1 |
| Fagron | Prednisolone | 22807-821 | 1 |
| Fagron | Prednisolone | 22B07-B20-220050 | 3 |
| Fagron | Prednisolone | 22B07-B21-22188 | 1 |
| Fagron | Prednisolone | 22b07-B21-222188 | 1 |
| Fagron | Prednisolone | 23E30-B04-234317 | 1 |
| Fagron | Prednisolone | 2834 | 1 |
| Fagron | Prednisolone | 2915E-02105 | 1 |
| Fagron | Prednisolone | 3518E-02105 | 1 |
| Fagron | Prednisolone | 4313E-02105 | 1 |
| Fagron | Prednisolone | 613Q-02105 | 1 |
| Fagron | Prednisolone | 8576886 | 1 |
| Fagron | Prednisolone | B01-2007308 | 1 |
| Fagron | Prednisolone | B01-2008209 | 2 |
| Fagron | Prednisolone | B02-1945408 | 1 |
| Fagron | Prednisolone | B02-2153300 | 1 |
| Fagron | Prednisolone | B09-1977207 | 2 |
| Fagron | Prednisolone | B09-1977208 | 1 |
| Fagron | Prednisolone | B09-2004809 | 2 |
| Fagron | Prednisolone | b14-1912200 | 1 |
| Fagron | Prednisolone | BO9-1977207 | 1 |
| Fagron | Prednisolone | K04C20121006 | 1 |
| Fagron | Prednisolone | K04C20130203M | 1 |
| Fagron | Prednisolone | K04C20131102 | 1 |
| Fagron | Prednisolone | K04C20140502 | 2 |
| Fagron | Prednisolone | KO4C20121006 | 1 |
| Fagron | Prednisolone | NEPL151202 | 1 |
| Fagron | Prednisolone | NEPL160202 | 1 |
| Fagron | Prednisolone | NEPL160705 | 1 |
| Fagron | Prednisolone | NEPL170209 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednisolone | NEPL170210 | 1 |
| Fagron | Prednisolone | NEPL170605 | 3 |
| Fagron | Prednisolone | NEPL1711 | 1 |
| Fagron | Prednisolone | NEPL171111 | 1 |
| Fagron | Prednisolone | NEPL180603 | 1 |
| Fagron | Prednisolone | NEPL190306 | 1 |
| Fagron | Prednisolone | NEPL190405 | 4 |
| Fagron | Prednisolone | nepl190811 | 1 |
| Fagron | Prednisolone | NEPL190811 | 2 |
| Fagron | Prednisolone | NEPL200714 | 1 |
| Fagron | Prednisolone | NEPL211006 | 2 |
| Fagron | Prednisolone | NPL190306 | 1 |
| Fargo | Prednisolone | 12D30-N04 | 1 |
| Fargon / AHD | Prednisolone | 18C19-B07-351226 | 1 |
| Fargon/19.07.2013/Noweda | Prednisolone | 12D30-N04 | 2 |
| Fargon/AHD | Prednisolone | 18A29-B02-348044 | 1 |
| Fargon/Kehr | Prednisolone | 22B07-B21-224304 | 1 |
| Fargon | Prednisolone | 16134308 | 1 |
| Fargon | Prednisolone | 19E28-B14-191220 | 1 |
| Fargon | Prednisolone | FPO1409P | 1 |
| Fargron | Prednisolone | 13E15-N06 | 1 |
| Fiebig | Prednisolone | 22B07-B21-222189 | 2 |
| Fischar/Gehe | Prednisolone | 14A30-B02-294968 | 1 |
| Fragon/Phoenix | Prednisolone | 15K03-B04-314226 | 1 |
| Fragon/Phoenix | Prednisolone | 16C15-B02-324943 | 1 |
| Fragon | Prednisolone | 18C19-B07-351225 | 1 |
| Gehe amax | Prednisolone | 16134310 | 1 |
| Gehe amax | Prednisolone | 1702020-01 | 1 |
| Gehe amax | Prednisolone | 1702020-02 | 1 |
| Gehe amax | Prednisolone | 17277704 | 1 |
| Gehe amax | Prednisolone | 17277720 | 2 |
| Gehe/Fragon | Prednisolone | 16E09B07328150 | 1 |
| Gehe | Prednisolone | 11j26-N04 | 2 |
| Gehe | Prednisolone | 1212021-01 | 2 |
| Gehe | Prednisolone | 1212021-02 | 1 |
| Gehe | Prednisolone | 12324216 | 2 |
| Gehe | Prednisolone | 12C22-N05 | 1 |
| Gehe | Prednisolone | 13343107 | 1 |
| Gehe | Prednisolone | 13A07-N14 | 2 |
| Gehe | Prednisolone | 13E15-No6 | 1 |
| Gehe | Prednisolone | 14A30-B02-294968 | 1 |
| Gehe | Prednisolone | 1501047-01 | 3 |
| Gehe | Prednisolone | 16134302 | 1 |
| Gehe | Prednisolone | 16134314 | 1 |
| Gehe | Prednisolone | 16C15-B01 | 1 |
| Gehe | Prednisolone | 16C15-B01-321979 | 1 |
| Gehe | Prednisolone | 16C-15-B02 | 1 |
| Gehe | Prednisolone | 16E09-B07 | 1 |
| GEHE | Prednisolone | 1702020-02 | 1 |
| Gehe | Prednisolone | 172777002 | 1 |
| Gehe | Prednisolone | 17277710 | 1 |
| Gehe | Prednisolone | 17277718 | 3 |
| Gehe | Prednisolone | 17F07-B05-341574 | 1 |
| Gehe | Prednisolone | 17G28-B03 | 1 |
| Gehe | Prednisolone | 18H07-B04 | 1 |
| Gehe | Prednisolone | 18H07-B04-355630 | 2 |
| Gehe | Prednisolone | 18H07-B04-355631 | 1 |
| Gehe | Prednisolone | 19E28-B14_191220 | 1 |
| Gehe | Prednisolone | 19H19-B02 | 1 |
| Gehe | Prednisolone | 20004564002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Prednisolone | 21003654012 | 1 |
| GEHE | Prednisolone | 21K27-B04-216441 | 1 |
| Gehe | Prednisolone | 23E30-B04-235950 | 1 |
| Gehe-Fragon | Prednisolone | 14B18B05294966 | 1 |
| GUMO | Prednisolone | 19K27-B09_20048 | 1 |
| Hedinger | Prednisolone | P2018/116 | 1 |
| Henan / Ebert | Prednisolone | 16134316 | 1 |
| Henan / Gehe | Prednisolone | 1501047-01 | 2 |
| Henan Lihua Pharmace... | Prednisolone | 2104012-01 | 1 |
| Henan/Gehe | Prednisolone | 1501047-01 | 2 |
| Henan/Noweda | Prednisolone | K04120190303 | 1 |
| Holdermann | Prednisolone | 23002419003 | 1 |
| Holdermann | Prednisolone | 23E30-B04-235950 | 1 |
| Holdermann | Prednisolone | 24C07-B05-238309 | 1 |
| Ichthyol / Phoenix | Prednisolone | 16C15-B01-320761 | 1 |
| Ichthyol gesellschaft | Prednisolone | 15400003 | 1 |
| JENNE | Prednisolone | 23002419002 | 1 |
| Jenne | Prednisolone | 23002419003 | 1 |
| Kehr Holdermann | Prednisolone | 2401004-01 | 1 |
| Kehr | Prednisolone | 2205002-01 | 1 |
| Kehr | Prednisolone | 23D24-B06-227228 | 1 |
| Kehr | Prednisolone | 23D24-B06-227230 | 1 |
| Kehr-Holdermann | Prednisolone | 2205002-01 | 2 |
| Krieger | Prednisolone | 21003654010 | 1 |
| Krieger | Prednisolone | 3416 | 1 |
| Leyh Pharma | Prednisolone | 16A20-B03-319015 | 1 |
| Nachprüfung | Prednisolone | 2082019-8 | 1 |
| Noweda PKH Halle | Prednisolone | 1607011-01 | 2 |
| Noweda | Prednisolone | 1108055-05 | 1 |
| Noweda | Prednisolone | 1212021-02 | 1 |
| Noweda | Prednisolone | 15206101 | 1 |
| Noweda | Prednisolone | 1607011-01 | 1 |
| Noweda | Prednisolone | 16134316 | 1 |
| Noweda | Prednisolone | 16H04-B03-332930 | 1 |
| Noweda | Prednisolone | 18A29-B02-348041 | 1 |
| Noweda | Prednisolone | 1905005-01 | 1 |
| Noweda | Prednisolone | 19E28-B14-191220 | 2 |
| Noweda | Prednisolone | 20004564003 | 1 |
| Noweda | Prednisolone | 20004564005 | 1 |
| Noweda | Prednisolone | 20H20-B01-200829 | 1 |
| Noweda | Prednisolone | 21003654002 | 1 |
| Noweda | Prednisolone | 21003654017 | 1 |
| Noweda | Prednisolone | 21107-B03-213752 | 1 |
| Noweda | Prednisolone | 2205002-01 | 7 |
| Noweda | Prednisolone | 2205022_01 | 1 |
| Noweda | Prednisolone | 22B07-B21-222189 | 1 |
| Noweda | Prednisolone | 23002419002 | 3 |
| noweda | Prednisolone | 23002419003 | 1 |
| Noweda | Prednisolone | 23002419003 | 2 |
| noweda | Prednisolone | 23002419006 | 1 |
| Noweda | Prednisolone | 23002419006 | 2 |
| Noweda | Prednisolone | 23E30-B04-233602 | 1 |
| Noweda | Prednisolone | 2401004-01 | 2 |
| Noweda | Prednisolone | 24C07-B05-238310 | 1 |
| Noweda-Euro | Prednisolone | K04I20210211 | 2 |
| Otto Geilenkirchen | Prednisolone | 16134305 | 1 |
| Phoenix 01.08.2017 8,69EUR | Prednisolone | 16E09-B07-328150 | 1 |
| Phoenix 14.11.2017 | Prednisolone | 16H04-B03-332929 | 1 |
| phoenix 5.4.2013 | Prednisolone | 1108055-04 | 1 |
| Phoenix | Prednisolone | 15400003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Prednisolone | 16134310 | 1 |
| Phoenix | Prednisolone | 16134315 | 1 |
| Phoenix | Prednisolone | 16H04B03332930 | 1 |
| Phoenix | Prednisolone | 17277703 | 1 |
| Phoenix | Prednisolone | 17277711 | 1 |
| Phoenix | Prednisolone | 20004564005 | 4 |
| Phoenix | Prednisolone | 20004564009 | 1 |
| Phoenix | Prednisolone | 200602406 | 1 |
| Phoenix | Prednisolone | 21003654020 | 3 |
| Phoenix | Prednisolone | 23002419002 | 1 |
| Phoenix | Prednisolone | 3220 | 1 |
| Phönix Gotha | Prednisolone | 1232417 | 1 |
| Phönix Gotha | Prednisolone | 12324213 | 1 |
| Phönix Gotha | Prednisolone | 12324217 | 1 |
| Phönix Gotha | Prednisolone | 13343105 | 1 |
| Phönix Gotha | Prednisolone | 13343111 | 1 |
| Phönix Gotha | Prednisolone | 13343112 | 2 |
| Phönix/Euro | Prednisolone | 1501047-03 | 1 |
| Phönix/Euro | Prednisolone | 1702020-02 | 1 |
| Phönix/Fagon | Prednisolone | 16C15-B01-324942 | 1 |
| Phönix/Noweda | Prednisolone | 21003654002 | 1 |
| Phönix | Prednisolone | 12324216 | 1 |
| Phönix | Prednisolone | 13A07N14 | 1 |
| Phönix | Prednisolone | 13E15-N06 | 2 |
| Phönix | Prednisolone | 14B18-B05-294966 | 1 |
| Phönix | Prednisolone | 1501047-01 | 2 |
| Phönix | Prednisolone | 16134305 | 1 |
| Phönix | Prednisolone | 16134314 | 1 |
| Phönix | Prednisolone | 17277704 | 1 |
| phönix | Prednisolone | 17277716 | 1 |
| Phönix | Prednisolone | 17277720 | 1 |
| Phönix | Prednisolone | 17277723 | 2 |
| Phönix | Prednisolone | 18A29B02348540 | 1 |
| Phönix | Prednisolone | 19K27-B09-200489 | 2 |
| Phönix | Prednisolone | 2003019-01 | 1 |
| Phönix | Prednisolone | 23002419007 | 1 |
| Röntgen | Prednisolone | 170202001 | 1 |
| Sanacorp WE:01.08.20... | Prednisolone | 1501047-01 | 1 |
| Sanacorp | Prednisolone | 1108055-03 | 1 |
| Sanacorp | Prednisolone | 12324221 | 1 |
| Sanacorp | Prednisolone | 13343112 | 1 |
| Sanacorp | Prednisolone | 13E15-N06 | 1 |
| Sanacorp | Prednisolone | 13H07-B02-285592 | 1 |
| Sanacorp | Prednisolone | 13j28-b06-289670 | 1 |
| sanacorp | Prednisolone | 14/10-B03-302266 | 1 |
| Sanacorp | Prednisolone | 14/10-B03-302269 | 1 |
| Sanacorp | Prednisolone | 16134310 | 1 |
| Sanacorp | Prednisolone | 16H04-B03_332930 | 1 |
| Sanacorp | Prednisolone | 17F07-B05-341575 | 1 |
| Sanacorp | Prednisolone | 18AB02 | 1 |
| Sanacorp | Prednisolone | 20001355002 | 1 |
| Sanacorp | Prednisolone | 21I07-B03-213752 | 1 |
| Sanacorp | Prednisolone | 21K27-B04-0002 | 1 |
| Sanacorp | Prednisolone | 2205002-01 | 3 |
| Sanacorp | Prednisolone | 22B07-B20-220068 | 1 |
| Sanacorp | Prednisolone | 22B07-B21-224306 | 1 |
| Sanacorp | Prednisolone | 23002419002 | 1 |
| Sanacorp | Prednisolone | 23002419003 | 1 |
| Sanacorp | Prednisolone | 23002419006 | 1 |
| Sanacorp | Prednisolone | 23E30-B04-235951 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sonnenberg-Apotheke | Prednisolone | 12324219 | 1 |
| Tianjin Tianyao Pharm/AHD | Prednisolone | 19H19-B02-194548 | 1 |
| Tianyao Pharma/Phönix | Prednisolone | 1212021-01 | 1 |
| Tianyao Pharma/Phönix | Prednisolone | NEPL110103 | 1 |
| Tianyoa Pharma | Prednisolone | 1212021-02 | 2 |

- 253 881 spectra from 1665 *Apo-Ident* customers from a total of 51 651 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Prednisolone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prednisolone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 1162 | 14 | 157 150 |
| **Type B** | 0 | 1012 | 0 | 211 928 |
| **Type C** | 0 | 2956 | 49 | 253 881 |

The substance/substance group *Prednisolone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 98.8095 % (> 98.5544 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4071 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.3694 % (> 98.2696 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20773 | 21303 | 9.25 | 154.25 |
| 21303 | 21303 | 0.00 | 149.31 |
| 21449 | 21449 | 0.00 | 149.12 |
| 21604 | 21604 | 0.00 | 149.66 |
| 21660 | 21449 | 3.77 | 151.40 |
| 21849 | 21849 | 0.00 | 138.21 |
| 22435 | 22435 | 0.00 | 150.75 |
| 22467 | 22467 | 0.00 | 139.23 |
| 22651 | 21449 | 9.54 | 156.62 |
| 22709 | 22709 | 0.00 | 146.35 |
| 22783 | 22435 | 3.58 | 151.60 |
| 22803 | 22435 | 9.70 | 148.69 |
| 25192 | 25192 | 0.00 | 147.84 |
| 25688 | 25688 | 0.00 | 150.89 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prednisolone acetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20089-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prednisolone acetate; Prednisoloni acetas

### Special notes

When selecting the *Prednisolone acetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prednisolone acetate | 9 | 14 | 441 |

### Second-stage model

For differentiation of the substance/substance group *Prednisolone acetate* the following second-stage model is used:

- Submodel 08

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prednisolone acetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisone | 72.93 | 50.42 |
| ⋮ | ⋮ | ⋮ |
| Ephedrine hydrochloride | >50 | 146.64 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prednisolone acetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prednisolone acetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Prednisolone acetate | 12091814 | 20784 | 80 | 20120416 |
| Caelo | Prednisolone acetate | 12324502 | 20877 | 40 | 20121112 |
| Caelo | Prednisolone acetate | 13262605 | 21448 | 60 | 20130923 |
| Caelo | Prednisolone acetate | 13262605 | 21450 | 60 | 20130923 |
| Caelo | Prednisolone acetate | 13262605 | 21450SI | 47 | 20130923 |
| Euro OTC | Prednisolone acetate | 1306040 | 21096 | 40 | 20130812 |
| Euro OTC | Prednisolone acetate | 1209028-03 | 21530 | 60 | AR-15-FG-010480-01 |
| Euro OTC | Prednisolone acetate | 1512020 | 22297 | 45 | 20160119* |
| Euro OTC | Prednisolone acetate | 1512020 | 22297SI | 44 | 20160119* |
| Euro OTC | Prednisolone acetate | 2010016 | 25525 | 40 | 20210104* |
| Euro OTC | Prednisolone acetate | 2010016 | 25525SI | 40 | 20210104* |
| Fagron | Prednisolone acetate | 12H14-N07 | 20795 | 40 | 20120829 |
| Fagron | Prednisolone acetate | 12H14-N07 | 20795SI | 49 | 20120829 |
| Fagron | Prednisolone acetate | 15I23-B04-345785 | 24587 | 40 | 20151014 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 685 spectra of 14 reference samples from the substance/substance group *Prednisolone acetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 641 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1178 spectra of 30 reference samples from the substance/substance group *Prednisolone acetate*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Prednisolone acetate | 180673 | 24534 | 40 |
| Caelo | Prednisolone acetate | 20001950 | 25215 | 40 |
| Caelo | Prednisolone acetate | 22001230 | 26129 | 30 |
| Caelo | Prednisolone acetate | 24000952002 | 27580 | 40 |
| Euro OTC | Prednisolone acetate | 1607010 | 22710 | 40 |
| Euro OTC | Prednisolone acetate | 1701041 | 23142 | 40 |
| Euro OTC | Prednisolone acetate | 1805009 | 24133 | 40 |
| Euro OTC | Prednisolone acetate | 1903031 | 24636 | 40 |
| Euro OTC | Prednisolone acetate | 1911014 | 24960 | 40 |
| Euro OTC | Prednisolone acetate | 2201028 | 25954 | 40 |
| Euro OTC | Prednisolone acetate | 2309013 | 27008 | 30 |
| Euro OTC | Prednisolone acetate | 2410006 | 27459 | 30 |
| Fagron | Prednisolone acetate | 21K18-B05-220957 | 26169 | 40 |
| Fagron | Prednisolone acetate | 23G05-B13-228543 | 26916 | 40 |
| Caelo | Prednisolone acetate | 13262605 | 21448SI† | 44 |
| Caelo | Prednisolone acetate | 180673 | 24534SI | 80 |
| Caelo | Prednisolone acetate | 20001950 | 25215SI | 40 |
| Caelo | Prednisolone acetate | 22001230 | 26129SI | 40 |
| Caelo | Prednisolone acetate | 24000952002 | 27580SI | 40 |
| Euro OTC | Prednisolone acetate | 1607010 | 22710SI | 40 |
| Euro OTC | Prednisolone acetate | 1701041 | 23142SI | 24 |
| Euro OTC | Prednisolone acetate | 1805009 | 24133SI | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Prednisolone acetate | 1903031 | 24636SI | 40 |
| Euro OTC | Prednisolone acetate | 1911014 | 24960SI | 40 |
| Euro OTC | Prednisolone acetate | 2201028 | 25954SI | 40 |
| Euro OTC | Prednisolone acetate | 2309013 | 27008SI | 40 |
| Euro OTC | Prednisolone acetate | 2410006 | 27459SI | 30 |
| Fagron | Prednisolone acetate | 15I23-B04-345785 | 24587SI[†] | 40 |
| Fagron | Prednisolone acetate | 21K18-B05-220957 | 26169SI | 30 |
| Fagron | Prednisolone acetate | 23G05-B13-228543 | 26916SI | 40 |

- 211 762 spectra from a total of 4271 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3876 spectra from 1142 *Apo-Ident* customers from 456 batches from the substance/substance group *Prednisolone acetate*.

- Among them are spectra of independent samples from 440 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednisolone acetate | 15398303 | 1 |
| | Prednisolone acetate | 17086101 | 1 |
| | Prednisolone acetate | 2010016-01 | 1 |
| | Prednisolone acetate | 21001844006 | 4 |
| | Prednisolone acetate | 21001844007 | 1 |
| | Prednisolone acetate | 21001844008 | 3 |
| | Prednisolone acetate | 21001844012 | 9 |
| | Prednisolone acetate | 22001230 | 1 |
| | Prednisolone acetate | 22001230001 | 15 |
| | Prednisolone acetate | 22001230002 | 3 |
| | Prednisolone acetate | 22001230003 | 12 |
| | Prednisolone acetate | 22001230004 | 20 |
| | Prednisolone acetate | 22001230005 | 10 |
| | Prednisolone acetate | 22001230007 | 31 |
| | Prednisolone acetate | 22001230008 | 2 |
| | Prednisolone acetate | 22001230009 | 2 |
| | Prednisolone acetate | 22001230010 | 3 |
| | Prednisolone acetate | 2201028 | 3 |
| | Prednisolone acetate | 2201028-01 | 15 |
| | Prednisolone acetate | 2201028-02 | 14 |
| | Prednisolone acetate | 2201028-0201/24P | 1 |
| | Prednisolone acetate | 22I27-B10-223685 | 4 |
| | Prednisolone acetate | 230901301 | 1 |
| | Prednisolone acetate | 2309013-01 | 26 |
| | Prednisolone acetate | 23090-13-01 | 1 |
| | Prednisolone acetate | 23G05-B13-228652 | 1 |
| | Prednisolone acetate | 24000952002 | 14 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednisolone acetate | 24000952003 | 14 |
| | Prednisolone acetate | 2400952002 | 1 |
| | Prednisolone acetate | 2400952003 | 1 |
| | Prednisolone acetate | 2410006-01 | 3 |
| | Prednisolone acetate | 24D29-B04-002377 | 2 |
| | Prednisolone acetate | 30003 | 1 |
| | Prednisolone acetate | B10-2236805 | 2 |
| | Prednisolone acetate | B10-2237606 | 2 |
| | Prednisolone acetate | PA/M/007/20 | 1 |
| | Prednisolone acetate | PAC001/0424 | 1 |
| | Prednisolone acetate | PAC001/0523 | 1 |
| A.H. 23.05.13 ek: 5,40EUR | Prednisolone acetate | 13A07-N07 | 1 |
| A.H.D. | Prednisolone acetate | 14175514 | 1 |
| AEP | Prednisolone acetate | 20001950003 | 2 |
| AHD 06.03.15 | Prednisolone acetate | 14175508 | 1 |
| AHD 23.10.14 EK17,24 | Prednisolone acetate | 13262601 | 1 |
| AHD/EuRho | Prednisolone acetate | 1911014-01 | 2 |
| AHD/Euro | Prednisolone acetate | 1805009-001 | 1 |
| AHD | Prednisolone acetate | 15055202 | 1 |
| AHD | Prednisolone acetate | 17086105 | 1 |
| AHD | Prednisolone acetate | 1903031-01 | 1 |
| AHD | Prednisolone acetate | 22001230001 | 1 |
| AHD | Prednisolone acetate | 22001230002 | 1 |
| AHD | Prednisolone acetate | 22001230003 | 3 |
| AHD | Prednisolone acetate | 22001230004 | 1 |
| AHD | Prednisolone acetate | 22001230005 | 3 |
| AHD | Prednisolone acetate | 22001230007 | 1 |
| AHD | Prednisolone acetate | 2309013-01 | 1 |
| AHD | Prednisolone acetate | 24000952002 | 2 |
| Alliamce Healthcare | Prednisolone acetate | 22001230001 | 1 |
| Alliance Healthcare | Prednisolone acetate | 12091807 | 1 |
| Alliance Healthcare | Prednisolone acetate | 13262605 | 2 |
| Alliance Healthcare | Prednisolone acetate | 1903031-02 | 1 |
| Alliance Healthcare | Prednisolone acetate | 1911014-02 | 2 |
| Alliance Healthcare | Prednisolone acetate | 20001950001 | 1 |
| Alliance Healthcare | Prednisolone acetate | 2010016-01 | 3 |
| Alliance Healthcare | Prednisolone acetate | 22001230007 | 1 |
| Alliance Healthcare | Prednisolone acetate | 2201028-01 | 2 |
| Alliance Healthcare | Prednisolone acetate | 2309013-01 | 1 |
| Alliance | Prednisolone acetate | 22001230004 | 1 |
| Alliance | Prednisolone acetate | 22001230005 | 1 |
| Alliance | Prednisolone acetate | 2201028-01 | 1 |
| Alliance | Prednisolone acetate | 24000952002 | 1 |
| Alliance | Prednisolone acetate | K07A20190507 | 1 |
| AllianceHealthcare | Prednisolone acetate | 15055201 | 1 |
| Allianz Healthcare | Prednisolone acetate | 18067310 | 1 |
| Anuh Pharma | Prednisolone acetate | 21001844006 | 1 |
| ANZAG | Prednisolone acetate | 12091802 | 2 |
| Anzag | Prednisolone acetate | 13A07N07 | 1 |
| Anzag | Prednisolone acetate | 16246812 | 1 |
| Anzag | Prednisolone acetate | 192969005 | 1 |
| Anzag | Prednisolone acetate | 2309013-01 | 1 |
| apo-ident/Noweda | Prednisolone acetate | 2010016-01 | 1 |
| apo-ident/Phoenix | Prednisolone acetate | 190272002 | 1 |
| apo-ident | Prednisolone acetate | 1512020-01 | 1 |
| apo-ident | Prednisolone acetate | 1805009-02 | 1 |
| apomix | Prednisolone acetate | 16246804 | 1 |
| Avik Pharmaceutical ... | Prednisolone acetate | 19C28-B02-361964 | 1 |
| Beiersdorf AG | Prednisolone acetate | 15055201 | 1 |
| Beiersdorf AG | Prednisolone acetate | 15398302 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Prednisolone acetate | 17185601 | 1 |
| Bombastus | Prednisolone acetate | 2255 | 1 |
| cae | Prednisolone acetate | 21001844004 | 1 |
| Caeasar/Loretz,Fa.Gehe | Prednisolone acetate | 14380910 | 1 |
| Cael Sanacorp 05.02.2016 | Prednisolone acetate | 14175509 | 1 |
| Cael Sanacorp 05.02.2016 | Prednisolone acetate | 14380901 | 1 |
| Caeleo/ Kehr | Prednisolone acetate | 21001844002 | 1 |
| Caelo | Prednisolone acetate | | 3 |
| Caelo | Prednisolone acetate | 11080403 | 1 |
| Caelo | Prednisolone acetate | 11158002 | 1 |
| Caelo | Prednisolone acetate | 11158003 | 1 |
| Caelo | Prednisolone acetate | 11L21-N03 | 1 |
| Caelo | Prednisolone acetate | 12001844003 | 1 |
| Caelo | Prednisolone acetate | 1209028-02 | 2 |
| Caelo | Prednisolone acetate | 12091802 | 6 |
| Caelo | Prednisolone acetate | 12091803 | 3 |
| Caelo | Prednisolone acetate | 12091804 | 8 |
| Caelo | Prednisolone acetate | 12091806 | 3 |
| Caelo | Prednisolone acetate | 12091807 | 5 |
| Caelo | Prednisolone acetate | 12091808 | 5 |
| Caelo | Prednisolone acetate | 12091810 | 2 |
| Caelo | Prednisolone acetate | 12091813 | 1 |
| Caelo | Prednisolone acetate | 12091814 | 7 |
| Caelo | Prednisolone acetate | 12091815 | 2 |
| Caelo | Prednisolone acetate | 12324502 | 13 |
| Caelo | Prednisolone acetate | 12324503 | 1 |
| Caelo | Prednisolone acetate | 12324504 | 6 |
| Caelo | Prednisolone acetate | 12324505 | 16 |
| Caelo | Prednisolone acetate | 12324506 | 11 |
| Caelo | Prednisolone acetate | 12324508 | 9 |
| Caelo | Prednisolone acetate | 12324509 | 2 |
| Caelo | Prednisolone acetate | 12324514 | 5 |
| Caelo | Prednisolone acetate | 1234506 | 1 |
| Caelo | Prednisolone acetate | 12L05-N01 | 1 |
| Caelo | Prednisolone acetate | 1306040-01 | 1 |
| Caelo | Prednisolone acetate | 1306040-02 | 1 |
| Caelo | Prednisolone acetate | 13121715 | 1 |
| Caelo | Prednisolone acetate | 13262601 | 17 |
| Caelo | Prednisolone acetate | 13262602 | 8 |
| Caelo | Prednisolone acetate | 13262603 | 8 |
| Caelo | Prednisolone acetate | 13262605 | 13 |
| Caelo | Prednisolone acetate | 13262606 | 4 |
| Caelo | Prednisolone acetate | 13262609 | 4 |
| Caelo | Prednisolone acetate | 13343112 | 1 |
| Caelo | Prednisolone acetate | 1406014-01 | 2 |
| Caelo | Prednisolone acetate | 1406014-02 | 2 |
| Caelo | Prednisolone acetate | 14175508 | 16 |
| Caelo | Prednisolone acetate | 14175509 | 9 |
| Caelo | Prednisolone acetate | 14175512 | 1 |
| Caelo | Prednisolone acetate | 14175513 | 10 |
| Caelo | Prednisolone acetate | 14175514 | 7 |
| Caelo | Prednisolone acetate | 14380302 | 1 |
| Caelo | Prednisolone acetate | 14380901 | 19 |
| Caelo | Prednisolone acetate | 14380902 | 14 |
| Caelo | Prednisolone acetate | 14380903 | 2 |
| Caelo | Prednisolone acetate | 14380904 | 2 |
| Caelo | Prednisolone acetate | 14380905 | 21 |
| Caelo | Prednisolone acetate | 14380909 | 14 |
| Caelo | Prednisolone acetate | 14380910 | 10 |
| Caelo | Prednisolone acetate | 1475509 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolone acetate | 1480905 | 1 |
| Caelo | Prednisolone acetate | 15055201 | 9 |
| Caelo | Prednisolone acetate | 15055202 | 16 |
| Caelo | Prednisolone acetate | 15055203 | 2 |
| Caelo | Prednisolone acetate | 15055206 | 10 |
| Caelo | Prednisolone acetate | 151202001 | 1 |
| Caelo | Prednisolone acetate | 1512020-01 | 4 |
| Caelo | Prednisolone acetate | 1523-B04-336299 | 1 |
| Caelo | Prednisolone acetate | 15298401 | 1 |
| Caelo | Prednisolone acetate | 15344002 | 1 |
| Caelo | Prednisolone acetate | 15396304 | 1 |
| Caelo | Prednisolone acetate | 15398302 | 14 |
| Caelo | Prednisolone acetate | 15398303 | 10 |
| Caelo | Prednisolone acetate | 15398304 | 8 |
| Caelo | Prednisolone acetate | 15398306 | 6 |
| Caelo | Prednisolone acetate | 15398307 | 10 |
| Caelo | Prednisolone acetate | 15398401 | 12 |
| Caelo | Prednisolone acetate | 15398402 | 15 |
| Caelo | Prednisolone acetate | 15398407 | 10 |
| Caelo | Prednisolone acetate | 15398408 | 11 |
| Caelo | Prednisolone acetate | 15B03B05302564 | 1 |
| Caelo | Prednisolone acetate | 15B03-B05-302564 | 2 |
| Caelo | Prednisolone acetate | 16/AKD2 | 1 |
| Caelo | Prednisolone acetate | 160701001 | 3 |
| Caelo | Prednisolone acetate | 1607010-01 | 6 |
| Caelo | Prednisolone acetate | 1616I-02106 | 1 |
| Caelo | Prednisolone acetate | 162446808 | 1 |
| Caelo | Prednisolone acetate | 162468 | 2 |
| Caelo | Prednisolone acetate | 16246801 | 17 |
| Caelo | Prednisolone acetate | 16246802 | 13 |
| Caelo | Prednisolone acetate | 16246803 | 20 |
| Caelo | Prednisolone acetate | 16246803-14317/1 | 1 |
| Caelo | Prednisolone acetate | 16246803-70317/1 | 1 |
| Caelo | Prednisolone acetate | 16246804 | 14 |
| Caelo | Prednisolone acetate | 16246805 | 2 |
| Caelo | Prednisolone acetate | 16246806 | 15 |
| Caelo | Prednisolone acetate | 16246807 | 18 |
| Caelo | Prednisolone acetate | 16246808 | 15 |
| Caelo | Prednisolone acetate | 16246809 | 3 |
| Caelo | Prednisolone acetate | 16246811 | 8 |
| Caelo | Prednisolone acetate | 16246812 | 11 |
| Caelo | Prednisolone acetate | 1624801 | 1 |
| Caelo | Prednisolone acetate | 1624806 | 1 |
| Caelo | Prednisolone acetate | 16248808 | 1 |
| Caelo | Prednisolone acetate | 165246802 | 1 |
| Caelo | Prednisolone acetate | 170104-01 | 1 |
| Caelo | Prednisolone acetate | 170104101 | 2 |
| Caelo | Prednisolone acetate | 1701041-01 | 3 |
| Caelo | Prednisolone acetate | 1701041-02 | 4 |
| Caelo | Prednisolone acetate | 17041802 | 1 |
| Caelo | Prednisolone acetate | 17086101 | 25 |
| Caelo | Prednisolone acetate | 170861015494 | 1 |
| Caelo | Prednisolone acetate | 17086102 | 12 |
| Caelo | Prednisolone acetate | 17086103 | 19 |
| Caelo | Prednisolone acetate | 17086103/1110917 | 1 |
| Caelo | Prednisolone acetate | 17086104 | 26 |
| Caelo | Prednisolone acetate | 17086105 | 26 |
| Caelo | Prednisolone acetate | 17086106 | 2 |
| Caelo | Prednisolone acetate | 17185601 | 30 |
| Caelo | Prednisolone acetate | 171856010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolone acetate | 17185602 | 29 |
| Caelo | Prednisolone acetate | 17185603 | 30 |
| Caelo | Prednisolone acetate | 17185604 | 4 |
| Caelo | Prednisolone acetate | 17401041-02 | 1 |
| Caelo | Prednisolone acetate | 1786103 | 1 |
| Caelo | Prednisolone acetate | 18004401 | 28 |
| Caelo | Prednisolone acetate | 18004402 | 22 |
| Caelo | Prednisolone acetate | 18004403 | 3 |
| Caelo | Prednisolone acetate | 18004903 | 1 |
| Caelo | Prednisolone acetate | 1805009 | 1 |
| Caelo | Prednisolone acetate | 180500901 | 1 |
| Caelo | Prednisolone acetate | 1805009-01 | 6 |
| Caelo | Prednisolone acetate | 1805009-02 | 2 |
| Caelo | Prednisolone acetate | 180500903 | 1 |
| Caelo | Prednisolone acetate | 1805009-03 | 1 |
| Caelo | Prednisolone acetate | 18067301 | 4 |
| Caelo | Prednisolone acetate | 18067302 | 24 |
| Caelo | Prednisolone acetate | 180673025724 | 1 |
| Caelo | Prednisolone acetate | 18067303 | 28 |
| Caelo | Prednisolone acetate | 18067307 | 38 |
| Caelo | Prednisolone acetate | 18067308 | 3 |
| Caelo | Prednisolone acetate | 18067309 | 36 |
| Caelo | Prednisolone acetate | 18067309P-190226-2 | 1 |
| Caelo | Prednisolone acetate | 18067309-P20180115Ma | 1 |
| Caelo | Prednisolone acetate | 18067310 | 32 |
| Caelo | Prednisolone acetate | 18067313 | 1 |
| Caelo | Prednisolone acetate | 18067314 | 31 |
| Caelo | Prednisolone acetate | 18067314P-191022-8 | 1 |
| Caelo | Prednisolone acetate | 18067316 | 1 |
| Caelo | Prednisolone acetate | 18067317 | 21 |
| Caelo | Prednisolone acetate | 18067320 | 47 |
| Caelo | Prednisolone acetate | 18067323 | 2 |
| Caelo | Prednisolone acetate | 18067324 | 28 |
| Caelo | Prednisolone acetate | 18067324-B04 | 1 |
| Caelo | Prednisolone acetate | 18067325 | 6 |
| Caelo | Prednisolone acetate | 18398303 | 1 |
| Caelo | Prednisolone acetate | 1867309 | 1 |
| Caelo | Prednisolone acetate | 1867314 | 1 |
| Caelo | Prednisolone acetate | 19010303 | 1 |
| Caelo | Prednisolone acetate | 1903031-01 | 3 |
| Caelo | Prednisolone acetate | 1911014-01 | 1 |
| Caelo | Prednisolone acetate | 1911014-02 | 1 |
| Caelo | Prednisolone acetate | 19269004 | 2 |
| Caelo | Prednisolone acetate | 192969003 | 30 |
| Caelo | Prednisolone acetate | 192969004 | 34 |
| Caelo | Prednisolone acetate | 192969004P-200220-2 | 1 |
| Caelo | Prednisolone acetate | 192969005 | 38 |
| Caelo | Prednisolone acetate | 19J08-F02-365546 | 1 |
| Caelo | Prednisolone acetate | 19J0B-F02-366051 | 1 |
| Caelo | Prednisolone acetate | 2000019500002 | 1 |
| Caelo | Prednisolone acetate | 20001950001 | 13 |
| Caelo | Prednisolone acetate | 200019500010 | 1 |
| Caelo | Prednisolone acetate | 20001950002 | 18 |
| Caelo | Prednisolone acetate | 20001950003 | 12 |
| Caelo | Prednisolone acetate | 20001950004 | 13 |
| Caelo | Prednisolone acetate | 2000195001 | 1 |
| Caelo | Prednisolone acetate | 2000195004 | 1 |
| Caelo | Prednisolone acetate | 200019550002 | 1 |
| Caelo | Prednisolone acetate | 200034843003 | 1 |
| Caelo | Prednisolone acetate | 20003817016 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolone acetate | 20003843001 | 32 |
| Caelo | Prednisolone acetate | 20003843003 | 45 |
| Caelo | Prednisolone acetate | 2000384300301972024 | 1 |
| Caelo | Prednisolone acetate | 20003843004 | 22 |
| Caelo | Prednisolone acetate | 200038443001 | 1 |
| Caelo | Prednisolone acetate | 200038443003 | 1 |
| Caelo | Prednisolone acetate | 20160727Ma1 | 1 |
| Caelo | Prednisolone acetate | 21001844001 | 1 |
| Caelo | Prednisolone acetate | 21001844002 | 25 |
| Caelo | Prednisolone acetate | 21001844003 | 22 |
| Caelo | Prednisolone acetate | 21001844004 | 16 |
| Caelo | Prednisolone acetate | 21001844006 | 15 |
| Caelo | Prednisolone acetate | 21001844006/221228 | 1 |
| Caelo | Prednisolone acetate | 21001844007 | 24 |
| Caelo | Prednisolone acetate | 21001844008 | 14 |
| Caelo | Prednisolone acetate | 21001844010 | 5 |
| Caelo | Prednisolone acetate | 21001844012 | 1 |
| Caelo | Prednisolone acetate | 21001844013 | 1 |
| Caelo | Prednisolone acetate | 2100184402 | 1 |
| Caelo | Prednisolone acetate | 2100184404 | 1 |
| Caelo | Prednisolone acetate | 2101844002 | 1 |
| Caelo | Prednisolone acetate | 21071808 | 1 |
| Caelo | Prednisolone acetate | 22001230001 | 7 |
| Caelo | Prednisolone acetate | 22001230002 | 8 |
| Caelo | Prednisolone acetate | 22001230003 | 9 |
| Caelo | Prednisolone acetate | 22001230004 | 1 |
| Caelo | Prednisolone acetate | 2200123001 | 1 |
| Caelo | Prednisolone acetate | 2200123002 | 1 |
| Caelo | Prednisolone acetate | 2201028 | 1 |
| Caelo | Prednisolone acetate | 23051812 | 1 |
| Caelo | Prednisolone acetate | 26011905 | 1 |
| Caelo | Prednisolone acetate | 27051301 | 1 |
| Caelo | Prednisolone acetate | 313I-02106 | 1 |
| Caelo | Prednisolone acetate | 32304 | 1 |
| Caelo | Prednisolone acetate | 32304015 | 1 |
| Caelo | Prednisolone acetate | 4313A-02106 | 1 |
| Caelo | Prednisolone acetate | 5031511 | 1 |
| Caelo | Prednisolone acetate | 5398304 | 1 |
| Caelo | Prednisolone acetate | 6021306 | 1 |
| Caelo | Prednisolone acetate | 717Q-02106 | 1 |
| Caelo | Prednisolone acetate | 8067320 | 1 |
| Caelo | Prednisolone acetate | 80673201 | 1 |
| Caelo | Prednisolone acetate | 8699 | 1 |
| Caelo | Prednisolone acetate | F02-3660501 | 1 |
| Caeol/Noweda | Prednisolone acetate | 16246802 | 1 |
| Caesar & Lorenz GmbH | Prednisolone acetate | 21001844006 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 18067310 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 21001844006 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 17185603 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20001950003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 21001844008 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 22001230001 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 192969003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 192969003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 17086105 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 17185601 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20003843003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20001950001 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 21000607004 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20003843001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Prednisolone acetate | 21001844004 | 1 |
| Caesar & Loretz GmbH/E | Prednisolone acetate | 192969005 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 18067320 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 192969005 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20003843003 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednisolone acetate | 18067324 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednisolone acetate | 192969003 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednisolone acetate | 21001844002 | 1 |
| Caesar & Loretz GmbH/Gehe | Prednisolone acetate | 21001844007 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20001950004 | 2 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20003843004 | 3 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 22001230001 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 18067320 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 192969004 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20003843001 | 1 |
| Caesar & Loretz GmbH/Kehr | Prednisolone acetate | 192969004 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 18067320 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20C06-F02-3700407 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 22001230002 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | F12-3742909 | 1 |
| Caesar & Loretz GmbH/Ph | Prednisolone acetate | 192969005 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 1911014-02 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 192969005 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20001950004 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 20003843003 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 21001844003 | 2 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 21001844008 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 22001230001 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 22001230004 | 1 |
| Caesar & Loretz GmbH... | Prednisolone acetate | 22001230002 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 17185603 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 180667317 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067303 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067307 | 5 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067309 | 2 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067310 | 8 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067314 | 7 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067317 | 9 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067320 | 3 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067323 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067324 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 18067325 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 1903031-01 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 192969002 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 192969003 | 9 |
| Caesar & Loretz GmbH | Prednisolone acetate | 192969004 | 8 |
| Caesar & Loretz GmbH | Prednisolone acetate | 192969005 | 15 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20001950001 | 11 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20001950002 | 9 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20001950003 | 7 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20001950004 | 8 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20001950005 | 3 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20003843001 | 11 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20003843002 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20003843003 | 11 |
| Caesar & Loretz GmbH | Prednisolone acetate | 20003843004 | 9 |
| Caesar & Loretz GmbH | Prednisolone acetate | 2001950002 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 21001844002 | 6 |
| Caesar & Loretz GmbH | Prednisolone acetate | 21001844003 | 10 |
| Caesar & Loretz GmbH | Prednisolone acetate | 21001844004 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Prednisolone acetate | 21001844006 | 2 |
| Caesar & Loretz GmbH | Prednisolone acetate | 21001844007 | 3 |
| Caesar & Loretz GmbH | Prednisolone acetate | 21001844008 | 3 |
| Caesar & Loretz GmbH | Prednisolone acetate | 21001844010 | 2 |
| Caesar & Loretz GmbH | Prednisolone acetate | 22001230001 | 3 |
| Caesar & Loretz GmbH | Prednisolone acetate | 22001230002 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 22001230003 | 1 |
| Caesar & Loretz GmbH | Prednisolone acetate | 22001230004 | 1 |
| Caesar & Loretz Hild... | Prednisolone acetate | 18067317 | 1 |
| Caesar & Loretz/Geil... | Prednisolone acetate | 18067320 | 1 |
| Caesar / Ebert & Jacobi | Prednisolone acetate | 17185603 | 1 |
| Caesar Loretz | Prednisolone acetate | 192969005 | 2 |
| Caesar&Loretz GmbH,0... | Prednisolone acetate | 17086103 | 2 |
| Caesar&Loretz GmbH | Prednisolone acetate | 15396408 | 1 |
| Caesar&Loretz GmbH | Prednisolone acetate | 18067324 | 1 |
| Caesar&Loretz GmbH | Prednisolone acetate | 20003843003 | 1 |
| Caesar&Loretz GmbH | Prednisolone acetate | 22001230002 | 1 |
| Caesar&loretz,AHC,29... | Prednisolone acetate | 15398306 | 1 |
| Caesar&loretz,Phoeni... | Prednisolone acetate | | 1 |
| Caesar&loretz,Phoenix | Prednisolone acetate | 13262606 | 1 |
| Caesar&loretz,Phoenix | Prednisolone acetate | 14175513 | 1 |
| Caesar&Loretz,Phönix... | Prednisolone acetate | 15398302 | 1 |
| caesar&loretz,Phönix | Prednisolone acetate | 15055202 | 2 |
| caesar&loretz | Prednisolone acetate | 14380909 | 1 |
| Caesar&Loretz | Prednisolone acetate | 18067320 | 1 |
| Caesar&LoretzGmbH,11... | Prednisolone acetate | 16246803 | 1 |
| Cealo/Gehe | Prednisolone acetate | 20001950002 | 1 |
| Cealo | Prednisolone acetate | 14175513 | 1 |
| cealo | Prednisolone acetate | 18067303 | 1 |
| Cealo | Prednisolone acetate | 19296004 | 1 |
| Cealo | Prednisolone acetate | 192969005 | 1 |
| Cealo | Prednisolone acetate | 20001950001 | 1 |
| Cealo | Prednisolone acetate | 21001844004 | 1 |
| Ceasar & Loretz GmbH... | Prednisolone acetate | 18067303 | 1 |
| celo | Prednisolone acetate | 21001844004 | 1 |
| Delta | Prednisolone acetate | 17086103 | 1 |
| Delta | Prednisolone acetate | 17185602 | 1 |
| Delta | Prednisolone acetate | 18067314 | 1 |
| Ebert & Jacobi | Prednisolone acetate | 15398307 | 1 |
| EuRho / Fiebig | Prednisolone acetate | 1903031-01 | 1 |
| EuRho / Gehe | Prednisolone acetate | 1903031-01 | 1 |
| EuRho/Gehe | Prednisolone acetate | 1805009-03 | 1 |
| EuRho/Noweda | Prednisolone acetate | 18004401 | 1 |
| EuRho/Phönix | Prednisolone acetate | 1805009-03 | 1 |
| EuRho/Phönix | Prednisolone acetate | 1903031-01 | 1 |
| Eurho/Phönix | Prednisolone acetate | 201001601 | 1 |
| EuRho/Phönix | Prednisolone acetate | 201001601 | 1 |
| EuRho/Phönix | Prednisolone acetate | 2010016-01 | 1 |
| Eurho/Sanacorp | Prednisolone acetate | 1805009-01 | 2 |
| EuRho/Sanacorp | Prednisolone acetate | 1903031-01 | 3 |
| EuRho | Prednisolone acetate | 1306040-03 | 1 |
| EuRho | Prednisolone acetate | 1406014-02 | 1 |
| EuRho | Prednisolone acetate | 1512020-01 | 1 |
| EuRho | Prednisolone acetate | 1701041-01 | 1 |
| EuRho | Prednisolone acetate | 170104102 | 1 |
| EuRho | Prednisolone acetate | 1701041-02 | 1 |
| EuRho | Prednisolone acetate | 1805009-01 | 2 |
| EuRho | Prednisolone acetate | 1805009-02 | 1 |
| EuRho | Prednisolone acetate | 1911014-01 | 3 |
| EuRho | Prednisolone acetate | 1911014-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Prednisolone acetate | 2010016-01 | 4 |
| Euro OTC | Prednisolone acetate | | 1 |
| Euro OTC | Prednisolone acetate | 1/01041-01 | 1 |
| Euro OTC | Prednisolone acetate | 1108043-01 | 2 |
| Euro OTC | Prednisolone acetate | 1108043-02 | 13 |
| Euro OTC | Prednisolone acetate | 1203028-03 | 1 |
| Euro OTC | Prednisolone acetate | 1209028 | 1 |
| Euro OTC | Prednisolone acetate | 1209028-01 | 3 |
| Euro OTC | Prednisolone acetate | 1209028-02 | 11 |
| Euro OTC | Prednisolone acetate | 1209028-03 | 2 |
| Euro OTC | Prednisolone acetate | 1305009-01 | 1 |
| Euro OTC | Prednisolone acetate | 1306010-01 | 1 |
| Euro OTC | Prednisolone acetate | 1306040-01 | 22 |
| Euro OTC | Prednisolone acetate | 130604002 | 2 |
| Euro OTC | Prednisolone acetate | 1306040-02 | 14 |
| Euro OTC | Prednisolone acetate | 1306040-03 | 1 |
| Euro OTC | Prednisolone acetate | 1306040-1 | 1 |
| Euro OTC | Prednisolone acetate | 13262601 | 1 |
| Euro OTC | Prednisolone acetate | 13262606 | 1 |
| Euro OTC | Prednisolone acetate | 1406012-02 | 1 |
| Euro OTC | Prednisolone acetate | 1406014-01 | 17 |
| Euro OTC | Prednisolone acetate | 1406014-02 | 13 |
| Euro OTC | Prednisolone acetate | 1407010-01 | 1 |
| Euro OTC | Prednisolone acetate | 14406014-02 | 1 |
| Euro OTC | Prednisolone acetate | 1460614-01 | 1 |
| Euro OTC | Prednisolone acetate | 1501036 | 1 |
| Euro OTC | Prednisolone acetate | 150103601 | 3 |
| Euro OTC | Prednisolone acetate | 1501036-01 | 20 |
| Euro OTC | Prednisolone acetate | 150103602 | 1 |
| Euro OTC | Prednisolone acetate | 1501036-02 | 35 |
| Euro OTC | Prednisolone acetate | 151202001 | 1 |
| Euro OTC | Prednisolone acetate | 1512020-01 | 34 |
| Euro OTC | Prednisolone acetate | 1607010 | 1 |
| Euro OTC | Prednisolone acetate | 160701001 | 2 |
| Euro OTC | Prednisolone acetate | 1607010-01 | 97 |
| Euro OTC | Prednisolone acetate | 1607010-10 | 1 |
| Euro OTC | Prednisolone acetate | 161005PA | 1 |
| Euro OTC | Prednisolone acetate | 16246801 | 2 |
| Euro OTC | Prednisolone acetate | 170104-02 | 1 |
| Euro OTC | Prednisolone acetate | 1701041 | 2 |
| Euro OTC | Prednisolone acetate | 170104101 | 3 |
| Euro OTC | Prednisolone acetate | 1701041-01 | 54 |
| Euro OTC | Prednisolone acetate | 170104102 | 1 |
| Euro OTC | Prednisolone acetate | 1701041-02 | 55 |
| Euro OTC | Prednisolone acetate | 1701041-03 | 8 |
| Euro OTC | Prednisolone acetate | 170413PA/1607010-01 | 1 |
| Euro OTC | Prednisolone acetate | 17086101 | 1 |
| Euro OTC | Prednisolone acetate | 18004403 | 1 |
| Euro OTC | Prednisolone acetate | 1805009 | 5 |
| Euro OTC | Prednisolone acetate | 1805009-01 | 57 |
| Euro OTC | Prednisolone acetate | 1805009-02 | 39 |
| Euro OTC | Prednisolone acetate | 1805009-03 | 14 |
| Euro OTC | Prednisolone acetate | 18050099-01 | 1 |
| Euro OTC | Prednisolone acetate | 180509-01 | 1 |
| Euro OTC | Prednisolone acetate | 180509-03 | 1 |
| Euro OTC | Prednisolone acetate | 18067302 | 1 |
| Euro OTC | Prednisolone acetate | 18067320 | 3 |
| Euro OTC | Prednisolone acetate | 1903031 | 6 |
| Euro OTC | Prednisolone acetate | 190303101 | 4 |
| Euro OTC | Prednisolone acetate | 1903031-01 | 93 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Prednisolone acetate | 190303102 | 1 |
| Euro OTC | Prednisolone acetate | 1903031-02 | 27 |
| Euro OTC | Prednisolone acetate | 1911014 | 1 |
| Euro OTC | Prednisolone acetate | 191101401 | 3 |
| Euro OTC | Prednisolone acetate | 1911014-01 | 105 |
| Euro OTC | Prednisolone acetate | 191101402 | 3 |
| Euro OTC | Prednisolone acetate | 1911014-02 | 45 |
| Euro OTC | Prednisolone acetate | 1911014-03 | 1 |
| Euro OTC | Prednisolone acetate | 191104-01 | 1 |
| Euro OTC | Prednisolone acetate | 191104-02 | 1 |
| Euro OTC | Prednisolone acetate | 19111014 | 1 |
| Euro OTC | Prednisolone acetate | 2(1903031-01) | 1 |
| Euro OTC | Prednisolone acetate | 200540 | 2 |
| Euro OTC | Prednisolone acetate | 2010010-01 | 1 |
| Euro OTC | Prednisolone acetate | 201001601 | 4 |
| Euro OTC | Prednisolone acetate | 2010016-01 | 113 |
| Euro OTC | Prednisolone acetate | 20-10016-01 | 1 |
| Euro OTC | Prednisolone acetate | 2201028 | 1 |
| Euro OTC | Prednisolone acetate | 2201028-01 | 52 |
| Euro OTC | Prednisolone acetate | 2201028-02 | 4 |
| Euro OTC | Prednisolone acetate | 2201028-1 | 1 |
| Euro OTC | Prednisolone acetate | 220128-01 | 1 |
| Euro OTC | Prednisolone acetate | 221028-01 | 1 |
| Euro OTC | Prednisolone acetate | 2215I-02106 | 1 |
| Euro OTC | Prednisolone acetate | 2413Q02106 | 1 |
| Euro OTC | Prednisolone acetate | 2507212106 | 1 |
| Euro OTC | Prednisolone acetate | 2517Q-02106 | 1 |
| Euro OTC | Prednisolone acetate | 2714U-02106 | 1 |
| Euro OTC | Prednisolone acetate | 289295 | 1 |
| Euro OTC | Prednisolone acetate | 2918E-02106 | 1 |
| Euro OTC | Prednisolone acetate | 5012I-02106 | 1 |
| Euro OTC | Prednisolone acetate | 514U2106 | 1 |
| Euro OTC | Prednisolone acetate | 711212106 | 1 |
| Euro OTC | Prednisolone acetate | 911014-021 | 1 |
| Euro OTC | Prednisolone acetate | K07A20140304M | 1 |
| Euro OTC | Prednisolone acetate | K07A20170803M | 1 |
| Euro OTC | Prednisolone acetate | K07A20190507 | 7 |
| Euro OTC | Prednisolone acetate | K07D20161003M | 1 |
| Euro OTC | Prednisolone acetate | P161 | 1 |
| Euro/ Gehe | Prednisolone acetate | 1911014-02 | 1 |
| EUro/AHD | Prednisolone acetate | 1306040-01 | 1 |
| EUro/AHD | Prednisolone acetate | 1306040-02 | 1 |
| Euro/Phönix | Prednisolone acetate | 1805009-02 | 1 |
| Euro/Sana | Prednisolone acetate | 1805009-01 | 1 |
| Euro/Sanacorp | Prednisolone acetate | 1805009-02 | 1 |
| Euro/Sanacorp | Prednisolone acetate | 1911014-01 | 2 |
| Euro/Sanacorp | Prednisolone acetate | 20J01-F12-374299 | 1 |
| EuRoh/ Gehe | Prednisolone acetate | 18004402 | 1 |
| Euroo/Gehe | Prednisolone acetate | 1501036-02 | 1 |
| Fa.Phönix | Prednisolone acetate | 18067309 | 1 |
| Fa.Phönix | Prednisolone acetate | 2201028-01 | 4 |
| fagro | Prednisolone acetate | 15B03-B05-302564 | 1 |
| Fagron | Prednisolone acetate | | 3 |
| Fagron | Prednisolone acetate | 113Q-02106 | 1 |
| Fagron | Prednisolone acetate | 115B03-B05-308582 | 1 |
| Fagron | Prednisolone acetate | 11A31-N03 | 1 |
| Fagron | Prednisolone acetate | 11I09N-08 | 1 |
| Fagron | Prednisolone acetate | 11I09-N08 | 1 |
| Fagron | Prednisolone acetate | 12324502 | 1 |
| Fagron | Prednisolone acetate | 12C19-N03 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednisolone acetate | 12C19-N03 | 1 |
| Fagron | Prednisolone acetate | 12G25-N05 | 5 |
| Fagron | Prednisolone acetate | 12h14-n07 | 1 |
| Fagron | Prednisolone acetate | 12H14-N07 | 4 |
| Fagron | Prednisolone acetate | 12H14-NO7 | 1 |
| Fagron | Prednisolone acetate | 12J10/N05 | 1 |
| Fagron | Prednisolone acetate | 12J10-N05 | 1 |
| Fagron | Prednisolone acetate | 12k20-b04293971 | 1 |
| Fagron | Prednisolone acetate | 12L05-N01 | 5 |
| Fagron | Prednisolone acetate | 12L11-B04-286905 | 1 |
| Fagron | Prednisolone acetate | 12L11-B40 | 1 |
| Fagron | Prednisolone acetate | 12L11-B40-286905 | 10 |
| Fagron | Prednisolone acetate | 13262605 | 1 |
| Fagron | Prednisolone acetate | 13a07n07 | 1 |
| Fagron | Prednisolone acetate | 13A07-N07 | 7 |
| Fagron | Prednisolone acetate | 13D03-N06 | 1 |
| Fagron | Prednisolone acetate | 13K20-B04-289494 | 2 |
| Fagron | Prednisolone acetate | 13K20-B04-289495 | 3 |
| Fagron | Prednisolone acetate | 13K20-B04-293970 | 1 |
| Fagron | Prednisolone acetate | 13K20-B04-293971 | 3 |
| Fagron | Prednisolone acetate | 14380909 | 1 |
| Fagron | Prednisolone acetate | 14D04-B03-299294 | 4 |
| Fagron | Prednisolone acetate | 14D04B03299295 | 1 |
| Fagron | Prednisolone acetate | 14G30-B13 | 2 |
| Fagron | Prednisolone acetate | 14G30-B13-299293 | 5 |
| Fagron | Prednisolone acetate | 14G30-B13-302562 | 1 |
| Fagron | Prednisolone acetate | 15/23-B04-334668 | 1 |
| Fagron | Prednisolone acetate | 15/23-B04-334688 | 1 |
| Fagron | Prednisolone acetate | 15/23-B04-334702 | 1 |
| Fagron | Prednisolone acetate | 15/23-B04-336299 | 1 |
| Fagron | Prednisolone acetate | 15/23-B04-341793 | 1 |
| Fagron | Prednisolone acetate | 15/23-B04-345785 | 1 |
| Fagron | Prednisolone acetate | 15055201 | 1 |
| Fagron | Prednisolone acetate | 1523-B04 | 1 |
| Fagron | Prednisolone acetate | 1523-b04-345785 | 1 |
| Fagron | Prednisolone acetate | 15-23-B04-346700 | 1 |
| Fagron | Prednisolone acetate | 15398401 | 1 |
| Fagron | Prednisolone acetate | 15803-B05 | 1 |
| Fagron | Prednisolone acetate | 15B03_B05_302564 | 2 |
| Fagron | Prednisolone acetate | 15B03-B05 | 3 |
| Fagron | Prednisolone acetate | 15b03-b05-302564 | 1 |
| Fagron | Prednisolone acetate | 15B03B05302564 | 1 |
| Fagron | Prednisolone acetate | 15B03-B05-302564 | 17 |
| Fagron | Prednisolone acetate | 15B03-B05-302566 | 3 |
| Fagron | Prednisolone acetate | 15B03-B05-308574 | 2 |
| Fagron | Prednisolone acetate | 15B03-B05-308582 | 9 |
| Fagron | Prednisolone acetate | 15BO3-B05-302564 | 1 |
| Fagron | Prednisolone acetate | 15F29-B07-317179 | 4 |
| Fagron | Prednisolone acetate | 15F29-B07-321001 | 2 |
| Fagron | Prednisolone acetate | 15F29-B07-323268 | 2 |
| Fagron | Prednisolone acetate | 15I23-B04 | 2 |
| Fagron | Prednisolone acetate | 15I23-B04-327929 | 1 |
| Fagron | Prednisolone acetate | 15I23-B04-331154 | 8 |
| Fagron | Prednisolone acetate | 15I23-B04-334688 | 1 |
| Fagron | Prednisolone acetate | 15I23-B04-334702 | 4 |
| Fagron | Prednisolone acetate | 15i23-b04-336299 | 1 |
| Fagron | Prednisolone acetate | 15I23-B04-336299 | 2 |
| Fagron | Prednisolone acetate | 15I23-B04-340335 | 1 |
| Fagron | Prednisolone acetate | 15I23-B04-341793 | 2 |
| Fagron | Prednisolone acetate | 15I23-B04-345785 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prednisolone acetate | 15I23-B04-346700 | 1 |
| Fagron | Prednisolone acetate | 1512351-b04-336299 | 1 |
| Fagron | Prednisolone acetate | 15123-B04-324088 | 1 |
| Fagron | Prednisolone acetate | 15123-B04-327929 | 1 |
| Fagron | Prednisolone acetate | 15123-B04-341793 | 1 |
| Fagron | Prednisolone acetate | 15123-B4-334688 | 1 |
| Fagron | Prednisolone acetate | 1607010-01 | 1 |
| Fagron | Prednisolone acetate | 17189601 | 1 |
| Fagron | Prednisolone acetate | 1805009-01 | 1 |
| Fagron | Prednisolone acetate | 180713a | 1 |
| Fagron | Prednisolone acetate | 1911014-01 | 1 |
| Fagron | Prednisolone acetate | 19C28-B02-361965 | 1 |
| Fagron | Prednisolone acetate | 19J08 | 1 |
| Fagron | Prednisolone acetate | 19J08-F02 | 2 |
| Fagron | Prednisolone acetate | 19J08-F02-365546 | 1 |
| Fagron | Prednisolone acetate | 19J08-F02-366051 | 1 |
| Fagron | Prednisolone acetate | 200540-0013 | 1 |
| Fagron | Prednisolone acetate | 20C06-F02 | 3 |
| Fagron | Prednisolone acetate | 20C06-F02-370047 | 2 |
| Fagron | Prednisolone acetate | 20C06-F02-370049 | 4 |
| Fagron | Prednisolone acetate | 20J01-F12 | 1 |
| Fagron | Prednisolone acetate | 20J01-F12-374299 | 2 |
| Fagron | Prednisolone acetate | 20J01-F12-374300 | 3 |
| Fagron | Prednisolone acetate | 20J01-F12-374302 | 1 |
| Fagron | Prednisolone acetate | 20J02-F12 | 1 |
| Fagron | Prednisolone acetate | 21K18-B05-220957 | 3 |
| Fagron | Prednisolone acetate | 5444 | 1 |
| Fagron | Prednisolone acetate | 6082013D | 1 |
| Fagron | Prednisolone acetate | F02-3700409 | 2 |
| Fagron | Prednisolone acetate | F12-3742909 | 1 |
| Fagron | Prednisolone acetate | F12-374299 | 1 |
| Fagron | Prednisolone acetate | F12-3743000 | 3 |
| Fagron | Prednisolone acetate | K07A20130903M | 1 |
| Fagron | Prednisolone acetate | K07D20150105M | 2 |
| Fagron | Prednisolone acetate | K07D20150503M | 3 |
| Fagron | Prednisolone acetate | pa/m/013/19 | 1 |
| Fagron | Prednisolone acetate | PA/M/016/19 | 2 |
| Faoron/noweda | Prednisolone acetate | 12L11-B40-286905 | 3 |
| Fargo/Noweda | Prednisolone acetate | 15I23-B04-345785 | 2 |
| Fargo | Prednisolone acetate | 12025-N05 | 1 |
| Fargon | Prednisolone acetate | 13A07-N07 | 1 |
| Fiebig | Prednisolone acetate | 1501036-01 | 1 |
| Fiebig | Prednisolone acetate | 18067303 | 1 |
| Fiebig | Prednisolone acetate | 18067307 | 1 |
| Fiebig | Prednisolone acetate | 18067317 | 1 |
| Finteler Apotheke | Prednisolone acetate | 16246812 | 1 |
| Finteler Apotheke | Prednisolone acetate | 17086103 | 1 |
| Fragron | Prednisolone acetate | K07A20131101M | 1 |
| Gehe / EuRho | Prednisolone acetate | 1911014-02 | 1 |
| GEHE 03.07.2014 | Prednisolone acetate | 13262605 | 1 |
| Gehe amax | Prednisolone acetate | 17086101 | 2 |
| Gehe amax | Prednisolone acetate | 1911014-01 | 1 |
| Gehe Rostock | Prednisolone acetate | 2201028 | 1 |
| Gehe/EuRho 10.09.2021 | Prednisolone acetate | 2010016-01 | 2 |
| Gehe/EuRo | Prednisolone acetate | 1701041-02 | 1 |
| Gehe/EuRoh | Prednisolone acetate | 191101402 | 1 |
| Gehe | Prednisolone acetate | 1209028-01 | 1 |
| Gehe | Prednisolone acetate | 1209028-02 | 2 |
| Gehe | Prednisolone acetate | 12H14-N07 | 1 |
| Gehe | Prednisolone acetate | 13262609 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Prednisolone acetate | 1406014-01 | 1 |
| Gehe | Prednisolone acetate | 1501036-02 | 2 |
| Gehe | Prednisolone acetate | 1512020-01 | 1 |
| Gehe | Prednisolone acetate | 15B03-B05-302566 | 1 |
| Gehe | Prednisolone acetate | 15I23-B04-327929 | 1 |
| Gehe | Prednisolone acetate | 160701001 | 1 |
| Gehe | Prednisolone acetate | 1607010-01 | 1 |
| Gehe | Prednisolone acetate | 16246803 | 2 |
| Gehe | Prednisolone acetate | 16246806 | 2 |
| GEHE | Prednisolone acetate | 16246807 | 1 |
| Gehe | Prednisolone acetate | 16246812 | 1 |
| Gehe | Prednisolone acetate | 1701041-01 | 2 |
| Gehe | Prednisolone acetate | 1701041-02 | 2 |
| Gehe | Prednisolone acetate | 17185601 | 1 |
| GEHE | Prednisolone acetate | 17185601 | 1 |
| Gehe | Prednisolone acetate | 17185602 | 2 |
| Gehe | Prednisolone acetate | 1805009-01 | 1 |
| Gehe | Prednisolone acetate | 1805009-03 | 1 |
| GEHE | Prednisolone acetate | 18067302 | 1 |
| Gehe | Prednisolone acetate | 18067303 | 2 |
| Gehe | Prednisolone acetate | 18067309 | 1 |
| Gehe | Prednisolone acetate | 18067310 | 1 |
| Gehe | Prednisolone acetate | 18067314 | 2 |
| Gehe | Prednisolone acetate | 1903031-01 | 1 |
| GEHE | Prednisolone acetate | 1903031-01 | 1 |
| Gehe | Prednisolone acetate | 1911014-01 | 2 |
| Gehe | Prednisolone acetate | 192969004 | 1 |
| Gehe | Prednisolone acetate | 2010016-01 | 2 |
| Gehe | Prednisolone acetate | 22001230004 | 2 |
| Gehe | Prednisolone acetate | 2201028 | 1 |
| Gehe | Prednisolone acetate | 2201028-01 | 2 |
| Gehe | Prednisolone acetate | 2201028-02 | 3 |
| Gehe | Prednisolone acetate | 2309013-01 | 2 |
| Gehe | Prednisolone acetate | 24000952003/32/25P | 1 |
| Gehe | Prednisolone acetate | 24000952006 | 1 |
| gehe | Prednisolone acetate | 2410006-01 | 1 |
| Gehe | Prednisolone acetate | 2410006-01 | 2 |
| Gehe-Berlin | Prednisolone acetate | 2309013-01 | 3 |
| Gutenberg-Apotheke | Prednisolone acetate | 12L11-B40-286915 | 2 |
| Hanan/Phoenix | Prednisolone acetate | K07A20180303M | 1 |
| Henan / Gehe | Prednisolone acetate | 1607010-01 | 2 |
| Henan / Noweda | Prednisolone acetate | 20001950002 | 2 |
| Henan Lihua Pharm/AHD | Prednisolone acetate | 18067310 | 1 |
| Henan Lihua Pharmace... | Prednisolone acetate | 14G30-B13 | 1 |
| Henan Lihua Pharmace... | Prednisolone acetate | 1903031-01 | 1 |
| Henan Lihua Pharmace... | Prednisolone acetate | 2010016-01 | 1 |
| Henan Lihua Pharmace... | Prednisolone acetate | 2201028-01 | 3 |
| Henan Lihua/Phönix | Prednisolone acetate | 1911014-02 | 1 |
| Henan Lihus Pharm. C... | Prednisolone acetate | 1903031-0 | 1 |
| Henan Lihus Pharm. C... | Prednisolone acetate | 1911014-02 | 1 |
| Henan LP / Gehe | Prednisolone acetate | 192969005 | 1 |
| Henan/Alliance | Prednisolone acetate | 18067314 | 1 |
| Henan/Noweda | Prednisolone acetate | K07A20170803M | 1 |
| Henan/Noweda | Prednisolone acetate | K07A20180603M | 2 |
| Henan/Phoenix | Prednisolone acetate | K07A20190507 | 2 |
| holdermann euro | Prednisolone acetate | 1209028-02 | 2 |
| Holdermann | Prednisolone acetate | 24000952003 | 1 |
| Jenne | Prednisolone acetate | 24000952003 | 1 |
| Kehr Holdermann | Prednisolone acetate | 22001230010 | 1 |
| Kehr | Prednisolone acetate | 1406014-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Krieger | Prednisolone acetate | 22001230009 | 2 |
| L30 | Prednisolone acetate | 18004402 | 1 |
| L30 | Prednisolone acetate | 18067303 | 1 |
| Lihua Pharm | Prednisolone acetate | K07A20140302M | 1 |
| Lihua Pharma | Prednisolone acetate | 1406014-01 | 1 |
| Max Jenne/Euro | Prednisolone acetate | 1911014-01 | 1 |
| Nachprüfung | Prednisolone acetate | 1019I-02106 | 1 |
| Nachprüfung | Prednisolone acetate | 2082019-2 | 1 |
| NMoweda | Prednisolone acetate | 2201028-01 | 1 |
| Noweda 13.11. EK 17,81 | Prednisolone acetate | ko7A20200901 | 2 |
| Noweda 18.05.2015 | Prednisolone acetate | 14D04-B03-299294 | 1 |
| Noweda Taucha | Prednisolone acetate | 190303101 | 1 |
| Noweda/EuRo | Prednisolone acetate | 1607010-01 | 1 |
| Noweda | Prednisolone acetate | 1209028-01 | 1 |
| Noweda | Prednisolone acetate | 12324506 | 1 |
| Noweda | Prednisolone acetate | 12L11-B40-286905 | 1 |
| noweda | Prednisolone acetate | 14175513 | 1 |
| Noweda | Prednisolone acetate | 15055202 | 1 |
| Noweda | Prednisolone acetate | 1512020-1 | 1 |
| Noweda | Prednisolone acetate | 1523-B04-334688 | 1 |
| Noweda | Prednisolone acetate | 15398303 | 1 |
| Noweda | Prednisolone acetate | 1701041-02 | 1 |
| Noweda | Prednisolone acetate | 17010410203707556 | 1 |
| Noweda | Prednisolone acetate | 17185602 | 1 |
| Noweda | Prednisolone acetate | 1805009-01 | 1 |
| Noweda | Prednisolone acetate | 18067302 | 1 |
| Noweda | Prednisolone acetate | 18067325 | 1 |
| Noweda | Prednisolone acetate | 1903031-01 | 2 |
| Noweda | Prednisolone acetate | 1903301_01 | 1 |
| Noweda | Prednisolone acetate | 191101401 | 1 |
| Noweda | Prednisolone acetate | 1911014-01 | 5 |
| Noweda | Prednisolone acetate | 1911014-02 | 3 |
| Noweda | Prednisolone acetate | 192969003 | 1 |
| Noweda | Prednisolone acetate | 192969004 | 2 |
| Noweda | Prednisolone acetate | 19J08-F02-366051 | 1 |
| Noweda | Prednisolone acetate | 2010016-01 | 3 |
| Noweda | Prednisolone acetate | 22001230001 | 2 |
| Noweda | Prednisolone acetate | 22001230002 | 1 |
| Noweda | Prednisolone acetate | 22001230004 | 1 |
| Noweda | Prednisolone acetate | 22001230005 | 1 |
| Noweda | Prednisolone acetate | 22001230007 | 2 |
| Noweda | Prednisolone acetate | 22001230009 | 1 |
| Noweda | Prednisolone acetate | 2201028 | 1 |
| Noweda | Prednisolone acetate | 2201028-01 | 8 |
| Noweda | Prednisolone acetate | 2201028-02 | 5 |
| Noweda | Prednisolone acetate | 230901301 | 1 |
| Noweda | Prednisolone acetate | 2309013-01 | 8 |
| Noweda | Prednisolone acetate | 24000952002 | 2 |
| Noweda | Prednisolone acetate | K07D20150105M | 1 |
| Phoenix | Prednisolone acetate | | 2 |
| Phoenix | Prednisolone acetate | 12L11-B40-286905 | 1 |
| Phoenix | Prednisolone acetate | 14380905 | 1 |
| Phoenix | Prednisolone acetate | 17185601 | 1 |
| Phoenix | Prednisolone acetate | 17185602 | 2 |
| Phoenix | Prednisolone acetate | 18067310 | 1 |
| Phoenix | Prednisolone acetate | 18067314 | 2 |
| Phoenix | Prednisolone acetate | 1911014-01 | 1 |
| Phoenix | Prednisolone acetate | 1911014-02 | 1 |
| Phoenix | Prednisolone acetate | 192969004 | 2 |
| Phoenix | Prednisolone acetate | 1972024 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Prednisolone acetate | 20001950001 | 1 |
| phoenix | Prednisolone acetate | 20003843003 | 2 |
| Phoenix | Prednisolone acetate | 20003843003 | 1 |
| Phoenix | Prednisolone acetate | 200540 | 1 |
| Phoenix | Prednisolone acetate | 2010016-01 | 1 |
| Phoenix | Prednisolone acetate | 2010016-1 | 1 |
| Phoenix | Prednisolone acetate | 21001844002 | 1 |
| Phoenix | Prednisolone acetate | 22001230001 | 1 |
| Phoenix | Prednisolone acetate | 22001230003 | 1 |
| Phoenix | Prednisolone acetate | 22001230005 | 1 |
| Phoenix | Prednisolone acetate | 2200123004 | 1 |
| Phoenix | Prednisolone acetate | 2201028-01 | 2 |
| Phoenix | Prednisolone acetate | 2201028-02 | 2 |
| Phoenix | Prednisolone acetate | 2309013-01 | 1 |
| Phoenix | Prednisolone acetate | 3369 | 1 |
| Phönix 09.05.2019 | Prednisolone acetate | 1805009-02 | 1 |
| Phönix 17.05.2019 | Prednisolone acetate | 1805009-01 | 2 |
| Phönix 23.08.2019 | Prednisolone acetate | 18067320 | 1 |
| Phönix Gotha | Prednisolone acetate | 18067310 | 1 |
| Phönix Gotha | Prednisolone acetate | 18067314 | 1 |
| Phönix W.E:17.03.18 ... | Prednisolone acetate | 17185601 | 1 |
| Phönix, Avik Pharmac... | Prednisolone acetate | 19J08-F02-365543 | 1 |
| Phönix/Noweda | Prednisolone acetate | 21001844007 | 2 |
| Phönix | Prednisolone acetate | 11158008 | 1 |
| Phönix | Prednisolone acetate | 1209028-02 | 1 |
| Phönix | Prednisolone acetate | 12324506 | 1 |
| phönix | Prednisolone acetate | 14380902 | 2 |
| phönix | Prednisolone acetate | 14380910 | 1 |
| phönix | Prednisolone acetate | 1438910 | 1 |
| phönix | Prednisolone acetate | 1512020-01 | 1 |
| phönix | Prednisolone acetate | 15398303 | 1 |
| Phönix | Prednisolone acetate | 15398303 | 1 |
| phönix | Prednisolone acetate | 15398402 | 1 |
| phönix | Prednisolone acetate | 16246803 | 3 |
| Phönix | Prednisolone acetate | 16246804 | 1 |
| phönix | Prednisolone acetate | 16246806 | 1 |
| phönix | Prednisolone acetate | 16246807 | 1 |
| Phönix | Prednisolone acetate | 17185602 | 2 |
| Phönix | Prednisolone acetate | 17185603 | 1 |
| Phönix | Prednisolone acetate | 1805009-01 | 1 |
| Phönix | Prednisolone acetate | 18067303 | 3 |
| Phönix | Prednisolone acetate | 18067317 | 1 |
| Phönix | Prednisolone acetate | 18067320 | 1 |
| PHÖNIX | Prednisolone acetate | 18067320 | 1 |
| Phönix | Prednisolone acetate | 1903031-01 | 1 |
| Phönix | Prednisolone acetate | 192969004 | 1 |
| Phönix | Prednisolone acetate | 192969005 | 2 |
| Phönix | Prednisolone acetate | 20001950001 | 1 |
| Phönix | Prednisolone acetate | 20003843003 | 1 |
| Phönix | Prednisolone acetate | 2001950001 | 1 |
| Phönix | Prednisolone acetate | 21001844002 | 2 |
| Phönix | Prednisolone acetate | 21001844012 | 1 |
| Phönix | Prednisolone acetate | 2200001230007 | 1 |
| Phönix | Prednisolone acetate | 22001230004 | 1 |
| Phönix | Prednisolone acetate | 2201028-02 | 1 |
| Phönix | Prednisolone acetate | 2309012-01 | 1 |
| Phönix | Prednisolone acetate | 2309013-01 | 1 |
| Phönix | Prednisolone acetate | 24000952002 | 1 |
| PhönixWE:10.02.2017 ... | Prednisolone acetate | 16246806 | 1 |
| Post Apotheke | Prednisolone acetate | 18067301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Röntgen | Prednisolone acetate | 1911014-02 | 1 |
| Röntgen | Prednisolone acetate | 192969004 | 1 |
| Sana | Prednisolone acetate | 15L23B04345785 | 1 |
| Sanacorp 07.06.2019 … | Prednisolone acetate | 18067307 | 1 |
| Sanacorp 14.03.2017 … | Prednisolone acetate | 16246802 | 1 |
| Sanacorp | Prednisolone acetate | 12091808 | 1 |
| sanacorp | Prednisolone acetate | 14380909 | 1 |
| Sanacorp | Prednisolone acetate | 15055206 | 1 |
| Sanacorp | Prednisolone acetate | 15398408 | 1 |
| Sanacorp | Prednisolone acetate | 15123-B04-334688 | 2 |
| Sanacorp | Prednisolone acetate | 15123-B04-341793 | 1 |
| Sanacorp | Prednisolone acetate | 17086104 | 1 |
| Sanacorp | Prednisolone acetate | 17185601 | 1 |
| Sanacorp | Prednisolone acetate | 17185602 | 1 |
| Sanacorp | Prednisolone acetate | 17185603 | 1 |
| Sanacorp | Prednisolone acetate | 18067303 | 2 |
| Sanacorp | Prednisolone acetate | 18067307 | 1 |
| Sanacorp | Prednisolone acetate | 18067309 | 2 |
| Sanacorp | Prednisolone acetate | 19003031-01 | 1 |
| Sanacorp | Prednisolone acetate | 1911014-01 | 1 |
| sanacorp | Prednisolone acetate | 19J08-F02-365542 | 1 |
| sanacorp | Prednisolone acetate | 200607 | 1 |
| Sanacorp | Prednisolone acetate | 20J01-F12-3743000 | 1 |
| Sanacorp | Prednisolone acetate | 21001844012 | 1 |
| Sanacorp | Prednisolone acetate | 22001230001 | 1 |
| Sanacorp | Prednisolone acetate | 22001230002 | 1 |
| Sanacorp | Prednisolone acetate | 22001230003 | 1 |
| Sanacorp | Prednisolone acetate | 2201028-01 | 1 |
| Sanacorp | Prednisolone acetate | 2309013-01 | 4 |
| Sanacorp | Prednisolone acetate | 24000952002 | 2 |
| Sanacorp | Prednisolone acetate | K07A20200902 | 1 |
| Sanofi / Gehe | Prednisolone acetate | 16246801 | 1 |
| Spangro 08.05.2018 | Prednisolone acetate | 17185601 | 1 |
| Spangro 30.5.14 | Prednisolone acetate | 13262606 | 1 |
| Symbiotica Spec./Phönix | Prednisolone acetate | 1306040-02 | 1 |
| Symbiotika/Anzag | Prednisolone acetate | 1306040-01 | 1 |
| VDL;7,15EUR, 21:06:14 | Prednisolone acetate | 13262602 | 1 |
| Wolf-Apotheke | Prednisolone acetate | 14380911 | 1 |
| xxx | Prednisolone acetate | 1701041-01 | 2 |

- 253 010 spectra from 1665 *Apo-Ident* customers from a total of 51 711 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Prednisolone acetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prednisolone acetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 685 | 0 | 157 641 |
| **Type B** | 0 | 1178 | 0 | 211 762 |
| **Type C** | 0 | 3863 | 13 | 253 010 |

The substance/substance group *Prednisolone acetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1241 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4907 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6646 % (> 99.5872 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20784 | 22297 | 8.85 | 85.50 |
| 20795 | 22297 | 9.67 | 78.20 |
| 20877 | 22297 | 10.81 | 83.66 |
| 21096 | 21530 | 5.91 | 79.84 |
| 21448 | 22297 | 7.39 | 81.75 |
| 21450 | 22297 | 7.34 | 80.55 |
| 21530 | 21530 | 0.00 | 77.65 |
| 22297 | 22297 | 0.00 | 82.75 |
| 24587 | 22297 | 14.30 | 76.16 |
| 25525 | 25525 | 0.00 | 78.30 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prednisolone hydrogen succinate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20838-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prednisolone hydrogen succinate; Prednisoloni hydrogenosuccinas

### Special notes

When selecting the *Prednisolone hydrogen succinate* substance/substance group, the following information is displayed to the user:

- Advice: Currently no longer available from major pharmaceutical manufacturers. Therefore, batch maintenance is currently not possible.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prednisolone hydrogen succinate | 3 | 2 | 10 |

### Second-stage model

For differentiation of the substance/substance group *Prednisolone hydrogen succinate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prednisolone hydrogen succinate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Estriol | 80.49 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prednisolone hydrogen succinate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prednisolone hydrogen succinate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Prednisolone hydrogen suc… | 2011003 | 25644 | 40 | 20201223* |
| Fagron | Prednisolone hydrogen suc… | 13D16-N11 | 20956 | 40 | 1509250 |
| Fagron | Prednisolone hydrogen suc… | 14G29-B07-304733 | 22652 | 40 | 1701370 |
| Fagron | Prednisolone hydrogen suc… | 14G29-B07-304733 | 22723 | 40 | 20140825 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 160 spectra of 4 reference samples from the substance/substance group *Prednisolone hydrogen succinate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 166 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 2 reference samples from the substance/substance group *Prednisolone hydrogen succinate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Prednisolone hydrogen suc… | 12A20-N11 | 20838 | 40 |
| Fagron | Prednisolone hydrogen suc… | 15C11-B05-344778 | 24058 | 40 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 16 spectra from 12 *Apo-Ident* customers from 11 batches from the substance/substance group *Prednisolone hydrogen succinate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisolone hydrogen suc… | 12A20-N11 | 1 |
| Caelo | Prednisolone hydrogen suc… | 14G29-B07 | 1 |
| Caelo | Prednisolone hydrogen suc… | 15C11B05328275 | 1 |
| Caelo | Prednisolone hydrogen suc… | 15C11-B05-305533 | 1 |
| Caelo | Prednisolone hydrogen suc… | 19081502 | 1 |
| Fagron | Prednisolone hydrogen suc… | 12L14-N04 | 1 |
| Fagron | Prednisolone hydrogen suc… | 14G29-B07-304733 | 1 |
| Fagron | Prednisolone hydrogen suc… | 15c11-B05338297 | 1 |
| Fagron | Prednisolone hydrogen suc… | 15C11-B05-338297 | 2 |
| Fagron | Prednisolone hydrogen suc… | 15C11-B05-344778 | 5 |
| Phönix | Prednisolone hydrogen suc… | 13H24-N04 | 1 |

- 256 870 spectra from 1666 *Apo-Ident* customers from a total of 52 142 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Prednisolone hydrogen succinate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prednisolone hydrogen succinate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 160 | 0 | 158 166 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 16 | 0 | 256 870 |

The substance/substance group *Prednisolone hydrogen succinate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.2500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20956 | 20956 | 0.00 | 82.73 |
| 22652 | 22652 | 0.00 | 80.49 |
| 22723 | 22652 | 3.22 | 82.14 |
| 25644 | 25644 | 0.00 | 83.28 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all


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substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prednisone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20002-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prednisone; Prednisonum

### Special notes

When selecting the *Prednisone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prednisone | 6 | 10 | 58 |

### Second-stage model

For differentiation of the substance/substance group *Prednisone* the following second-stage model is used:

- Submodel 08

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prednisone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 69.45 | – |
| ⋮ | ⋮ | ⋮ |
| Prednisolone acetate | >50 | 37.12 |
| Ephedrine hydrochloride | >50 | 137.13 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prednisone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prednisone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Prednisone | 12232716 | 21408 | 60 | 20120829 |
| Caelo | Prednisone | 12232716 | 21409 | 60 | 20120829 |
| Caelo | Prednisone | 192455 | 24895 | 40 | 31102019* |
| Euro OTC | Prednisone | 1401042-02 | 21616 | 60 | 1605276 |
| Euro OTC | Prednisone | 1604051 | 22557 | 40 | 20160523* |
| Euro OTC | Prednisone | 1604051 | 22557SI | 40 | 20160523* |
| Fagron | Prednisone | 13C14-B40-289148 | 21573 | 60 | 20131223 |
| Fagron | Prednisone | 16J19-B02-328642 | 23227 | 40 | 20161221 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 400 spectra of 8 reference samples from the substance/substance group *Prednisone*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 926 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 889 spectra of 24 reference samples from the substance/substance group *Prednisone*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Prednisone | 171665 | 23341 | 20 |
| Caelo | Prednisone | 17166504 | 23578 | 30 |
| Caelo | Prednisone | 21003706 | 25993 | 40 |
| Caelo | Prednisone | 23000981 | 26974 | 40 |
| Euro OTC | Prednisone | 1702008 | 23179 | 40 |
| Fagron | Prednisone | 22A14-B08-213641 | 26133 | 40 |
| Fagron | Prednisone | 23A04-B03-226162 | 26618 | 40 |
| Fagron | Prednisone | 24A30-B09-237512 | 27373 | 40 |
| Fagron | Prednisone (base micronized) | 24I10-B054 | BR20116 | 40 |
| Fagron | Prednisone (base micronized) | 24I10-B055 | BR20117 | 40 |
| Caelo | Prednisone | 12232716 | 21408SI† | 60 |
| Caelo | Prednisone | 12232716 | 21409SI† | 60 |
| Caelo | Prednisone | 171665 | 23341SI | 30 |
| Caelo | Prednisone | 17166504 | 23578SI | 30 |
| Caelo | Prednisone | 192455 | 24895SI† | 40 |
| Caelo | Prednisone | 21003706 | 25993SI | 40 |
| Caelo | Prednisone | 23000981 | 26974SI | 40 |
| Euro OTC | Prednisone | 1702008 | 23179SI | 29 |
| Fagron | Prednisone | 16J19-B02-328642 | 23227SI† | 30 |
| Fagron | Prednisone | 22A14-B08-213641 | 26133SI | 40 |
| Fagron | Prednisone | 23A04-B03-226162 | 26618SI | 40 |
| Fagron | Prednisone | 24A30-B09-237512 | 27373SI | 40 |
| Fagron | Prednisone (base micronized) | 24I10-B054 | BR20116SI | 20 |
| Fagron | Prednisone (base micronized) | 24I10-B055 | BR20117SI | 20 |

- 212 051 spectra from a total of 4274 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 105 spectra from 58 *Apo-Ident* customers from 59 batches from the substance/substance group *Prednisone*.
- Among them are spectra of independent samples from 58 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prednisone | 21003706007 | 1 |
| | Prednisone | 21003706008 | 1 |
| Caelo | Prednisone | 10037817 | 1 |
| Caelo | Prednisone | 10037826 | 1 |
| Caelo | Prednisone | 12177604 | 1 |
| Caelo | Prednisone | 12232705 | 3 |
| Caelo | Prednisone | 12232712 | 1 |
| Caelo | Prednisone | 12232713 | 1 |
| Caelo | Prednisone | 12232714 | 1 |
| Caelo | Prednisone | 13262302 | 1 |
| Caelo | Prednisone | 13262304 | 3 |
| Caelo | Prednisone | 15218602 | 5 |
| Caelo | Prednisone | 15218606 | 5 |
| Caelo | Prednisone | 15218607 | 1 |
| Caelo | Prednisone | 16277201 | 1 |
| Caelo | Prednisone | 16277206 | 1 |
| Caelo | Prednisone | 17166501 | 2 |
| Caelo | Prednisone | 17166502 | 5 |
| Caelo | Prednisone | 17166503 | 1 |
| Caelo | Prednisone | 17166504 | 1 |
| Caelo | Prednisone | 17166507 | 3 |
| Caelo | Prednisone | 17166508 | 2 |
| Caelo | Prednisone | 171666508 | 1 |
| Caelo | Prednisone | 18058701 | 1 |
| Caelo | Prednisone | 18108003 | 1 |
| Caelo | Prednisone | 18108004 | 2 |
| Caelo | Prednisone | 19245501 | 2 |
| Caelo | Prednisone | 19245502 | 1 |
| Caelo | Prednisone | 204312107 | 1 |
| Caelo | Prednisone | 21000576001 | 1 |
| Caelo | Prednisone | 21000576002 | 1 |
| Caelo | Prednisone | 21003706002 | 1 |
| Caelo | Prednisone | 21003706003 | 1 |
| Caelo | Prednisone | 21003706005 | 1 |
| Caelo | Prednisone | 21003706007 | 1 |
| Caelo | Prednisone | 2114Q2107 | 1 |
| Caelo | Prednisone | 28021401 | 1 |
| Caelo | Prednisone | 28021403 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Prednisone | 5087 | 1 |
| Caesar & Loretz GmbH… | Prednisone | 18108004 | 1 |
| Caesar & Loretz GmbH | Prednisone | 17166508 | 1 |
| Caesar & Loretz GmbH | Prednisone | 18108003 | 3 |
| Caesar & Loretz GmbH | Prednisone | 18108004 | 1 |
| Caesar & Loretz GmbH | Prednisone | 20001277001 | 1 |
| Caesar & Loretz GmbH | Prednisone | 21003706006 | 1 |
| Euro OTC | Prednisone | 1401042-02 | 1 |
| Euro OTC | Prednisone | 150043-03 | 1 |
| Euro OTC | Prednisone | 1501043-01 | 2 |
| Euro OTC | Prednisone | 1501043-02 | 1 |
| Euro OTC | Prednisone | 1501043-03 | 5 |
| Euro OTC | Prednisone | 1604051-01 | 3 |
| Euro OTC | Prednisone | 1604501-01 | 1 |
| Euro OTC | Prednisone | 1702008-01 | 3 |
| Euro OTC | Prednisone | 172008-01 | 1 |
| Fagron | Prednisone | 12E02-N01 | 1 |
| Fagron | Prednisone | 12E02-N10 | 1 |
| Fagron | Prednisone | 12L14-M03 | 1 |
| Fagron | Prednisone | 13C13-N08 | 1 |
| Fagron | Prednisone | 15218608 | 1 |
| Fagron | Prednisone | 16H04-B04-334368 | 1 |
| Fagron | Prednisone | 20F19-F02-371975 | 1 |
| Fagron | Prednisone | 21021401 | 1 |
| Gehe | Prednisone | 12232714 | 1 |
| Gehe | Prednisone | 12L14-M03 | 1 |
| Gehe | Prednisone | 13C13-N08 | 1 |
| Gehe | Prednisone | 17166508 | 1 |
| Noweda | Prednisone | 17166501 | 1 |
| Noweda | Prednisone | 17166503 | 1 |
| Noweda | Prednisone | 21003060027 | 1 |
| Phönix | Prednisone | 11D08-N05 | 1 |
| sanacorp | Prednisone | 13262302 | 1 |
| Sanacorp | Prednisone | 16277206 | 1 |

- 256 781 spectra from 1666 *Apo-Ident* customers from a total of 52 094 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Prednisone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prednisone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 889 | 0 | 212 051 |
| **Type C** | 0 | 103 | 2 | 256 781 |

The substance/substance group *Prednisone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3251 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.0952 % (> 95.2381 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21408 | 22557 | 13.85 | 120.49 |
| 21409 | 22557 | 10.59 | 119.66 |
| 21573 | 21616 | 9.09 | 120.99 |
| 21616 | 21616 | 0.00 | 117.31 |
| 22557 | 22557 | 0.00 | 115.96 |
| 23227 | 24895 | 4.85 | 115.13 |
| 24895 | 24895 | 0.00 | 115.20 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Pregnenolone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20721-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Pregnenolone; Pregnenolonum

### Special notes

When selecting the *Pregnenolone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Pregnenolone | 11 | 10 | 48 |

### Second-stage model

For differentiation of the substance/substance group *Pregnenolone* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Pregnenolone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prasterone | 71.80 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Pregnenolone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Pregnenolone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Pregnenolone | 1204040-01 | 20721 | 40 | 1404311 |
| Euro OTC | Pregnenolone | 1312007-01 | 21679 | 60 | 8985 |
| Euro OTC | Pregnenolone | 1602001 | 22375 | 45 | 20160208* |
| Euro OTC | Pregnenolone | 1612019 | 22979 | 40 | 20170131* |
| Euro OTC | Pregnenolone | 1908021 | 24849 | 40 | 20190913* |
| Euro OTC | Pregnenolone | 1908020 | 24932 | 40 | 20191018* |
| Euro OTC | Pregnenolone | 2006014 | 25325 | 40 | 20200803* |
| Euro OTC | Pregnenolone | 2104008 | 25685 | 50 | 20210510* |
| Fagron | Pregnenolone | 15B11-B07-310278 | 22355 | 45 | 9338 |
| Fagron | Pregnenolone | 18L27-B02-357840 | 24704 | 40 | 20190220 |
| Fagron | Pregnenolone | 22I19-B02 | 26445 | 40 | 20221201* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 480 spectra of 11 reference samples from the substance/substance group *Pregnenolone*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 846 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 460 spectra of 13 reference samples from the substance/substance group *Pregnenolone*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Pregnenolone | 1606028 | 22706 | 40 |
| Euro OTC | Pregnenolone | 1709017 | 23696 | 40 |
| Euro OTC | Pregnenolone | 1909013 | 24954 | 40 |
| Euro OTC | Pregnenolone | 2001037 | 25129 | 40 |
| Euro OTC | Pregnenolone | 2006015 | 25342 | 40 |
| Euro OTC | Pregnenolone | 2101012 | 25539 | 40 |
| Euro OTC | Pregnenolone | 2108003 | 25765 | 40 |
| Euro OTC | Pregnenolone | 2203003 | 26029 | 40 |
| Euro OTC | Pregnenolone | 2201037 | 26033 | 40 |
| Fagron | Pregnenolone | 23I28-B11-233503 | 27057 | 40 |
| Euro OTC | Pregnenolone | 2203003 | 26029SI | 20 |
| Euro OTC | Pregnenolone | 2201037 | 26033SI | 20 |
| Fagron | Pregnenolone | 23I28-B11-233503 | 27057SI | 20 |

- 212 480 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 234 spectra from 26 *Apo-Ident* customers from 51 batches from the substance/substance group *Pregnenolone*.

- Among them are spectra of independent samples from 48 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Pregnenolone | 23D11-B02-226331 | 1 |
| | Pregnenolone | 23E29-B02-233061 | 2 |
| | Pregnenolone | 23I28-B11-233501 | 1 |
| | Pregnenolone | 23I28-B11-233503 | 1 |
| Audor Pharma | Pregnenolone | A141215/46 | 1 |
| Audor Pharma | Pregnenolone | AP10L10-M01P | 1 |
| Audor Pharma | Pregnenolone | AP1109007-01P | 1 |
| Audor Pharma | Pregnenolone | APC07-150801(M)P | 3 |
| Audor Pharma | Pregnenolone | APC07-160801(M)P | 2 |
| Audor Pharma | Pregnenolone | APc07-180201 | 1 |
| Audor Pharma | Pregnenolone | APC07-180201 | 2 |
| Audor Pharma | Pregnenolone | APC07-180201(M)P | 3 |
| Audor Pharma | Pregnenolone | APc07-180702(M)-1P | 1 |
| Audor Pharma | Pregnenolone | APC07-180702(M)-1P | 1 |
| Audor Pharma | Pregnenolone | APC07-180702(M)-2P | 1 |
| bitte ergänzen | Pregnenolone | | 1 |
| Euro OTC | Pregnenolone | 1312007-01 | 1 |
| Euro OTC | Pregnenolone | 1402025-01 | 1 |
| Euro OTC | Pregnenolone | 1506002-01 | 10 |
| Euro OTC | Pregnenolone | 1602001-01 | 22 |
| Euro OTC | Pregnenolone | 1606028-01 | 29 |
| Euro OTC | Pregnenolone | 1612019-01 | 51 |
| Euro OTC | Pregnenolone | 1908021-01 | 2 |
| Euro OTC | Pregnenolone | 1908021-02 | 1 |
| Euro OTC | Pregnenolone | 2001037-01 | 25 |
| Euro OTC | Pregnenolone | 2001037-02 | 3 |
| Euro OTC | Pregnenolone | 2006015-01 | 5 |
| Euro OTC | Pregnenolone | 2006015-02 | 36 |
| Euro OTC | Pregnenolone | 2101012-01 | 2 |
| Euro OTC | Pregnenolone | 2108003-01 | 1 |
| Euro OTC | Pregnenolone | 2203003-01 | 2 |
| Fagron | Pregnenolone | 14B18-B04-291917 | 1 |
| Fagron | Pregnenolone | 16L29-B02331611 | 1 |
| Fagron | Pregnenolone | 19E01-B01-364473 | 1 |
| Fagron | Pregnenolone | 19J25-F02 | 1 |
| Fagron | Pregnenolone | 19J25-F02-367245 | 1 |
| Fagron | Pregnenolone | 19L09-F01-372068 | 1 |
| Fagron | Pregnenolone | 20104-F04-378102 | 1 |
| Fagron | Pregnenolone | 20I04-F04-374073 | 1 |
| Fagron | Pregnenolone | 23G20-B02-233060 | 1 |
| Fagron | Pregnenolone | 23I28-B11-233499 | 1 |
| Fagron | Pregnenolone | F01-3720608 | 1 |
| Fagron | Pregnenolone | F02-3672405 | 1 |
| Fagron | Pregnenolone | F04-3784905 | 1 |
| gehe | Pregnenolone | Apc07160801 | 1 |
| Haihang Industry | Pregnenolone | 20140329 | 1 |
| Koisser Pharma | Pregnenolone | ZH-131001 | 1 |
| Koisser | Pregnenolone | ZH-130802 | 1 |
| KS Pharma | Pregnenolone | ZH-111119 | 1 |
| NWM CHina | Pregnenolone | PR150329 | 1 |
| NWM Shandong Northwe... | Pregnenolone | PRN151219 | 1 |

- 256 652 spectra from 1666 *Apo-Ident* customers from a total of 52 103 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,


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the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Pregnenolone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Pregnenolone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 460 | 0 | 212 480 |
| **Type C** | 0 | 228 | 6 | 256 652 |

The substance/substance group *Pregnenolone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.6957 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.4359 % (> 96.1538 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20721 | 20721 | 0.00 | 97.53 |
| 21679 | 21679 | 0.00 | 97.28 |
| 22355 | 22355 | 0.00 | 102.30 |
| 22375 | 22375 | 0.00 | 97.52 |
| 22979 | 22979 | 0.00 | 98.66 |
| 24704 | 26445 | 7.29 | 101.60 |
| 24849 | 24849 | 0.00 | 97.91 |
| 24932 | 24932 | 0.00 | 101.61 |
| 25325 | 25325 | 0.00 | 101.51 |
| 25685 | 25685 | 0.00 | 102.90 |
| 26445 | 26445 | 0.00 | 100.56 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at

least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prilocaine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005414-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prilocaine; Prilocainum

### Special notes

When selecting the *Prilocaine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prilocaine | 3 | 3 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Prilocaine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prilocaine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 122.26 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prilocaine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prilocaine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Prilocaine | 2208012 | 26336 | 40 | 20221018* |
| Euro OTC | Prilocaine | 2310022 | 27370 | 40 | 20240826* |
| Fagron | Prilocaine | 25C06-B053 | BR20118 | 40 | 20250122* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 120 spectra of 3 reference samples from the substance/substance group *Prilocaine*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 206 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 230 spectra of 8 reference samples from the substance/substance group *Prilocaine*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Prilocaine | 1909017-01 | 25782 | 50 |
| Fagron | Prilocaine | 24I05-B037 | BR20119 | 40 |
| Fagron | Prilocaine | 24H27-B008 | BR20120 | 40 |
| Euro OTC | Prilocaine | 2208012 | 26336SI† | 20 |
| Euro OTC | Prilocaine | 2310022 | 27370SI† | 20 |
| Fagron | Prilocaine | 25C06-B053 | BR20118SI† | 20 |
| Fagron | Prilocaine | 24I05-B037 | BR20119SI | 20 |
| Fagron | Prilocaine | 24H27-B008 | BR20120SI | 20 |

- 212 710 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Prilocaine*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

### Validation results

The validation runs checked whether the substance/substance group *Prilocaine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prilocaine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 120 | 0 | 158 206 |
| **Type B** | 0 | 228 | 2 | 212 710 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Prilocaine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 99.1304 % (> 97.8261 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26336 | 26336 | 0.00 | 198.28 |
| 27370 | 27370 | 0.00 | 200.46 |
| BR20118 | BR20118 | 0.00 | 202.23 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Prilocaine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21048-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Prilocaine hydrochloride; Prilocaini hydrochloridum

### Special notes

When selecting the *Prilocaine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Prilocaine hydrochloride | 4 | 3 | 20 |

### Second-stage model

For differentiation of the substance/substance group *Prilocaine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Prilocaine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Amphetamine sulfate | 80.78 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Prilocaine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Prilocaine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Prilocaine hydrochloride | 15230305 | 21926 | 60 | 20150723 |
| Fagron | Prilocaine hydrochloride | 13I02-N03 | 21048 | 40 | 1403257 |
| Fagron | Prilocaine hydrochloride | 13I02-N03 | 21050 | 40 | 20130918 |
| Fagron | Prilocaine hydrochloride | 14H13-B03-297591 | 21800 | 60 | AR-15-FG-016323-01 |
| Fagron | Prilocaine hydrochloride | 23A13-B01-225390 | 26612 | 40 | 20230208 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 240 spectra of 5 reference samples from the substance/substance group *Prilocaine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 086 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 5 reference samples from the substance/substance group *Prilocaine hydrochloride*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Prilocaine hydrochloride | 15390101 | 23250 | 40 |
| Fagron | Prilocaine hydrochloride | 20B25-F04-369313 | 25484 | 40 |
| Fagron | Prilocaine hydrochloride | 24A16-B11-234645 | 27187 | 40 |
| Fagron | Prilocaine hydrochloride | 23A13-B01-225390 | 26612SI† | 20 |
| Fagron | Prilocaine hydrochloride | 24A16-B11-234645 | 27187SI | 20 |

- 212 780 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 35 spectra from 22 *Apo-Ident* customers from 23 batches from the substance/substance group *Prilocaine hydrochloride*.

- Among them are spectra of independent samples from 19 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Prilocaine hydrochloride | 21G10-B21-213674 | 3 |
| Caelo | Prilocaine hydrochloride | 14A03-B34-290281 | 1 |
| Caelo | Prilocaine hydrochloride | 15230304 | 1 |
| Caelo | Prilocaine hydrochloride | 15230305 | 1 |
| Caelo | Prilocaine hydrochloride | 15390101 | 1 |
| Fagron | Prilocaine hydrochloride | | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Prilocaine hydrochloride | 13I032-N03 | 1 |
| Fagron | Prilocaine hydrochloride | 14H13-B03-297591 | 1 |
| Fagron | Prilocaine hydrochloride | 14H13-B03-297593 | 1 |
| Fagron | Prilocaine hydrochloride | 15E15-B04-307730 | 1 |
| Fagron | Prilocaine hydrochloride | 15L21-B02_332956 | 1 |
| Fagron | Prilocaine hydrochloride | 15L21-B02-319234 | 1 |
| Fagron | Prilocaine hydrochloride | 15L21-B02325756 | 1 |
| Fagron | Prilocaine hydrochloride | 15L21-B02332956 | 1 |
| Fagron | Prilocaine hydrochloride | 15L21-B02-332956 | 2 |
| Fagron | Prilocaine hydrochloride | 17H02-B05-340539 | 3 |
| Fagron | Prilocaine hydrochloride | 17H02-B05-348769 | 5 |
| Fagron | Prilocaine hydrochloride | 17Ho2Bo5348769 | 1 |
| Fagron | Prilocaine hydrochloride | 18B22-B04-356468 | 1 |
| Fagron | Prilocaine hydrochloride | 21F07-B14 | 1 |
| Fagron | Prilocaine hydrochloride | 21G10-B21-213674 | 1 |
| Fagron | Prilocaine hydrochloride | F04-3766906 | 3 |
| Fargon | Prilocaine hydrochloride | 17HO2-B05 | 1 |
| GEHE 02.05.2013 | Prilocaine hydrochloride | | 1 |

- 256 851 spectra from 1666 *Apo-Ident* customers from a total of 52 131 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Prilocaine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Prilocaine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 240 | 0 | 158 086 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 35 | 0 | 256 851 |

The substance/substance group *Prilocaine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 82.8571 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21048 | 21048 | 0.00 | 101.23 |
| 21050 | 21048 | 3.53 | 101.97 |
| 21800 | 21800 | 0.00 | 104.42 |
| 21926 | 21800 | 4.59 | 101.20 |
| 26612 | 21048 | 11.14 | 104.37 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Procaine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20042-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Procaine hydrochloride; Procaini hydrochloridum

### Special notes

When selecting the *Procaine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Procaine hydrochloride | 8 | 7 | 89 |

### Second-stage model

For differentiation of the substance/substance group *Procaine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Procaine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 147.51 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Procaine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Procaine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Procaine hydrochloride | 13109906 | 21785 | 60 | AR-15-FG-008935-01 |
| Caelo | Procaine hydrochloride | 15006906 | 22247 | 60 | 20150209 |
| Caelo | Procaine hydrochloride | 19000709003 | 25436 | 40 | 20200120 |
| Caelo | Procaine hydrochloride | 23000279004 | 26742 | 40 | 20230306 |
| Caelo | Procaine hydrochloride | 23000279004 | 26742SI | 20 | 20230306 |
| Euro OTC | Procaine hydrochloride | 1601014 | 22306 | 60 | 20160203* |
| Euro OTC | Procaine hydrochloride | 2210004 | 26442 | 40 | 20221116* |
| Fagron | Procaine hydrochloride | 13F12-B40-301798 | 22260 | 60 | 20141210 |
| Fagron | Procaine hydrochloride | 15J27-B10-322937 | 23379 | 40 | 20151113 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 9 reference samples from the substance/substance group *Procaine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 906 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 310 spectra of 9 reference samples from the substance/substance group *Procaine hydrochloride*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Procaine hydrochloride | 161378 | 22624 | 40 |
| Caelo | Procaine hydrochloride | 171675 | 23634 | 40 |
| Caelo | Procaine hydrochloride | 182764 | 24393 | 40 |
| Caelo | Procaine hydrochloride | 190440 | 24526 | 40 |
| Caelo | Procaine hydrochloride | 21003774005 | 26307 | 40 |
| Caelo | Procaine hydrochloride | 24001422 | 27309 | 30 |
| Fagron | Procaine hydrochloride | 22K02-B01-226161 | 26552 | 40 |
| Caelo | Procaine hydrochloride | 21003774005 | 26307SI | 20 |
| Fagron | Procaine hydrochloride | 22K02-B01-226161 | 26552SI | 20 |

- 212 630 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 212 spectra from 136 *Apo-Ident* customers from 93 batches from the substance/substance group *Procaine hydrochloride*.

- Among them are spectra of independent samples from 89 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Procaine hydrochloride | 21003774005 | 1 |
| | Procaine hydrochloride | 22002755005 | 1 |
| | Procaine hydrochloride | 23000279003 | 1 |
| | Procaine hydrochloride | 23000279004 | 3 |
| | Procaine hydrochloride | 23000279007 | 2 |
| | Procaine hydrochloride | 23000279008 | 1 |
| | Procaine hydrochloride | 3000279004 | 1 |
| Alliance Health 09.0... | Procaine hydrochloride | 1104012-05 | 1 |
| Anzag | Procaine hydrochloride | 60998058 | 1 |
| Caelo | Procaine hydrochloride | 10159721 | 1 |
| Caelo | Procaine hydrochloride | 10159723 | 1 |
| Caelo | Procaine hydrochloride | 10159729 | 1 |
| Caelo | Procaine hydrochloride | 11370203 | 1 |
| Caelo | Procaine hydrochloride | 11370204 | 1 |
| Caelo | Procaine hydrochloride | 11370206 | 1 |
| Caelo | Procaine hydrochloride | 11370215 | 1 |
| Caelo | Procaine hydrochloride | 11370216 | 2 |
| Caelo | Procaine hydrochloride | 11370219 | 1 |
| Caelo | Procaine hydrochloride | 12177801 | 5 |
| Caelo | Procaine hydrochloride | 13/09-N08 | 1 |
| Caelo | Procaine hydrochloride | 13109905 | 1 |
| Caelo | Procaine hydrochloride | 13109906 | 1 |
| Caelo | Procaine hydrochloride | 13109908 | 2 |
| Caelo | Procaine hydrochloride | 13109915 | 1 |
| Caelo | Procaine hydrochloride | 13109916 | 2 |
| Caelo | Procaine hydrochloride | 131099903 | 1 |
| Caelo | Procaine hydrochloride | 13130-N06 | 1 |
| Caelo | Procaine hydrochloride | 13F12-B40-302510 | 1 |
| Caelo | Procaine hydrochloride | 14164408 | 1 |
| Caelo | Procaine hydrochloride | 14164409 | 1 |
| Caelo | Procaine hydrochloride | 14164413 | 1 |
| Caelo | Procaine hydrochloride | 15006902 | 1 |
| Caelo | Procaine hydrochloride | 15006906 | 3 |
| Caelo | Procaine hydrochloride | 15006909 | 1 |
| Caelo | Procaine hydrochloride | 15006912 | 4 |
| Caelo | Procaine hydrochloride | 15006913 | 1 |
| Caelo | Procaine hydrochloride | 1601014-02 | 1 |
| Caelo | Procaine hydrochloride | 16137812 | 5 |
| Caelo | Procaine hydrochloride | 16173906 | 2 |
| Caelo | Procaine hydrochloride | 17167504 | 1 |
| Caelo | Procaine hydrochloride | 17167505 | 1 |
| Caelo | Procaine hydrochloride | 17167506 | 2 |
| Caelo | Procaine hydrochloride | 17343306 | 1 |
| Caelo | Procaine hydrochloride | 17343311 | 1 |
| Caelo | Procaine hydrochloride | 18041806 | 1 |
| Caelo | Procaine hydrochloride | 18276407 | 4 |
| Caelo | Procaine hydrochloride | 19000709001 | 1 |
| Caelo | Procaine hydrochloride | 19000709003 | 9 |
| Caelo | Procaine hydrochloride | 19044008 | 2 |
| Caelo | Procaine hydrochloride | 192848001 | 1 |
| Caelo | Procaine hydrochloride | 192848002 | 7 |
| Caelo | Procaine hydrochloride | 192848005 | 1 |
| Caelo | Procaine hydrochloride | 20001278003 | 3 |
| Caelo | Procaine hydrochloride | 20001278004 | 2 |
| Caelo | Procaine hydrochloride | 20001278005 | 1 |
| Caelo | Procaine hydrochloride | 20004565003 | 3 |
| Caelo | Procaine hydrochloride | 20004565004 | 1 |
| Caelo | Procaine hydrochloride | 21003774002 | 5 |
| Caelo | Procaine hydrochloride | 22002755005 | 1 |
| Caelo | Procaine hydrochloride | 60998127 | 2 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Procaine hydrochloride | 7011506 | 1 |
| Caesar & Loretz GmbH... | Procaine hydrochloride | 23000279004 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 14164413 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 1601014-02 | 2 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 17343306 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 18276407 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 19000709003 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 19044008 | 1 |
| CAESAR & LORETZ GMBH | Procaine hydrochloride | 192848001 | 2 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 192848005 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 20001278003 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 20004565003 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 21003774002 | 1 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 21003774005 | 3 |
| Caesar & Loretz GmbH | Procaine hydrochloride | 21003775002 | 1 |
| China Medica | Procaine hydrochloride | 13109911 | 1 |
| Chongging Southwest No.2 | Procaine hydrochloride | 20001278004 | 1 |
| Euro OTC | Procaine hydrochloride | 1003001-01 | 1 |
| Euro OTC | Procaine hydrochloride | 1003001-02 | 1 |
| Euro OTC | Procaine hydrochloride | 1104012-01 | 1 |
| Euro OTC | Procaine hydrochloride | 1104012-03 | 3 |
| Euro OTC | Procaine hydrochloride | 1104012-04 | 3 |
| Euro OTC | Procaine hydrochloride | 1104012-05 | 4 |
| Euro OTC | Procaine hydrochloride | 1104012-3 | 1 |
| Euro OTC | Procaine hydrochloride | 110412-02 | 1 |
| Euro OTC | Procaine hydrochloride | 1405027-01 | 4 |
| Euro OTC | Procaine hydrochloride | 1405027-02 | 1 |
| Euro OTC | Procaine hydrochloride | 16001014-02 | 1 |
| Euro OTC | Procaine hydrochloride | 1601014-01 | 9 |
| Euro OTC | Procaine hydrochloride | 1601014-02 | 20 |
| Euro OTC | Procaine hydrochloride | 1601014-02 | 1 |
| Euro OTC | Procaine hydrochloride | 16014014-02 | 1 |
| Euro OTC | Procaine hydrochloride | 200644 | 1 |
| Euro OTC | Procaine hydrochloride | 5127 | 1 |
| Fagron | Procaine hydrochloride | 10H11-N25 | 1 |
| Fagron | Procaine hydrochloride | 12I10-N07 | 1 |
| Fagron | Procaine hydrochloride | 13/30-N06 | 1 |
| Fagron | Procaine hydrochloride | 13F12-B40 | 1 |
| Fagron | Procaine hydrochloride | 13I09-N08 | 1 |
| Fagron | Procaine hydrochloride | 15006906 | 1 |
| Fagron | Procaine hydrochloride | 1651212 | 1 |
| Fagron | Procaine hydrochloride | 193768 | 1 |
| Fagron | Procaine hydrochloride | 20A30-B15-197566 | 1 |
| Gatt-Koller / Phoenix | Procaine hydrochloride | 4428/10122714 | 2 |
| Gehe | Procaine hydrochloride | 19044008 | 1 |
| Guzugzhou Tengyue Ch... | Procaine hydrochloride | 20201033 | 2 |
| Herstellung | Procaine hydrochloride | 12177801 | 1 |
| Koisser | Procaine hydrochloride | 11370218 | 1 |
| Nachprüfung | Procaine hydrochloride | 2082019-5 | 1 |
| Noweda | Procaine hydrochloride | 1309N08 | 1 |
| Noweda | Procaine hydrochloride | 1601014-02 | 1 |
| Noweda | Procaine hydrochloride | 22002755005 | 1 |
| Noweda | Procaine hydrochloride | 23000279004 | 1 |
| Phönix 08.01.2014 | Procaine hydrochloride | 1104012-03 | 1 |
| Phönix Gotha | Procaine hydrochloride | 190311 | 1 |
| Sanacorp | Procaine hydrochloride | 20004565003 | 1 |
| Sanacorp | Procaine hydrochloride | 21003774002 | 2 |
| siehe WE-Prüfprotokoll | Procaine hydrochloride | 39/12 | 1 |
| VEB Jenapharmn | Procaine hydrochloride | 1011989 | 1 |

- 256 674 spectra from 1666 *Apo-Ident* customers from a total of 52 060 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Procaine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Procaine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 310 | 0 | 212 630 |
| **Type C** | 0 | 212 | 0 | 256 674 |

The substance/substance group *Procaine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0645 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.1698 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21785 | 21785 | 0.00 | 194.91 |
| 22247 | 22306 | 6.73 | 197.16 |
| 22260 | 21785 | 6.79 | 195.99 |
| 22306 | 22306 | 0.00 | 195.04 |
| 23379 | 22306 | 3.22 | 195.35 |
| 25436 | 26442 | 13.77 | 200.61 |
| 26442 | 26442 | 0.00 | 198.98 |
| 26742 | 26442 | 9.29 | 201.77 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at


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least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Progesterone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20024-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Progesterone; Progesteronum

### Special notes

When selecting the *Progesterone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Progesterone | 14 | 83 | 587 |

### Second-stage model

For differentiation of the substance/substance group *Progesterone* the following second-stage model is used:

- Submodel 05

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Progesterone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Spironolactone | 62.04 | 57.66 |
| ⋮ | ⋮ | ⋮ |
| Testosterone propionate | 63.73 | 53.97 |
| Fusidic acid | >50 | 101.71 |
| Povidone | >50 | 108.26 |
| Povidone iodine | >50 | 124.30 |
| Ubidecarenone | >50 | 125.36 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Progesterone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Progesterone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Progesterone | 15319601 | 22831 | 40 | 20151014 |
| Caelo | Progesterone | 17060903 | 23249 | 40 | 20170315 |
| Caelo | Progesterone | 20002672 | 25658 | 50 | 20200914* |
| Caelo | Progesterone | 20002672 | 25658SI | 50 | 20200914* |
| Euro OTC | Progesterone | 1111053-01 | 20718 | 40 | 20120119 |
| Euro OTC | Progesterone | 1506033 | 21868 | 60 | 0000010482 |
| Euro OTC | Progesterone | 1506033 | 21868SI | 30 | 0000010482 |
| Euro OTC | Progesterone | 1506034 | 21870 | 60 | 0000010483 |
| Euro OTC | Progesterone | 1509008 | 21907 | 60 | 20150914* |
| Euro OTC | Progesterone | 1511008 | 22226 | 60 | 20151119* |
| Euro OTC | Progesterone | 1601009 | 22301 | 45 | 20160128* |
| Euro OTC | Progesterone | 1601009 | 22301SI | 45 | 20160128* |
| Euro OTC | Progesterone | 1601001 | 22303 | 45 | 20160128* |
| Euro OTC | Progesterone | 1603004 | 22525 | 40 | 20160406* |
| Euro OTC | Progesterone | 2006018 | 25273 | 40 | 20200716* |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Progesterone | 2006018 | 25273SI | 31 | 20200716* |
| Euro OTC | Progesterone | 2103019 | 25684 | 50 | 20210427* |
| Euro OTC | Progesterone | 2103019 | 25684SI | 50 | 20210427* |
| Fagron | Progesterone | 16A20-B02-319103 | 22830 | 40 | 20160209 |
| Fagron | Progesterone | 16A20-B02-319103 | 22830SI | 40 | 20160209 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 916 spectra of 20 reference samples from the substance/substance group *Progesterone*. These samples are listed above in the *calibration samples* section. The reference samples come from 14 different batches.

- 157 410 spectra from a total of 2943 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 6690 spectra of 176 reference samples from the substance/substance group *Progesterone*.

- Among them are spectra of independent samples from 83 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Progesterone | 170609 | 23329 | 40 |
| Caelo | Progesterone | 172778 | 23838 | 40 |
| Caelo | Progesterone | 191287 | 24750 | 40 |
| Caelo | Progesterone | 21002413 | 25792 | 40 |
| Caelo | Progesterone | 22001580 | 26252 | 40 |
| Caelo | Progesterone | 22001577 | 26256 | 40 |
| Caelo | Progesterone | 22003208 | 26485 | 40 |
| Caelo | Progesterone | 23003401 | 27104 | 40 |
| Euro OTC | Progesterone | 1603012 | 22529 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Progesterone | 1605013 | 22556 | 40 |
| Euro OTC | Progesterone | 1606033 | 22704 | 40 |
| Euro OTC | Progesterone | 1605032 | 22705 | 40 |
| Euro OTC | Progesterone | 1609016 | 22788 | 40 |
| Euro OTC | Progesterone | 1609001 | 22819 | 40 |
| Euro OTC | Progesterone | 1701038 | 23138 | 40 |
| Euro OTC | Progesterone | 1702026 | 23148 | 40 |
| Euro OTC | Progesterone | 1707012 | 23536 | 40 |
| Euro OTC | Progesterone | 1705028 | 23541 | 40 |
| Euro OTC | Progesterone | 1709012 | 23732 | 40 |
| Euro OTC | Progesterone | 1801036 | 23947 | 40 |
| Euro OTC | Progesterone | 1802030 | 24067 | 40 |
| Euro OTC | Progesterone | 1806020 | 24138 | 40 |
| Euro OTC | Progesterone | 1809018 | 24328 | 40 |
| Euro OTC | Progesterone | 1809017 | 24334 | 40 |
| Euro OTC | Progesterone | 1603012-01 | 24335 | 40 |
| Euro OTC | Progesterone | 1811033 | 24345 | 40 |
| Euro OTC | Progesterone | 1901021 | 24447 | 40 |
| Euro OTC | Progesterone | 1901022 | 24455 | 40 |
| Euro OTC | Progesterone | 1904033 | 24606 | 40 |
| Euro OTC | Progesterone | 1905023 | 24765 | 40 |
| Euro OTC | Progesterone | 1905022 | 24790 | 40 |
| Euro OTC | Progesterone | 1908002 | 24834 | 40 |
| Euro OTC | Progesterone | 1908003 | 24863 | 40 |
| Euro OTC | Progesterone | 1911006 | 24962 | 40 |
| Euro OTC | Progesterone | 1911007 | 24970 | 40 |
| Euro OTC | Progesterone | 2001036 | 25077 | 40 |
| Euro OTC | Progesterone | 2003037 | 25110 | 40 |
| Euro OTC | Progesterone | 2003042 | 25111 | 40 |
| Euro OTC | Progesterone | 2003036 | 25112 | 40 |
| Euro OTC | Progesterone | 2005019 | 25255 | 40 |
| Euro OTC | Progesterone | 2005018 | 25256 | 40 |
| Euro OTC | Progesterone | 2007029 | 25262 | 40 |
| Euro OTC | Progesterone | 2006017 | 25263 | 40 |
| Euro OTC | Progesterone | 2007028 | 25276 | 40 |
| Euro OTC | Progesterone | 2010005 | 25474 | 40 |
| Euro OTC | Progesterone | 2103020 | 25683 | 50 |
| Euro OTC | Progesterone | 2108010 | 25819 | 50 |
| Euro OTC | Progesterone | 2108011 | 25831 | 50 |
| Euro OTC | Progesterone | 2111009 | 25917 | 40 |
| Euro OTC | Progesterone | 2111008 | 25921 | 40 |
| Euro OTC | Progesterone | 2203007 | 26032 | 40 |
| Euro OTC | Progesterone | 2203006 | 26034 | 40 |
| Euro OTC | Progesterone | 2207002 | 26214 | 40 |
| Euro OTC | Progesterone | 2210017 | 26425 | 40 |
| Euro OTC | Progesterone | 2210016 | 26443 | 40 |
| Euro OTC | Progesterone | 2301049 | 26577 | 30 |
| Euro OTC | Progesterone | 2307007 | 26760 | 40 |
| Euro OTC | Progesterone | 2307006 | 26761 | 40 |
| Euro OTC | Progesterone | 2308001 | 26886 | 30 |
| Euro OTC | Progesterone | 2308002 | 26887 | 30 |
| Euro OTC | Progesterone | 2309026 | 26937 | 40 |
| Euro OTC | Progesterone | 2311009 | 27013 | 40 |
| Euro OTC | Progesterone | 2311010 | 27014 | 40 |
| Euro OTC | Progesterone | 2401013 | 27088 | 40 |
| Euro OTC | Progesterone | 2401014 | 27089 | 40 |
| Euro OTC | Progesterone | 2402023 | 27143 | 40 |
| Euro OTC | Progesterone | 2404001 | 27203 | 40 |
| Euro OTC | Progesterone | 2404005 | 27204 | 40 |
| Euro OTC | Progesterone | 2405006 | 27205 | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Progesterone | 2405005 | 27208 | 40 |
| Euro OTC | Progesterone | 2406015 | 27284 | 40 |
| Euro OTC | Progesterone | 2406014 | 27285 | 40 |
| Euro OTC | Progesterone | 2407018 | 27354 | 40 |
| Euro OTC | Progesterone | 2407019 | 27355 | 30 |
| Euro OTC | Progesterone | 2409003 | 27398 | 40 |
| Euro OTC | Progesterone | 2410011 | 27461 | 40 |
| Euro OTC | Progesterone | 2410010 | 27462 | 40 |
| Euro OTC | Progesterone | 2411014 | 27524 | 40 |
| Euro OTC | Progesterone | 2501023 | 27525 | 40 |
| Euro OTC | Progesterone | 2411015 | 27526 | 40 |
| Euro OTC | Progesterone | 2501024 | 27527 | 40 |
| Fagron | Progesterone | 19H20-F02-364866 | 25046 | 40 |
| Fagron | Progesterone | 22H12-B01-222409 | 26407 | 40 |
| Caelo | Progesterone | 15319601 | 22831SI† | 40 |
| Caelo | Progesterone | 17060903 | 23249SI† | 20 |
| Caelo | Progesterone | 170609 | 23329SI | 20 |
| Caelo | Progesterone | 172778 | 23838SI | 30 |
| Caelo | Progesterone | 170609 | 23844 | 40 |
| Caelo | Progesterone | 170609 | 23844SI | 23 |
| Caelo | Progesterone | 191287 | 24750SI | 40 |
| Caelo | Progesterone | 21002413 | 25792SI | 40 |
| Caelo | Progesterone | 22001580 | 26252SI | 40 |
| Caelo | Progesterone | 22001577 | 26256SI | 40 |
| Caelo | Progesterone | 22003208 | 26485SI | 35 |
| Caelo | Progesterone | 23003401 | 27104SI | 20 |
| Euro OTC | Progesterone | 1506033 | 21868SI† | 5 |
| Euro OTC | Progesterone | 1506034 | 21870SI† | 59 |
| Euro OTC | Progesterone | 1509008 | 21907SI† | 53 |
| Euro OTC | Progesterone | 1511008 | 22226SI† | 27 |
| Euro OTC | Progesterone | 1601001 | 22303SI† | 44 |
| Euro OTC | Progesterone | 1603004 | 22525SI† | 31 |
| Euro OTC | Progesterone | 1603012 | 22529SI | 29 |
| Euro OTC | Progesterone | 1605013 | 22556SI | 30 |
| Euro OTC | Progesterone | 1606033 | 22704SI | 30 |
| Euro OTC | Progesterone | 1605032 | 22705SI | 38 |
| Euro OTC | Progesterone | 1609016 | 22788SI | 30 |
| Euro OTC | Progesterone | 1609001 | 22819SI | 30 |
| Euro OTC | Progesterone | 1701038 | 23138SI | 20 |
| Euro OTC | Progesterone | 1702026 | 23148SI | 20 |
| Euro OTC | Progesterone | 1707012 | 23536SI | 28 |
| Euro OTC | Progesterone | 1705028 | 23541SI | 25 |
| Euro OTC | Progesterone | 1709012 | 23732SI | 40 |
| Euro OTC | Progesterone | 1801036 | 23947SI | 20 |
| Euro OTC | Progesterone | 1802030 | 24067SI | 32 |
| Euro OTC | Progesterone | 1806020 | 24138SI | 35 |
| Euro OTC | Progesterone | 1809018 | 24328SI | 30 |
| Euro OTC | Progesterone | 1809017 | 24334SI | 40 |
| Euro OTC | Progesterone | 1603012-01 | 24335SI | 20 |
| Euro OTC | Progesterone | 1811033 | 24345SI | 30 |
| Euro OTC | Progesterone | 1901021 | 24447SI | 40 |
| Euro OTC | Progesterone | 1901022 | 24455SI | 40 |
| Euro OTC | Progesterone | 1904033 | 24606SI | 39 |
| Euro OTC | Progesterone | 1905023 | 24765SI | 40 |
| Euro OTC | Progesterone | 1905022 | 24790SI | 40 |
| Euro OTC | Progesterone | 1908002 | 24834SI | 40 |
| Euro OTC | Progesterone | 1908003 | 24863SI | 40 |
| Euro OTC | Progesterone | 1911006 | 24962SI | 40 |
| Euro OTC | Progesterone | 1911007 | 24970SI | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Progesterone | 2001036 | 25077SI | 40 |
| Euro OTC | Progesterone | 2003037 | 25110SI | 40 |
| Euro OTC | Progesterone | 2003042 | 25111SI | 40 |
| Euro OTC | Progesterone | 2003036 | 25112SI | 40 |
| Euro OTC | Progesterone | 2005019 | 25255SI | 30 |
| Euro OTC | Progesterone | 2005018 | 25256SI | 40 |
| Euro OTC | Progesterone | 2007029 | 25262SI | 39 |
| Euro OTC | Progesterone | 2006017 | 25263SI | 40 |
| Euro OTC | Progesterone | 2007028 | 25276SI | 40 |
| Euro OTC | Progesterone | 2010005 | 25474SI | 40 |
| Euro OTC | Progesterone | 2103020 | 25683SI | 50 |
| Euro OTC | Progesterone | 2108010 | 25819SI | 50 |
| Euro OTC | Progesterone | 2108011 | 25831SI | 50 |
| Euro OTC | Progesterone | 2111009 | 25917SI | 40 |
| Euro OTC | Progesterone | 2111008 | 25921SI | 40 |
| Euro OTC | Progesterone | 2203007 | 26032SI | 40 |
| Euro OTC | Progesterone | 2203006 | 26034SI | 40 |
| Euro OTC | Progesterone | 2207002 | 26214SI | 40 |
| Euro OTC | Progesterone | 2210017 | 26425SI | 40 |
| Euro OTC | Progesterone | 2210016 | 26443SI | 40 |
| Euro OTC | Progesterone | 2301049 | 26577SI | 40 |
| Euro OTC | Progesterone | 2307007 | 26760SI | 40 |
| Euro OTC | Progesterone | 2307006 | 26761SI | 40 |
| Euro OTC | Progesterone | 2308001 | 26886SI | 31 |
| Euro OTC | Progesterone | 2308002 | 26887SI | 31 |
| Euro OTC | Progesterone | 2309026 | 26937SI | 40 |
| Euro OTC | Progesterone | 2311009 | 27013SI | 35 |
| Euro OTC | Progesterone | 2311010 | 27014SI | 40 |
| Euro OTC | Progesterone | 2401013 | 27088SI | 35 |
| Euro OTC | Progesterone | 2401014 | 27089SI | 40 |
| Euro OTC | Progesterone | 2402023 | 27143SI | 40 |
| Euro OTC | Progesterone | 2404001 | 27203SI | 38 |
| Euro OTC | Progesterone | 2404005 | 27204SI | 35 |
| Euro OTC | Progesterone | 2405006 | 27205SI | 39 |
| Euro OTC | Progesterone | 2405005 | 27208SI | 40 |
| Euro OTC | Progesterone | 2406015 | 27284SI | 40 |
| Euro OTC | Progesterone | 2406014 | 27285SI | 36 |
| Euro OTC | Progesterone | 2407018 | 27354SI | 40 |
| Euro OTC | Progesterone | 2407019 | 27355SI | 39 |
| Euro OTC | Progesterone | 2409003 | 27398SI | 40 |
| Euro OTC | Progesterone | 2410011 | 27461SI | 30 |
| Euro OTC | Progesterone | 2410010 | 27462SI | 40 |
| Euro OTC | Progesterone | 2411014 | 27524SI | 39 |
| Euro OTC | Progesterone | 2501023 | 27525SI | 40 |
| Euro OTC | Progesterone | 2411015 | 27526SI | 40 |
| Euro OTC | Progesterone | 2501024 | 27527SI | 40 |
| Fagron | Progesterone | 19H20-F02-364866 | 25046SI | 40 |
| Fagron | Progesterone | 22H12-B01-222409 | 26407SI | 40 |

- 206 250 spectra from a total of 4196 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 3369 spectra from 509 *Apo-Ident* customers from 611 batches from the substance/substance group *Progesterone*.
- Among them are spectra of independent samples from 586 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Progesterone | 14253906 | 1 |
| | Progesterone | 20F-F12-372268 | 1 |
| | Progesterone | 21001388007 | 1 |
| | Progesterone | 21001388008 | 1 |
| | Progesterone | 21001388011 | 2 |
| | Progesterone | 21001388013 | 1 |
| | Progesterone | 21001388017 | 3 |
| | Progesterone | 21001388020 | 1 |
| | Progesterone | 2108010-01 | 1 |
| | Progesterone | 22001580001 | 3 |
| | Progesterone | 22001580002 | 1 |
| | Progesterone | 22001580003 | 1 |
| | Progesterone | 22003208002 | 1 |
| | Progesterone | 22041400M | 1 |
| | Progesterone | 2207002-01 | 3 |
| | Progesterone | 2210016-01 | 1 |
| | Progesterone | 22A31-F02-381709 | 1 |
| | Progesterone | 22A31-F02-381711 | 1 |
| | Progesterone | 22A31-F02-381712 | 2 |
| | Progesterone | 22A31-Fo2-381710 | 1 |
| | Progesterone | 22H12-B01-222409 | 4 |
| | Progesterone | 22H12-B01-222410 | 4 |
| | Progesterone | 22K17-B10-224492 | 1 |
| | Progesterone | 23002143002 | 7 |
| | Progesterone | 23002143003 | 7 |
| | Progesterone | 23003576001 | 1 |
| | Progesterone | 23003576002 | 2 |
| | Progesterone | 2301049-01 | 3 |
| | Progesterone | 2307006-01 | 1 |
| | Progesterone | 2307007-01 | 1 |
| | Progesterone | 2308001-01 | 1 |
| | Progesterone | 2309026-01 | 3 |
| | Progesterone | 2309026-02 | 3 |
| | Progesterone | 2311009-01 | 1 |
| | Progesterone | 23B08B03227299 | 1 |
| | Progesterone | 23B08-B03-227300 | 1 |
| | Progesterone | 23H07-B03-230995 | 4 |
| | Progesterone | 23H07-B04-230619 | 1 |
| | Progesterone | 23H07B04230996 | 1 |
| | Progesterone | 23H07-B04-230996 | 4 |
| | Progesterone | 23H07-B04-230997 | 4 |
| | Progesterone | 23H07-B04-230998 | 1 |
| | Progesterone | 23H07-B04-232937 | 3 |
| | Progesterone | 2401013-01 | 2 |
| | Progesterone | 2401013-02 | 1 |
| | Progesterone | 2404005-01 | 3 |
| | Progesterone | 2405005-01 | 1 |
| | Progesterone | 2406014-01 | 1 |
| | Progesterone | 2406015-01 | 1 |
| | Progesterone | 2407019-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Progesterone | 24F03-B04-003659 | 1 |
| | Progesterone | 24F03-B04-003660 | 1 |
| | Progesterone | 25A22-B06-006569 | 1 |
| | Progesterone | C01-230408 | 1 |
| | Progesterone | C01-230619 | 1 |
| | Progesterone | EU-HTT211213M | 1 |
| | Progesterone | EU-HTT230308M | 1 |
| A.H. 03.06.13 ek: 6,50EUR | Progesterone | 1304014-01 | 1 |
| AHD | Progesterone | 13I11-N11 | 1 |
| Alli | Progesterone | 23B08-B03-227300 | 1 |
| Alliance Healthcare | Progesterone | 1206024-02 | 1 |
| Alliance Healthcare | Progesterone | 23003576002 | 2 |
| Alliance | Progesterone | 15i11-b05-315224 | 1 |
| Alliance | Progesterone | 15I11-B05-315224 | 2 |
| Alliance | Progesterone | 22K17-B10-224492 | 2 |
| allianz | Progesterone | 15/11-B05-315224 | 3 |
| Anzag 07.04.2016 | Progesterone | APC01-150708P | 1 |
| Anzag | Progesterone | 13K28-B01-293478 | 1 |
| Anzag | Progesterone | 14k11-b04-300921 | 1 |
| Anzag | Progesterone | 2515A-03235 | 1 |
| Audor Pharma | Progesterone | APC01-120613P | 1 |
| Audor Pharma | Progesterone | APC01-120708P | 3 |
| Audor Pharma | Progesterone | APC01-141212P | 1 |
| Audor Pharma | Progesterone | APC01-150311P | 1 |
| Audor Pharma | Progesterone | APC01-150708P | 5 |
| Audor Pharma | Progesterone | APC01-151114P | 9 |
| Audor Pharma | Progesterone | APC01-160201 | 1 |
| Audor Pharma | Progesterone | APC01-160201P | 8 |
| Audor Pharma | Progesterone | APC01-170828P | 1 |
| Audor Pharma | Progesterone | APC01-171101P | 31 |
| Audor Pharma | Progesterone | APC01-180128P | 1 |
| Audor Pharma | Progesterone | APC01-180610P | 12 |
| Audor Pharma | Progesterone | APC01-181003P | 15 |
| Audor Pharma | Progesterone | APCO1-181003P | 1 |
| Audor Pharma | Progesterone | APOC01-1700828P | 2 |
| Audor Pharma | Progesterone | C01-120708P | 1 |
| Audor Pharma | Progesterone | C01-180128 | 10 |
| Audor Pharma | Progesterone | C01-181003 | 1 |
| cae | Progesterone | 20004530001 | 1 |
| Caelo | Progesterone | 11177207 | 1 |
| Caelo | Progesterone | 11177219 | 3 |
| Caelo | Progesterone | 11177221 | 2 |
| Caelo | Progesterone | 117348404 | 1 |
| Caelo | Progesterone | 12195828 | 1 |
| Caelo | Progesterone | 12195902 | 1 |
| Caelo | Progesterone | 12195905 | 3 |
| Caelo | Progesterone | 12195906 | 4 |
| Caelo | Progesterone | 12195907 | 6 |
| Caelo | Progesterone | 12195912 | 3 |
| Caelo | Progesterone | 12195913 | 3 |
| Caelo | Progesterone | 12195914 | 3 |
| Caelo | Progesterone | 12195920 | 8 |
| Caelo | Progesterone | 12195924 | 10 |
| Caelo | Progesterone | 12195926 | 19 |
| Caelo | Progesterone | 12195928 | 7 |
| Caelo | Progesterone | 12A19-N04 | 2 |
| Caelo | Progesterone | 130404002 | 2 |
| Caelo | Progesterone | 13155902 | 10 |
| Caelo | Progesterone | 13155920 | 1 |
| Caelo | Progesterone | 13155921 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Progesterone | 13155927 | 4 |
| Caelo | Progesterone | 13155928 | 3 |
| Caelo | Progesterone | 13155929 | 1 |
| Caelo | Progesterone | 13G11-N02 | 1 |
| Caelo | Progesterone | 13HI01-N03 | 1 |
| Caelo | Progesterone | 140100201 | 1 |
| Caelo | Progesterone | 14253911 | 6 |
| Caelo | Progesterone | 14253915 | 2 |
| Caelo | Progesterone | 14253929 | 1 |
| Caelo | Progesterone | 14253930 | 1 |
| Caelo | Progesterone | 14H13-B05-3002016 | 1 |
| Caelo | Progesterone | 14K11-B04-300920 | 2 |
| Caelo | Progesterone | 1511-B05-313598 | 1 |
| Caelo | Progesterone | 15124902 | 1 |
| Caelo | Progesterone | 15124910 | 4 |
| Caelo | Progesterone | 15124919 | 2 |
| Caelo | Progesterone | 15319601 | 7 |
| Caelo | Progesterone | 15319602 | 1 |
| Caelo | Progesterone | 15319603 | 42 |
| Caelo | Progesterone | 15319604 | 1 |
| Caelo | Progesterone | 15319607 | 3 |
| Caelo | Progesterone | 15319608 | 7 |
| Caelo | Progesterone | 15319618 | 4 |
| Caelo | Progesterone | 15319619 | 1 |
| Caelo | Progesterone | 15319620 | 1 |
| Caelo | Progesterone | 15C31-808 | 1 |
| Caelo | Progesterone | 15I11-B05 | 1 |
| Caelo | Progesterone | 15I11-B05-314184 | 2 |
| Caelo | Progesterone | 160100902 | 1 |
| Caelo | Progesterone | 16015B14-315279 | 1 |
| Caelo | Progesterone | 1605013-02 | 1 |
| Caelo | Progesterone | 16103601 | 2 |
| Caelo | Progesterone | 16103602 | 4 |
| Caelo | Progesterone | 16103603 | 11 |
| Caelo | Progesterone | 16103604 | 1 |
| Caelo | Progesterone | 16103605 | 3 |
| Caelo | Progesterone | 16103606 | 13 |
| Caelo | Progesterone | 16103607 | 1 |
| Caelo | Progesterone | 16103609 | 30 |
| Caelo | Progesterone | 16103610 | 4 |
| Caelo | Progesterone | 16103613 | 20 |
| Caelo | Progesterone | 161036303 | 9 |
| Caelo | Progesterone | 16203605 | 1 |
| Caelo | Progesterone | 16A20-B02-319103 | 1 |
| Caelo | Progesterone | 16D13-B04 | 1 |
| Caelo | Progesterone | 16J05-B04-328263 | 1 |
| Caelo | Progesterone | 16L29-B03-330995 | 1 |
| Caelo | Progesterone | 17/21-B03-343284 | 1 |
| Caelo | Progesterone | 17060901 | 41 |
| Caelo | Progesterone | 17060903 | 7 |
| Caelo | Progesterone | 17060904 | 6 |
| Caelo | Progesterone | 17060905 | 2 |
| Caelo | Progesterone | 17060907 | 10 |
| Caelo | Progesterone | 17060909 | 14 |
| Caelo | Progesterone | 17060910 | 3 |
| Caelo | Progesterone | 17060911 | 2 |
| Caelo | Progesterone | 1706093 | 1 |
| Caelo | Progesterone | 17149903 | 1 |
| Caelo | Progesterone | 17149904 | 9 |
| Caelo | Progesterone | 17149905 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Progesterone | 17149906 | 10 |
| Caelo | Progesterone | 17149907 | 1 |
| Caelo | Progesterone | 1719907 | 10 |
| Caelo | Progesterone | 1721bo3342134 | 1 |
| Caelo | Progesterone | 17277801 | 22 |
| Caelo | Progesterone | 1734801 | 1 |
| Caelo | Progesterone | 1734804 | 2 |
| Caelo | Progesterone | 17348401 | 2 |
| Caelo | Progesterone | 17348402 | 6 |
| Caelo | Progesterone | 17348403 | 10 |
| Caelo | Progesterone | 17348404 | 14 |
| Caelo | Progesterone | 17348405 | 3 |
| Caelo | Progesterone | 17348407 | 5 |
| Caelo | Progesterone | 17348409 | 6 |
| Caelo | Progesterone | 1760911 | 1 |
| Caelo | Progesterone | 17C15-B03-333671 | 1 |
| Caelo | Progesterone | 17I21-B03-342136 | 1 |
| Caelo | Progesterone | 18098801 | 25 |
| Caelo | Progesterone | 182632802 | 1 |
| Caelo | Progesterone | 1826380 | 1 |
| Caelo | Progesterone | 182638004 | 5 |
| Caelo | Progesterone | 182638005 | 5 |
| Caelo | Progesterone | 182638009 | 1 |
| Caelo | Progesterone | 18263801 | 3 |
| Caelo | Progesterone | 182638010 | 16 |
| Caelo | Progesterone | 18263802 | 3 |
| Caelo | Progesterone | 18263804 | 17 |
| Caelo | Progesterone | 18263807 | 4 |
| Caelo | Progesterone | 18263809 | 15 |
| Caelo | Progesterone | 18263811 | 1 |
| Caelo | Progesterone | 18B06-B10 | 1 |
| Caelo | Progesterone | 18B06-B10-346702 | 1 |
| Caelo | Progesterone | 18F22-B04-351435 | 1 |
| Caelo | Progesterone | 18f22-B04-354899 | 1 |
| Caelo | Progesterone | 18F22-B04-355395 | 1 |
| Caelo | Progesterone | 19000591002 | 13 |
| Caelo | Progesterone | 19000591005 | 7 |
| Caelo | Progesterone | 19051502 | 1 |
| Caelo | Progesterone | 19128702 | 1 |
| Caelo | Progesterone | 19128705 | 2 |
| Caelo | Progesterone | 19A25-B01-360450 | 1 |
| Caelo | Progesterone | 20004178001 | 1 |
| Caelo | Progesterone | 20004179001 | 5 |
| Caelo | Progesterone | 20004530002 | 7 |
| Caelo | Progesterone | 20004530003 | 2 |
| Caelo | Progesterone | 200303701 | 1 |
| Caelo | Progesterone | 2005019-01 | 1 |
| Caelo | Progesterone | 2006500002 | 1 |
| Caelo | Progesterone | 21001388 | 1 |
| Caelo | Progesterone | 21001388001 | 2 |
| Caelo | Progesterone | 21001388003 | 7 |
| Caelo | Progesterone | 21001388007 | 2 |
| Caelo | Progesterone | 21001388008 | 1 |
| Caelo | Progesterone | 21001388010 | 2 |
| Caelo | Progesterone | 21001388020 | 3 |
| Caelo | Progesterone | 2100138804 | 1 |
| Caelo | Progesterone | 21002413001 | 1 |
| Caelo | Progesterone | 258/61 | 1 |
| Caelo | Progesterone | 27121303 | 1 |
| Caelo | Progesterone | 4814A-03235 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Progesterone | 4817Q-03235 | 1 |
| Caelo | Progesterone | 7101401 | 1 |
| Caelo | Progesterone | 9031705 | 1 |
| Caelo | Progesterone | 9195408 | 1 |
| Caelo | Progesterone | 9195429 | 1 |
| Caelo | Progesterone | B03333671 | 1 |
| Caelo | Progesterone | C01-120613 | 1 |
| Caelo | Progesterone | EU-HTT160708 | 1 |
| Caelo | Progesterone | EU-HTT180317 | 1 |
| Caelo | Progesterone | HTT140302 | 1 |
| Caeolo/Gehe | Progesterone | 17060903 | 2 |
| Caesar & Loretz GmbH... | Progesterone | 18263804 | 1 |
| Caesar & Loretz GmbH... | Progesterone | 21001388003 | 1 |
| Caesar & Loretz GmbH... | Progesterone | 182638010 | 1 |
| Caesar & Loretz GmbH... | Progesterone | 21001388003 | 1 |
| Caesar & Loretz GmbH/Gehe | Progesterone | 18263801 | 1 |
| Caesar & Loretz GmbH/Gehe | Progesterone | 18263809 | 1 |
| Caesar & Loretz GmbH... | Progesterone | 18263804 | 1 |
| Caesar & Loretz GmbH... | Progesterone | 18263804 | 1 |
| Caesar & Loretz GmbH... | Progesterone | 20004530002 | 1 |
| Caesar & Loretz GmbH/phö | Progesterone | 182638004 | 1 |
| Caesar & Loretz GmbH... | Progesterone | 21001388003 | 1 |
| Caesar & Loretz GmbH | Progesterone | 17060910 | 1 |
| Caesar & Loretz GmbH | Progesterone | 17348404 | 1 |
| Caesar & Loretz GmbH | Progesterone | 17348405 | 1 |
| Caesar & Loretz GmbH | Progesterone | 17348407 | 2 |
| Caesar & Loretz GmbH | Progesterone | 17348409 | 2 |
| Caesar & Loretz GmbH | Progesterone | 182638004 | 5 |
| Caesar & Loretz GmbH | Progesterone | 182638010 | 9 |
| Caesar & Loretz GmbH | Progesterone | 18263804 | 6 |
| Caesar & Loretz GmbH | Progesterone | 18263807 | 3 |
| Caesar & Loretz GmbH | Progesterone | 18263809 | 5 |
| Caesar & Loretz GmbH | Progesterone | 20004530002 | 4 |
| Caesar & Loretz GmbH | Progesterone | 2007029-01 | 1 |
| Caesar & Loretz GmbH | Progesterone | 21001388001 | 3 |
| Caesar & Loretz GmbH | Progesterone | 21001388003 | 2 |
| Caesar & Loretz GmbH | Progesterone | 21001388004 | 4 |
| Caesar & Loretz GmbH | Progesterone | 21001388007 | 2 |
| Caesar & Loretz GmbH | Progesterone | 21001388011 | 1 |
| Caesar & Loretz GmbH | Progesterone | 23002143003 | 1 |
| Caesar & Loretz GmbH | Progesterone | EUHTT190101 | 1 |
| Caesar & Loretz/Geil... | Progesterone | 17060904 | 1 |
| Caesar & Loretz/Noweda | Progesterone | 19000591004 | 3 |
| Caesar & Loretz/Noweda | Progesterone | 19128705 | 4 |
| Caesar u Loretz | Progesterone | 13155920 | 1 |
| Caesar u Loretz | Progesterone | 15124919 | 1 |
| Caesar&Lorenz | Progesterone | 16103605 | 1 |
| Caesar/Noweda | Progesterone | 12195912 | 1 |
| Cealo/Noweda | Progesterone | 16103607 | 1 |
| Changzhou Jiaerke Pharma | Progesterone | 1308015-01 | 1 |
| China Medica | Progesterone | 1308015-01 | 1 |
| Ebert u. Jacobi 1... | Progesterone | 15C31-B06-312963 | 1 |
| Ebert-Jacobi | Progesterone | 16J05-B04-328263 | 1 |
| EuRho/EuRho | Progesterone | 1904033-01 | 1 |
| EuRho | Progesterone | 1304040-02 | 1 |
| euRho | Progesterone | 2103020-01 | 1 |
| EuRho | Progesterone | 2203007-01 | 1 |
| Euro OTC | Progesterone | | 2 |
| Euro OTC | Progesterone | 1111053-01 | 6 |
| Euro OTC | Progesterone | 1206024-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Progesterone | 1211004-01 | 5 |
| Euro OTC | Progesterone | 12195924 | 1 |
| Euro OTC | Progesterone | 130404001 | 1 |
| Euro OTC | Progesterone | 1304040-01 | 6 |
| Euro OTC | Progesterone | 1304040-02 | 3 |
| Euro OTC | Progesterone | 1308015-01 | 3 |
| Euro OTC | Progesterone | 1401002-01 | 5 |
| Euro OTC | Progesterone | 1403019-01 | 2 |
| Euro OTC | Progesterone | 1406022-01 | 1 |
| Euro OTC | Progesterone | 140602202 | 1 |
| Euro OTC | Progesterone | 1406022-02 | 2 |
| Euro OTC | Progesterone | 1406910-01 | 1 |
| Euro OTC | Progesterone | 1409019-01 | 1 |
| Euro OTC | Progesterone | 1409029-01 | 6 |
| Euro OTC | Progesterone | 1409029-1 | 1 |
| Euro OTC | Progesterone | 140910-01 | 1 |
| Euro OTC | Progesterone | 141104301 | 1 |
| Euro OTC | Progesterone | 1411043-01 | 4 |
| Euro OTC | Progesterone | 15/11-B05-315224 | 1 |
| Euro OTC | Progesterone | 1502030-01 | 2 |
| Euro OTC | Progesterone | 1503012-01 | 7 |
| Euro OTC | Progesterone | 1503033-01 | 1 |
| Euro OTC | Progesterone | 1506033-01 | 51 |
| Euro OTC | Progesterone | 1509008_01 | 1 |
| Euro OTC | Progesterone | 1509008-01 | 7 |
| Euro OTC | Progesterone | 1509008-02 | 31 |
| Euro OTC | Progesterone | 160100901 | 1 |
| Euro OTC | Progesterone | 1601009-01 | 55 |
| Euro OTC | Progesterone | 1601009-02 | 52 |
| Euro OTC | Progesterone | 1603004-01 | 46 |
| Euro OTC | Progesterone | 1603012-01 | 1 |
| Euro OTC | Progesterone | 1605013-01 | 35 |
| Euro OTC | Progesterone | 1605013-02 | 45 |
| Euro OTC | Progesterone | 160501303 | 2 |
| Euro OTC | Progesterone | 1605013-03 | 6 |
| Euro OTC | Progesterone | 1605032-01 | 46 |
| Euro OTC | Progesterone | 160532-01 | 15 |
| Euro OTC | Progesterone | 1609001-01 | 65 |
| Euro OTC | Progesterone | 1701038-01 | 30 |
| Euro OTC | Progesterone | 170103802 | 9 |
| Euro OTC | Progesterone | 1701038-02 | 33 |
| Euro OTC | Progesterone | 170138-01 | 20 |
| Euro OTC | Progesterone | 1704012-01 | 8 |
| Euro OTC | Progesterone | 1705028 | 1 |
| Euro OTC | Progesterone | 170502801 | 1 |
| Euro OTC | Progesterone | 1705028-01 | 64 |
| Euro OTC | Progesterone | 1706009-01 | 9 |
| Euro OTC | Progesterone | 1709012-01 | 100 |
| Euro OTC | Progesterone | 17I08-B04 | 1 |
| Euro OTC | Progesterone | 1801036-01 | 27 |
| Euro OTC | Progesterone | 1801036-02 | 16 |
| Euro OTC | Progesterone | 18041816 | 1 |
| Euro OTC | Progesterone | 1806020-01 | 55 |
| Euro OTC | Progesterone | 1806020-02 | 1 |
| Euro OTC | Progesterone | 180901701 | 20 |
| Euro OTC | Progesterone | 1809017-01 | 60 |
| Euro OTC | Progesterone | 1809017-02 | 1 |
| Euro OTC | Progesterone | 1809018-02 | 1 |
| Euro OTC | Progesterone | 1811033-01 | 64 |
| Euro OTC | Progesterone | 1901021-01 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Progesterone | 1901022-01 | 36 |
| Euro OTC | Progesterone | 1904033_01 | 1 |
| Euro OTC | Progesterone | 1904033-01 | 6 |
| Euro OTC | Progesterone | 190433-01 | 1 |
| Euro OTC | Progesterone | 1905022-01 | 4 |
| Euro OTC | Progesterone | 1905023-01 | 3 |
| Euro OTC | Progesterone | 1908002-01 | 12 |
| Euro OTC | Progesterone | 1908003-01 | 3 |
| Euro OTC | Progesterone | 1911006-01 | 1 |
| Euro OTC | Progesterone | 1911007-01 | 39 |
| Euro OTC | Progesterone | 19A25-B01-360449 | 1 |
| Euro OTC | Progesterone | 2001036-01 | 1 |
| Euro OTC | Progesterone | 2003036-01 | 2 |
| Euro OTC | Progesterone | 2003037-01 | 1 |
| Euro OTC | Progesterone | 2003042 | 2 |
| Euro OTC | Progesterone | 200304201 | 2 |
| Euro OTC | Progesterone | 2003042-01 | 1 |
| Euro OTC | Progesterone | 2005018-01 | 4 |
| Euro OTC | Progesterone | 2005019-01 | 19 |
| Euro OTC | Progesterone | 2006017-02 | 3 |
| Euro OTC | Progesterone | 2006018-01 | 96 |
| Euro OTC | Progesterone | 200618-01 | 1 |
| Euro OTC | Progesterone | 2007028-02 | 3 |
| Euro OTC | Progesterone | 2007029-01 | 126 |
| Euro OTC | Progesterone | 2010005-01 | 56 |
| Euro OTC | Progesterone | 2103019-01 | 3 |
| Euro OTC | Progesterone | 2103020-01 | 107 |
| Euro OTC | Progesterone | 210801001 | 1 |
| Euro OTC | Progesterone | 2108010-01 | 97 |
| Euro OTC | Progesterone | 2108011-01 | 3 |
| Euro OTC | Progesterone | 2111008-01 | 3 |
| Euro OTC | Progesterone | 2111009-01 | 5 |
| Euro OTC | Progesterone | 2203006-01 | 3 |
| Euro OTC | Progesterone | 2203007-01 | 7 |
| Euro OTC | Progesterone | 2210016-01 | 1 |
| Euro OTC | Progesterone | 2210017 | 1 |
| Euro OTC | Progesterone | 2210017-01 | 1 |
| Euro OTC | Progesterone | 27061713 | 1 |
| Euro OTC | Progesterone | 5102 | 1 |
| Euro OTC | Progesterone | 5104 | 1 |
| Euro OTC | Progesterone | 7406022-01 | 1 |
| Euro OTC | Progesterone | 818A-03235 | 1 |
| Euro OTC | Progesterone | c01-111218 | 1 |
| Euro OTC | Progesterone | c01-130301 | 1 |
| Euro OTC | Progesterone | C01-130301(M) | 2 |
| Euro OTC | Progesterone | C01-130301M | 1 |
| Euro OTC | Progesterone | co1-111218(M) | 1 |
| Euro OTC | Progesterone | EuroOTC | 1 |
| Euro OTC | Progesterone | HTT160102 | 1 |
| Euro/ Sanacorp | Progesterone | C01-131116(M) | 1 |
| EURO/Noweda | Progesterone | 191100701 | 1 |
| EURO/Noweda | Progesterone | 200304201 | 1 |
| Euro | Progesterone | 1509008-02 | 1 |
| Europh-Jenne | Progesterone | 1406022-01 | 1 |
| Fagron | Progesterone | | 2 |
| Fagron | Progesterone | 1-111218 | 1 |
| Fagron | Progesterone | 12A19-N04 | 1 |
| Fagron | Progesterone | 12D05-N06 | 3 |
| Fagron | Progesterone | 12G05-N17 | 6 |
| Fagron | Progesterone | 12K05-N01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Progesterone | 12k05-n07 | 1 |
| Fagron | Progesterone | 12K05-N07 | 1 |
| Fagron | Progesterone | 13/11-N11 | 1 |
| Fagron | Progesterone | 1311-N11 | 1 |
| Fagron | Progesterone | 13A02N01 | 1 |
| Fagron | Progesterone | 13A02-N01 | 3 |
| Fagron | Progesterone | 13AC2-N01 | 1 |
| Fagron | Progesterone | 13b08-n01 | 1 |
| Fagron | Progesterone | 13G11-N02 | 6 |
| Fagron | Progesterone | 13h01-n03 | 1 |
| Fagron | Progesterone | 13H01-N03 | 7 |
| Fagron | Progesterone | 13I11-N11 | 2 |
| Fagron | Progesterone | 13k28-b30-288261 | 1 |
| Fagron | Progesterone | 13K28-B30-288261 | 1 |
| Fagron | Progesterone | 13K28-B30-288262 | 1 |
| Fagron | Progesterone | 13K-B30-288261 | 1 |
| Fagron | Progesterone | 14C10-B01 | 1 |
| Fagron | Progesterone | 14C10B0129347 | 1 |
| Fagron | Progesterone | 14c10-b01-293478 | 1 |
| Fagron | Progesterone | 14c10-B01-293478 | 1 |
| Fagron | Progesterone | 14C10-B01-293478 | 2 |
| Fagron | Progesterone | 14D22-B04 | 2 |
| Fagron | Progesterone | 14D22B04293476 | 1 |
| Fagron | Progesterone | 14D22-B04-293476 | 2 |
| Fagron | Progesterone | 14D22-B04-293477 | 1 |
| Fagron | Progesterone | 14D22-B293479 | 1 |
| Fagron | Progesterone | 14D22-Bo4 | 1 |
| Fagron | Progesterone | 14H13-B05-300216 | 7 |
| Fagron | Progesterone | 14k11-b04 | 1 |
| Fagron | Progesterone | 14K11-B04 | 3 |
| Fagron | Progesterone | 14K11-B04_300921 | 1 |
| Fagron | Progesterone | 14K11-B04-3000920 | 1 |
| Fagron | Progesterone | 14K11B04300920 | 1 |
| Fagron | Progesterone | 14K11-B04-300920 | 6 |
| Fagron | Progesterone | 14K11-B04-300921 | 3 |
| Fagron | Progesterone | 14L15-B05-302292 | 2 |
| Fagron | Progesterone | 14O22-B04-293476 | 1 |
| Fagron | Progesterone | 15/11-B05-315224 | 3 |
| Fagron | Progesterone | 1511-805 | 1 |
| Fagron | Progesterone | 1511-B05-313598 | 2 |
| Fagron | Progesterone | 1511-B05-313598GB | 1 |
| Fagron | Progesterone | 1511-B05-314184 | 1 |
| Fagron | Progesterone | 1511-B05-314842 | 1 |
| Fagron | Progesterone | 1511B05-315224 | 1 |
| Fagron | Progesterone | 15B12-B04-304837 | 2 |
| Fagron | Progesterone | 15B12-Bo4-304838 | 1 |
| Fagron | Progesterone | 15C31-B06 | 3 |
| Fagron | Progesterone | 15C31B06308439 | 1 |
| Fagron | Progesterone | 15C31-B06-308439 | 8 |
| Fagron | Progesterone | 15C31-B06-308786 | 1 |
| Fagron | Progesterone | 15C31-B06-308796 | 6 |
| Fagron | Progesterone | 15C31-B06-309790 | 3 |
| Fagron | Progesterone | 15C31-B06-312963 | 1 |
| Fagron | Progesterone | 15C31-B06-313599 | 1 |
| Fagron | Progesterone | 15C31-B06-316105 | 3 |
| Fagron | Progesterone | 15C31-Bo6-308796 | 1 |
| Fagron | Progesterone | 15I11-B05 | 1 |
| Fagron | Progesterone | 15I11-B05-313598 | 2 |
| Fagron | Progesterone | 15I11-B05-314184 | 4 |
| Fagron | Progesterone | 15I11-B05-314842 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Progesterone | 15I11-B05-315224 | 3 |
| Fagron | Progesterone | 1605013-03 | 1 |
| Fagron | Progesterone | 160A20-B02-321373 | 1 |
| Fagron | Progesterone | 16a20-b02-318667 | 1 |
| Fagron | Progesterone | 16A20-B02-318667 | 3 |
| Fagron | Progesterone | 16A20-B02-318668 | 1 |
| Fagron | Progesterone | 16A20-B02-319103 | 2 |
| Fagron | Progesterone | 16A20-B02-321373 | 2 |
| Fagron | Progesterone | 16A20-B02-321374 | 4 |
| Fagron | Progesterone | 16a20-b02-321375 | 1 |
| Fagron | Progesterone | 16A20-B02-321375 | 2 |
| Fagron | Progesterone | 16D13-B04-323636 | 1 |
| Fagron | Progesterone | 16g115-b04-325136 | 1 |
| Fagron | Progesterone | 16g15-b04 | 1 |
| Fagron | Progesterone | 16G15-B04 | 2 |
| Fagron | Progesterone | 16G15-B04-325135 | 2 |
| Fagron | Progesterone | 16G15-B04325136 | 1 |
| Fagron | Progesterone | 16G15-B04-325136 | 4 |
| Fagron | Progesterone | 16G15B04-325279 | 1 |
| Fagron | Progesterone | 16G15-B04325279 | 1 |
| Fagron | Progesterone | 16G15-B04-325279 | 6 |
| Fagron | Progesterone | 16G15-B04-325755 | 4 |
| Fagron | Progesterone | 16G15-B04-32579 | 1 |
| Fagron | Progesterone | 16g15-b04-326487 | 1 |
| Fagron | Progesterone | 16G15-B04-326487 | 3 |
| Fagron | Progesterone | 16J05-B04-328263 | 3 |
| Fagron | Progesterone | 16J05-B04-328303 | 3 |
| Fagron | Progesterone | 16l11-B04-314184 | 1 |
| Fagron | Progesterone | 16L29-B03 | 1 |
| Fagron | Progesterone | 16L29-B03-302060 | 1 |
| Fagron | Progesterone | 16L29-B03-330995 | 2 |
| Fagron | Progesterone | 16l29b03332060 | 1 |
| Fagron | Progesterone | 16L29-B03-332060 | 5 |
| Fagron | Progesterone | 16L29-B03-332505 | 4 |
| Fagron | Progesterone | 16L29-B-332061 | 1 |
| Fagron | Progesterone | 17/21-B03-341517 | 1 |
| Fagron | Progesterone | 17/21-B03-341518 | 1 |
| Fagron | Progesterone | 17/21-B03-342134 | 2 |
| Fagron | Progesterone | 17/21-B03-342135 | 2 |
| Fagron | Progesterone | 17/21-B03-343284 | 2 |
| Fagron | Progesterone | 17060911 | 1 |
| Fagron | Progesterone | 1721B03342134 | 1 |
| Fagron | Progesterone | 1721-B03-342136 | 1 |
| Fagron | Progesterone | 17C15-B03 | 1 |
| Fagron | Progesterone | 17C15B03333671 | 2 |
| Fagron | Progesterone | 17C15-B03-333671 | 3 |
| Fagron | Progesterone | 17C15-B03-333671 | 1 |
| Fagron | Progesterone | 17C15-B03-333672 | 2 |
| Fagron | Progesterone | 17d25-b06 | 1 |
| Fagron | Progesterone | 17D25-B06-339651 | 3 |
| Fagron | Progesterone | 17D25-B06-339655 | 2 |
| Fagron | Progesterone | 17I08-B04 | 1 |
| Fagron | Progesterone | 17I08-B04-344773 | 1 |
| Fagron | Progesterone | 17I21-803 | 1 |
| Fagron | Progesterone | 17I21-B03 | 1 |
| Fagron | Progesterone | 17I21-B03-341516 | 2 |
| Fagron | Progesterone | 17I21-B03-341518 | 2 |
| Fagron | Progesterone | 17I21-B03-341520 | 3 |
| Fagron | Progesterone | 17I21-B03-342135 | 1 |
| Fagron | Progesterone | 17I21-B03-343284 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Progesterone | 18806-B10-349153 | 1 |
| Fagron | Progesterone | 18B06_B10_349775 | 1 |
| Fagron | Progesterone | 18B06-B10 | 7 |
| Fagron | Progesterone | 18B06-B10-346701 | 5 |
| Fagron | Progesterone | 18B06-B10-346702 | 2 |
| Fagron | Progesterone | 18B06-B10-346704 | 4 |
| Fagron | Progesterone | 18B06B10347484 | 1 |
| Fagron | Progesterone | 18B06-B10-347484 | 4 |
| Fagron | Progesterone | 18B06-B10-349153 | 1 |
| Fagron | Progesterone | 18B06-B10-349775 | 3 |
| Fagron | Progesterone | 18F22_B04_354899 | 1 |
| Fagron | Progesterone | 18F22-B04 | 5 |
| Fagron | Progesterone | 18F-22-B04 | 1 |
| Fagron | Progesterone | 18F22-B04-351145 | 3 |
| Fagron | Progesterone | 18F22-B04-351435 | 3 |
| Fagron | Progesterone | 18F22-B04-351998 | 2 |
| Fagron | Progesterone | 18F22-B04-352735 | 3 |
| Fagron | Progesterone | 18F22-B04-352736 | 1 |
| Fagron | Progesterone | 18f22-B04-353582 | 1 |
| Fagron | Progesterone | 18F22-B04-353582 | 2 |
| Fagron | Progesterone | 18F22-B04353582-P201 | 1 |
| Fagron | Progesterone | 18F22-B04-354899 | 3 |
| Fagron | Progesterone | 18F22-B04-354900 | 4 |
| Fagron | Progesterone | 18F22-B04-354901 | 2 |
| Fagron | Progesterone | 18F22-B04-355395 | 7 |
| Fagron | Progesterone | 18F22-HTT180317 | 1 |
| Fagron | Progesterone | 1910213235 | 1 |
| Fagron | Progesterone | 19A25-B01 | 1 |
| Fagron | Progesterone | 19A25-B01-360448 | 1 |
| Fagron | Progesterone | 19A25-B01-360449 | 8 |
| Fagron | Progesterone | 19A25-B01-360450 | 1 |
| Fagron | Progesterone | 19A25-B01-360452 | 1 |
| Fagron | Progesterone | 19A25-B01-360458 | 3 |
| Fagron | Progesterone | 19H20-F02 | 9 |
| Fagron | Progesterone | 19H20-F02-364866 | 3 |
| Fagron | Progesterone | 19H20-F02-364867 | 2 |
| Fagron | Progesterone | 19H20-F02-364868 | 4 |
| Fagron | Progesterone | 19H20-F02-364869 | 2 |
| Fagron | Progesterone | 19H20-F02-364870 | 2 |
| Fagron | Progesterone | 19H20-F02-364871 | 1 |
| Fagron | Progesterone | 19H2O-F02-364866 | 1 |
| Fagron | Progesterone | 19J22-F05 | 2 |
| Fagron | Progesterone | 19J22-F05-3655503 | 1 |
| Fagron | Progesterone | 19J22F05-365551 | 1 |
| Fagron | Progesterone | 19J22-F05-365551 | 3 |
| Fagron | Progesterone | 19J22-F05-365552 | 4 |
| Fagron | Progesterone | 19J22-F05-365553 | 7 |
| Fagron | Progesterone | 19J22-F05-365555 | 1 |
| Fagron | Progesterone | 19J22-F05-365556 | 2 |
| Fagron | Progesterone | 19K11-F04 | 3 |
| Fagron | Progesterone | 19K11-F04-3660209 | 1 |
| Fagron | Progesterone | 19K11-F04-366029 | 2 |
| Fagron | Progesterone | 19K11-F04-366031 | 1 |
| Fagron | Progesterone | 19K11-F04-366033 | 2 |
| Fagron | Progesterone | 200650-0003 | 1 |
| Fagron | Progesterone | 200650-0004 | 2 |
| Fagron | Progesterone | 200650-315224 | 1 |
| Fagron | Progesterone | 20103-F01-374019 | 2 |
| Fagron | Progesterone | 20103-F01-374023 | 1 |
| Fagron | Progesterone | 20103-F01-375531 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Progesterone | 20170427Ma6 | 1 |
| Fagron | Progesterone | 20F18-F12 | 3 |
| Fagron | Progesterone | 20F18-F12-32269 | 1 |
| Fagron | Progesterone | 20F18-F12-3722607 | 1 |
| Fagron | Progesterone | 20F18-F12-372267 | 4 |
| Fagron | Progesterone | 20F18-F12-372268 | 4 |
| Fagron | Progesterone | 20F18-f12-372269 | 1 |
| Fagron | Progesterone | 20F18-F12-372269 | 1 |
| Fagron | Progesterone | 20F18-F12-372270 | 11 |
| Fagron | Progesterone | 20F18-F12-372271 | 1 |
| Fagron | Progesterone | 20F18-F12-372272 | 6 |
| Fagron | Progesterone | 20F18-F12-372274 | 1 |
| Fagron | Progesterone | 20F18-F12-372275 | 3 |
| Fagron | Progesterone | 20I03-F01-374018 | 5 |
| Fagron | Progesterone | 20I03-F01-374019 | 3 |
| Fagron | Progesterone | 20I03-F01-374023 | 2 |
| Fagron | Progesterone | 20i03F01375531 | 1 |
| Fagron | Progesterone | 20I03-F01-375531 | 1 |
| Fagron | Progesterone | 21E11-F01 | 1 |
| Fagron | Progesterone | 21E11-F01-378406 | 3 |
| Fagron | Progesterone | 21F01-F02-378515 | 1 |
| Fagron | Progesterone | 21G14F04 | 1 |
| Fagron | Progesterone | 21G14-F04 | 2 |
| Fagron | Progesterone | 21G14-F04-379182 | 5 |
| Fagron | Progesterone | 21G14-F04-379183 | 9 |
| Fagron | Progesterone | 21G14-F04-379607 | 3 |
| Fagron | Progesterone | 21G14-F04-379608 | 1 |
| Fagron | Progesterone | 21G14-F04-381038 | 3 |
| Fagron | Progesterone | 21G14-FO4-379607 | 1 |
| Fagron | Progesterone | 22A31-F02 | 1 |
| Fagron | Progesterone | 22A31-F02-381709 | 4 |
| Fagron | Progesterone | 22A31-f02-381710 | 1 |
| Fagron | Progesterone | 22A31-F02-381711 | 2 |
| Fagron | Progesterone | 22A31-F02-381712 | 2 |
| Fagron | Progesterone | 22A31-F02-381713 | 1 |
| Fagron | Progesterone | 22A31-F02-381714 | 5 |
| Fagron | Progesterone | 22D05-F03-382185 | 1 |
| Fagron | Progesterone | 22H12-B01 | 4 |
| Fagron | Progesterone | 22h12-b01-222411 | 1 |
| Fagron | Progesterone | 22H12-B02-226405 | 1 |
| Fagron | Progesterone | 22H12-Bo1 | 1 |
| Fagron | Progesterone | 23B08_B03_227303 | 1 |
| Fagron | Progesterone | 23B08-B03-227300 | 1 |
| Fagron | Progesterone | 23B08-B03-227303 | 2 |
| Fagron | Progesterone | 23H07-B04-232935 | 1 |
| Fagron | Progesterone | 375779 | 1 |
| Fagron | Progesterone | 5013I-03235 | 1 |
| Fagron | Progesterone | ApC01-180128P | 1 |
| Fagron | Progesterone | C01-120322 | 1 |
| Fagron | Progesterone | C01-130301 | 1 |
| Fagron | Progesterone | C01-170814 | 1 |
| Fagron | Progesterone | C01-171216 | 1 |
| Fagron | Progesterone | EU_HTT190405 | 1 |
| Fagron | Progesterone | EU-HTT160502 | 1 |
| Fagron | Progesterone | EU-HTT160705 | 2 |
| Fagron | Progesterone | EU-HTT180317 | 1 |
| Fagron | Progesterone | EU-HTT190101 | 1 |
| Fagron | Progesterone | EU-HTT190405 | 1 |
| Fagron | Progesterone | EU-HTT200401 | 3 |
| Fagron | Progesterone | EU-HTT211213M | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Progesterone | EU-HTT220202M | 1 |
| Fagron | Progesterone | EU-HTT220316M | 1 |
| Fagron | Progesterone | EU-HTT221213M | 1 |
| Fagron | Progesterone | F01-3740202 | 1 |
| Fagron | Progesterone | F01-3740203 | 2 |
| Fagron | Progesterone | F01-3755301 | 1 |
| Fagron | Progesterone | F02-3648606 | 1 |
| Fagron | Progesterone | F0238171001 | 1 |
| Fagron | Progesterone | F05_3655501 | 1 |
| Fagron | Progesterone | F05-3655505 | 1 |
| Fagron | Progesterone | F12-3722607 | 3 |
| Fagron | Progesterone | F12-3722609 | 2 |
| Fagron | Progesterone | F12-3722700 | 1 |
| Fagron | Progesterone | F12-3722702 | 1 |
| Fagron | Progesterone | F12-3722704 | 2 |
| Fagron | Progesterone | F12-372271 | 1 |
| Fagron | Progesterone | HTT140207 | 1 |
| Fagron | Progesterone | HTT140302 | 1 |
| Fagron | Progesterone | HTT140413 | 1 |
| Fagron | Progesterone | HTT140503 | 1 |
| Fagron | Progesterone | HTT140903 | 1 |
| Fagron | Progesterone | HTT150201 | 3 |
| Fagron | Progesterone | intern20180619Ma3 | 1 |
| Fargon | Progesterone | 16L29-B03-332505 | 1 |
| fargon | Progesterone | 18I03-B02-355396 | 1 |
| Fargon | Progesterone | 19J22-F-05-365555 | 1 |
| Fargon | Progesterone | 20F18-F12-372269 | 1 |
| Fiebig | Progesterone | 17060909 | 1 |
| Fiebig | Progesterone | 17I21-B03 | 1 |
| Fragon | Progesterone | 13A02-N02 | 1 |
| fragron | Progesterone | 16A20-B02-319103 | 1 |
| Gehe | Progesterone | 15319608 | 1 |
| Gehe | Progesterone | 17060903 | 1 |
| Gehe | Progesterone | 18B06-B10-347484 | 1 |
| Gehe | Progesterone | 2309026-02 | 1 |
| Geilenkirchen | Progesterone | 16103605 | 1 |
| Geilenkirchen | Progesterone | 16103614 | 1 |
| Geilenkirchen | Progesterone | 17060904 | 2 |
| Geilenkirchen | Progesterone | 17060909 | 1 |
| Geilenkirchen | Progesterone | 17348407 | 2 |
| Hubei Gedian Humanwe… | Progesterone | 1809017-01 | 2 |
| Hubei Gedian Humanwell | Progesterone | EU-HTT200401 | 1 |
| Klenk | Progesterone | C01-120322 | 1 |
| Kögl | Progesterone | 1802398 | 1 |
| L12 | Progesterone | 1605013-01 | 1 |
| L12 | Progesterone | 17060909 | 2 |
| L30 | Progesterone | 17060910 | 1 |
| L30 | Progesterone | 18B06-B10-349775 | 1 |
| Muster | Progesterone | HTT150801 | 1 |
| Muster | Progesterone | HTT151101 | 1 |
| Noweda | Progesterone | 18B06-B10-349775 | 1 |
| Noweda | Progesterone | 19K11-F04-366029 | 1 |
| Noweda | Progesterone | 22A31-F02-381709 | 1 |
| Noweda | Progesterone | 22H12-B01-222409 | 1 |
| Noweda | Progesterone | 22H12-B01-222411 | 1 |
| Noweda | Progesterone | 23002143004 | 1 |
| Noweda | Progesterone | 23B08-B03-227299 | 5 |
| Noweda | Progesterone | 23B08-B03-227300 | 1 |
| Noweda | Progesterone | 23H07_B04-230619 | 1 |
| Noweda | Progesterone | 23H07-B03-230134 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Progesterone | 23H07-B04_232937 | 1 |
| Noweda | Progesterone | 23H07-B04-230619 | 1 |
| Noweda | Progesterone | 23H07-B04-230996 | 1 |
| Noweda | Progesterone | 23H07-B04-230997 | 2 |
| Noweda | Progesterone | 23H07-B04-232937 | 1 |
| Noweda | Progesterone | 23H07-B04-230996 | 1 |
| Noweda | Progesterone | 32H07-B04-230996 | 1 |
| Noweda | Progesterone | F04-3660209 | 1 |
| Parthe Apotheke | Progesterone | 71/21 | 1 |
| PHOENIX am 18.03.2014 | Progesterone | 13A02-N01 | 1 |
| Phoenix 09.12.14 | Progesterone | 13H01-N03 | 1 |
| Phoenix 28.03.2014 | Progesterone | 13G11-N02 | 1 |
| Phoenix/Cealo | Progesterone | 17/21-B03-341517 | 1 |
| Phoenix | Progesterone | 20F18-F12 | 1 |
| Phoenix | Progesterone | 20F18-F12-372270 | 1 |
| Phoenix | Progesterone | EU-HTT190405 | 1 |
| Phönix | Progesterone | 13155920 | 1 |
| Phönix | Progesterone | 15319604 | 1 |
| Phönix | Progesterone | 15319620 | 1 |
| Phönix | Progesterone | 1605013-01 | 1 |
| Phönix | Progesterone | 16A20-B02-319103 | 1 |
| Phönix | Progesterone | 16G15-B04_325135 | 1 |
| phönix | Progesterone | 16g15-b04-326487 | 1 |
| Phönix | Progesterone | 2003042-01 | 1 |
| phönix | Progesterone | 20F18-F12-372269 | 1 |
| Phönix | Progesterone | 20F18-F12-372269 | 1 |
| Phönix | Progesterone | 21E11-F013778406 | 1 |
| Phönix | Progesterone | 23002143003 | 1 |
| Sanacorp Caesar & Lo... | Progesterone | 21001388003 | 2 |
| Sanacorp Verbund | Progesterone | 20I03-F01-374020 | 1 |
| Sanacorp | Progesterone | 12195914 | 1 |
| Sanacorp | Progesterone | 12195928 | 1 |
| Sanacorp | Progesterone | 13155902 | 1 |
| Sanacorp | Progesterone | 13A02-N01 | 1 |
| Sanacorp | Progesterone | 14C10-B01-293478 | 1 |
| sanacorp | Progesterone | 15124902 | 1 |
| Sanacorp | Progesterone | 15C31-B06-312963 | 3 |
| Sanacorp | Progesterone | 17D25-B06 | 1 |
| Sanacorp | Progesterone | 1809017-01 | 1 |
| Sanacorp | Progesterone | 19H20-F02-364869 | 1 |
| Sanacorp | Progesterone | 19J22-F05 | 1 |
| Sanacorp | Progesterone | 2007029-01 | 1 |
| Sanacorp | Progesterone | 20F18-F12 | 2 |
| Sanacorp | Progesterone | 21001388007 | 2 |
| Sanacorp | Progesterone | 21001388015 | 1 |
| Sanacorp | Progesterone | 21001388016 | 1 |
| Sanacorp | Progesterone | 2111009-01 | 1 |
| Sanacorp | Progesterone | 2207002-02 | 1 |
| Sanacorp | Progesterone | 23002143003 | 1 |
| Sanacorp | Progesterone | 23003576001 | 1 |
| Sanacorp | Progesterone | 2301049-01 | 1 |
| Sanacorp | Progesterone | 2309026-01 | 1 |
| Sanacorp | Progesterone | 2309026-02 | 1 |
| Sanacorp | Progesterone | 23H07-B03-230995 | 1 |
| unbekannt | Progesterone | 104704 | 1 |
| Vdl 28.04.14;Preis 39,95 | Progesterone | | 1 |
| VDL;07.11.14;39,95 euro | Progesterone | 13155921 | 1 |

- 253 517 spectra from 1666 *Apo-Ident* customers from a total of 51 546 batches from a further

724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Progesterone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Progesterone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 916 | 0 | 157 410 |
| **Type B** | 0 | 6690 | 0 | 206 250 |
| **Type C** | 0 | 3320 | 49 | 253 517 |

The substance/substance group *Progesterone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.3450 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.9103 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.5456 % (> 98.4565 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20718 | 22303 | 3.51 | 65.17 |
| 21868 | 21868 | 0.00 | 73.79 |
| 21870 | 21870 | 0.00 | 70.64 |
| 21907 | 21907 | 0.00 | 72.15 |
| 22226 | 22226 | 0.00 | 66.60 |
| 22301 | 22301 | 0.00 | 74.22 |
| 22303 | 22303 | 0.00 | 69.39 |
| 22525 | 22525 | 0.00 | 80.90 |
| 22830 | 21907 | 3.70 | 81.14 |
| 22831 | 22303 | 3.68 | 73.38 |
| 23249 | 22303 | 5.43 | 69.27 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25273 | 25273 | 0.00 | 68.27 |
| 25658 | 25658 | 0.00 | 70.49 |
| 25684 | 25684 | 0.00 | 71.59 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Proline** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21034-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Proline; Prolinum

### Special notes

When selecting the *Proline* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Proline | 9 | 5 | 2 |

### Second-stage model

For differentiation of the substance/substance group *Proline* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Proline* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 82.76 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Proline* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Proline*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Proline | 1606010 | 22677 | 40 | 20160714* |
| Euro OTC | Proline | 1705021 | 23546 | 40 | 20170720* |
| Euro OTC | Proline | 1801047 | 23961 | 40 | 20180206* |
| Euro OTC | Proline | 2009012 | 25418 | 40 | 20200928* |
| Euro OTC | Proline | 2111021 | 25916 | 40 | 20220112* |
| Euro OTC | Proline | 2205012 | 26210 | 40 | 20220608* |
| Euro OTC | Proline | 2205012 | 26210SI | 20 | 20220608* |
| Euro OTC | Proline | 2308005 | 26870 | 40 | 20230824* |
| Euro OTC | Proline | 2308005 | 26870SI | 20 | 20230824* |
| Fagron | Proline | 15D13-B02-308152 | 22270 | 60 | 1704059 |
| Fagron | Proline | 16J14-B01-327195 | 23109 | 40 | 20161116 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 420 spectra of 11 reference samples from the substance/substance group *Proline*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 906 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 250 spectra of 7 reference samples from the substance/substance group *Proline*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Proline | L1210046-01 | 21103 | 40 |
| Euro OTC | Proline | 1606010-01 | 23013 | 40 |
| Euro OTC | Proline | 1812009 | 24419 | 40 |
| Euro OTC | Proline | 1909002 | 24844 | 40 |
| Fagron | Proline | 24J17-B05-004943 | 27570 | 40 |
| Euro OTC | Proline | 1606010-01 | 23100 | 40 |
| Euro OTC | Proline | 2111021 | 25916SI† | 10 |

- 212 690 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2 spectra from 2 *Apo-Ident* customers from 2 batches from the substance/substance group *Proline*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Proline | L1210046-03 | 1 |
| Fagron | Proline | 20J01-F13-374496 | 1 |

- 256 884 spectra from 1666 *Apo-Ident* customers from a total of 52 151 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Proline* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Proline* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 250 | 0 | 212 690 |
| **Type C** | 0 | 2 | 0 | 256 884 |

The substance/substance group *Proline* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6000 %) |
| **Type C** | 100.0000 % (> 99.9032 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22270 | 22270 | 0.00 | 217.55 |
| 22677 | 22677 | 0.00 | 176.94 |
| 23109 | 22270 | 4.61 | 219.94 |
| 23546 | 23546 | 0.00 | 187.28 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23961 | 23961 | 0.00 | 211.65 |
| 25418 | 25418 | 0.00 | 220.62 |
| 25916 | 25916 | 0.00 | 219.50 |
| 26210 | 26210 | 0.00 | 216.55 |
| 26870 | 26870 | 0.00 | 216.07 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Propafenone hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10007124-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Propafenone hydrochloride; Propafenoni hydrochloridum

### Special notes

When selecting the *Propafenone hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Propafenone hydrochloride | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Propafenone hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Propafenone hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 122.33 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Propafenone hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Propafenone hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Midas Phar… | Propafenone hydrochloride | 2408P051 | 27528 | 40 | 20240110* |
| Midas Phar… | Propafenone hydrochloride | 2408P051 | 27528SI | 20 | 20240110* |
| Midas Phar… | Propafenone hydrochloride | 2409P002 | 27529 | 40 | 20240110* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 100 spectra of 3 reference samples from the substance/substance group *Propafenone hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 226 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Propafenone hydrochloride*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Midas Pharma GmbH | Propafenone hydrochloride | 2409P003 | 27530 | 40 |
| Midas Pharma GmbH | Propafenone hydrochloride | 2409P002 | 27529SI† | 20 |
| Midas Pharma GmbH | Propafenone hydrochloride | 2409P003 | 27530SI | 20 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Propafenone hydrochloride*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

### Validation results

The validation runs checked whether the substance/substance group *Propafenone hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Propafenone hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 100 | 0 | 158 226 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Propafenone hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 94.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 27528 | 27528 | 0.00 | 187.59 |
| 27529 | 27529 | 0.00 | 187.69 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Propranolol hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20954-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Propranolol hydrochloride; Propranololi hydrochloridum

### Special notes

When selecting the *Propranolol hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Propranolol hydrochloride | 6 | 6 | 206 |

### Second-stage model

For differentiation of the substance/substance group *Propranolol hydrochloride* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Propranolol hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 114.92 | – |
| ⋮ | ⋮ | ⋮ |
| Atropine sulfate | >50 | 78.45 |
| Mometasone furoate | >50 | 111.00 |
| Phenytoin | >50 | 118.24 |
| Saccharin sodium | >50 | 165.47 |
| Potassium sorbate | >50 | 227.60 |
| Quinoline yellow | >50 | 233.09 |
| Magnesium hydrogen citrate | >50 | 264.60 |
| Hydrocortisone | >50 | 314.34 |
| Calcium orotate dihydrate | >50 | 423.95 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Propranolol hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Propranolol hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Propranolol hydrochloride | 12370712 | 21396 | 60 | 20130116 |
| Caelo | Propranolol hydrochloride | 12370712 | 21410 | 60 | 20130116 |
| Caelo | Propranolol hydrochloride | 15283302 | 22590 | 40 | 20150929 |
| Fagron | Propranolol hydrochloride | 13I13-N04 | 20954 | 40 | 1402307 |
| Fagron | Propranolol hydrochloride | 15F16-B02-312979 | 22591 | 40 | 20150630 |
| Fagron | Propranolol hydrochloride | 18D23-B09-363591 | 25174 | 40 | 20180525 |
| Fagron | Propranolol hydrochloride | 20G30-F01-373061 | 25483 | 40 | 20200828 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 7 reference samples from the substance/substance group *Propranolol hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 300 spectra of 9 reference samples from the substance/substance group *Propranolol hydrochloride*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Propranolol hydrochloride | 171722 | 23650 | 40 |
| Caelo | Propranolol hydrochloride | 173330 | 23836 | 40 |
| Caelo | Propranolol hydrochloride | 192472 | 24878 | 40 |
| Caelo | Propranolol hydrochloride | 23000119 | 26718 | 40 |
| Fagron | Propranolol hydrochloride | 23A11-B01-224499 | 26616 | 40 |
| Fagron | Propranolol hydrochloride | 25A11-B19-006830 | 27599 | 40 |
| Caelo | Propranolol hydrochloride | 23000119 | 26718SI | 20 |
| Fagron | Propranolol hydrochloride | 23A11-B01-224499 | 26616SI | 20 |
| Fagron | Propranolol hydrochloride | 25A11-B19-006830 | 27599SI | 20 |

- 212 640 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1658 spectra from 636 *Apo-Ident* customers from 224 batches from the substance/substance group *Propranolol hydrochloride*.

- Among them are spectra of independent samples from 204 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Propranolol hydrochloride | 192472001 | 1 |
| | Propranolol hydrochloride | 21002211012 | 3 |
| | Propranolol hydrochloride | 21002211013 | 2 |
| | Propranolol hydrochloride | 21002211014 | 5 |
| | Propranolol hydrochloride | 21002211016 | 3 |
| | Propranolol hydrochloride | 2100221104 | 1 |
| | Propranolol hydrochloride | 2102211012 | 1 |
| | Propranolol hydrochloride | 21J13-F02-380307 | 2 |
| | Propranolol hydrochloride | 21L01-B01-220233 | 1 |
| | Propranolol hydrochloride | 21L01-B01-222417 | 8 |
| | Propranolol hydrochloride | 23000119001 | 5 |
| | Propranolol hydrochloride | 23000119002 | 51 |
| | Propranolol hydrochloride | 2300019002 | 1 |
| | Propranolol hydrochloride | 2300119002 | 1 |
| | Propranolol hydrochloride | 230019002 | 1 |
| | Propranolol hydrochloride | 23003559002 | 17 |
| | Propranolol hydrochloride | 23003559008 | 7 |
| | Propranolol hydrochloride | 23E05-B05-229475 | 18 |
| | Propranolol hydrochloride | 23E05-B05-231731 | 7 |
| | Propranolol hydrochloride | 23E05-B05-233780 | 1 |
| | Propranolol hydrochloride | 23E05-B05-2337800 | 1 |
| | Propranolol hydrochloride | 24A25-B06-000742 | 1 |
| | Propranolol hydrochloride | 25000031001 | 2 |
| | Propranolol hydrochloride | B01-2241007 | 1 |
| | Propranolol hydrochloride | B01-2244909 | 1 |
| | Propranolol hydrochloride | B05-2317301 | 4 |
| | Propranolol hydrochloride | B05-2337800 | 3 |
| | Propranolol hydrochloride | B05-2378000 | 1 |
| | Propranolol hydrochloride | M220726 | 1 |
| /O. Geilenkirchen | Propranolol hydrochloride | 15422502 | 1 |
| 1924720008 | Propranolol hydrochloride | 192472008 | 2 |
| AEP | Propranolol hydrochloride | 23000119002 | 1 |
| AHD | Propranolol hydrochloride | 15422501 | 1 |
| AHD | Propranolol hydrochloride | 17172204 | 2 |
| AHD | Propranolol hydrochloride | 17333001 | 1 |
| AHD | Propranolol hydrochloride | 17333006 | 1 |
| AHD | Propranolol hydrochloride | 18179402 | 3 |
| AHD | Propranolol hydrochloride | 23003559008 | 1 |
| AHD | Propranolol hydrochloride | 941895 | 1 |
| Alliance health | Propranolol hydrochloride | 13E15-B40-294297 | 1 |
| Alliance Healthcare | Propranolol hydrochloride | 17172204 | 1 |
| allianz | Propranolol hydrochloride | 15283302 | 1 |
| Anzag | Propranolol hydrochloride | 231229(230000119002) | 1 |
| Anzag | Propranolol hydrochloride | 250724(23003559002) | 1 |
| apomix | Propranolol hydrochloride | 15K11-B01-316401 | 1 |
| Audor Pharma | Propranolol hydrochloride | 15K11-B01 | 1 |
| cae | Propranolol hydrochloride | 20003220002 | 1 |
| Caelo | Propranolol hydrochloride | | 1 |
| Caelo | Propranolol hydrochloride | 12370703 | 1 |
| Caelo | Propranolol hydrochloride | 12370709 | 1 |
| Caelo | Propranolol hydrochloride | 12370710 | 1 |
| Caelo | Propranolol hydrochloride | 12370712 | 1 |
| Caelo | Propranolol hydrochloride | 12a27-n04 | 1 |
| Caelo | Propranolol hydrochloride | 12D27-N14 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Propranolol hydrochloride | 13/13-N04 | 3 |
| Caelo | Propranolol hydrochloride | 13379804 | 1 |
| Caelo | Propranolol hydrochloride | 13379806 | 1 |
| Caelo | Propranolol hydrochloride | 13379807 | 5 |
| Caelo | Propranolol hydrochloride | 13379809 | 3 |
| Caelo | Propranolol hydrochloride | 13E15-B40-289355 | 2 |
| Caelo | Propranolol hydrochloride | 13I13N04 | 1 |
| Caelo | Propranolol hydrochloride | 150082405 | 1 |
| Caelo | Propranolol hydrochloride | 15082401 | 4 |
| Caelo | Propranolol hydrochloride | 15082404 | 1 |
| Caelo | Propranolol hydrochloride | 15082405 | 2 |
| Caelo | Propranolol hydrochloride | 15179405 | 1 |
| Caelo | Propranolol hydrochloride | 15283301 | 14 |
| Caelo | Propranolol hydrochloride | 15283302 | 5 |
| Caelo | Propranolol hydrochloride | 154225 | 1 |
| Caelo | Propranolol hydrochloride | 15422501 | 13 |
| Caelo | Propranolol hydrochloride | 15422502 | 14 |
| Caelo | Propranolol hydrochloride | 15422505 | 7 |
| Caelo | Propranolol hydrochloride | 15422505-3032017/2 | 1 |
| Caelo | Propranolol hydrochloride | 1542251 | 1 |
| Caelo | Propranolol hydrochloride | 15F16-B02 | 1 |
| Caelo | Propranolol hydrochloride | 15F16-B02-312979 | 3 |
| Caelo | Propranolol hydrochloride | 15k11-B01 | 1 |
| Caelo | Propranolol hydrochloride | 15K11-B01-316401 | 1 |
| Caelo | Propranolol hydrochloride | 16138302 | 10 |
| Caelo | Propranolol hydrochloride | 16138302-3417/2 | 1 |
| Caelo | Propranolol hydrochloride | 16138304 | 18 |
| Caelo | Propranolol hydrochloride | 16138306 | 8 |
| Caelo | Propranolol hydrochloride | 1616E-03609 | 1 |
| Caelo | Propranolol hydrochloride | 16E09-B09-326637 | 11 |
| Caelo | Propranolol hydrochloride | 16E09-B09-330547 | 3 |
| Caelo | Propranolol hydrochloride | 16E09-B09-333442 | 1 |
| Caelo | Propranolol hydrochloride | 17106PRRII | 1 |
| Caelo | Propranolol hydrochloride | 1712203 | 1 |
| Caelo | Propranolol hydrochloride | 1712204 | 1 |
| Caelo | Propranolol hydrochloride | 1712205 | 1 |
| Caelo | Propranolol hydrochloride | 17172203 | 22 |
| Caelo | Propranolol hydrochloride | 17172203-20112017/1 | 1 |
| Caelo | Propranolol hydrochloride | 17172204 | 18 |
| Caelo | Propranolol hydrochloride | 17172205 | 8 |
| Caelo | Propranolol hydrochloride | 1733001 | 1 |
| Caelo | Propranolol hydrochloride | 17333001 | 34 |
| Caelo | Propranolol hydrochloride | 173330015654 | 1 |
| Caelo | Propranolol hydrochloride | 17333005 | 1 |
| Caelo | Propranolol hydrochloride | 17333006 | 13 |
| Caelo | Propranolol hydrochloride | 17333008 | 1 |
| Caelo | Propranolol hydrochloride | 1733301 | 2 |
| Caelo | Propranolol hydrochloride | 1733306 | 1 |
| Caelo | Propranolol hydrochloride | 17K22-B03-342731 | 1 |
| Caelo | Propranolol hydrochloride | 17K22-B03-344247 | 2 |
| Caelo | Propranolol hydrochloride | 17K22-B03-345013 | 4 |
| Caelo | Propranolol hydrochloride | 17K22-B03-347251 | 5 |
| Caelo | Propranolol hydrochloride | 18179402 | 65 |
| Caelo | Propranolol hydrochloride | 18179403 | 34 |
| Caelo | Propranolol hydrochloride | 18179405 | 49 |
| Caelo | Propranolol hydrochloride | 18179406 | 1 |
| Caelo | Propranolol hydrochloride | 181799402 | 1 |
| Caelo | Propranolol hydrochloride | 18D23-B09 | 1 |
| Caelo | Propranolol hydrochloride | 18D23-B09-351774 | 2 |
| Caelo | Propranolol hydrochloride | 18D23-B09-355583 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Propranolol hydrochloride | 18D23-B09-359713 | 5 |
| Caelo | Propranolol hydrochloride | 19242008 | 1 |
| Caelo | Propranolol hydrochloride | 19247001 | 1 |
| Caelo | Propranolol hydrochloride | 1924720008 | 1 |
| Caelo | Propranolol hydrochloride | 192472001 | 45 |
| Caelo | Propranolol hydrochloride | 192472002 | 1 |
| Caelo | Propranolol hydrochloride | 192472003 | 42 |
| Caelo | Propranolol hydrochloride | 192472008 | 24 |
| Caelo | Propranolol hydrochloride | 19272001 | 1 |
| Caelo | Propranolol hydrochloride | 20003220002 | 24 |
| Caelo | Propranolol hydrochloride | 20003220003 | 1 |
| Caelo | Propranolol hydrochloride | 20003220004 | 22 |
| Caelo | Propranolol hydrochloride | 2000322002 | 4 |
| Caelo | Propranolol hydrochloride | 2000322004 | 3 |
| Caelo | Propranolol hydrochloride | 2003220002 | 1 |
| Caelo | Propranolol hydrochloride | 2003220004 | 1 |
| Caelo | Propranolol hydrochloride | 210002211001 | 1 |
| Caelo | Propranolol hydrochloride | 21002211001 | 40 |
| Caelo | Propranolol hydrochloride | 21002211002 | 23 |
| Caelo | Propranolol hydrochloride | 21002211007 | 27 |
| Caelo | Propranolol hydrochloride | 21002211010 | 19 |
| Caelo | Propranolol hydrochloride | 21002211012 | 25 |
| Caelo | Propranolol hydrochloride | 21002211013 | 13 |
| Caelo | Propranolol hydrochloride | 21002211014 | 2 |
| Caelo | Propranolol hydrochloride | 21002211016 | 2 |
| Caelo | Propranolol hydrochloride | 2100221102 | 5 |
| Caelo | Propranolol hydrochloride | 2100221107 | 1 |
| Caelo | Propranolol hydrochloride | 210507-01 | 1 |
| Caelo | Propranolol hydrochloride | 21052PRRII | 1 |
| Caelo | Propranolol hydrochloride | 21J13-F02-380307 | 1 |
| Caelo | Propranolol hydrochloride | 23000119002 | 1 |
| Caelo | Propranolol hydrochloride | 2771 | 1 |
| Caelo | Propranolol hydrochloride | m130104 | 1 |
| Caelo | Propranolol hydrochloride | M130104 | 1 |
| Caelo | Propranolol hydrochloride | M141203 | 1 |
| Caelo | Propranolol hydrochloride | M180207 | 1 |
| Caeo/Noweda | Propranolol hydrochloride | 15283302 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 15422502 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 18179405 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 18179405 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 21002211013 | 1 |
| Caesar & Loretz GmbH/ E | Propranolol hydrochloride | 18179402 | 2 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 192472003 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 20003220002 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 20003220004 | 2 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 192472008 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 20003220002 | 2 |
| Caesar & Loretz GmbH/Gehe | Propranolol hydrochloride | 20003220002 | 2 |
| Caesar & Loretz GmbH/Gehe | Propranolol hydrochloride | 21002211001 | 2 |
| Caesar & Loretz GmbH/Gehe | Propranolol hydrochloride | 21002211010 | 4 |
| Caesar & Loretz GmbH/Gehe | Propranolol hydrochloride | 21002211012 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 21002211010 | 2 |
| Caesar & Loretz GmbH/Kehr | Propranolol hydrochloride | 18179402 | 1 |
| Caesar & Loretz GmbH/Kehr | Propranolol hydrochloride | 18179405 | 1 |
| Caesar & Loretz GmbH/Kehr | Propranolol hydrochloride | 192472001 | 1 |
| Caesar & Loretz GmbH/Kehr | Propranolol hydrochloride | 21002211013 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 18179402 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 18179403 | 1 |
| Caesar & Loretz GmbH/Otto | Propranolol hydrochloride | 192472001 | 1 |
| Caesar & Loretz GmbH/Otto | Propranolol hydrochloride | 192472008 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 192472001 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 192472001 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 192472003 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 192472008 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 21002211002 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 20003220002 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 20003220004 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 21002211001 | 1 |
| Caesar & Loretz GmbH... | Propranolol hydrochloride | 21002211012 | 1 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | | 1 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 18179402 | 11 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 18179403 | 16 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 18179405 | 17 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 19247001 | 1 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 192472001 | 11 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 192472003 | 11 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 192472008 | 19 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 20003220002 | 12 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 20003220004 | 10 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211001 | 23 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211002 | 7 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211007 | 12 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211010 | 3 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211012 | 13 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211013 | 2 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211014 | 2 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 21002211016 | 1 |
| Caesar & Loretz GmbH | Propranolol hydrochloride | 23000119002 | 1 |
| Caesar u Loretz | Propranolol hydrochloride | 13379807 | 1 |
| Caesar&Loretz GmbH | Propranolol hydrochloride | 18179405 | 1 |
| Caleo | Propranolol hydrochloride | 192472008 | 1 |
| Calo/AHD | Propranolol hydrochloride | 15082401 | 1 |
| Caselo | Propranolol hydrochloride | 18179405 | 1 |
| Cealo, GEHE | Propranolol hydrochloride | 20003220002 | 1 |
| Changhzhou Yabang Ph... | Propranolol hydrochloride | 20G30-F01-373061 | 1 |
| Changzhou / Faron | Propranolol hydrochloride | M151204 | 1 |
| Changzhou / Gehe | Propranolol hydrochloride | M140808 | 1 |
| Changzhou Yabang Pha... | Propranolol hydrochloride | 15F16-B02 | 1 |
| Euro OTC | Propranolol hydrochloride | 13379806 | 1 |
| Euro OTC | Propranolol hydrochloride | 13I13-N04 | 1 |
| Euro OTC | Propranolol hydrochloride | 15K11B01-320607 | 1 |
| Euro OTC | Propranolol hydrochloride | 15K11-B01-322717 | 1 |
| Fa.Phönix | Propranolol hydrochloride | 18179402 | 1 |
| Fagron | Propranolol hydrochloride | | 2 |
| Fagron | Propranolol hydrochloride | 10L20N08 | 2 |
| Fagron | Propranolol hydrochloride | 11D01-N11 | 1 |
| Fagron | Propranolol hydrochloride | 11I19-N09 | 1 |
| Fagron | Propranolol hydrochloride | 11L01-N05 | 2 |
| Fagron | Propranolol hydrochloride | 12A27-N04 | 1 |
| Fagron | Propranolol hydrochloride | 12D27-N14 | 4 |
| Fagron | Propranolol hydrochloride | 12F29-N06 | 4 |
| Fagron | Propranolol hydrochloride | 12F29-NO6 | 1 |
| Fagron | Propranolol hydrochloride | 12K06N07 | 1 |
| Fagron | Propranolol hydrochloride | 12K06-N07 | 8 |
| Fagron | Propranolol hydrochloride | 13/13-N04 | 4 |
| Fagron | Propranolol hydrochloride | 1313-N04 | 2 |
| Fagron | Propranolol hydrochloride | 13E15_B40-297021 | 1 |
| Fagron | Propranolol hydrochloride | 13E15-B40 | 5 |
| Fagron | Propranolol hydrochloride | 13E15-B40-289355 | 12 |
| Fagron | Propranolol hydrochloride | 13E15-B40-294297 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Propranolol hydrochloride | 13E15-B40-297021 | 6 |
| Fagron | Propranolol hydrochloride | 13I13-N04 | 9 |
| Fagron | Propranolol hydrochloride | 13J13-N04 | 3 |
| Fagron | Propranolol hydrochloride | 13l13-N04 | 1 |
| Fagron | Propranolol hydrochloride | 15F16-B02 | 1 |
| Fagron | Propranolol hydrochloride | 15F16B02312979 | 1 |
| Fagron | Propranolol hydrochloride | 15F16-B02-312979 | 4 |
| Fagron | Propranolol hydrochloride | 15K11_B01_322717 | 1 |
| Fagron | Propranolol hydrochloride | 15K11-B01 | 4 |
| Fagron | Propranolol hydrochloride | 15K11-B01_320607 | 1 |
| Fagron | Propranolol hydrochloride | 15K11-B01-16401 | 1 |
| Fagron | Propranolol hydrochloride | 15K11-B01-316401 | 12 |
| Fagron | Propranolol hydrochloride | 15K11-B01-320607 | 8 |
| Fagron | Propranolol hydrochloride | 15K11-B01-322717 | 4 |
| Fagron | Propranolol hydrochloride | 15K11-Bo1-316401 | 1 |
| Fagron | Propranolol hydrochloride | 16138302 | 1 |
| Fagron | Propranolol hydrochloride | 16E09-B09 | 3 |
| Fagron | Propranolol hydrochloride | 16E09-B09-326637 | 8 |
| Fagron | Propranolol hydrochloride | 16E09B09330547 | 1 |
| Fagron | Propranolol hydrochloride | 16E09-B09-330547 | 9 |
| Fagron | Propranolol hydrochloride | 16E09-B09333442 | 1 |
| Fagron | Propranolol hydrochloride | 16E09-B09-333442 | 14 |
| Fagron | Propranolol hydrochloride | 17333001 | 1 |
| Fagron | Propranolol hydrochloride | 17K22-B03 | 5 |
| Fagron | Propranolol hydrochloride | 17K22-B03_347251 | 1 |
| Fagron | Propranolol hydrochloride | 17K22-B03-30048 | 1 |
| Fagron | Propranolol hydrochloride | 17k22-B03-342731 | 2 |
| Fagron | Propranolol hydrochloride | 17K22-B03-342731 | 8 |
| Fagron | Propranolol hydrochloride | 17K22-B03-344247 | 4 |
| Fagron | Propranolol hydrochloride | 17K22-B03-345013 | 1 |
| Fagron | Propranolol hydrochloride | 17K-22-B03-345013 | 1 |
| Fagron | Propranolol hydrochloride | 17k22-b03-347251 | 1 |
| Fagron | Propranolol hydrochloride | 17K22-B03-347251 | 5 |
| Fagron | Propranolol hydrochloride | 17K22-b03-350048 | 1 |
| Fagron | Propranolol hydrochloride | 17K22-B03-350048 | 6 |
| Fagron | Propranolol hydrochloride | 18041807 | 1 |
| Fagron | Propranolol hydrochloride | 18D_23-B09-351774 | 1 |
| Fagron | Propranolol hydrochloride | 18D23-B0 | 1 |
| Fagron | Propranolol hydrochloride | 18D23-B09 | 16 |
| Fagron | Propranolol hydrochloride | 18d23b09351774 | 1 |
| Fagron | Propranolol hydrochloride | 18D23-B09-351774 | 18 |
| Fagron | Propranolol hydrochloride | 18D23-B09-3555583 | 1 |
| Fagron | Propranolol hydrochloride | 18D23-B09-355583 | 12 |
| Fagron | Propranolol hydrochloride | 18D23-B09-357778 | 3 |
| Fagron | Propranolol hydrochloride | 18D23-B09-359713 | 19 |
| Fagron | Propranolol hydrochloride | 18D23-B09-363591 | 9 |
| Fagron | Propranolol hydrochloride | 20250711-8 | 1 |
| Fagron | Propranolol hydrochloride | 20G30-F01 | 4 |
| Fagron | Propranolol hydrochloride | 20G30-F01-0001 | 1 |
| Fagron | Propranolol hydrochloride | 20G30-F01-37 | 1 |
| Fagron | Propranolol hydrochloride | 20G30-F01-373060 | 17 |
| Fagron | Propranolol hydrochloride | 20G30-F01-373060/M200409 | 1 |
| Fagron | Propranolol hydrochloride | 20G30-F01-373061 | 12 |
| Fagron | Propranolol hydrochloride | 21J13-F02-380307 | 17 |
| Fagron | Propranolol hydrochloride | 21J3-F02_380307 | 1 |
| Fagron | Propranolol hydrochloride | 21j3-f02-380307 | 1 |
| Fagron | Propranolol hydrochloride | 21L01-B01-220233 | 1 |
| Fagron | Propranolol hydrochloride | 21L01-B01-222417 | 3 |
| Fagron | Propranolol hydrochloride | 23E05-B05-229475 | 2 |
| Fagron | Propranolol hydrochloride | 28051508 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Propranolol hydrochloride | 3(18D23-B09-359713) | 1 |
| Fagron | Propranolol hydrochloride | 3050PRII | 1 |
| Fagron | Propranolol hydrochloride | 3050PRRII | 2 |
| Fagron | Propranolol hydrochloride | 31101201 | 1 |
| Fagron | Propranolol hydrochloride | 3112U-03609 | 1 |
| Fagron | Propranolol hydrochloride | 3913M-03609 | 1 |
| Fagron | Propranolol hydrochloride | 4(20G30-F01-373060) | 1 |
| Fagron | Propranolol hydrochloride | 402310015 | 1 |
| Fagron | Propranolol hydrochloride | 4071401 | 1 |
| Fagron | Propranolol hydrochloride | 5101 | 1 |
| Fagron | Propranolol hydrochloride | 700556-0001 | 1 |
| Fagron | Propranolol hydrochloride | 8D23-B09-3577781 | 1 |
| Fagron | Propranolol hydrochloride | 9CMK6AA71374 | 1 |
| Fagron | Propranolol hydrochloride | 9L09-N06 | 1 |
| Fagron | Propranolol hydrochloride | B09-3597103 | 1 |
| Fagron | Propranolol hydrochloride | B09-3635901 | 2 |
| Fagron | Propranolol hydrochloride | F01-3730600 | 2 |
| Fagron | Propranolol hydrochloride | F01-3730601 | 3 |
| Fagron | Propranolol hydrochloride | M130104 | 1 |
| Fagron | Propranolol hydrochloride | M141203 | 1 |
| Fagron | Propranolol hydrochloride | M151204 | 3 |
| Fagron | Propranolol hydrochloride | M170602 | 4 |
| Fagron | Propranolol hydrochloride | M180207 | 9 |
| Fagron | Propranolol hydrochloride | M200409 | 4 |
| Fagron | Propranolol hydrochloride | M210630 | 1 |
| Fargon | Propranolol hydrochloride | 12K06-N07 | 1 |
| Fargon | Propranolol hydrochloride | 18D23-B09 | 1 |
| Fargon | Propranolol hydrochloride | 18D23-B09-359713 | 1 |
| Fargon | Propranolol hydrochloride | M140808 | 1 |
| Fischar/Alliance Hea... | Propranolol hydrochloride | 18D23-B09 | 2 |
| fragon/AHD | Propranolol hydrochloride | 13/13-N04 | 1 |
| Fragon/Anzag | Propranolol hydrochloride | 18D23-B09-359713 | 1 |
| Gehe Kassel 26.06.2015 | Propranolol hydrochloride | 15082401 | 1 |
| Gehe | Propranolol hydrochloride | | 1 |
| Gehe | Propranolol hydrochloride | 16E09-B09 | 1 |
| Gehe | Propranolol hydrochloride | 17172203 | 1 |
| Gehe | Propranolol hydrochloride | 17172205 | 2 |
| Gehe | Propranolol hydrochloride | 18179403 | 1 |
| GEHE | Propranolol hydrochloride | 18179405 | 1 |
| Gehe | Propranolol hydrochloride | 18D23 | 1 |
| Gehe | Propranolol hydrochloride | 192472003 | 1 |
| Gehe | Propranolol hydrochloride | 20003220004 | 1 |
| Gehe | Propranolol hydrochloride | 23000119002 | 2 |
| Gehe | Propranolol hydrochloride | 23E-05-B05-233780 | 1 |
| Gehe | Propranolol hydrochloride | M220726 | 2 |
| Gutenberg-Apotheke | Propranolol hydrochloride | 13I13-N04 | 1 |
| Ichthyol-Gesellschaf... | Propranolol hydrochloride | 16138302 | 1 |
| InfectoPharm | Propranolol hydrochloride | J0512011 | 1 |
| Inresa 22.09.15 | Propranolol hydrochloride | 3043PRRII | 1 |
| IPCA / Gehe | Propranolol hydrochloride | 192472003 | 2 |
| Jenne | Propranolol hydrochloride | 17333001 | 1 |
| JENNE | Propranolol hydrochloride | 17333001 | 1 |
| Jenne | Propranolol hydrochloride | 21002211013 | 1 |
| Kehr | Propranolol hydrochloride | 21L01-B01-222417 | 1 |
| Kehr | Propranolol hydrochloride | 23E05-B05-233780 | 1 |
| Kehr | Propranolol hydrochloride | M180207 | 1 |
| kontrolle | Propranolol hydrochloride | kontrolleAP210113-01 | 1 |
| L12 | Propranolol hydrochloride | 16E09-B09-326637 | 1 |
| L12 | Propranolol hydrochloride | 17K22-B03-350048 | 1 |
| L12 | Propranolol hydrochloride | 18D23-B09-355583 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| L30 | Propranolol hydrochloride | 15K11-B01-320607 | 1 |
| Land IpCA Laboratories | Propranolol hydrochloride | 15422502 | 1 |
| Löwen City-Apotheke … | Propranolol hydrochloride | 4012013 | 1 |
| Max Jenne | Propranolol hydrochloride | 192472003 | 1 |
| Nachprüfung | Propranolol hydrochloride | 2082019-1 | 1 |
| Noweda | Propranolol hydrochloride | | 1 |
| Noweda | Propranolol hydrochloride | 15K11-B01-322717 | 1 |
| Noweda | Propranolol hydrochloride | 17K22-B03-344247 | 2 |
| Noweda | Propranolol hydrochloride | 18179402 | 2 |
| Noweda | Propranolol hydrochloride | 18179405 | 2 |
| Noweda | Propranolol hydrochloride | 18179405/2x | 1 |
| Noweda | Propranolol hydrochloride | 192472001 | 1 |
| Noweda | Propranolol hydrochloride | 192472003 | 2 |
| Noweda | Propranolol hydrochloride | 192472008 | 1 |
| Noweda | Propranolol hydrochloride | 20003220002 | 1 |
| Noweda | Propranolol hydrochloride | 20003220004 | 1 |
| Noweda | Propranolol hydrochloride | 2100221002 | 1 |
| Noweda | Propranolol hydrochloride | 21002211012 | 1 |
| Noweda | Propranolol hydrochloride | 21002211013 | 3 |
| Noweda | Propranolol hydrochloride | 21002211016 | 1 |
| Noweda | Propranolol hydrochloride | 23000119002 | 5 |
| Noweda | Propranolol hydrochloride | 23E05-B05-229475 | 1 |
| Noweda | Propranolol hydrochloride | 23E05-B05-231731 | 2 |
| Noweda | Propranolol hydrochloride | 23E05-B05-233780 | 5 |
| Phoenix/Fargron | Propranolol hydrochloride | 15K11-B01-322717 | 2 |
| Phoenix | Propranolol hydrochloride | 16138304 | 1 |
| Phoenix | Propranolol hydrochloride | 17K22-B03-344247 | 1 |
| Phoenix | Propranolol hydrochloride | 18179402 | 1 |
| Phoenix | Propranolol hydrochloride | 18D23-B09-355583 | 1 |
| Phoenix | Propranolol hydrochloride | 192472003 | 1 |
| Phoenix | Propranolol hydrochloride | 21002211002 | 2 |
| Phönix/Fragon | Propranolol hydrochloride | 18D23-B09-357778 | 1 |
| Phönix/Fragon | Propranolol hydrochloride | 20G30-F01-373060 | 1 |
| Phönix | Propranolol hydrochloride | 15k11-b01-322717 | 1 |
| Phönix | Propranolol hydrochloride | 15k11-B01-322717 | 1 |
| phönix | Propranolol hydrochloride | 16e09-b09 | 1 |
| phönix | Propranolol hydrochloride | 16e09b09326637 | 1 |
| Phönix | Propranolol hydrochloride | 16E09-B09-326637 | 1 |
| Phönix | Propranolol hydrochloride | 17172203 | 1 |
| Phönix | Propranolol hydrochloride | 18179402 | 1 |
| phönix | Propranolol hydrochloride | 2/AKD3 | 1 |
| PHÖNIX | Propranolol hydrochloride | 21002211002 | 1 |
| Sanacorp | Propranolol hydrochloride | 12370712 | 1 |
| Sanacorp | Propranolol hydrochloride | 16138304 | 1 |
| Sanacorp | Propranolol hydrochloride | 18D23-B09-351774 | 1 |
| Sanacorp | Propranolol hydrochloride | 20G30-F01 | 1 |
| Sanacorp | Propranolol hydrochloride | 21002211001 | 1 |
| Sanacorp | Propranolol hydrochloride | 23000119002 | 1 |
| Sanacorp | Propranolol hydrochloride | 23E05-B05-229475 | 1 |
| VDL | Propranolol hydrochloride | 18D23-B09-359713 | 1 |
| WE:Phönix 12.08.2016 | Propranolol hydrochloride | 15422502 | 1 |

- 255 228 spectra from 1666 *Apo-Ident* customers from a total of 51 929 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Propranolol hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Propranolol hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 300 | 0 | 212 640 |
| **Type C** | 0 | 1645 | 13 | 255 228 |

The substance/substance group *Propranolol hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.2159 % (> 99.0350 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20954 | 20954 | 0.00 | 236.85 |
| 21396 | 20954 | 4.26 | 234.88 |
| 21410 | 20954 | 21.79 | 234.95 |
| 22590 | 20954 | 9.02 | 235.19 |
| 22591 | 20954 | 25.31 | 240.74 |
| 25174 | 20954 | 34.90 | 242.23 |
| 25483 | 20954 | 44.48 | 243.11 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Propyl-4-hydroxybenzoate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20981-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Propyl-4-hydroxybenzoate; Propylis parahydroxybenzoas

### Special notes

When selecting the *Propyl-4-hydroxybenzoate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Propyl-4-hydroxybenzoate | 5 | 3 | 76 |

### Second-stage model

For differentiation of the substance/substance group *Propyl-4-hydroxybenzoate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Propyl-4-hydroxybenzoate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 92.85 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Propyl-4-hydroxybenzoate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Propyl-4-hydroxybenzoate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Propyl-4-hydroxybenzoate | 11373523 | 20981 | 40 | 1402440 |
| Caelo | Propyl-4-hydroxybenzoate | 13365009 | 21758 | 60 | 20131203 |
| Caelo | Propyl-4-hydroxybenzoate | 162595 | 22754 | 40 | 20161005* |
| Caelo | Propyl-4-hydroxybenzoate | 162595 | 22765 | 40 | 20161005* |
| Caelo | Propyl-4-hydroxybenzoate | 190732 | 24497 | 40 | 20190404* |
| Caelo | Propyl-4-hydroxybenzoate | 22002607 | 26367 | 40 | 20220930* |
| Caelo | Propyl-4-hydroxybenzoate | 22002607 | 26367SI | 20 | 20220930* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 280 spectra of 7 reference samples from the substance/substance group *Propyl-4-hydroxybenzoate*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

- 158 046 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 5 reference samples from the substance/substance group *Propyl-4-hydroxybenzoate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Propyl-4-hydroxybenzoate | 171970 | 23675 | 40 |
| Caelo | Propyl-4-hydroxybenzoate | 23000158 | 26708 | 40 |
| Gatt-Koller | Propyl-4-hydroxybenzoate | 22J02745 | 27098 | 30 |
| Caelo | Propyl-4-hydroxybenzoate | 23000158 | 26708SI | 20 |
| Gatt-Koller | Propyl-4-hydroxybenzoate | 22J02745 | 27098SI | 20 |

- 212 790 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 355 spectra from 261 *Apo-Ident* customers from 79 batches from the substance/substance group *Propyl-4-hydroxybenzoate*.

- Among them are spectra of independent samples from 75 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Propyl-4-hydroxybenzoate | 191700004 | 1 |
| | Propyl-4-hydroxybenzoate | 191700004280622/1 | 1 |
| | Propyl-4-hydroxybenzoate | 21000901006 | 3 |
| | Propyl-4-hydroxybenzoate | 21000901013 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Propyl-4-hydroxybenzoate | 23000158002 | 16 |
| | Propyl-4-hydroxybenzoate | 23000158005 | 9 |
| | Propyl-4-hydroxybenzoate | 23000158007 | 2 |
| | Propyl-4-hydroxybenzoate | 23003512003 | 5 |
| | Propyl-4-hydroxybenzoate | 24001698001 | 1 |
| AHD | Propyl-4-hydroxybenzoate | 11373523 | 1 |
| Anzag | Propyl-4-hydroxybenzoate | 11373512 | 2 |
| apomix | Propyl-4-hydroxybenzoate | 13100217 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 1108211931 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 11102609 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 11102611 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 11102624 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 11121709 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 113735 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 11373505 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 11373512 | 3 |
| Caelo | Propyl-4-hydroxybenzoate | 11373518 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 113735223 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 11373523 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 11373524 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 13051504 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 13100208 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 13100215 | 7 |
| Caelo | Propyl-4-hydroxybenzoate | 13100217 | 3 |
| Caelo | Propyl-4-hydroxybenzoate | 13100218 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 13100219 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 13365006 | 5 |
| Caelo | Propyl-4-hydroxybenzoate | 13365009 | 3 |
| Caelo | Propyl-4-hydroxybenzoate | 13365011 | 5 |
| Caelo | Propyl-4-hydroxybenzoate | 13365012 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 14359005 | 8 |
| Caelo | Propyl-4-hydroxybenzoate | 14359006 | 4 |
| Caelo | Propyl-4-hydroxybenzoate | 14359008 | 26 |
| Caelo | Propyl-4-hydroxybenzoate | 14359009 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 14359019 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 14359020 | 4 |
| Caelo | Propyl-4-hydroxybenzoate | 14359025 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 15246501 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 15246502 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 15276514 | 4 |
| Caelo | Propyl-4-hydroxybenzoate | 16259505 | 16 |
| Caelo | Propyl-4-hydroxybenzoate | 16259516 | 16 |
| Caelo | Propyl-4-hydroxybenzoate | 16259520 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 16359006 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 17343101 | 12 |
| Caelo | Propyl-4-hydroxybenzoate | 17343105 | 3 |
| Caelo | Propyl-4-hydroxybenzoate | 17343108 | 9 |
| Caelo | Propyl-4-hydroxybenzoate | 17343110 | 8 |
| Caelo | Propyl-4-hydroxybenzoate | 19073203 | 14 |
| Caelo | Propyl-4-hydroxybenzoate | 1913I-01931 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 191700002 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 191700004 | 34 |
| Caelo | Propyl-4-hydroxybenzoate | 191700007 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 191700009 | 3 |
| Caelo | Propyl-4-hydroxybenzoate | 19170004 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 21000601006 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 21000733001 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 21000733002 | 11 |
| Caelo | Propyl-4-hydroxybenzoate | 21000901006 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Propyl-4-hydroxybenzoate | 220420 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 221014PAS01 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 23000158002 | 2 |
| Caelo | Propyl-4-hydroxybenzoate | 290114PML03 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 3041408 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 3115M-01931 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 3217M-01931 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 4314U-01931 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 713Q-01931 | 1 |
| Caelo | Propyl-4-hydroxybenzoate | 82792159 | 1 |
| Caesar & Loretz GmbH... | Propyl-4-hydroxybenzoate | 19073203 | 1 |
| Caesar & Loretz GmbH... | Propyl-4-hydroxybenzoate | 19073203 | 1 |
| Caesar & Loretz GmbH/GEHE | Propyl-4-hydroxybenzoate | 17343108 | 1 |
| Caesar & Loretz GmbH... | Propyl-4-hydroxybenzoate | 191700002 | 1 |
| Caesar & Loretz GmbH... | Propyl-4-hydroxybenzoate | 191700004 | 2 |
| Caesar & Loretz GmbH... | Propyl-4-hydroxybenzoate | 17343110 | 1 |
| Caesar & Loretz GmbH | Propyl-4-hydroxybenzoate | 191700004 | 12 |
| Caesar & Loretz GmbH | Propyl-4-hydroxybenzoate | 21000733002 | 1 |
| Caesar & Loretz GmbH | Propyl-4-hydroxybenzoate | 21000733005 | 2 |
| Caesar & Loretz GmbH | Propyl-4-hydroxybenzoate | 21000901006 | 1 |
| Caesar & Loretz GmbH | Propyl-4-hydroxybenzoate | 21000901013 | 1 |
| Caesar & Loretz GmbHAnzag | Propyl-4-hydroxybenzoate | 191700004 | 1 |
| Caesar & Loretz | Propyl-4-hydroxybenzoate | 15276514 | 1 |
| Caesar &Loretz GmbH | Propyl-4-hydroxybenzoate | 13100215 | 1 |
| Caesar/Noweda | Propyl-4-hydroxybenzoate | 3710M-01931 | 2 |
| Carlo/Phönix/5,95 | Propyl-4-hydroxybenzoate | 19073203 | 1 |
| Euro OTC | Propyl-4-hydroxybenzoate | 2509025 | 1 |
| Fagron | Propyl-4-hydroxybenzoate | 12B13-N04 | 1 |
| Fagron | Propyl-4-hydroxybenzoate | 610M-01931 | 1 |
| GATT-KOLLER/PHOENIX | Propyl-4-hydroxybenzoate | 5080/11130214 | 1 |
| Gatt-Koller | Propyl-4-hydroxybenzoate | 1800302 | 1 |
| Gehe 5.3.14 | Propyl-4-hydroxybenzoate | 13100215 | 1 |
| Gehe | Propyl-4-hydroxybenzoate | 16259505 | 2 |
| Hänseler | Propyl-4-hydroxybenzoate | | 1 |
| Kehr | Propyl-4-hydroxybenzoate | 23000158002 | 1 |
| Noweda | Propyl-4-hydroxybenzoate | 11373505 | 1 |
| Noweda | Propyl-4-hydroxybenzoate | 14359005 | 1 |
| Noweda | Propyl-4-hydroxybenzoate | 14359020 | 1 |
| Noweda | Propyl-4-hydroxybenzoate | 17343101 | 1 |
| Noweda | Propyl-4-hydroxybenzoate | 17343105 | 1 |
| PHOENIX 10.03.2014 | Propyl-4-hydroxybenzoate | 11373526 | 1 |
| Phoenix | Propyl-4-hydroxybenzoate | 13100215 | 1 |
| Phoenix | Propyl-4-hydroxybenzoate | 19073203 | 1 |
| Phönix 14.01.2014 | Propyl-4-hydroxybenzoate | 11373526 | 1 |
| PHÖNIX | Propyl-4-hydroxybenzoate | 16259505 | 1 |
| Phönix | Propyl-4-hydroxybenzoate | 17343108 | 1 |
| Sanacorp | Propyl-4-hydroxybenzoate | 16259505 | 1 |
| Sanacorp | Propyl-4-hydroxybenzoate | 16259516 | 1 |
| Sanacorp | Propyl-4-hydroxybenzoate | 191700004 | 1 |
| Sanacorp | Propyl-4-hydroxybenzoate | 23000158002 | 2 |
| Sanacorp | Propyl-4-hydroxybenzoate | 23000158005 | 1 |
| Sanacorp | Propyl-4-hydroxybenzoate | AKD3 | 1 |
| Sanarcorp | Propyl-4-hydroxybenzoate | 17343101 | 1 |
| Sanarcorp | Propyl-4-hydroxybenzoate | 191700009 | 1 |
| siehe WE-Prüfprotokoll | Propyl-4-hydroxybenzoate | 84/11 | 1 |

- 256 531 spectra from 1666 *Apo-Ident* customers from a total of 52 077 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Propyl-4-hydroxybenzoate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Propyl-4-hydroxybenzoate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 351 | 4 | 256 531 |

The substance/substance group *Propyl-4-hydroxybenzoate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.8732 % (> 98.0282 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20981 | 20981 | 0.00 | 180.57 |
| 21758 | 26367 | 11.06 | 173.60 |
| 22754 | 22754 | 0.00 | 191.08 |
| 22765 | 22765 | 0.00 | 187.26 |
| 24497 | 24497 | 0.00 | 198.26 |
| 26367 | 26367 | 0.00 | 188.31 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Propyphenazone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20805-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Propyphenazone; Propyphenazonum

### Special notes

When selecting the *Propyphenazone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Propyphenazone | 6 | 4 | 36 |

### Second-stage model

For differentiation of the substance/substance group *Propyphenazone* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Propyphenazone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Griseofulvin | 86.80 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Propyphenazone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Propyphenazone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Propyphenazone | 12039103 | 20805 | 40 | 1402051 |
| Caelo | Propyphenazone | 13332206 | 21454 | 60 | 20131009 |
| Caelo | Propyphenazone | 23000810002 | 26747 | 40 | 20230526 |
| Caelo | Propyphenazone | 23000810002 | 26747SI | 20 | 20230526 |
| Fagron | Propyphenazone | 16E02-B08-327928 | 23261 | 40 | 20160602 |
| Fagron | Propyphenazone | 16H25-B01-334972 | 23922 | 40 | 20161227 |
| Fagron | Propyphenazone | 20C20-B08-202174 | 25492 | 40 | 20200326 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 280 spectra of 7 reference samples from the substance/substance group *Propyphenazone*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 5 reference samples from the substance/substance group *Propyphenazone*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Propyphenazone | 15348908 | 23254 | 40 |
| Caelo | Propyphenazone | 172776 | 23861 | 40 |
| Caelo | Propyphenazone | 190190 | 24528 | 40 |
| Fagron | Propyphenazone | 23G05-B08-229442 | 26904 | 40 |
| Fagron | Propyphenazone | 23G05-B08-229442 | 26904SI | 20 |

- 212 760 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 83 spectra from 34 *Apo-Ident* customers from 41 batches from the substance/substance group *Propyphenazone*.
- Among them are spectra of independent samples from 36 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Propyphenazone | 21000426007 | 1 |
| Anzag | Propyphenazone | 19019003 | 1 |
| Anzag | Propyphenazone | 21000426004 | 1 |
| Caelo | Propyphenazone | 12039101 | 2 |
| Caelo | Propyphenazone | 12039103 | 1 |
| Caelo | Propyphenazone | 12039112 | 1 |
| Caelo | Propyphenazone | 13036702 | 2 |
| Caelo | Propyphenazone | 13137104 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Propyphenazone | 13332205 | 3 |
| Caelo | Propyphenazone | 15122502 | 1 |
| Caelo | Propyphenazone | 15122504 | 3 |
| Caelo | Propyphenazone | 15122505 | 1 |
| Caelo | Propyphenazone | 15348901 | 2 |
| Caelo | Propyphenazone | 15348902 | 2 |
| Caelo | Propyphenazone | 15348904 | 2 |
| Caelo | Propyphenazone | 15348908 | 2 |
| Caelo | Propyphenazone | 15348910 | 1 |
| Caelo | Propyphenazone | 15348912 | 2 |
| Caelo | Propyphenazone | 15348913 | 6 |
| Caelo | Propyphenazone | 15348914 | 2 |
| Caelo | Propyphenazone | 17351302 | 1 |
| Caelo | Propyphenazone | 17351304 | 4 |
| Caelo | Propyphenazone | 17351305 | 1 |
| Caelo | Propyphenazone | 190190003 | 4 |
| Caelo | Propyphenazone | 19019003 | 4 |
| Caesar & Loretz GmbH | Propyphenazone | 17351304 | 1 |
| Caesar & Loretz GmbH | Propyphenazone | 21000426002 | 1 |
| Caleo/Direkt | Propyphenazone | 19019003 | 1 |
| Caleo/Noweda | Propyphenazone | 15348913 | 1 |
| Euro OTC | Propyphenazone | | 1 |
| Fagron | Propyphenazone | 13B12-B02-297171 | 1 |
| Fagron | Propyphenazone | 13K20-B03 | 2 |
| Fagron | Propyphenazone | 13K20-B03-302291 | 1 |
| Fagron | Propyphenazone | 13K20-B03-311715 | 3 |
| Fagron | Propyphenazone | 13k20-b03-319137 | 1 |
| Fagron | Propyphenazone | 13K20B03319137 | 1 |
| Fagron | Propyphenazone | 13K20-B03-319137 | 3 |
| Fagron | Propyphenazone | 13K-B03-319137 | 1 |
| Fagron | Propyphenazone | 16E02-B08-327928 | 2 |
| Fagron | Propyphenazone | 17G03-B01-347588 | 4 |
| Fagron | Propyphenazone | 20A15-B04-196781 | 1 |
| Fagron | Propyphenazone | 20C20-B08-202174 | 1 |
| Fargon | Propyphenazone | 11H31-N07 | 1 |
| Gatt-Koller / Phoenix | Propyphenazone | 419/02123112 | 1 |
| Gatt-Koller | Propyphenazone | 1800011 | 1 |
| Nachprüfung vom 31.0… | Propyphenazone | 13B12-B02-297171 | 1 |
| Pharmachem | Propyphenazone | 15348913 | 1 |
| Raben-Apotheke Mildenau | Propyphenazone | 12039103 | 1 |

- 256 803 spectra from 1666 *Apo-Ident* customers from a total of 52 112 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Propyphenazone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Propyphenazone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 83 | 0 | 256 803 |

The substance/substance group *Propyphenazone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.7711 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20805 | 20805 | 0.00 | 104.41 |
| 21454 | 20805 | 14.17 | 103.67 |
| 23261 | 20805 | 17.41 | 109.48 |
| 23922 | 20805 | 24.40 | 112.39 |
| 25492 | 20805 | 18.02 | 106.79 |
| 26747 | 20805 | 20.71 | 108.48 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Pyridoxal-5-phosphate hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20830-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Pyridoxal-5-phosphate hydrate

### Special notes

When selecting the *Pyridoxal-5-phosphate hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Pyridoxal-5-phosphate hydrate | 11 | 8 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Pyridoxal-5-phosphate hydrate* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Pyridoxal-5-phosphate hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 47.83 | – |
| Silver protein | 59.65 | – |
| ⋮ | ⋮ | ⋮ |
| Sodium citrate | >50 | 74.50 |
| Levocarnitine | >50 | 177.04 |
| Capsaicin | >50 | 194.96 |
| Oxybutynin hydrochloride | >50 | 206.59 |
| Alfatradiol | >50 | 206.66 |
| Prednicarbate | >50 | 316.60 |
| Quinine hydrochloride dihydrate | >50 | 376.30 |
| Ciprofloxacin hydrochloride | >50 | 477.02 |
| Tetracaine | >50 | 489.97 |
| Methoxsalen | >50 | 490.99 |
| Heparin sodium | >50 | 534.49 |
| Cyproterone acetate | >50 | 548.21 |
| Norethisterone acetate | >50 | 598.61 |
| Amitriptyline hydrochloride | >50 | 867.33 |
| Valine | >50 | 1063.97 |
| Triclosan | >50 | 1109.72 |
| Amifampridine | >50 | 1345.76 |
| Sucrose | >50 | 1575.17 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Pyridoxal-5-phosphate hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Pyridoxal-5-phosphate hydrate*:


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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Pyridoxal 5'-phosphate mo… | 24I11-B024 | BR20090 | 40 | 20241002* |
| Fagron | Pyridoxal 5'-phosphate mo… | 24I26-B038 | BR20092 | 40 | 20241024* |
| Fagron | Pyridoxal 5'-phosphate mo… | 24I26-B038 | BR20092SI | 20 | 20241024* |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1302029-01 | 20830 | 40 | 8897 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1302029-01 | 21097 | 40 | 20130315 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1701015 | 23133 | 40 | 20170220* |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1701015-01 | 23276 | 40 | 20170220 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1808030 | 24329 | 40 | 20181019* |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1902022 | 24542 | 40 | 20190320* |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1908001 | 24833 | 40 | 20190903* |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1910027 | 24923 | 40 | 20191217* |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2102013 | 25594 | 40 | 20210317* |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2104017 | 25674 | 40 | 20210602* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 500 spectra of 13 reference samples from the substance/substance group *Pyridoxal-5-phosphate hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 826 spectra from a total of 2946 batches from further 495 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 420 spectra of 13 reference samples from the substance/substance group *Pyridoxal-5-phosphate hydrate*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Pyridoxal 5'-phosphate mo… | 24I12-B075 | BR20091 | 40 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1711030 | 23877 | 40 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2001043 | 25130 | 40 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2003038 | 25151 | 40 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2110012 | 25876 | 50 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2211016 | 26589 | 40 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2412006 | 27511 | 40 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2412007 | 27515 | 40 |
| Fagron | Pyridoxal 5'-phosphate mo… | 24I11-B024 | BR20090SI† | 20 |
| Fagron | Pyridoxal 5'-phosphate mo… | 24I12-B075 | BR20091SI | 20 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2110012 | 25876SI | 10 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2211016 | 26589SI | 20 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2412006 | 27511SI | 20 |

- 212 520 spectra from a total of 4278 batches from further 871 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 43 spectra from 14 *Apo-Ident* customers from 18 batches from the substance/substance group *Pyridoxal-5-phosphate hydrate*.
- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Pyridoxal-5-phosphate hydrate | 2211015-02 | 1 |
| | Pyridoxal-5-phosphate hydrate | 2211016-01 | 2 |
| | Pyridoxal-5-phosphate hydrate | 2211016-02 | 3 |
| | Pyridoxal-5-phosphate hydrate | 2412006-01 | 3 |
| Denk | Pyridoxal-5-phosphate hydrate | 20171202 | 1 |
| Denk | Pyridoxal-5-phosphate hydrate | C041402802 | 1 |
| EuRho | Pyridoxal-5-phosphate hydrate | 2003038-01 | 4 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1701015-01 | 3 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1711030-01 | 2 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1808030 | 1 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1808030-01 | 2 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1808030-02 | 4 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1902022-01 | 1 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 1908001-01 | 4 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2003038-01 | 1 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2003038-02 | 1 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2110012-02 | 5 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2211016-01 | 1 |
| Euro OTC | Pyridoxal-5-phosphate hydrate | 2211016-02 | 1 |
| Fagron | Pyridoxal-5-phosphate hydrate | 2001043-01 | 1 |
| Inresa Arznei | Pyridoxal-5-phosphate hydrate | 13100411 | 1 |

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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- 256 843 spectra from 1666 *Apo-Ident* customers from a total of 52 137 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Pyridoxal-5-phosphate hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Pyridoxal-5-phosphate hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 500 | 0 | 157 826 |
| **Type B** | 0 | 420 | 0 | 212 520 |
| **Type C** | 0 | 43 | 0 | 256 843 |

The substance/substance group *Pyridoxal-5-phosphate hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5714 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 86.0465 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20830 | 20830 | 0.00 | 94.27 |
| 21097 | 20830 | 6.86 | 88.01 |
| 23133 | 23133 | 0.00 | 84.08 |
| 23276 | 20830 | 14.77 | 101.17 |
| 24329 | 24329 | 0.00 | 163.47 |
| 24542 | 24542 | 0.00 | 127.88 |
| 24833 | 24833 | 0.00 | 131.65 |
| 24923 | 24923 | 0.00 | 146.15 |

*continued on the next page*

*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25594 | 25594 | 0.00 | 130.71 |
| 25674 | 25674 | 0.00 | 122.96 |
| BR20090 | BR20090 | 0.00 | 88.34 |
| BR20092 | BR20092 | 0.00 | 114.22 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Pyridoxine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20440-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Pyridoxine hydrochloride; Pyridoxini hydrochloridum

### Special notes

When selecting the *Pyridoxine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Pyridoxine hydrochloride | 8 | 12 | 65 |

### Second-stage model

For differentiation of the substance/substance group *Pyridoxine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Pyridoxine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 116.22 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Pyridoxine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Pyridoxine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Pyridoxine hydrochloride | 14262302 | 21675 | 60 | 20141002 |
| Caelo | Pyridoxine hydrochloride | 162225 | 22770 | 40 | 20160825* |
| Euro OTC | Pyridoxine hydrochloride | 1401044-01 | 21678 | 60 | 20140221 |
| Euro OTC | Pyridoxine hydrochloride | 1407009-01 | 21773 | 60 | 20140807 |
| Euro OTC | Pyridoxine hydrochloride | 1507012 | 21846 | 60 | 20150721* |
| Euro OTC | Pyridoxine hydrochloride | 1601039 | 22300 | 60 | 20160203* |
| Euro OTC | Pyridoxine hydrochloride | 2211006 | 26439 | 40 | 20221125* |
| Fagron | Pyridoxine hydrochloride | 22B07-B25-218396 | 26145 | 40 | 20220423 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 420 spectra of 8 reference samples from the substance/substance group *Pyridoxine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 906 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 540 spectra of 15 reference samples from the substance/substance group *Pyridoxine hydrochloride*.

- Among them are spectra of independent samples from 12 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Pyridoxine hydrochloride | 180287 | 24024 | 40 |
| Caelo | Pyridoxine hydrochloride | 21004047002 | 25973 | 40 |
| Caelo | Pyridoxine hydrochloride | 23001551 | 26839 | 40 |
| Euro OTC | Pyridoxine hydrochloride | 1604063 | 22569 | 40 |
| Euro OTC | Pyridoxine hydrochloride | 1608035 | 22798 | 40 |
| Euro OTC | Pyridoxine hydrochloride | 1710014 | 23735 | 40 |
| Euro OTC | Pyridoxine hydrochloride | 1806022-01 | 24189 | 40 |
| Euro OTC | Pyridoxine hydrochloride | 1908009 | 24838 | 40 |
| Euro OTC | Pyridoxine hydrochloride | 2107011 | 25778 | 50 |
| Euro OTC | Pyridoxine hydrochloride | 2204009 | 26227 | 40 |
| Euro OTC | Pyridoxine hydrochloride | 2309025 | 27001 | 40 |
| Fagron | Pyridoxine hydrochloride | 24A17-B09-236138 | 27171 | 40 |
| Caelo | Pyridoxine hydrochloride | 21004047002 | 25973SI | 10 |
| Euro OTC | Pyridoxine hydrochloride | 2204009 | 26227SI | 20 |
| Fagron | Pyridoxine hydrochloride | 22B07-B25-218396 | 26145SI† | 20 |

- 212 400 spectra from a total of 4274 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

provided by the customer regarding manufacturer and batch number.

- 135 spectra from 38 *Apo-Ident* customers from 66 batches from the substance/substance group *Pyridoxine hydrochloride*.
- Among them are spectra of independent samples from 65 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Pyridoxine hydrochloride | 21004047008 | 1 |
| | Pyridoxine hydrochloride | 21004047010 | 1 |
| | Pyridoxine hydrochloride | 23000263003 | 1 |
| | Pyridoxine hydrochloride | 24A17-B09-236138 | 1 |
| | Pyridoxine hydrochloride | 24I06-B10-004191 | 1 |
| Caelo | Pyridoxine hydrochloride | 11021406 | 1 |
| Caelo | Pyridoxine hydrochloride | 11197009 | 1 |
| Caelo | Pyridoxine hydrochloride | 12102510 | 1 |
| Caelo | Pyridoxine hydrochloride | 12214102 | 2 |
| Caelo | Pyridoxine hydrochloride | 12214119 | 2 |
| Caelo | Pyridoxine hydrochloride | 13102509 | 2 |
| Caelo | Pyridoxine hydrochloride | 13102510 | 2 |
| Caelo | Pyridoxine hydrochloride | 13102516 | 1 |
| Caelo | Pyridoxine hydrochloride | 14262302 | 3 |
| Caelo | Pyridoxine hydrochloride | 14262306 | 1 |
| Caelo | Pyridoxine hydrochloride | 15218702 | 6 |
| Caelo | Pyridoxine hydrochloride | 15218707 | 1 |
| Caelo | Pyridoxine hydrochloride | 15218709 | 1 |
| Caelo | Pyridoxine hydrochloride | 15218710 | 2 |
| Caelo | Pyridoxine hydrochloride | 15218713 | 3 |
| Caelo | Pyridoxine hydrochloride | 16222501 | 5 |
| Caelo | Pyridoxine hydrochloride | 16222504 | 1 |
| Caelo | Pyridoxine hydrochloride | 16222506 | 2 |
| Caelo | Pyridoxine hydrochloride | 16222514 | 3 |
| Caelo | Pyridoxine hydrochloride | 16222515 | 2 |
| Caelo | Pyridoxine hydrochloride | 16222520 | 1 |
| Caelo | Pyridoxine hydrochloride | 16222521 | 1 |
| Caelo | Pyridoxine hydrochloride | 18028703 | 2 |
| Caelo | Pyridoxine hydrochloride | 18217603 | 1 |
| Caelo | Pyridoxine hydrochloride | 18217608 | 5 |
| Caelo | Pyridoxine hydrochloride | 18217614 | 1 |
| Caelo | Pyridoxine hydrochloride | 19091203 | 2 |
| Caelo | Pyridoxine hydrochloride | 20003108002 | 2 |
| Caelo | Pyridoxine hydrochloride | 20003108003 | 1 |
| Caelo | Pyridoxine hydrochloride | 21004047002 | 1 |
| Caesar & Loretz GmbH... | Pyridoxine hydrochloride | 11197009 | 5 |
| Caesar & Loretz GmbH... | Pyridoxine hydrochloride | 12214102 | 5 |
| Caesar & Loretz GmbH... | Pyridoxine hydrochloride | 12214110 | 2 |
| Caesar & Loretz GmbH... | Pyridoxine hydrochloride | 12214115 | 7 |
| Caesar & Loretz GmbH... | Pyridoxine hydrochloride | 12214119 | 2 |
| Caesar & Loretz GmbH... | Pyridoxine hydrochloride | 18217608 | 1 |
| Caesar & Loretz GmbH... | Pyridoxine hydrochloride | 19091203 | 1 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 18217603 | 1 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 18217606 | 1 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 190912002 | 2 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 19091203 | 1 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 19091204 | 1 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 21004047002 | 2 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 21004047003 | 3 |
| Caesar & Loretz GmbH | Pyridoxine hydrochloride | 21004047007 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 1110001-01 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 1206022-02 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Pyridoxine hydrochloride | 1601039-01 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 1604063-01 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 160803501 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 1608035-02 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 17001401 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 1710014-01 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 1806022-01 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 180602202 | 1 |
| Euro OTC | Pyridoxine hydrochloride | 1908009-02 | 5 |
| Euro OTC | Pyridoxine hydrochloride | 2204009-01 | 1 |
| euro-oct | Pyridoxine hydrochloride | UQ60313085/0 | 1 |
| Fagron | Pyridoxine hydrochloride | 12e02-n02 | 1 |
| Fagron | Pyridoxine hydrochloride | 1608035-01 | 1 |
| Fagron | Pyridoxine hydrochloride | 20A29-F10-369782 | 1 |
| Fagron | Pyridoxine hydrochloride | 21A25-F01-376555 | 2 |
| Fagron | Pyridoxine hydrochloride | 21I01-B02-213683 | 1 |
| Fagron | Pyridoxine hydrochloride | 22B07-B26-222420 | 1 |
| Fagron | Pyridoxine hydrochloride | 24A17-B09-231734 | 1 |
| Fagron | Pyridoxine hydrochloride | L13080030 | 1 |
| Farmalabor | Pyridoxine hydrochloride | P1701531-000 | 1 |
| Sanacorp | Pyridoxine hydrochloride | 21004047008 | 2 |
| Sanacorp | Pyridoxine hydrochloride | 21004047010 | 2 |
| Sanacorp | Pyridoxine hydrochloride | 2211006-02 | 1 |
| Sanacorp | Pyridoxine hydrochloride | 23000263002 | 1 |
| Sanacorp | Pyridoxine hydrochloride | 23000263003 | 3 |

- 256 751 spectra from 1666 *Apo-Ident* customers from a total of 52 087 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Pyridoxine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Pyridoxine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 540 | 0 | 212 400 |
| **Type C** | 0 | 135 | 0 | 256 751 |

The substance/substance group *Pyridoxine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8889 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 95.5556 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several

new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21675 | 21846 | 8.54 | 209.90 |
| 21678 | 21846 | 8.88 | 209.42 |
| 21773 | 21846 | 1.82 | 212.75 |
| 21846 | 21846 | 0.00 | 212.30 |
| 22300 | 22300 | 0.00 | 212.93 |
| 22770 | 22770 | 0.00 | 212.42 |
| 26145 | 21846 | 11.19 | 212.17 |
| 26439 | 26439 | 0.00 | 210.95 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Quetiapine fumarate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005949-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Quetiapine fumarate; Quetiapini fumaras

### Special notes

When selecting the *Quetiapine fumarate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Quetiapine fumarate | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Quetiapine fumarate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Quetiapine fumarate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 147.21 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Quetiapine fumarate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Quetiapine fumarate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Hetero Dru... | Quetiapine fumarate | QU22040055 | 26402 | 40 | 20220510 |
| ZCL Chemic... | Quetiapine fumarate | QTP4206421 | 25834 | 50 | 2301088 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 90 spectra of 2 reference samples from the substance/substance group *Quetiapine fumarate*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

- 158 236 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 90 spectra of 4 reference samples from the substance/substance group *Quetiapine fumarate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| ZCL Chemicals Ltd. | Quetiapine fumarate | QTP4214921 | 25899 | 50 |
| Hetero Drugs Ltd. | Quetiapine fumarate | QU22040055 | 26402SI† | 20 |
| ZCL Chemicals Ltd. | Quetiapine fumarate | QTP4206421 | 25834SI† | 10 |
| ZCL Chemicals Ltd. | Quetiapine fumarate | QTP4214921 | 25899SI | 10 |

- 212 850 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Quetiapine fumarate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Quetiapine fumarate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Quetiapine fumarate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 90 | 0 | 158 236 |
| **Type B** | 0 | 77 | 13 | 212 850 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Quetiapine fumarate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 93.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 85.5556 % (> 82.2222 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25834 | 25834 | 0.00 | 220.93 |
| 26402 | 25834 | 19.03 | 231.46 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Quinidine sulfate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20819-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Quinidine sulfate dihydrate; Chinidini sulfas; Quinidine sulfate

### Special notes

When selecting the *Quinidine sulfate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Quinidine sulfate dihydrate | 6 | 4 | 6 |

### Second-stage model

For differentiation of the substance/substance group *Quinidine sulfate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Quinidine sulfate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 91.42 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Quinidine sulfate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Quinidine sulfate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Quinidine sulfate dihydrate | 12L04-N10 | 20819 | 40 | AR-14-FG-013249-01 |
| Fagron | Quinidine sulfate dihydrate | 12J16-B03 | 21217 | 39 | 1412323 |
| Fagron | Quinidine sulfate dihydrate | 14I04-B09-304357 | 21810 | 60 | AR-15-FG-015409-01 |
| Fagron | Quinidine sulfate dihydrate | 22A17-B09-222135 | 26331 | 40 | 20220304 |
| Fagron | Quinidine sulfate dihydrate | 22A17-B09-222135 | 26331SI | 20 | 20220304 |
| Fagron | Quinidine sulfate dihydrate | 23E17-B03-230370 | 26903 | 40 | 20230605 |
| Fagron | Quinidine sulfate dihydrate | 24E08-B13-001927 | 27408 | 40 | 20240705 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 279 spectra of 7 reference samples from the substance/substance group *Quinidine sulfate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 047 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 190 spectra of 6 reference samples from the substance/substance group *Quinidine sulfate dihydrate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Quinidine sulfate dihydrate | 16A06-B04-324954 | 22970 | 40 |
| Fagron | Quinidine sulfate dihydrate | 18B01-B08-350965 | 24181 | 40 |
| Fagron | Quinidine sulfate dihydrate | 20C23-F02-373172 | 25485 | 40 |
| Fagron | Quinidine sulfate dihydrate | 21E06-B01-213612 | 25901 | 40 |
| Fagron | Quinidine sulfate dihydrate | 21E06-B01-213612 | 25901SI | 10 |
| Fagron | Quinidine sulfate dihydrate | 23E17-B03-230370 | 26903SI† | 20 |

- 212 750 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 8 spectra from 8 *Apo-Ident* customers from 7 batches from the substance/substance group *Quinidine sulfate dihydrate*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Quinidine sulfate dihydrate | 22A17-809-225368 | 1 |
| | Quinidine sulfate dihydrate | 24E08-B13-001927 | 2 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| buchler GmbH | Quinidine sulfate dihydrate | 16a06-b04-340797 | 1 |
| Caelo | Quinidine sulfate dihydrate | 16A06-B04-330856 | 1 |
| Fagron | Quinidine sulfate dihydrate | 13G08-N02 | 1 |
| Fagron | Quinidine sulfate dihydrate | 18B01-B08-356315 | 1 |
| Fagron | Quinidine sulfate dihydrate | 21E06-B01-213612 | 1 |

- 256 878 spectra from 1666 *Apo-Ident* customers from a total of 52 146 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Quinidine sulfate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Quinidine sulfate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 279 | 0 | 158 047 |
| **Type B** | 0 | 190 | 0 | 212 750 |
| **Type C** | 0 | 8 | 0 | 256 878 |

The substance/substance group *Quinidine sulfate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8495 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.8421 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20819 | 20819 | 0.00 | 191.65 |
| 21217 | 21217 | 0.00 | 191.89 |
| 21810 | 21810 | 0.00 | 191.46 |
| 26331 | 21810 | 9.54 | 191.96 |
| 26903 | 21810 | 4.38 | 194.06 |
| 27408 | 21810 | 8.90 | 191.79 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Quinine hydrochloride dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20547-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Quinine hydrochloride dihydrate; Chinini hydrochloridum dihydricum

### Special notes

When selecting the *Quinine hydrochloride dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Quinine hydrochloride dihydrate | 7 | 3 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Quinine hydrochloride dihydrate* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Quinine hydrochloride dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 85.22 | – |
| ⋮ | ⋮ | ⋮ |
| Ciprofloxacin hydrochloride | >50 | 155.04 |
| Capsaicin | >50 | 166.16 |
| Sodium citrate | >50 | 167.16 |
| Oxybutynin hydrochloride | >50 | 194.62 |
| Levocarnitine | >50 | 293.42 |
| Heparin sodium | >50 | 305.79 |
| Pyridoxal-5-phosphate hydrate | >50 | 333.61 |
| Prednicarbate | >50 | 352.51 |
| Methoxsalen | >50 | 361.36 |
| Cyproterone acetate | >50 | 470.55 |
| Tetracaine | >50 | 515.45 |
| Triclosan | >50 | 589.07 |
| Alfatradiol | >50 | 666.33 |
| Sucrose | >50 | 911.59 |
| Norethisterone acetate | >50 | 1007.18 |
| Amitriptyline hydrochloride | >50 | 1120.62 |
| Amifampridine | >50 | 1156.74 |
| Valine | >50 | 1624.41 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Quinine hydrochloride dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Quinine hydrochloride dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Quinine hydrochloride dih… | 15376201 | 22309 | 60 | 20151105 |
| Caelo | Quinine hydrochloride dih… | 16283302 | 23577 | 40 | 1802260 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Quinine hydrochloride dih… | 20002720 | 25621 | 40 | 20201119* |
| Fagron | Quinine hydrochloride dih… | 13G10-N07 | 21235 | 30 | 20130809 |
| Fagron | Quinine hydrochloride dih… | 13I30-B02-295630 | 21809 | 60 | AR-15-FG-015410-01 |
| Fagron | Quinine hydrochloride dih… | 20B26-F03-370029 | 25491 | 40 | 20200501 |
| Fagron | Quinine hydrochloride dih… | 21E06-B02-213598 | 26332 | 40 | 20210615 |
| Fagron | Quinine hydrochloride dih… | 21E06-B02-213598 | 26332SI | 20 | 20210615 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 330 spectra of 8 reference samples from the substance/substance group *Quinine hydrochloride dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 996 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 3 reference samples from the substance/substance group *Quinine hydrochloride dihydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Quinine hydrochloride dih… | 180226 | 24022 | 40 |
| Fagron | Quinine hydrochloride dih… | 15A20-B03-319027 | 23573 | 40 |
| Fagron | Quinine hydrochloride dih… | 16K01-B05-340171 | 23920 | 40 |

- 212 820 spectra from a total of 4284 batches from further 872 substances. These spectra were

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 25 spectra from 21 *Apo-Ident* customers from 19 batches from the substance/substance group *Quinine hydrochloride dihydrate*.
- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Quinine hydrochloride dih… | 12316604 | 1 |
| Caelo | Quinine hydrochloride dih… | 12316605 | 1 |
| Caelo | Quinine hydrochloride dih… | 12316611 | 2 |
| Caelo | Quinine hydrochloride dih… | 12316617 | 1 |
| Caelo | Quinine hydrochloride dih… | 13D24-N06 | 1 |
| Caelo | Quinine hydrochloride dih… | 15227701 | 1 |
| Caelo | Quinine hydrochloride dih… | 15376201 | 2 |
| Caelo | Quinine hydrochloride dih… | 153776201 | 1 |
| Caelo | Quinine hydrochloride dih… | 153796204 | 1 |
| Caelo | Quinine hydrochloride dih… | 16283302 | 1 |
| Caelo | Quinine hydrochloride dih… | 16283305 | 3 |
| Caelo | Quinine hydrochloride dih… | 180226002 | 1 |
| Caelo | Quinine hydrochloride dih… | 18022602 | 1 |
| Caelo | Quinine hydrochloride dih… | 18022604 | 1 |
| Caelo | Quinine hydrochloride dih… | 18022605 | 1 |
| Caelo | Quinine hydrochloride dih… | 20002720002 | 1 |
| Caesar & Loretz GmbH | Quinine hydrochloride dih… | 180226002 | 1 |
| Caesar & Loretz GmbH | Quinine hydrochloride dih… | 18022605 | 1 |
| Fagron | Quinine hydrochloride dih… | 10N129B | 1 |
| Fagron | Quinine hydrochloride dih… | 13G10-N07 | 1 |
| Gatt-Koller | Quinine hydrochloride dih… | 3500/08103810 | 1 |

- 256 861 spectra from 1666 *Apo-Ident* customers from a total of 52 134 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Quinine hydrochloride dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Quinine hydrochloride dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 330 | 0 | 157 996 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 25 | 0 | 256 861 |


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The substance/substance group *Quinine hydrochloride dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1818 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 76.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21235 | 25621 | 16.78 | 154.85 |
| 21809 | 21809 | 0.00 | 148.88 |
| 22309 | 23577 | 5.96 | 154.97 |
| 23577 | 23577 | 0.00 | 152.76 |
| 25491 | 23577 | 10.00 | 154.05 |
| 25621 | 25621 | 0.00 | 155.12 |
| 26332 | 21809 | 9.91 | 154.58 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Quinine sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21057-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Quinine sulfate; Chinini sulfas

### Special notes

When selecting the *Quinine sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Quinine sulfate | 6 | 3 | 6 |

### Second-stage model

For differentiation of the substance/substance group *Quinine sulfate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Quinine sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 102.04 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Quinine sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Quinine sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Quinine sulfate | 13024604 | 21429 | 60 | AR-16-FG-005472-01 |
| Fagron | Quinine sulfate | 13J23-N03 | 21057 | 40 | 1404401 |
| Fagron | Quinine sulfate | 14B27-B01 | 21277 | 40 | AR-16-FG-009455-01 |
| Fagron | Quinine sulfate | 22B24-B03-216222 | 26143 | 40 | 20220423 |
| Fagron | Quinine sulfate | 22B24-B03-216222 | 26143SI | 20 | 20220423 |
| Fagron | Quinine sulfate | 23C09-B03-229466 | 26681 | 40 | 20230327 |
| Fagron | Quinine sulfate | 23C09-B03-229466 | 26681SI | 20 | 20230327 |
| Fagron | Quinine sulfate | 24A30-B02-004896 | 27566 | 40 | 20240411 |
| Fagron | Quinine sulfate | 24A30-B02-004896 | 27566SI | 20 | 20240411 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 9 reference samples from the substance/substance group *Quinine sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.


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- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 4 reference samples from the substance/substance group *Quinine sulfate*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Quinine sulfate | 15230005 | 22959 | 40 |
| Caelo | Quinine sulfate | 170616 | 23281 | 40 |
| Caelo | Quinine sulfate | 180630 | 24032 | 40 |
| Caelo | Quinine sulfate | 170616 | 23316 | 40 |

- 212 780 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 9 spectra from 3 *Apo-Ident* customers from 6 batches from the substance/substance group *Quinine sulfate*.
- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Quinine sulfate | 15B06B03304359 | 1 |
| Gatt-Koller / Phoenix | Quinine sulfate | 2503/07143314 | 1 |
| Gatt-Koller / Phoenix | Quinine sulfate | 4928/11132214 | 1 |
| Gatt-Koller | Quinine sulfate | 1801042 | 1 |
| Gatt-Koller | Quinine sulfate | 1803149 | 4 |
| KÖGL | Quinine sulfate | 1901102 | 1 |

- 256 877 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Quinine sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Quinine sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 8 | 1 | 256 877 |

The substance/substance group *Quinine sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21057 | 21057 | 0.00 | 179.98 |
| 21277 | 21277 | 0.00 | 175.69 |
| 21429 | 21429 | 0.00 | 179.57 |
| 26143 | 21277 | 7.36 | 169.74 |
| 26681 | 21057 | 10.49 | 173.67 |
| 27566 | 21057 | 7.83 | 175.69 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all


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substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Quinoline yellow** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20456-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Quinoline yellow

### Special notes

When selecting the *Quinoline yellow* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Quinoline yellow | 6 | 3 | 62 |

### Second-stage model

For differentiation of the substance/substance group *Quinoline yellow* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Quinoline yellow* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 61.01 | – |
| ⋮ | ⋮ | ⋮ |
| Saccharin sodium | >50 | 23.97 |
| Atropine sulfate | >50 | 102.90 |
| Mometasone furoate | >50 | 104.81 |
| Magnesium hydrogen citrate | >50 | 180.75 |
| Hydrocortisone | >50 | 237.06 |
| Propranolol hydrochloride | >50 | 247.53 |
| Phenytoin | >50 | 373.67 |
| Potassium sorbate | >50 | 392.09 |
| Calcium orotate dihydrate | >50 | 430.32 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Quinoline yellow* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Quinoline yellow*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Quinoline yellow | 12042010 | 20922 | 40 | 20120314 |
| Caelo | Quinoline yellow | 13109108 | 21305 | 40 | 1711481 |
| Caelo | Quinoline yellow | 17034101 | 23400 | 40 | 1709327 |
| Caelo | Quinoline yellow | 172277 | 23685 | 30 | 20171020* |
| Caelo | Quinoline yellow | 172277 | 24812 | 40 | 20171020* |
| Caelo | Quinoline yellow | 20002519012 | 26737 | 40 | 231105522 |
| Caelo | Quinoline yellow | 23002618 | 26962 | 40 | 20231103* |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 270 spectra of 7 reference samples from the substance/substance group *Quinoline yellow*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 056 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 220 spectra of 6 reference samples from the substance/substance group *Quinoline yellow*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Quinoline yellow | 16050101 | 23401 | 40 |
| Caelo | Quinoline yellow | 190734 | 24555 | 40 |
| Fagron | Quinoline yellow | 12E24-N01 | 20731 | 60 |
| Caelo | Quinoline yellow | 190734 | 24725 | 40 |
| Caelo | Quinoline yellow | 20002519012 | 26737SI† | 20 |
| Caelo | Quinoline yellow | 23002618 | 26962SI† | 20 |

- 212 720 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 191 spectra from 108 *Apo-Ident* customers from 65 batches from the substance/substance group *Quinoline yellow*.

- Among them are spectra of independent samples from 62 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Quinoline yellow | 20002519008 | 1 |
| | Quinoline yellow | 20002519010 | 1 |
| | Quinoline yellow | 20002519011 | 1 |
| | Quinoline yellow | 20002519012 | 1 |
| | Quinoline yellow | 20002519014 | 1 |
| | Quinoline yellow | 23002618001 | 1 |
| | Quinoline yellow | 23002618002 | 3 |
| Caelo | Quinoline yellow | 11089606 | 1 |
| Caelo | Quinoline yellow | 11089608 | 1 |
| Caelo | Quinoline yellow | 11089610 | 1 |
| Caelo | Quinoline yellow | 118E-03146 | 1 |
| Caelo | Quinoline yellow | 12042002 | 3 |
| Caelo | Quinoline yellow | 12042004 | 1 |
| Caelo | Quinoline yellow | 12042007 | 3 |
| Caelo | Quinoline yellow | 12042010 | 1 |
| Caelo | Quinoline yellow | 12051810 | 1 |
| Caelo | Quinoline yellow | 13109102 | 2 |
| Caelo | Quinoline yellow | 13109109 | 1 |
| Caelo | Quinoline yellow | 14049401 | 2 |
| Caelo | Quinoline yellow | 14274305 | 1 |
| Caelo | Quinoline yellow | 14274309 | 1 |
| Caelo | Quinoline yellow | 14363202 | 4 |
| Caelo | Quinoline yellow | 14363207 | 1 |
| Caelo | Quinoline yellow | 15276801 | 2 |
| Caelo | Quinoline yellow | 15276802 | 1 |
| Caelo | Quinoline yellow | 15276803 | 2 |
| Caelo | Quinoline yellow | 15276804 | 2 |
| Caelo | Quinoline yellow | 15276807 | 1 |
| Caelo | Quinoline yellow | 16050101 | 8 |
| Caelo | Quinoline yellow | 16050106 | 4 |
| Caelo | Quinoline yellow | 16050108 | 2 |
| Caelo | Quinoline yellow | 17034101 | 4 |
| Caelo | Quinoline yellow | 17034102 | 7 |
| Caelo | Quinoline yellow | 17034104 | 8 |
| Caelo | Quinoline yellow | 172277003 | 1 |
| Caelo | Quinoline yellow | 17227701 | 9 |
| Caelo | Quinoline yellow | 17227702 | 1 |
| Caelo | Quinoline yellow | 17227703 | 7 |
| Caelo | Quinoline yellow | 17227705 | 1 |
| Caelo | Quinoline yellow | 17227706 | 9 |
| Caelo | Quinoline yellow | 17227708 | 1 |
| Caelo | Quinoline yellow | 17227709 | 4 |
| Caelo | Quinoline yellow | 190734001 | 1 |
| Caelo | Quinoline yellow | 190734002 | 5 |
| Caelo | Quinoline yellow | 190734003 | 10 |
| Caelo | Quinoline yellow | 190734004 | 2 |
| Caelo | Quinoline yellow | 19073401 | 12 |
| Caelo | Quinoline yellow | 20002519003 | 1 |
| Caelo | Quinoline yellow | 20002519004 | 1 |
| Caelo | Quinoline yellow | 20002519005 | 5 |
| Caelo | Quinoline yellow | 20002519006 | 2 |
| Caelo | Quinoline yellow | 20301211-6 | 1 |
| Caelo | Quinoline yellow | 713E-03146 | 1 |
| Caesar & Loretz GmbH... | Quinoline yellow | 190734004 | 2 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH… | Quinoline yellow | 20002519012 | 1 |
| Caesar & Loretz GmbH… | Quinoline yellow | 20002519003 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 17227705 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 190734001 | 4 |
| Caesar & Loretz GmbH | Quinoline yellow | 190734002 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 190734003 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 190734004 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 19073401 | 2 |
| Caesar & Loretz GmbH | Quinoline yellow | 20002519003 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 20002519004 | 2 |
| Caesar & Loretz GmbH | Quinoline yellow | 20002519005 | 2 |
| Caesar & Loretz GmbH | Quinoline yellow | 20002519006 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 20002519007 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 20002519008 | 2 |
| Caesar & Loretz GmbH | Quinoline yellow | 20002519009 | 1 |
| Caesar & Loretz GmbH | Quinoline yellow | 2002519006 | 1 |
| Fagron | Quinoline yellow | 100427 | 1 |
| Fagron | Quinoline yellow | 11F30-N04 | 1 |
| Fagron | Quinoline yellow | 11K08-N01 | 2 |
| Fagron | Quinoline yellow | 12B08-N08 | 1 |
| Fagron | Quinoline yellow | 12E24-N05 | 1 |
| Fagron | Quinoline yellow | 12L11-N07 | 1 |
| Fagron | Quinoline yellow | 14D18-B02-295783 | 1 |
| Fagron | Quinoline yellow | 17227705 | 1 |
| Fagron | Quinoline yellow | 9878 | 1 |
| Klosterring | Quinoline yellow | 17227706 | 1 |
| Noweda | Quinoline yellow | 17227706 | 1 |
| PHOENIX | Quinoline yellow | 12042004 | 1 |
| Phoenix | Quinoline yellow | 20002519003 | 1 |
| phönix | Quinoline yellow | 15276803 | 1 |
| Phönix | Quinoline yellow | 16050108 | 1 |
| sanacorp | Quinoline yellow | 3214M-03146 | 1 |

- 256 695 spectra from 1666 *Apo-Ident* customers from a total of 52 088 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Quinoline yellow* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Quinoline yellow* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 270 | 0 | 158 056 |
| **Type B** | 0 | 220 | 0 | 212 720 |
| **Type C** | 0 | 191 | 0 | 256 695 |

The substance/substance group *Quinoline yellow* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7778 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.2727 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 96.8586 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20922 | 21305 | 17.69 | 140.99 |
| 21305 | 21305 | 0.00 | 136.33 |
| 23400 | 23400 | 0.00 | 148.99 |
| 23685 | 23685 | 0.00 | 147.74 |
| 24812 | 24812 | 0.00 | 144.02 |
| 26737 | 26737 | 0.00 | 133.14 |
| 26962 | 26962 | 0.00 | 146.84 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Resocrinol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20938-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Resocrinol; Resorcinolum

### Special notes

When selecting the *Resocrinol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Resocrinol | 9 | 6 | 106 |

### Second-stage model

For differentiation of the substance/substance group *Resocrinol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Resocrinol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Hydroquinone | 37.19 | – |
| Sodium cromoglicate | 97.95 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Resocrinol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Resocrinol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Resocrinol | 13293108 | 21471 | 60 | AR-15-FG-006906-01 |
| Caelo | Resocrinol | 161533 | 22632 | 40 | 20160524* |
| Caelo | Resocrinol | 182166 | 25196 | 40 | 20181114* |
| Caelo | Resocrinol | 22002981 | 26504 | 40 | 20221014* |
| Caelo | Resocrinol | 22002981 | 26504SI | 20 | 20221014* |
| Caelo | Resocrinol | 23001796 | 26969 | 40 | 20230814* |
| Caelo | Resocrinol | 23001796 | 26969SI | 20 | 20230814* |
| Caelo | Resocrinol | 24000513 | 27136 | 40 | 20240226* |
| Fagron | Resocrinol | 12G24-N04 | 20938 | 40 | 1401462 |
| Fagron | Resocrinol | 13I18-B09-291533 | 21706 | 45 | 20130606 |
| Fagron | Resocrinol | 19J21-B16-195450 | 25171 | 40 | 20191105 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 425 spectra of 11 reference samples from the substance/substance group *Resocrinol*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 901 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 260 spectra of 7 reference samples from the substance/substance group *Resocrinol*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Resocrinol | 20003735 | 25736 | 50 |
| Caelo | Resocrinol | 21004158 | 26005 | 40 |
| Caelo | Resocrinol | 23003284 | 27117 | 40 |
| Fagron | Resocrinol | 17H03-B11-338899 | 23921 | 40 |
| Fagron | Resocrinol | 21F14-B01-213197 | 27240 | 40 |
| Fagron | Resocrinol | 24H21-B05-007236 | 27593 | 40 |
| Caelo | Resocrinol | 21004158 | 26005SI | 10 |

- 212 680 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 258 spectra from 177 *Apo-Ident* customers from 112 batches from the substance/substance group *Resocrinol*.

- Among them are spectra of independent samples from 106 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Resocrinol | 20L29-B13-204180 | 1 |
| | Resocrinol | 21004158004 | 2 |
| | Resocrinol | 21004158008 | 2 |
| | Resocrinol | 21F14-B01-213197 | 2 |
| | Resocrinol | 22002981004 | 2 |
| | Resocrinol | 24H21-B05-007236 | 2 |
| | Resocrinol | 90972 | 1 |
| | Resocrinol | B0121319007 | 1 |
| AHD | Resocrinol | 220002981006 | 1 |
| Anzag | Resocrinol | 18216615 | 1 |
| apomix | Resocrinol | 11L19-N19 | 1 |
| Caelo | Resocrinol | 10111210 | 1 |
| Caelo | Resocrinol | 10218809 | 2 |
| Caelo | Resocrinol | 11309610 | 4 |
| Caelo | Resocrinol | 11d29-n14 | 2 |
| Caelo | Resocrinol | 12255614 | 2 |
| Caelo | Resocrinol | 12G24-N04 | 2 |
| Caelo | Resocrinol | 13/18-B19-291534 | 1 |
| Caelo | Resocrinol | 13293103 | 1 |
| Caelo | Resocrinol | 13293110 | 1 |
| Caelo | Resocrinol | 13293115 | 2 |
| Caelo | Resocrinol | 15009502 | 1 |
| Caelo | Resocrinol | 15009507 | 8 |
| Caelo | Resocrinol | 15009511 | 4 |
| Caelo | Resocrinol | 15009515 | 2 |
| Caelo | Resocrinol | 15K24-B02-317584 | 1 |
| Caelo | Resocrinol | 16/13082 | 1 |
| Caelo | Resocrinol | 16153306 | 1 |
| Caelo | Resocrinol | 16153307 | 1 |
| Caelo | Resocrinol | 16153309 | 8 |
| Caelo | Resocrinol | 16153312 | 1 |
| Caelo | Resocrinol | 16153313 | 5 |
| Caelo | Resocrinol | 16271807 | 1 |
| Caelo | Resocrinol | 16D29-B01 | 1 |
| Caelo | Resocrinol | 18015601 | 1 |
| Caelo | Resocrinol | 18015603 | 1 |
| Caelo | Resocrinol | 18111703 | 1 |
| Caelo | Resocrinol | 18130901 | 3 |
| Caelo | Resocrinol | 182166002 | 1 |
| Caelo | Resocrinol | 18216601 | 1 |
| Caelo | Resocrinol | 18216603 | 7 |
| Caelo | Resocrinol | 18216607 | 2 |
| Caelo | Resocrinol | 18216609 | 1 |
| Caelo | Resocrinol | 18216610 | 1 |
| Caelo | Resocrinol | 18216611 | 7 |
| Caelo | Resocrinol | 18216615 | 1 |
| Caelo | Resocrinol | 19061305 | 1 |
| Caelo | Resocrinol | 19J21-16-I95450 | 1 |
| Caelo | Resocrinol | 20003735002 | 2 |
| Caelo | Resocrinol | 20003735007 | 3 |
| Caelo | Resocrinol | 2003735006 | 1 |
| Caelo | Resocrinol | 2041512 | 1 |
| Caelo | Resocrinol | 206370-0003 | 1 |
| Caelo | Resocrinol | 21004158004 | 2 |
| Caelo | Resocrinol | 24092001 | 1 |
| Caelo | Resocrinol | 5052 | 1 |
| Caesar & Loretz GmbH... | Resocrinol | 18216603 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Resocrinol | 182166002 | 1 |
| Caesar & Loretz GmbH/L30 | Resocrinol | 21000873008 | 1 |
| Caesar & Loretz GmbH... | Resocrinol | 20003735007 | 1 |
| Caesar & Loretz GmbH... | Resocrinol | 18216601 | 1 |
| Caesar & Loretz GmbH | Resocrinol | 18216607 | 1 |
| Caesar & Loretz GmbH | Resocrinol | 18216609 | 1 |
| Caesar & Loretz GmbH | Resocrinol | 18216611 | 1 |
| Caesar & Loretz GmbH | Resocrinol | 18216613 | 1 |
| Caesar & Loretz GmbH | Resocrinol | 20003735005 | 2 |
| Caesar & Loretz GmbH | Resocrinol | 20003735006 | 2 |
| Caesar & Loretz GmbH | Resocrinol | 20003735007 | 2 |
| Caesar & Loretz GmbH | Resocrinol | 21004158008 | 1 |
| Euro OTC | Resocrinol | 11/13-N02 | 1 |
| Euro OTC | Resocrinol | 16D29-B01-329760 | 1 |
| Fagron | Resocrinol | 10B01-N06 | 2 |
| Fagron | Resocrinol | 11/13-N02 | 2 |
| Fagron | Resocrinol | 11/13-no2 | 1 |
| Fagron | Resocrinol | 1112013A | 1 |
| Fagron | Resocrinol | 118b09291534 | 1 |
| Fagron | Resocrinol | 11A19-N09 | 1 |
| Fagron | Resocrinol | 11D29-N14 | 1 |
| Fagron | Resocrinol | 11L19-N19 | 2 |
| Fagron | Resocrinol | 12G24-N004 | 1 |
| Fagron | Resocrinol | 12g24-N04 | 1 |
| Fagron | Resocrinol | 12G24-N04 | 10 |
| Fagron | Resocrinol | 12K30-N03 | 4 |
| Fagron | Resocrinol | 13/17071 | 1 |
| Fagron | Resocrinol | 13/18-B09-291534 | 1 |
| Fagron | Resocrinol | 13E24-N10 | 8 |
| Fagron | Resocrinol | 13I18-B09 | 2 |
| Fagron | Resocrinol | 13I18-B09-291533 | 1 |
| Fagron | Resocrinol | 13I18-B09-291534 | 1 |
| Fagron | Resocrinol | 14/15-B02-307749 | 1 |
| Fagron | Resocrinol | 14/16062 | 1 |
| Fagron | Resocrinol | 14/19050 | 1 |
| Fagron | Resocrinol | 1415B02307749 | 1 |
| Fagron | Resocrinol | 14G10B06 | 1 |
| Fagron | Resocrinol | 14G10-B06-296296 | 7 |
| Fagron | Resocrinol | 14G10-B06-296297 | 2 |
| Fagron | Resocrinol | 14J15-B02 | 2 |
| Fagron | Resocrinol | 14J15-B02-307749 | 5 |
| Fagron | Resocrinol | 15/18082 | 1 |
| Fagron | Resocrinol | 15K24-B02-317584 | 3 |
| Fagron | Resocrinol | 1613082 | 1 |
| Fagron | Resocrinol | 16D29-B01 | 1 |
| Fagron | Resocrinol | 16d29b01323046 | 1 |
| Fagron | Resocrinol | 16D29-B01-323046 | 5 |
| Fagron | Resocrinol | 16D29-B01-329760 | 3 |
| Fagron | Resocrinol | 16d29b01332738 | 1 |
| Fagron | Resocrinol | 16D29-B01-332738 | 2 |
| Fagron | Resocrinol | 17H03-B11-338899 | 3 |
| Fagron | Resocrinol | 17H03-B11-342399 | 1 |
| Fagron | Resocrinol | 18/19081 | 1 |
| Fagron | Resocrinol | 18B08-B05-347787 | 8 |
| Fagron | Resocrinol | 18K20-B01-355679 | 1 |
| Fagron | Resocrinol | 19J21-B16195450 | 1 |
| Fagron | Resocrinol | 19J21-B16-195450 | 1 |
| Fagron | Resocrinol | 20E07-B09-200551 | 2 |
| Fagron | Resocrinol | 20129-B13 | 1 |
| Fagron | Resocrinol | 20L29-B13 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Resocrinol | 20L29-B13-204180 | 6 |
| Fagron | Resocrinol | 211217(20L29-B13-204180) | 1 |
| Fagron | Resocrinol | 2112I-02170 | 1 |
| Fagron | Resocrinol | 88735 | 1 |
| Fagron | Resocrinol | B09-2005501 | 1 |
| Fagron | Resocrinol | B16-1954500 | 1 |
| Fargon/ Phönix | Resocrinol | 16D29-B01-323046 | 1 |
| Fargon | Resocrinol | 15K24-B02-317584 | 1 |
| Gehe | Resocrinol | 11L13-N02 | 1 |
| Gehe | Resocrinol | 13E24-N10 | 1 |
| Holdermann | Resocrinol | 21003592004 | 1 |
| L12 | Resocrinol | 16153306 | 1 |
| Noweda/Fargon | Resocrinol | 16029-B01-329760 | 1 |
| Noweda | Resocrinol | 1318b09291533 | 1 |
| Noweda | Resocrinol | 13E24-N10 | 1 |
| Noweda | Resocrinol | 14G10-B06-296 | 1 |
| Noweda | Resocrinol | 2003735007 | 1 |
| Noweda | Resocrinol | 21004158004 | 1 |
| Phoenix WE: 13.07.2015 | Resocrinol | 14G10-B06-296296 | 1 |
| Phoenix goettin | Resocrinol | 13I18-B09-291534 | 1 |
| Phönix Gotha | Resocrinol | 14G10-B06-296296 | 1 |
| Phönix | Resocrinol | 20L29-B13 | 1 |
| Sanacorp | Resocrinol | 16D29-Bo1-323046 | 1 |
| vdl | Resocrinol | 12G24-N04 | 1 |

- 256 628 spectra from 1666 *Apo-Ident* customers from a total of 52 042 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Resocrinol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Resocrinol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 425 | 0 | 157 901 |
| **Type B** | 0 | 260 | 0 | 212 680 |
| **Type C** | 0 | 257 | 1 | 256 628 |

The substance/substance group *Resocrinol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5882 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6923 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6124 % (> 98.4496 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)


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In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20938 | 20938 | 0.00 | 49.71 |
| 21471 | 21471 | 0.00 | 44.99 |
| 21706 | 22632 | 7.79 | 41.44 |
| 22632 | 22632 | 0.00 | 44.36 |
| 25171 | 21471 | 11.26 | 40.56 |
| 25196 | 25196 | 0.00 | 43.58 |
| 26504 | 26504 | 0.00 | 41.05 |
| 26969 | 26969 | 0.00 | 56.13 |
| 27136 | 27136 | 0.00 | 44.62 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Riboflavin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20409-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Riboflavin; Riboflavinum

### Special notes

When selecting the *Riboflavin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Riboflavin | 12 | 14 | 71 |

### Second-stage model

For differentiation of the substance/substance group *Riboflavin* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Riboflavin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 32.61 | 10.36 |
| Riboflavin sodium phosphate hydrate | 32.92 | – |
| Sodium cromoglicate | 69.11 | – |
| ⋮ | ⋮ | ⋮ |
| Bacitracin | >50 | 29.67 |
| Colistin sulfate | >50 | 31.95 |
| Amphotericin B | >50 | 46.61 |
| Nystatin | >50 | 54.75 |
| Calcium pantothenate | >50 | 55.99 |
| Cyanocobalamin | >50 | 56.38 |
| Triamcinolone | >50 | 62.98 |
| Tosylchloramide sodium | >50 | 63.79 |
| Calcium glycerophosphate | >50 | 68.64 |
| Estradiol hemihydrate | >50 | 75.27 |
| Hyoscine hydrobromide | >50 | 80.47 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 95.73 |
| alpha-tocopheryl acetate dry concentrate | >50 | 96.25 |
| Estriol | >50 | 114.99 |
| Methylcobalamin | >50 | 118.07 |
| Gelatine, white | >50 | 121.42 |
| SyrSpend® SF Alka | >50 | 147.42 |
| Carmellose sodium | >50 | 153.13 |
| Rice starch | >50 | 162.09 |
| Oxalic acid | >50 | 198.68 |
| SyrSpend® SF pH4 | >50 | 249.59 |
| Corn starch | >50 | 258.71 |
| Wheat starch | >50 | 277.72 |
| Acacia, dried dispersion | >50 | 301.52 |
| Potato starch | >50 | 302.33 |
| Fructose | >50 | 314.15 |
| Maltodextrin | >50 | 349.57 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Riboflavin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Riboflavin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Riboflavin | 12003317 | 20925 | 40 | 1405155 |
| Caelo | Riboflavin | 13305203 | 21389 | 60 | AR-15-FG-005686-01 |
| Caelo | Riboflavin | 14322008 | 22492 | 40 | AR-16-FG-013669-01 |
| Caelo | Riboflavin | 21000916 | 25654 | 40 | 20210408* |
| Euro OTC | Riboflavin | 1701050 | 23004 | 40 | 20170214* |
| Euro OTC | Riboflavin | 1701050-01 | 23091 | 40 | 20170214 |
| Euro OTC | Riboflavin | 2002026 | 25157 | 40 | 20200512* |
| Euro OTC | Riboflavin | 2102005 | 25600 | 40 | 20210330* |
| Fagron | Riboflavin | 13D02-N03 | 20825 | 40 | AR-15-FG-000733-01 |
| Fagron | Riboflavin | 13D02-N03 | 20914 | 40 | 20130405 |
| Fagron | Riboflavin | 15G20-B13-310997 | 21955 | 60 | 20150819 |
| Fagron | Riboflavin | 16B18-B06-319026 | 22655 | 40 | AR-16-FG-014466-01 |
| Fagron | Riboflavin | 17G14-B05-337885 | 23714 | 40 | AR-18-FG-000141-01 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 560 spectra of 13 reference samples from the substance/substance group *Riboflavin*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.
- 157 766 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 660 spectra of 19 reference samples from the substance/substance group *Riboflavin*.
- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Riboflavin | 15330708 | 23579 | 40 |
| Caelo | Riboflavin | 172722 | 23649 | 40 |
| Caelo | Riboflavin | 192609 | 24884 | 40 |
| Caelo | Riboflavin | 22003300 | 26473 | 40 |
| Caelo | Riboflavin | 23003154 | 27129 | 40 |
| Euro OTC | Riboflavin | 1707017 | 23612 | 40 |
| Euro OTC | Riboflavin | 1801018 | 23880 | 40 |
| Euro OTC | Riboflavin | 1809004 | 24297 | 40 |
| Euro OTC | Riboflavin | 1810005 | 24307 | 40 |
| Euro OTC | Riboflavin | 2009015 | 25423 | 40 |
| Euro OTC | Riboflavin | 2210022 | 26437 | 40 |
| Euro OTC | Riboflavin | 2408013 | 27401 | 40 |
| Fagron | Riboflavin | 22D13-B02-219504 | 26398 | 40 |
| Fagron | Riboflavin | 25A14-B04-009711 | 27635 | 40 |
| Caelo | Riboflavin | 22003300 | 26473SI | 20 |
| Caelo | Riboflavin | 23003154 | 27129SI | 20 |
| Euro OTC | Riboflavin | 2408013 | 27401SI | 20 |
| Fagron | Riboflavin | 22D13-B02-219504 | 26398SI | 20 |
| Fagron | Riboflavin | 25A14-B04-009711 | 27635SI | 20 |

- 212 280 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 123 spectra from 52 *Apo-Ident* customers from 77 batches from the substance/substance group *Riboflavin*.

- Among them are spectra of independent samples from 71 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Riboflavin | 20004481001 | 1 |
| | Riboflavin | 21000916006 | 1 |
| | Riboflavin | 22003300001 | 1 |
| | Riboflavin | 22H31-B04-223759 | 2 |
| | Riboflavin | 22J26-B01 | 1 |
| | Riboflavin | 22J26-B01-226169 | 1 |
| | Riboflavin | 22l13-b16-226589 | 1 |
| | Riboflavin | 22L13-B16-226589 | 1 |
| | Riboflavin | 23003154001 | 1 |
| | Riboflavin | 23003154005 | 2 |
| | Riboflavin | 24000155001 | 1 |
| Anzag/Anzag 11.09.18 | Riboflavin | 18B22-B01-347142 | 1 |
| Caelo | Riboflavin | 15330708 | 2 |
| Caelo | Riboflavin | 17272204 | 2 |
| Caelo | Riboflavin | 17G14-B05-337885 | 1 |
| Caelo | Riboflavin | 21000916002 | 2 |
| Caelo | Riboflavin | 21000916003 | 1 |
| Caelo | Riboflavin | 21000916007 | 1 |
| Caesar & Loretz GmbH... | Riboflavin | 19000560002 | 1 |
| Caesar & Loretz GmbH... | Riboflavin | 18123401 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Riboflavin | 19000560002 | 1 |
| Caesar & Loretz GmbH | Riboflavin | 21000916002 | 1 |
| EuRho | Riboflavin | 1810005-01 | 1 |
| Euro OTC | Riboflavin | 1701050-02 | 1 |
| Euro OTC | Riboflavin | 1707017-01 | 1 |
| Euro OTC | Riboflavin | 19G17-B07 | 1 |
| Euro OTC | Riboflavin | 2102005-02 | 1 |
| Euro OTC | Riboflavin | L1210048-01 | 1 |
| Euro OTC | Riboflavin | L1305039-01 | 1 |
| Fagr9n 06.11.19 | Riboflavin | 19F10B07191754 | 1 |
| Fagron | Riboflavin | 11K02-N01 | 1 |
| Fagron | Riboflavin | 13J29-B04-287533 | 1 |
| Fagron | Riboflavin | 13J29-B04-287534 | 1 |
| Fagron | Riboflavin | 14B03B07292071 | 1 |
| Fagron | Riboflavin | 14E01-B10-296718 | 2 |
| Fagron | Riboflavin | 14K03-B04-304718 | 1 |
| Fagron | Riboflavin | 15G20-B13-310997 | 2 |
| Fagron | Riboflavin | 15I09-B02-315216 | 1 |
| Fagron | Riboflavin | 167720-0005 | 2 |
| Fagron | Riboflavin | 16B18_b06_319026 | 1 |
| Fagron | Riboflavin | 16B18-B06-321484 | 1 |
| Fagron | Riboflavin | 16E18-B05-325274 | 1 |
| Fagron | Riboflavin | 16E-18-B05-325274 | 1 |
| Fagron | Riboflavin | 16I12-B05-329618 | 1 |
| Fagron | Riboflavin | 16J12-B05-329618 | 2 |
| Fagron | Riboflavin | 1701050-01 | 1 |
| Fagron | Riboflavin | 17G14-B05-337885 | 1 |
| Fagron | Riboflavin | 17H10-B06-340170 | 3 |
| Fagron | Riboflavin | 18822-B01-347142 | 2 |
| Fagron | Riboflavin | 18D05-B04 | 1 |
| Fagron | Riboflavin | 18D05B04349962 | 1 |
| Fagron | Riboflavin | 18J10-B01 | 2 |
| Fagron | Riboflavin | 18J10-B01-355004 | 4 |
| Fagron | Riboflavin | 18J10-B01-356142 | 1 |
| Fagron | Riboflavin | 19F10-B07-191754 | 4 |
| Fagron | Riboflavin | 19F-10-B07-191754 | 1 |
| Fagron | Riboflavin | 19g17-b07-192788 | 1 |
| Fagron | Riboflavin | 19G17-B07-192788 | 5 |
| Fagron | Riboflavin | 19G17-B07-200577 | 5 |
| Fagron | Riboflavin | 19GT-B07-192788 | 2 |
| Fagron | Riboflavin | 20a14-b04-196790 | 1 |
| Fagron | Riboflavin | 20A14-B04-196790 | 1 |
| Fagron | Riboflavin | 20A14-BO4-196790 | 1 |
| Fagron | Riboflavin | 21A14-B03-210578 | 6 |
| Fagron | Riboflavin | 21D07-B10-218559 | 3 |
| Fagron | Riboflavin | 22B26-B01 | 1 |
| Fagron | Riboflavin | 22D13-B02 | 3 |
| Fagron | Riboflavin | 22D13-B02-219504 | 1 |
| Fagron | Riboflavin | 22L13-B16-226589 | 1 |
| Fagron | Riboflavin | BO4-1967900 | 1 |
| Fagron | Riboflavin | BO4-1967900 | 1 |
| Fagron | Riboflavin | BO7-2005707 | 1 |
| Fagron | Riboflavin | RIB3061HF | 2 |
| Fagron | Riboflavin | UQ00510683 | 1 |
| Fagron | Riboflavin | UQ60910194 | 1 |
| Fagron | Riboflavin | UQ70210050 | 1 |
| Fagron | Riboflavin | UQ80810145 | 1 |
| Fagron | Riboflavin | UQ90410074 | 1 |
| Gatt-Koller | Riboflavin | 1803007 | 1 |
| Noweda | Riboflavin | 18J10-B01-355004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Riboflavin | 19F01-B07-191754 | 1 |
| Noweda | Riboflavin | 22D13-B02-219504 | 3 |
| Vdl 09.05.14;Preis 7,45 | Riboflavin | 13305203/15R05 | 1 |

- 256 763 spectra from 1666 *Apo-Ident* customers from a total of 52 076 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Riboflavin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Riboflavin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 560 | 0 | 157 766 |
| **Type B** | 0 | 660 | 0 | 212 280 |
| **Type C** | 0 | 122 | 1 | 256 763 |

The substance/substance group *Riboflavin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9286 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0909 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.1870 % (> 96.7480 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20825 | 20825 | 0.00 | 84.55 |
| 20914 | 20825 | 15.08 | 84.63 |
| 20925 | 20925 | 0.00 | 93.45 |

*continued on the next page*


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*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21389 | 21389 | 0.00 | 94.11 |
| 21955 | 21389 | 12.52 | 97.06 |
| 22492 | 22492 | 0.00 | 100.12 |
| 22655 | 22655 | 0.00 | 100.00 |
| 23004 | 23004 | 0.00 | 90.35 |
| 23091 | 23714 | 18.99 | 92.77 |
| 23714 | 23714 | 0.00 | 95.85 |
| 25157 | 25157 | 0.00 | 90.16 |
| 25600 | 25600 | 0.00 | 110.80 |
| 25654 | 25654 | 0.00 | 100.83 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Riboflavin sodium phosphate hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20948-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Riboflavin sodium phosphate hydrate; Riboflavini natrii phosphas hydricum

### Special notes

When selecting the *Riboflavin sodium phosphate hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Riboflavin sodium phosphate hydrate | 8 | 3 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Riboflavin sodium phosphate hydrate* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Riboflavin sodium phosphate hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 40.41 | – |
| Carbomers | 41.60 | 41.23 |
| Magnesium citrate | 47.37 | 36.17 |
| ⋮ | ⋮ | ⋮ |
| Mg-Ca-K colamine phosphate | >50 | 110.11 |
| Gentamicin sulfate | >50 | 110.60 |
| Neomycin sulfate | >50 | 218.82 |
| Tobramycin sulfate | >50 | 283.78 |
| Zinc gluconate | >50 | 342.50 |
| Sodium tetraborate | >50 | 637.18 |
| Finasteride | >50 | 677.42 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Riboflavin sodium phosphate hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Riboflavin sodium phosphate hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Riboflavin sodium phospha… | 2306014 | 26856 | 40 | 20230831* |
| Fagron | Riboflavin sodium phospha… | 13I26-N06 | 20948 | 40 | 1403705 |
| Fagron | Riboflavin sodium phospha… | 15J02-B03-313137 | 22269 | 60 | AR-16-FG-009883-02 |
| Fagron | Riboflavin sodium phospha… | 17A03-B01-335897 | 23713 | 40 | AR-18-FG-000920-01 |
| Fagron | Riboflavin sodium phospha… | 20L02-B02-202655 | 25494 | 40 | 2105284 |
| Fagron | Riboflavin sodium phospha… | 21E19-B01-213684 | 26162 | 40 | 20210702 |
| Fagron | Riboflavin sodium phospha… | 22D20-B02-221099 | 26461 | 40 | 20220625 |
| Fagron | Riboflavin sodium phospha… | 23E16-B05-229478 | 26829 | 40 | 20230602 |
| Fagron | Riboflavin sodium phospha… | 23E16-B05-229478 | 26829SI | 20 | 20230602 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *Riboflavin sodium phosphate hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 966 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 165 spectra of 5 reference samples from the substance/substance group *Riboflavin sodium phosphate hydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Riboflavin sodium phospha… | 2302008 | 26659 | 40 |
| Fagron | Riboflavin sodium phospha… | 14J31-B07-300519 | 21707 | 45 |
| Fagron | Riboflavin sodium phospha… | 17H03-B13-347175 | 24113 | 40 |
| Euro OTC | Riboflavin sodium phospha… | 2302008 | 26659SI | 20 |
| Fagron | Riboflavin sodium phospha… | 21E19-B01-213684 | 26162SI† | 20 |

- 212 775 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 6 spectra from 1 *Apo-Ident* customers from 5 batches from the substance/substance group *Riboflavin sodium phosphate hydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Riboflavin sodium phospha… | 20H27 | 1 |
| Fagron | Riboflavin sodium phospha… | 20H27-B07-201994 | 1 |
| Fagron | Riboflavin sodium phospha… | 20L02-B02-202655 | 1 |
| Fagron | Riboflavin sodium phospha… | 21E19-B01-213684 | 2 |
| Sigma Aldrich | Riboflavin sodium phospha… | MKCG3538 | 1 |

- 256 880 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Riboflavin sodium phosphate hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Riboflavin sodium phosphate hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 165 | 0 | 212 775 |
| **Type C** | 0 | 6 | 0 | 256 880 |

The substance/substance group *Riboflavin sodium phosphate hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.3636 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20948 | 20948 | 0.00 | 51.07 |
| 22269 | 22269 | 0.00 | 64.97 |
| 23713 | 23713 | 0.00 | 92.32 |
| 25494 | 25494 | 0.00 | 97.96 |
| 26162 | 25494 | 18.23 | 112.07 |
| 26461 | 25494 | 10.14 | 101.40 |
| 26829 | 25494 | 48.53 | 127.71 |
| 26856 | 26856 | 0.00 | 82.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ropivacaine hydrochloride monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10002307-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ropivacaine hydrochloride monohydrate; Ropivacaini hydrochloridum monohydricum

### Special notes

When selecting the *Ropivacaine hydrochloride monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ropivacaine hydrochloride monohydrate | 5 | 2 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Ropivacaine hydrochloride monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ropivacaine hydrochloride monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 78.00 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ropivacaine hydrochloride monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ropivacaine hydrochloride monohydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ropivacaine hydrochloride… | 181569 | 24871 | 40 | 20180802* |
| Euro OTC | Ropivacaine hydrochloride… | 1707006 | 23704 | 40 | 20171013* |
| Euro OTC | Ropivacaine hydrochloride… | 1903027 | 24607 | 40 | 20190416* |
| Fagron | Ropivacaine hydrochloride… | 20I17-F09-375251 | 25920 | 40 | 2204443 |
| Fagron | Ropivacaine hydrochloride… | 22D25-B06 | 26444 | 40 | 20220812* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 5 reference samples from the substance/substance group *Ropivacaine hydrochloride monohydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 5 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 126 spectra from a total of 2952 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 90 spectra of 3 reference samples from the substance/substance group *Ropivacaine hydrochloride monohydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ropivacaine hydrochloride… | 191139 | 24872 | 40 |
| Euro OTC | Ropivacaine hydrochloride… | 2106016 | 25919 | 40 |
| Euro OTC | Ropivacaine hydrochloride… | 2106016 | 25919SI | 10 |

- 212 850 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Ropivacaine hydrochloride monohydrate*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ropivacaine hydrochloride monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*.

For this purpose, all relevant spectra of the various substances were compared with *Ropivacaine hydrochloride monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 90 | 0 | 212 850 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Ropivacaine hydrochloride monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 93.3333 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23704 | 23704 | 0.00 | 184.17 |
| 24607 | 24607 | 0.00 | 183.70 |
| 24871 | 24871 | 0.00 | 179.31 |
| 25920 | 25920 | 0.00 | 169.77 |
| 26444 | 26444 | 0.00 | 180.35 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Saccharin sodium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20200-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Saccharin sodium; Saccharinum natricum; Sodium saccharin

### Special notes

When selecting the *Saccharin sodium* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Saccharin sodium | 10 | 6 | 77 |

### Second-stage model

For differentiation of the substance/substance group *Saccharin sodium* the following second-stage model is used:

- Submodel 14

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Saccharin sodium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Quinoline yellow | 82.97 | 24.20 |
| ⋮ | ⋮ | ⋮ |
| Mometasone furoate | >50 | 95.20 |
| Atropine sulfate | >50 | 104.98 |
| Propranolol hydrochloride | >50 | 174.13 |
| Magnesium hydrogen citrate | >50 | 195.29 |
| Hydrocortisone | >50 | 210.76 |
| Phenytoin | >50 | 266.56 |
| Calcium orotate dihydrate | >50 | 287.49 |
| Potassium sorbate | >50 | 411.94 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Saccharin sodium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Saccharin sodium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Saccharin sodium | 172110 | 23643 | 40 | 20170831* |
| Caelo | Saccharin sodium | 162210 | 23857 | 39 | 20160811* |
| Caelo | Saccharin sodium | 172592 | 24409 | 40 | 20171206* |
| Caelo | Saccharin sodium | 19000658 | 25214 | 40 | 20200121* |
| Caelo | Saccharin sodium | 21003326 | 26008 | 40 | 20220105* |
| Caelo | Saccharin sodium | 23003299 | 27121 | 40 | 20240124* |
| Fagron | Saccharin sodium | 13I20-B06-291654 | 23020 | 40 | AR-17-FG-012457-01 |
| Fagron | Saccharin sodium | 14F30-B02-296322 | 23452 | 40 | AR-17-FG-022421-01 |
| Fagron | Saccharin sodium | 14F30-B02-296322 | 23453 | 40 | AR-18-FG-007117-02 |
| Fagron | Saccharin sodium | 18L06-B01-361488 | 25178 | 40 | 20190130 |
| Fagron | Saccharin sodium | 22K28-B09-221810 | 26615 | 40 | 20230112 |
| Fagron | Saccharin sodium | 22K28-B09-221810 | 26615SI | 20 | 20230112 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 459 spectra of 12 reference samples from the substance/substance group *Saccharin sodium*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 867 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 270 spectra of 8 reference samples from the substance/substance group *Saccharin sodium*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Saccharin sodium | 15087704 | 22769 | 40 |
| Caelo | Saccharin sodium | 182104 | 24381 | 40 |
| Caelo | Saccharin sodium | 190964 | 24499 | 40 |
| Caelo | Saccharin sodium | 22003584 | 26489 | 40 |
| Caelo | Saccharin sodium | 23000898 | 26701 | 40 |
| Caelo | Saccharin sodium | 24001228 | 27251 | 40 |
| Caelo | Saccharin sodium | 21003326 | 26008SI† | 10 |
| Caelo | Saccharin sodium | 22003584 | 26489SI | 20 |

- 212 670 spectra from a total of 4280 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 471 spectra from 349 *Apo-Ident* customers from 80 batches from the substance/substance group *Saccharin sodium*.
- Among them are spectra of independent samples from 77 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Saccharin sodium | | 1 |
| | Saccharin sodium | 21003326011 | 1 |
| | Saccharin sodium | 21003326015 | 4 |
| | Saccharin sodium | 21003326024 | 10 |
| | Saccharin sodium | 2200354008 | 1 |
| | Saccharin sodium | 22003558008 | 1 |
| | Saccharin sodium | 22003584008 | 5 |
| | Saccharin sodium | 22003584014 | 5 |
| | Saccharin sodium | 23000898005 | 4 |
| | Saccharin sodium | 23003240002 | 5 |
| | Saccharin sodium | 23003299010 | 4 |
| 17270001 | Saccharin sodium | 17211002 | 1 |
| Alliance Healtcare | Saccharin sodium | 20004198009 | 1 |
| Cael Sanacorp 05.02.2016 | Saccharin sodium | 15087703 | 1 |
| Caeleo/ Krieger | Saccharin sodium | 17329407 | 1 |
| Caelo | Saccharin sodium | | 1 |
| Caelo | Saccharin sodium | 11025605 | 1 |
| Caelo | Saccharin sodium | 11025610 | 1 |
| Caelo | Saccharin sodium | 11172805 | 3 |
| Caelo | Saccharin sodium | 11172814 | 1 |
| Caelo | Saccharin sodium | 12139803 | 1 |
| Caelo | Saccharin sodium | 1236207 | 1 |
| Caelo | Saccharin sodium | 12362607 | 3 |
| Caelo | Saccharin sodium | 13205411 | 1 |
| Caelo | Saccharin sodium | 13205414 | 3 |
| Caelo | Saccharin sodium | 13205417 | 1 |
| Caelo | Saccharin sodium | 1402970 | 1 |
| Caelo | Saccharin sodium | 14029705 | 6 |
| Caelo | Saccharin sodium | 14029707 | 3 |
| Caelo | Saccharin sodium | 14029709 | 1 |
| Caelo | Saccharin sodium | 14029710 | 3 |
| Caelo | Saccharin sodium | 14213402 | 3 |
| Caelo | Saccharin sodium | 14213405 | 5 |
| Caelo | Saccharin sodium | 15084101 | 6 |
| Caelo | Saccharin sodium | 15087703 | 7 |
| Caelo | Saccharin sodium | 15087704 | 12 |
| Caelo | Saccharin sodium | 15087707 | 3 |
| Caelo | Saccharin sodium | 15087713 | 18 |
| Caelo | Saccharin sodium | 16221005 | 14 |
| Caelo | Saccharin sodium | 16221009 | 4 |
| Caelo | Saccharin sodium | 16221010 | 1 |
| Caelo | Saccharin sodium | 17211001 | 2 |
| Caelo | Saccharin sodium | 17211002 | 18 |
| Caelo | Saccharin sodium | 17211002P-190808-4 | 1 |
| Caelo | Saccharin sodium | 17211005 | 2 |
| Caelo | Saccharin sodium | 17329309 | 1 |
| Caelo | Saccharin sodium | 17329310 | 10 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Saccharin sodium | 17329405 | 4 |
| Caelo | Saccharin sodium | 17329407 | 11 |
| Caelo | Saccharin sodium | 17329409 | 17 |
| Caelo | Saccharin sodium | 18210407 | 13 |
| Caelo | Saccharin sodium | 19000658002 | 12 |
| Caelo | Saccharin sodium | 19000658005 | 5 |
| Caelo | Saccharin sodium | 1906403 | 1 |
| Caelo | Saccharin sodium | 190964001 | 8 |
| Caelo | Saccharin sodium | 19096403 | 17 |
| Caelo | Saccharin sodium | 19096408 | 1 |
| Caelo | Saccharin sodium | 20000953001 | 13 |
| Caelo | Saccharin sodium | 20000953003 | 2 |
| Caelo | Saccharin sodium | 20000953006 | 6 |
| Caelo | Saccharin sodium | 20004198004 | 5 |
| Caelo | Saccharin sodium | 20004198005 | 8 |
| Caelo | Saccharin sodium | 20004198009 | 16 |
| Caelo | Saccharin sodium | 21003326006 | 6 |
| Caelo | Saccharin sodium | 21003326007 | 1 |
| Caelo | Saccharin sodium | 21003326011 | 5 |
| Caelo | Saccharin sodium | 21003326015 | 3 |
| Caelo | Saccharin sodium | 21003326019 | 7 |
| Caelo | Saccharin sodium | 21003326024 | 1 |
| Caelo | Saccharin sodium | 21092015A | 1 |
| Caelo | Saccharin sodium | 22003584014 | 2 |
| Caelo | Saccharin sodium | 220905(21003326011) | 1 |
| Caelo | Saccharin sodium | 3414M-02206 | 1 |
| Caelo | Saccharin sodium | 3518E-02206 | 1 |
| Caelo | Saccharin sodium | 8121801 | 1 |
| Caelo | Saccharin sodium | 90542309 | 1 |
| Caelo | Saccharin sodium | 9381714 | 1 |
| Caelo | Saccharin sodium | B190964001 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 21003326011 | 2 |
| Caesar & Loretz GmbH... | Saccharin sodium | 21003326015 | 3 |
| Caesar & Loretz GmbH... | Saccharin sodium | 17329407 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 13205418 | 2 |
| Caesar & Loretz GmbH... | Saccharin sodium | 20004198005 | 1 |
| Caesar & Loretz GmbH/AHD | Saccharin sodium | 20004198005 | 1 |
| Caesar & Loretz GmbH/AHD | Saccharin sodium | 21003326019 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 20000953001 | 1 |
| Caesar & Loretz GmbH/E | Saccharin sodium | 21003326011 | 1 |
| Caesar & Loretz GmbH/Gehe | Saccharin sodium | 20000953 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 21003326006 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 21003326006 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 21003326024 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 19096403 | 2 |
| Caesar & Loretz GmbH/Sa | Saccharin sodium | 20004198004 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 20004198004 | 1 |
| Caesar & Loretz GmbH... | Saccharin sodium | 20004198006 | 1 |
| Caesar & Loretz GmbH | Saccharin sodium | 17211002 | 1 |
| Caesar & Loretz GmbH | Saccharin sodium | 17329310 | 2 |
| Caesar & Loretz GmbH | Saccharin sodium | 17329311 | 1 |
| Caesar & Loretz GmbH | Saccharin sodium | 17329409 | 1 |
| Caesar & Loretz GmbH | Saccharin sodium | 18210407 | 4 |
| Caesar & Loretz GmbH | Saccharin sodium | 19000658002 | 1 |
| Caesar & Loretz GmbH | Saccharin sodium | 190964001 | 3 |
| Caesar & Loretz GmbH | Saccharin sodium | 19096403 | 4 |
| Caesar & Loretz GmbH | Saccharin sodium | 20000953001 | 6 |
| Caesar & Loretz GmbH | Saccharin sodium | 20004198004 | 1 |
| Caesar & Loretz GmbH | Saccharin sodium | 20004198005 | 5 |
| Caesar & Loretz GmbH | Saccharin sodium | 20004198009 | 7 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Saccharin sodium | 21003326006 | 5 |
| Caesar & Loretz GmbH | Saccharin sodium | 21003326011 | 2 |
| Caesar & Loretz GmbH | Saccharin sodium | 21003326015 | 1 |
| Caesar & Loretz GmbH | Saccharin sodium | 21003326019 | 7 |
| Caesar & Loretz Hild... | Saccharin sodium | 190964001 | 1 |
| Caesar & Loretz Hilden | Saccharin sodium | 17329407 | 1 |
| Caesar & Loretz/Geil... | Saccharin sodium | 20000953001 | 1 |
| Caesar Loretz | Saccharin sodium | 20000953001 | 1 |
| Caesar&Lorenz | Saccharin sodium | 19000658005 | 1 |
| Caesar&loretz,Phoenix | Saccharin sodium | 15084101 | 1 |
| Cealo/ Noweda | Saccharin sodium | 17329407 | 1 |
| cealo | Saccharin sodium | 15087703 | 1 |
| Cealo | Saccharin sodium | 17329405 | 1 |
| Cealo | Saccharin sodium | 19000658002 | 1 |
| Euro OTC | Saccharin sodium | 15087704 | 1 |
| Euro OTC | Saccharin sodium | 15087713 | 1 |
| Fagron | Saccharin sodium | 12A13-N03 | 2 |
| Fagron | Saccharin sodium | 12K26-N09 | 1 |
| Fagron | Saccharin sodium | 13D19-N01 | 1 |
| Fagron | Saccharin sodium | SH349/12 | 1 |
| Fargon | Saccharin sodium | 12A13-N03 | 1 |
| Gehe | Saccharin sodium | 18210407 | 2 |
| Gehe | Saccharin sodium | 21003326011 | 1 |
| Gehe | Saccharin sodium | 23003240002 | 1 |
| Henry Lamotte/AHD | Saccharin sodium | 17329405 | 1 |
| Ichthyol-Gesellschaft | Saccharin sodium | 16221009 | 1 |
| Jenne | Saccharin sodium | 15087707 | 1 |
| Jenne | Saccharin sodium | 22003584008 | 1 |
| Kehr | Saccharin sodium | 17329407 | 1 |
| Nachprüfung von Nove... | Saccharin sodium | 14029707 | 2 |
| Noweda | Saccharin sodium | 20000953001 | 1 |
| Noweda | Saccharin sodium | 20000953003 | 1 |
| noweda | Saccharin sodium | 21003326024 | 1 |
| Noweda | Saccharin sodium | 21003326024 | 1 |
| Noweda | Saccharin sodium | 22003584014 | 1 |
| Pharmachem | Saccharin sodium | 17329407 | 1 |
| Phoenix | Saccharin sodium | 14F30-B02-296322 | 1 |
| Phönix | Saccharin sodium | 17329407 | 1 |
| Phönix | Saccharin sodium | 19000658002 | 1 |
| Phönix | Saccharin sodium | 22003584014 | 1 |
| Sana 03.11.14 EK 3,95 | Saccharin sodium | 14029707 | 1 |
| sanacorp | Saccharin sodium | 13205418 | 1 |
| Sanacorp | Saccharin sodium | 17211002 | 2 |

- 256 415 spectra from 1666 *Apo-Ident* customers from a total of 52 074 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Saccharin sodium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Saccharin sodium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 459 | 0 | 157 867 |
| **Type B** | 0 | 270 | 0 | 212 670 |
| **Type C** | 0 | 471 | 0 | 256 415 |

The substance/substance group *Saccharin sodium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6928 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.7778 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 98.7261 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23020 | 23020 | 0.00 | 176.87 |
| 23452 | 23452 | 0.00 | 190.99 |
| 23453 | 23453 | 0.00 | 192.84 |
| 23643 | 23643 | 0.00 | 223.85 |
| 23857 | 23857 | 0.00 | 224.11 |
| 24409 | 24409 | 0.00 | 217.23 |
| 25178 | 23857 | 29.89 | 214.30 |
| 25214 | 25214 | 0.00 | 143.24 |
| 26008 | 26008 | 0.00 | 155.63 |
| 26615 | 23643 | 25.39 | 226.00 |
| 27121 | 27121 | 0.00 | 187.66 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Salbutamol sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20476-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Salbutamol sulfate; Salbutamol sulphate; Salbutamoli sulfas

### Special notes

When selecting the *Salbutamol sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Salbutamol sulfate | 4 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Salbutamol sulfate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Salbutamol sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 80.42 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Salbutamol sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Salbutamol sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Salbutamol sulfate | 13K12-N02 | 23232 | 40 | 1801521 |
| Fagron | Salbutamol sulfate | 17I21-B02 | 23993 | 40 | 20170311 |
| Fagron | Salbutamol sulfate | 22C07-B04-222382 | 26466 | 40 | 20220613 |
| Fagron | Salbutamol sulfate | 23H24-B03-231712 | 27038 | 40 | 20231116 |
| Fagron | Salbutamol sulfate | 23H24-B03-231712 | 27038SI | 20 | 20231116 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 180 spectra of 5 reference samples from the substance/substance group *Salbutamol sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 146 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are


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listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 320 spectra of 8 reference samples from the substance/substance group *Salbutamol sulfate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Salbutamol sulfate | 18H21-B03-364945 | 26077 | 40 |
| Fagron | Salbutamol sulfate | 13K12-N02 | 21691 | 60 |
| Fagron | Salbutamol sulfate | 13K12-N02 | 23231 | 40 |
| Fagron | Salbutamol sulfate | 13K12-N02 | 23454 | 40 |
| Fagron | Salbutamol sulfate | 13K12-N02 | 23455 | 40 |
| Fagron | Salbutamol sulfate | 13K12-N02 | 23755 | 40 |
| Fagron | Salbutamol sulfate | 13K12-N02 | 23756 | 40 |
| Fagron | Salbutamol sulfate | 18H21-B03-364945 | 26077SI | 20 |

- 212 620 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Salbutamol sulfate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Salbutamol sulfate | 13K12-N02 | 1 |

- 256 885 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Salbutamol sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Salbutamol sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 320 | 0 | 212 620 |
| **Type C** | 0 | 1 | 0 | 256 885 |

The substance/substance group *Salbutamol sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.1250 %) |
| **Type C** | 100.0000 % (> 99.9038 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23232 | 23232 | 0.00 | 258.37 |
| 23993 | 23232 | 42.47 | 257.75 |
| 26466 | 23232 | 38.65 | 265.77 |
| 27038 | 23232 | 37.05 | 267.59 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Salicylic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20015-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Salicylic acid; Acidum salicylicum

### Special notes

When selecting the *Salicylic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Salicylic acid | 9 | 23 | 615 |

### Second-stage model

For differentiation of the substance/substance group *Salicylic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Salicylic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dithranol | 137.13 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Salicylic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Salicylic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Salicylic acid | 13344002 | 21436 | 60 | 20131029 |
| Caelo | Salicylic acid | 13344018 | 21760 | 60 | 20131020 |
| Caelo | Salicylic acid | 160109 | 22443 | 60 | 20160229* |
| Caelo | Salicylic acid | 22001526 | 26113 | 40 | 20220516* |
| Caelo | Salicylic acid | 22001526 | 26113SI | 20 | 20220516* |
| Euro OTC | Salicylic acid | 1110020-01 | 20696 | 40 | 20120125 |
| Euro OTC | Salicylic acid | 1509007 | 21906 | 60 | 20150929* |
| Euro OTC | Salicylic acid | 2101028 | 25543 | 40 | 20210304* |
| Fagron | Salicylic acid | 16I15-B08-333932 | 23592 | 40 | 20170210 |
| Fagron | Salicylic acid | 190263 | 24591 | 40 | 20190121 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 460 spectra of 10 reference samples from the substance/substance group *Salicylic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 866 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1120 spectra of 31 reference samples from the substance/substance group *Salicylic acid*.

- Among them are spectra of independent samples from 23 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Salicylic acid | 160500 | 22448 | 60 |
| Caelo | Salicylic acid | 171333 | 23277 | 40 |
| Caelo | Salicylic acid | 173015 | 23827 | 40 |
| Caelo | Salicylic acid | 182300 | 24236 | 40 |
| Caelo | Salicylic acid | 192209 | 24883 | 40 |
| Caelo | Salicylic acid | 21003008 | 25857 | 50 |
| Caelo | Salicylic acid | 22001524 | 26103 | 40 |
| Caelo | Salicylic acid | 22001528 | 26104 | 40 |
| Caelo | Salicylic acid | 22001529 | 26105 | 40 |
| Caelo | Salicylic acid | 22001534 | 26106 | 40 |
| Caelo | Salicylic acid | 24000004 | 27235 | 40 |
| Euro OTC | Salicylic acid | 1605023 | 22685 | 40 |
| Euro OTC | Salicylic acid | 1707009 | 23556 | 40 |
| Euro OTC | Salicylic acid | 1801042 | 23968 | 40 |
| Euro OTC | Salicylic acid | 1901015 | 24471 | 40 |
| Euro OTC | Salicylic acid | 1910018 | 24925 | 40 |
| Euro OTC | Salicylic acid | 2108024 | 25821 | 50 |
| Euro OTC | Salicylic acid | 2201044 | 25950 | 40 |
| Euro OTC | Salicylic acid | 2208003 | 26280 | 40 |
| Euro OTC | Salicylic acid | 2308012 | 26872 | 40 |
| Euro OTC | Salicylic acid | 2311012 | 27154 | 40 |
| Euro OTC | Salicylic acid | 2407001 | 27290 | 40 |
| Fagron | Salicylic acid | 22E12-B05-227887 | 26609 | 40 |
| Caelo | Salicylic acid | 21003008 | 25857SI | 10 |
| Caelo | Salicylic acid | 22001524 | 26103SI | 20 |
| Caelo | Salicylic acid | 22001528 | 26104SI | 20 |
| Caelo | Salicylic acid | 22001529 | 26105SI | 20 |
| Caelo | Salicylic acid | 22001534 | 26106SI | 20 |
| Euro OTC | Salicylic acid | 2108024 | 25821SI | 10 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Salicylic acid | 2201044 | 25950SI | 40 |
| Euro OTC | Salicylic acid | 2208003 | 26280SI | 20 |

- 211 820 spectra from a total of 4264 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4715 spectra from 1355 *Apo-Ident* customers from 636 batches from the substance/substance group *Salicylic acid*.
- Among them are spectra of independent samples from 610 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Salicylic acid | 181023/4 | 1 |
| | Salicylic acid | 20003823016 | 3 |
| | Salicylic acid | 20004424015 | 2 |
| | Salicylic acid | 20A29-B31 | 1 |
| | Salicylic acid | 21003008003 | 1 |
| | Salicylic acid | 21003008015 | 3 |
| | Salicylic acid | 21003008016 | 13 |
| | Salicylic acid | 21003008017 | 1 |
| | Salicylic acid | 2100300816 | 1 |
| | Salicylic acid | 2101028-01 | 1 |
| | Salicylic acid | 22001524003 | 1 |
| | Salicylic acid | 22001528001 | 1 |
| | Salicylic acid | 22001528002 | 8 |
| | Salicylic acid | 22001528003 | 8 |
| | Salicylic acid | 2200152802 | 1 |
| | Salicylic acid | 22001529002 | 39 |
| | Salicylic acid | 22001529003 | 6 |
| | Salicylic acid | 22001529004 | 2 |
| | Salicylic acid | 220015298002 | 1 |
| | Salicylic acid | 22001534003 | 26 |
| | Salicylic acid | 22001534004 | 4 |
| | Salicylic acid | 22001534007 | 12 |
| | Salicylic acid | 2200159002 | 1 |
| | Salicylic acid | 2201044-01 | 1 |
| | Salicylic acid | 2201044-02 | 1 |
| | Salicylic acid | 2201044-2 | 1 |
| | Salicylic acid | 2208003 | 1 |
| | Salicylic acid | 2208003-01 | 7 |
| | Salicylic acid | 2208003-02 | 17 |
| | Salicylic acid | 22D07-B03-221811 | 8 |
| | Salicylic acid | 22D0-B03-221811 | 1 |
| | Salicylic acid | 22DS07-B03-221811 | 1 |
| | Salicylic acid | 22j26-b06-227888 | 1 |
| | Salicylic acid | 22J26-B06-227888 | 3 |
| | Salicylic acid | 22J26-B06-2278888 | 1 |
| | Salicylic acid | 22J26-B06-228342 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Salicylic acid | 22J26-B06-228343 | 1 |
| | Salicylic acid | 230002014003 | 1 |
| | Salicylic acid | 23002014002 | 5 |
| | Salicylic acid | 23002014003 | 25 |
| | Salicylic acid | 23003599001 | 3 |
| | Salicylic acid | 23003599002 | 7 |
| | Salicylic acid | 23003599005 | 1 |
| | Salicylic acid | 2308012 | 1 |
| | Salicylic acid | 2308012-01 | 19 |
| | Salicylic acid | 2311012-01 | 5 |
| | Salicylic acid | 2388012-01 | 1 |
| | Salicylic acid | 23B01-237155 | 1 |
| | Salicylic acid | 23B01-B01-232363 | 2 |
| | Salicylic acid | 23B01-B01-237155 | 2 |
| | Salicylic acid | 23J20-B03-236811 | 1 |
| | Salicylic acid | 24000004002 | 2 |
| | Salicylic acid | 24000004004 | 2 |
| | Salicylic acid | 2400003001 | 1 |
| | Salicylic acid | 2400004004 | 1 |
| | Salicylic acid | 24000043001 | 29 |
| | Salicylic acid | 2400043001 | 1 |
| | Salicylic acid | 24001959003 | 1 |
| | Salicylic acid | 2407001-01 | 1 |
| | Salicylic acid | B06-2278808 | 2 |
| | Salicylic acid | B06-2283403 | 1 |
| | Salicylic acid | B03-2218101 | 1 |
| | Salicylic acid | RAS2117000 | 1 |
| | Salicylic acid | RAS2218900 | 1 |
| | Salicylic acid | RAS2300100 | 1 |
| 12.2016 | Salicylic acid | 12134709 | 2 |
| 14076202 | Salicylic acid | | 1 |
| ACM | Salicylic acid | KNC0461J15 | 1 |
| AHC | Salicylic acid | 20004424011 | 1 |
| AHC | Salicylic acid | 22001529002 | 1 |
| AHD 22.07.14 | Salicylic acid | 134002 | 1 |
| AHD | Salicylic acid | 13344002 | 1 |
| AHD | Salicylic acid | 1509007-01 | 1 |
| AHD | Salicylic acid | 192209003 | 1 |
| AHD | Salicylic acid | 22001524003 | 1 |
| AHD | Salicylic acid | 22001528002 | 2 |
| AHD | Salicylic acid | 22001529003 | 1 |
| AHD | Salicylic acid | 22001534007 | 1 |
| AHD | Salicylic acid | 2311012-01 | 1 |
| AHD | Salicylic acid | 24000043001 | 1 |
| Alli | Salicylic acid | 22001524003 | 1 |
| Alliance 19.12.12 | Salicylic acid | 11311906 | 1 |
| Alliance Healthcare | Salicylic acid | 12036215 | 2 |
| Alliance Healthcare | Salicylic acid | 12036216 | 1 |
| Alliance Healthcare | Salicylic acid | 15211808 | 1 |
| Alliance Healthcare | Salicylic acid | 20004424012 | 1 |
| Alliance Healthcare | Salicylic acid | 22001528003 | 2 |
| Alliance Healthcare | Salicylic acid | 2311012-01 | 2 |
| Alliance Healthcare | Salicylic acid | 24000043001 | 1 |
| Alliance | Salicylic acid | 21003008016 | 1 |
| Alliance | Salicylic acid | 2201044-02 | 1 |
| Anzag/Anzag 11.09.18 | Salicylic acid | 18F05-B02-350586 | 1 |
| Anzag/Henry Lamotte | Salicylic acid | 1334018 | 1 |
| Anzag | Salicylic acid | 16050013 | 2 |
| Anzag | Salicylic acid | 16050014 | 1 |
| Anzag | Salicylic acid | 21003008016 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag | Salicylic acid | 22001529002 | 2 |
| Anzag | Salicylic acid | 2400004301 | 1 |
| Anzag | Salicylic acid | 240408(22001529002) | 1 |
| apo ident | Salicylic acid | 1605023-01 | 1 |
| apomix | Salicylic acid | 1303020-01 | 1 |
| apomix | Salicylic acid | 2108024-01 | 1 |
| Bombastus | Salicylic acid | 12036223 | 1 |
| Bombastus | Salicylic acid | 12323403 | 1 |
| Bombastus | Salicylic acid | 14L02-B02-303557 | 1 |
| Bombastus | Salicylic acid | 16050017 | 1 |
| Bombastus | Salicylic acid | 1605023-01 | 1 |
| Bombastus | Salicylic acid | 17301505 | 1 |
| Caaelo | Salicylic acid | 14336911 | 1 |
| Caela | Salicylic acid | 16312001 | 1 |
| Caelo | Salicylic acid | | 8 |
| Caelo | Salicylic acid | 10001612 | 1 |
| Caelo | Salicylic acid | 10112014B | 1 |
| Caelo | Salicylic acid | 102455-0001 | 1 |
| Caelo | Salicylic acid | 10291803 | 1 |
| Caelo | Salicylic acid | 10291817 | 1 |
| Caelo | Salicylic acid | 10355907 | 1 |
| Caelo | Salicylic acid | 10355911 | 2 |
| Caelo | Salicylic acid | 10355912 | 1 |
| Caelo | Salicylic acid | 10355916 | 1 |
| Caelo | Salicylic acid | 1045 | 1 |
| Caelo | Salicylic acid | 11197103 | 1 |
| Caelo | Salicylic acid | 11197106 | 1 |
| Caelo | Salicylic acid | 11197117 | 1 |
| Caelo | Salicylic acid | 11197118 | 1 |
| Caelo | Salicylic acid | 11197123 | 4 |
| Caelo | Salicylic acid | 11311902 | 2 |
| Caelo | Salicylic acid | 11311903 | 1 |
| Caelo | Salicylic acid | 11311905 | 1 |
| Caelo | Salicylic acid | 11311906 | 2 |
| Caelo | Salicylic acid | 11311910 | 2 |
| Caelo | Salicylic acid | 11311917 | 4 |
| Caelo | Salicylic acid | 11311922 | 9 |
| Caelo | Salicylic acid | 11311923 | 2 |
| Caelo | Salicylic acid | 117027-2 | 1 |
| Caelo | Salicylic acid | 1197106 | 1 |
| Caelo | Salicylic acid | 12036202 | 3 |
| Caelo | Salicylic acid | 12036208 | 1 |
| Caelo | Salicylic acid | 12036209 | 4 |
| Caelo | Salicylic acid | 12036210 | 3 |
| Caelo | Salicylic acid | 12036211 | 3 |
| Caelo | Salicylic acid | 12036215 | 2 |
| Caelo | Salicylic acid | 12036216 | 5 |
| Caelo | Salicylic acid | 12036217 | 2 |
| Caelo | Salicylic acid | 12036223 | 8 |
| Caelo | Salicylic acid | 12036225 | 4 |
| Caelo | Salicylic acid | 12036226 | 7 |
| Caelo | Salicylic acid | 12036315 | 1 |
| Caelo | Salicylic acid | 12134702 | 12 |
| Caelo | Salicylic acid | 12134707 | 6 |
| Caelo | Salicylic acid | 12134709 | 21 |
| Caelo | Salicylic acid | 12134710 | 1 |
| Caelo | Salicylic acid | 12134711 | 10 |
| Caelo | Salicylic acid | 12134712 | 4 |
| Caelo | Salicylic acid | 12134713 | 1 |
| Caelo | Salicylic acid | 12134714 | 18 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Salicylic acid | 12134715 | 7 |
| Caelo | Salicylic acid | 12134717 | 9 |
| Caelo | Salicylic acid | 12134719 | 4 |
| Caelo | Salicylic acid | 12134720 | 8 |
| Caelo | Salicylic acid | 12134721 | 3 |
| Caelo | Salicylic acid | 12134722 | 4 |
| Caelo | Salicylic acid | 123134712 | 1 |
| Caelo | Salicylic acid | 12323401 | 1 |
| Caelo | Salicylic acid | 12323402 | 2 |
| Caelo | Salicylic acid | 12323403 | 3 |
| Caelo | Salicylic acid | 1234 | 1 |
| Caelo | Salicylic acid | 1234709 | 1 |
| Caelo | Salicylic acid | 12374204 | 1 |
| Caelo | Salicylic acid | 12374205 | 8 |
| Caelo | Salicylic acid | 12374207 | 6 |
| Caelo | Salicylic acid | 12374207-3454311172 | 1 |
| Caelo | Salicylic acid | 12374208 | 2 |
| Caelo | Salicylic acid | 12374210 | 3 |
| Caelo | Salicylic acid | 12374211 | 18 |
| Caelo | Salicylic acid | 12374212 | 2 |
| Caelo | Salicylic acid | 12374213 | 11 |
| Caelo | Salicylic acid | 1274210 | 1 |
| Caelo | Salicylic acid | 12H10-N08 | 3 |
| Caelo | Salicylic acid | 1303020-01 | 2 |
| Caelo | Salicylic acid | 13032014A | 1 |
| Caelo | Salicylic acid | 13101707 | 1 |
| Caelo | Salicylic acid | 1310516 | 1 |
| Caelo | Salicylic acid | 13344002 | 20 |
| Caelo | Salicylic acid | 13344003 | 10 |
| Caelo | Salicylic acid | 13344013 | 11 |
| Caelo | Salicylic acid | 13344014 | 6 |
| Caelo | Salicylic acid | 13344018 | 20 |
| Caelo | Salicylic acid | 13344020 | 17 |
| Caelo | Salicylic acid | 1334403 | 1 |
| Caelo | Salicylic acid | 133454002 | 1 |
| Caelo | Salicylic acid | 13B14-No1 | 1 |
| Caelo | Salicylic acid | 13H01-N01 | 1 |
| Caelo | Salicylic acid | 13H01-N04 | 2 |
| Caelo | Salicylic acid | 1406027 | 1 |
| Caelo | Salicylic acid | 140602701 | 1 |
| Caelo | Salicylic acid | 1406027-02 | 3 |
| Caelo | Salicylic acid | 14076201 | 1 |
| Caelo | Salicylic acid | 14076202 | 6 |
| Caelo | Salicylic acid | 14076203 | 9 |
| Caelo | Salicylic acid | 14076204 | 11 |
| Caelo | Salicylic acid | 14076206 | 7 |
| Caelo | Salicylic acid | 14076207 | 10 |
| Caelo | Salicylic acid | 14076211 | 1 |
| Caelo | Salicylic acid | 14076212 | 1 |
| Caelo | Salicylic acid | 14300801 | 8 |
| Caelo | Salicylic acid | 14300802 | 6 |
| Caelo | Salicylic acid | 14300804 | 9 |
| Caelo | Salicylic acid | 14300805 | 11 |
| Caelo | Salicylic acid | 14300806 | 1 |
| Caelo | Salicylic acid | 14300808 | 1 |
| Caelo | Salicylic acid | 14300809 | 14 |
| Caelo | Salicylic acid | 1430802 | 1 |
| Caelo | Salicylic acid | 1433620 | 1 |
| Caelo | Salicylic acid | 14336904 | 2 |
| Caelo | Salicylic acid | 14336905 | 15 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Salicylic acid | 14336906 | 4 |
| Caelo | Salicylic acid | 14336907 | 26 |
| Caelo | Salicylic acid | 14336908 | 3 |
| Caelo | Salicylic acid | 14336911 | 25 |
| Caelo | Salicylic acid | 14336912 | 9 |
| Caelo | Salicylic acid | 14336919 | 24 |
| Caelo | Salicylic acid | 14336920 | 25 |
| Caelo | Salicylic acid | 14336921 | 1 |
| Caelo | Salicylic acid | 14E26-B04-294622 | 1 |
| Caelo | Salicylic acid | 14L02-B02-303558 | 1 |
| Caelo | Salicylic acid | 15081601 | 1 |
| Caelo | Salicylic acid | 15084401 | 4 |
| Caelo | Salicylic acid | 15084403 | 9 |
| Caelo | Salicylic acid | 15084404 | 3 |
| Caelo | Salicylic acid | 1509007-01 | 1 |
| Caelo | Salicylic acid | 1509007-02 | 2 |
| Caelo | Salicylic acid | 151224/1 | 1 |
| Caelo | Salicylic acid | 152117304 | 1 |
| Caelo | Salicylic acid | 15211803 | 1 |
| Caelo | Salicylic acid | 15211806 | 4 |
| Caelo | Salicylic acid | 15211807 | 2 |
| Caelo | Salicylic acid | 15211808 | 10 |
| Caelo | Salicylic acid | 15211809 | 14 |
| Caelo | Salicylic acid | 15211810 | 10 |
| Caelo | Salicylic acid | 15217301 | 6 |
| Caelo | Salicylic acid | 15217302 | 14 |
| Caelo | Salicylic acid | 15217303 | 9 |
| Caelo | Salicylic acid | 15217304 | 7 |
| Caelo | Salicylic acid | 15217305 | 6 |
| Caelo | Salicylic acid | 15217308 | 8 |
| Caelo | Salicylic acid | 15217309 | 1 |
| Caelo | Salicylic acid | 16/15-B08-332098 | 1 |
| Caelo | Salicylic acid | 1600917 | 1 |
| Caelo | Salicylic acid | 16010901 | 5 |
| Caelo | Salicylic acid | 16010901s | 1 |
| Caelo | Salicylic acid | 16010903 | 17 |
| Caelo | Salicylic acid | 16010904 | 12 |
| Caelo | Salicylic acid | 16010905 | 11 |
| Caelo | Salicylic acid | 16010906 | 17 |
| Caelo | Salicylic acid | 16010907 | 6 |
| Caelo | Salicylic acid | 16010908 | 3 |
| Caelo | Salicylic acid | 16010910 | 17 |
| Caelo | Salicylic acid | 16010911 | 4 |
| Caelo | Salicylic acid | 16010912 | 4 |
| Caelo | Salicylic acid | 160109123 | 1 |
| Caelo | Salicylic acid | 16010913 | 18 |
| Caelo | Salicylic acid | 16010916 | 5 |
| Caelo | Salicylic acid | 16010917 | 16 |
| Caelo | Salicylic acid | 16010918 | 11 |
| Caelo | Salicylic acid | 16010921 | 3 |
| Caelo | Salicylic acid | 16010922 | 16 |
| Caelo | Salicylic acid | 16010923 | 7 |
| Caelo | Salicylic acid | 16010972 | 1 |
| Caelo | Salicylic acid | 1601916 | 1 |
| Caelo | Salicylic acid | 160405AS | 1 |
| Caelo | Salicylic acid | 160500004 | 3 |
| Caelo | Salicylic acid | 16050003 | 2 |
| Caelo | Salicylic acid | 16050004 | 20 |
| Caelo | Salicylic acid | 16050005 | 11 |
| Caelo | Salicylic acid | 16050006 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Salicylic acid | 16050011 | 15 |
| Caelo | Salicylic acid | 16050012 | 16 |
| Caelo | Salicylic acid | 16050013 | 26 |
| Caelo | Salicylic acid | 16050014 | 30 |
| Caelo | Salicylic acid | 16050016 | 1 |
| Caelo | Salicylic acid | 16050017 | 20 |
| Caelo | Salicylic acid | 1605023-01 | 1 |
| Caelo | Salicylic acid | 1605023-02 | 2 |
| Caelo | Salicylic acid | 16072014A | 1 |
| Caelo | Salicylic acid | 163120 | 1 |
| Caelo | Salicylic acid | 16312001 | 24 |
| Caelo | Salicylic acid | 16312003 | 12 |
| Caelo | Salicylic acid | 16312004 | 2 |
| Caelo | Salicylic acid | 16312005 | 30 |
| Caelo | Salicylic acid | 16312008 | 1 |
| Caelo | Salicylic acid | 16312009 | 13 |
| Caelo | Salicylic acid | 16312010 | 25 |
| Caelo | Salicylic acid | 16312012 | 4 |
| Caelo | Salicylic acid | 16E02-B09-325355 | 1 |
| Caelo | Salicylic acid | 16I15-B08 | 1 |
| Caelo | Salicylic acid | 16i15-B08-0001 | 1 |
| Caelo | Salicylic acid | 170301506 | 1 |
| Caelo | Salicylic acid | 170509AS/16050012 | 1 |
| Caelo | Salicylic acid | 17051803 | 1 |
| Caelo | Salicylic acid | 1707009-01 | 4 |
| Caelo | Salicylic acid | 170700902 | 1 |
| Caelo | Salicylic acid | 17123301 | 1 |
| Caelo | Salicylic acid | 1713301 | 1 |
| Caelo | Salicylic acid | 1713307 | 1 |
| Caelo | Salicylic acid | 17133301 | 27 |
| Caelo | Salicylic acid | 17133303 | 23 |
| Caelo | Salicylic acid | 17133304 | 4 |
| Caelo | Salicylic acid | 17133307 | 60 |
| Caelo | Salicylic acid | 171333207 | 1 |
| Caelo | Salicylic acid | 1714Q1045 | 1 |
| Caelo | Salicylic acid | 17301502 | 25 |
| Caelo | Salicylic acid | 17301503 | 28 |
| Caelo | Salicylic acid | 17301504 | 5 |
| Caelo | Salicylic acid | 17301505 | 27 |
| Caelo | Salicylic acid | 17301506 | 57 |
| Caelo | Salicylic acid | 17301507 | 21 |
| Caelo | Salicylic acid | 17301509 | 36 |
| Caelo | Salicylic acid | 17301511 | 9 |
| Caelo | Salicylic acid | 17301512 | 31 |
| Caelo | Salicylic acid | 17301512/P-04041921 | 1 |
| Caelo | Salicylic acid | 17301612 | 1 |
| Caelo | Salicylic acid | 1738980 | 1 |
| Caelo | Salicylic acid | 17901506 | 1 |
| Caelo | Salicylic acid | 17C21-B09-337172 | 2 |
| Caelo | Salicylic acid | 17C21-B09-337173 | 1 |
| Caelo | Salicylic acid | 180050009 | 1 |
| Caelo | Salicylic acid | 180104201 | 1 |
| Caelo | Salicylic acid | 1801042-01 | 3 |
| Caelo | Salicylic acid | 18050002 | 12 |
| Caelo | Salicylic acid | 18050005 | 1 |
| Caelo | Salicylic acid | 18050006 | 40 |
| Caelo | Salicylic acid | 18050007 | 21 |
| Caelo | Salicylic acid | 18050009 | 28 |
| Caelo | Salicylic acid | 1805009 | 1 |
| Caelo | Salicylic acid | 18121412 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Salicylic acid | 181473001 | 9 |
| Caelo | Salicylic acid | 18147302 | 31 |
| Caelo | Salicylic acid | 18147303 | 13 |
| Caelo | Salicylic acid | 18147305 | 1 |
| Caelo | Salicylic acid | 18147307 | 1 |
| Caelo | Salicylic acid | 18147308 | 19 |
| Caelo | Salicylic acid | 18147310 | 28 |
| Caelo | Salicylic acid | 18147314 | 43 |
| Caelo | Salicylic acid | 18147315 | 5 |
| Caelo | Salicylic acid | 18147317 | 18 |
| Caelo | Salicylic acid | 18147321 | 47 |
| Caelo | Salicylic acid | 182300002P-200609-3 | 1 |
| Caelo | Salicylic acid | 18230002 | 3 |
| Caelo | Salicylic acid | 18230002P-200806-1 | 1 |
| Caelo | Salicylic acid | 18230004 | 18 |
| Caelo | Salicylic acid | 18230004/P-26041921 | 1 |
| Caelo | Salicylic acid | 18230007 | 46 |
| Caelo | Salicylic acid | 18230009 | 15 |
| Caelo | Salicylic acid | 18230010 | 1 |
| Caelo | Salicylic acid | 18230013 | 4 |
| Caelo | Salicylic acid | 18306909 | 1 |
| Caelo | Salicylic acid | 18E24-B03-354310 | 1 |
| Caelo | Salicylic acid | 18E24-B03-354311 | 1 |
| Caelo | Salicylic acid | 190263 | 6 |
| Caelo | Salicylic acid | 190312004 | 1 |
| Caelo | Salicylic acid | 1906105 | 1 |
| Caelo | Salicylic acid | 190612001 | 24 |
| Caelo | Salicylic acid | 190612003 | 1 |
| Caelo | Salicylic acid | 190612004 | 37 |
| Caelo | Salicylic acid | 19061201 | 3 |
| Caelo | Salicylic acid | 19061202 | 13 |
| Caelo | Salicylic acid | 19061205 | 38 |
| Caelo | Salicylic acid | 19061206 | 33 |
| Caelo | Salicylic acid | 19062001 | 1 |
| Caelo | Salicylic acid | 1906612001 | 1 |
| Caelo | Salicylic acid | 1910018-01 | 1 |
| Caelo | Salicylic acid | 1910018-03 | 1 |
| Caelo | Salicylic acid | 1913Q-01045 | 1 |
| Caelo | Salicylic acid | 1922090003 | 1 |
| Caelo | Salicylic acid | 192209001 | 32 |
| Caelo | Salicylic acid | 192209003 | 31 |
| Caelo | Salicylic acid | 192209006 | 9 |
| Caelo | Salicylic acid | 1961206 | 1 |
| Caelo | Salicylic acid | 200000147004 | 1 |
| Caelo | Salicylic acid | 20000146005 | 13 |
| Caelo | Salicylic acid | 20000147002 | 26 |
| Caelo | Salicylic acid | 20000147002/4720 | 1 |
| Caelo | Salicylic acid | 20000147004 | 29 |
| Caelo | Salicylic acid | 20000147006 | 18 |
| Caelo | Salicylic acid | 200004424004 | 1 |
| Caelo | Salicylic acid | 200004424012 | 1 |
| Caelo | Salicylic acid | 20003823008 | 33 |
| Caelo | Salicylic acid | 20003823010 | 7 |
| Caelo | Salicylic acid | 20003823011 | 2 |
| Caelo | Salicylic acid | 20003823014 | 5 |
| Caelo | Salicylic acid | 20003823015 | 2 |
| Caelo | Salicylic acid | 20003823016 | 12 |
| Caelo | Salicylic acid | 2000442004 | 1 |
| Caelo | Salicylic acid | 20004421006 | 1 |
| Caelo | Salicylic acid | 20004424001 | 19 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Salicylic acid | 20004424004 | 31 |
| Caelo | Salicylic acid | 20004424006 | 30 |
| Caelo | Salicylic acid | 20004424007 | 3 |
| Caelo | Salicylic acid | 20004424009 | 1 |
| Caelo | Salicylic acid | 20004424010 | 28 |
| Caelo | Salicylic acid | 20004424011 | 9 |
| Caelo | Salicylic acid | 20004424012 | 24 |
| Caelo | Salicylic acid | 20004424015 | 7 |
| Caelo | Salicylic acid | 2004424001 | 1 |
| Caelo | Salicylic acid | 20111306 | 1 |
| Caelo | Salicylic acid | 20151112-4 | 1 |
| Caelo | Salicylic acid | 2017-11-23-AXILU | 1 |
| Caelo | Salicylic acid | 20270312-2 | 1 |
| Caelo | Salicylic acid | 207102017/16050017 | 1 |
| Caelo | Salicylic acid | 210000488001 | 1 |
| Caelo | Salicylic acid | 21000488001 | 15 |
| Caelo | Salicylic acid | 21003008001 | 9 |
| Caelo | Salicylic acid | 21003008003 | 7 |
| Caelo | Salicylic acid | 21003008004 | 20 |
| Caelo | Salicylic acid | 21003008009 | 12 |
| Caelo | Salicylic acid | 21003008010 | 14 |
| Caelo | Salicylic acid | 21003008015 | 2 |
| Caelo | Salicylic acid | 21003008016 | 2 |
| Caelo | Salicylic acid | 21003008017 | 1 |
| Caelo | Salicylic acid | 2100488001 | 1 |
| Caelo | Salicylic acid | 2101028-01 | 1 |
| Caelo | Salicylic acid | 2103008004 | 1 |
| Caelo | Salicylic acid | 216E-03750 | 1 |
| Caelo | Salicylic acid | 220001524003 | 1 |
| Caelo | Salicylic acid | 22001158002 | 1 |
| Caelo | Salicylic acid | 22001524003 | 31 |
| Caelo | Salicylic acid | 22001528001 | 10 |
| Caelo | Salicylic acid | 22001528002 | 10 |
| Caelo | Salicylic acid | 22001528003 | 2 |
| Caelo | Salicylic acid | 22001534003 | 2 |
| Caelo | Salicylic acid | 23002014002 | 1 |
| Caelo | Salicylic acid | 23002014003 | 1 |
| Caelo | Salicylic acid | 23071510 | 1 |
| Caelo | Salicylic acid | 25041304 | 1 |
| Caelo | Salicylic acid | 2882 | 1 |
| Caelo | Salicylic acid | 31012023-01 | 1 |
| Caelo | Salicylic acid | 3111J01045 | 1 |
| Caelo | Salicylic acid | 3344003 | 1 |
| Caelo | Salicylic acid | 3601413011-12374211 | 1 |
| Caelo | Salicylic acid | 3816Q-01045 | 1 |
| Caelo | Salicylic acid | 3944581 | 1 |
| Caelo | Salicylic acid | 3948107 | 1 |
| Caelo | Salicylic acid | 4010Q-01045 | 1 |
| Caelo | Salicylic acid | 415593 | 1 |
| Caelo | Salicylic acid | 4515E-01045 | 1 |
| Caelo | Salicylic acid | 501171101 | 1 |
| Caelo | Salicylic acid | 5112V01405 | 1 |
| Caelo | Salicylic acid | 54168742 | 1 |
| Caelo | Salicylic acid | 6/20151706 | 1 |
| Caelo | Salicylic acid | 7071403 | 1 |
| Caelo | Salicylic acid | 72(18230009) | 1 |
| Caelo | Salicylic acid | 73(20004424001) | 1 |
| Caelo | Salicylic acid | 7466 | 1 |
| Caelo | Salicylic acid | 8170717 | 1 |
| Caelo | Salicylic acid | 8715 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Salicylic acid | 9091301 | 1 |
| Caelo | Salicylic acid | 9112013A | 1 |
| Caelo | Salicylic acid | 9220715 | 1 |
| Caelo | Salicylic acid | 922090031 | 1 |
| Caelo | Salicylic acid | 922090061 | 1 |
| Caelo | Salicylic acid | A-100513-1 | 1 |
| Caelo | Salicylic acid | A320004424007 | 1 |
| Caelo | Salicylic acid | RAS1135100 | 1 |
| Caelo | Salicylic acid | RAS1703500 | 1 |
| Caelo | Salicylic acid | test | 1 |
| Caelo | Salicylic acid | Validierungsmessung | 1 |
| Caeo | Salicylic acid | 1010905 | 1 |
| Caeolo/Alliance | Salicylic acid | 21003008010 | 1 |
| Caesaer/Jenne | Salicylic acid | 18050006 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 22001524003 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147308 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147310 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 22001528001 | 3 |
| Caesar & Loretz GmbH... | Salicylic acid | 17301512 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18050006 | 2 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000147004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20003823016 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147321 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147314 | 3 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147321 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000147002 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000147004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20003823008 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 21003008004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 21003008010 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 190612004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 19061206 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 11311904 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 12134714 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424001 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 11311917 | 1 |
| Caesar & Loretz GmbH/ AHD | Salicylic acid | 18230004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 21003008017 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 192209001 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 190612004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147314 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000147006 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424011 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424007 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147314 | 1 |
| Caesar & Loretz GmbH/AEP | Salicylic acid | 18230009 | 1 |
| Caesar & Loretz GmbH/AHD | Salicylic acid | 18147321 | 1 |
| Caesar & Loretz GmbH/AHD | Salicylic acid | 20004424004 | 1 |
| Caesar & Loretz GmbH/AHD | Salicylic acid | 20004424006 | 2 |
| Caesar & Loretz GmbH/AHD | Salicylic acid | 21003008004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18050006 | 1 |
| Caesar & Loretz GmbH/G | Salicylic acid | 20004424004 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 18147308 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 192209001 | 1 |
| Caesar & Loretz GmbH/GEHE | Salicylic acid | 192209006 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 20000146 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 20003823008 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 20003823014 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 20004424006 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 20004424011 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 21000488001 | 2 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 21003008001 | 1 |
| Caesar & Loretz GmbH/Gehe | Salicylic acid | 22001528001 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424010 | 2 |
| Caesar & Loretz GmbH... | Salicylic acid | 22001528002 | 2 |
| Caesar & Loretz GmbH/Gö | Salicylic acid | 18147321 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147314 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20003823008 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147308 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424011 | 1 |
| Caesar & Loretz GmbH/Kehr | Salicylic acid | 19061205 | 1 |
| Caesar & Loretz GmbH/Kehr | Salicylic acid | 192209006 | 1 |
| Caesar & Loretz GmbH/Kehr | Salicylic acid | 2100308015 | 1 |
| Caesar & Loretz GmbH/Now. | Salicylic acid | 18147321 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 190612004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 19061206 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 192209003 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424015 | 1 |
| Caesar & Loretz GmbH/Otto | Salicylic acid | 19061202 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424011 | 2 |
| Caesar & Loretz GmbH... | Salicylic acid | 22001524003 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 22001528002 | 2 |
| Caesar & Loretz GmbH... | Salicylic acid | 18147321 | 2 |
| Caesar & Loretz GmbH... | Salicylic acid | 18230007 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 19061205 | 3 |
| Caesar & Loretz GmbH... | Salicylic acid | 19061206 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20004424001 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 22001528001 | 2 |
| Caesar & Loretz GmbH... | Salicylic acid | 17301512 | 3 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000146005 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000147002 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000147004 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 20000147006 | 1 |
| Caesar & Loretz GmbH... | Salicylic acid | 18230009 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 11311922 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 13344003 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 14300809 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 16312001 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 16312005 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 16312012 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 17133301 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 17301509 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 17301511 | 2 |
| Caesar & Loretz GmbH | Salicylic acid | 17301512 | 6 |
| Caesar & Loretz GmbH | Salicylic acid | 18050002 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 18050006 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 18050009 | 4 |
| Caesar & Loretz GmbH | Salicylic acid | 18147302 | 9 |
| Caesar & Loretz GmbH | Salicylic acid | 18147303 | 6 |
| Caesar & Loretz GmbH | Salicylic acid | 18147308 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 18147310 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 18147313 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 18147314 | 6 |
| Caesar & Loretz GmbH | Salicylic acid | 18147315 | 2 |
| Caesar & Loretz GmbH | Salicylic acid | 18147317 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 18147321 | 17 |
| Caesar & Loretz GmbH | Salicylic acid | 18147322 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 18230004 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 18230007 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Salicylic acid | 18230009 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 18230013 | 2 |
| Caesar & Loretz GmbH | Salicylic acid | 1847302 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 190612001 | 11 |
| Caesar & Loretz GmbH | Salicylic acid | 190612003 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 190612004 | 6 |
| Caesar & Loretz GmbH | Salicylic acid | 19061201 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 19061202 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 19061205 | 9 |
| Caesar & Loretz GmbH | Salicylic acid | 19061206 | 9 |
| Caesar & Loretz GmbH | Salicylic acid | 192209001 | 8 |
| Caesar & Loretz GmbH | Salicylic acid | 192209003 | 9 |
| Caesar & Loretz GmbH | Salicylic acid | 192209004 | 2 |
| Caesar & Loretz GmbH | Salicylic acid | 192209006 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 20000146004 | 4 |
| Caesar & Loretz GmbH | Salicylic acid | 20000146005 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 20000147002 | 15 |
| Caesar & Loretz GmbH | Salicylic acid | 20000147004 | 14 |
| Caesar & Loretz GmbH | Salicylic acid | 20000147006 | 13 |
| Caesar & Loretz GmbH | Salicylic acid | 200004424011 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 2000147002 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 20003823008 | 11 |
| Caesar & Loretz GmbH | Salicylic acid | 20003823010 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 20003823011 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 20003823014 | 4 |
| Caesar & Loretz GmbH | Salicylic acid | 20003823015 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 20003823016 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424001 | 8 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424002 | 2 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424004 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424006 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424007 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424009 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424010 | 5 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424011 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424012 | 8 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424013 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 20004424015 | 4 |
| Caesar & Loretz GmbH | Salicylic acid | 21003008001 | 4 |
| Caesar & Loretz GmbH | Salicylic acid | 21003008003 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 21003008004 | 15 |
| Caesar & Loretz GmbH | Salicylic acid | 21003008009 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 21003008010 | 7 |
| Caesar & Loretz GmbH | Salicylic acid | 21003008015 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 21003008016 | 3 |
| Caesar & Loretz GmbH | Salicylic acid | 22001088004 | 1 |
| Caesar & Loretz GmbH | Salicylic acid | 22001524003 | 2 |
| Caesar & Loretz GmbH | Salicylic acid | 22001528001 | 8 |
| Caesar & Loretz GmbH | Salicylic acid | 22001528002 | 5 |
| Caesar & Loretz Hild... | Salicylic acid | 192209001 | 1 |
| Caesar & Loretz Hilden | Salicylic acid | 17301512 | 1 |
| Caesar & Loretz Hilden | Salicylic acid | 18230007 | 1 |
| Caesar & Loretz Hilden | Salicylic acid | 19061205 | 1 |
| Caesar & Loretz Hilden | Salicylic acid | 192209003 | 1 |
| Caesar & Loretz/Gehe | Salicylic acid | 20000147004 | 1 |
| Caesar & Loretz/Geil... | Salicylic acid | 17301509 | 1 |
| Caesar & Loretz/Sanacorp | Salicylic acid | 15217302 | 3 |
| Caesar & Loretz/Sanacorp | Salicylic acid | 17301503 | 1 |
| Caesar & Loretz | Salicylic acid | 17301502 | 1 |
| Caesar & Loretz | Salicylic acid | 21003008001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz | Salicylic acid | 21003008009 | 1 |
| Caesar / Ebert & Jacobi | Salicylic acid | 16312010 | 2 |
| Caesar Loretz | Salicylic acid | 192209001 | 1 |
| Caesar u. Loretz GmbH | Salicylic acid | 190612004 | 1 |
| Caesar u. Loretz GmbH | Salicylic acid | 192209006 | 1 |
| Caesar und Loretz GmbH | Salicylic acid | 16312003 | 1 |
| Caesar&Lorenz / Gehe | Salicylic acid | 18230004 | 1 |
| Caesar&Lorenz | Salicylic acid | 20004424006 | 1 |
| Caesar&Loretz GmbH,1... | Salicylic acid | 16312001 | 1 |
| Caesar&Loretz GmbH/Anzag | Salicylic acid | 12374204 | 1 |
| Caesar&Loretz GmbH/S... | Salicylic acid | 15217301 | 1 |
| Caesar&Loretz GmbH/S... | Salicylic acid | 18230009 | 1 |
| Caesar&loretz,Anzag | Salicylic acid | 12036211 | 1 |
| Caesar&loretz,Phoenix | Salicylic acid | 11197104 | 1 |
| Caesar&loretz,Phoenix | Salicylic acid | 14076212 | 1 |
| Caesar&loretz,Phoenix | Salicylic acid | 9220710 | 1 |
| Caesar&Loretz/AHD | Salicylic acid | 15211808 | 1 |
| Caesar&Loretz | Salicylic acid | 18230007 | 1 |
| Caesar&Loretz | Salicylic acid | 20004424011 | 1 |
| caesar | Salicylic acid | 15217301 | 1 |
| Caleo/n | Salicylic acid | 17301502 | 1 |
| Caleo/Phoenix | Salicylic acid | 21003008003 | 1 |
| Cealo/Gehe | Salicylic acid | 20000147004 | 1 |
| Cealo/Noweda | Salicylic acid | 17301509 | 1 |
| Cealo/Sanacorp | Salicylic acid | 17133307 | 1 |
| Cealo/Sanacorp | Salicylic acid | 20000147006 | 1 |
| Cealo | Salicylic acid | 15211806 | 1 |
| cealo | Salicylic acid | 18050007 | 1 |
| Cealo | Salicylic acid | 192209006 | 1 |
| Celo/ Sanacorp | Salicylic acid | 16010908 | 1 |
| Delta | Salicylic acid | 17133303 | 1 |
| E Plus | Salicylic acid | 16I15-B08-333932 | 1 |
| Ebert 24.08.16 | Salicylic acid | 16010903 | 1 |
| Ebert & Jacobi | Salicylic acid | 16010923 | 1 |
| EuRho 001 | Salicylic acid | 1509007-02 | 1 |
| Eurho/ Noweda | Salicylic acid | 1901015-01 | 1 |
| Eurho/ Noweda | Salicylic acid | 1901015-03 | 1 |
| EuRho/ Phönix | Salicylic acid | RAS1730100 | 1 |
| EuRho/Gehe | Salicylic acid | 1910018-01 | 1 |
| EuRho/Noweda | Salicylic acid | 1910018-02 | 1 |
| Eurho/Phoenix | Salicylic acid | 13B14-N01 | 2 |
| EuRho/VDL | Salicylic acid | 1801042-01 | 1 |
| EuRho | Salicylic acid | | 1 |
| EuRho | Salicylic acid | 1206007-01 | 2 |
| EuRho | Salicylic acid | 1303020-01 | 1 |
| EuRho | Salicylic acid | 1406027-01 | 2 |
| EuRho | Salicylic acid | 1406027-02 | 1 |
| EuRho | Salicylic acid | 1605023-02 | 1 |
| EuRho | Salicylic acid | 1707009-01 | 2 |
| EuRho | Salicylic acid | 1801042-01 | 2 |
| EuRho | Salicylic acid | 1901015-01 | 1 |
| EuRho | Salicylic acid | 1910018-01 | 1 |
| EuRho | Salicylic acid | 1910018-03 | 1 |
| EuRho | Salicylic acid | 2101028-01 | 1 |
| euro AHD | Salicylic acid | 1707009-025709 | 1 |
| Euro OTC | Salicylic acid | | 1 |
| Euro OTC | Salicylic acid | 102455 | 1 |
| Euro OTC | Salicylic acid | 1110020 | 1 |
| Euro OTC | Salicylic acid | 1110020-01 | 5 |
| Euro OTC | Salicylic acid | 115465478596 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Salicylic acid | 1206007-01 | 8 |
| Euro OTC | Salicylic acid | 130302001 | 1 |
| Euro OTC | Salicylic acid | 1303020-01 | 24 |
| Euro OTC | Salicylic acid | 1303020-02 | 4 |
| Euro OTC | Salicylic acid | 1406027-01 | 8 |
| Euro OTC | Salicylic acid | 140602702 | 1 |
| Euro OTC | Salicylic acid | 1406027-02 | 12 |
| Euro OTC | Salicylic acid | 1406027-02Mg1kg | 1 |
| Euro OTC | Salicylic acid | 14076202 | 1 |
| Euro OTC | Salicylic acid | 1408027 | 1 |
| Euro OTC | Salicylic acid | 14E26-B04-294622 | 1 |
| Euro OTC | Salicylic acid | 1509007/02 | 1 |
| Euro OTC | Salicylic acid | 1509007-01 | 26 |
| Euro OTC | Salicylic acid | 150900702 | 1 |
| Euro OTC | Salicylic acid | 1509007-02 | 9 |
| Euro OTC | Salicylic acid | 1511023B | 1 |
| Euro OTC | Salicylic acid | 15217301 | 1 |
| Euro OTC | Salicylic acid | 16/15-B08-330773 | 1 |
| Euro OTC | Salicylic acid | 16050013 | 1 |
| Euro OTC | Salicylic acid | 1605023/02 | 1 |
| Euro OTC | Salicylic acid | 160502301 | 2 |
| Euro OTC | Salicylic acid | 1605023-01 | 19 |
| Euro OTC | Salicylic acid | 160502302 | 1 |
| Euro OTC | Salicylic acid | 1605023-02 | 23 |
| Euro OTC | Salicylic acid | 160502331 | 1 |
| Euro OTC | Salicylic acid | 16E02-B09-325356 | 1 |
| Euro OTC | Salicylic acid | 1707009 | 1 |
| Euro OTC | Salicylic acid | 170700901 | 4 |
| Euro OTC | Salicylic acid | 1707009-01 | 26 |
| Euro OTC | Salicylic acid | 170700902 | 1 |
| Euro OTC | Salicylic acid | 1707009-02 | 14 |
| Euro OTC | Salicylic acid | 1707009-04 | 2 |
| Euro OTC | Salicylic acid | 1707009-1 | 1 |
| Euro OTC | Salicylic acid | 17133307 | 1 |
| Euro OTC | Salicylic acid | 17301509 | 1 |
| Euro OTC | Salicylic acid | 18001042-01 | 1 |
| Euro OTC | Salicylic acid | 1801042 | 1 |
| Euro OTC | Salicylic acid | 180104201 | 10 |
| Euro OTC | Salicylic acid | 1801042-01 | 54 |
| Euro OTC | Salicylic acid | 18050007 | 1 |
| Euro OTC | Salicylic acid | 19001501 | 1 |
| Euro OTC | Salicylic acid | 190018-03 | 1 |
| Euro OTC | Salicylic acid | 1901015-01 | 28 |
| Euro OTC | Salicylic acid | 1901015-02 | 14 |
| Euro OTC | Salicylic acid | 190101503 | 2 |
| Euro OTC | Salicylic acid | 1901015-03 | 12 |
| Euro OTC | Salicylic acid | 1901015-04 | 1 |
| Euro OTC | Salicylic acid | 1901018-03 | 1 |
| Euro OTC | Salicylic acid | 1910015-01 | 1 |
| Euro OTC | Salicylic acid | 191001801 | 2 |
| Euro OTC | Salicylic acid | 1910018-01 | 38 |
| Euro OTC | Salicylic acid | 1910018-02 | 9 |
| Euro OTC | Salicylic acid | 1910018-03 | 8 |
| Euro OTC | Salicylic acid | 1910018-18 | 1 |
| Euro OTC | Salicylic acid | 210102801 | 1 |
| Euro OTC | Salicylic acid | 2101028-01 | 23 |
| Euro OTC | Salicylic acid | 2108024_01 | 1 |
| Euro OTC | Salicylic acid | 2108024-01 | 11 |
| Euro OTC | Salicylic acid | 2201044-01 | 3 |
| Euro OTC | Salicylic acid | 2201044-02 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Salicylic acid | 22080003-01 | 1 |
| Euro OTC | Salicylic acid | 2208003-01 | 2 |
| Euro OTC | Salicylic acid | 2208003-02 | 2 |
| Euro OTC | Salicylic acid | ras1512800 | 1 |
| Euro OTC | Salicylic acid | RAS1703500 | 3 |
| Euro OTC | Salicylic acid | RAS1920400 | 1 |
| Euro/Phönix | Salicylic acid | 1801042-01 | 2 |
| Euro | Salicylic acid | 1509007-02 | 2 |
| Europ Ots Pharma | Salicylic acid | 12374205 | 1 |
| EurRho/ Anzag | Salicylic acid | 1509007-01 | 1 |
| Fa.Phönix | Salicylic acid | 18147302 | 1 |
| Fa.Phönix | Salicylic acid | 20003823008 | 1 |
| Fagaron | Salicylic acid | 14Lo2-B02-303558 | 1 |
| Fagron | Salicylic acid | | 2 |
| Fagron | Salicylic acid | 102455-0002 | 1 |
| Fagron | Salicylic acid | 11197121 | 1 |
| Fagron | Salicylic acid | 1140616 | 1 |
| Fagron | Salicylic acid | 11K10-N01 | 2 |
| Fagron | Salicylic acid | 11L19-N21 | 1 |
| Fagron | Salicylic acid | 12C20-N04 | 1 |
| Fagron | Salicylic acid | 12c20n12 | 1 |
| Fagron | Salicylic acid | 12C20-N12 | 5 |
| Fagron | Salicylic acid | 12H10-N03 | 8 |
| Fagron | Salicylic acid | 12H10-N08 | 5 |
| Fagron | Salicylic acid | 13344013 | 1 |
| Fagron | Salicylic acid | 13B14-N01 | 18 |
| Fagron | Salicylic acid | 13H01N01 | 1 |
| Fagron | Salicylic acid | 13H01-N01 | 6 |
| Fagron | Salicylic acid | 13H01N04 | 4 |
| Fagron | Salicylic acid | 13H01-N04 | 13 |
| Fagron | Salicylic acid | 13H01-N08 | 2 |
| Fagron | Salicylic acid | 13K08-B31-290852 | 5 |
| Fagron | Salicylic acid | 13K08-B31-290853 | 6 |
| Fagron | Salicylic acid | 14300801 | 1 |
| Fagron | Salicylic acid | 14300805 | 1 |
| Fagron | Salicylic acid | 14336920 | 1 |
| Fagron | Salicylic acid | 14B05B30 | 1 |
| Fagron | Salicylic acid | 14B05-B30 | 2 |
| Fagron | Salicylic acid | 14B05-B30-290854 | 5 |
| Fagron | Salicylic acid | 14E26_B04 | 1 |
| Fagron | Salicylic acid | 14E26B04 | 1 |
| Fagron | Salicylic acid | 14E26-B04 | 7 |
| Fagron | Salicylic acid | 14E26-B04_294623 | 1 |
| Fagron | Salicylic acid | 14E26-B04-294622 | 1 |
| Fagron | Salicylic acid | 14e26-b04-294623 | 1 |
| Fagron | Salicylic acid | 14e26-B04-294623 | 1 |
| Fagron | Salicylic acid | 14E26B04294623 | 1 |
| Fagron | Salicylic acid | 14E26-B04-294623 | 6 |
| Fagron | Salicylic acid | 14E26-B04-294624 | 7 |
| Fagron | Salicylic acid | 14E26-B04-296424 | 1 |
| Fagron | Salicylic acid | 14L02-B02 | 3 |
| Fagron | Salicylic acid | 14L02B02303557 | 1 |
| Fagron | Salicylic acid | 14L02-B02-303557 | 12 |
| Fagron | Salicylic acid | 14L02B02303558 | 1 |
| Fagron | Salicylic acid | 14L02-B02-303558 | 16 |
| Fagron | Salicylic acid | 15211809 | 1 |
| Fagron | Salicylic acid | 15217302 | 2 |
| Fagron | Salicylic acid | 16/15-B08-330773 | 4 |
| Fagron | Salicylic acid | 16/15-B08-331442 | 1 |
| Fagron | Salicylic acid | 16/15-B08-332098 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Salicylic acid | 16/15-B08-333933 | 3 |
| Fagron | Salicylic acid | 1615-B08-330773 | 1 |
| Fagron | Salicylic acid | 1615B08332098 | 1 |
| Fagron | Salicylic acid | 16A18-B04 | 2 |
| Fagron | Salicylic acid | 16A18-B04322904 | 1 |
| Fagron | Salicylic acid | 16A18-B04-322904 | 3 |
| Fagron | Salicylic acid | 16A18-B04-322905 | 2 |
| Fagron | Salicylic acid | 16A18B04322905 | 2 |
| Fagron | Salicylic acid | 16E02-B09-325355 | 1 |
| Fagron | Salicylic acid | 16E02-B09-325356 | 2 |
| Fagron | Salicylic acid | 16I15-B08 | 1 |
| Fagron | Salicylic acid | 16I15-B08-327353 | 2 |
| Fagron | Salicylic acid | 16I15B08330773 | 1 |
| Fagron | Salicylic acid | 16I15-B08-330773 | 1 |
| Fagron | Salicylic acid | 16I15-B08-332098 | 1 |
| Fagron | Salicylic acid | 16I15-B08-333932 | 3 |
| Fagron | Salicylic acid | 17301502 | 1 |
| Fagron | Salicylic acid | 17C21B09 | 1 |
| Fagron | Salicylic acid | 17C21-B09 | 2 |
| Fagron | Salicylic acid | 17c21-b09-337172 | 1 |
| Fagron | Salicylic acid | 17C21-B09-337172 | 3 |
| Fagron | Salicylic acid | 17C21-B09-337173 | 4 |
| Fagron | Salicylic acid | 17c21-b09-337860 | 1 |
| Fagron | Salicylic acid | 17C21-B09-337860 | 3 |
| Fagron | Salicylic acid | 1801042-01 | 1 |
| Fagron | Salicylic acid | 18E24-B03 | 1 |
| Fagron | Salicylic acid | 18E24-B03-354310 | 3 |
| Fagron | Salicylic acid | 18E24-B03-354311 | 5 |
| Fagron | Salicylic acid | 18E24-B03-354312 | 1 |
| Fagron | Salicylic acid | 18F05-B02 | 2 |
| Fagron | Salicylic acid | 18F05-B02-350586 | 6 |
| Fagron | Salicylic acid | 18F05B02350587 | 2 |
| Fagron | Salicylic acid | 18F05-B02-350587 | 8 |
| Fagron | Salicylic acid | 18F05-B02-351974 | 3 |
| Fagron | Salicylic acid | 18F05-B02-352210 | 4 |
| Fagron | Salicylic acid | 18F05-B02-352528 | 1 |
| Fagron | Salicylic acid | 18F15-B02-350587 | 1 |
| Fagron | Salicylic acid | 1901015-03 | 1 |
| Fagron | Salicylic acid | 190262 | 1 |
| Fagron | Salicylic acid | 190263 | 16 |
| Fagron | Salicylic acid | 190263RAS1818100 | 1 |
| Fagron | Salicylic acid | 190264 | 18 |
| Fagron | Salicylic acid | 19B12-B04 | 2 |
| Fagron | Salicylic acid | 19B12-B04-193458 | 1 |
| Fagron | Salicylic acid | 19B12-B04-193459 | 2 |
| Fagron | Salicylic acid | 19B12-B04-193460 | 7 |
| Fagron | Salicylic acid | 20A29-B31 | 1 |
| Fagron | Salicylic acid | 20A29B31197697 | 1 |
| Fagron | Salicylic acid | 20A29-B31-197697 | 6 |
| Fagron | Salicylic acid | 20E21-B03 | 5 |
| Fagron | Salicylic acid | 20e21-B03-200496 | 1 |
| Fagron | Salicylic acid | 20E21B03200496 | 1 |
| Fagron | Salicylic acid | 20E21-B03-200496 | 8 |
| Fagron | Salicylic acid | 20E21-Bo3-200496 | 1 |
| Fagron | Salicylic acid | 20E21-BO3-200496 | 1 |
| Fagron | Salicylic acid | 20E32-B03-200496 | 1 |
| Fagron | Salicylic acid | 20G20-B04 | 1 |
| Fagron | Salicylic acid | 20G20-B04-202192 | 3 |
| Fagron | Salicylic acid | 20G20-B04-202193 | 1 |
| Fagron | Salicylic acid | 21003008004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Salicylic acid | 21A26-B19-210110 | 3 |
| Fagron | Salicylic acid | 21a26-b19-210141 | 1 |
| Fagron | Salicylic acid | 21A26-B19-210141 | 3 |
| Fagron | Salicylic acid | 21G21-B04-217748 | 1 |
| Fagron | Salicylic acid | 21G30-B03-213843 | 1 |
| Fagron | Salicylic acid | 21G30B03215511 | 1 |
| Fagron | Salicylic acid | 21G30-B03-215511 | 7 |
| Fagron | Salicylic acid | 21G3O-B03-2155101 | 1 |
| Fagron | Salicylic acid | 21J06B11-217750 | 1 |
| Fagron | Salicylic acid | 21J06-B11-217750 | 2 |
| Fagron | Salicylic acid | 2201115 | 1 |
| Fagron | Salicylic acid | 22D07-0B03-221811 | 1 |
| Fagron | Salicylic acid | 22D07-B03-221811 | 1 |
| Fagron | Salicylic acid | 22E12-B05-224210 | 1 |
| Fagron | Salicylic acid | 22j23-b06-227888 | 1 |
| Fagron | Salicylic acid | 22J26-B06-227888 | 1 |
| Fagron | Salicylic acid | 290852 | 1 |
| Fagron | Salicylic acid | 3111Q-01045 | 1 |
| Fagron | Salicylic acid | AS28012021 | 1 |
| Fagron | Salicylic acid | B03-2004906 | 2 |
| Fagron | Salicylic acid | B19-210110 | 1 |
| Fagron | Salicylic acid | B31-1976907 | 3 |
| Fagron | Salicylic acid | RAS1135100 | 1 |
| Fagron | Salicylic acid | RAS1135300 | 1 |
| Fagron | Salicylic acid | RAS1808500 | 1 |
| Fagron | Salicylic acid | RAS1818100 | 4 |
| Fagron | Salicylic acid | RAS1929500 | 2 |
| Fagron | Salicylic acid | xxxxxxxx | 1 |
| Fargon / AHD | Salicylic acid | 20E21-B03-200496 | 2 |
| Fargon | Salicylic acid | 14L02-B02 | 1 |
| Farmalabor / Farmalabor | Salicylic acid | P1404195-002 | 1 |
| Fiebig/Maros | Salicylic acid | 1707009-02 | 1 |
| Fiebig | Salicylic acid | 15211810 | 1 |
| Fiebig | Salicylic acid | 16010905 | 1 |
| Fiebig | Salicylic acid | 17301506 | 1 |
| Fiebig | Salicylic acid | 17301509 | 1 |
| Fiebig | Salicylic acid | 18147321 | 1 |
| Fiebig | Salicylic acid | 22J26-B06-227888 | 1 |
| Fiebig | Salicylic acid | 23003599005 | 1 |
| Gehe / Spinnrad | Salicylic acid | 16050005 | 1 |
| Gehe amax | Salicylic acid | 12036223 | 1 |
| Gehe amax | Salicylic acid | 1801042-01 | 1 |
| Gehe amax | Salicylic acid | 18147302 | 1 |
| Gehe amax | Salicylic acid | 18147314 | 1 |
| Gehe/ Caesar & Loret… | Salicylic acid | 20000146005 | 1 |
| Gehe | Salicylic acid | | 1 |
| Gehe | Salicylic acid | 1050313 | 1 |
| Gehe | Salicylic acid | 11D15-N08 | 1 |
| Gehe | Salicylic acid | 1206007-01 | 1 |
| Gehe | Salicylic acid | 13B14-N01 | 1 |
| Gehe | Salicylic acid | 13H01-N04 | 1 |
| Gehe | Salicylic acid | 14336919 | 1 |
| Gehe | Salicylic acid | 14E26-B04-294624 | 1 |
| Gehe | Salicylic acid | 14L02-B02-303558 | 1 |
| GEHE | Salicylic acid | 1509007-02 | 3 |
| Gehe | Salicylic acid | 15217301 | 1 |
| Gehe | Salicylic acid | 15217304 | 1 |
| Gehe | Salicylic acid | 16010910 | 1 |
| Gehe | Salicylic acid | 16050013 | 2 |
| GEHE | Salicylic acid | 1605023-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| GEHE | Salicylic acid | 1605023-02 | 2 |
| Gehe | Salicylic acid | 16312003 | 1 |
| Gehe | Salicylic acid | 165023-02 | 1 |
| gehe | Salicylic acid | 16I15-B08-331442 | 1 |
| Gehe | Salicylic acid | 1707009-01 | 1 |
| GEHE | Salicylic acid | 1707009-01 | 1 |
| GEHE | Salicylic acid | 1707009-02 | 1 |
| Gehe | Salicylic acid | 17133301 | 1 |
| Gehe | Salicylic acid | 17133307 | 4 |
| GEHE | Salicylic acid | 17301502 | 2 |
| Gehe | Salicylic acid | 17301511 | 1 |
| GEHE | Salicylic acid | 17301511 | 1 |
| Gehe | Salicylic acid | 17C21-B09-337172 | 1 |
| Gehe | Salicylic acid | 18147314 | 1 |
| GEHE | Salicylic acid | 18147317 | 1 |
| Gehe | Salicylic acid | 18147321 | 1 |
| Gehe | Salicylic acid | 18230007 | 1 |
| GEHE | Salicylic acid | 18230009 | 1 |
| Gehe | Salicylic acid | 18F05-B02-350586 | 1 |
| Gehe | Salicylic acid | 20000147002 | 1 |
| Gehe | Salicylic acid | 20000147004 | 1 |
| Gehe | Salicylic acid | 20000147006 | 2 |
| Gehe | Salicylic acid | 20003823008 | 2 |
| Gehe | Salicylic acid | 2000442010 | 2 |
| Gehe | Salicylic acid | 20004424015 | 1 |
| Gehe | Salicylic acid | 21003008010 | 1 |
| Gehe | Salicylic acid | 21003008016 | 1 |
| Gehe | Salicylic acid | 21J06-B11-217750 | 1 |
| gehe | Salicylic acid | 22001529002 | 1 |
| Gehe | Salicylic acid | 22001529002 | 1 |
| GEHE | Salicylic acid | 22001529002 | 1 |
| gehe | Salicylic acid | 22003107004 | 1 |
| Gehe | Salicylic acid | 2208003-01 | 1 |
| Gehe | Salicylic acid | 2208003-02 | 2 |
| Gehe | Salicylic acid | 22D07-B03-221811 | 3 |
| gehe | Salicylic acid | 2308012-01 | 1 |
| Gehe | Salicylic acid | 2308012-01 | 1 |
| Gehe | Salicylic acid | 24000043001 | 2 |
| Gehe | Salicylic acid | 2400004301 | 1 |
| Geibo 5.7.21 | Salicylic acid | 20A29-B31-197697 | 1 |
| Geilenkirchen | Salicylic acid | 17301506 | 1 |
| Geilenkirchen | Salicylic acid | 192209001 | 2 |
| Gutenberg-Apotheke | Salicylic acid | 12374208 | 1 |
| Hänseler | Salicylic acid | | 7 |
| Hofmann & Sommer | Salicylic acid | 1230 | 3 |
| Holdermann | Salicylic acid | 14E26-B04294624 | 1 |
| Ichthyol/ Noweda | Salicylic acid | 17133303 | 1 |
| Ichthyol/Noweda | Salicylic acid | 13344003 | 1 |
| Ichthyol | Salicylic acid | 11311922 | 2 |
| Jenne | Salicylic acid | 12345 | 1 |
| Jenne | Salicylic acid | 18147314 | 1 |
| Jenne | Salicylic acid | 20000147004 | 1 |
| Jenne | Salicylic acid | 20003823016 | 2 |
| Jenne | Salicylic acid | 22001529003 | 1 |
| Jenne | Salicylic acid | 22J26B06-227888 | 1 |
| Kehr | Salicylic acid | 16312001 | 2 |
| Kehr | Salicylic acid | 16312012 | 1 |
| Kehr | Salicylic acid | 17301509 | 1 |
| Kehr | Salicylic acid | 2201044-02 | 1 |
| Kehr | Salicylic acid | 23002014003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Kehr | Salicylic acid | 23003599002 | 3 |
| Kehr | Salicylic acid | 24000043001 | 1 |
| Klenk | Salicylic acid | 12134722 | 1 |
| KÖGL | Salicylic acid | 1803840 | 2 |
| Krieger | Salicylic acid | 13032017-MW-A | 1 |
| Krieger | Salicylic acid | 16050012 | 1 |
| Krieger | Salicylic acid | 22001529002 | 1 |
| Krieger | Salicylic acid | 24000004004 | 1 |
| L30 | Salicylic acid | 16312005 | 1 |
| L30 | Salicylic acid | 17301505 | 1 |
| L30 | Salicylic acid | 17301507 | 1 |
| Max Jenne | Salicylic acid | 21003008004 | 1 |
| Max Jenne | Salicylic acid | 2400043001 | 1 |
| Midas | Salicylic acid | 16312010 | 1 |
| Novacyl / Ebert | Salicylic acid | 14336919 | 1 |
| Novacyl / Gehe | Salicylic acid | 16010912 | 1 |
| Novacyl / Gehe | Salicylic acid | 18147321 | 1 |
| Novacyl/Caesar & Lor... | Salicylic acid | 17301505 | 1 |
| Novacyl/Gehe Pharma ... | Salicylic acid | 17301507 | 1 |
| Novacyl/Phoenix | Salicylic acid | RAS1817400 | 1 |
| Novacyl/Phoenix | Salicylic acid | RAS1818100 | 2 |
| Novacyl/Phoenix | Salicylic acid | RAS1907500 | 1 |
| Novacyl | Salicylic acid | 1707009-02 | 1 |
| Novacyl | Salicylic acid | 1910018-01 | 1 |
| Novacyl | Salicylic acid | RAS1821600 | 1 |
| Novalyc / Gehe | Salicylic acid | 14336911 | 2 |
| Noweda/ Caesar&Loren... | Salicylic acid | 192209001 | 1 |
| Noweda/ Infecto Pharm | Salicylic acid | 16/15-08-330773 | 1 |
| Noweda/Fargon | Salicylic acid | 14L02-B02-303556 | 1 |
| Noweda | Salicylic acid | 12036215 | 1 |
| Noweda | Salicylic acid | 12036226 | 1 |
| Noweda | Salicylic acid | 1406027-01 | 1 |
| Noweda | Salicylic acid | 140602702 | 1 |
| Noweda | Salicylic acid | 14336907 | 2 |
| Noweda | Salicylic acid | 16/15-B08-330773 | 1 |
| Noweda | Salicylic acid | 16050011 | 1 |
| Noweda | Salicylic acid | 16050013 | 1 |
| Noweda | Salicylic acid | 1707009-02 | 2 |
| Noweda | Salicylic acid | 170700904 | 3 |
| Noweda | Salicylic acid | 17133304 | 1 |
| noweda | Salicylic acid | 17301502 | 1 |
| Noweda | Salicylic acid | 17304506 | 1 |
| Noweda | Salicylic acid | 180104201 | 1 |
| Noweda | Salicylic acid | 1801042-01 | 2 |
| Noweda | Salicylic acid | 181473001 | 2 |
| Noweda | Salicylic acid | 1901015 | 1 |
| Noweda | Salicylic acid | 1901015-01 | 1 |
| Noweda | Salicylic acid | 1901015-03 | 1 |
| Noweda | Salicylic acid | 190263 | 1 |
| Noweda | Salicylic acid | 19061206 | 1 |
| Noweda | Salicylic acid | 19B12-B04-193459 | 1 |
| Noweda | Salicylic acid | 20003823008 | 1 |
| noweda | Salicylic acid | 20004424015 | 1 |
| Noweda | Salicylic acid | 210802401 | 1 |
| Noweda | Salicylic acid | 21101411 | 1 |
| Noweda | Salicylic acid | 22001524003 | 1 |
| Noweda | Salicylic acid | 22001528002 | 1 |
| Noweda | Salicylic acid | 22001528003 | 2 |
| Noweda | Salicylic acid | 22001529002 | 4 |
| noweda | Salicylic acid | 22001534003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Salicylic acid | 22001534003 | 1 |
| Noweda | Salicylic acid | 2201044-01 | 1 |
| Noweda | Salicylic acid | 2208003_01 | 1 |
| Noweda | Salicylic acid | 2208003-02 | 1 |
| Noweda | Salicylic acid | 22J26-B06-228343 | 1 |
| Noweda | Salicylic acid | 23002014003 | 2 |
| Noweda | Salicylic acid | 23003599002 | 2 |
| Noweda | Salicylic acid | 2308012-01 | 2 |
| Noweda | Salicylic acid | 24000043001 | 1 |
| Noweda | Salicylic acid | AS10052021 | 1 |
| Noweda | Salicylic acid | P2021/113 | 1 |
| Noweda | Salicylic acid | RAS2300100 | 1 |
| Phoenix 09.10.2017 | Salicylic acid | 16050017 | 1 |
| Phoenix goettingen | Salicylic acid | 14300808 | 1 |
| Phoenix/Cealo | Salicylic acid | 1733303 | 1 |
| Phoenix/Cealo | Salicylic acid | 3414M-01045 | 1 |
| Phoenix | Salicylic acid | 12H10-No8 | 1 |
| Phoenix | Salicylic acid | 14076201 | 1 |
| Phoenix | Salicylic acid | 15211808 | 2 |
| Phoenix | Salicylic acid | 16050012 | 1 |
| Phoenix | Salicylic acid | 16312005 | 1 |
| Phoenix | Salicylic acid | 17301502 | 1 |
| Phoenix | Salicylic acid | 18050007 | 1 |
| Phoenix | Salicylic acid | 18050009 | 2 |
| Phoenix | Salicylic acid | 18147308 | 1 |
| Phoenix | Salicylic acid | 19061202 | 1 |
| Phoenix | Salicylic acid | 1910018-02 | 1 |
| Phoenix | Salicylic acid | 191411012 | 1 |
| Phoenix | Salicylic acid | 20004424006 | 1 |
| Phoenix | Salicylic acid | 20004424007 | 1 |
| Phoenix | Salicylic acid | 22001529002 | 2 |
| Phoenix | Salicylic acid | 22001534003 | 2 |
| Phoenix | Salicylic acid | 2208003-01 | 2 |
| Phoenox | Salicylic acid | 20000147004 | 1 |
| Phönix 02.08.2019 | Salicylic acid | 18230009 | 1 |
| Phönix Gotha | Salicylic acid | 12374207 | 1 |
| Phönix Gotha | Salicylic acid | 14076201 | 1 |
| Phönix Gotha | Salicylic acid | 14300801 | 1 |
| Phönix Gotha | Salicylic acid | 18050006 | 1 |
| Phönix/Noweda | Salicylic acid | 20004424010 | 1 |
| Phönix | Salicylic acid | 11311917 | 1 |
| Phönix | Salicylic acid | 12323401 | 1 |
| Phönix | Salicylic acid | 12374210 | 1 |
| Phönix | Salicylic acid | 12374211 | 1 |
| Phönix | Salicylic acid | 12C20-N12 | 1 |
| Phönix | Salicylic acid | 13K08-B31-290853 | 1 |
| Phönix | Salicylic acid | 1509007-02 | 1 |
| Phönix | Salicylic acid | 16050005 | 1 |
| Phönix | Salicylic acid | 16050012 | 1 |
| Phönix | Salicylic acid | 16a18-b04-322905 | 1 |
| Phönix | Salicylic acid | 1713303 | 1 |
| Phönix | Salicylic acid | 17301506 | 1 |
| Phönix | Salicylic acid | 17301507 | 1 |
| Phonix | Salicylic acid | 18050007 | 1 |
| Phönix | Salicylic acid | 18050009 | 3 |
| Phönix | Salicylic acid | 18147302 | 1 |
| Phönix | Salicylic acid | 18147303 | 2 |
| Phönix | Salicylic acid | 18147314 | 2 |
| PHÖNIX | Salicylic acid | 18230004 | 1 |
| Phönix | Salicylic acid | 190612001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Salicylic acid | 200004424001 | 1 |
| phönix | Salicylic acid | 20004424004 | 1 |
| Phönix | Salicylic acid | 20004424004 | 1 |
| Phönix | Salicylic acid | 20004424006 | 1 |
| Phönix | Salicylic acid | 20004424015 | 2 |
| Phönix | Salicylic acid | 2101028-01 | 1 |
| Phönix | Salicylic acid | 2108024-01 | 2 |
| Phönix | Salicylic acid | 22001529002 | 3 |
| Phönix | Salicylic acid | 22001534003 | 1 |
| phönix | Salicylic acid | 2208003-02 | 2 |
| phönix | Salicylic acid | 2308012-01 | 1 |
| Phönix | Salicylic acid | 24000004004 | 1 |
| Phönix | Salicylic acid | 3177 | 1 |
| Phönix | Salicylic acid | 68/AKD4 | 1 |
| Röntgen | Salicylic acid | 190612004 | 1 |
| Salicylsäure | Salicylic acid | 190612001 | 1 |
| Sana 04.02.17 Ek:13,83 | Salicylic acid | 16010910 | 1 |
| Sanacorp 28.01.15 EK… | Salicylic acid | 14076204 | 1 |
| Sanacorp | Salicylic acid | 11311922 | 1 |
| Sanacorp | Salicylic acid | 12134707 | 1 |
| Sanacorp | Salicylic acid | 12134712 | 1 |
| Sanacorp | Salicylic acid | 12134715 | 1 |
| Sanacorp | Salicylic acid | 123036223 | 1 |
| Sanacorp | Salicylic acid | 12374205 | 1 |
| Sanacorp | Salicylic acid | 12374210 | 1 |
| Sanacorp | Salicylic acid | 1303020-01 | 1 |
| Sanacorp | Salicylic acid | 13344014 | 1 |
| Sanacorp | Salicylic acid | 13344018 | 1 |
| Sanacorp | Salicylic acid | 15084404 | 1 |
| Sanacorp | Salicylic acid | 16010910 | 1 |
| Sanacorp | Salicylic acid | 16010912 | 1 |
| Sanacorp | Salicylic acid | 16050005 | 1 |
| Sanacorp | Salicylic acid | 16050012 | 1 |
| Sanacorp | Salicylic acid | 17133307 | 1 |
| Sanacorp | Salicylic acid | 171333307 | 1 |
| Sanacorp | Salicylic acid | 17301505 | 1 |
| Sanacorp | Salicylic acid | 17301506 | 1 |
| Sanacorp | Salicylic acid | 17301509 | 1 |
| Sanacorp | Salicylic acid | 17C21-B09-339446 | 1 |
| Sanacorp | Salicylic acid | 18050006 | 1 |
| Sanacorp | Salicylic acid | 18050007 | 1 |
| Sanacorp | Salicylic acid | 18147303 | 1 |
| Sanacorp | Salicylic acid | 1910018-03 | 1 |
| Sanacorp | Salicylic acid | 20000147002 | 1 |
| Sanacorp | Salicylic acid | 20004424013 | 3 |
| Sanacorp | Salicylic acid | 2000442406 | 1 |
| Sanacorp | Salicylic acid | 20E21-B03-200496 | 1 |
| Sanacorp | Salicylic acid | 21003008004 | 1 |
| Sanacorp | Salicylic acid | 2101028-01 | 1 |
| Sanacorp | Salicylic acid | 21A26-B19-210110 | 1 |
| sanacorp | Salicylic acid | 22001528002 | 1 |
| Sanacorp | Salicylic acid | 22001529002 | 3 |
| Sanacorp | Salicylic acid | 22001534003 | 1 |
| Sanacorp | Salicylic acid | 2208003-01 | 1 |
| Sanacorp | Salicylic acid | 23002014003 | 2 |
| Sanacorp | Salicylic acid | 2311012-01 | 1 |
| Sanacorp | Salicylic acid | 24000043001 | 3 |
| Sanacorp | Salicylic acid | 68/AKD2 | 1 |
| Spangropharm | Salicylic acid | 11197104 | 1 |
| VDL | Salicylic acid | 11197122 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| VDL | Salicylic acid | 22D07-B03-221811 | 1 |
| xxx | Salicylic acid | 4311A-01045 | 1 |

- 252 171 spectra from 1666 *Apo-Ident* customers from a total of 51 529 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Salicylic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Salicylic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 460 | 0 | 157 866 |
| **Type B** | 0 | 1120 | 0 | 211 820 |
| **Type C** | 0 | 4691 | 24 | 252 171 |

The substance/substance group *Salicylic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6957 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4643 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.4910 % (> 99.4274 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20696 | 21906 | 6.56 | 217.52 |
| 21436 | 21906 | 6.50 | 217.89 |
| 21760 | 21906 | 2.77 | 220.37 |
| 21906 | 21906 | 0.00 | 220.52 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22443 | 22443 | 0.00 | 209.97 |
| 23592 | 21906 | 3.49 | 221.45 |
| 24591 | 21906 | 5.08 | 221.50 |
| 25543 | 25543 | 0.00 | 220.25 |
| 26113 | 26113 | 0.00 | 212.75 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Serine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22289-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Serine; L-serine; Serinum

### Special notes

When selecting the *Serine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Serine | 8 | 9 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Serine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Serine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 81.65 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Serine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Serine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Serine | 1512012 | 22289 | 60 | 20160112* |
| Euro OTC | Serine | 1606020-01 | 22668 | 40 | 20160714 |
| Euro OTC | Serine | 1606020 | 22678 | 40 | 20160714* |
| Euro OTC | Serine | 1711033 | 23914 | 40 | 20171208* |
| Euro OTC | Serine | 1904034 | 24641 | 40 | 20190521* |
| Euro OTC | Serine | 1909027 | 24956 | 40 | 20191015* |
| Euro OTC | Serine | 2011007 | 25471 | 40 | 20201127* |
| Fagron | Serine | 21J20-B02-216460 | 26156 | 40 | 20220114 |
| Fagron | Serine | 21J20-B02-216460 | 26156SI | 20 | 20220114 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *Serine*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 157 966 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 410 spectra of 11 reference samples from the substance/substance group *Serine*.
- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Serine | 1611006 | 22922 | 40 |
| Euro OTC | Serine | 1809016 | 24296 | 40 |
| Euro OTC | Serine | 2006028 | 25305 | 40 |
| Euro OTC | Serine | 2107017 | 25776 | 50 |
| Euro OTC | Serine | 2206022 | 26275 | 40 |
| Euro OTC | Serine | 2302004 | 26599 | 40 |
| Euro OTC | Serine | 2308017 | 27206 | 40 |
| Euro OTC | Serine | 2501042 | 27624 | 40 |
| Fagron | Serine | 23J09-B02-235857 | 27049 | 40 |
| Euro OTC | Serine | 2206022 | 26275SI | 20 |
| Euro OTC | Serine | 2302004 | 26599SI | 20 |

- 212 530 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6 spectra from 2 *Apo-Ident* customers from 4 batches from the substance/substance group *Serine*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Serine | 1606020-01 | 3 |
| Euro OTC | Serine | 1904034-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Serine | 2006028-01 | 1 |
| Euro OTC | Serine | 2206022-01 | 1 |

- 256 880 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Serine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Serine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 410 | 0 | 212 530 |
| **Type C** | 0 | 6 | 0 | 256 880 |

The substance/substance group *Serine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5366 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22289 | 22289 | 0.00 | 202.35 |
| 22668 | 22678 | 5.99 | 208.57 |
| 22678 | 22678 | 0.00 | 208.52 |
| 23914 | 23914 | 0.00 | 206.63 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24641 | 24641 | 0.00 | 209.24 |
| 24956 | 24956 | 0.00 | 203.42 |
| 25471 | 25471 | 0.00 | 208.77 |
| 26156 | 23914 | 15.20 | 208.19 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sildenafil citrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20852-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sildenafil citrate; Sildenafili citras

### Special notes

When selecting the *Sildenafil citrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sildenafil citrate | 7 | 10 | 210 |

### Second-stage model

For differentiation of the substance/substance group *Sildenafil citrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sildenafil citrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 101.61 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sildenafil citrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sildenafil citrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sildenafil citrate | 160498 | 22446 | 60 | 20160307* |
| Caelo | Sildenafil citrate | 170715 | 23336 | 40 | 20170529* |
| Caelo | Sildenafil citrate | 170715 | 23345 | 40 | 20170529* |
| Euro OTC | Sildenafil citrate | 1311010-01 | 21621 | 60 | 20131209 |
| Euro OTC | Sildenafil citrate | 1311010-04 | 23178 | 40 | 20150309 |
| Euro OTC | Sildenafil citrate | 1908006 | 24843 | 40 | 20190906* |
| Fagron | Sildenafil citrate | 13F24-N03 | 20852 | 40 | 1402052 |
| Fagron | Sildenafil citrate | 13J15-N01 | 20927 | 80 | 20131030 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 400 spectra of 8 reference samples from the substance/substance group *Sildenafil citrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 926 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 540 spectra of 14 reference samples from the substance/substance group *Sildenafil citrate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sildenafil citrate | 190866 | 24545 | 40 |
| Caelo | Sildenafil citrate | 22000907 | 26248 | 40 |
| Caelo | Sildenafil citrate | 23003271 | 27247 | 40 |
| Euro OTC | Sildenafil citrate | 1807037 | 24192 | 40 |
| Euro OTC | Sildenafil citrate | 1902031 | 24469 | 40 |
| Euro OTC | Sildenafil citrate | 2003003 | 25380 | 40 |
| Euro OTC | Sildenafil citrate | 2111002 | 25896 | 50 |
| Euro OTC | Sildenafil citrate | 2301014 | 26580 | 40 |
| Euro OTC | Sildenafil citrate | 2403010 | 27287 | 40 |
| Fagron | Sildenafil citrate | 21G10-B25-219206 | 26072 | 40 |
| Caelo | Sildenafil citrate | 22000907 | 26248SI | 20 |
| Euro OTC | Sildenafil citrate | 2111002 | 25896SI | 50 |
| Euro OTC | Sildenafil citrate | 2301014 | 26580SI | 20 |
| Fagron | Sildenafil citrate | 21G10-B25-219206 | 26072SI | 40 |

- 212 400 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 858 spectra from 198 *Apo-Ident* customers from 218 batches from the substance/substance group *Sildenafil citrate*.

- Among them are spectra of independent samples from 209 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sildenafil citrate | 211002-01 | 1 |
| | Sildenafil citrate | 2111002-01 | 2 |
| | Sildenafil citrate | 22000907002 | 5 |
| | Sildenafil citrate | 22000907011 | 1 |
| | Sildenafil citrate | 22000907012 | 4 |
| | Sildenafil citrate | 22000907013 | 15 |
| | Sildenafil citrate | 22000907015 | 6 |
| | Sildenafil citrate | 22000907016 | 5 |
| | Sildenafil citrate | 22000907018 | 16 |
| | Sildenafil citrate | 22L13-B07-227924 | 4 |
| | Sildenafil citrate | 22L13-B07-227926 | 2 |
| | Sildenafil citrate | 22L13-B09-232399 | 2 |
| | Sildenafil citrate | 23000811001 | 6 |
| | Sildenafil citrate | 23000811003 | 4 |
| | Sildenafil citrate | 23003271002 | 1 |
| | Sildenafil citrate | 23003271003 | 12 |
| | Sildenafil citrate | 23003271004 | 14 |
| | Sildenafil citrate | 2301014-01 | 15 |
| | Sildenafil citrate | 23L11-B05-236845 | 1 |
| | Sildenafil citrate | 24002318002 | 2 |
| | Sildenafil citrate | 24002318003 | 2 |
| | Sildenafil citrate | 24002318004 | 2 |
| | Sildenafil citrate | 2403010-01 | 3 |
| | Sildenafil citrate | 7-22792004 | 1 |
| | Sildenafil citrate | B07-2279203 | 1 |
| | Sildenafil citrate | SLC/0221061 | 1 |
| | Sildenafil citrate | SLC/1123066 | 1 |
| AHC | Sildenafil citrate | 21B17-B09-203496 | 2 |
| AHC | Sildenafil citrate | 23003271003 | 1 |
| AHC | Sildenafil citrate | 2301014-01 | 1 |
| Alliance Health Care | Sildenafil citrate | 23003271003 | 1 |
| Alliance | Sildenafil citrate | | 1 |
| Alliance | Sildenafil citrate | 1311010-03 | 1 |
| Alliance | Sildenafil citrate | 22000907015 | 3 |
| Anzag | Sildenafil citrate | 2301014-01 | 2 |
| Beiersdorf | Sildenafil citrate | 17071503 | 6 |
| Caelo | Sildenafil citrate | | 1 |
| Caelo | Sildenafil citrate | 101051528 | 1 |
| Caelo | Sildenafil citrate | 1311010-06 | 1 |
| Caelo | Sildenafil citrate | 14074707 | 2 |
| Caelo | Sildenafil citrate | 14074709 | 1 |
| Caelo | Sildenafil citrate | 14074714 | 5 |
| Caelo | Sildenafil citrate | 14074715 | 5 |
| Caelo | Sildenafil citrate | 14074716 | 1 |
| Caelo | Sildenafil citrate | 1407474 | 1 |
| Caelo | Sildenafil citrate | 15097301 | 1 |
| Caelo | Sildenafil citrate | 15097302 | 1 |
| Caelo | Sildenafil citrate | 15097303 | 1 |
| Caelo | Sildenafil citrate | 15097306 | 1 |
| Caelo | Sildenafil citrate | 15097307 | 2 |
| Caelo | Sildenafil citrate | 15097308 | 1 |
| Caelo | Sildenafil citrate | 15097310 | 3 |
| Caelo | Sildenafil citrate | 15097311 | 1 |
| Caelo | Sildenafil citrate | 15097312 | 2 |
| Caelo | Sildenafil citrate | 15097315 | 1 |
| Caelo | Sildenafil citrate | 15097317 | 2 |
| Caelo | Sildenafil citrate | 15F11-B02-309081 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sildenafil citrate | 15F11-B02-314725 | 1 |
| Caelo | Sildenafil citrate | 16049801 | 1 |
| Caelo | Sildenafil citrate | 16049802 | 10 |
| Caelo | Sildenafil citrate | 16049805 | 1 |
| Caelo | Sildenafil citrate | 16049808 | 4 |
| Caelo | Sildenafil citrate | 16049810 | 2 |
| Caelo | Sildenafil citrate | 16049811 | 3 |
| Caelo | Sildenafil citrate | 16049812 | 1 |
| Caelo | Sildenafil citrate | 16049814 | 4 |
| Caelo | Sildenafil citrate | 16049819 | 3 |
| Caelo | Sildenafil citrate | 16049820 | 5 |
| Caelo | Sildenafil citrate | 16049821 | 13 |
| Caelo | Sildenafil citrate | 16049823 | 2 |
| Caelo | Sildenafil citrate | 16049824 | 1 |
| Caelo | Sildenafil citrate | 16049826 | 1 |
| Caelo | Sildenafil citrate | 16F30-B02-3241715 | 1 |
| Caelo | Sildenafil citrate | 17071502 | 2 |
| Caelo | Sildenafil citrate | 17071503 | 1 |
| Caelo | Sildenafil citrate | 17071504 | 21 |
| Caelo | Sildenafil citrate | 17344001 | 2 |
| Caelo | Sildenafil citrate | 17344003 | 11 |
| Caelo | Sildenafil citrate | 17344004 | 2 |
| Caelo | Sildenafil citrate | 17344005 | 9 |
| Caelo | Sildenafil citrate | 17344006 | 2 |
| Caelo | Sildenafil citrate | 17344008 | 4 |
| Caelo | Sildenafil citrate | 17344009 | 3 |
| Caelo | Sildenafil citrate | 1734401 | 1 |
| Caelo | Sildenafil citrate | 17344010 | 2 |
| Caelo | Sildenafil citrate | 17344014 | 3 |
| Caelo | Sildenafil citrate | 17344015 | 1 |
| Caelo | Sildenafil citrate | 18B13-B06-349160 | 2 |
| Caelo | Sildenafil citrate | 18B13-B06-351981 | 1 |
| Caelo | Sildenafil citrate | 1908006-01 | 2 |
| Caelo | Sildenafil citrate | 1908006-02 | 1 |
| Caelo | Sildenafil citrate | 190866001 | 2 |
| Caelo | Sildenafil citrate | 190866005 | 2 |
| Caelo | Sildenafil citrate | 19086603 | 3 |
| Caelo | Sildenafil citrate | 19086604 | 8 |
| Caelo | Sildenafil citrate | 19086605 | 12 |
| Caelo | Sildenafil citrate | 19086605P-191112-1 | 1 |
| Caelo | Sildenafil citrate | 19086605P-191212-1 | 1 |
| Caelo | Sildenafil citrate | 19086605P-200107-1 | 1 |
| Caelo | Sildenafil citrate | 19086605P-200206-2 | 1 |
| Caelo | Sildenafil citrate | 19086606 | 8 |
| Caelo | Sildenafil citrate | 19086606P-200319-5 | 1 |
| Caelo | Sildenafil citrate | 19086607 | 2 |
| Caelo | Sildenafil citrate | 190866606 | 1 |
| Caelo | Sildenafil citrate | 2000016003 | 1 |
| Caelo | Sildenafil citrate | 20000163002 | 9 |
| Caelo | Sildenafil citrate | 20000163002/01 | 1 |
| Caelo | Sildenafil citrate | 20000163003 | 5 |
| Caelo | Sildenafil citrate | 20000163004 | 6 |
| Caelo | Sildenafil citrate | 20000163005 | 1 |
| Caelo | Sildenafil citrate | 20000163006 | 3 |
| Caelo | Sildenafil citrate | 2000163003 | 2 |
| Caelo | Sildenafil citrate | 20004485002 | 2 |
| Caelo | Sildenafil citrate | 20004485003 | 7 |
| Caelo | Sildenafil citrate | 21000810001 | 6 |
| Caelo | Sildenafil citrate | 21000810002 | 2 |
| Caelo | Sildenafil citrate | 21000810003 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sildenafil citrate | 21000810004 | 3 |
| Caelo | Sildenafil citrate | 21000810006 | 2 |
| Caelo | Sildenafil citrate | 21000810008 | 4 |
| Caelo | Sildenafil citrate | 21000810010 | 4 |
| Caelo | Sildenafil citrate | 21000810011 | 2 |
| Caelo | Sildenafil citrate | 21000810012 | 1 |
| Caelo | Sildenafil citrate | 2100081008 | 1 |
| Caelo | Sildenafil citrate | 2100810006 | 1 |
| Caelo | Sildenafil citrate | 2101403 | 1 |
| Caelo | Sildenafil citrate | 22000907001 | 3 |
| Caelo | Sildenafil citrate | 22000907002 | 6 |
| Caelo | Sildenafil citrate | 22000907008 | 3 |
| Caelo | Sildenafil citrate | 22000907012 | 1 |
| Caelo | Sildenafil citrate | 2200090907015 | 1 |
| Caelo | Sildenafil citrate | 2200907002 | 1 |
| Caelo | Sildenafil citrate | 46049826 | 1 |
| Caelo | Sildenafil citrate | SLC/0420004 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 21000810008 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 22000907002 | 2 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 20004485003 | 1 |
| Caesar & Loretz GmbH/Gehe | Sildenafil citrate | 19086607 | 3 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 190866001 | 2 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 20000163003 | 2 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 21000810008 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 21000810013 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 21000810003 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 190866003 | 1 |
| Caesar & Loretz GmbH/Sana | Sildenafil citrate | 19086604 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 21000810006 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 21000810011 | 1 |
| Caesar & Loretz GmbH... | Sildenafil citrate | 22000907002 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 17344013 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 17344014 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 180737-01 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 190866005 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 19086601 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 19086603 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 19086605 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 19086606 | 12 |
| Caesar & Loretz GmbH | Sildenafil citrate | 19086607 | 2 |
| Caesar & Loretz GmbH | Sildenafil citrate | 20000163002 | 3 |
| Caesar & Loretz GmbH | Sildenafil citrate | 20004485003 | 3 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810003 | 7 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810004 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810006 | 5 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810007 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810008 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810011 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810012 | 4 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810013 | 2 |
| Caesar & Loretz GmbH | Sildenafil citrate | 21000810014 | 2 |
| Caesar & Loretz GmbH | Sildenafil citrate | 2100081003 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | 22000907001 | 6 |
| Caesar & Loretz GmbH | Sildenafil citrate | 22000907002 | 2 |
| Caesar & Loretz GmbH | Sildenafil citrate | 22000907006 | 2 |
| Caesar & Loretz GmbH | Sildenafil citrate | 22000907013 | 2 |
| Caesar & Loretz GmbH | Sildenafil citrate | 22000907018 | 1 |
| Caesar & Loretz GmbH | Sildenafil citrate | B01-2018201 | 1 |
| Cealo/Sanacorp | Sildenafil citrate | 14074703 | 2 |
| Cealo | Sildenafil citrate | 16049805 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Cealo | Sildenafil citrate | 20000163005 | 1 |
| Eu Rho | Sildenafil citrate | 1902031-01 | 1 |
| Eu Rho | Sildenafil citrate | 1908006-01 | 1 |
| EuRho | Sildenafil citrate | 2111002-01 | 2 |
| Euro OTC | Sildenafil citrate | | 1 |
| Euro OTC | Sildenafil citrate | 10061706 | 1 |
| Euro OTC | Sildenafil citrate | 101031827 | 1 |
| Euro OTC | Sildenafil citrate | 103031328 | 1 |
| Euro OTC | Sildenafil citrate | 13110-01 | 1 |
| Euro OTC | Sildenafil citrate | 1311010 | 1 |
| Euro OTC | Sildenafil citrate | 1311010-01 | 4 |
| Euro OTC | Sildenafil citrate | 1311010-02 | 2 |
| Euro OTC | Sildenafil citrate | 131101003 | 1 |
| Euro OTC | Sildenafil citrate | 1311010-03 | 6 |
| Euro OTC | Sildenafil citrate | 131101004 | 1 |
| Euro OTC | Sildenafil citrate | 1311010-04 | 3 |
| Euro OTC | Sildenafil citrate | 1311010-05 | 6 |
| Euro OTC | Sildenafil citrate | 1311010-06 | 11 |
| Euro OTC | Sildenafil citrate | 1311010-07 | 1 |
| Euro OTC | Sildenafil citrate | 1311010-6 | 1 |
| Euro OTC | Sildenafil citrate | 14051402 | 1 |
| Euro OTC | Sildenafil citrate | 15081830 | 1 |
| Euro OTC | Sildenafil citrate | 15097301 | 1 |
| Euro OTC | Sildenafil citrate | 17061405 | 1 |
| Euro OTC | Sildenafil citrate | 17081504 | 1 |
| Euro OTC | Sildenafil citrate | 1807037-01 | 22 |
| Euro OTC | Sildenafil citrate | 1807037-01x2 | 1 |
| Euro OTC | Sildenafil citrate | 19011907 | 1 |
| Euro OTC | Sildenafil citrate | 1902031-01 | 30 |
| Euro OTC | Sildenafil citrate | 19080006-01 | 1 |
| Euro OTC | Sildenafil citrate | 1908006-01 | 24 |
| Euro OTC | Sildenafil citrate | 1908006-02 | 9 |
| Euro OTC | Sildenafil citrate | 19b07-b02-191473 | 1 |
| Euro OTC | Sildenafil citrate | 2003003-01 | 17 |
| Euro OTC | Sildenafil citrate | 2003003-02 | 12 |
| Euro OTC | Sildenafil citrate | 2111002-01 | 19 |
| Euro OTC | Sildenafil citrate | 2111002-1 | 1 |
| Euro OTC | Sildenafil citrate | 2301014-01 | 3 |
| Euro OTC | Sildenafil citrate | 27021802 | 1 |
| Euro OTC | Sildenafil citrate | 311010-06 | 1 |
| Euro OTC | Sildenafil citrate | 5117Q-03684 | 1 |
| Euro | Sildenafil citrate | 1311010-06 | 1 |
| Euro | Sildenafil citrate | 190020031-01 | 1 |
| Fagron | Sildenafil citrate | 13J15-N01 | 2 |
| Fagron | Sildenafil citrate | 14H11-B01-303183 | 1 |
| Fagron | Sildenafil citrate | 15F11-B02 | 2 |
| Fagron | Sildenafil citrate | 15F11-B02-314725 | 1 |
| Fagron | Sildenafil citrate | 15f11-b02-320186 | 1 |
| Fagron | Sildenafil citrate | 15F11-B02-320186 | 1 |
| Fagron | Sildenafil citrate | 15F11-B02-525175 | 3 |
| Fagron | Sildenafil citrate | 16049812 | 1 |
| Fagron | Sildenafil citrate | 16049817 | 1 |
| Fagron | Sildenafil citrate | 16A18-B08 | 2 |
| Fagron | Sildenafil citrate | 16F30-B02 | 1 |
| Fagron | Sildenafil citrate | 16F30-B02-324715 | 3 |
| Fagron | Sildenafil citrate | 16F30-B02-331449 | 1 |
| Fagron | Sildenafil citrate | 16F30-B02-331450 | 4 |
| Fagron | Sildenafil citrate | 16F30-B02-334977 | 2 |
| Fagron | Sildenafil citrate | 16F30-BO2-324715 | 1 |
| Fagron | Sildenafil citrate | 17071505 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sildenafil citrate | 17H31-B02-342459 | 4 |
| Fagron | Sildenafil citrate | 18B13-B06 | 1 |
| Fagron | Sildenafil citrate | 18B13-B06-347389 | 2 |
| Fagron | Sildenafil citrate | 18B13-B06-348000 | 1 |
| Fagron | Sildenafil citrate | 18B13-B06-348001 | 2 |
| Fagron | Sildenafil citrate | 18B13-B06-349160 | 2 |
| Fagron | Sildenafil citrate | 18B13-B06-351981 | 1 |
| Fagron | Sildenafil citrate | 18B13-B06-353827 | 1 |
| Fagron | Sildenafil citrate | 19807-B02-194729 | 1 |
| Fagron | Sildenafil citrate | 19807-B02-194730 | 1 |
| Fagron | Sildenafil citrate | 19B07-802-194730 | 1 |
| Fagron | Sildenafil citrate | 19B07-B02-191472 | 1 |
| Fagron | Sildenafil citrate | 19B07-B02-191473 | 4 |
| Fagron | Sildenafil citrate | 19B07-B02-191474 | 1 |
| Fagron | Sildenafil citrate | 19B07-B02-194728 | 2 |
| Fagron | Sildenafil citrate | 19B07-B02-194729 | 2 |
| Fagron | Sildenafil citrate | 19K12-B01-195593 | 1 |
| Fagron | Sildenafil citrate | 19K12-B01-195594 | 6 |
| Fagron | Sildenafil citrate | 19K12-BO1-195594 | 1 |
| Fagron | Sildenafil citrate | 19K12-BO1-195595 | 1 |
| Fagron | Sildenafil citrate | 20J26-B01-201822 | 7 |
| Fagron | Sildenafil citrate | 20J26-B01-202653 | 1 |
| Fagron | Sildenafil citrate | 21B17-B09-203496 | 3 |
| Fagron | Sildenafil citrate | 21G10-B25 | 1 |
| Fagron | Sildenafil citrate | 21G10-B25-219206 | 2 |
| Fagron | Sildenafil citrate | 2OJ26-B01-201823 | 1 |
| Fagron | Sildenafil citrate | B01-2018202 | 2 |
| Fagron | Sildenafil citrate | BO9-2034906 | 1 |
| Fargon | Sildenafil citrate | 19B07-B02-194727 | 2 |
| Gehe | Sildenafil citrate | 13F24-N03 | 1 |
| Gehe | Sildenafil citrate | 16049805 | 1 |
| GEHE | Sildenafil citrate | 17344003 | 1 |
| Gehe | Sildenafil citrate | 17344008 | 1 |
| Gehe | Sildenafil citrate | 19086606 | 2 |
| GEHE | Sildenafil citrate | 23000811001 | 3 |
| Gehe | Sildenafil citrate | 2403010-01 | 4 |
| Gutenberg-Apotheke | Sildenafil citrate | 1311010-01 | 1 |
| Jenne | Sildenafil citrate | 22000907015 | 1 |
| Noweda/ Caesar & Lor… | Sildenafil citrate | 19086607 | 1 |
| Noweda | Sildenafil citrate | 18B13-B06-347389 | 1 |
| Noweda | Sildenafil citrate | 18B13-B06-348002 | 1 |
| Noweda | Sildenafil citrate | 19086603 | 1 |
| Noweda | Sildenafil citrate | 19086607 | 1 |
| Noweda | Sildenafil citrate | 19B07-B02-194728 | 1 |
| Noweda | Sildenafil citrate | 19B07-BO2-191473 | 1 |
| Noweda | Sildenafil citrate | 21000810008 | 1 |
| Noweda | Sildenafil citrate | 2111002-01 | 4 |
| Noweda | Sildenafil citrate | 2403010-01 | 1 |
| Noweda | Sildenafil citrate | SLC/0518011 | 1 |
| ph euro | Sildenafil citrate | 1908006-02 | 2 |
| Phoenix | Sildenafil citrate | 22000907015 | 1 |
| Phönix | Sildenafil citrate | 1311010-04 | 2 |
| Phönix | Sildenafil citrate | 2003003-01 | 1 |
| Phönix | Sildenafil citrate | 22000907018 | 1 |
| Phönix | Sildenafil citrate | 473102016SC | 1 |
| Phönx/Polpharma | Sildenafil citrate | 1311010-01 | 1 |
| Polpharma/Phoenix | Sildenafil citrate | 131101001 | 1 |
| Sanacorp WE 21.04.17… | Sildenafil citrate | 16049808 | 1 |
| Sanacorp WE 21.04.17… | Sildenafil citrate | 16049814 | 5 |
| Sanacorp | Sildenafil citrate | 1311010-04 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Sildenafil citrate | 14H11-B01-297519 | 2 |
| Sanacorp | Sildenafil citrate | 19B07-b02-191473 | 1 |
| Sanacorp | Sildenafil citrate | 2003003-02 | 1 |
| Sanacorp | Sildenafil citrate | 2111002-01 | 1 |
| Shangei tengben Biot… | Sildenafil citrate | 20200110 | 1 |

- 256 028 spectra from 1666 *Apo-Ident* customers from a total of 51 936 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sildenafil citrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sildenafil citrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 540 | 0 | 212 400 |
| **Type C** | 0 | 856 | 2 | 256 028 |

The substance/substance group *Sildenafil citrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.8889 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7669 % (> 99.4172 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20852 | 20852 | 0.00 | 189.35 |
| 20927 | 20852 | 10.87 | 190.69 |
| 21621 | 24843 | 13.09 | 188.51 |
| 22446 | 22446 | 0.00 | 191.82 |
| 23178 | 23336 | 25.50 | 192.82 |
| 23336 | 23336 | 0.00 | 195.22 |
| 23345 | 23345 | 0.00 | 192.23 |
| 24843 | 24843 | 0.00 | 191.40 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Silver protein** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20178-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Silver protein; Argentum proteinicum

### Special notes

When selecting the *Silver protein* substance/substance group, the following information is displayed to the user:

- Advice for the identification of silver protein: Silver protein acetyltannate is a similar substance, which is not included in the database. An additional analysis of identity may be required, e.g. identity test for Acetyl Ph. Eur. 2.3.1 - does not give a blue colour.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Silver protein | 4 | 3 | 24 |

### Second-stage model

For differentiation of the substance/substance group *Silver protein* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Silver protein* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 41.20 | – |
| Cannabis flower, THC-dominant type | 74.11 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Silver protein* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Silver protein*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Silver protein | 190092 | 24559 | 40 | 20190221* |
| Caelo | Silver protein | 22000752 | 26126 | 30 | 20220511* |
| Fagron | Silver protein | 23D24-B08-229456 | 26820 | 40 | 20230512 |
| Fagron | Silver protein | 23J19-B03-235267 | 27037 | 40 | 20231108 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 150 spectra of 4 reference samples from the substance/substance group *Silver protein*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 176 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 190 spectra of 6 reference samples from the substance/substance group *Silver protein*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Silver protein | 21001315 | 25801 | 50 |
| Caelo | Silver protein | 24001987 | 27430 | 40 |
| Fagron | Silver protein | 24D17-B09-238717 | 27377 | 40 |
| Caelo | Silver protein | 22000752 | 26126SI† | 20 |
| Fagron | Silver protein | 23D24-B08-229456 | 26820SI† | 20 |
| Fagron | Silver protein | 23J19-B03-235267 | 27037SI† | 20 |

- 212 750 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 73 spectra from 51 *Apo-Ident* customers from 26 batches from the substance/substance group *Silver protein*.
- Among them are spectra of independent samples from 24 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Silver protein | 21001315005 | 1 |
| | Silver protein | 22000752007 | 3 |
| | Silver protein | 22001101018 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Silver protein | 22F22-B01-220214 | 3 |
| | Silver protein | 23d24-b08-229456 | 1 |
| | Silver protein | 23D24-B08-229465 | 1 |
| | Silver protein | 23D24-B08-233762 | 2 |
| | Silver protein | 23J19-B03-235267 | 2 |
| | Silver protein | 24001987001 | 1 |
| | Silver protein | 24001987002 | 2 |
| | Silver protein | 24D17-B09-004538 | 8 |
| | Silver protein | 24D17-B09-238717 | 2 |
| | Silver protein | B0822945006 | 1 |
| | Silver protein | B08-2294506 | 1 |
| | Silver protein | B09-2387107 | 2 |
| | Silver protein | PTOR22-0172 | 1 |
| | Silver protein | PTOR23-0666 | 1 |
| 2206030-01 | Silver protein | 2206030-01 | 1 |
| Caelo | Silver protein | 22000752001 | 3 |
| Caelo | Silver protein | 22000752003 | 8 |
| Caelo | Silver protein | 22000752004 | 1 |
| Caelo | Silver protein | 22000752005 | 1 |
| Caelo | Silver protein | 22000752006 | 1 |
| Caelo | Silver protein | 22000752007 | 3 |
| Caelo | Silver protein | 22002752007 | 1 |
| Caesar & Loretz GmbH… | Silver protein | 22000752005 | 1 |
| Caesar & Loretz GmbH | Silver protein | 22000752001 | 3 |
| Caesar & Loretz GmbH | Silver protein | 22000752003 | 1 |
| Caesar & Loretz GmbH | Silver protein | 22000752006 | 1 |
| Caesar & Loretz GmbH | Silver protein | 22000752007 | 2 |
| Euro OTC | Silver protein | 2206030-01 | 1 |
| Fagron | Silver protein | 22D14B06216102 | 1 |
| Fagron | Silver protein | 22D14-B06-216102 | 1 |
| Fagron | Silver protein | 22F22-B01-220214 | 4 |
| Fagron | Silver protein | PTOR22-0172 | 1 |
| Gehe | Silver protein | 22000752005 | 1 |
| Noweda | Silver protein | 22000752007 | 1 |
| Noweda | Silver protein | 22F22-B01-220214 | 1 |
| Noweda | Silver protein | 24D17-B09-004538 | 1 |
| Sanacorp | Silver protein | 23D24-B08-233762 | 1 |

- 256 813 spectra from 1666 *Apo-Ident* customers from a total of 52 128 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Silver protein* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Silver protein* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 150 | 0 | 158 176 |
| **Type B** | 0 | 190 | 0 | 212 750 |
| **Type C** | 0 | 72 | 1 | 256 813 |


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The substance/substance group *Silver protein* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.8421 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.6301 % (> 94.5205 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24559 | 24559 | 0.00 | 50.97 |
| 26126 | 26126 | 0.00 | 31.06 |
| 26820 | 24559 | 17.69 | 43.93 |
| 27037 | 24559 | 15.55 | 53.78 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium acetate trihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20984-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium acetate trihydrate; Natrii acetas trihydricum

### Special notes

When selecting the *Sodium acetate trihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium acetate trihydrate | 6 | 10 | 37 |

### Second-stage model

For differentiation of the substance/substance group *Sodium acetate trihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium acetate trihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 42.07 | – |
| Sodium cromoglicate | 60.16 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium acetate trihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium acetate trihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium acetate trihydrate | 12316506 | 20984 | 40 | 1402111 |
| Caelo | Sodium acetate trihydrate | 13411404 | 21441 | 60 | 20140113 |
| Caelo | Sodium acetate trihydrate | 172003 | 23812 | 40 | 20171107* |
| Euro OTC | Sodium acetate trihydrate | 1507020 | 21861 | 60 | 20150723* |
| Euro OTC | Sodium acetate trihydrate | 1706008 | 23547 | 40 | 20170710* |
| Euro OTC | Sodium acetate trihydrate | 2002041 | 25131 | 40 | 20200331* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 280 spectra of 6 reference samples from the substance/substance group *Sodium acetate trihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 490 spectra of 13 reference samples from the substance/substance group *Sodium acetate trihydrate*.

- Among them are spectra of independent samples from 10 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium acetate trihydrate | 163007 | 22760 | 40 |
| Caelo | Sodium acetate trihydrate | 183152 | 24370 | 40 |
| Caelo | Sodium acetate trihydrate | 21003448002 | 25983 | 40 |
| Caelo | Sodium acetate trihydrate | 22000375 | 26009 | 40 |
| Caelo | Sodium acetate trihydrate | 22003140 | 26478 | 30 |
| Caelo | Sodium acetate trihydrate | 24000576 | 27124 | 40 |
| Euro OTC | Sodium acetate trihydrate | 1608032 | 22802 | 40 |
| Euro OTC | Sodium acetate trihydrate | 1901026 | 24595 | 40 |
| Euro OTC | Sodium acetate trihydrate | 1906023 | 24811 | 40 |
| Euro OTC | Sodium acetate trihydrate | 2007023 | 25312 | 40 |
| Caelo | Sodium acetate trihydrate | 21003448002 | 25983SI | 40 |
| Caelo | Sodium acetate trihydrate | 22000375 | 26009SI | 40 |
| Caelo | Sodium acetate trihydrate | 22003140 | 26478SI | 20 |

- 212 450 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 104 spectra from 70 *Apo-Ident* customers from 39 batches from the substance/substance group *Sodium acetate trihydrate*.

- Among them are spectra of independent samples from 37 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium acetate trihydrate | 21003723003 | 3 |
| | Sodium acetate trihydrate | 22000375003 | 1 |
| | Sodium acetate trihydrate | 22000375004 | 1 |
| | Sodium acetate trihydrate | 22000375008 | 1 |
| | Sodium acetate trihydrate | 22003140008 | 3 |
| | Sodium acetate trihydrate | 24000576005 | 1 |
| Anzag 02.11.20 6,55EUR | Sodium acetate trihydrate | 220110NT | 1 |
| Caelo | Sodium acetate trihydrate | 10353017 | 1 |
| Caelo | Sodium acetate trihydrate | 12027202 | 1 |
| Caelo | Sodium acetate trihydrate | 12027217 | 1 |
| Caelo | Sodium acetate trihydrate | 12027228 | 1 |
| Caelo | Sodium acetate trihydrate | 12316501 | 1 |
| Caelo | Sodium acetate trihydrate | 13295601 | 1 |
| Caelo | Sodium acetate trihydrate | 13295606 | 1 |
| Caelo | Sodium acetate trihydrate | 13411404 | 1 |
| Caelo | Sodium acetate trihydrate | 13411418 | 2 |
| Caelo | Sodium acetate trihydrate | 15118701 | 5 |
| Caelo | Sodium acetate trihydrate | 151452009 | 1 |
| Caelo | Sodium acetate trihydrate | 15145204 | 5 |
| Caelo | Sodium acetate trihydrate | 15145205 | 1 |
| Caelo | Sodium acetate trihydrate | 15145209 | 5 |
| Caelo | Sodium acetate trihydrate | 15145218 | 3 |
| Caelo | Sodium acetate trihydrate | 16300705 | 1 |
| Caelo | Sodium acetate trihydrate | 16300706 | 5 |
| Caelo | Sodium acetate trihydrate | 16300711 | 9 |
| Caelo | Sodium acetate trihydrate | 16300712 | 1 |
| Caelo | Sodium acetate trihydrate | 18006801 | 7 |
| Caelo | Sodium acetate trihydrate | 18173602 | 3 |
| Caelo | Sodium acetate trihydrate | 18315203 | 3 |
| Caelo | Sodium acetate trihydrate | 18315208 | 2 |
| Caelo | Sodium acetate trihydrate | 192116002 | 1 |
| Caelo | Sodium acetate trihydrate | 21000786002 | 3 |
| Caelo | Sodium acetate trihydrate | 21000786006 | 2 |
| Caelo | Sodium acetate trihydrate | 21003448002 | 3 |
| Caelo | Sodium acetate trihydrate | 22000375003 | 2 |
| Caesar & Lorenz GmbH | Sodium acetate trihydrate | 16300706 | 1 |
| Caesar & Loretz GmbH… | Sodium acetate trihydrate | 21003448002 | 1 |
| Caesar & Loretz GmbH | Sodium acetate trihydrate | 192116003 | 1 |
| Caesar & Loretz GmbH | Sodium acetate trihydrate | 21000786002 | 2 |
| Caesar & Loretz GmbH | Sodium acetate trihydrate | 21003448002 | 1 |
| Caesar & Loretz GmbH | Sodium acetate trihydrate | 22000375004 | 1 |
| Caesar & Loretz GmbH | Sodium acetate trihydrate | 22000375008 | 1 |
| Ebert & Jacobi | Sodium acetate trihydrate | 15145209 | 1 |
| Ebert KKH 13.10.16 | Sodium acetate trihydrate | 15145204 | 1 |
| Ebert KKH 13.10.16 | Sodium acetate trihydrate | 15145209 | 1 |
| Euro OTC | Sodium acetate trihydrate | 1005020V-01 | 1 |
| Euro OTC | Sodium acetate trihydrate | 2002041-01 | 1 |
| Euro OTC | Sodium acetate trihydrate | 2007023-01 | 1 |
| Gehe | Sodium acetate trihydrate | 21003723003 | 1 |
| Noweda | Sodium acetate trihydrate | 21003448002 | 1 |
| Noweda | Sodium acetate trihydrate | 21003723003 | 3 |
| Phönix Gotha | Sodium acetate trihydrate | 12316506 | 1 |
| Sanacorp | Sodium acetate trihydrate | 13295601 | 1 |

- 256 782 spectra from 1666 *Apo-Ident* customers from a total of 52 114 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are docu-


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mented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium acetate trihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium acetate trihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 490 | 0 | 212 450 |
| **Type C** | 0 | 104 | 0 | 256 782 |

The substance/substance group *Sodium acetate trihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.7755 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 94.2308 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20984 | 20984 | 0.00 | 98.91 |
| 21441 | 25131 | 9.00 | 101.97 |
| 21861 | 21861 | 0.00 | 87.17 |
| 23547 | 23547 | 0.00 | 92.94 |
| 23812 | 23812 | 0.00 | 94.75 |
| 25131 | 25131 | 0.00 | 106.67 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,

thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium ascorbate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20520-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium ascorbate; Natrii ascorbas

### Special notes

When selecting the *Sodium ascorbate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium ascorbate | 8 | 54 | 36 |

### Second-stage model

For differentiation of the substance/substance group *Sodium ascorbate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium ascorbate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Aluminium chloride hexahydrate | 88.64 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium ascorbate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium ascorbate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium ascorbate | 15429905 | 22899 | 40 | 20160118 |
| Caelo | Sodium ascorbate | 182620 | 24386 | 40 | 20181112* |
| Caelo | Sodium ascorbate | 20001049 | 25554 | 40 | 20200731* |
| Euro OTC | Sodium ascorbate | 1406018-01 | 21583 | 60 | 1411165 |
| Euro OTC | Sodium ascorbate | 1406018-01 | 21789 | 60 | 20140724 |
| Euro OTC | Sodium ascorbate | 1507030 | 21853 | 60 | 20150811* |
| Euro OTC | Sodium ascorbate | 1506018 | 21865 | 60 | 20150706* |
| Euro OTC | Sodium ascorbate | 1510017 | 21946 | 60 | 20151102* |
| Euro OTC | Sodium ascorbate | 1601007 | 22304 | 60 | 20160120* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 480 spectra of 9 reference samples from the substance/substance group *Sodium ascorbate*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 846 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 2459 spectra of 64 reference samples from the substance/substance group *Sodium ascorbate*.

- Among them are spectra of independent samples from 54 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium ascorbate | 162857 | 22761 | 40 |
| Caelo | Sodium ascorbate | 172235 | 23809 | 40 |
| Caelo | Sodium ascorbate | 180326 | 24029 | 40 |
| Caelo | Sodium ascorbate | 191393 | 24751 | 40 |
| Caelo | Sodium ascorbate | 192304 | 24896 | 40 |
| Caelo | Sodium ascorbate | 22002242 | 26365 | 30 |
| Caelo | Sodium ascorbate | 23002840 | 27103 | 40 |
| Caelo | Sodium ascorbate | 24000403 | 27245 | 40 |
| Caelo | Sodium ascorbate | 24002134 | 27448 | 40 |
| Euro OTC | Sodium ascorbate | 1604001 | 22524 | 40 |
| Euro OTC | Sodium ascorbate | 1607044 | 22690 | 40 |
| Euro OTC | Sodium ascorbate | 1611015 | 22864 | 40 |
| Euro OTC | Sodium ascorbate | 1701054 | 23134 | 40 |
| Euro OTC | Sodium ascorbate | 1703012 | 23152 | 40 |
| Euro OTC | Sodium ascorbate | 1705013 | 23430 | 40 |
| Euro OTC | Sodium ascorbate | 1705014 | 23432 | 40 |
| Euro OTC | Sodium ascorbate | 1803005 | 24069 | 40 |
| Euro OTC | Sodium ascorbate | 1807043 | 24149 | 40 |
| Euro OTC | Sodium ascorbate | 1811002 | 24337 | 40 |
| Euro OTC | Sodium ascorbate | 1902021 | 24460 | 40 |
| Euro OTC | Sodium ascorbate | 1906005 | 24786 | 40 |
| Euro OTC | Sodium ascorbate | 1906004 | 24807 | 40 |
| Euro OTC | Sodium ascorbate | 1908026 | 24930 | 40 |
| Euro OTC | Sodium ascorbate | 2003024 | 25164 | 40 |
| Euro OTC | Sodium ascorbate | 2007008 | 25320 | 40 |
| Euro OTC | Sodium ascorbate | 2007009 | 25321 | 40 |
| Euro OTC | Sodium ascorbate | 2007010 | 25322 | 40 |
| Euro OTC | Sodium ascorbate | 2007011 | 25340 | 40 |
| Euro OTC | Sodium ascorbate | 2104010 | 25670 | 40 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Sodium ascorbate | 2105016 | 25710 | 50 |
| Euro OTC | Sodium ascorbate | 2201001 | 25963 | 40 |
| Euro OTC | Sodium ascorbate | 2201002 | 25965 | 40 |
| Euro OTC | Sodium ascorbate | 2205026 | 26187 | 40 |
| Euro OTC | Sodium ascorbate | 2205025 | 26193 | 40 |
| Euro OTC | Sodium ascorbate | 2208013 | 26274 | 40 |
| Euro OTC | Sodium ascorbate | 2208014 | 26278 | 39 |
| Euro OTC | Sodium ascorbate | 2211010 | 26420 | 40 |
| Euro OTC | Sodium ascorbate | 2211011 | 26441 | 40 |
| Euro OTC | Sodium ascorbate | 2308007 | 26933 | 40 |
| Euro OTC | Sodium ascorbate | 2308009 | 26935 | 40 |
| Euro OTC | Sodium ascorbate | 2308008 | 26936 | 40 |
| Euro OTC | Sodium ascorbate | 2402016 | 27197 | 40 |
| Euro OTC | Sodium ascorbate | 2402011 | 27199 | 40 |
| Euro OTC | Sodium ascorbate | 2402014 | 27201 | 40 |
| Euro OTC | Sodium ascorbate | 2402015 | 27202 | 40 |
| Euro OTC | Sodium ascorbate | 2402001 | 27270 | 40 |
| Euro OTC | Sodium ascorbate | 2402002 | 27271 | 40 |
| Euro OTC | Sodium ascorbate | 2402003 | 27272 | 40 |
| Euro OTC | Sodium ascorbate | 2402010 | 27273 | 40 |
| Euro OTC | Sodium ascorbate | 2402005 | 27356 | 40 |
| Euro OTC | Sodium ascorbate | 2402004 | 27357 | 40 |
| Euro OTC | Sodium ascorbate | 2402006 | 27358 | 40 |
| Euro OTC | Sodium ascorbate | 2402007 | 27359 | 40 |
| Euro OTC | Sodium ascorbate | 2402008 | 27618 | 40 |
| Caelo | Sodium ascorbate | 22002242 | 26365SI | 20 |
| Euro OTC | Sodium ascorbate | 1906004 | 24935 | 40 |
| Euro OTC | Sodium ascorbate | 1902021 | 24943 | 40 |
| Euro OTC | Sodium ascorbate | 1906005 | 24976 | 40 |
| Euro OTC | Sodium ascorbate | 2201001 | 25963SI | 40 |
| Euro OTC | Sodium ascorbate | 2201002 | 25965SI | 40 |
| Euro OTC | Sodium ascorbate | 2205026 | 26187SI | 20 |
| Euro OTC | Sodium ascorbate | 2205025 | 26193SI | 20 |
| Euro OTC | Sodium ascorbate | 2208013 | 26274SI | 20 |
| Euro OTC | Sodium ascorbate | 2208014 | 26278SI | 20 |

- 210 481 spectra from a total of 4233 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 45 spectra from 17 *Apo-Ident* customers from 36 batches from the substance/substance group *Sodium ascorbate*.
- Among them are spectra of independent samples from 36 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium ascorbate | 23002840003 | 1 |
| | Sodium ascorbate | 24002134002 | 1 |
| Caelo | Sodium ascorbate | 14079404 | 1 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium ascorbate | 15180505 | 1 |
| Caelo | Sodium ascorbate | 15429917 | 1 |
| Caelo | Sodium ascorbate | 1604001-01 | 1 |
| Caelo | Sodium ascorbate | 1628505 | 1 |
| Caelo | Sodium ascorbate | 16285710 | 1 |
| Caelo | Sodium ascorbate | 17223504 | 1 |
| Caelo | Sodium ascorbate | 17356201 | 1 |
| Caelo | Sodium ascorbate | 27091302 | 1 |
| Caesar & Loretz GmbH/gehe | Sodium ascorbate | 19139304 | 1 |
| Caesar & Loretz GmbH | Sodium ascorbate | 18262001 | 1 |
| Caesar & Loretz GmbH | Sodium ascorbate | 18262009 | 1 |
| Caesar & Loretz GmbH | Sodium ascorbate | 21001574004 | 2 |
| Caesar & Loretz GmbH | Sodium ascorbate | 21003620003 | 1 |
| Euro OTC | Sodium ascorbate | 11081401 | 1 |
| Euro OTC | Sodium ascorbate | 11121301 | 1 |
| Euro OTC | Sodium ascorbate | 12061407 | 1 |
| Euro OTC | Sodium ascorbate | 1210026-01 | 1 |
| Euro OTC | Sodium ascorbate | 13031402 | 1 |
| Euro OTC | Sodium ascorbate | 13051406 | 1 |
| Euro OTC | Sodium ascorbate | 16091301 | 1 |
| Euro OTC | Sodium ascorbate | 170105401 | 1 |
| Euro OTC | Sodium ascorbate | 1703012-01 | 1 |
| Euro OTC | Sodium ascorbate | 200708-01 | 1 |
| Euro OTC | Sodium ascorbate | 20091303 | 1 |
| Euro OTC | Sodium ascorbate | 2208013-01 | 2 |
| Euro OTC | Sodium ascorbate | 28081304 | 1 |
| Euro OTC | Sodium ascorbate | 4021401 | 1 |
| Euro OTC | Sodium ascorbate | 7011405 | 1 |
| Euro OTC | Sodium ascorbate | L1308005-01 | 1 |
| Fagron | Sodium ascorbate | 12L27-N03 | 1 |
| Fagron | Sodium ascorbate | 13C15-N01 | 1 |
| Gatt-Koller | Sodium ascorbate | 1802317 | 3 |
| Pharma Greven | Sodium ascorbate | HPN1904025 | 6 |

- 256 841 spectra from 1666 *Apo-Ident* customers from a total of 52 117 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium ascorbate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium ascorbate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 2459 | 0 | 210 481 |
| **Type C** | 0 | 45 | 0 | 256 841 |

The substance/substance group *Sodium ascorbate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.7560 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 86.6667 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21583 | 21583 | 0.00 | 159.14 |
| 21789 | 21865 | 4.13 | 183.24 |
| 21853 | 21853 | 0.00 | 176.66 |
| 21865 | 21865 | 0.00 | 179.37 |
| 21946 | 21946 | 0.00 | 172.86 |
| 22304 | 22304 | 0.00 | 188.00 |
| 22899 | 22304 | 4.36 | 189.34 |
| 24386 | 24386 | 0.00 | 187.46 |
| 25554 | 25554 | 0.00 | 188.85 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium benzoate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006331-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium benzoate; Natrii benzoas

### Special notes

When selecting the *Sodium benzoate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium benzoate | 11 | 18 | 201 |

### Second-stage model

For differentiation of the substance/substance group *Sodium benzoate* the following second-stage model is used:

- Submodel 18

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium benzoate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Diphenylcyclopropenone | 53.55 | 16.56 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium benzoate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium benzoate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium benzoate | 11267016 | 20752 | 40 | 20110923 |
| Caelo | Sodium benzoate | 13178619 | 21607 | 60 | 20130624 |
| Euro OTC | Sodium benzoate | 1409040-01 | 21713 | 60 | 20141021 |
| Euro OTC | Sodium benzoate | 1506019 | 21825 | 60 | 20150623* |
| Euro OTC | Sodium benzoate | 1510044 | 22236 | 60 | 20151109* |
| Euro OTC | Sodium benzoate | 1602020 | 22363 | 60 | 20160225* |
| Euro OTC | Sodium benzoate | 1610037 | 22867 | 40 | 20161202* |
| Euro OTC | Sodium benzoate | 1701045 | 22997 | 40 | 20170207* |
| Euro OTC | Sodium benzoate | 1711019 | 23900 | 40 | 20171205* |
| Euro OTC | Sodium benzoate | 2001018 | 25081 | 40 | 20200205* |
| Euro OTC | Sodium benzoate | 2009005 | 25379 | 40 | 20201001* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 540 spectra of 11 reference samples from the substance/substance group *Sodium benzoate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 786 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 830 spectra of 22 reference samples from the substance/substance group *Sodium benzoate*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium benzoate | 161371 | 22474 | 60 |
| Caelo | Sodium benzoate | 170558 | 23283 | 40 |
| Caelo | Sodium benzoate | 173530 | 23784 | 40 |
| Caelo | Sodium benzoate | 190541 | 24544 | 40 |
| Caelo | Sodium benzoate | 21001722 | 25805 | 50 |
| Caelo | Sodium benzoate | 22001421 | 26253 | 40 |
| Caelo | Sodium benzoate | 24001874 | 27336 | 40 |
| Euro OTC | Sodium benzoate | 1607005 | 22670 | 40 |
| Euro OTC | Sodium benzoate | 1707024 | 23613 | 40 |
| Euro OTC | Sodium benzoate | 1803034 | 24068 | 40 |
| Euro OTC | Sodium benzoate | 1809005 | 24301 | 40 |
| Euro OTC | Sodium benzoate | 1901043 | 24481 | 40 |
| Euro OTC | Sodium benzoate | 2109016 | 25893 | 50 |
| Euro OTC | Sodium benzoate | 2207025 | 26269 | 40 |
| Euro OTC | Sodium benzoate | 2302017 | 26583 | 40 |
| Euro OTC | Sodium benzoate | 2308011 | 26908 | 40 |
| Euro OTC | Sodium benzoate | 2501001 | 27498 | 40 |
| Fagron | Sodium benzoate | 15B16-B07-308570 | 22895 | 40 |
| Caelo | Sodium benzoate | 22001421 | 26253SI | 20 |
| Euro OTC | Sodium benzoate | 2109016 | 25893SI | 10 |
| Euro OTC | Sodium benzoate | 2207025 | 26269SI | 20 |
| Euro OTC | Sodium benzoate | 2302017 | 26583SI | 20 |

- 212 110 spectra from a total of 4269 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are

listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1057 spectra from 638 *Apo-Ident* customers from 210 batches from the substance/substance group *Sodium benzoate*.
- Among them are spectra of independent samples from 201 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium benzoate | 15044104(Retest) | 1 |
| | Sodium benzoate | 192296016 | 2 |
| | Sodium benzoate | 2001018-01 | 2 |
| | Sodium benzoate | 2009005 | 1 |
| | Sodium benzoate | 21001722008 | 1 |
| | Sodium benzoate | 2109016-01 | 2 |
| | Sodium benzoate | 22001421002 | 6 |
| | Sodium benzoate | 22001421009 | 2 |
| | Sodium benzoate | 22001421011 | 1 |
| | Sodium benzoate | 22001421013 | 1 |
| | Sodium benzoate | 22001421014 | 11 |
| | Sodium benzoate | 22001421019 | 1 |
| | Sodium benzoate | 22001421021 | 13 |
| | Sodium benzoate | 22001421024 | 2 |
| | Sodium benzoate | 22001421025 | 1 |
| | Sodium benzoate | 2200142104 | 1 |
| | Sodium benzoate | 2207025-01 | 6 |
| | Sodium benzoate | 230801101 | 1 |
| | Sodium benzoate | 2308011-01 | 11 |
| | Sodium benzoate | 2308011-02 | 13 |
| | Sodium benzoate | 24001874004 | 5 |
| | Sodium benzoate | 24001874009 | 5 |
| | Sodium benzoate | 24001874011 | 1 |
| | Sodium benzoate | 421021 | 1 |
| | Sodium benzoate | AP210712-01 | 1 |
| AHC | Sodium benzoate | 20001291001 | 3 |
| AHD | Sodium benzoate | 1711019-01 | 3 |
| AHD | Sodium benzoate | 17137606 | 1 |
| AHD | Sodium benzoate | 192296011 | 1 |
| AHD | Sodium benzoate | 22001421011 | 1 |
| AHD | Sodium benzoate | 22001421019 | 1 |
| AHD | Sodium benzoate | 22001421025 | 1 |
| AHD | Sodium benzoate | 2308011-02 | 1 |
| AHD | Sodium benzoate | 24001874002 | 1 |
| Alliance Healthcare | Sodium benzoate | 1304024-01 | 1 |
| Alliance Healthcare | Sodium benzoate | 2207025-01 | 1 |
| Alliance Healthcare | Sodium benzoate | 24001874010 | 1 |
| Alliance/EurRho | Sodium benzoate | 2009005-01 | 1 |
| Alliance | Sodium benzoate | 2009005-01 | 1 |
| Anzag | Sodium benzoate | 20003762002 | 1 |
| Anzag | Sodium benzoate | 20003762010 | 3 |
| Anzag | Sodium benzoate | 21001722009 | 2 |
| Bombastus | Sodium benzoate | 1404011-01 | 1 |
| Bombastus | Sodium benzoate | 17055805 | 1 |
| Bombastus | Sodium benzoate | 17353011 | 1 |
| Caelo | Sodium benzoate | | 1 |
| Caelo | Sodium benzoate | 10003762015 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium benzoate | 10544104 | 1 |
| Caelo | Sodium benzoate | 11267016 | 1 |
| Caelo | Sodium benzoate | 11346109 | 3 |
| Caelo | Sodium benzoate | 1209018-0 | 1 |
| Caelo | Sodium benzoate | 12158401 | 1 |
| Caelo | Sodium benzoate | 12158418 | 1 |
| Caelo | Sodium benzoate | 12158419 | 4 |
| Caelo | Sodium benzoate | 12158424 | 1 |
| Caelo | Sodium benzoate | 12158439 | 4 |
| Caelo | Sodium benzoate | 12J23-N05 | 1 |
| Caelo | Sodium benzoate | 13178603 | 2 |
| Caelo | Sodium benzoate | 13178605 | 3 |
| Caelo | Sodium benzoate | 13178613 | 1 |
| Caelo | Sodium benzoate | 13178619 | 2 |
| Caelo | Sodium benzoate | 13178627 | 1 |
| Caelo | Sodium benzoate | 13178635 | 5 |
| Caelo | Sodium benzoate | 13178647 | 2 |
| Caelo | Sodium benzoate | 13H01-N02 | 1 |
| Caelo | Sodium benzoate | 14166714 | 1 |
| Caelo | Sodium benzoate | 14328702 | 1 |
| Caelo | Sodium benzoate | 1503022-01 | 1 |
| Caelo | Sodium benzoate | 15044102 | 6 |
| Caelo | Sodium benzoate | 15044104 | 9 |
| Caelo | Sodium benzoate | 1506019-01 | 1 |
| Caelo | Sodium benzoate | 151208NB | 1 |
| Caelo | Sodium benzoate | 15135001 | 7 |
| Caelo | Sodium benzoate | 15363401 | 12 |
| Caelo | Sodium benzoate | 15363409 | 3 |
| Caelo | Sodium benzoate | 15363413 | 2 |
| Caelo | Sodium benzoate | 15363414 | 1 |
| Caelo | Sodium benzoate | 15363424 | 11 |
| Caelo | Sodium benzoate | 1610037-01 | 1 |
| Caelo | Sodium benzoate | 161371 | 1 |
| Caelo | Sodium benzoate | 16137103 | 12 |
| Caelo | Sodium benzoate | 16137104 | 2 |
| Caelo | Sodium benzoate | 16137112 | 6 |
| Caelo | Sodium benzoate | 16137118 | 9 |
| Caelo | Sodium benzoate | 17055801 | 5 |
| Caelo | Sodium benzoate | 17055805 | 7 |
| Caelo | Sodium benzoate | 17055806 | 1 |
| Caelo | Sodium benzoate | 17061306 | 1 |
| Caelo | Sodium benzoate | 17137603 | 1 |
| Caelo | Sodium benzoate | 17137604 | 3 |
| Caelo | Sodium benzoate | 17137606 | 18 |
| Caelo | Sodium benzoate | 17137607 | 1 |
| Caelo | Sodium benzoate | 17137609 | 1 |
| Caelo | Sodium benzoate | 1735011 | 2 |
| Caelo | Sodium benzoate | 17353001 | 22 |
| Caelo | Sodium benzoate | 17353002 | 1 |
| Caelo | Sodium benzoate | 17353006 | 2 |
| Caelo | Sodium benzoate | 17353011 | 12 |
| Caelo | Sodium benzoate | 18055805 | 1 |
| Caelo | Sodium benzoate | 1809005-01 | 1 |
| Caelo | Sodium benzoate | 18161201 | 17 |
| Caelo | Sodium benzoate | 18161202 | 1 |
| Caelo | Sodium benzoate | 18161209 | 1 |
| Caelo | Sodium benzoate | 18161211 | 22 |
| Caelo | Sodium benzoate | 18161214 | 1 |
| Caelo | Sodium benzoate | 1827 | 1 |
| Caelo | Sodium benzoate | 1901043-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium benzoate | 19054104 | 10 |
| Caelo | Sodium benzoate | 19054105 | 4 |
| Caelo | Sodium benzoate | 19054106 | 1 |
| Caelo | Sodium benzoate | 19054114 | 22 |
| Caelo | Sodium benzoate | 19091801 | 1 |
| Caelo | Sodium benzoate | 191031709 | 1 |
| Caelo | Sodium benzoate | 192296003 | 27 |
| Caelo | Sodium benzoate | 192296004 | 1 |
| Caelo | Sodium benzoate | 192296011 | 10 |
| Caelo | Sodium benzoate | 192296015 | 12 |
| Caelo | Sodium benzoate | 192296016 | 5 |
| Caelo | Sodium benzoate | 20001291001 | 2 |
| Caelo | Sodium benzoate | 20001291005 | 8 |
| Caelo | Sodium benzoate | 2000376007 | 1 |
| Caelo | Sodium benzoate | 2000376009 | 1 |
| Caelo | Sodium benzoate | 20003762002 | 1 |
| Caelo | Sodium benzoate | 20003762003 | 13 |
| Caelo | Sodium benzoate | 20003762007 | 10 |
| Caelo | Sodium benzoate | 20003762009 | 32 |
| Caelo | Sodium benzoate | 20003762010 | 1 |
| Caelo | Sodium benzoate | 20003762013 | 4 |
| Caelo | Sodium benzoate | 20003762015 | 4 |
| Caelo | Sodium benzoate | 20003792010 | 1 |
| Caelo | Sodium benzoate | 2001291001 | 1 |
| Caelo | Sodium benzoate | 210014722004 | 1 |
| Caelo | Sodium benzoate | 21001722003 | 13 |
| Caelo | Sodium benzoate | 21001722006 | 11 |
| Caelo | Sodium benzoate | 21001722008 | 21 |
| Caelo | Sodium benzoate | 21001722020 | 6 |
| Caelo | Sodium benzoate | 2100172203 | 2 |
| Caelo | Sodium benzoate | 2100172206 | 1 |
| Caelo | Sodium benzoate | 2109016-01 | 1 |
| Caelo | Sodium benzoate | 2200142002 | 1 |
| Caelo | Sodium benzoate | 22001421001 | 5 |
| Caelo | Sodium benzoate | 22001421002 | 15 |
| Caelo | Sodium benzoate | 22001421009 | 4 |
| Caelo | Sodium benzoate | 22001421013 | 1 |
| Caelo | Sodium benzoate | 22001421014 | 3 |
| Caelo | Sodium benzoate | 2215Q-01891 | 1 |
| Caelo | Sodium benzoate | 24021501 | 1 |
| Caelo | Sodium benzoate | 3037647 | 1 |
| Caelo | Sodium benzoate | 3918M-01891 | 1 |
| Caelo | Sodium benzoate | 4315A-01891 | 1 |
| Caelo | Sodium benzoate | 5117A-01891 | 1 |
| Caelo | Sodium benzoate | 5211I-01891 | 1 |
| Caelo | Sodium benzoate | 91443209 | 2 |
| Caelo | Sodium benzoate | NB20180313 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 19054114 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 21001722008 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 20003762013 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 20003762009 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 19054114 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 21001722003 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 192296011 | 1 |
| Caesar & Loretz GmbH/AHD | Sodium benzoate | 20003762013 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 192296003 | 1 |
| Caesar & Loretz GmbH/E | Sodium benzoate | 20003762007 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 19054104 | 1 |
| Caesar & Loretz GmbH… | Sodium benzoate | 20003762009 | 1 |
| Caesar & Loretz GmbH/GEHE | Sodium benzoate | 192296003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Gehe | Sodium benzoate | 192296015 | 2 |
| Caesar & Loretz GmbH/Gehe | Sodium benzoate | 20003762002 | 2 |
| Caesar & Loretz GmbH/Gehe | Sodium benzoate | 20003762010 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 19054114 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 20003762009 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 21001722003 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 21001722008 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 20003762009 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 20001291005 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 22001421002 | 1 |
| Caesar & Loretz GmbH... | Sodium benzoate | 20003762013 | 1 |
| Caesar & Loretz GmbH | Sodium benzoate | 18161201 | 1 |
| Caesar & Loretz GmbH | Sodium benzoate | 18161211 | 1 |
| Caesar & Loretz GmbH | Sodium benzoate | 19054104 | 2 |
| Caesar & Loretz GmbH | Sodium benzoate | 19054114 | 4 |
| Caesar & Loretz GmbH | Sodium benzoate | 192296003 | 3 |
| Caesar & Loretz GmbH | Sodium benzoate | 192296011 | 5 |
| Caesar & Loretz GmbH | Sodium benzoate | 192296015 | 3 |
| Caesar & Loretz GmbH | Sodium benzoate | 20001291001 | 3 |
| Caesar & Loretz GmbH | Sodium benzoate | 20001291005 | 3 |
| Caesar & Loretz GmbH | Sodium benzoate | 20003762003 | 8 |
| Caesar & Loretz GmbH | Sodium benzoate | 20003762007 | 6 |
| Caesar & Loretz GmbH | Sodium benzoate | 20003762009 | 6 |
| Caesar & Loretz GmbH | Sodium benzoate | 20003762013 | 3 |
| Caesar & Loretz GmbH | Sodium benzoate | 21001722003 | 6 |
| Caesar & Loretz GmbH | Sodium benzoate | 21001722004 | 2 |
| Caesar & Loretz GmbH | Sodium benzoate | 21001722006 | 9 |
| Caesar & Loretz GmbH | Sodium benzoate | 21001722008 | 7 |
| Caesar & Loretz GmbH | Sodium benzoate | 21001722009 | 2 |
| Caesar & Loretz GmbH | Sodium benzoate | 21001722020 | 3 |
| Caesar & Loretz GmbH | Sodium benzoate | 22001421001 | 3 |
| Caesar & Loretz GmbH | Sodium benzoate | 22001421002 | 4 |
| Caesar & Loretz GmbH | Sodium benzoate | 22001421014 | 1 |
| Caesar & Loretz Hilden | Sodium benzoate | 18161201 | 1 |
| Caesar&Lorenz | Sodium benzoate | 20003762015 | 1 |
| Calo/Krieger | Sodium benzoate | 19054104 | 1 |
| calo | Sodium benzoate | 17055805 | 1 |
| Chiesi/Krieger | Sodium benzoate | 17353011 | 1 |
| EuRho / Noweda | Sodium benzoate | 2009005-01 | 1 |
| EuRho / Phoenix | Sodium benzoate | 2001018-01 | 1 |
| EuRho Anzag | Sodium benzoate | 1304024-01 | 1 |
| EuRho/Sanacorp | Sodium benzoate | 190104302 | 1 |
| EuRho | Sodium benzoate | 1112006-01 | 1 |
| EuRho | Sodium benzoate | 2009005-01 | 1 |
| Euro OCT / Noweda | Sodium benzoate | 1510044-01 | 1 |
| Euro OTC | Sodium benzoate | 1007019-01 | 1 |
| Euro OTC | Sodium benzoate | 1112006-01 | 1 |
| Euro OTC | Sodium benzoate | 1209018-01 | 4 |
| Euro OTC | Sodium benzoate | 1209018-18 | 1 |
| Euro OTC | Sodium benzoate | 130402401 | 2 |
| Euro OTC | Sodium benzoate | 1304024-01 | 6 |
| Euro OTC | Sodium benzoate | 1307013-01 | 2 |
| Euro OTC | Sodium benzoate | 1309027-01 | 2 |
| Euro OTC | Sodium benzoate | 14040-01 | 1 |
| Euro OTC | Sodium benzoate | 1404011-01 | 4 |
| Euro OTC | Sodium benzoate | 1409040-01 | 2 |
| Euro OTC | Sodium benzoate | 15060119-01 | 1 |
| Euro OTC | Sodium benzoate | 1506019-01 | 7 |
| Euro OTC | Sodium benzoate | 151004401 | 4 |
| Euro OTC | Sodium benzoate | 1510044-01 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Sodium benzoate | 1510044-0104932321 | 1 |
| Euro OTC | Sodium benzoate | 15363424 | 1 |
| Euro OTC | Sodium benzoate | 1602020-01 | 2 |
| Euro OTC | Sodium benzoate | 1607005-01 | 5 |
| Euro OTC | Sodium benzoate | 161003701 | 1 |
| Euro OTC | Sodium benzoate | 1610037-01 | 3 |
| Euro OTC | Sodium benzoate | 16137112 | 1 |
| Euro OTC | Sodium benzoate | 1701045 | 1 |
| Euro OTC | Sodium benzoate | 1701045-01 | 5 |
| Euro OTC | Sodium benzoate | 170702401 | 1 |
| Euro OTC | Sodium benzoate | 1707024-01 | 3 |
| Euro OTC | Sodium benzoate | 171101901 | 1 |
| Euro OTC | Sodium benzoate | 1711019-01 | 3 |
| Euro OTC | Sodium benzoate | 1803034-01 | 3 |
| Euro OTC | Sodium benzoate | 1809005 | 1 |
| Euro OTC | Sodium benzoate | 180900501 | 2 |
| Euro OTC | Sodium benzoate | 1809005-01 | 17 |
| Euro OTC | Sodium benzoate | 1841 | 1 |
| Euro OTC | Sodium benzoate | 1901043 | 1 |
| Euro OTC | Sodium benzoate | 190104301 | 1 |
| Euro OTC | Sodium benzoate | 1901043-01 | 5 |
| Euro OTC | Sodium benzoate | 1901043-02 | 11 |
| Euro OTC | Sodium benzoate | 1946 | 1 |
| Euro OTC | Sodium benzoate | 2001018 | 1 |
| Euro OTC | Sodium benzoate | 200101801 | 1 |
| Euro OTC | Sodium benzoate | 2001018-01 | 13 |
| Euro OTC | Sodium benzoate | 20010-18-01 | 1 |
| Euro OTC | Sodium benzoate | 200900501 | 1 |
| Euro OTC | Sodium benzoate | 2009005-01 | 17 |
| Euro OTC | Sodium benzoate | 210901601 | 1 |
| Euro OTC | Sodium benzoate | 2109016-01 | 11 |
| Euro OTC | Sodium benzoate | 2109016-02 | 1 |
| Euro OTC | Sodium benzoate | 2132 | 1 |
| Euro OTC | Sodium benzoate | 2207025-01 | 1 |
| Euro OTC | Sodium benzoate | 2302017-01 | 1 |
| Euro OTC | Sodium benzoate | 2604040V-05 | 1 |
| Euro Rho | Sodium benzoate | 1803034-01 | 1 |
| Euro/ Phönix | Sodium benzoate | 1404011-01 | 1 |
| EuroTOC / Noweda | Sodium benzoate | 130902701 | 1 |
| Fagron | Sodium benzoate | 12C05-N04 | 1 |
| Fagron | Sodium benzoate | 12D02-N06 | 1 |
| Fagron | Sodium benzoate | 12G04-N04 | 1 |
| Fagron | Sodium benzoate | 12H08-N06 | 1 |
| Fagron | Sodium benzoate | 12J23-N05 | 3 |
| Fagron | Sodium benzoate | 13/27b03288805 | 1 |
| Fagron | Sodium benzoate | 13/27B03288805 | 1 |
| Fagron | Sodium benzoate | 13/27-B03-288805 | 1 |
| Fagron | Sodium benzoate | 13/27-B03-288806 | 2 |
| Fagron | Sodium benzoate | 13C14-N01 | 4 |
| Fagron | Sodium benzoate | 13C14-NO1 | 1 |
| Fagron | Sodium benzoate | 13H01-N02 | 1 |
| Fagron | Sodium benzoate | 13I27-B03288805 | 1 |
| Fagron | Sodium benzoate | 13I27-B03-288806 | 3 |
| Fagron | Sodium benzoate | 13l27-B03-288806 | 1 |
| Fagron | Sodium benzoate | 1412 | 1 |
| Fagron | Sodium benzoate | 14E12-B07 | 1 |
| Fagron | Sodium benzoate | 14E12B07296717 | 1 |
| Fagron | Sodium benzoate | 14E12-B07-306570 | 1 |
| Fagron | Sodium benzoate | 14E12Bo7296717 | 1 |
| Fagron | Sodium benzoate | 14E12BO7296717 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sodium benzoate | 1510044-01 | 2 |
| Fagron | Sodium benzoate | 15363403 | 1 |
| Fagron | Sodium benzoate | 15B16-B07 | 1 |
| Fagron | Sodium benzoate | 15B16-B07-306571 | 2 |
| Fagron | Sodium benzoate | 15B16-B07-308570 | 1 |
| Fagron | Sodium benzoate | 1602020-01 | 1 |
| Fagron | Sodium benzoate | 16B23-B06-322528 | 1 |
| Fagron | Sodium benzoate | 24011401 | 1 |
| Fagron | Sodium benzoate | test | 1 |
| Fiebig 27.06.13 EK3,34 | Sodium benzoate | 1304024-01 | 1 |
| Gehe | Sodium benzoate | 1404011-01 | 1 |
| Gehe | Sodium benzoate | 15044102 | 1 |
| Gehe | Sodium benzoate | 1610037-01 | 1 |
| GEHE | Sodium benzoate | 17137606 | 1 |
| Gehe | Sodium benzoate | 17317606 | 1 |
| GEHE | Sodium benzoate | 17353006 | 2 |
| Gehe | Sodium benzoate | 21001722006 | 1 |
| Gehe | Sodium benzoate | 2109016-01 | 1 |
| Gehe | Sodium benzoate | 22001421009 | 1 |
| Gehe | Sodium benzoate | 22001421014 | 1 |
| Hedinger/Phönix | Sodium benzoate | 15363413 | 1 |
| Hedinger | Sodium benzoate | 13I27-B03 | 1 |
| Holdermann | Sodium benzoate | 22001421013 | 1 |
| Jenne | Sodium benzoate | 20003762007 | 1 |
| Kehr | Sodium benzoate | 1701045-01 | 1 |
| L12 | Sodium benzoate | 17137606 | 2 |
| Nachtestung | Sodium benzoate | 300/18 | 1 |
| Noweda | Sodium benzoate | 1209018-01 | 1 |
| Noweda | Sodium benzoate | 16137103 | 1 |
| Noweda | Sodium benzoate | 16137112 | 1 |
| Noweda | Sodium benzoate | 1707024-01 | 2 |
| Noweda | Sodium benzoate | 1711019-01 | 1 |
| Noweda | Sodium benzoate | 18161201 | 1 |
| Noweda | Sodium benzoate | 189005-01 | 1 |
| Noweda | Sodium benzoate | 1901043-01 | 4 |
| Noweda | Sodium benzoate | 1901043-02 | 2 |
| Noweda | Sodium benzoate | 192296016 | 1 |
| Noweda | Sodium benzoate | 22001421014 | 1 |
| Noweda | Sodium benzoate | 2207025-01 | 1 |
| Noweda | Sodium benzoate | 2300011-01 | 1 |
| Noweda | Sodium benzoate | 2302017-01 | 2 |
| Noweda | Sodium benzoate | 2308011-01 | 2 |
| Noweda | Sodium benzoate | 2308011-02 | 5 |
| Noweda | Sodium benzoate | 24001874004 | 1 |
| Noweda | Sodium benzoate | 240018740096 | 1 |
| Pala | Sodium benzoate | 192296003 | 1 |
| Phoenix goettin | Sodium benzoate | 13I27-B03-288806 | 1 |
| Phoenix | Sodium benzoate | 1610037-01 | 1 |
| Phoenix | Sodium benzoate | 1809005-01 | 5 |
| Phoenix | Sodium benzoate | 18161211 | 7 |
| Phoenix | Sodium benzoate | 2003762009 | 1 |
| Phoenix | Sodium benzoate | 2201421009 | 1 |
| Phönix Gotha | Sodium benzoate | 18161211 | 2 |
| Phönix Gotha | Sodium benzoate | 19054114 | 1 |
| Phönix | Sodium benzoate | 1510044/01 | 1 |
| Phönix | Sodium benzoate | 17137606 | 1 |
| Phönix | Sodium benzoate | 18161201 | 1 |
| Phönix | Sodium benzoate | 192296004 | 2 |
| Phönix | Sodium benzoate | 192296015 | 1 |
| sana | Sodium benzoate | 13178635 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Sodium benzoate | 192296015 | 1 |
| Sanacorp | Sodium benzoate | 20001291005 | 1 |
| Sanacorp | Sodium benzoate | 22001421009 | 1 |
| Sanacorp | Sodium benzoate | 2308011-02 | 1 |
| Standgefäß Apotheke,… | Sodium benzoate | 1510044-01 | 2 |
| Unisan | Sodium benzoate | 1404011-01 | 1 |

- 255 829 spectra from 1666 *Apo-Ident* customers from a total of 51 945 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium benzoate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium benzoate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 540 | 0 | 157 786 |
| **Type B** | 0 | 830 | 0 | 212 110 |
| **Type C** | 0 | 1056 | 1 | 255 829 |

The substance/substance group *Sodium benzoate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8889 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2771 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.9054 % (> 99.6216 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20752 | 22236 | 20.66 | 163.21 |
| 21607 | 22363 | 13.53 | 159.94 |
| 21713 | 22236 | 14.90 | 164.45 |
| 21825 | 21825 | 0.00 | 151.50 |
| 22236 | 22236 | 0.00 | 165.83 |
| 22363 | 22363 | 0.00 | 155.29 |
| 22867 | 22867 | 0.00 | 156.06 |
| 22997 | 22997 | 0.00 | 156.05 |
| 23900 | 23900 | 0.00 | 150.99 |
| 25081 | 25081 | 0.00 | 153.64 |
| 25379 | 25379 | 0.00 | 212.39 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium chondroitin sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24283-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium chondroitin sulfate; Sodium chondroitin sulphate

### Special notes

When selecting the *Sodium chondroitin sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium chondroitin sulfate | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Sodium chondroitin sulfate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium chondroitin sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 27.74 | – |
| Cannabis flower, CBD-dominant type | 40.21 | – |
| Sodium cromoglicate | 59.81 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium chondroitin sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium chondroitin sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Yino Pharma | Sodium chondroitin sulfate | YN010511806006 | 24284 | 40 | 20180912* |
| Yino Pharma | Sodium chondroitin sulfate | YN010511805005 | 24285 | 40 | 20180912* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 80 spectra of 2 reference samples from the substance/substance group *Sodium chondroitin sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 246 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *Sodium chondroitin sulfate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Yino Pharma | Sodium chondroitin sulfate | YN010511806007 | 24283 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Sodium chondroitin sulfate*.

- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium chondroitin sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium chondroitin sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or

incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 80 | 0 | 158 246 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Sodium chondroitin sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 92.5000 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24284 | 24284 | 0.00 | 77.62 |
| 24285 | 24285 | 0.00 | 72.31 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium citrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20662-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium citrate; Natrii citras

### Special notes

When selecting the *Sodium citrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium citrate | 11 | 20 | 428 |

### Second-stage model

For differentiation of the substance/substance group *Sodium citrate* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium citrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 50.24 | – |
| ⋮ | ⋮ | ⋮ |
| Capsaicin | >50 | 142.97 |
| Heparin sodium | >50 | 178.26 |
| Sucrose | >50 | 223.24 |
| Quinine hydrochloride dihydrate | >50 | 258.51 |
| Pyridoxal-5-phosphate hydrate | >50 | 329.38 |
| Levocarnitine | >50 | 333.07 |
| Oxybutynin hydrochloride | >50 | 347.07 |
| Amifampridine | >50 | 433.48 |
| Alfatradiol | >50 | 440.56 |
| Prednicarbate | >50 | 480.83 |
| Ciprofloxacin hydrochloride | >50 | 579.53 |
| Triclosan | >50 | 605.56 |
| Methoxsalen | >50 | 645.84 |
| Tetracaine | >50 | 776.25 |
| Cyproterone acetate | >50 | 1007.97 |
| Norethisterone acetate | >50 | 1137.78 |
| Amitriptyline hydrochloride | >50 | 2088.57 |
| Valine | >50 | 2666.32 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium citrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium citrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium citrate | 12045026 | 20918 | 40 | 20120307 |
| Caelo | Sodium citrate | 13089335 | 21670 | 60 | AR-15-FG-000405-01 |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium citrate | 14112517 | 21718 | 60 | 20140416 |
| Euro OTC | Sodium citrate | 1506041 | 21839 | 60 | 0000010492 |
| Euro OTC | Sodium citrate | 1511017 | 21997 | 60 | 20151130* |
| Euro OTC | Sodium citrate | 1610016 | 22859 | 40 | 20161102* |
| Euro OTC | Sodium citrate | 1701029 | 22996 | 40 | 20170126* |
| Euro OTC | Sodium citrate | 2007022 | 25324 | 40 | 20200820* |
| Fagron | Sodium citrate | 12E04-N05 | 20662 | 40 | 20120516 |
| Fagron | Sodium citrate | 14A13-B02-294541 | 21778 | 60 | 20140424 |
| Fagron | Sodium citrate | 16F10-B01-326088 | 22843 | 40 | 20160711 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 540 spectra of 11 reference samples from the substance/substance group *Sodium citrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 786 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 850 spectra of 23 reference samples from the substance/substance group *Sodium citrate*.

- Among them are spectra of independent samples from 20 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium citrate | 162179 | 22618 | 40 |
| Caelo | Sodium citrate | 173236 | 23789 | 40 |
| Caelo | Sodium citrate | 182083 | 24218 | 40 |
| Caelo | Sodium citrate | 190890 | 24533 | 40 |
| Caelo | Sodium citrate | 20002150 | 25229 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium citrate | 22002778 | 26501 | 40 |
| Euro OTC | Sodium citrate | 1604030 | 22510 | 40 |
| Euro OTC | Sodium citrate | 1607040 | 22687 | 40 |
| Euro OTC | Sodium citrate | 1710006 | 23614 | 40 |
| Euro OTC | Sodium citrate | 1807035 | 24151 | 40 |
| Euro OTC | Sodium citrate | 1901035 | 24487 | 40 |
| Euro OTC | Sodium citrate | 1909020 | 24862 | 40 |
| Euro OTC | Sodium citrate | 2002040 | 25127 | 40 |
| Euro OTC | Sodium citrate | 2101007 | 25550 | 40 |
| Euro OTC | Sodium citrate | 2206011 | 26221 | 40 |
| Euro OTC | Sodium citrate | 2212001 | 26419 | 30 |
| Euro OTC | Sodium citrate | 2307019 | 26862 | 40 |
| Fagron | Sodium citrate | 22A15-B18-219203 | 26154 | 40 |
| Fagron | Sodium citrate | 22K17-B15-223095 | 26983 | 40 |
| Fagron | Sodium citrate | 25A31-B03-009651 | 27640 | 40 |
| Caelo | Sodium citrate | 22002778 | 26501SI | 20 |
| Euro OTC | Sodium citrate | 2206011 | 26221SI | 20 |
| Fagron | Sodium citrate | 22A15-B18-219203 | 26154SI | 20 |

- 212 090 spectra from a total of 4267 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2414 spectra from 1098 *Apo-Ident* customers from 441 batches from the substance/substance group *Sodium citrate*.

- Among them are spectra of independent samples from 427 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium citrate | | 1 |
| | Sodium citrate | 1234 | 1 |
| | Sodium citrate | 1710006-01 | 1 |
| | Sodium citrate | 18208302 | 2 |
| | Sodium citrate | 190890002 | 1 |
| | Sodium citrate | 190890007 | 1 |
| | Sodium citrate | 21002580012 | 1 |
| | Sodium citrate | 21002580015 | 1 |
| | Sodium citrate | 21002580018 | 1 |
| | Sodium citrate | 21002580019 | 1 |
| | Sodium citrate | 2101007-01 | 1 |
| | Sodium citrate | 22002778001 | 1 |
| | Sodium citrate | 22002778003 | 7 |
| | Sodium citrate | 22002778007 | 33 |
| | Sodium citrate | 22002778008 | 2 |
| | Sodium citrate | 2206011-01 | 2 |
| | Sodium citrate | 2212001 | 1 |
| | Sodium citrate | 2212001-001 | 1 |
| | Sodium citrate | 2212001-01 | 18 |
| | Sodium citrate | 221200102 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium citrate | 2212001-02 | 4 |
| | Sodium citrate | 2212001-03 | 3 |
| | Sodium citrate | 230004730002 | 1 |
| | Sodium citrate | 23000473001 | 1 |
| | Sodium citrate | 23000473002 | 22 |
| | Sodium citrate | 230019-01 | 1 |
| | Sodium citrate | 23003487003 | 14 |
| | Sodium citrate | 23003487004 | 2 |
| | Sodium citrate | 23003487005 | 10 |
| | Sodium citrate | 23003487008 | 1 |
| | Sodium citrate | 2307019-01 | 5 |
| | Sodium citrate | 3118872 | 3 |
| | Sodium citrate | 3132630 | 1 |
| AHD | Sodium citrate | 1607040-01 | 2 |
| AHD | Sodium citrate | 1701029-01 | 2 |
| AHD | Sodium citrate | 1710006-01 | 2 |
| AHD | Sodium citrate | 17323602 | 2 |
| AHD | Sodium citrate | 1901035-01 | 1 |
| AHD | Sodium citrate | 22002778003 | 1 |
| Alli | Sodium citrate | 22002778007 | 1 |
| Alliance healfcare | Sodium citrate | 17h07b04347340 | 1 |
| Alliance Healthcare | Sodium citrate | 1211030-01 | 1 |
| Alliance | Sodium citrate | 22002778003 | 2 |
| Alliance | Sodium citrate | 2202778003 | 1 |
| Alliance | Sodium citrate | 23003487003 | 1 |
| Anzag | Sodium citrate | 1512705 | 1 |
| Anzag | Sodium citrate | 20A20-F03-369331 | 1 |
| Anzag | Sodium citrate | 21002580012 | 1 |
| Anzag | Sodium citrate | 2212001-01 | 1 |
| ApoIdent/ Phoenix | Sodium citrate | 1710006-01 | 1 |
| apo-ident | Sodium citrate | 1701029-01 | 1 |
| Apo-ident | Sodium citrate | 3065202 | 1 |
| Audor Pharma | Sodium citrate | 171000601 | 1 |
| Aug. Hedinger | Sodium citrate | 8765456 | 1 |
| Bombastus | Sodium citrate | 73155098 | 1 |
| Caelo | Sodium citrate | | 13 |
| Caelo | Sodium citrate | 1042 | 1 |
| Caelo | Sodium citrate | 1107011-01 | 1 |
| Caelo | Sodium citrate | 11081514 | 1 |
| Caelo | Sodium citrate | 11121303 | 1 |
| Caelo | Sodium citrate | 11219012 | 6 |
| Caelo | Sodium citrate | 1123588946 | 1 |
| Caelo | Sodium citrate | 11304311 | 3 |
| Caelo | Sodium citrate | 1151351 | 2 |
| Caelo | Sodium citrate | 1161207 | 2 |
| Caelo | Sodium citrate | 1200002828764 | 1 |
| Caelo | Sodium citrate | 12045001 | 1 |
| Caelo | Sodium citrate | 12045002 | 1 |
| Caelo | Sodium citrate | 12045004 | 4 |
| Caelo | Sodium citrate | 12045006 | 1 |
| Caelo | Sodium citrate | 12045008 | 4 |
| Caelo | Sodium citrate | 12045011 | 6 |
| Caelo | Sodium citrate | 12045012 | 1 |
| Caelo | Sodium citrate | 12045016 | 5 |
| Caelo | Sodium citrate | 12045016-3451311172 | 1 |
| Caelo | Sodium citrate | 12045019 | 4 |
| Caelo | Sodium citrate | 12045024 | 5 |
| Caelo | Sodium citrate | 12045026 | 7 |
| Caelo | Sodium citrate | 1223test | 1 |
| Caelo | Sodium citrate | 1234 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium citrate | 123456 | 2 |
| Caelo | Sodium citrate | 1234567 | 1 |
| Caelo | Sodium citrate | 123456789 | 1 |
| Caelo | Sodium citrate | 1234test | 1 |
| Caelo | Sodium citrate | 1234Test | 3 |
| Caelo | Sodium citrate | 12358Test | 1 |
| Caelo | Sodium citrate | 123658 | 1 |
| Caelo | Sodium citrate | 123e2 | 1 |
| Caelo | Sodium citrate | 123test | 6 |
| Caelo | Sodium citrate | 123Test | 16 |
| Caelo | Sodium citrate | 123tst | 1 |
| Caelo | Sodium citrate | 1256825 | 1 |
| Caelo | Sodium citrate | 125874566 | 1 |
| Caelo | Sodium citrate | 128896 | 1 |
| Caelo | Sodium citrate | 12897 | 1 |
| Caelo | Sodium citrate | 13/24-B13-287921 | 1 |
| Caelo | Sodium citrate | 1308908 | 1 |
| Caelo | Sodium citrate | 13089304 | 2 |
| Caelo | Sodium citrate | 13089305 | 1 |
| Caelo | Sodium citrate | 13089308 | 7 |
| Caelo | Sodium citrate | 13089314 | 1 |
| Caelo | Sodium citrate | 13089317 | 7 |
| Caelo | Sodium citrate | 13089319 | 4 |
| Caelo | Sodium citrate | 13089325 | 3 |
| Caelo | Sodium citrate | 13089329 | 1 |
| Caelo | Sodium citrate | 13089331 | 5 |
| Caelo | Sodium citrate | 13089335 | 8 |
| Caelo | Sodium citrate | 131103501 | 1 |
| Caelo | Sodium citrate | 1319A-01900 | 1 |
| Caelo | Sodium citrate | 1404033-01 | 3 |
| Caelo | Sodium citrate | 140510/1 | 1 |
| Caelo | Sodium citrate | 140731NC | 1 |
| Caelo | Sodium citrate | 14112502 | 26 |
| Caelo | Sodium citrate | 14112517 | 12 |
| Caelo | Sodium citrate | 14112518 | 1 |
| Caelo | Sodium citrate | 14112520 | 1 |
| Caelo | Sodium citrate | 1411502 | 1 |
| Caelo | Sodium citrate | 1412014-01 | 1 |
| Caelo | Sodium citrate | 14360407 | 1 |
| Caelo | Sodium citrate | 14369402 | 2 |
| Caelo | Sodium citrate | 14369406 | 9 |
| Caelo | Sodium citrate | 14369407 | 49 |
| Caelo | Sodium citrate | 14369411 | 3 |
| Caelo | Sodium citrate | 14369413 | 22 |
| Caelo | Sodium citrate | 14369414 | 1 |
| Caelo | Sodium citrate | 14369415 | 1 |
| Caelo | Sodium citrate | 14369416 | 1 |
| Caelo | Sodium citrate | 14369423 | 21 |
| Caelo | Sodium citrate | 14369424 | 2 |
| Caelo | Sodium citrate | 1469413 | 1 |
| Caelo | Sodium citrate | 14838 | 1 |
| Caelo | Sodium citrate | 14A13-B02_300395 | 1 |
| Caelo | Sodium citrate | 1506041-01 | 1 |
| Caelo | Sodium citrate | 151101701 | 1 |
| Caelo | Sodium citrate | 1511017-01 | 8 |
| Caelo | Sodium citrate | 15212705 | 5 |
| Caelo | Sodium citrate | 154662 | 1 |
| Caelo | Sodium citrate | 15C27-B01-309893 | 1 |
| Caelo | Sodium citrate | 160704001 | 1 |
| Caelo | Sodium citrate | 1607040-01 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium citrate | 160955707 | 1 |
| Caelo | Sodium citrate | 16095702 | 4 |
| Caelo | Sodium citrate | 16095707 | 9 |
| Caelo | Sodium citrate | 1610016-01 | 4 |
| Caelo | Sodium citrate | 16217901 | 1 |
| Caelo | Sodium citrate | 16217902 | 1 |
| Caelo | Sodium citrate | 16217905 | 19 |
| Caelo | Sodium citrate | 16217906 | 1 |
| Caelo | Sodium citrate | 16217908 | 1 |
| Caelo | Sodium citrate | 16217909 | 11 |
| Caelo | Sodium citrate | 16217912 | 3 |
| Caelo | Sodium citrate | 16217913 | 1 |
| Caelo | Sodium citrate | 16217914 | 5 |
| Caelo | Sodium citrate | 16217915 | 2 |
| Caelo | Sodium citrate | 16F10-B01-326093 | 1 |
| Caelo | Sodium citrate | 16F10-B01-327510 | 1 |
| Caelo | Sodium citrate | 170102901 | 1 |
| Caelo | Sodium citrate | 1701029-01 | 5 |
| Caelo | Sodium citrate | 17081501 | 1 |
| Caelo | Sodium citrate | 1710006-02 | 1 |
| Caelo | Sodium citrate | 171006-02 | 1 |
| Caelo | Sodium citrate | 171025NC/16217909 | 1 |
| Caelo | Sodium citrate | 171212021 | 1 |
| Caelo | Sodium citrate | 17323601 | 34 |
| Caelo | Sodium citrate | 17323602 | 7 |
| Caelo | Sodium citrate | 17323603 | 6 |
| Caelo | Sodium citrate | 17323608 | 39 |
| Caelo | Sodium citrate | 17323609 | 8 |
| Caelo | Sodium citrate | 1732361 | 1 |
| Caelo | Sodium citrate | 17323612 | 5 |
| Caelo | Sodium citrate | 1732601 | 1 |
| Caelo | Sodium citrate | 1732608 | 1 |
| Caelo | Sodium citrate | 1792380 | 1 |
| Caelo | Sodium citrate | 17H7-B04-345098 | 1 |
| Caelo | Sodium citrate | 18028305 | 1 |
| Caelo | Sodium citrate | 1807035-01 | 6 |
| Caelo | Sodium citrate | 1807035-02 | 2 |
| Caelo | Sodium citrate | 1807053-01 | 1 |
| Caelo | Sodium citrate | 18208302 | 24 |
| Caelo | Sodium citrate | 18208303 | 8 |
| Caelo | Sodium citrate | 18208305 | 1 |
| Caelo | Sodium citrate | 18208307 | 23 |
| Caelo | Sodium citrate | 18208308 | 4 |
| Caelo | Sodium citrate | 18208313 | 8 |
| Caelo | Sodium citrate | 18208314 | 3 |
| Caelo | Sodium citrate | 18208315 | 32 |
| Caelo | Sodium citrate | 18G25-B07-352737 | 1 |
| Caelo | Sodium citrate | 1901035-01 | 3 |
| Caelo | Sodium citrate | 190890002 | 11 |
| Caelo | Sodium citrate | 190890003 | 2 |
| Caelo | Sodium citrate | 190890004 | 3 |
| Caelo | Sodium citrate | 190890005 | 3 |
| Caelo | Sodium citrate | 190890007 | 19 |
| Caelo | Sodium citrate | 190890009 | 29 |
| Caelo | Sodium citrate | 19089001 | 4 |
| Caelo | Sodium citrate | 19089002 | 6 |
| Caelo | Sodium citrate | 19089003 | 11 |
| Caelo | Sodium citrate | 19089004 | 32 |
| Caelo | Sodium citrate | 19089009 | 1 |
| Caelo | Sodium citrate | 1909020-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium citrate | 19121802 | 1 |
| Caelo | Sodium citrate | 20002150001 | 2 |
| Caelo | Sodium citrate | 20002150003 | 4 |
| Caelo | Sodium citrate | 20004144004 | 1 |
| Caelo | Sodium citrate | 20004144005 | 3 |
| Caelo | Sodium citrate | 20004144008 | 1 |
| Caelo | Sodium citrate | 20004144010 | 1 |
| Caelo | Sodium citrate | 2016-01-28AVIGr | 1 |
| Caelo | Sodium citrate | 20170412 | 1 |
| Caelo | Sodium citrate | 2019Q-01900 | 1 |
| Caelo | Sodium citrate | 21002580003 | 4 |
| Caelo | Sodium citrate | 21002580004 | 6 |
| Caelo | Sodium citrate | 21002580007 | 4 |
| Caelo | Sodium citrate | 21002580008 | 2 |
| Caelo | Sodium citrate | 21002580009 | 2 |
| Caelo | Sodium citrate | 21002580010 | 6 |
| Caelo | Sodium citrate | 21002580011 | 3 |
| Caelo | Sodium citrate | 21002580012 | 16 |
| Caelo | Sodium citrate | 21002580013 | 1 |
| Caelo | Sodium citrate | 21002580015 | 2 |
| Caelo | Sodium citrate | 21002580016 | 9 |
| Caelo | Sodium citrate | 21002580018 | 8 |
| Caelo | Sodium citrate | 21002580019 | 1 |
| Caelo | Sodium citrate | 21121203 | 1 |
| Caelo | Sodium citrate | 2116A-01900 | 1 |
| Caelo | Sodium citrate | 22002778002 | 1 |
| Caelo | Sodium citrate | 22002778003 | 7 |
| Caelo | Sodium citrate | 22002778007 | 11 |
| Caelo | Sodium citrate | 220516(190890009) | 1 |
| Caelo | Sodium citrate | 220914PML01 | 1 |
| Caelo | Sodium citrate | 23003487003 | 1 |
| Caelo | Sodium citrate | 23003487005 | 1 |
| Caelo | Sodium citrate | 2345678 | 1 |
| Caelo | Sodium citrate | 2413A-01900 | 1 |
| Caelo | Sodium citrate | 25383143 | 1 |
| Caelo | Sodium citrate | 2543 | 1 |
| Caelo | Sodium citrate | 2815A-01900 | 1 |
| Caelo | Sodium citrate | 2818A-01900 | 1 |
| Caelo | Sodium citrate | 2908022-01 | 1 |
| Caelo | Sodium citrate | 30081802 | 1 |
| Caelo | Sodium citrate | 3040611 | 1 |
| Caelo | Sodium citrate | 4111Q-01900 | 1 |
| Caelo | Sodium citrate | 459842 | 1 |
| Caelo | Sodium citrate | 4680 | 1 |
| Caelo | Sodium citrate | 49131-01900 | 1 |
| Caelo | Sodium citrate | 50815PMS01 | 1 |
| Caelo | Sodium citrate | 516-01900 | 1 |
| Caelo | Sodium citrate | 70214PJK01 | 1 |
| Caelo | Sodium citrate | 8/AKD41 | 1 |
| Caelo | Sodium citrate | AM1007248703 | 1 |
| Caelo | Sodium citrate | K-280313-1 | 1 |
| Caelo | Sodium citrate | P-07081921/18208313 | 1 |
| Caelo | Sodium citrate | Test | 3 |
| Caelo | Sodium citrate | Test123 | 1 |
| Caelo | Sodium citrate | test13 | 1 |
| Caelo | Sodium citrate | Testmessung | 1 |
| Caelo | Sodium citrate | TestmessungnachRep | 1 |
| Caelo | Sodium citrate | Validierungsmessung | 1 |
| caeo | Sodium citrate | 22002778003 | 1 |
| Caesar & Loretz / Gehe | Sodium citrate | 21002580016 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz / Sa... | Sodium citrate | 190890007 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 14369406 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 20004144005 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 21002580003 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 18208302 | 2 |
| Caesar & Loretz GmbH... | Sodium citrate | 21002580018 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 20002150001 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 190890002 | 1 |
| Caesar & Loretz GmbH /AHD | Sodium citrate | 22002778007 | 1 |
| Caesar & Loretz GmbH/ AHD | Sodium citrate | 18208315 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 190890007 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 190890004 | 2 |
| Caesar & Loretz GmbH... | Sodium citrate | 19089003 | 1 |
| Caesar & Loretz GmbH/Gehe | Sodium citrate | 18208302 | 1 |
| Caesar & Loretz GmbH/Gehe | Sodium citrate | 18208315 | 1 |
| Caesar & Loretz GmbH/Gehe | Sodium citrate | 21002580003 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 190890009 | 1 |
| Caesar & Loretz GmbH/K | Sodium citrate | 190890009 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 18208307 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 190890009 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 19089002 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 22002778003 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 1701029-01 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 18208315 | 2 |
| Caesar & Loretz GmbH... | Sodium citrate | 190890009 | 1 |
| Caesar & Loretz GmbH... | Sodium citrate | 19089004 | 2 |
| Caesar & Loretz GmbH | Sodium citrate | 13089334 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 14112517 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 14369406 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 1607040-01 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 17323601 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 17323608 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 18208302 | 4 |
| Caesar & Loretz GmbH | Sodium citrate | 18208305 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 18208307 | 4 |
| Caesar & Loretz GmbH | Sodium citrate | 18208308 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 18208315 | 5 |
| Caesar & Loretz GmbH | Sodium citrate | 190890002 | 3 |
| Caesar & Loretz GmbH | Sodium citrate | 190890003 | 3 |
| Caesar & Loretz GmbH | Sodium citrate | 190890004 | 2 |
| Caesar & Loretz GmbH | Sodium citrate | 190890007 | 8 |
| Caesar & Loretz GmbH | Sodium citrate | 190890009 | 9 |
| Caesar & Loretz GmbH | Sodium citrate | 19089002 | 2 |
| Caesar & Loretz GmbH | Sodium citrate | 19089003 | 3 |
| Caesar & Loretz GmbH | Sodium citrate | 19089004 | 7 |
| Caesar & Loretz GmbH | Sodium citrate | 1909020-01 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 20002150003 | 4 |
| Caesar & Loretz GmbH | Sodium citrate | 2100250012 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580004 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580007 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580009 | 2 |
| Caesar & Loretz GmbH | Sodium citrate | 2100258001 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580010 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580011 | 3 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580012 | 3 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580015 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 21002580016 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 22002778003 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 22002778007 | 1 |
| Caesar & Loretz GmbH | Sodium citrate | 23000473002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz/Geil… | Sodium citrate | 190890007 | 1 |
| Caesar&Loretz GmbH/Anzag | Sodium citrate | 14369407 | 1 |
| Caesar&Loretz GmbH | Sodium citrate | 12045026 | 1 |
| Caesar&Loretz GmbH | Sodium citrate | 14112502 | 1 |
| Caesar/Noweda | Sodium citrate | 12045008 | 1 |
| Caeser und Loretz GmbH | Sodium citrate | 18208308 | 1 |
| Caleo | Sodium citrate | 18208302 | 1 |
| Calo, Hilden/ Phönix | Sodium citrate | 19089004 | 1 |
| Cealo / Otto Geilenk… | Sodium citrate | 14369407 | 2 |
| Cealo/Sanacorp | Sodium citrate | 21002580012 | 1 |
| Cealo | Sodium citrate | 190890007 | 1 |
| Defektur | Sodium citrate | 19121902 | 1 |
| Delta Apotheke | Sodium citrate | 17323608 | 1 |
| Eigenherstellung Defektur | Sodium citrate | 5082103 | 1 |
| Eigenherstellung/ De… | Sodium citrate | 12102101 | 1 |
| EuRho / Alliance | Sodium citrate | 1807035-02 | 1 |
| EuRho / Noweda | Sodium citrate | 1807035-01 | 1 |
| EuRho / Phoenix | Sodium citrate | 151101017-01 | 1 |
| EuRho 14.07.15 Gehe | Sodium citrate | 1404033-01 | 2 |
| EuRho/ AHD | Sodium citrate | 1701029-01 | 1 |
| EuRho/ Phönix | Sodium citrate | 3048768 | 1 |
| EuRho/Gehe | Sodium citrate | 1901035-01 | 2 |
| EuRho/Jenne | Sodium citrate | 1909020-01 | 1 |
| EuRho/Noweda | Sodium citrate | 2206011-01 | 1 |
| EuRho/Sanacorp | Sodium citrate | 1107011-02 | 1 |
| EuRho/Sanacorp | Sodium citrate | 1506041-01 | 1 |
| EuRho | Sodium citrate | 1070102901 | 1 |
| EuRho | Sodium citrate | 1107011-02 | 1 |
| EuRho | Sodium citrate | 1205026-02 | 1 |
| EuRho | Sodium citrate | 1211030-01 | 1 |
| EuRho | Sodium citrate | 1311035-01 | 1 |
| EuRho | Sodium citrate | 140403301 | 1 |
| EuRho | Sodium citrate | 1412014-01 | 1 |
| EuRho | Sodium citrate | 1607040-01 | 5 |
| EuRho | Sodium citrate | 1610016-01 | 2 |
| EuRho | Sodium citrate | 1901035-01 | 1 |
| Eurho | Sodium citrate | 2007022-01 | 1 |
| EuRho | Sodium citrate | 2007022-01 | 1 |
| Eurho | Sodium citrate | 2101007-01 | 1 |
| EuRho | Sodium citrate | 3032981 | 1 |
| EuRho | Sodium citrate | 3108854 | 1 |
| EuRho | Sodium citrate | 4611M-01900 | 1 |
| Euro Gehe | Sodium citrate | 1909020-01 | 1 |
| Euro OTC | Sodium citrate | | 7 |
| Euro OTC | Sodium citrate | 100800903 | 1 |
| Euro OTC | Sodium citrate | 1017I-01900 | 1 |
| Euro OTC | Sodium citrate | 1073240 | 1 |
| Euro OTC | Sodium citrate | 1107011-01 | 1 |
| Euro OTC | Sodium citrate | 1107011-02 | 1 |
| Euro OTC | Sodium citrate | 1205026-02 | 4 |
| Euro OTC | Sodium citrate | 1211030-01 | 10 |
| Euro OTC | Sodium citrate | 12345 | 2 |
| Euro OTC | Sodium citrate | 1305001-01 | 11 |
| Euro OTC | Sodium citrate | 1311025-01 | 1 |
| Euro OTC | Sodium citrate | 1311035-01 | 28 |
| Euro OTC | Sodium citrate | 13I24-B13-287921 | 1 |
| Euro OTC | Sodium citrate | 140403301 | 5 |
| Euro OTC | Sodium citrate | 1404033-01 | 15 |
| Euro OTC | Sodium citrate | 1412014-01 | 18 |
| Euro OTC | Sodium citrate | 1413M-01900 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Sodium citrate | 14201401 | 1 |
| Euro OTC | Sodium citrate | 1506041-01 | 18 |
| Euro OTC | Sodium citrate | 150922-1078 | 1 |
| Euro OTC | Sodium citrate | 151101701 | 3 |
| Euro OTC | Sodium citrate | 1511017-01 | 29 |
| Euro OTC | Sodium citrate | 15111017-01 | 1 |
| Euro OTC | Sodium citrate | 1521017-01 | 1 |
| Euro OTC | Sodium citrate | 15212705 | 1 |
| Euro OTC | Sodium citrate | 156422 | 1 |
| Euro OTC | Sodium citrate | 16070-01 | 1 |
| Euro OTC | Sodium citrate | 1607040-01 | 20 |
| Euro OTC | Sodium citrate | 160740-01 | 1 |
| Euro OTC | Sodium citrate | 161001601 | 1 |
| Euro OTC | Sodium citrate | 1610016-01 | 44 |
| Euro OTC | Sodium citrate | 1610016601 | 1 |
| Euro OTC | Sodium citrate | 1645265 | 3 |
| Euro OTC | Sodium citrate | 17010006-02 | 1 |
| Euro OTC | Sodium citrate | 170102901 | 1 |
| Euro OTC | Sodium citrate | 1701029-01 | 41 |
| Euro OTC | Sodium citrate | 1701029-02 | 1 |
| Euro OTC | Sodium citrate | 17061407 | 1 |
| Euro OTC | Sodium citrate | 1710006-01 | 13 |
| Euro OTC | Sodium citrate | 1710006-015607 | 1 |
| Euro OTC | Sodium citrate | 1710006-02 | 10 |
| Euro OTC | Sodium citrate | 171006-02 | 1 |
| Euro OTC | Sodium citrate | 180703501 | 1 |
| Euro OTC | Sodium citrate | 1807035-01 | 32 |
| Euro OTC | Sodium citrate | 1807035-01ciclo | 1 |
| Euro OTC | Sodium citrate | 1807035-02 | 11 |
| Euro OTC | Sodium citrate | 180735-01 | 1 |
| Euro OTC | Sodium citrate | 1819A-01900 | 1 |
| Euro OTC | Sodium citrate | 187035-01 | 1 |
| Euro OTC | Sodium citrate | 19009020-01 | 1 |
| Euro OTC | Sodium citrate | 190103501 | 1 |
| Euro OTC | Sodium citrate | 1901035-01 | 53 |
| Euro OTC | Sodium citrate | 19090120-01 | 1 |
| Euro OTC | Sodium citrate | 1909020 | 1 |
| Euro OTC | Sodium citrate | 1909020-01 | 38 |
| Euro OTC | Sodium citrate | 190902-01 | 1 |
| Euro OTC | Sodium citrate | 190920 | 1 |
| Euro OTC | Sodium citrate | 2002040-01 | 31 |
| Euro OTC | Sodium citrate | 2002040-1 | 1 |
| Euro OTC | Sodium citrate | 200702201 | 1 |
| Euro OTC | Sodium citrate | 2007022-01 | 37 |
| Euro OTC | Sodium citrate | 20200810-6 | 1 |
| Euro OTC | Sodium citrate | 20A20-F03-369331 | 1 |
| Euro OTC | Sodium citrate | 2101007 | 2 |
| Euro OTC | Sodium citrate | 210100701 | 1 |
| Euro OTC | Sodium citrate | 2101007-01 | 48 |
| Euro OTC | Sodium citrate | 2114M1900 | 1 |
| Euro OTC | Sodium citrate | 2206011-01 | 38 |
| Euro OTC | Sodium citrate | 22101305 | 1 |
| Euro OTC | Sodium citrate | 2212001-01 | 3 |
| Euro OTC | Sodium citrate | 2212001-02 | 1 |
| Euro OTC | Sodium citrate | 22606011-01 | 1 |
| Euro OTC | Sodium citrate | 23062015C | 1 |
| Euro OTC | Sodium citrate | 25425 | 2 |
| Euro OTC | Sodium citrate | 2546426 | 1 |
| Euro OTC | Sodium citrate | 2903001-01 | 1 |
| Euro OTC | Sodium citrate | 30111301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Sodium citrate | 3021717 | 1 |
| Euro OTC | Sodium citrate | 3032805 | 3 |
| Euro OTC | Sodium citrate | 3032981 | 1 |
| Euro OTC | Sodium citrate | 3048768 | 4 |
| Euro OTC | Sodium citrate | 30611044 | 5 |
| Euro OTC | Sodium citrate | 3065202 | 2 |
| Euro OTC | Sodium citrate | 3087522 | 2 |
| Euro OTC | Sodium citrate | 3095222 | 3 |
| Euro OTC | Sodium citrate | 3108854 | 1 |
| Euro OTC | Sodium citrate | 3454 | 1 |
| Euro OTC | Sodium citrate | 345678 | 1 |
| Euro OTC | Sodium citrate | 358528 | 1 |
| Euro OTC | Sodium citrate | 4716E-01900 | 1 |
| Euro OTC | Sodium citrate | 48(08598497) | 1 |
| Euro OTC | Sodium citrate | 5116E-01900 | 1 |
| Euro OTC | Sodium citrate | 815757/6745 | 1 |
| Euro OTC | Sodium citrate | 901035-011 | 1 |
| euro//Noweda | Sodium citrate | 1701029-01 | 1 |
| Euro/Phönix | Sodium citrate | 1305001-01 | 1 |
| Euro/Phönix | Sodium citrate | 1610016-01 | 1 |
| Euro | Sodium citrate | 1815M-01900 | 1 |
| Europ Ots Pharma | Sodium citrate | 13089304 | 1 |
| Fagron | Sodium citrate | 1017Q-01900 | 1 |
| Fagron | Sodium citrate | 1161207 | 3 |
| Fagron | Sodium citrate | 1172108 | 1 |
| Fagron | Sodium citrate | 1176767 | 3 |
| Fagron | Sodium citrate | 1190802 | 1 |
| Fagron | Sodium citrate | 1211142 | 2 |
| Fagron | Sodium citrate | 1219546 | 2 |
| Fagron | Sodium citrate | 1227297 | 3 |
| Fagron | Sodium citrate | 1232850 | 2 |
| Fagron | Sodium citrate | 12339502 | 1 |
| Fagron | Sodium citrate | 1234468 | 1 |
| Fagron | Sodium citrate | 1234567 | 1 |
| Fagron | Sodium citrate | 123456test | 1 |
| Fagron | Sodium citrate | 1241068 | 1 |
| Fagron | Sodium citrate | 1250221 | 2 |
| Fagron | Sodium citrate | 1262240 | 4 |
| Fagron | Sodium citrate | 12A05-N04 | 2 |
| Fagron | Sodium citrate | 12E04-N05 | 1 |
| Fagron | Sodium citrate | 12I10-N01 | 1 |
| Fagron | Sodium citrate | 12J26-N02 | 3 |
| Fagron | Sodium citrate | 13/24-B13-287921 | 3 |
| Fagron | Sodium citrate | 13089331 | 1 |
| Fagron | Sodium citrate | 13A07-N01 | 6 |
| Fagron | Sodium citrate | 13A07-NO1 | 1 |
| Fagron | Sodium citrate | 13B28-N02 | 6 |
| Fagron | Sodium citrate | 13D09N01 | 1 |
| Fagron | Sodium citrate | 13D09-N01 | 5 |
| Fagron | Sodium citrate | 13I24-B13-287921 | 2 |
| Fagron | Sodium citrate | 13l24-B13 | 1 |
| Fagron | Sodium citrate | 14112502 | 2 |
| Fagron | Sodium citrate | 14369402 | 2 |
| Fagron | Sodium citrate | 14A13_b02_300395 | 1 |
| Fagron | Sodium citrate | 14A13-B02-294541 | 8 |
| Fagron | Sodium citrate | 14A13B02300395 | 1 |
| Fagron | Sodium citrate | 14A13-B02-300395 | 4 |
| Fagron | Sodium citrate | 1511017-01 | 1 |
| Fagron | Sodium citrate | 15C27 | 1 |
| Fagron | Sodium citrate | 15C27-B01-309893 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sodium citrate | 15-C27-B01-309893 | 1 |
| Fagron | Sodium citrate | 15C27-B01-312231 | 6 |
| Fagron | Sodium citrate | 15C27-B01-316106 | 2 |
| Fagron | Sodium citrate | 15c27-b01-321097 | 1 |
| Fagron | Sodium citrate | 15C27B01-321097 | 1 |
| Fagron | Sodium citrate | 15C27-B01-321097 | 1 |
| Fagron | Sodium citrate | 15C27-B01-3211097 | 1 |
| Fagron | Sodium citrate | 15C27-B01-323451 | 3 |
| Fagron | Sodium citrate | 15C27-B01-3234551 | 1 |
| Fagron | Sodium citrate | 160614 | 1 |
| Fagron | Sodium citrate | 16217912 | 2 |
| Fagron | Sodium citrate | 16F10-B01-326088 | 2 |
| Fagron | Sodium citrate | 16F10-B01-327510 | 5 |
| Fagron | Sodium citrate | 16F10-B1-327510 | 1 |
| Fagron | Sodium citrate | 1710006-01 | 1 |
| Fagron | Sodium citrate | 179915 | 3 |
| Fagron | Sodium citrate | 179915-0001 | 2 |
| Fagron | Sodium citrate | 17A26-B04-331525 | 1 |
| Fagron | Sodium citrate | 17A26-B04-331528 | 14 |
| Fagron | Sodium citrate | 17A26-B04-332866 | 1 |
| Fagron | Sodium citrate | 17A26-B04-332871 | 26 |
| Fagron | Sodium citrate | 17A26-B04-335680 | 24 |
| Fagron | Sodium citrate | 17A26-B04-335883 | 2 |
| Fagron | Sodium citrate | 17H04-B04-345098 | 1 |
| Fagron | Sodium citrate | 17H07 | 1 |
| Fagron | Sodium citrate | 17H07-B04 | 2 |
| Fagron | Sodium citrate | 17H07-B04_338530 | 28 |
| Fagron | Sodium citrate | 17H07-B04-341746 | 5 |
| Fagron | Sodium citrate | 17H07-B04-345098 | 2 |
| Fagron | Sodium citrate | 1807035-01 | 1 |
| Fagron | Sodium citrate | 18B14-B08 | 1 |
| Fagron | Sodium citrate | 18B14-B08-348067 | 6 |
| Fagron | Sodium citrate | 18C05-B03 | 2 |
| Fagron | Sodium citrate | 18C05-B03350564 | 1 |
| Fagron | Sodium citrate | 18C05-B03-350564 | 3 |
| Fagron | Sodium citrate | 18G25-B07 | 2 |
| Fagron | Sodium citrate | 18G25-B07-352737 | 4 |
| Fagron | Sodium citrate | 18G25-B07-354623 | 2 |
| Fagron | Sodium citrate | 18G25-B07-354812 | 4 |
| Fagron | Sodium citrate | 18L13B023549449 | 1 |
| Fagron | Sodium citrate | 18l13b02359449 | 1 |
| Fagron | Sodium citrate | 18L13-B02-359449 | 11 |
| Fagron | Sodium citrate | 18L13-B02-359451 | 3 |
| Fagron | Sodium citrate | 18L13-Bo2-359449 | 1 |
| Fagron | Sodium citrate | 18L13-BO2-359449 | 1 |
| Fagron | Sodium citrate | 19F19-B01 | 2 |
| Fagron | Sodium citrate | 19F19-B01-363699 | 2 |
| Fagron | Sodium citrate | 19F19-B01-363701 | 4 |
| Fagron | Sodium citrate | 19I26-F01-365434 | 4 |
| Fagron | Sodium citrate | 19I26F01365444 | 1 |
| Fagron | Sodium citrate | 19I26FO1365444 | 1 |
| Fagron | Sodium citrate | 19l26-F01-365434 | 1 |
| Fagron | Sodium citrate | 2007022-01 | 1 |
| Fagron | Sodium citrate | 20A20F03 | 1 |
| Fagron | Sodium citrate | 20A20-F03 | 4 |
| Fagron | Sodium citrate | 20A20-F03-069331 | 1 |
| Fagron | Sodium citrate | 20A20-f03-368130 | 1 |
| Fagron | Sodium citrate | 20A20-F03-368130 | 11 |
| Fagron | Sodium citrate | 20A20-F03-369331 | 5 |
| Fagron | Sodium citrate | 20A20-F03-369333 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sodium citrate | 20B24-F03-374173 | 1 |
| Fagron | Sodium citrate | 20K19-F02 | 1 |
| Fagron | Sodium citrate | 20K19-F02-376135 | 1 |
| Fagron | Sodium citrate | 20K19-F02-376136 | 2 |
| Fagron | Sodium citrate | 22K17-B15-221097 | 2 |
| Fagron | Sodium citrate | 22K17-B15-22197 | 1 |
| Fagron | Sodium citrate | 2412130I | 1 |
| Fagron | Sodium citrate | 20A20-F03-368130 | 1 |
| Fagron | Sodium citrate | 20A20-F03-369331 | 1 |
| Fagron | Sodium citrate | 20A0-F03-368130 | 1 |
| Fagron | Sodium citrate | 20B24-F03374173 | 1 |
| Fagron | Sodium citrate | 20K19-F02-376135 | 1 |
| Fagron | Sodium citrate | 306084 | 1 |
| Fagron | Sodium citrate | 31051202 | 1 |
| Fagron | Sodium citrate | 3311E-01900 | 1 |
| Fagron | Sodium citrate | 712A-01900 | 1 |
| Fagron | Sodium citrate | 801-3636909 | 1 |
| Fagron | Sodium citrate | 815Q-01900 | 1 |
| Fagron | Sodium citrate | F03-368130 | 1 |
| Fagron | Sodium citrate | F03-3681300 | 1 |
| Fagron | Sodium citrate | F0336813000 | 1 |
| Fagron | Sodium citrate | F03-3693301 | 1 |
| Fagron | Sodium citrate | Probe | 1 |
| Fargo/Phoenix | Sodium citrate | 1511017-01 | 1 |
| Fargon GmbH & Co.KG | Sodium citrate | 16F10-B01-326088 | 1 |
| Fargon/Alliance HC | Sodium citrate | 13/24-B13-287921 | 1 |
| fargon | Sodium citrate | 100772-114-91 | 1 |
| Fiebig | Sodium citrate | 12J26-N02 | 1 |
| Fiebig | Sodium citrate | 1607002-01 | 2 |
| Fiebig | Sodium citrate | 1610016-01 | 1 |
| Fiebig | Sodium citrate | 190890002 | 1 |
| Fiebig | Sodium citrate | 22002778003 | 1 |
| Fragon | Sodium citrate | 18L13-B02-359449 | 1 |
| Gatt-Koller | Sodium citrate | 1073/04121412 | 1 |
| Gehe 26.05.2014 | Sodium citrate | 13B28-N02 | 1 |
| Gehe amax | Sodium citrate | 1610016-01 | 1 |
| Gehe Rostock | Sodium citrate | 2002040-01 | 1 |
| Gehe/Euro | Sodium citrate | 1412014-01 | 6 |
| Gehe | Sodium citrate | 12045026 | 1 |
| Gehe | Sodium citrate | 1311035-01 | 1 |
| Gehe | Sodium citrate | 1404033-01 | 1 |
| Gehe | Sodium citrate | 14369413 | 2 |
| GEHE | Sodium citrate | 1710006-02 | 1 |
| GEHE | Sodium citrate | 17A26-B04-331525 | 6 |
| GEHE | Sodium citrate | 17A26-B04-332866 | 5 |
| GEHE | Sodium citrate | 17H507-A04-347340 | 1 |
| Gehe | Sodium citrate | 18B14-B08-348067 | 1 |
| Gehe | Sodium citrate | 18G25-B07 | 1 |
| gehe | Sodium citrate | 18G25-B07-354812 | 1 |
| Gehe | Sodium citrate | 18L13-B02-359449 | 1 |
| Gehe | Sodium citrate | 1901035-01 | 3 |
| Gehe | Sodium citrate | 19089003 | 1 |
| Gehe | Sodium citrate | 2007022-01 | 1 |
| GEHE | Sodium citrate | 21002580016 | 1 |
| Gehe | Sodium citrate | 2101007-01 | 1 |
| Gehe | Sodium citrate | 22002778007 | 2 |
| Gehe | Sodium citrate | 2206011-01 | 1 |
| Gehe | Sodium citrate | 2212001-01 | 4 |
| GEHE | Sodium citrate | 2212001-01 | 1 |
| Gehe | Sodium citrate | 23000473002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Sodium citrate | 240213 | 1 |
| Hageda | Sodium citrate | 2002040-01 | 1 |
| HiperScan | Sodium citrate | | 1 |
| Jenne | Sodium citrate | 21002580007 | 1 |
| Jenne | Sodium citrate | 23000473002 | 1 |
| Jenne | Sodium citrate | 250512(2307019-01) | 1 |
| Jungbunzlauer/Phoenix | Sodium citrate | 20A20-F03 | 1 |
| Kehr | Sodium citrate | 17A26-B04-331525 | 1 |
| Kehr | Sodium citrate | 22K17-B15-223095 | 1 |
| Kehr | Sodium citrate | 23000473002 | 1 |
| Krieger | Sodium citrate | 23000473002 | 1 |
| L12 | Sodium citrate | 16217905 | 1 |
| L12 | Sodium citrate | 17323608 | 1 |
| Max Jenne | Sodium citrate | 190890002 | 1 |
| Merck | Sodium citrate | | 2 |
| Merck | Sodium citrate | 37/17 | 1 |
| Merck | Sodium citrate | AM0602648542 | 1 |
| Merck | Sodium citrate | AM1005848809 | 1 |
| Merck | Sodium citrate | AM1171048839 | 1 |
| Merck | Sodium citrate | AM1171148726 | 1 |
| Merk | Sodium citrate | AM0602648 | 1 |
| Nachprüfung | Sodium citrate | 1205026-02 | 1 |
| Nachprüfung | Sodium citrate | 14112517 | 2 |
| Noweda | Sodium citrate | 11127001 | 1 |
| Noweda | Sodium citrate | 12045026 | 1 |
| Noweda | Sodium citrate | 14A13-B02-294541 | 1 |
| Noweda | Sodium citrate | 1511017-01 | 1 |
| Noweda | Sodium citrate | 16095707 | 1 |
| Noweda | Sodium citrate | 1701029-01 | 1 |
| Noweda | Sodium citrate | 1710006-01 | 1 |
| Noweda | Sodium citrate | 17H07-B04 | 1 |
| Noweda | Sodium citrate | 17H07-B04-341746 | 1 |
| Noweda | Sodium citrate | 17H07-B04-345098 | 1 |
| Noweda | Sodium citrate | 18208315 | 2 |
| Noweda | Sodium citrate | 1901035-01 | 1 |
| Noweda | Sodium citrate | 1909020-01 | 1 |
| Noweda | Sodium citrate | 19F19-B01-363699 | 1 |
| Noweda | Sodium citrate | 22002778007 | 5 |
| Noweda | Sodium citrate | 2202778003 | 1 |
| Noweda | Sodium citrate | 2212001-01 | 1 |
| Noweda | Sodium citrate | 2212001-02 | 1 |
| Noweda | Sodium citrate | 22K17-B15-221097 | 1 |
| Noweda | Sodium citrate | 2307019-01 | 1 |
| Noweda | Sodium citrate | 3032981 | 1 |
| Nowedan 15.11.2019 | Sodium citrate | 1909020-01 | 1 |
| Phoenix /Fargon | Sodium citrate | 20A20-F03-368130 | 1 |
| Phoenix 30.05.2016 | Sodium citrate | 14369423 | 1 |
| Phoenix/Noweda | Sodium citrate | 1506041-01 | 2 |
| Phoenix | Sodium citrate | 1506041-01 | 1 |
| Phoenix | Sodium citrate | 1511017-01 | 2 |
| Phoenix | Sodium citrate | 1710006-02 | 1 |
| Phoenix | Sodium citrate | 1901035-01 | 2 |
| Phoenix | Sodium citrate | 191291911 | 1 |
| Phoenix | Sodium citrate | 20a20-f03-368130 | 1 |
| Phoenix | Sodium citrate | 22002778007 | 1 |
| Phoenix | Sodium citrate | 2212001-01 | 1 |
| Phoenix | Sodium citrate | 23003487005 | 2 |
| Phoenix | Sodium citrate | 2307019-01 | 1 |
| Phoenix | Sodium citrate | 3422 | 1 |
| Phönix | Sodium citrate | 12045019 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Sodium citrate | 12045024 | 1 |
| Phönix | Sodium citrate | 1205026-02 | 1 |
| Phönix | Sodium citrate | 1807035-01 | 2 |
| Phönix | Sodium citrate | 1807035-02 | 1 |
| Phönix | Sodium citrate | 190890007 | 1 |
| Phönix | Sodium citrate | 21002580012 | 1 |
| Phönix | Sodium citrate | 22002778003 | 3 |
| Phönix | Sodium citrate | 22002778007 | 2 |
| Phönix | Sodium citrate | 22K17-B15-223095 | 1 |
| Phönix | Sodium citrate | 23003487005 | 1 |
| Retest | Sodium citrate | 1610016-01 | 1 |
| Röntgen | Sodium citrate | 17323601 | 1 |
| Sanacoro W.E:15.05.1… | Sodium citrate | 14112502 | 1 |
| Sanacorp 17.08.2016 | Sodium citrate | 14369424 | 2 |
| Sanacorp | Sodium citrate | 13089308 | 1 |
| Sanacorp | Sodium citrate | 13089331 | 1 |
| Sanacorp | Sodium citrate | 1311035-01 | 1 |
| Sanacorp | Sodium citrate | 1436407 | 1 |
| Sanacorp | Sodium citrate | 17A26-B04-332866 | 1 |
| Sanacorp | Sodium citrate | 190890007 | 1 |
| Sanacorp | Sodium citrate | 2012364 | 1 |
| Sanacorp | Sodium citrate | 21002580012 | 1 |
| Sanacorp | Sodium citrate | 21002580013 | 1 |
| Sanacorp | Sodium citrate | 21002580019 | 1 |
| Sanacorp | Sodium citrate | 2101007-01 | 1 |
| Sanacorp | Sodium citrate | 22002778007 | 1 |
| Sanacorp | Sodium citrate | 2206011-01 | 2 |
| Sanacorp | Sodium citrate | 2212001-01 | 2 |
| Sanacorp | Sodium citrate | 23003487003 | 1 |
| Sanacorp | Sodium citrate | EuRho | 1 |
| Test | Sodium citrate | | 1 |
| TEST | Sodium citrate | | 1 |
| Test | Sodium citrate | 1234 | 1 |
| Test | Sodium citrate | 12345 | 1 |
| Test | Sodium citrate | 123456 | 1 |
| Unisan | Sodium citrate | 1701029-01 | 1 |
| Unisan | Sodium citrate | S/WReferenzUmstell | 1 |
| VDL;16.05.15;3,83EUR | Sodium citrate | 14369406 | 1 |
| wepa | Sodium citrate | 1909020-01 | 1 |

- 254 472 spectra from 1664 *Apo-Ident* customers from a total of 51 732 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium citrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium citrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 540 | 0 | 157 786 |
| **Type B** | 0 | 850 | 0 | 212 090 |
| **Type C** | 0 | 2294 | 120 | 254 472 |


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The substance/substance group *Sodium citrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8889 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2941 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 95.0290 % (> 94.9047 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20662 | 21839 | 6.75 | 138.33 |
| 20918 | 21670 | 8.49 | 138.57 |
| 21670 | 21670 | 0.00 | 137.07 |
| 21718 | 21670 | 4.03 | 136.29 |
| 21778 | 21670 | 5.50 | 138.00 |
| 21839 | 21839 | 0.00 | 139.64 |
| 21997 | 21997 | 0.00 | 140.51 |
| 22843 | 21997 | 8.92 | 143.59 |
| 22859 | 22859 | 0.00 | 148.24 |
| 22996 | 22996 | 0.00 | 140.78 |
| 25324 | 25324 | 0.00 | 144.41 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium cromoglicate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20775-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium cromoglicate; Cromolyn sodium; Natrii cromoglicas

### Special notes

When selecting the *Sodium cromoglicate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium cromoglicate | 11 | 13 | 17 |

### Second-stage model

For differentiation of the substance/substance group *Sodium cromoglicate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium cromoglicate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 97.37 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium cromoglicate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium cromoglicate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium cromoglicate | 11114501 | 20776 | 80 | 20110518 |
| Caelo | Sodium cromoglicate | 13232802 | 21375 | 20 | 1505352 |
| Caelo | Sodium cromoglicate | 13232802 | 21376 | 110 | 20130905 |
| Caelo | Sodium cromoglicate | 15224404 | 21990 | 60 | 20150625 |
| Caelo | Sodium cromoglicate | 20003498 | 25641 | 40 | 20201120* |
| Euro OTC | Sodium cromoglicate | 1403017-01 | 21981 | 60 | 20140505 |
| Euro OTC | Sodium cromoglicate | 1510018 | 22231 | 60 | 20151109* |
| Euro OTC | Sodium cromoglicate | 1703027 | 23383 | 40 | 20170405* |
| Euro OTC | Sodium cromoglicate | 2012005 | 25570 | 40 | 20210115* |
| Euro OTC | Sodium cromoglicate | 2407017 | 27366 | 40 | 20240814* |
| Fagron | Sodium cromoglicate | 12C09-N02 | 20775 | 79 | 1401553 |
| Fagron | Sodium cromoglicate | 13G24-N04 | 21260 | 40 | 20130515 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 669 spectra of 12 reference samples from the substance/substance group *Sodium cromoglicate*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 657 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 570 spectra of 16 reference samples from the substance/substance group *Sodium cromoglicate*.

- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium cromoglicate | 173081 | 23855 | 30 |
| Caelo | Sodium cromoglicate | 182657 | 24382 | 40 |
| Euro OTC | Sodium cromoglicate | 1112003-01 | 20778 | 40 |
| Euro OTC | Sodium cromoglicate | 1711024 | 23871 | 40 |
| Euro OTC | Sodium cromoglicate | 1811016 | 24424 | 40 |
| Euro OTC | Sodium cromoglicate | 2004037 | 25268 | 40 |
| Euro OTC | Sodium cromoglicate | 2007031 | 25454 | 40 |
| Euro OTC | Sodium cromoglicate | 2211013 | 26432 | 40 |
| Euro OTC | Sodium cromoglicate | 2306002 | 26767 | 40 |
| Euro OTC | Sodium cromoglicate | 2306008 | 26768 | 40 |
| Euro OTC | Sodium cromoglicate | 2505016 | 27672 | 40 |
| Fagron | Sodium cromoglicate | 15C23-B01-307751 | 22972 | 40 |
| Fagron | Sodium cromoglicate | 23A04-B02-224458 | 26608 | 40 |
| Euro OTC | Sodium cromoglicate | 2211013 | 26432SI | 20 |
| Euro OTC | Sodium cromoglicate | 2306002 | 26767SI | 20 |
| Fagron | Sodium cromoglicate | 23A04-B02-224458 | 26608SI | 20 |

- 212 370 spectra from a total of 4274 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 30 spectra from 21 *Apo-Ident* customers from 20 batches from the substance/substance group *Sodium cromoglicate*.
- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium cromoglicate | 22000548003 | 1 |
| | Sodium cromoglicate | 23003607001 | 1 |
| Bombastus | Sodium cromoglicate | 15414502 | 1 |
| Caelo | Sodium cromoglicate | 12301101 | 1 |
| Caelo | Sodium cromoglicate | 12301102 | 1 |
| Caelo | Sodium cromoglicate | 15224404 | 1 |
| Caelo | Sodium cromoglicate | 16270705 | 3 |
| Caelo | Sodium cromoglicate | 17308104 | 1 |
| Caelo | Sodium cromoglicate | 18265704 | 2 |
| Caelo | Sodium cromoglicate | 18265707 | 1 |
| Caelo | Sodium cromoglicate | 20003498009 | 1 |
| Caelo | Sodium cromoglicate | 20003499001 | 2 |
| Caelo | Sodium cromoglicate | 5113A-02831 | 1 |
| Caesar & Loretz GmbH | Sodium cromoglicate | 18265706 | 5 |
| E Plus | Sodium cromoglicate | 15414502 | 1 |
| Euro OTC | Sodium cromoglicate | 1403017-01 | 1 |
| Euro OTC | Sodium cromoglicate | 1510018-01 | 1 |
| Euro OTC | Sodium cromoglicate | 170302701 | 1 |
| Euro OTC | Sodium cromoglicate | 1850002692 | 1 |
| Fagron | Sodium cromoglicate | 13E22-N11 | 1 |
| Fagron | Sodium cromoglicate | 13G24-N04 | 1 |
| Sanacorp | Sodium cromoglicate | 20003499001 | 1 |

- 256 856 spectra from 1666 *Apo-Ident* customers from a total of 52 133 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium cromoglicate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium cromoglicate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 668 | 1 | 157 657 |
| **Type B** | 0 | 570 | 0 | 212 370 |
| **Type C** | 0 | 30 | 0 | 256 856 |

The substance/substance group *Sodium cromoglicate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 99.8505 % (> 99.4021 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.9474 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 80.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20775 | 20775 | 0.00 | 246.43 |
| 20776 | 22231 | 42.38 | 254.44 |
| 21260 | 22231 | 15.24 | 246.57 |
| 21375 | 21375 | 0.00 | 299.39 |
| 21376 | 21375 | 22.87 | 266.32 |
| 21981 | 22231 | 26.34 | 218.75 |
| 21990 | 22231 | 23.15 | 235.76 |
| 22231 | 22231 | 0.00 | 234.87 |
| 23383 | 23383 | 0.00 | 226.04 |
| 25570 | 25570 | 0.00 | 235.33 |
| 25641 | 25641 | 0.00 | 235.19 |
| 27366 | 27366 | 0.00 | 321.25 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium cyclamate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20917-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium cyclamate; Natrii cyclamas

### Special notes

When selecting the *Sodium cyclamate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium cyclamate | 6 | 3 | 43 |

### Second-stage model

For differentiation of the substance/substance group *Sodium cyclamate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium cyclamate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 114.35 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium cyclamate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium cyclamate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium cyclamate | 12256803 | 20917 | 40 | 1401418 |
| Caelo | Sodium cyclamate | 12105622 | 21380 | 40 | 20120423 |
| Caelo | Sodium cyclamate | 182167 | 24379 | 40 | 20181023* |
| Caelo | Sodium cyclamate | 20004287009 | 26234 | 40 | 20201216 |
| Caelo | Sodium cyclamate | 20004287009 | 26234SI | 20 | 20201216 |
| Caelo | Sodium cyclamate | 24002330 | 27429 | 40 | 20241028* |
| Gatt-Koller | Sodium cyclamate | 23J00242 | 26702 | 40 | 20230308 |
| Gatt-Koller | Sodium cyclamate | 23J00242 | 26702SI | 20 | 20230308 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 280 spectra of 8 reference samples from the substance/substance group *Sodium cyclamate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Sodium cyclamate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium cyclamate | 16119302 | 23259 | 40 |
| Caelo | Sodium cyclamate | 170411 | 23853 | 40 |
| Caelo | Sodium cyclamate | 22003585 | 26716 | 40 |
| Caelo | Sodium cyclamate | 22003585 | 26716SI | 20 |

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 258 spectra from 207 *Apo-Ident* customers from 45 batches from the substance/substance group *Sodium cyclamate*.

- Among them are spectra of independent samples from 43 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium cyclamate | 20004287013 | 1 |
| | Sodium cyclamate | 20004287014 | 1 |
| | Sodium cyclamate | 20004287017 | 6 |
| | Sodium cyclamate | 22003585002 | 6 |
| | Sodium cyclamate | 22003585006 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium cyclamate | 2203585006 | 1 |
| | Sodium cyclamate | 23003590004 | 6 |
| Caelo | Sodium cyclamate | 10380915 | 2 |
| Caelo | Sodium cyclamate | 11204205 | 1 |
| Caelo | Sodium cyclamate | 14149602 | 1 |
| Caelo | Sodium cyclamate | 15201601 | 2 |
| Caelo | Sodium cyclamate | 15201603 | 1 |
| Caelo | Sodium cyclamate | 15201606 | 2 |
| Caelo | Sodium cyclamate | 15201608 | 4 |
| Caelo | Sodium cyclamate | 15201614 | 1 |
| Caelo | Sodium cyclamate | 16119302 | 4 |
| Caelo | Sodium cyclamate | 16119302/2280217 | 1 |
| Caelo | Sodium cyclamate | 16119308 | 8 |
| Caelo | Sodium cyclamate | 16119310 | 1 |
| Caelo | Sodium cyclamate | 17041102 | 8 |
| Caelo | Sodium cyclamate | 17362202 | 7 |
| Caelo | Sodium cyclamate | 17362203 | 1 |
| Caelo | Sodium cyclamate | 17362207 | 8 |
| Caelo | Sodium cyclamate | 17362208 | 8 |
| Caelo | Sodium cyclamate | 179617362207 | 1 |
| Caelo | Sodium cyclamate | 17961821675 | 1 |
| Caelo | Sodium cyclamate | 18053101 | 1 |
| Caelo | Sodium cyclamate | 182167002 | 6 |
| Caelo | Sodium cyclamate | 182167004 | 6 |
| Caelo | Sodium cyclamate | 182167005 | 7 |
| Caelo | Sodium cyclamate | 18216702 | 9 |
| Caelo | Sodium cyclamate | 18216704 | 7 |
| Caelo | Sodium cyclamate | 18216707 | 19 |
| Caelo | Sodium cyclamate | 200004287003 | 1 |
| Caelo | Sodium cyclamate | 20004278013 | 1 |
| Caelo | Sodium cyclamate | 20004285001 | 7 |
| Caelo | Sodium cyclamate | 20004287003 | 4 |
| Caelo | Sodium cyclamate | 20004287005 | 6 |
| Caelo | Sodium cyclamate | 20004287007 | 7 |
| Caelo | Sodium cyclamate | 20004287009 | 8 |
| Caelo | Sodium cyclamate | 20004287011 | 4 |
| Caelo | Sodium cyclamate | 20004287013 | 3 |
| Caelo | Sodium cyclamate | 20004287014 | 4 |
| Caelo | Sodium cyclamate | 200042887005 | 1 |
| Caelo | Sodium cyclamate | 22003585002 | 3 |
| Caelo | Sodium cyclamate | 3092002 | 1 |
| Caeol/ Noweda | Sodium cyclamate | 16119302 | 1 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 20004287013 | 1 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 18216704 | 1 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 182167004 | 2 |
| Caesar & Loretz GmbH/AHD | Sodium cyclamate | 20004287013 | 1 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 182167005 | 1 |
| Caesar & Loretz GmbH/Gehe | Sodium cyclamate | 20004285001 | 3 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 20004287003 | 1 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 20004287007 | 1 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 20004287014 | 1 |
| Caesar & Loretz GmbH... | Sodium cyclamate | 20004287007 | 1 |
| Caesar & Loretz GmbH | Sodium cyclamate | 12105622 | 1 |
| Caesar & Loretz GmbH | Sodium cyclamate | 17362208 | 3 |
| Caesar & Loretz GmbH | Sodium cyclamate | 182167002 | 3 |
| Caesar & Loretz GmbH | Sodium cyclamate | 182167004 | 4 |
| Caesar & Loretz GmbH | Sodium cyclamate | 182167005 | 4 |
| Caesar & Loretz GmbH | Sodium cyclamate | 18216702 | 3 |
| Caesar & Loretz GmbH | Sodium cyclamate | 18216707 | 4 |
| Caesar & Loretz GmbH | Sodium cyclamate | 20004285001 | 2 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Sodium cyclamate | 20004287003 | 3 |
| Caesar & Loretz GmbH | Sodium cyclamate | 20004287013 | 1 |
| Caesar & Loretz GmbH | Sodium cyclamate | 20004287014 | 2 |
| Caesar&Loretz GmbH/ … | Sodium cyclamate | 16119308 | 1 |
| Euro OTC | Sodium cyclamate | 16119302 | 1 |
| Gehe | Sodium cyclamate | 22003585002 | 1 |
| GEHE | Sodium cyclamate | 22003585006 | 1 |
| Holdermann | Sodium cyclamate | 20004287013 | 1 |
| Holdermann | Sodium cyclamate | 22003585002 | 1 |
| Kehr | Sodium cyclamate | 22003585006 | 2 |
| Noweda | Sodium cyclamate | 20004287017 | 3 |
| Noweda | Sodium cyclamate | 22003585006 | 1 |
| Phoenix | Sodium cyclamate | 20004287014 | 1 |
| Phoenix | Sodium cyclamate | 22003585002 | 1 |
| Phoenix | Sodium cyclamate | 787/03100611 | 1 |
| Phönix | Sodium cyclamate | 182167002 | 1 |

- 256 628 spectra from 1666 *Apo-Ident* customers from a total of 52 109 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium cyclamate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium cyclamate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 256 | 2 | 256 628 |

The substance/substance group *Sodium cyclamate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.2248 % (> 98.0620 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20917 | 20917 | 0.00 | 181.08 |
| 21380 | 20917 | 17.34 | 179.38 |
| 24379 | 24379 | 0.00 | 183.53 |
| 26234 | 24379 | 11.98 | 182.37 |
| 26702 | 27429 | 47.08 | 180.63 |
| 27429 | 27429 | 0.00 | 184.37 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium dihydrogen phosphate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005937-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium dihydrogen phosphate dihydrate; Natrii dihydrogenophosphas dihydricus

### Special notes

When selecting the *Sodium dihydrogen phosphate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium dihydrogen phosphate dihydrate | 4 | 3 | 17 |

### Second-stage model

For differentiation of the substance/substance group *Sodium dihydrogen phosphate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium dihydrogen phosphate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 57.63 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium dihydrogen phosphate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium dihydrogen phosphate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium dihydrogen phospha… | 22001753 | 26560 | 40 | 20220706* |
| Caelo | Sodium dihydrogen phospha… | 22001753 | 26560SI | 20 | 20220706* |
| Caelo | Sodium dihydrogen phospha… | 24001049 | 27310 | 30 | 20240502* |
| Euro OTC | Sodium dihydrogen phospha… | 2106004 | 25786 | 50 | 20210624* |
| Euro OTC | Sodium dihydrogen phospha… | 2204005 | 26101 | 40 | 20220517* |
| Euro OTC | Sodium dihydrogen phospha… | 2204005 | 26101SI | 20 | 20220517* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 6 reference samples from the substance/substance group *Sodium dihydrogen*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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*phosphate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

- 158 126 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 4 reference samples from the substance/substance group *Sodium dihydrogen phosphate dihydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium dihydrogen phospha… | 21001537 | 25802 | 50 |
| Euro OTC | Sodium dihydrogen phospha… | 2109011 | 25817 | 50 |
| Euro OTC | Sodium dihydrogen phospha… | 2307018 | 26860 | 40 |
| Euro OTC | Sodium dihydrogen phospha… | 2307018 | 26860SI | 20 |

- 212 780 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 31 spectra from 28 *Apo-Ident* customers from 17 batches from the substance/substance group *Sodium dihydrogen phosphate dihydrate*.

- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium dihydrogen phospha… | 22001753006 | 2 |
| | Sodium dihydrogen phospha… | 22001753011 | 5 |
| | Sodium dihydrogen phospha… | 2204005-01 | 1 |
| | Sodium dihydrogen phospha… | 220400502 | 1 |
| | Sodium dihydrogen phospha… | 2204005-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium dihydrogen phospha… | 23003513002 | 2 |
| | Sodium dihydrogen phospha… | 2400049002 | 1 |
| | Sodium dihydrogen phospha… | 24001049002 | 2 |
| | Sodium dihydrogen phospha… | 24001049005 | 4 |
| Caelo | Sodium dihydrogen phospha… | 12198506 | 1 |
| Caelo | Sodium dihydrogen phospha… | 12198510 | 1 |
| Caelo | Sodium dihydrogen phospha… | 12198517 | 2 |
| Caelo | Sodium dihydrogen phospha… | 13D08-N25 | 1 |
| Euro OTC | Sodium dihydrogen phospha… | 1209004-01 | 2 |
| Euro OTC | Sodium dihydrogen phospha… | 1305028-01 | 2 |
| Fagron | Sodium dihydrogen phospha… | 12L05-N05 | 1 |
| Gehe | Sodium dihydrogen phospha… | 12198510 | 1 |
| Phönix | Sodium dihydrogen phospha… | 21001537002 | 1 |

- 256 855 spectra from 1666 *Apo-Ident* customers from a total of 52 136 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium dihydrogen phosphate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium dihydrogen phosphate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 31 | 0 | 256 855 |

The substance/substance group *Sodium dihydrogen phosphate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 80.6452 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25786 | 25786 | 0.00 | 99.40 |
| 26101 | 26101 | 0.00 | 58.36 |
| 26560 | 26560 | 0.00 | 55.87 |
| 27310 | 27310 | 0.00 | 53.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium edetate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20937-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium edetate; Dinatrii edetas

### Special notes

When selecting the *Sodium edetate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium edetate | 7 | 18 | 249 |

### Second-stage model

For differentiation of the substance/substance group *Sodium edetate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium edetate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 98.28 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium edetate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium edetate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium edetate | 13142009 | 21362 | 40 | 20130524 |
| Caelo | Sodium edetate | 161364 | 22465 | 60 | 20160504* |
| Euro OTC | Sodium edetate | 1609023 | 22915 | 40 | 20170106* |
| Euro OTC | Sodium edetate | 1812016 | 24414 | 40 | 20190116* |
| Fagron | Sodium edetate | 13E15-N05 | 20937 | 40 | 1402193 |
| Fagron | Sodium edetate | 16F21-B02-325085 | 22926 | 40 | 20160713 |
| Fagron | Sodium edetate | 22G15-B01-224176 | 26394 | 40 | 20220803 |
| Fagron | Sodium edetate | 22G15-B01-224176 | 26394SI | 20 | 20220803 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 8 reference samples from the substance/substance group *Sodium edetate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 006 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 800 spectra of 21 reference samples from the substance/substance group *Sodium edetate*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium edetate | 172618 | 23663 | 40 |
| Caelo | Sodium edetate | 20001878 | 25209 | 40 |
| Caelo | Sodium edetate | 21001224 | 25803 | 40 |
| Caelo | Sodium edetate | 22003154 | 26486 | 40 |
| Caelo | Sodium edetate | 24001067 | 27329 | 40 |
| Euro OTC | Sodium edetate | 1609023-01 | 22950 | 40 |
| Euro OTC | Sodium edetate | 1704011 | 23390 | 40 |
| Euro OTC | Sodium edetate | 1806007 | 24157 | 40 |
| Euro OTC | Sodium edetate | 1807025 | 24159 | 40 |
| Euro OTC | Sodium edetate | 1901032 | 24472 | 40 |
| Euro OTC | Sodium edetate | 1909030 | 24958 | 40 |
| Euro OTC | Sodium edetate | 2004003 | 25168 | 40 |
| Euro OTC | Sodium edetate | 2008009 | 25314 | 40 |
| Euro OTC | Sodium edetate | 2205014 | 26188 | 40 |
| Euro OTC | Sodium edetate | 2209004 | 26335 | 40 |
| Euro OTC | Sodium edetate | 2402026 | 27155 | 40 |
| Euro OTC | Sodium edetate | 2501003 | 27506 | 40 |
| Fagron | Sodium edetate | 24C25-B37-001217 | 27380 | 40 |
| Caelo | Sodium edetate | 172618 | 23818 | 40 |
| Euro OTC | Sodium edetate | 2205014 | 26188SI | 20 |
| Euro OTC | Sodium edetate | 2209004 | 26335SI | 20 |

- 212 140 spectra from a total of 4269 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1130 spectra from 651 *Apo-Ident* customers from 263 batches from the substance/substance group *Sodium edetate*.
- Among them are spectra of independent samples from 249 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium edetate | | 1 |
| | Sodium edetate | 13142009 | 1 |
| | Sodium edetate | 20004094011 | 1 |
| | Sodium edetate | 21001224017 | 3 |
| | Sodium edetate | 21122-F04-380679 | 1 |
| | Sodium edetate | 21H12-B03-213591 | 2 |
| | Sodium edetate | 21H12-B03-215577 | 1 |
| | Sodium edetate | 21I22-F04-380679 | 1 |
| | Sodium edetate | 21L06-B01 | 1 |
| | Sodium edetate | 21L06-B01-217364 | 3 |
| | Sodium edetate | 22000319004 | 1 |
| | Sodium edetate | 22000319007 | 11 |
| | Sodium edetate | 22000319008 | 1 |
| | Sodium edetate | 22003154003 | 14 |
| | Sodium edetate | 22003154005 | 1 |
| | Sodium edetate | 22003154009 | 6 |
| | Sodium edetate | 220031545009 | 1 |
| | Sodium edetate | 23001480004 | 1 |
| | Sodium edetate | 23A27-B01-230833 | 2 |
| | Sodium edetate | 23A27-B01-235141 | 4 |
| | Sodium edetate | 23A27-B01-235142 | 1 |
| | Sodium edetate | 24000126005 | 6 |
| | Sodium edetate | 24001067004 | 1 |
| | Sodium edetate | 24001067006 | 3 |
| | Sodium edetate | 24C25-B37-001217 | 4 |
| | Sodium edetate | 601EK285 | 1 |
| | Sodium edetate | 601K020 | 1 |
| Alliance Healthcare | Sodium edetate | 12181714 | 1 |
| Alliance Healthcare | Sodium edetate | 21001224002 | 1 |
| Anzag | Sodium edetate | 13K19-B02-290051 | 1 |
| Anzag | Sodium edetate | 18H03-B04-358927 | 1 |
| Anzag | Sodium edetate | 240206(22003154003) | 1 |
| apoident | Sodium edetate | 1807044-01 | 1 |
| apomix | Sodium edetate | 14G03-B05-307737 | 1 |
| Bombastus | Sodium edetate | | 1 |
| Bombastus | Sodium edetate | 16136404 | 1 |
| Caelo | Sodium edetate | | 1 |
| Caelo | Sodium edetate | 10887102 | 1 |
| Caelo | Sodium edetate | 11074608 | 2 |
| Caelo | Sodium edetate | 11074703 | 1 |
| Caelo | Sodium edetate | 12181702 | 1 |
| Caelo | Sodium edetate | 12181703 | 3 |
| Caelo | Sodium edetate | 12181704 | 1 |
| Caelo | Sodium edetate | 12181706 | 2 |
| Caelo | Sodium edetate | 12181711 | 13 |
| Caelo | Sodium edetate | 12181714 | 4 |
| Caelo | Sodium edetate | 12254507 | 2 |
| Caelo | Sodium edetate | 12345 | 1 |
| Caelo | Sodium edetate | 12E16-N04 | 1 |
| Caelo | Sodium edetate | 13/23-N03-3472312131 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium edetate | 13142002 | 4 |
| Caelo | Sodium edetate | 13142004 | 4 |
| Caelo | Sodium edetate | 13142008 | 6 |
| Caelo | Sodium edetate | 13142009 | 11 |
| Caelo | Sodium edetate | 13142010 | 2 |
| Caelo | Sodium edetate | 13142014 | 1 |
| Caelo | Sodium edetate | 13142015 | 5 |
| Caelo | Sodium edetate | 13142018 | 4 |
| Caelo | Sodium edetate | 13395002 | 3 |
| Caelo | Sodium edetate | 13395007 | 4 |
| Caelo | Sodium edetate | 13E15-N05 | 2 |
| Caelo | Sodium edetate | 13E15-NO5 | 1 |
| Caelo | Sodium edetate | 13K19-B02-290051 | 1 |
| Caelo | Sodium edetate | 14031801 | 1 |
| Caelo | Sodium edetate | 1427006 | 1 |
| Caelo | Sodium edetate | 14270505 | 2 |
| Caelo | Sodium edetate | 14270506 | 4 |
| Caelo | Sodium edetate | 14G03-B05-307737 | 1 |
| Caelo | Sodium edetate | 15035603 | 3 |
| Caelo | Sodium edetate | 15035604 | 4 |
| Caelo | Sodium edetate | 15116602 | 4 |
| Caelo | Sodium edetate | 15116603 | 15 |
| Caelo | Sodium edetate | 1517E-01925 | 1 |
| Caelo | Sodium edetate | 15427703 | 15 |
| Caelo | Sodium edetate | 15427704 | 3 |
| Caelo | Sodium edetate | 15427705 | 4 |
| Caelo | Sodium edetate | 15427710 | 13 |
| Caelo | Sodium edetate | 15427712 | 1 |
| Caelo | Sodium edetate | 15427714 | 25 |
| Caelo | Sodium edetate | 15427717 | 11 |
| Caelo | Sodium edetate | 1547717 | 1 |
| Caelo | Sodium edetate | 16110103/1 | 1 |
| Caelo | Sodium edetate | 16136403 | 4 |
| Caelo | Sodium edetate | 16136404 | 5 |
| Caelo | Sodium edetate | 16337302 | 10 |
| Caelo | Sodium edetate | 16337305 | 3 |
| Caelo | Sodium edetate | 16337312 | 24 |
| Caelo | Sodium edetate | 16337313 | 2 |
| Caelo | Sodium edetate | 16337316 | 14 |
| Caelo | Sodium edetate | 166337312 | 1 |
| Caelo | Sodium edetate | 16F21-B02-327696 | 1 |
| Caelo | Sodium edetate | 17336102 | 22 |
| Caelo | Sodium edetate | 17336107 | 5 |
| Caelo | Sodium edetate | 17336115 | 25 |
| Caelo | Sodium edetate | 17D25-B08 | 1 |
| Caelo | Sodium edetate | 17d25-b08-339881 | 1 |
| Caelo | Sodium edetate | 17D25-B08-341590 | 2 |
| Caelo | Sodium edetate | 17D25-B08-343253 | 2 |
| Caelo | Sodium edetate | 18007102 | 15 |
| Caelo | Sodium edetate | 18007104 | 3 |
| Caelo | Sodium edetate | 18007110 | 22 |
| Caelo | Sodium edetate | 18007112 | 3 |
| Caelo | Sodium edetate | 18007113 | 2 |
| Caelo | Sodium edetate | 18H03-B03-353918 | 1 |
| Caelo | Sodium edetate | 18H03-B04 | 1 |
| Caelo | Sodium edetate | 18H03-B04-352162 | 3 |
| Caelo | Sodium edetate | 18H03B04356574 | 1 |
| Caelo | Sodium edetate | 18H03-B04-357771 | 3 |
| Caelo | Sodium edetate | 191896007 | 21 |
| Caelo | Sodium edetate | 19189603 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium edetate | 200004094004 | 1 |
| Caelo | Sodium edetate | 20004094001 | 11 |
| Caelo | Sodium edetate | 20004094002 | 1 |
| Caelo | Sodium edetate | 20004094004 | 17 |
| Caelo | Sodium edetate | 20004094006 | 2 |
| Caelo | Sodium edetate | 20004094011 | 4 |
| Caelo | Sodium edetate | 20004424015 | 1 |
| Caelo | Sodium edetate | 21001224002 | 2 |
| Caelo | Sodium edetate | 21001224003 | 14 |
| Caelo | Sodium edetate | 21001224005 | 8 |
| Caelo | Sodium edetate | 21001224006 | 1 |
| Caelo | Sodium edetate | 21001224013 | 10 |
| Caelo | Sodium edetate | 21001224015 | 12 |
| Caelo | Sodium edetate | 21001224016 | 1 |
| Caelo | Sodium edetate | 21001224017 | 8 |
| Caelo | Sodium edetate | 21001224019 | 1 |
| Caelo | Sodium edetate | 21001224031 | 1 |
| Caelo | Sodium edetate | 2100128002 | 1 |
| Caelo | Sodium edetate | 2101414 | 1 |
| Caelo | Sodium edetate | 22000319004 | 2 |
| Caelo | Sodium edetate | 22000319007 | 7 |
| Caelo | Sodium edetate | 220304NE | 1 |
| Caelo | Sodium edetate | 2913M1925 | 1 |
| Caelo | Sodium edetate | 3211I-01925 | 1 |
| Caelo | Sodium edetate | 3913A-01925 | 1 |
| Caelo | Sodium edetate | 601EC350 | 1 |
| Caelo | Sodium edetate | 601EF200 | 4 |
| Caelo | Sodium edetate | 601EH014 | 1 |
| Caelo | Sodium edetate | 92159379 | 1 |
| Caelo | Sodium edetate | B03-3617200 | 1 |
| Caelo | Sodium edetate | P-14011921/17336102 | 1 |
| Caelo | Sodium edetate | P-16061621/15427703 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 13142004 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 20004094004 | 1 |
| Caesar & Loretz GmbH Og | Sodium edetate | 21001224017 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 12181711 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 20004094002 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 21001224005 | 1 |
| Caesar & Loretz GmbH/GEHE | Sodium edetate | 17336115 | 1 |
| Caesar & Loretz GmbH/Gehe | Sodium edetate | 21001224017 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 191896010 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 21000128002 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 21001224017 | 1 |
| Caesar & Loretz GmbH/sana | Sodium edetate | 21000128002 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 16337316 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 18007112 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 191896007 | 1 |
| Caesar & Loretz GmbH… | Sodium edetate | 21001224005 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 13142008 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 14270505 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 15427705 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 16337312 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 17336115 | 6 |
| Caesar & Loretz GmbH | Sodium edetate | 1736115 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 18007102 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 18007104 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 18007110 | 4 |
| Caesar & Loretz GmbH | Sodium edetate | 18007112 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 18007113 | 4 |
| Caesar & Loretz GmbH | Sodium edetate | 191896007 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Sodium edetate | 19189603 | 3 |
| Caesar & Loretz GmbH | Sodium edetate | 20004094001 | 4 |
| Caesar & Loretz GmbH | Sodium edetate | 20004094004 | 13 |
| Caesar & Loretz GmbH | Sodium edetate | 20004094006 | 3 |
| Caesar & Loretz GmbH | Sodium edetate | 20004094011 | 3 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224002 | 2 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224003 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224005 | 2 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224012 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224013 | 3 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224015 | 6 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224017 | 3 |
| Caesar & Loretz GmbH | Sodium edetate | 21001224019 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 22000319004 | 1 |
| Caesar & Loretz GmbH | Sodium edetate | 22000319007 | 1 |
| Caesar&Loretz | Sodium edetate | 21001224005 | 1 |
| Carl Roth | Sodium edetate | 159280302 | 1 |
| Celo/Noweda | Sodium edetate | 18007102 | 1 |
| Ceolo | Sodium edetate | 1909030-01 | 1 |
| Cranach-Apotheke | Sodium edetate | 11a31-no6 | 1 |
| Euro OTC | Sodium edetate | 15427703 | 1 |
| Euro OTC | Sodium edetate | 16337312 | 1 |
| Euro OTC | Sodium edetate | 1909030 | 1 |
| Euro OTC | Sodium edetate | 190903001 | 1 |
| Euro OTC | Sodium edetate | 1909030-01 | 2 |
| Euro OTC | Sodium edetate | 2004003-01 | 1 |
| Euro OTC | Sodium edetate | 21001224013 | 1 |
| Euro OTC | Sodium edetate | E300033328 | 1 |
| Fagron | Sodium edetate | 11A31-N06 | 1 |
| Fagron | Sodium edetate | 11A31-N06Retest | 1 |
| Fagron | Sodium edetate | 12E12-N04 | 1 |
| Fagron | Sodium edetate | 12E16-N04 | 2 |
| Fagron | Sodium edetate | 12g25-n12 | 1 |
| Fagron | Sodium edetate | 12G25-N12 | 3 |
| Fagron | Sodium edetate | 13/23-N03 | 6 |
| Fagron | Sodium edetate | 13E15-B10-289034 | 1 |
| Fagron | Sodium edetate | 13E15-N05 | 12 |
| Fagron | Sodium edetate | 13G15-N03 | 4 |
| Fagron | Sodium edetate | 13I23-N03 | 10 |
| Fagron | Sodium edetate | 13I23-NO3 | 1 |
| Fagron | Sodium edetate | 13K19B02 | 1 |
| Fagron | Sodium edetate | 13K19-B02 | 1 |
| Fagron | Sodium edetate | 13K19-B02-289035 | 1 |
| Fagron | Sodium edetate | 13k19-b02-290051 | 2 |
| Fagron | Sodium edetate | 13K19B02290051 | 1 |
| Fagron | Sodium edetate | 13K19-B02-290051 | 11 |
| Fagron | Sodium edetate | 13K19-B02-290052 | 3 |
| Fagron | Sodium edetate | 13K19-B02-296324 | 1 |
| Fagron | Sodium edetate | 14G03-B05 | 5 |
| Fagron | Sodium edetate | 14G03-B05_307737 | 1 |
| Fagron | Sodium edetate | 14G03-B05-303420 | 1 |
| Fagron | Sodium edetate | 14G03-B05-303422 | 1 |
| Fagron | Sodium edetate | 14G03-B05-30773 | 1 |
| Fagron | Sodium edetate | 14G03-B05-307737 | 8 |
| Fagron | Sodium edetate | 14G03B05309971 | 1 |
| Fagron | Sodium edetate | 14G03-B05-309971 | 2 |
| Fagron | Sodium edetate | 15D01-B05-315877 | 2 |
| Fagron | Sodium edetate | 15D01-B05-317369 | 2 |
| Fagron | Sodium edetate | 164599-0001 | 1 |
| Fagron | Sodium edetate | 16F21-B02 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sodium edetate | 16F21-B02-323069 | 1 |
| Fagron | Sodium edetate | 16F21-B02-323074 | 2 |
| Fagron | Sodium edetate | 16F21-B02-324370 | 4 |
| Fagron | Sodium edetate | 16f21b02325085 | 1 |
| Fagron | Sodium edetate | 16F21-B02-325085 | 6 |
| Fagron | Sodium edetate | 16F21-B02-325891 | 3 |
| Fagron | Sodium edetate | 16f21-b02-327696 | 1 |
| Fagron | Sodium edetate | 16F21B02327696 | 1 |
| Fagron | Sodium edetate | 16F21-B02-327696 | 5 |
| Fagron | Sodium edetate | 16F21-B02-329900 | 5 |
| Fagron | Sodium edetate | 16f21-b02-330959 | 1 |
| Fagron | Sodium edetate | 16F21-B02-332039 | 1 |
| Fagron | Sodium edetate | 16F21-B02-333607 | 1 |
| Fagron | Sodium edetate | 16F21-B02-333610 | 3 |
| Fagron | Sodium edetate | 17D25-B08 | 5 |
| Fagron | Sodium edetate | 17D25-B08-334827 | 4 |
| Fagron | Sodium edetate | 17D25-B08-334827 | 1 |
| Fagron | Sodium edetate | 17D25-B08-336718 | 4 |
| Fagron | Sodium edetate | 17D25-B08-338202 | 4 |
| Fagron | Sodium edetate | 17D25-B08-339881 | 4 |
| Fagron | Sodium edetate | 17D25B08343253 | 1 |
| Fagron | Sodium edetate | 17D25-B08-343253 | 4 |
| Fagron | Sodium edetate | 17D25-B08-343254 | 1 |
| Fagron | Sodium edetate | 17D25-Bo8-336718 | 1 |
| Fagron | Sodium edetate | 18H03 | 1 |
| Fagron | Sodium edetate | 18H03-B04 | 3 |
| Fagron | Sodium edetate | 18H03-B04-352162 | 1 |
| Fagron | Sodium edetate | 18H03-B04-353034 | 8 |
| Fagron | Sodium edetate | 18H03-B04-353918 | 6 |
| Fagron | Sodium edetate | 18H03-B04-355280 | 7 |
| Fagron | Sodium edetate | 18h03-b04-356574 | 1 |
| Fagron | Sodium edetate | 18H03-B04-356574 | 6 |
| Fagron | Sodium edetate | 18H03-B04-35674 | 1 |
| Fagron | Sodium edetate | 18H03-B04-357771 | 8 |
| Fagron | Sodium edetate | 18H03-B04-357774 | 8 |
| Fagron | Sodium edetate | 18h03b04358927 | 1 |
| Fagron | Sodium edetate | 18H03B04-358927 | 1 |
| Fagron | Sodium edetate | 18H03-B04-358927 | 6 |
| Fagron | Sodium edetate | 18H09-B04-355280 | 1 |
| Fagron | Sodium edetate | 18K14-B03 | 5 |
| Fagron | Sodium edetate | 18K14-B03-358930 | 13 |
| Fagron | Sodium edetate | 18K14-B03-358931 | 1 |
| Fagron | Sodium edetate | 18K14B03358934 | 1 |
| Fagron | Sodium edetate | 18K14-B03-358934 | 4 |
| Fagron | Sodium edetate | 18K14-B03-361720 | 16 |
| Fagron | Sodium edetate | 18K14-B03-361721 | 2 |
| Fagron | Sodium edetate | 20f23 | 1 |
| Fagron | Sodium edetate | 20F23-F03 | 1 |
| Fagron | Sodium edetate | 20F23-F03-372618 | 6 |
| Fagron | Sodium edetate | 21/22-F04 | 1 |
| Fagron | Sodium edetate | 21122-F04_380679 | 1 |
| Fagron | Sodium edetate | 21122-F04-380105 | 1 |
| Fagron | Sodium edetate | 2122-F04-380679 | 1 |
| Fagron | Sodium edetate | 215I-01925 | 1 |
| Fagron | Sodium edetate | 218U-01925 | 1 |
| Fagron | Sodium edetate | 21I22-F04 | 2 |
| Fagron | Sodium edetate | 21I22-F04_380679 | 1 |
| Fagron | Sodium edetate | 21I22-F04-380105 | 1 |
| Fagron | Sodium edetate | 21I22F04380679 | 1 |
| Fagron | Sodium edetate | 21I22-F04-380679 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sodium edetate | 21I22-F04-380679 | 1 |
| Fagron | Sodium edetate | 21L06-B01-217364 | 1 |
| Fagron | Sodium edetate | 352162 | 1 |
| Fagron | Sodium edetate | 361720 | 1 |
| Fagron | Sodium edetate | -37261008 | 2 |
| Fagron | Sodium edetate | 5012Q-01925 | 1 |
| Fagron | Sodium edetate | 5218Q-01925 | 1 |
| Fagron | Sodium edetate | 5315A-01925 | 1 |
| Fagron | Sodium edetate | 601EB174 | 1 |
| Fagron | Sodium edetate | 601EB262 | 1 |
| Fagron | Sodium edetate | 601EC350 | 2 |
| Fagron | Sodium edetate | 601EE047 | 4 |
| Fagron | Sodium edetate | 601EF172 | 4 |
| Fagron | Sodium edetate | 601EF200 | 3 |
| Fagron | Sodium edetate | 601EH014 | 1 |
| Fagron | Sodium edetate | 601EI153 | 2 |
| Fagron | Sodium edetate | 601H1300 | 2 |
| Fagron | Sodium edetate | 601H9118 | 1 |
| Fagron | Sodium edetate | 601HA062 | 5 |
| Fagron | Sodium edetate | 6O1EI153 | 1 |
| Fagron | Sodium edetate | 813Q-01925 | 1 |
| Fagron | Sodium edetate | 914E-01925 | 1 |
| Fagron | Sodium edetate | B01-2173006 | 1 |
| Fagron | Sodium edetate | B03-2135901 | 1 |
| Fagron | Sodium edetate | B03-3617200 | 1 |
| Fagron | Sodium edetate | B03-3617201 | 1 |
| Fagron | Sodium edetate | F03-3726108 | 2 |
| Fagron | Sodium edetate | F04-3806709 | 1 |
| Fagron | Sodium edetate | NE5736385 | 1 |
| Fargo/Phönix | Sodium edetate | 18K14-B03 | 1 |
| Fargo/Sana | Sodium edetate | 20004094006 | 1 |
| Fargon/Noweda | Sodium edetate | 18H03-B04-356574 | 2 |
| Fargon/Phönix | Sodium edetate | BO3-3617201 | 1 |
| Fargon | Sodium edetate | 18H03-B04 | 1 |
| Fargon | Sodium edetate | 18H03-B04-353034 | 1 |
| Fargron / Noweda | Sodium edetate | 16f21-b0-330959 | 1 |
| Fiebig | Sodium edetate | 16F21-B02-327696 | 1 |
| Fiebig | Sodium edetate | 18007110 | 1 |
| Fragon/Noweda | Sodium edetate | 18H03-B04-358927 | 1 |
| Gehe | Sodium edetate | 13142018 | 1 |
| Gehe | Sodium edetate | 13E15-N05 | 1 |
| Gehe | Sodium edetate | 15427710 | 1 |
| Gehe | Sodium edetate | 21L06-B01-217364 | 1 |
| Gehe | Sodium edetate | 22003154005 | 1 |
| Gehe | Sodium edetate | 24001067006 | 1 |
| Kehr/Fargon | Sodium edetate | 17d25-b08-343253 | 1 |
| kehr | Sodium edetate | 17D25-B08-339881 | 1 |
| Kehr | Sodium edetate | 21L06-B01 | 1 |
| L12 | Sodium edetate | 15427704 | 2 |
| Nachprüfung | Sodium edetate | 601HA062 | 2 |
| Noweda/Gehe | Sodium edetate | 14G03-B05-307737 | 1 |
| Noweda | Sodium edetate | 15427710 | 1 |
| Noweda | Sodium edetate | 16337312 | 1 |
| Noweda | Sodium edetate | 18K14-B03-361720 | 1 |
| Noweda | Sodium edetate | 22000319007 | 1 |
| noweda | Sodium edetate | 22003154003 | 1 |
| Noweda | Sodium edetate | 22003154003 | 3 |
| Noweda | Sodium edetate | 24000126005 | 1 |
| Noweda | Sodium edetate | 24001067006 | 1 |
| Noweda | Sodium edetate | 2400107006 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Sodium edetate | 601H1300 | 1 |
| Noweda | Sodium edetate | B03-3617200 | 1 |
| Phoenix Goettin | Sodium edetate | 13G15-N03 | 1 |
| Phoenix Goettin | Sodium edetate | 13G15-N03 | 1 |
| Phoenix | Sodium edetate | 15427704 | 1 |
| Phoenix | Sodium edetate | 16F21-B02-333607 | 1 |
| Phoenix | Sodium edetate | 18007110 | 1 |
| Phoenix | Sodium edetate | 3411 | 1 |
| Phönix | Sodium edetate | 11074702 | 1 |
| Phönix | Sodium edetate | 13142004 | 1 |
| phönix | Sodium edetate | 13142018 | 1 |
| Phönix | Sodium edetate | 13E15-B10 | 1 |
| Phönix | Sodium edetate | 13E15-N05 | 2 |
| Phönix | Sodium edetate | 13G15-N03 | 1 |
| phönix | Sodium edetate | 13K19-B02-290051 | 1 |
| phönix | Sodium edetate | 15427703 | 1 |
| phönix | Sodium edetate | 15427704 | 1 |
| Phönix | Sodium edetate | 164599-0001 | 1 |
| Phönix | Sodium edetate | 16F21-B02-327696 | 1 |
| Phönix | Sodium edetate | 18007110 | 1 |
| Phönix | Sodium edetate | 18H03-B04-353034 | 1 |
| Phönix | Sodium edetate | 18K14-B03-358930 | 2 |
| Phönix | Sodium edetate | 200471805 | 1 |
| Phönix | Sodium edetate | 601ef200 | 1 |
| Röntgen | Sodium edetate | 16337302 | 1 |
| Röntgen | Sodium edetate | 20004094001 | 1 |
| Sanacorp 28.06.2016 | Sodium edetate | 15D01-B05-315877 | 2 |
| Sanacorp | Sodium edetate | 12G25-N12 | 2 |
| Sanacorp | Sodium edetate | 13E15-N05 | 1 |
| Sanacorp | Sodium edetate | 1505603 | 1 |
| Sanacorp | Sodium edetate | 164599-0001 | 1 |
| sanacorp | Sodium edetate | 16F21-B02-324370 | 1 |
| Sanacorp | Sodium edetate | 17336115 | 1 |
| Sanacorp | Sodium edetate | 20004094004 | 1 |
| Sanacorp | Sodium edetate | 21h12-b03-213591 | 2 |
| Sanacorp | Sodium edetate | 21i22-F04-380679 | 1 |
| Sanacorp | Sodium edetate | 21L06-B01-217364 | 2 |
| Sanacorp | Sodium edetate | 22000319007 | 1 |
| Sanacorp | Sodium edetate | 6/AKD14 | 1 |
| VDL | Sodium edetate | 22000319008 | 1 |
| Vincenten/ Sanacorp | Sodium edetate | 18K14-B03-3617200 | 1 |

- 255 756 spectra from 1666 *Apo-Ident* customers from a total of 51 894 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium edetate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium edetate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 800 | 0 | 212 140 |
| **Type C** | 0 | 1128 | 2 | 255 756 |

The substance/substance group *Sodium edetate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8230 % (> 99.5575 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20937 | 20937 | 0.00 | 142.58 |
| 21362 | 22465 | 5.23 | 142.46 |
| 22465 | 22465 | 0.00 | 144.47 |
| 22915 | 22915 | 0.00 | 143.77 |
| 22926 | 22465 | 8.03 | 141.83 |
| 24414 | 24414 | 0.00 | 141.23 |
| 26394 | 20937 | 7.40 | 144.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium salicylate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21037-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium salicylate; Natrii salicylas

### Special notes

When selecting the *Sodium salicylate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium salicylate | 4 | 3 | 7 |

### Second-stage model

For differentiation of the substance/substance group *Sodium salicylate* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium salicylate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Dithranol | 74.88 | 16.20 |
| ⋮ | ⋮ | ⋮ |
| Dequalinium chloride | >50 | 50.47 |
| Benzoic acid | >50 | 51.09 |
| Acetylsalicylic acid | >50 | 104.30 |
| Eosin Y | >50 | 156.74 |
| Oxytetracycline hydrochloride | >50 | 261.41 |
| Levothyroxin sodium | >50 | 580.74 |
| Tannin | >50 | 1207.07 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium salicylate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium salicylate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium salicylate | 12158307 | 21037 | 40 | 1403225 |
| Caelo | Sodium salicylate | 13140513 | 21689 | 60 | 20130531 |
| Caelo | Sodium salicylate | 163053 | 23052 | 40 | 20161118* |
| Gatt-Koller | Sodium salicylate | 22J02278 | 26705 | 40 | 20221206 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 180 spectra of 4 reference samples from the substance/substance group *Sodium salicylate*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

- 158 146 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 5 reference samples from the substance/substance group *Sodium salicylate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium salicylate | 16305301 | 22879 | 40 |
| Caelo | Sodium salicylate | 20002958001 | 25428 | 40 |
| Gatt-Koller | Sodium salicylate | 23J02384 | 27094 | 40 |
| Gatt-Koller | Sodium salicylate | 22J02278 | 26705SI† | 20 |
| Gatt-Koller | Sodium salicylate | 23J02384 | 27094SI | 20 |

- 212 780 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 8 spectra from 6 *Apo-Ident* customers from 7 batches from the substance/substance group *Sodium salicylate*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium salicylate | 18061305 | 1 |
| Caelo | Sodium salicylate | 20002958001 | 1 |
| Caesar & Loretz GmbH | Sodium salicylate | 20004439001 | 2 |
| Fagron | Sodium salicylate | 102091210 | 1 |
| GATT-KOLLER/PHOENIX | Sodium salicylate | 4853/11124512 | 1 |
| Gehe | Sodium salicylate | 13G31-B03-287961 | 1 |
| Phoenix | Sodium salicylate | 12158309 | 1 |

- 256 878 spectra from 1666 *Apo-Ident* customers from a total of 52 146 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium salicylate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium salicylate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 8 | 0 | 256 878 |

The substance/substance group *Sodium salicylate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21037 | 21037 | 0.00 | 198.96 |
| 21689 | 21037 | 5.62 | 198.92 |
| 23052 | 23052 | 0.00 | 187.68 |
| 26705 | 21037 | 26.65 | 183.68 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium sulfate decahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20124-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium sulfate decahydrate; Natrii sulfas decahydricus; Sodium sulphate decahydrate

### Special notes

When selecting the *Sodium sulfate decahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium sulfate decahydrate | 2 | 2 | 30 |

### Second-stage model

For differentiation of the substance/substance group *Sodium sulfate decahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium sulfate decahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 45.74 | – |
| Cannabis flower, CBD-dominant type | 70.36 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium sulfate decahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium sulfate decahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium sulfate decahydrate | 23001158 | 27082 | 40 | 20230609* |
| Caelo | Sodium sulfate decahydrate | 23001158 | 27082SI | 20 | 20230609* |
| Euro OTC | Sodium sulfate decahydrate | 2111018 | 26149 | 40 | 20211126* |
| Euro OTC | Sodium sulfate decahydrate | 2111018 | 26149SI | 20 | 20211126* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 120 spectra of 4 reference samples from the substance/substance group *Sodium sulfate decahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 206 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 100 spectra of 3 reference samples from the substance/substance group *Sodium sulfate decahydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Sodium sulfate decahydrate | 1708012-02 | 24274 | 40 |
| Euro OTC | Sodium sulfate decahydrate | 2301001 | 27086 | 40 |
| Euro OTC | Sodium sulfate decahydrate | 2301001 | 27086SI | 20 |

- 212 840 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 74 spectra from 30 *Apo-Ident* customers from 30 batches from the substance/substance group *Sodium sulfate decahydrate*.

- Among them are spectra of independent samples from 30 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium sulfate decahydrate | 21000766021 | 1 |
| Caaelo | Sodium sulfate decahydrate | 11294603 | 2 |
| Caelo | Sodium sulfate decahydrate | 11012207 | 1 |
| Caelo | Sodium sulfate decahydrate | 11012210 | 2 |
| Caelo | Sodium sulfate decahydrate | 12157001 | 1 |
| Caelo | Sodium sulfate decahydrate | 12157005 | 13 |
| Caelo | Sodium sulfate decahydrate | 12157006 | 3 |
| Caelo | Sodium sulfate decahydrate | 12157007 | 1 |
| Caelo | Sodium sulfate decahydrate | 12157011 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium sulfate decahydrate | 12157012 | 18 |
| Caelo | Sodium sulfate decahydrate | 12157013 | 1 |
| Caelo | Sodium sulfate decahydrate | 12256902 | 1 |
| Caelo | Sodium sulfate decahydrate | 12257901 | 1 |
| Caelo | Sodium sulfate decahydrate | 12257902 | 5 |
| Caelo | Sodium sulfate decahydrate | 18101202 | 1 |
| Caelo | Sodium sulfate decahydrate | 205026 | 1 |
| Caelo | Sodium sulfate decahydrate | 61599506 | 1 |
| Caelo | Sodium sulfate decahydrate | 70706387 | 1 |
| EuRho | Sodium sulfate decahydrate | 1210005-01 | 1 |
| Euro OTC | Sodium sulfate decahydrate | 1108035-01 | 3 |
| Euro OTC | Sodium sulfate decahydrate | 1108035-02 | 2 |
| Euro OTC | Sodium sulfate decahydrate | 121000502 | 2 |
| Euro OTC | Sodium sulfate decahydrate | 1210005-02 | 2 |
| Euro OTC | Sodium sulfate decahydrate | 4312I-01920 | 1 |
| Fagron | Sodium sulfate decahydrate | 1464 | 1 |
| Fagron | Sodium sulfate decahydrate | 2134 | 1 |
| fargon/Sanacorp | Sodium sulfate decahydrate | 12H31-N04 | 1 |
| Fiebig 29.04.13 ek: 5,64EUR | Sodium sulfate decahydrate | 1210005-01 | 1 |
| Gehe | Sodium sulfate decahydrate | 12257902 | 1 |
| Hedinger/Phönix | Sodium sulfate decahydrate | 205025 | 1 |
| nachprüfung | Sodium sulfate decahydrate | C1069 | 1 |
| Unisan | Sodium sulfate decahydrate | 11294605 | 1 |

- 256 812 spectra from 1666 *Apo-Ident* customers from a total of 52 123 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium sulfate decahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium sulfate decahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 120 | 0 | 158 206 |
| **Type B** | 0 | 100 | 0 | 212 840 |
| **Type C** | 0 | 74 | 0 | 256 812 |

The substance/substance group *Sodium sulfate decahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 94.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 91.8919 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)


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In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26149 | 26149 | 0.00 | 152.74 |
| 27082 | 27082 | 0.00 | 166.73 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sodium tetraborate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20179-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sodium tetraborate; Borax

### Special notes

When selecting the *Sodium tetraborate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sodium tetraborate | 9 | 14 | 33 |

### Second-stage model

For differentiation of the substance/substance group *Sodium tetraborate* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sodium tetraborate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 40.27 | – |
| Sodium cromoglicate | 48.19 | – |
| Cannabis flower, CBD-dominant type | 54.77 | – |
| ⋮ | ⋮ | ⋮ |
| Magnesium citrate | >50 | 55.51 |
| Riboflavin sodium phosphate hydrate | >50 | 60.06 |
| Carbomers | >50 | 121.40 |
| Gentamicin sulfate | >50 | 127.98 |
| Mg-Ca-K colamine phosphate | >50 | 183.51 |
| Zinc gluconate | >50 | 192.66 |
| Tobramycin sulfate | >50 | 255.09 |
| Neomycin sulfate | >50 | 264.00 |
| Finasteride | >50 | 1488.03 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sodium tetraborate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sodium tetraborate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sodium tetraborate | 13290118 | 21438 | 60 | 1412042 |
| Caelo | Sodium tetraborate | 161372 | 22475 | 60 | 20160624* |
| Caelo | Sodium tetraborate | 161372 | 22621 | 40 | 20160624* |
| Euro OTC | Sodium tetraborate | 1404025-01 | 21656 | 60 | 20140514 |
| Euro OTC | Sodium tetraborate | 1507024 | 21854 | 60 | 20150730* |
| Euro OTC | Sodium tetraborate | 1510032 | 22235 | 60 | 20151118* |
| Euro OTC | Sodium tetraborate | 1711002 | 23892 | 40 | 20171128* |
| Euro OTC | Sodium tetraborate | 2004009 | 25150 | 40 | 20200511* |
| Euro OTC | Sodium tetraborate | 2008006 | 25350 | 40 | 20200904* |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Sodium tetraborate | 2107002 | 25770 | 40 | 20210727* |
| Euro OTC | Sodium tetraborate | 2107002 | 25770SI | 40 | 20210727* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 540 spectra of 11 reference samples from the substance/substance group *Sodium tetraborate*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 786 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1020 spectra of 25 reference samples from the substance/substance group *Sodium tetraborate*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium tetraborate | 21000651002 | 25985 | 40 |
| Caelo | Sodium tetraborate | 24000302 | 27244 | 40 |
| Euro OTC | Sodium tetraborate | 1603043 | 22508 | 40 |
| Euro OTC | Sodium tetraborate | 1607036 | 22713 | 40 |
| Euro OTC | Sodium tetraborate | 1701046 | 22990 | 40 |
| Euro OTC | Sodium tetraborate | 1804014 | 24093 | 40 |
| Euro OTC | Sodium tetraborate | 2111003 | 25895 | 50 |
| Euro OTC | Sodium tetraborate | 2202006 | 25944 | 40 |
| Euro OTC | Sodium tetraborate | 2202007 | 25956 | 40 |
| Euro OTC | Sodium tetraborate | 2202005 | 25968 | 40 |
| Euro OTC | Sodium tetraborate | 2209019 | 26334 | 40 |
| Euro OTC | Sodium tetraborate | 2307005 | 26885 | 40 |
| Euro OTC | Sodium tetraborate | 2310017 | 27000 | 40 |
| Euro OTC | Sodium tetraborate | 2501040 | 27625 | 40 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sodium tetraborate | 21000651002 | 25985SI | 40 |
| Caelo | Sodium tetraborate | 24000302 | 27244SI | 40 |
| Euro OTC | Sodium tetraborate | 2008006 | 25350SI† | 40 |
| Euro OTC | Sodium tetraborate | 2111003 | 25895SI | 50 |
| Euro OTC | Sodium tetraborate | 2202006 | 25944SI | 40 |
| Euro OTC | Sodium tetraborate | 2202007 | 25956SI | 40 |
| Euro OTC | Sodium tetraborate | 2202005 | 25968SI | 40 |
| Euro OTC | Sodium tetraborate | 2209019 | 26334SI | 40 |
| Euro OTC | Sodium tetraborate | 2307005 | 26885SI | 40 |
| Euro OTC | Sodium tetraborate | 2310017 | 27000SI | 40 |
| Euro OTC | Sodium tetraborate | 2501040 | 27625SI | 40 |

- 211 920 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 57 spectra from 44 *Apo-Ident* customers from 35 batches from the substance/substance group *Sodium tetraborate*.

- Among them are spectra of independent samples from 33 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sodium tetraborate | 2202006-01 | 1 |
| | Sodium tetraborate | 2310017-01 | 1 |
| | Sodium tetraborate | 2310017-02 | 2 |
| Borax Francais | Sodium tetraborate | 1402002-01 | 1 |
| Caelo | Sodium tetraborate | 11369412 | 1 |
| Caelo | Sodium tetraborate | 11369431 | 1 |
| Caelo | Sodium tetraborate | 1309032-01 | 1 |
| Caelo | Sodium tetraborate | 13290118 | 1 |
| Caelo | Sodium tetraborate | 14310905 | 2 |
| Caelo | Sodium tetraborate | 150702401 | 1 |
| Caelo | Sodium tetraborate | 1607036-01 | 1 |
| Caelo | Sodium tetraborate | 16081801 | 1 |
| Caelo | Sodium tetraborate | 16137201 | 1 |
| Caelo | Sodium tetraborate | 16137205 | 1 |
| Caelo | Sodium tetraborate | 21051402 | 1 |
| Caesar & Loretz GmbH | Sodium tetraborate | 20000902001 | 1 |
| EuRho | Sodium tetraborate | 1607036-01 | 2 |
| Euro OTC | Sodium tetraborate | | 1 |
| Euro OTC | Sodium tetraborate | 130203401 | 1 |
| Euro OTC | Sodium tetraborate | 1302034-01 | 1 |
| Euro OTC | Sodium tetraborate | 1309032-01 | 1 |
| Euro OTC | Sodium tetraborate | 13111207 | 1 |
| Euro OTC | Sodium tetraborate | 1408006-01 | 1 |
| Euro OTC | Sodium tetraborate | 1503043-01 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Sodium tetraborate | 1507024-01 | 3 |
| Euro OTC | Sodium tetraborate | 160304301 | 1 |
| Euro OTC | Sodium tetraborate | 1607036-01 | 2 |
| Euro OTC | Sodium tetraborate | 1701046-01 | 1 |
| Euro OTC | Sodium tetraborate | 1711002-01 | 8 |
| Euro OTC | Sodium tetraborate | 1804014-01 | 3 |
| Euro OTC | Sodium tetraborate | 2004009-01 | 1 |
| Euro OTC | Sodium tetraborate | 2008006-01 | 3 |
| Euro OTC | Sodium tetraborate | 2107002-01 | 2 |
| Euro OTC | Sodium tetraborate | 22020005-01 | 1 |
| Euro/Alliance Healthcare | Sodium tetraborate | 171100201 | 1 |
| Fagron | Sodium tetraborate | 12H09-N03 | 1 |
| Gatt-Koller / Phoenix | Sodium tetraborate | 6187/01142114 | 1 |
| Phoenix | Sodium tetraborate | 1603043-01 | 1 |
| Sanacorp | Sodium tetraborate | 171100201 | 1 |

- 256 829 spectra from 1666 *Apo-Ident* customers from a total of 52 119 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sodium tetraborate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sodium tetraborate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 540 | 0 | 157 786 |
| **Type B** | 0 | 1020 | 0 | 211 920 |
| **Type C** | 0 | 56 | 1 | 256 829 |

The substance/substance group *Sodium tetraborate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8889 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.4118 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.2456 % (> 92.9825 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21438 | 21438 | 0.00 | 132.22 |
| 21656 | 22475 | 8.18 | 133.84 |
| 21854 | 21854 | 0.00 | 116.48 |
| 22235 | 22235 | 0.00 | 118.31 |
| 22475 | 22475 | 0.00 | 129.41 |
| 22621 | 22621 | 0.00 | 126.88 |
| 23892 | 23892 | 0.00 | 104.79 |
| 25150 | 25150 | 0.00 | 131.94 |
| 25350 | 25350 | 0.00 | 105.29 |
| 25770 | 25770 | 0.00 | 131.84 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sorbic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20881-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sorbic acid; Acidum sorbicum

### Special notes

When selecting the *Sorbic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sorbic acid | 10 | 3 | 116 |

### Second-stage model

For differentiation of the substance/substance group *Sorbic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sorbic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 81.84 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sorbic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sorbic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sorbic acid | 12038025 | 20881 | 40 | 20120315 |
| Caelo | Sorbic acid | 13334008 | 21460 | 60 | AR-15-FG-007849-01 |
| Caelo | Sorbic acid | 14380714 | 22593 | 40 | 20150209 |
| Caelo | Sorbic acid | 162080 | 22616 | 40 | 20160722* |
| Caelo | Sorbic acid | 15382002 | 22826 | 40 | 20151112 |
| Caelo | Sorbic acid | 172056 | 23851 | 40 | 20170823* |
| Caelo | Sorbic acid | 162080 | 23859 | 40 | 20160722* |
| Caelo | Sorbic acid | 20002774 | 25615 | 40 | 20200910* |
| Caelo | Sorbic acid | 22000825 | 26120 | 40 | 20220513* |
| Caelo | Sorbic acid | 22000825 | 26120SI | 20 | 20220513* |
| Caelo | Sorbic acid | 23002243 | 26951 | 40 | 20230914* |
| Caelo | Sorbic acid | 23002243 | 26951SI | 20 | 20230914* |
| Caelo | Sorbic acid | 25000045 | 27545 | 40 | 20250121* |
| Caelo | Sorbic acid | 25000045 | 27545SI | 20 | 20250121* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 520 spectra of 14 reference samples from the substance/substance group *Sorbic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 806 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 3 reference samples from the substance/substance group *Sorbic acid*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sorbic acid | 14176214 | 22592 | 40 |
| Caelo | Sorbic acid | 182876 | 24384 | 40 |
| Caelo | Sorbic acid | 191114 | 24569 | 40 |

- 212 820 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 834 spectra from 503 *Apo-Ident* customers from 123 batches from the substance/substance group *Sorbic acid*.

- Among them are spectra of independent samples from 116 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sorbic acid | 22000825005 | 1 |
| | Sorbic acid | 22000825006 | 1 |
| | Sorbic acid | 22000825009 | 2 |
| | Sorbic acid | 22000825011 | 1 |
| | Sorbic acid | 22000825015 | 1 |
| | Sorbic acid | 22000825016 | 7 |
| | Sorbic acid | 22000825020 | 6 |
| | Sorbic acid | 22000825105 | 2 |
| | Sorbic acid | 22000825106 | 4 |
| | Sorbic acid | 2200825020 | 1 |
| | Sorbic acid | 230002243003 | 1 |
| | Sorbic acid | 23002243003 | 12 |
| | Sorbic acid | 24000027006 | 3 |
| acidum sorbicum | Sorbic acid | 17343411 | 1 |
| AHD | Sorbic acid | 22000825020 | 1 |
| ALH | Sorbic acid | 15382007 | 1 |
| Alliance Healthcare | Sorbic acid | 20000110010 | 1 |
| Alliance Healthcare | Sorbic acid | 20004209014 | 1 |
| Alliance | Sorbic acid | 22000825016 | 1 |
| Alliance | Sorbic acid | 22000825020 | 1 |
| Anzag | Sorbic acid | 12038016 | 1 |
| Caelo | Sorbic acid | | 1 |
| Caelo | Sorbic acid | 10120303 | 1 |
| Caelo | Sorbic acid | 10305208 | 1 |
| Caelo | Sorbic acid | 10305209 | 1 |
| Caelo | Sorbic acid | 105505 | 1 |
| Caelo | Sorbic acid | 11203806 | 2 |
| Caelo | Sorbic acid | 11203807 | 10 |
| Caelo | Sorbic acid | 11203812 | 1 |
| Caelo | Sorbic acid | 12038002 | 1 |
| Caelo | Sorbic acid | 12038009 | 1 |
| Caelo | Sorbic acid | 12038012 | 1 |
| Caelo | Sorbic acid | 12038016 | 6 |
| Caelo | Sorbic acid | 12038020 | 4 |
| Caelo | Sorbic acid | 12038025 | 1 |
| Caelo | Sorbic acid | 12330608 | 8 |
| Caelo | Sorbic acid | 12330618 | 12 |
| Caelo | Sorbic acid | 13334003 | 4 |
| Caelo | Sorbic acid | 13334008 | 6 |
| Caelo | Sorbic acid | 13334010 | 7 |
| Caelo | Sorbic acid | 14176206 | 7 |
| Caelo | Sorbic acid | 14176207 | 1 |
| Caelo | Sorbic acid | 14176209 | 6 |
| Caelo | Sorbic acid | 14176212 | 8 |
| Caelo | Sorbic acid | 14176213 | 1 |
| Caelo | Sorbic acid | 14176214 | 12 |
| Caelo | Sorbic acid | 14380702 | 3 |
| Caelo | Sorbic acid | 14380704 | 1 |
| Caelo | Sorbic acid | 14380706 | 7 |
| Caelo | Sorbic acid | 14380713 | 2 |
| Caelo | Sorbic acid | 14380714 | 11 |
| Caelo | Sorbic acid | 14380715 | 1 |
| Caelo | Sorbic acid | 15123912 | 1 |
| Caelo | Sorbic acid | 15382001 | 1 |
| Caelo | Sorbic acid | 15382002 | 12 |
| Caelo | Sorbic acid | 15382007 | 4 |
| Caelo | Sorbic acid | 15382010 | 15 |
| Caelo | Sorbic acid | 16206012 | 1 |
| Caelo | Sorbic acid | 162080 | 1 |
| Caelo | Sorbic acid | 16208005 | 31 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sorbic acid | 16208007 | 1 |
| Caelo | Sorbic acid | 16208009 | 22 |
| Caelo | Sorbic acid | 16208011 | 13 |
| Caelo | Sorbic acid | 16208012 | 8 |
| Caelo | Sorbic acid | 16208015 | 12 |
| Caelo | Sorbic acid | 16208016 | 19 |
| Caelo | Sorbic acid | 16208018 | 2 |
| Caelo | Sorbic acid | 16208020 | 18 |
| Caelo | Sorbic acid | 1620808005 | 1 |
| Caelo | Sorbic acid | 162508016 | 1 |
| Caelo | Sorbic acid | 170427AS/16208005 | 1 |
| Caelo | Sorbic acid | 1734301 | 1 |
| Caelo | Sorbic acid | 17343401 | 17 |
| Caelo | Sorbic acid | 17343411 | 26 |
| Caelo | Sorbic acid | 17343411P-190225-13 | 1 |
| Caelo | Sorbic acid | 17343422 | 16 |
| Caelo | Sorbic acid | 18215610 | 1 |
| Caelo | Sorbic acid | 1827669 | 1 |
| Caelo | Sorbic acid | 18284605 | 1 |
| Caelo | Sorbic acid | 18286716 | 1 |
| Caelo | Sorbic acid | 18287602 | 2 |
| Caelo | Sorbic acid | 18287605 | 30 |
| Caelo | Sorbic acid | 18287609 | 27 |
| Caelo | Sorbic acid | 18287616 | 22 |
| Caelo | Sorbic acid | 18287616P-191111-5 | 1 |
| Caelo | Sorbic acid | 1887618 | 1 |
| Caelo | Sorbic acid | 191114 | 1 |
| Caelo | Sorbic acid | 191114001 | 20 |
| Caelo | Sorbic acid | 191114002 | 22 |
| Caelo | Sorbic acid | 19111405 | 1 |
| Caelo | Sorbic acid | 19114002 | 2 |
| Caelo | Sorbic acid | 200000110010 | 1 |
| Caelo | Sorbic acid | 20000110010 | 6 |
| Caelo | Sorbic acid | 200004209003 | 2 |
| Caelo | Sorbic acid | 20004209003 | 21 |
| Caelo | Sorbic acid | 20004209011 | 16 |
| Caelo | Sorbic acid | 20004209014 | 20 |
| Caelo | Sorbic acid | 2000420911 | 1 |
| Caelo | Sorbic acid | 200042209011 | 1 |
| Caelo | Sorbic acid | 21041801 | 1 |
| Caelo | Sorbic acid | 220008250009 | 2 |
| Caelo | Sorbic acid | 22000825005 | 4 |
| Caelo | Sorbic acid | 22000825006 | 4 |
| Caelo | Sorbic acid | 22000825009 | 4 |
| Caelo | Sorbic acid | 22000825015 | 1 |
| Caelo | Sorbic acid | 22000825016 | 8 |
| Caelo | Sorbic acid | 22000825020 | 1 |
| Caelo | Sorbic acid | 22000825105 | 1 |
| Caelo | Sorbic acid | 22000825106 | 1 |
| Caelo | Sorbic acid | 2200825009 | 1 |
| Caelo | Sorbic acid | 2200825020 | 1 |
| Caelo | Sorbic acid | 221019(20004209014) | 1 |
| Caelo | Sorbic acid | 24000027006 | 1 |
| Caelo | Sorbic acid | 28041726 | 1 |
| Caelo | Sorbic acid | 29071201 | 1 |
| Caelo | Sorbic acid | 4016I-01048 | 1 |
| Caelo | Sorbic acid | 4811Q-01048 | 1 |
| Caelo | Sorbic acid | 5012E-01048 | 1 |
| Caelo | Sorbic acid | 72687038 | 1 |
| Caelo | Sorbic acid | 80538258 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sorbic acid | 9280207 | 1 |
| Caelo | Sorbic acid | 93557220 | 2 |
| Caelo | Sorbic acid | P0538258 | 1 |
| Caeo/ Phoenix | Sorbic acid | 18287616 | 1 |
| Caesar & Lorenz GmbH | Sorbic acid | 18287609 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 191114001 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 18287616 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 16208009 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 191114002 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 18287616 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 19111405 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 22000825006 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20000110005 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 19111406 | 1 |
| Caesar & Loretz GmbH/Gehe | Sorbic acid | 191114001 | 1 |
| Caesar & Loretz GmbH/Gehe | Sorbic acid | 191114002 | 1 |
| Caesar & Loretz GmbH/Gehe | Sorbic acid | 22000825006 | 2 |
| Caesar & Loretz GmbH... | Sorbic acid | 18287609 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 191114001 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20004209003 | 1 |
| Caesar & Loretz GmbH/K | Sorbic acid | 20004209014 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 191114001 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20004209003 | 2 |
| Caesar & Loretz GmbH... | Sorbic acid | 20000110005 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20000110010 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20004209003 | 1 |
| Caesar & Loretz GmbH/Sana | Sorbic acid | 18287606 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 191114005 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20000110010 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20004209003 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20004209006 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 20004209010 | 4 |
| Caesar & Loretz GmbH... | Sorbic acid | 20004209011 | 1 |
| Caesar & Loretz GmbH... | Sorbic acid | 22000825016 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 18287605 | 7 |
| Caesar & Loretz GmbH | Sorbic acid | 18287609 | 7 |
| Caesar & Loretz GmbH | Sorbic acid | 18287615 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 18287616 | 12 |
| Caesar & Loretz GmbH | Sorbic acid | 191114001 | 11 |
| Caesar & Loretz GmbH | Sorbic acid | 191114002 | 2 |
| Caesar & Loretz GmbH | Sorbic acid | 20000110010 | 2 |
| Caesar & Loretz GmbH | Sorbic acid | 20004209002 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 20004209003 | 7 |
| Caesar & Loretz GmbH | Sorbic acid | 20004209008 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 20004209011 | 2 |
| Caesar & Loretz GmbH | Sorbic acid | 20004209014 | 14 |
| Caesar & Loretz GmbH | Sorbic acid | 22000825006 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 22000825009 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 22000825020 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 22000825105 | 1 |
| Caesar & Loretz GmbH | Sorbic acid | 22000825106 | 2 |
| Caesar & Loretz/Noweda | Sorbic acid | 14380706 | 1 |
| Caesar/Gehe | Sorbic acid | 17343422 | 1 |
| Cealo/Gehe | Sorbic acid | 22000825009 | 1 |
| Cealo | Sorbic acid | 16208011 | 1 |
| Ebert & Jacobi | Sorbic acid | 16208005 | 1 |
| Euro OTC | Sorbic acid | 12038020 | 1 |
| Euro OTC | Sorbic acid | o216E-01048 | 1 |
| Fa.Phönix | Sorbic acid | 16208011 | 1 |
| Fagron | Sorbic acid | 121394 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sorbic acid | 13334008 | 1 |
| Fagron | Sorbic acid | 14176206 | 1 |
| Fagron | Sorbic acid | 17343422 | 1 |
| Fiebig | Sorbic acid | 168009 | 1 |
| Finze | Sorbic acid | 9280207 | 1 |
| Fischar | Sorbic acid | 16208005 | 1 |
| Gatt-Koller / Phoenix | Sorbic acid | 2575/07142914 | 1 |
| Gehe Rostock | Sorbic acid | 191114001 | 1 |
| Gehe | Sorbic acid | 16208011 | 1 |
| Gehe | Sorbic acid | 16208012 | 1 |
| gehe | Sorbic acid | 16208016 | 1 |
| Gehe | Sorbic acid | 17343401 | 1 |
| GEHE | Sorbic acid | 17343401 | 1 |
| Gehe | Sorbic acid | 18287605 | 1 |
| Gehe | Sorbic acid | 18287609 | 2 |
| Gehe | Sorbic acid | 191114002 | 1 |
| Gehe | Sorbic acid | 20004209011 | 1 |
| Gehe | Sorbic acid | 2200825020 | 1 |
| Geilenkirchen | Sorbic acid | 16208009 | 1 |
| H.Lamotte | Sorbic acid | 17343401 | 1 |
| Kehr-Holdermann | Sorbic acid | 22000825105 | 1 |
| L12 | Sorbic acid | 15382010 | 1 |
| L12 | Sorbic acid | 18287602 | 1 |
| Noweda | Sorbic acid | 12038016 | 1 |
| Noweda | Sorbic acid | 12330608 | 1 |
| Noweda | Sorbic acid | 14176206 | 1 |
| Noweda | Sorbic acid | 1418M-01048 | 1 |
| Noweda | Sorbic acid | 14380706 | 1 |
| Noweda | Sorbic acid | 16208020 | 1 |
| Noweda | Sorbic acid | 18287605 | 3 |
| Noweda | Sorbic acid | 18287609 | 1 |
| Noweda | Sorbic acid | 20000110010 | 1 |
| Noweda | Sorbic acid | 20004209003 | 2 |
| Noweda | Sorbic acid | 22000825011 | 1 |
| Noweda | Sorbic acid | 22000825020 | 2 |
| Noweda | Sorbic acid | 23002243003 | 1 |
| Noweda | Sorbic acid | 24000027006 | 1 |
| Phoenix 17.4.13 | Sorbic acid | 12038020 | 1 |
| PHOENIX 12.05.2014 | Sorbic acid | 13334008 | 1 |
| Phoenix 22.03.2017 6,67EUR | Sorbic acid | 15382010 | 1 |
| Phoenix | Sorbic acid | 11203813 | 1 |
| Phoenix | Sorbic acid | 191114001 | 1 |
| Phoenix | Sorbic acid | 20004209003 | 1 |
| Phönix | Sorbic acid | 12330618 | 1 |
| phönix | Sorbic acid | 15382010 | 1 |
| Phönix | Sorbic acid | 16208005 | 1 |
| Phönix | Sorbic acid | 16208020 | 1 |
| Phönix | Sorbic acid | 18287605 | 1 |
| Phönix | Sorbic acid | 20000110010 | 1 |
| Phönix | Sorbic acid | 24000027006 | 1 |
| PHÖNIX | Sorbic acid | 9308627 | 1 |
| Sanacorp | Sorbic acid | 12038016 | 1 |
| Sanacorp | Sorbic acid | 13334008 | 1 |
| Sanacorp | Sorbic acid | 16208020 | 1 |
| Sanacorp | Sorbic acid | 18287605 | 2 |
| Sanacorp | Sorbic acid | 20004209003 | 1 |
| Sanacorp | Sorbic acid | 22000825006 | 1 |
| Sanacorp | Sorbic acid | 22000825008 | 1 |
| Sanacorp | Sorbic acid | 23002243003 | 1 |
| SanacorpWE: 23.09.14... | Sorbic acid | 14176212 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Th. Geyer | Sorbic acid | 17343411 | 1 |
| vdl 28.04.2014 preis:5,79 | Sorbic acid | | 1 |
| VDL;5,78EUR;18.12 | Sorbic acid | 14176206 | 1 |

- 256 052 spectra from 1666 *Apo-Ident* customers from a total of 52 032 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sorbic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sorbic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 520 | 0 | 157 806 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 834 | 0 | 256 052 |

The substance/substance group *Sorbic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8462 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 99.2806 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20881 | 23851 | 7.22 | 135.48 |
| 21460 | 21460 | 0.00 | 135.71 |
| 22593 | 23859 | 5.56 | 136.52 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22616 | 22616 | 0.00 | 140.21 |
| 22826 | 21460 | 8.18 | 132.80 |
| 23851 | 23851 | 0.00 | 134.75 |
| 23859 | 23859 | 0.00 | 135.05 |
| 25615 | 25615 | 0.00 | 132.46 |
| 26120 | 26120 | 0.00 | 154.12 |
| 26951 | 26951 | 0.00 | 161.59 |
| 27545 | 27545 | 0.00 | 141.64 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sorbitol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20075-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sorbitol; Sorbitolum

### Special notes

When selecting the *Sorbitol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sorbitol | 9 | 14 | 161 |

### Second-stage model

For differentiation of the substance/substance group *Sorbitol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sorbitol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 49.76 | – |
| Polymyxin B sulfate | 69.93 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sorbitol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sorbitol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sorbitol | 13278217 | 21485 | 40 | 20130920 |
| Caelo | Sorbitol | 16038501 | 22847 | 40 | 20160315 |
| Caelo | Sorbitol | 163531 | 23028 | 40 | 20170119* |
| Caelo | Sorbitol | 16353107 | 23442 | 40 | 20170119 |
| Caelo | Sorbitol | 20001873 | 25226 | 40 | 20200722* |
| Euro OTC | Sorbitol | 1506052 | 21834 | 60 | 20150713* |
| Euro OTC | Sorbitol | 1512016 | 22293 | 60 | 20160113* |
| Euro OTC | Sorbitol | 1604007 | 22539 | 40 | 20160428* |
| Euro OTC | Sorbitol | 1610018 | 22849 | 40 | 20161121* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 9 reference samples from the substance/substance group *Sorbitol*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 926 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 680 spectra of 20 reference samples from the substance/substance group *Sorbitol*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sorbitol | 181636 | 24220 | 40 |
| Caelo | Sorbitol | 190173 | 24562 | 40 |
| Caelo | Sorbitol | 192579 | 24898 | 40 |
| Caelo | Sorbitol | 22003595 | 26503 | 40 |
| Caelo | Sorbitol | 23000792 | 26707 | 40 |
| Caelo | Sorbitol | 24000391 | 27252 | 40 |
| Euro OTC | Sorbitol | 1810010 | 24306 | 40 |
| Euro OTC | Sorbitol | 2008016 | 25333 | 40 |
| Euro OTC | Sorbitol | 2108021 | 25878 | 50 |
| Euro OTC | Sorbitol | 2207023 | 26271 | 40 |
| Euro OTC | Sorbitol | 2407005 | 27396 | 40 |
| Euro OTC | Sorbitol | 2411016 | 27463 | 40 |
| Fagron | Sorbitol | 22B07-B02-218419 | 26153 | 40 |
| Fagron | Sorbitol | 22J22-B02 | 26446 | 40 |
| Caelo | Sorbitol | 22003595 | 26503SI | 20 |
| Euro OTC | Sorbitol | 2108021 | 25878SI | 10 |
| Euro OTC | Sorbitol | 2207023 | 26271SI | 20 |
| Euro OTC | Sorbitol | 2407005 | 27396SI | 20 |
| Euro OTC | Sorbitol | 2411016 | 27463SI | 20 |
| Fagron | Sorbitol | 22B07-B02-218419 | 26153SI | 20 |

- 212 260 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 498 spectra from 208 *Apo-Ident* customers from 166 batches from the substance/substance group *Sorbitol*.
- Among them are spectra of independent samples from 160 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sorbitol | 192579006 | 1 |
| | Sorbitol | 21003580009 | 1 |
| | Sorbitol | 21003580014 | 1 |
| | Sorbitol | 21003580017 | 2 |
| | Sorbitol | 2108021-01 | 1 |
| | Sorbitol | 22003595002 | 1 |
| | Sorbitol | 22003595005 | 5 |
| | Sorbitol | 22003595007 | 2 |
| | Sorbitol | 22003595008 | 2 |
| | Sorbitol | 2200359500864/23P | 1 |
| | Sorbitol | 22003595009 | 1 |
| | Sorbitol | 2207023-03 | 1 |
| | Sorbitol | 23000792004 | 4 |
| | Sorbitol | 23000792005 | 5 |
| | Sorbitol | 2300792005 | 1 |
| | Sorbitol | 24000391002 | 4 |
| | Sorbitol | 2407005-01 | 1 |
| Bombastus | Sorbitol | 13278206 | 2 |
| Cael Noweda | Sorbitol | 17140903 | 3 |
| Caela/ L2 | Sorbitol | 16038501 | 1 |
| Caelo | Sorbitol | | 1 |
| Caelo | Sorbitol | 10383323 | 1 |
| Caelo | Sorbitol | 1083330 | 1 |
| Caelo | Sorbitol | 113793 | 1 |
| Caelo | Sorbitol | 11379320 | 1 |
| Caelo | Sorbitol | 11379321 | 1 |
| Caelo | Sorbitol | 11379322 | 1 |
| Caelo | Sorbitol | 11379332 | 2 |
| Caelo | Sorbitol | 11379333 | 1 |
| Caelo | Sorbitol | 11379336 | 2 |
| Caelo | Sorbitol | 11379337 | 2 |
| Caelo | Sorbitol | 12249108 | 2 |
| Caelo | Sorbitol | 12249109 | 2 |
| Caelo | Sorbitol | 12249110 | 4 |
| Caelo | Sorbitol | 12249124 | 2 |
| Caelo | Sorbitol | 12249126 | 2 |
| Caelo | Sorbitol | 12249139 | 1 |
| Caelo | Sorbitol | 12249140 | 1 |
| Caelo | Sorbitol | 12345 | 1 |
| Caelo | Sorbitol | 12L07-N12 | 1 |
| Caelo | Sorbitol | 13278204 | 1 |
| Caelo | Sorbitol | 13278206 | 1 |
| Caelo | Sorbitol | 13278216 | 2 |
| Caelo | Sorbitol | 13278218 | 1 |
| Caelo | Sorbitol | 13278239 | 1 |
| Caelo | Sorbitol | 13278241 | 1 |
| Caelo | Sorbitol | 13278246 | 2 |
| Caelo | Sorbitol | 13278247 | 1 |
| Caelo | Sorbitol | 13278249 | 1 |
| Caelo | Sorbitol | 13278250 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sorbitol | 133335307 | 1 |
| Caelo | Sorbitol | 13335304 | 1 |
| Caelo | Sorbitol | 13335307 | 3 |
| Caelo | Sorbitol | 14250806 | 1 |
| Caelo | Sorbitol | 14250807 | 1 |
| Caelo | Sorbitol | 14250808 | 1 |
| Caelo | Sorbitol | 15012708 | 1 |
| Caelo | Sorbitol | 15118901 | 3 |
| Caelo | Sorbitol | 15118902 | 2 |
| Caelo | Sorbitol | 15118912 | 1 |
| Caelo | Sorbitol | 15208302 | 4 |
| Caelo | Sorbitol | 15208303 | 2 |
| Caelo | Sorbitol | 15208305 | 4 |
| Caelo | Sorbitol | 15208306 | 4 |
| Caelo | Sorbitol | 15208309 | 3 |
| Caelo | Sorbitol | 15208310 | 5 |
| Caelo | Sorbitol | 15208311 | 3 |
| Caelo | Sorbitol | 16038501 | 5 |
| Caelo | Sorbitol | 16038502 | 3 |
| Caelo | Sorbitol | 16038503 | 1 |
| Caelo | Sorbitol | 16038514 | 9 |
| Caelo | Sorbitol | 16038515 | 9 |
| Caelo | Sorbitol | 1604007-01 | 1 |
| Caelo | Sorbitol | 1610018-01 | 1 |
| Caelo | Sorbitol | 16101303 | 1 |
| Caelo | Sorbitol | 16231208 | 1 |
| Caelo | Sorbitol | 162353107 | 1 |
| Caelo | Sorbitol | 16353102 | 3 |
| Caelo | Sorbitol | 16353107 | 3 |
| Caelo | Sorbitol | 16353108 | 4 |
| Caelo | Sorbitol | 17011305 | 1 |
| Caelo | Sorbitol | 17140902 | 9 |
| Caelo | Sorbitol | 17140903 | 11 |
| Caelo | Sorbitol | 17140904 | 8 |
| Caelo | Sorbitol | 1714090903 | 1 |
| Caelo | Sorbitol | 17366301 | 15 |
| Caelo | Sorbitol | 17366304 | 7 |
| Caelo | Sorbitol | 17366305 | 3 |
| Caelo | Sorbitol | 18163605 | 2 |
| Caelo | Sorbitol | 18163606 | 9 |
| Caelo | Sorbitol | 18163607 | 6 |
| Caelo | Sorbitol | 181636606 | 1 |
| Caelo | Sorbitol | 18281603 | 2 |
| Caelo | Sorbitol | 18281605 | 5 |
| Caelo | Sorbitol | 18281605P-190624-2 | 1 |
| Caelo | Sorbitol | 18281610 | 2 |
| Caelo | Sorbitol | 19017304 | 5 |
| Caelo | Sorbitol | 19017305 | 1 |
| Caelo | Sorbitol | 19017307 | 11 |
| Caelo | Sorbitol | 19017308 | 1 |
| Caelo | Sorbitol | 19017312 | 5 |
| Caelo | Sorbitol | 192579001 | 4 |
| Caelo | Sorbitol | 192579002 | 1 |
| Caelo | Sorbitol | 192579006 | 2 |
| Caelo | Sorbitol | 192579007 | 4 |
| Caelo | Sorbitol | 200003822010 | 1 |
| Caelo | Sorbitol | 2000322010 | 1 |
| Caelo | Sorbitol | 20003822001 | 3 |
| Caelo | Sorbitol | 20003822005 | 6 |
| Caelo | Sorbitol | 20003822006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sorbitol | 20003822008 | 1 |
| Caelo | Sorbitol | 20003822010 | 2 |
| Caelo | Sorbitol | 20003822011 | 1 |
| Caelo | Sorbitol | 20003822012 | 1 |
| Caelo | Sorbitol | 20003822016 | 2 |
| Caelo | Sorbitol | 20021501 | 1 |
| Caelo | Sorbitol | 2003822012 | 1 |
| Caelo | Sorbitol | 21003580001 | 2 |
| Caelo | Sorbitol | 21003580002 | 1 |
| Caelo | Sorbitol | 21003580007 | 1 |
| Caelo | Sorbitol | 21003580008 | 1 |
| Caelo | Sorbitol | 225282222169 | 1 |
| Caelo | Sorbitol | 23071201 | 1 |
| Caelo | Sorbitol | 23081401 | 1 |
| Caelo | Sorbitol | 26071402 | 1 |
| Caelo | Sorbitol | 4091401 | 1 |
| Caelo | Sorbitol | 5021307 | 1 |
| Caelo | Sorbitol | 8081402 | 1 |
| Caerlo | Sorbitol | 17366304 | 2 |
| Caesar & Loretz GmbH... | Sorbitol | 19017307 | 1 |
| Caesar & Loretz GmbH... | Sorbitol | 192579007 | 1 |
| Caesar & Loretz GmbH... | Sorbitol | 18163607 | 1 |
| Caesar & Loretz GmbH... | Sorbitol | 18281603 | 1 |
| Caesar & Loretz GmbH... | Sorbitol | 19017305 | 1 |
| Caesar & Loretz GmbH... | Sorbitol | 19017307 | 2 |
| Caesar & Loretz GmbH/Gehe | Sorbitol | 19017308 | 5 |
| Caesar & Loretz GmbH/Gehe | Sorbitol | 19017312 | 1 |
| Caesar & Loretz GmbH/Gehe | Sorbitol | 192579007 | 1 |
| Caesar & Loretz GmbH/Gehe | Sorbitol | 20003822008 | 2 |
| Caesar & Loretz GmbH... | Sorbitol | 19017302 | 2 |
| Caesar & Loretz GmbH... | Sorbitol | 192579002 | 1 |
| Caesar & Loretz GmbH | Sorbitol | 16353108 | 2 |
| Caesar & Loretz GmbH | Sorbitol | 18163606 | 2 |
| Caesar & Loretz GmbH | Sorbitol | 18163607 | 4 |
| Caesar & Loretz GmbH | Sorbitol | 18281602 | 3 |
| Caesar & Loretz GmbH | Sorbitol | 18281605 | 4 |
| Caesar & Loretz GmbH | Sorbitol | 19017302 | 1 |
| Caesar & Loretz GmbH | Sorbitol | 19017304 | 1 |
| Caesar & Loretz GmbH | Sorbitol | 19017307 | 2 |
| Caesar & Loretz GmbH | Sorbitol | 19017312 | 4 |
| Caesar & Loretz GmbH | Sorbitol | 192579002 | 2 |
| Caesar & Loretz GmbH | Sorbitol | 192579004 | 2 |
| Caesar & Loretz GmbH | Sorbitol | 192579006 | 3 |
| Caesar & Loretz GmbH | Sorbitol | 20003822001 | 2 |
| Caesar & Loretz GmbH | Sorbitol | 20003822005 | 1 |
| Caesar & Loretz GmbH | Sorbitol | 20003822010 | 1 |
| Caesar & Loretz GmbH | Sorbitol | 21003580007 | 1 |
| Caesar & Loretz GmbH | Sorbitol | 21003580008 | 4 |
| Caesar & Loretz GmbH | Sorbitol | 21003580009 | 1 |
| Caesar u. Loretz GmbH | Sorbitol | 20003822006 | 1 |
| EuRho/Anzag | Sorbitol | 3518E-02298 | 1 |
| EuRho/Anzag | Sorbitol | 4712I-02298 | 1 |
| eurho | Sorbitol | 1301019-01 | 1 |
| EuRho | Sorbitol | 1501048-01 | 2 |
| EuRho | Sorbitol | 161001802 | 1 |
| Euro OTC | Sorbitol | | 1 |
| Euro OTC | Sorbitol | 1301019-01 | 3 |
| Euro OTC | Sorbitol | 1311034-01 | 2 |
| Euro OTC | Sorbitol | 1404007-01 | 2 |
| Euro OTC | Sorbitol | 1406014-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Sorbitol | 1501048-01 | 2 |
| Euro OTC | Sorbitol | 1506052-01 | 4 |
| Euro OTC | Sorbitol | 150652-01 | 1 |
| Euro OTC | Sorbitol | 1512016-01 | 6 |
| Euro OTC | Sorbitol | 1604007-01 | 4 |
| Euro OTC | Sorbitol | 1610018-01 | 16 |
| Euro OTC | Sorbitol | 1610018-02 | 3 |
| Euro OTC | Sorbitol | 1610018-03 | 8 |
| Euro OTC | Sorbitol | 1810010-01 | 2 |
| Euro OTC | Sorbitol | 1810010-02 | 2 |
| Euro OTC | Sorbitol | 2008016-01 | 2 |
| Euro OTC | Sorbitol | 2008016-02 | 2 |
| Euro OTC | Sorbitol | 200816-01 | 1 |
| Euro OTC | Sorbitol | 2108021-01 | 1 |
| Euro OTC | Sorbitol | 3217M-02298 | 1 |
| Euro OTC | Sorbitol | 3617I-02298 | 1 |
| Euro OTC | Sorbitol | 700476 | 1 |
| Fagron | Sorbitol | | 1 |
| Fagron | Sorbitol | 11I09-N11 | 1 |
| Fagron | Sorbitol | 12E30-N24 | 3 |
| Fagron | Sorbitol | 12J15-N01 | 1 |
| Fagron | Sorbitol | 12L17-N12 | 3 |
| Fagron | Sorbitol | 13278249 | 1 |
| Fagron | Sorbitol | 13D08-N27 | 1 |
| Fagron | Sorbitol | 13E07-B40 | 2 |
| Fagron | Sorbitol | 13G04-N04 | 1 |
| Fagron | Sorbitol | 14E21-B02 | 1 |
| Fagron | Sorbitol | M721140 | 1 |
| Fagron | Sorbitol | M721140/12L17-N12 | 1 |
| Gatt-Koller / Phoenix | Sorbitol | 1718/0513 | 1 |
| Gatt-Koller / Phoenix | Sorbitol | 1718/05134013 | 1 |
| Gehe 01.09.2014 | Sorbitol | 13278217 | 1 |
| GEHE 28.11.2014 | Sorbitol | 13278245 | 1 |
| GEHE | Sorbitol | 16353108 | 1 |
| Gehe | Sorbitol | 18163606 | 1 |
| GEHE | Sorbitol | 19017305 | 1 |
| Gehe | Sorbitol | 21003580009 | 1 |
| Gehe | Sorbitol | 22003595005 | 1 |
| Gehe | Sorbitol | 22003595007 | 1 |
| Gehe | Sorbitol | 22003595008 | 1 |
| Hänseler | Sorbitol | | 1 |
| Herba ACM | Sorbitol | 22J01085 | 1 |
| Jenne / Euro | Sorbitol | 2008016-01 | 2 |
| Jenne | Sorbitol | 22003595008 | 1 |
| Jenne | Sorbitol | 231018(22003595008) | 1 |
| L10 | Sorbitol | 16353108 | 1 |
| Merck | Sorbitol | 13D08-N27 | 1 |
| Noweda/ Ichthyol | Sorbitol | 1512016-01 | 1 |
| Noweda | Sorbitol | 17140903 | 1 |
| Noweda | Sorbitol | 22003595008 | 1 |
| Noweda | Sorbitol | 2300792005 | 1 |
| Phoenix 12.08.2013 | Sorbitol | 12249108 | 1 |
| phoenix? | Sorbitol | 22003595007 | 1 |
| Phönix Berlin | Sorbitol | 22003595005 | 1 |
| PHÖNIX | Sorbitol | 18281603 | 1 |
| phönix | Sorbitol | 21003580002 | 1 |
| Sana | Sorbitol | 18281603 | 1 |
| Sanacorp | Sorbitol | 1610018-01 | 1 |
| Sanacorp | Sorbitol | 16353107 | 1 |
| siehe Protokoll | Sorbitol | 15208310 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spangro 17.05.19 | Sorbitol | 17140902 | 1 |

- 256 388 spectra from 1666 *Apo-Ident* customers from a total of 51 992 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sorbitol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sorbitol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 680 | 0 | 212 260 |
| **Type C** | 0 | 498 | 0 | 256 388 |

The substance/substance group *Sorbitol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.1176 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 98.7952 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21485 | 21834 | 6.10 | 92.07 |
| 21834 | 21834 | 0.00 | 96.71 |
| 22293 | 22293 | 0.00 | 89.97 |
| 22539 | 22539 | 0.00 | 89.52 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22847 | 21834 | 3.20 | 92.97 |
| 22849 | 22849 | 0.00 | 89.75 |
| 23028 | 23028 | 0.00 | 97.82 |
| 23442 | 21834 | 5.76 | 97.91 |
| 25226 | 25226 | 0.00 | 111.46 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sotalol hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 22656-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sotalol hydrochloride; Sotaloli hydrochloridum

### Special notes

When selecting the *Sotalol hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sotalol hydrochloride | 3 | 2 | 3 |

### Second-stage model

For differentiation of the substance/substance group *Sotalol hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sotalol hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 135.78 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sotalol hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sotalol hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sotalol hydrochloride | 20000112 | 25199 | 40 | 20200210* |
| Caelo | Sotalol hydrochloride | 24002039 | 27442 | 40 | 20241121* |
| Caelo | Sotalol hydrochloride | 24002039 | 27442SI | 20 | 20241121* |
| Fagron | Sotalol hydrochloride | 21E21-B04-218998 | 26324 | 40 | 20210702 |
| Fagron | Sotalol hydrochloride | 21E21-B04-218998 | 26324SI | 20 | 20210702 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 160 spectra of 5 reference samples from the substance/substance group *Sotalol hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 166 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 100 spectra of 3 reference samples from the substance/substance group *Sotalol hydrochloride*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Sotalol hydrochloride | 24J01-B01-007140 | 27601 | 40 |
| Inresa | Sotalol hydrochloride | 369-MC | 22656 | 40 |
| Fagron | Sotalol hydrochloride | 24J01-B01-007140 | 27601SI | 20 |

- 212 840 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4 spectra from 2 *Apo-Ident* customers from 3 batches from the substance/substance group *Sotalol hydrochloride*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Holdermann | Sotalol hydrochloride | 23003423001 | 2 |
| Kehr | Sotalol hydrochloride | 21001470007 | 1 |
| Noweda | Sotalol hydrochloride | 24002039001 | 1 |

- 256 882 spectra from 1666 *Apo-Ident* customers from a total of 52 150 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sotalol hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sotalol hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 160 | 0 | 158 166 |
| **Type B** | 0 | 100 | 0 | 212 840 |
| **Type C** | 0 | 4 | 0 | 256 882 |

The substance/substance group *Sotalol hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.2500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 94.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25199 | 25199 | 0.00 | 224.00 |
| 26324 | 27442 | 4.60 | 224.38 |
| 27442 | 27442 | 0.00 | 223.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Soy lecithin (instant form)** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20539-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Soy lecithin (instant form); Lecithinum e sojae plv.

### Special notes

When selecting the *Soy lecithin (instant form)* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Soy lecithin (instant form) | 6 | 3 | 43 |

### Second-stage model

For differentiation of the substance/substance group *Soy lecithin (instant form)* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Soy lecithin (instant form)* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Mupirocin calcium | 66.61 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Soy lecithin (instant form)* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Soy lecithin (instant form)*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Soy lecithin (instant form) | 13030504 | 20985 | 40 | 1404399 |
| Caelo | Soy lecithin (instant form) | 173224 | 24244 | 40 | 20171218* |
| Caelo | Soy lecithin (instant form) | 191879 | 24749 | 40 | 20190712* |
| Caelo | Soy lecithin (instant form) | 20002522003 | 25521 | 40 | 20200924 |
| Caelo | Soy lecithin (instant form) | 24002528 | 27547 | 40 | 20250115* |
| Caelo | Soy lecithin (instant form) | 24002528 | 27547SI | 20 | 20250115* |
| Caelo | Soy lecithin (instant form) | 25000921 | 27664 | 40 | 20250508* |
| Caelo | Soy lecithin (instant form) | 25000921 | 27664SI | 20 | 20250508* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 280 spectra of 8 reference samples from the substance/substance group *Soy lecithin (instant form)*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 170 spectra of 4 reference samples from the substance/substance group *Soy lecithin (instant form)*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Soy lecithin (instant form) | 13279813 | 21523 | 40 |
| Caelo | Soy lecithin (instant form) | 17118101 | 23370 | 40 |
| Caelo | Soy lecithin (instant form) | 21001068004 | 25784 | 50 |
| Caelo | Soy lecithin (instant form) | 17118101 | 23445 | 40 |

- 212 770 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 87 spectra from 49 *Apo-Ident* customers from 45 batches from the substance/substance group *Soy lecithin (instant form)*.

- Among them are spectra of independent samples from 43 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Soy lecithin (instant form) | 23000766003 | 2 |
| | Soy lecithin (instant form) | 24002528002 | 2 |
| Caelo | Soy lecithin (instant form) | | 1 |
| Caelo | Soy lecithin (instant form) | 11371504 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Soy lecithin (instant form) | 12139001 | 3 |
| Caelo | Soy lecithin (instant form) | 12139011 | 3 |
| Caelo | Soy lecithin (instant form) | 12139012 | 1 |
| Caelo | Soy lecithin (instant form) | 13030503 | 1 |
| Caelo | Soy lecithin (instant form) | 13030506 | 1 |
| Caelo | Soy lecithin (instant form) | 13279806 | 1 |
| Caelo | Soy lecithin (instant form) | 13279814 | 1 |
| Caelo | Soy lecithin (instant form) | 14196305 | 1 |
| Caelo | Soy lecithin (instant form) | 14281605 | 1 |
| Caelo | Soy lecithin (instant form) | 14281606 | 2 |
| Caelo | Soy lecithin (instant form) | 14281618 | 4 |
| Caelo | Soy lecithin (instant form) | 14281620 | 1 |
| Caelo | Soy lecithin (instant form) | 15262701 | 4 |
| Caelo | Soy lecithin (instant form) | 15262704 | 4 |
| Caelo | Soy lecithin (instant form) | 1526704 | 1 |
| Caelo | Soy lecithin (instant form) | 16223302 | 4 |
| Caelo | Soy lecithin (instant form) | 17081501 | 2 |
| Caelo | Soy lecithin (instant form) | 17118101 | 1 |
| Caelo | Soy lecithin (instant form) | 17118102 | 1 |
| Caelo | Soy lecithin (instant form) | 17118105 | 2 |
| Caelo | Soy lecithin (instant form) | 17118108 | 1 |
| Caelo | Soy lecithin (instant form) | 17322401 | 3 |
| Caelo | Soy lecithin (instant form) | 17322402 | 1 |
| Caelo | Soy lecithin (instant form) | 17322405 | 5 |
| Caelo | Soy lecithin (instant form) | 18282701 | 3 |
| Caelo | Soy lecithin (instant form) | 19009101 | 3 |
| Caelo | Soy lecithin (instant form) | 19009113 | 1 |
| Caelo | Soy lecithin (instant form) | 20000718005 | 1 |
| Caelo | Soy lecithin (instant form) | 21001068003 | 1 |
| Caelo | Soy lecithin (instant form) | 21001068004 | 1 |
| Caelo | Soy lecithin (instant form) | 21002621003 | 1 |
| Caesar & Loretz GmbH Gehe | Soy lecithin (instant form) | 21001068004 | 1 |
| Caesar & Loretz GmbH... | Soy lecithin (instant form) | 12139013 | 1 |
| Caesar & Loretz GmbH... | Soy lecithin (instant form) | 20002522003 | 2 |
| Caesar & Loretz GmbH... | Soy lecithin (instant form) | 20000718001 | 1 |
| Caesar & Loretz GmbH... | Soy lecithin (instant form) | 20000718005 | 1 |
| Caesar & Loretz GmbH... | Soy lecithin (instant form) | 19009110 | 1 |
| Caesar & Loretz GmbH... | Soy lecithin (instant form) | 19009107 | 1 |
| Caesar & Loretz GmbH | Soy lecithin (instant form) | 14281603 | 1 |
| Caesar & Loretz GmbH | Soy lecithin (instant form) | 19009103 | 2 |
| Caesar & Loretz GmbH | Soy lecithin (instant form) | 19187901 | 2 |
| Caesar &Loretz GmbH | Soy lecithin (instant form) | 13030503 | 1 |
| Caesar &Loretz GmbH | Soy lecithin (instant form) | 13279813 | 1 |
| Gehe | Soy lecithin (instant form) | 19187901 | 1 |
| Gehe | Soy lecithin (instant form) | 21002621003 | 1 |
| INTR/ Sana | Soy lecithin (instant form) | 16223302 | 1 |
| Sanacorp | Soy lecithin (instant form) | 14196305 | 1 |
| Sanacorp | Soy lecithin (instant form) | 17322405 | 1 |
| siehe WE-Prüfprotokoll | Soy lecithin (instant form) | 31/14 | 1 |

- 256 799 spectra from 1666 *Apo-Ident* customers from a total of 52 110 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Soy lecithin (instant form)* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Soy lecithin (instant form)* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 170 | 0 | 212 770 |
| **Type C** | 0 | 87 | 0 | 256 799 |

The substance/substance group *Soy lecithin (instant form)* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.4706 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 93.1034 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20985 | 20985 | 0.00 | 124.58 |
| 24244 | 24244 | 0.00 | 126.99 |
| 24749 | 24749 | 0.00 | 124.09 |
| 25521 | 24244 | 18.67 | 128.13 |
| 27547 | 27547 | 0.00 | 118.26 |
| 27664 | 27664 | 0.00 | 121.06 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Spironolactone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21032-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Spironolactone; Spironolactonum

### Special notes

When selecting the *Spironolactone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Spironolactone | 9 | 17 | 251 |

### Second-stage model

For differentiation of the substance/substance group *Spironolactone* the following second-stage model is used:

- Submodel 05

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Spironolactone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 103.04 | – |
| ⋮ | ⋮ | ⋮ |
| Progesterone | >50 | 63.04 |
| Testosterone propionate | >50 | 65.81 |
| Povidone iodine | >50 | 77.18 |
| Fusidic acid | >50 | 83.98 |
| Ubidecarenone | >50 | 135.31 |
| Povidone | >50 | 151.30 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Spironolactone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Spironolactone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Spironolactone | 14378715 | 22385 | 40 | 20150211 |
| Caelo | Spironolactone | 160773 | 22444 | 60 | 20160415* |
| Caelo | Spironolactone | 190158 | 24548 | 40 | 20190308* |
| Caelo | Spironolactone | 20001838 | 25213 | 40 | 20200617* |
| Euro OTC | Spironolactone | 1212034-01 | 21032 | 50 | 1403151 |
| Euro OTC | Spironolactone | 1212034-01 | 21076 | 42 | 20130215 |
| Euro OTC | Spironolactone | 1602006 | 22369 | 45 | 20160309* |
| Euro OTC | Spironolactone | 2006012 | 25311 | 40 | 20200821* |
| Euro OTC | Spironolactone | 2006012 | 25311SI | 33 | 20200821* |
| Fagron | Spironolactone | 15G22-B10-311159 | 22386 | 40 | 20150728 |
| Fagron | Spironolactone | 16E20-B06-322016 | 22942 | 40 | 20160531 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 470 spectra of 11 reference samples from the substance/substance group *Spironolactone*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 856 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 883 spectra of 25 reference samples from the substance/substance group *Spironolactone*.

- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Spironolactone | 16077305 | 22954 | 40 |
| Caelo | Spironolactone | 171165 | 23327 | 40 |
| Caelo | Spironolactone | 172432 | 23660 | 40 |
| Caelo | Spironolactone | 182080 | 24391 | 40 |
| Caelo | Spironolactone | 191979 | 24748 | 40 |
| Caelo | Spironolactone | 22000904013 | 26739 | 40 |
| Caelo | Spironolactone | 24000134003 | 27579 | 40 |
| Euro OTC | Spironolactone | 1612002 | 22909 | 40 |
| Euro OTC | Spironolactone | 1711013 | 23888 | 40 |
| Euro OTC | Spironolactone | 1809020 | 24324 | 40 |
| Euro OTC | Spironolactone | 1907001 | 24782 | 40 |
| Euro OTC | Spironolactone | 2203010 | 26086 | 40 |
| Fagron | Spironolactone | 22B07-B14-227278 | 26543 | 40 |
| Fagron | Spironolactone | 24C07-B04-007368 | 27602 | 40 |
| Fagron | Spironolactone | 120A20240801 | BR20035 | 40 |
| Fagron | Spironolactone | 120A20240802 | BR20036 | 40 |
| Fagron | Spironolactone | 10A20240801 | BR20037SI | 20 |
| Caelo | Spironolactone | 22000904013 | 26739SI | 31 |
| Caelo | Spironolactone | 24000134003 | 27579SI | 37 |
| Euro OTC | Spironolactone | 2203010 | 26086SI | 10 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Spironolactone | 22B07-B14-227278 | 26543SI | 35 |
| Fagron | Spironolactone | 24C07-B04-007368 | 27602SI | 30 |
| Fagron | Spironolactone | 120A20240801 | BR20035SI | 20 |
| Fagron | Spironolactone | 120A20240802 | BR20036SI | 20 |
| Fagron | Spironolactone | 120A20240801 | BR20037 | 40 |

- 212 057 spectra from a total of 4270 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1418 spectra from 516 *Apo-Ident* customers from 261 batches from the substance/substance group *Spironolactone*.

- Among them are spectra of independent samples from 251 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Spironolactone | | 1 |
| | Spironolactone | 191023/4 | 1 |
| | Spironolactone | 21H27-B05-218182 | 2 |
| | Spironolactone | 21H27-B05-222385 | 1 |
| | Spironolactone | 22000904001 | 4 |
| | Spironolactone | 22000904002 | 3 |
| | Spironolactone | 22000904007 | 3 |
| | Spironolactone | 22000904008 | 8 |
| | Spironolactone | 22000904011 | 3 |
| | Spironolactone | 22000904012 | 6 |
| | Spironolactone | 22000904013 | 14 |
| | Spironolactone | 22000904015 | 13 |
| | Spironolactone | 22000904018 | 10 |
| | Spironolactone | 22B07-B14-227277 | 1 |
| | Spironolactone | 22B07-B14-227278 | 1 |
| | Spironolactone | 2300124006 | 1 |
| | Spironolactone | 23001294004 | 4 |
| | Spironolactone | 23001294005 | 17 |
| | Spironolactone | 23001294006 | 18 |
| | Spironolactone | 23F12-B02-233763 | 1 |
| | Spironolactone | 24000134003 | 7 |
| | Spironolactone | 24001140001 | 5 |
| | Spironolactone | 24001140002 | 9 |
| | Spironolactone | B02-2337603 | 2 |
| | Spironolactone | B04-2387200 | 1 |
| | Spironolactone | BO2-2337603 | 1 |
| | Spironolactone | SA1740 | 1 |
| AHD 23.07.2020 | Spironolactone | 190158003 | 1 |
| AHD | Spironolactone | 22000904008 | 1 |
| AHD | Spironolactone | 22000904012 | 1 |
| AHD | Spironolactone | 23001294005 | 1 |
| AHD | Spironolactone | 24000134003 | 1 |
| Alliance Healthcare | Spironolactone | 12049119 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Healthcare | Spironolactone | 12049129 | 1 |
| Alliance | Spironolactone | 22000904018 | 1 |
| Alliance | Spironolactone | 24000134003 | 1 |
| Anzag | Spironolactone | 191163002 | 2 |
| Anzag | Spironolactone | 20003886003 | 2 |
| Anzag | Spironolactone | 21000085007 | 1 |
| Anzag | Spironolactone | 241128(23001294006) | 1 |
| Anzag | Spironolactone | 250428(24001140002) | 1 |
| Anzag | Spironolactone | 250731(24001140002) | 1 |
| apomix | Spironolactone | 16077320 | 1 |
| Caelo | Spironolactone | | 1 |
| Caelo | Spironolactone | 10159914 | 1 |
| Caelo | Spironolactone | 1090216 | 1 |
| Caelo | Spironolactone | 10H24-N10 | 1 |
| Caelo | Spironolactone | 11042602 | 1 |
| Caelo | Spironolactone | 11042607 | 1 |
| Caelo | Spironolactone | 1110917/16077320 | 1 |
| Caelo | Spironolactone | 11G28-N03 | 1 |
| Caelo | Spironolactone | 12049103 | 1 |
| Caelo | Spironolactone | 12049105 | 2 |
| Caelo | Spironolactone | 12049109 | 1 |
| Caelo | Spironolactone | 12049110 | 2 |
| Caelo | Spironolactone | 12049118 | 3 |
| Caelo | Spironolactone | 12049123 | 3 |
| Caelo | Spironolactone | 12049130 | 4 |
| Caelo | Spironolactone | 13124303 | 7 |
| Caelo | Spironolactone | 13124304 | 5 |
| Caelo | Spironolactone | 13124309 | 6 |
| Caelo | Spironolactone | 13124314 | 2 |
| Caelo | Spironolactone | 13124315 | 6 |
| Caelo | Spironolactone | 13124317 | 3 |
| Caelo | Spironolactone | 13124320 | 3 |
| Caelo | Spironolactone | 13124321 | 2 |
| Caelo | Spironolactone | 131243315 | 1 |
| Caelo | Spironolactone | 1314309 | 1 |
| Caelo | Spironolactone | 13190309 | 3 |
| Caelo | Spironolactone | 140202901 | 1 |
| Caelo | Spironolactone | 1437807 | 1 |
| Caelo | Spironolactone | 1437815 | 1 |
| Caelo | Spironolactone | 14378701 | 2 |
| Caelo | Spironolactone | 14378702 | 4 |
| Caelo | Spironolactone | 14378703 | 1 |
| Caelo | Spironolactone | 14378709 | 4 |
| Caelo | Spironolactone | 14378710 | 5 |
| Caelo | Spironolactone | 14378715 | 8 |
| Caelo | Spironolactone | 14378717 | 3 |
| Caelo | Spironolactone | 14378718 | 9 |
| Caelo | Spironolactone | 14378719 | 1 |
| Caelo | Spironolactone | 14378721 | 2 |
| Caelo | Spironolactone | 1438721 | 1 |
| Caelo | Spironolactone | 1496810000858 | 1 |
| Caelo | Spironolactone | 150401601 | 1 |
| Caelo | Spironolactone | 15G22-B10 | 1 |
| Caelo | Spironolactone | 160773 | 1 |
| Caelo | Spironolactone | 16077302 | 16 |
| Caelo | Spironolactone | 16077303 | 17 |
| Caelo | Spironolactone | 16077305 | 10 |
| Caelo | Spironolactone | 16077306 | 8 |
| Caelo | Spironolactone | 16077307 | 1 |
| Caelo | Spironolactone | 16077309 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Spironolactone | 1607731 | 1 |
| Caelo | Spironolactone | 16077311 | 14 |
| Caelo | Spironolactone | 16077312 | 20 |
| Caelo | Spironolactone | 16077312/1230817 | 1 |
| Caelo | Spironolactone | 16077316 | 1 |
| Caelo | Spironolactone | 16077319 | 5 |
| Caelo | Spironolactone | 16077320 | 11 |
| Caelo | Spironolactone | 16077324 | 1 |
| Caelo | Spironolactone | 16077325 | 20 |
| Caelo | Spironolactone | 16077326 | 17 |
| Caelo | Spironolactone | 161200201 | 1 |
| Caelo | Spironolactone | 16A14-B05-317123 | 1 |
| Caelo | Spironolactone | 16D15-B06-320903 | 1 |
| Caelo | Spironolactone | 16H20-B06-322016 | 1 |
| Caelo | Spironolactone | 17116501 | 1 |
| Caelo | Spironolactone | 171165012 | 1 |
| Caelo | Spironolactone | 17116502 | 9 |
| Caelo | Spironolactone | 17H16-B05-341740 | 1 |
| Caelo | Spironolactone | 17H16-B05-344771 | 1 |
| Caelo | Spironolactone | 18004803 | 10 |
| Caelo | Spironolactone | 18004902 | 3 |
| Caelo | Spironolactone | 18004904 | 22 |
| Caelo | Spironolactone | 18004908 | 12 |
| Caelo | Spironolactone | 18004912 | 1 |
| Caelo | Spironolactone | 18004913 | 4 |
| Caelo | Spironolactone | 18004915 | 13 |
| Caelo | Spironolactone | 18004915P-190531-5 | 1 |
| Caelo | Spironolactone | 18004917 | 22 |
| Caelo | Spironolactone | 18004917P-190604-1 | 1 |
| Caelo | Spironolactone | 18004919 | 1 |
| Caelo | Spironolactone | 18004920 | 17 |
| Caelo | Spironolactone | 18004922 | 1 |
| Caelo | Spironolactone | 180208003 | 1 |
| Caelo | Spironolactone | 18205004 | 1 |
| Caelo | Spironolactone | 18208003 | 12 |
| Caelo | Spironolactone | 18208004 | 11 |
| Caelo | Spironolactone | 18208005 | 1 |
| Caelo | Spironolactone | 18208008 | 15 |
| Caelo | Spironolactone | 18208008P-191007-1 | 1 |
| Caelo | Spironolactone | 18208010 | 12 |
| Caelo | Spironolactone | 190158001 | 11 |
| Caelo | Spironolactone | 190158003 | 1 |
| Caelo | Spironolactone | 190158004 | 1 |
| Caelo | Spironolactone | 19015801 | 1 |
| Caelo | Spironolactone | 19015802 | 1 |
| Caelo | Spironolactone | 190158022 | 1 |
| Caelo | Spironolactone | 19015803 | 23 |
| Caelo | Spironolactone | 19015804 | 16 |
| Caelo | Spironolactone | 19015805 | 3 |
| Caelo | Spironolactone | 19015809 | 8 |
| Caelo | Spironolactone | 19015809P-200507-2 | 1 |
| Caelo | Spironolactone | 1907001-01 | 2 |
| Caelo | Spironolactone | 191163001 | 9 |
| Caelo | Spironolactone | 191163002 | 28 |
| Caelo | Spironolactone | 191163003 | 1 |
| Caelo | Spironolactone | 191163004 | 8 |
| Caelo | Spironolactone | 191163008 | 14 |
| Caelo | Spironolactone | 20003605013 | 1 |
| Caelo | Spironolactone | 2000386003 | 1 |
| Caelo | Spironolactone | 20003886003 | 27 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Spironolactone | 20003886004 | 2 |
| Caelo | Spironolactone | 20003886005 | 8 |
| Caelo | Spironolactone | 2013U-03249 | 1 |
| Caelo | Spironolactone | 210000085007 | 1 |
| Caelo | Spironolactone | 21000085001 | 3 |
| Caelo | Spironolactone | 21000085002 | 13 |
| Caelo | Spironolactone | 210000850022 | 1 |
| Caelo | Spironolactone | 21000085004 | 11 |
| Caelo | Spironolactone | 21000085006 | 1 |
| Caelo | Spironolactone | 21000085007 | 12 |
| Caelo | Spironolactone | 21000085008 | 5 |
| Caelo | Spironolactone | 21000085009 | 22 |
| Caelo | Spironolactone | 21000085010 | 13 |
| Caelo | Spironolactone | 21000085012 | 2 |
| Caelo | Spironolactone | 21000085015 | 15 |
| Caelo | Spironolactone | 21000085017 | 13 |
| Caelo | Spironolactone | 21000085018 | 3 |
| Caelo | Spironolactone | 2100008508 | 1 |
| Caelo | Spironolactone | 2100008509 | 3 |
| Caelo | Spironolactone | 210000855007 | 1 |
| Caelo | Spironolactone | 2100085007 | 1 |
| Caelo | Spironolactone | 2100085017 | 2 |
| Caelo | Spironolactone | 22000904001 | 14 |
| Caelo | Spironolactone | 22000904002 | 19 |
| Caelo | Spironolactone | 22000904008 | 2 |
| Caelo | Spironolactone | 22000904012 | 2 |
| Caelo | Spironolactone | 22000904018 | 1 |
| Caelo | Spironolactone | 2200090404002 | 1 |
| Caelo | Spironolactone | 22121701 | 1 |
| Caelo | Spironolactone | 5013Q-03249 | 1 |
| Caeol/ Noweda | Spironolactone | 16077305 | 2 |
| Caeol/Noweda | Spironolactone | 16077303 | 1 |
| Caeol/Noweda | Spironolactone | 18208008 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 18004915 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 18004920 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 22000904002 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 21000085002 | 2 |
| Caesar & Loretz GmbH... | Spironolactone | 21000085010 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 22000904001 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 19015803 | 1 |
| Caesar & Loretz GmbH/AHD | Spironolactone | 21000085002 | 1 |
| Caesar & Loretz GmbH/AHD | Spironolactone | 21000085010 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 191163008 | 1 |
| Caesar & Loretz GmbH/Gehe | Spironolactone | 190158001 | 2 |
| Caesar & Loretz GmbH/Gehe | Spironolactone | 19015803 | 2 |
| Caesar & Loretz GmbH/Gehe | Spironolactone | 19015804 | 1 |
| Caesar & Loretz GmbH/Gehe | Spironolactone | 191163004 | 1 |
| Caesar & Loretz GmbH/GEHE | Spironolactone | 191163008 | 1 |
| Caesar & Loretz GmbH/GEHE | Spironolactone | 21000085002 | 1 |
| Caesar & Loretz GmbH/Gehe | Spironolactone | 21000085007 | 1 |
| Caesar & Loretz GmbH/Gehe | Spironolactone | 21000085010 | 2 |
| Caesar & Loretz GmbH/Gehe | Spironolactone | 24001140002 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 18208010 | 3 |
| Caesar & Loretz GmbH... | Spironolactone | 19015803 | 2 |
| Caesar & Loretz GmbH... | Spironolactone | 19015804 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 19015809 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 191163004 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 21000085007 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 18208010 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 190158004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Spironolactone | 20003886003 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 21000085004 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 18004915 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 12049129 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 18004917 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 18004920 | 2 |
| Caesar & Loretz GmbH | Spironolactone | 18208003 | 4 |
| Caesar & Loretz GmbH | Spironolactone | 18208004 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 18208008 | 4 |
| Caesar & Loretz GmbH | Spironolactone | 18208010 | 5 |
| Caesar & Loretz GmbH | Spironolactone | 190158001 | 14 |
| Caesar & Loretz GmbH | Spironolactone | 190158004 | 2 |
| Caesar & Loretz GmbH | Spironolactone | 19015803 | 2 |
| Caesar & Loretz GmbH | Spironolactone | 19015804 | 11 |
| Caesar & Loretz GmbH | Spironolactone | 19015809 | 3 |
| Caesar & Loretz GmbH | Spironolactone | 191163001 | 2 |
| Caesar & Loretz GmbH | Spironolactone | 191163002 | 7 |
| Caesar & Loretz GmbH | Spironolactone | 191163004 | 3 |
| Caesar & Loretz GmbH | Spironolactone | 191163008 | 7 |
| Caesar & Loretz GmbH | Spironolactone | 20003886002 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 20003886003 | 4 |
| Caesar & Loretz GmbH | Spironolactone | 20003886004 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 20003886005 | 8 |
| Caesar & Loretz GmbH | Spironolactone | 21000085001 | 3 |
| Caesar & Loretz GmbH | Spironolactone | 21000085002 | 5 |
| Caesar & Loretz GmbH | Spironolactone | 21000085004 | 9 |
| Caesar & Loretz GmbH | Spironolactone | 21000085006 | 2 |
| Caesar & Loretz GmbH | Spironolactone | 21000085007 | 7 |
| Caesar & Loretz GmbH | Spironolactone | 21000085008 | 8 |
| Caesar & Loretz GmbH | Spironolactone | 21000085009 | 4 |
| Caesar & Loretz GmbH | Spironolactone | 21000085010 | 10 |
| Caesar & Loretz GmbH | Spironolactone | 21000085015 | 3 |
| Caesar & Loretz GmbH | Spironolactone | 21000085017 | 7 |
| Caesar & Loretz GmbH | Spironolactone | 21000085018 | 2 |
| Caesar & Loretz GmbH | Spironolactone | 22000904001 | 12 |
| Caesar & Loretz GmbH | Spironolactone | 22000904002 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 22000904004 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 22000904008 | 1 |
| Caesar & Loretz GmbH | Spironolactone | 22000904018 | 1 |
| Caesar & Loretz GmbH... | Spironolactone | 20003886005 | 1 |
| Caesar u Loretz | Spironolactone | 12049119 | 1 |
| Caesar u. Loretz / G... | Spironolactone | 18208010 | 1 |
| Caesar und Loretz GmbH | Spironolactone | 191163008 | 1 |
| Caesar&Loretz GmbH | Spironolactone | 19015804 | 1 |
| Caesar&loretz,Anzag | Spironolactone | 13124309 | 1 |
| Caesar&loretz,Phoenix | Spironolactone | 11042603 | 1 |
| Caesar&loretz,Phoenix | Spironolactone | 11042613 | 1 |
| Caesar/Lorenz | Spironolactone | 13124303 | 1 |
| Cealo/Gehe | Spironolactone | 18004803 | 2 |
| Cealo/Jenne | Spironolactone | 221006(22000904002) | 1 |
| Cealo/Sanacorp | Spironolactone | 20003886003 | 3 |
| EuRho / Noweda | Spironolactone | 200612-01 | 1 |
| Eurho/Anzag | Spironolactone | 190700101 | 1 |
| EuRho | Spironolactone | 1101013-01 | 1 |
| EuRho | Spironolactone | 2203010-01 | 1 |
| Euro OTC | Spironolactone | 1000403502 | 1 |
| Euro OTC | Spironolactone | 1004035 | 1 |
| Euro OTC | Spironolactone | 1101013-01 | 1 |
| Euro OTC | Spironolactone | 1212034-01 | 6 |
| Euro OTC | Spironolactone | 1402029-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Spironolactone | 14378721 | 1 |
| Euro OTC | Spironolactone | 1504016-01 | 3 |
| Euro OTC | Spironolactone | 16020006-01 | 1 |
| Euro OTC | Spironolactone | 1602006-01 | 5 |
| Euro OTC | Spironolactone | 1602006-02 | 1 |
| Euro OTC | Spironolactone | 1612002_01 | 1 |
| Euro OTC | Spironolactone | 161200201 | 1 |
| Euro OTC | Spironolactone | 1612002-01 | 5 |
| Euro OTC | Spironolactone | 16E20-B06-322016 | 1 |
| Euro OTC | Spironolactone | 171101301 | 1 |
| Euro OTC | Spironolactone | 1711013-01 | 9 |
| Euro OTC | Spironolactone | 180902001 | 1 |
| Euro OTC | Spironolactone | 1809020-01 | 5 |
| Euro OTC | Spironolactone | 1809020-02 | 1 |
| Euro OTC | Spironolactone | 190700-01 | 1 |
| Euro OTC | Spironolactone | 1907001-01 | 9 |
| Euro OTC | Spironolactone | 2006012-01 | 6 |
| Euro OTC | Spironolactone | 3513E-03249 | 1 |
| Fagron | Spironolactone | | 1 |
| Fagron | Spironolactone | 10C29-N09 | 1 |
| Fagron | Spironolactone | 10H24-N10 | 1 |
| Fagron | Spironolactone | 12/17-n01 | 1 |
| Fagron | Spironolactone | 12/17-N01 | 1 |
| Fagron | Spironolactone | 12I17-N01 | 1 |
| Fagron | Spironolactone | 12J15-N04 | 1 |
| Fagron | Spironolactone | 13D12-N08 | 2 |
| Fagron | Spironolactone | 13G03-N09 | 1 |
| Fagron | Spironolactone | 13G16-B08 | 1 |
| Fagron | Spironolactone | 13G16-B08-288051 | 1 |
| Fagron | Spironolactone | 14B20B06294618 | 1 |
| Fagron | Spironolactone | 14B20-B06-294618 | 5 |
| Fagron | Spironolactone | 14j02-b02-303621 | 1 |
| Fagron | Spironolactone | 14J02-B02-303621 | 5 |
| Fagron | Spironolactone | 14J02-B02-303622 | 1 |
| Fagron | Spironolactone | 14J02-B303621 | 1 |
| Fagron | Spironolactone | 15G22-B10-311159 | 2 |
| Fagron | Spironolactone | 16A14-B05 | 1 |
| Fagron | Spironolactone | 16A14-B05-317123 | 1 |
| Fagron | Spironolactone | 16A14-B05-525187 | 1 |
| Fagron | Spironolactone | 16D15-B06-320903 | 1 |
| Fagron | Spironolactone | 16E20-B06-322016 | 1 |
| Fagron | Spironolactone | 16E20-B06-325478 | 2 |
| Fagron | Spironolactone | 16I06-B04 | 1 |
| Fagron | Spironolactone | 16I06B04329443 | 1 |
| Fagron | Spironolactone | 16I06-B04-329443 | 1 |
| Fagron | Spironolactone | 17116502 | 1 |
| Fagron | Spironolactone | 17E22-B11-335454 | 2 |
| Fagron | Spironolactone | 17E22-B11-335455 | 2 |
| Fagron | Spironolactone | 17H16-B05 | 2 |
| Fagron | Spironolactone | 17H16-B05-341739 | 2 |
| Fagron | Spironolactone | 17H16-B05-344771 | 3 |
| Fagron | Spironolactone | 18208003 | 1 |
| Fagron | Spironolactone | 18A24-B03 | 1 |
| Fagron | Spironolactone | 18A24-B03-348018 | 5 |
| Fagron | Spironolactone | 18A24-B03-349548 | 6 |
| Fagron | Spironolactone | 18A24-B03-354314 | 2 |
| Fagron | Spironolactone | 18G12-B01-356145 | 3 |
| Fagron | Spironolactone | 19C29-B06-191465 | 3 |
| Fagron | Spironolactone | 19H23-B06-194244 | 1 |
| Fagron | Spironolactone | 19H23-B06-194245 | 1 |

*continued on the next page*

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Spironolactone | 19H23-B06-194567 | 1 |
| Fagron | Spironolactone | 19H23-B06-194569 | 2 |
| Fagron | Spironolactone | 19H23-B06-194245 | 1 |
| Fagron | Spironolactone | 2006012-01 | 2 |
| Fagron | Spironolactone | 20B24-B04 | 2 |
| Fagron | Spironolactone | 20B24-B04-200519 | 1 |
| Fagron | Spironolactone | 20B24-B04-200520 | 5 |
| Fagron | Spironolactone | 20H19-B01-202267 | 3 |
| Fagron | Spironolactone | 20H19-B01-213618 | 2 |
| Fagron | Spironolactone | 21H27-B05-217974 | 3 |
| Fagron | Spironolactone | 21H27-B05-222385 | 1 |
| Fagron | Spironolactone | 22000904005 | 2 |
| Fagron | Spironolactone | 2415E-03249 | 1 |
| Fagron | Spironolactone | 2517Q03249 | 1 |
| Fagron | Spironolactone | 2918E-03249 | 1 |
| Fagron | Spironolactone | 80616-7 | 1 |
| Fagron | Spironolactone | B01-2022607 | 1 |
| Fagron | Spironolactone | B04-2005109 | 2 |
| Fagron | Spironolactone | B04-2005200 | 1 |
| Fagron | Spironolactone | eln170404 | 1 |
| Fagron | Spironolactone | SA1063 | 4 |
| Fiebig | Spironolactone | 191163001 | 1 |
| Fiebig | Spironolactone | 19h23-b06-194567 | 1 |
| Fiebig | Spironolactone | B06-1945607 | 1 |
| Gehe | Spironolactone | 12049105 | 1 |
| Gehe | Spironolactone | 13D12-N08 | 1 |
| GEHE | Spironolactone | 16077325 | 1 |
| gehe | Spironolactone | 17E22-B11-335455 | 1 |
| Gehe | Spironolactone | 17H16-B05-341740 | 1 |
| Gehe | Spironolactone | 18208003 | 1 |
| Gehe | Spironolactone | 19015803 | 1 |
| Gehe | Spironolactone | 191163008 | 1 |
| Gehe | Spironolactone | 21000085010 | 1 |
| Gehe | Spironolactone | 22000904001 | 1 |
| Gehe | Spironolactone | 22000904008 | 1 |
| Gehe | Spironolactone | 22000904011 | 1 |
| Gehe | Spironolactone | 240905(22000904018) | 1 |
| Gutenberg-Apotheke | Spironolactone | 13124304 | 2 |
| Jenne | Spironolactone | 14378715 | 1 |
| Jenne | Spironolactone | 250709(24001140010) | 1 |
| kehr | Spironolactone | 22000904007 | 1 |
| Kehr | Spironolactone | 22000904008 | 1 |
| Kehr | Spironolactone | 22000904012 | 1 |
| kehr | Spironolactone | 23001294004 | 2 |
| kehr | Spironolactone | 24000134002 | 1 |
| kehr | Spironolactone | 24001140004 | 1 |
| Max Jenne | Spironolactone | 22000904001 | 2 |
| Noweda/ Caesar&Loren… | Spironolactone | 18208008 | 1 |
| Noweda | Spironolactone | 1101013-0 | 1 |
| Noweda | Spironolactone | 14378710 | 1 |
| Noweda | Spironolactone | 1504016-01 | 1 |
| Noweda | Spironolactone | 1602006-01 | 1 |
| Noweda | Spironolactone | 1612002-01 | 1 |
| noweda | Spironolactone | 16A14-B05-525187 | 1 |
| Noweda | Spironolactone | 19H23-B06-194245 | 1 |
| Noweda | Spironolactone | 21000085017 | 1 |
| Noweda | Spironolactone | 22000904001 | 1 |
| Noweda | Spironolactone | 22000904012 | 1 |
| Noweda | Spironolactone | 22000904013 | 2 |
| Noweda | Spironolactone | 2203010-01 | 3 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Spironolactone | 23001294005 | 1 |
| Noweda | Spironolactone | 23001294006 | 2 |
| Noweeda | Spironolactone | 22000904005 | 1 |
| Phoenix | Spironolactone | 1612002-01 | 2 |
| Phoenix | Spironolactone | 18208008 | 1 |
| Phoenix | Spironolactone | 18A24-B03-354314 | 1 |
| Phoenix | Spironolactone | 19C29-B06-191465 | 1 |
| Phoenix | Spironolactone | 19H23-B06-1942405 | 2 |
| Phoenix | Spironolactone | 22000904018 | 1 |
| Phönix | Spironolactone | 1101013-03 | 1 |
| Phönix | Spironolactone | 1711013-01 | 3 |
| Phönix | Spironolactone | 17H16-B05-344771 | 1 |
| Phönix | Spironolactone | 1809020-01 | 2 |
| Phönix | Spironolactone | 18208003 | 1 |
| Phönix | Spironolactone | 18208004 | 1 |
| Phönix | Spironolactone | 20003886005 | 2 |
| Phönix | Spironolactone | 2006012-01 | 1 |
| Phönix | Spironolactone | 21000085007 | 1 |
| Sanacorp/Phoenix | Spironolactone | 13124315 | 2 |
| Sanacorp | Spironolactone | 11042612 | 1 |
| Sanacorp | Spironolactone | 12049103 | 2 |
| Sanacorp | Spironolactone | 12049130 | 1 |
| Sanacorp | Spironolactone | 1212034-01 | 1 |
| Sanacorp | Spironolactone | 13124304 | 1 |
| Sanacorp | Spironolactone | 13124315 | 1 |
| Sanacorp | Spironolactone | 16077325 | 2 |
| Sanacorp | Spironolactone | 18004913 | 1 |
| Sanacorp | Spironolactone | 18208004 | 1 |
| Sanacorp | Spironolactone | 191163002 | 3 |
| Sanacorp | Spironolactone | 19H23-B06-194567 | 1 |
| Sanacorp | Spironolactone | 20003886005 | 1 |
| Sanacorp | Spironolactone | 22000904018 | 1 |
| Sanacorp | Spironolactone | 23001294006 | 1 |
| Sanacorp | Spironolactone | 9330610 | 1 |
| WE Phönix 25.11..201… | Spironolactone | 16077303 | 1 |
| Zhejiang Langhua /Phönix | Spironolactone | 18004917 | 2 |
| Zhejiang Langhua /Phönix | Spironolactone | 18208003 | 1 |
| Zhejiang Langhua Pha… | Spironolactone | Q3312 | 1 |
| Zhejiang/Phoenix | Spironolactone | OT00E1902002 | 1 |

- 255 468 spectra from 1666 *Apo-Ident* customers from a total of 51 897 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Spironolactone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Spironolactone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 470 | 0 | 157 856 |
| **Type B** | 0 | 883 | 0 | 212 057 |
| **Type C** | 0 | 1308 | 110 | 255 468 |

The substance/substance group *Spironolactone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7234 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3205 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 92.2426 % (> 92.0310 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21032 | 21032 | 0.00 | 124.47 |
| 21076 | 21032 | 4.37 | 120.63 |
| 22369 | 22369 | 0.00 | 129.01 |
| 22385 | 22369 | 6.64 | 118.94 |
| 22386 | 22444 | 5.27 | 118.82 |
| 22444 | 22444 | 0.00 | 119.16 |
| 22942 | 22369 | 3.82 | 123.08 |
| 24548 | 24548 | 0.00 | 118.85 |
| 25213 | 25213 | 0.00 | 114.18 |
| 25311 | 25311 | 0.00 | 125.47 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Starch** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20790-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Starch; Amylum Maydis; Amylum oryzae; Corn starch; Potato starch; Rice starch; Solani amylum; SyrSpend® SF Alka; SyrSpend® SF pH4; SyrSpend® SF pH4 neo (Maize starch); Tritici amylum; Wheat starch

### Special notes

When selecting the *Starch* substance/substance group, the following information is displayed to the user:

- Advice for the identification of SyrSpend® SF Alka: Please shake the sample before the measurement to ensure an even particle distribution.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Starch | 39 | 31 | 602 |

### Second-stage model

For differentiation of the substance/substance group *Starch* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Starch* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 26.94 | – |
| Maltodextrin | 27.34 | 21.63 |
| Acacia, dried dispersion | 32.61 | 19.94 |
| Cannabis flower, CBD-dominant type | 38.83 | – |
| Sodium cromoglicate | 49.49 | – |
| Calcium glycerophosphate | 68.11 | 35.60 |
| ⋮ | ⋮ | ⋮ |
| Carmellose sodium | >50 | 15.58 |
| Colistin sulfate | >50 | 27.35 |
| Polymyxin B sulfate | >50 | 32.17 |
| Cyanocobalamin | >50 | 41.31 |
| Bacitracin | >50 | 48.79 |
| Riboflavin | >50 | 59.70 |
| Amphotericin B | >50 | 70.24 |
| Tosylchloramide sodium | >50 | 72.74 |
| Oxalic acid | >50 | 76.03 |
| Fructose | >50 | 76.55 |
| Calcium pantothenate | >50 | 78.65 |
| Nystatin | >50 | 79.94 |
| Gelatine, white | >50 | 97.57 |
| Hyoscine hydrobromide | >50 | 106.55 |
| alpha-tocopheryl acetate dry concentrate | >50 | 116.18 |
| Estradiol hemihydrate | >50 | 128.43 |
| Triamcinolone | >50 | 130.63 |
| Methylcobalamin | >50 | 155.02 |
| Estriol | >50 | 165.48 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Starch* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Starch*:


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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Corn starch | 13154914 | 21827 | 60 | 20130529 |
| Caelo | Corn starch | 161385 | 22450 | 60 | 20160621* |
| Caelo | Corn starch | 182748 | 24361 | 40 | 20181031* |
| Caelo | Corn starch | 24001513 | 27324 | 40 | 20240722* |
| Klenk | Corn starch | 0064A200427-01 | 25383 | 40 | 20200515 |
| Caelo | Potato starch | 12360213 | 20996 | 40 | 1403494 |
| Caelo | Potato starch | 14033815 | 21965 | 60 | 20140207 |
| Caelo | Potato starch | 161237 | 22449 | 60 | 20160621* |
| Caelo | Potato starch | 24001388 | 27321 | 40 | 20240722* |
| Klenk | Potato starch | 0094A170123 | 23923 | 40 | 20170309 |
| Klenk | Potato starch | 0094A180919-01 | 25382 | 40 | 20200804 |
| Caelo | Rice starch | 12068525 | 20790 | 40 | 20120327 |
| Caelo | Rice starch | 16144501 | 22585 | 40 | 20160504 |
| Euro OTC | Rice starch | 1912005 | 25080 | 40 | 20200109* |
| Euro OTC | Rice starch | 2101008 | 25534 | 40 | 20210129* |
| Euro OTC | Rice starch | 2107016 | 25767 | 50 | 20210816* |
| Fagron | Rice starch | 16B25-B01-327231 | 23219 | 40 | 20160308 |
| Fagron | Rice starch | 16B25-B01-327231 | 23220 | 40 | AR-17-FG-015298-02 |
| Fagron | SyrSpend® SF Alka | 17D11-B04-332593 | 23448 | 40 | 20170505 |
| Fagron | SyrSpend® SF Alka | 17D11-B04-332593 | 23449 | 40 | 20170505 |
| Fagron | SyrSpend® SF Alka | 17F14-B02-335945 | 23750 | 20 | 1804106 |
| Fagron | SyrSpend® SF Alka | 18B21-B08-347192 | 24112 | 40 | 1809264 |
| Fagron | SyrSpend® SF Alka | 18C13-B11-350851 | 24290 | 40 | 20180502 |
| Fagron | SyrSpend® SF Alka | 20B25-F06-369913 | 25363 | 40 | 20200424 |
| Fagron | SyrSpend® SF Alka | 23B16-F01-384773 | 27029 | 40 | 20230502 |
| Fagron | SyrSpend® SF pH4 | 15A26-B04-311720 | 22496 | 40 | 1608352 |
| Fagron | SyrSpend® SF pH4 | 15A26-B04-311720 | 22497 | 40 | 20150223 |
| Fagron | SyrSpend® SF pH4 | 15A26-B04-305667 | 22719 | 40 | 1701055 |
| Fagron | SyrSpend® SF pH4 | 19L05-F10-368874 | 25369 | 40 | 20200320 |
| Fagron | SyrSpend® SF pH4 | 22L20-F03-384076 | 26613 | 40 | 20230124 |
| Fagron | SyrSpend® SF pH4 | 22L20-F03-384076 | 26613SI | 20 | 20230124 |
| Fagron | SyrSpend® SF pH4 | 23H11-F02-385247 | 27030 | 40 | 20231005 |
| Fagron | SyrSpend® SF pH4 | 23E23-F05-385178 | 27056 | 40 | 20230807 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 21G23-F02-379002 | 25755 | 50 | 2112411 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23A18-H15-00941 | 26568 | 40 | 20230120 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23C21-H01-00941 | 26677 | 40 | 20230328 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23C21-H01-00941 | 26677SI | 20 | 20230328 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23K02-H08-00941 | 27180 | 40 | 20231113 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 24B28-H08-00941 | 27192 | 40 | 20240308 |
| Caelo | Wheat starch | 14023203 | 21447 | 60 | AR-16-FG-011433-01 |
| Caelo | Wheat starch | 15124707 | 22246 | 60 | 20150527 |
| Caelo | Wheat starch | 23002728 | 27107 | 40 | 20240123* |
| Klenk | Wheat starch | 0104A141114 | 21973 | 60 | 20141210 |
| Klenk | Wheat starch | 0104A160512 | 23510 | 40 | 20160628 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 1860 spectra of 44 reference samples from the substance/substance group *Starch*. These samples are listed above in the *calibration samples* section. The reference samples come from 39 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 156 466 spectra from a total of 2918 batches from further 490 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1670 spectra of 50 reference samples from the substance/substance group *Starch*.
- Among them are spectra of independent samples from 31 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Corn starch | 16138505 | 23217 | 40 |
| Caelo | Corn starch | 172873 | 23813 | 40 |
| Caelo | Corn starch | 170474 | 24037 | 40 |
| Caelo | Potato starch | 15062921 | 23189 | 40 |
| Caelo | Potato starch | 173003 | 23811 | 40 |
| Caelo | Potato starch | 20001764 | 25660 | 40 |
| Caelo | Potato starch | 21004156 | 26015 | 30 |
| Caelo | Rice starch | 162180 | 22642 | 40 |
| Caelo | Rice starch | 190169 | 24551 | 40 |
| Caelo | Rice starch | 190168 | 24553 | 40 |
| Caelo | Rice starch | 20001724 | 25661 | 40 |
| Caelo | Rice starch | 23001380 | 27254 | 40 |
| Caelo | Rice starch | 2405002 | 27276 | 40 |
| Caelo | Rice starch | 24002685 | 27548 | 40 |
| Euro OTC | Rice starch | 2204008 | 26200 | 40 |
| Euro OTC | Rice starch | 2301042 | 26596 | 40 |
| Euro OTC | Rice starch | 2309004 | 26932 | 40 |
| Euro OTC | Rice starch | 2501022 | 27501 | 40 |
| Fagron | SyrSpend® SF Alka | 15H11-B04-311722 | 22494 | 40 |
| Fagron | SyrSpend® SF Alka | 22B04-F07-381936 | 26457 | 40 |
| Fagron | SyrSpend® SF Alka | 22K18-F04-38394 | 27028 | 40 |
| Fagron | SyrSpend® SF pH4 | 15H13-B03-314611 | 23450 | 40 |
| Fagron | SyrSpend® SF pH4 | 16J10-B03-330757 | 23749 | 40 |
| Fagron | SyrSpend® SF pH4 | 23B13-F02-384539 | 26731 | 40 |
| Fagron | SyrSpend® SF pH4 | 24B12-F02-004163 | 27588 | 40 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 22B04-F01-381138 | 25936 | 40 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23L01-H01-00941 | 27181 | 40 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 24A09-H07-00941 | 27182 | 40 |
| Caelo | Wheat starch | 15421507 | 23509 | 40 |
| Caelo | Wheat starch | 181200 | 24014 | 40 |
| Caelo | Wheat starch | 192516 | 24885 | 40 |
| Caelo | Corn starch | 24001513 | 27324SI† | 20 |
| Caelo | Potato starch | 21004156 | 26015SI | 10 |
| Caelo | Potato starch | 24001388 | 27321SI† | 20 |

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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Rice starch | 2204008 | 26200SI | 20 |
| Euro OTC | Rice starch | 2301042 | 26596SI | 20 |
| Euro OTC | Rice starch | 2309004 | 26932SI | 20 |
| Fagron | SyrSpend® SF Alka | 15H11-B04-311722 | 22495 | 40 |
| Fagron | SyrSpend® SF Alka | 15H11-B04-311722 | 22718 | 40 |
| Fagron | SyrSpend® SF Alka | 17F14-B02-335945 | 23750† | 20 |
| Fagron | SyrSpend® SF Alka | 15H11-B04-311722 | 23768 | 40 |
| Fagron | SyrSpend® SF Alka | 22B04-F07-381936 | 26457SI | 20 |
| Fagron | SyrSpend® SF Alka | 22K18-F04-38394 | 27028SI | 20 |
| Fagron | SyrSpend® SF Alka | 23B16-F01-384773 | 27029SI† | 20 |
| Fagron | SyrSpend® SF pH4 | 15H13-B03-314611 | 23451 | 40 |
| Fagron | SyrSpend® SF pH4 | 23B13-F02-384539 | 26731SI | 20 |
| Fagron | SyrSpend® SF pH4 | 23H11-F02-385247 | 27030SI† | 20 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 22B04-F01-381138 | 25936SI | 10 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23K02-H08-00941 | 27180SI† | 20 |
| Caelo | Wheat starch | 23002728 | 27107SI† | 20 |

- 211 270 spectra from a total of 4249 batches from further 866 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2167 spectra from 555 *Apo-Ident* customers from 621 batches from the substance/substance group *Starch*.

- Among them are spectra of independent samples from 581 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Wheat starch | 104A221027-01 | 2 |
| | SyrSpend® SF Alka | 17932050 | 1 |
| | Corn starch | 20004426010 | 1 |
| | Corn starch | 20004426018 | 1 |
| | Corn starch | 20004426022 | 4 |
| | Rice starch | 20004428022 | 3 |
| | Rice starch | 20004428041 | 1 |
| | Wheat starch | 21002057002 | 1 |
| | Wheat starch | 21002057008 | 1 |
| | Wheat starch | 21002057011 | 2 |
| | SyrSpend® SF Alka | 21B26-F07-378830 | 1 |
| | SyrSpend® SF Alka | 21F24-F03-526598 | 1 |
| | Wheat starch | 22001409007 | 2 |
| | Wheat starch | 221027-01 | 1 |
| | SyrSpend® SF pH4 | 22109-F01-283384 | 1 |
| | SyrSpend® SF pH4 | 22109-F03-383490 | 1 |
| | SyrSpend® SF Alka | 22A12-F20-381408 | 1 |
| | SyrSpend® SF Alka | 22A12-F22-382195 | 6 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | SyrSpend® SF Alka | 22B04-F06-381564 | 1 |
| | SyrSpend® SF Alka | 22B04-F07-381936 | 2 |
| | SyrSpend® SF Alka | 22I04-F02-383639 | 1 |
| | SyrSpend® SF pH4 | 22I09-F02-383489 | 3 |
| | SyrSpend® SF pH4 | 22I09-F03 | 1 |
| | SyrSpend® SF pH4 | 22I09-F03-383490 | 2 |
| | SyrSpend® SF Alka | 22J04F02383639 | 1 |
| | SyrSpend® SF Alka | 22J04-F02-383639 | 2 |
| | SyrSpend® SF Alka | 22J04-F06-3636502 | 3 |
| | SyrSpend® SF Alka | 22J04-F06-383652 | 12 |
| | SyrSpend® SF Alka | 22J04-F06-38365261/23P | 1 |
| | SyrSpend® SF Alka | 22J04-F08-383658 | 10 |
| | SyrSpend® SF Alka | 22J04-F11-383746 | 16 |
| | SyrSpend® SF Alka | 22J10-F03-2837201 | 1 |
| | SyrSpend® SF Alka | 22J10-F03-383721 | 29 |
| | SyrSpend® SF Alka | 22J31-F01-526993 | 1 |
| | SyrSpend® SF Alka | 22j31-F01-526993 | 1 |
| | SyrSpend® SF Alka | 22JO4-F06-383652 | 1 |
| | SyrSpend® SF pH4 | 22K08-F02-383826 | 9 |
| | SyrSpend® SF pH4 | 22k08-F02-93826 | 1 |
| | SyrSpend® SF Alka | 22K17-F04-384631 | 2 |
| | SyrSpend® SF Alka | 22K17-F05-384376 | 5 |
| | SyrSpend® SF Alka | 22K18-F01-384185 | 12 |
| | SyrSpend® SF pH4 | 22KO-F02_383826 | 1 |
| | SyrSpend® SF pH4 | 22L20-F03-384076 | 3 |
| | Rice starch | 23001380003 | 3 |
| | Corn starch | 23003415001 | 1 |
| | SyrSpend® SF Alka | 23816-F03-384777 | 2 |
| | SyrSpend® SF pH4 | 23A03-F09-384187 | 2 |
| | SyrSpend® SF pH4 | 23A03-F10-384538 | 4 |
| | SyrSpend® SF Alka | 23A18-F07-384725 | 8 |
| | SyrSpend® SF Alka | 23A18-F12-384724 | 7 |
| | SyrSpend® SF pH4 neo (Mai… | 23A18-H-00941 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | 23A18-H15-0094001 | 2 |
| | SyrSpend® SF pH4 neo (Mai… | 23A18-H15-00941 | 5 |
| | SyrSpend® SF pH4 | 23B13-F02-384539 | 5 |
| | SyrSpend® SF pH4 | 23B13-FO2-3845309 | 1 |
| | SyrSpend® SF Alka | 23B16-F01-384773 | 9 |
| | SyrSpend® SF Alka | 23B16F02-384774 | 1 |
| | SyrSpend® SF Alka | 23B16-F02-384774 | 6 |
| | SyrSpend® SF Alka | 23B16-F03-384777 | 3 |
| | SyrSpend® SF Alka | 23B16-F04-384778 | 1 |
| | SyrSpend® SF Alka | 23B16-FO2-3847704 | 2 |
| | SyrSpend® SF pH4 neo (Mai… | 23C21-H01-00941 | 2 |
| | SyrSpend® SF pH4 neo (Mai… | 23D20-H09-00941 | 1 |
| | SyrSpend® SF pH4 | 23E22-F01-384947 | 3 |
| | SyrSpend® SF pH4 | 23E22-F02-384949 | 2 |
| | SyrSpend® SF pH4 | 23E22-F03384948 | 1 |
| | SyrSpend® SF pH4 | 23E22-F03-384948 | 11 |
| | SyrSpend® SF pH4 | 23E23-F04-385081 | 5 |
| | SyrSpend® SF pH4 | 23E23-F05-385116 | 1 |
| | SyrSpend® SF pH4 | 23E-F04-385081 | 2 |
| | SyrSpend® SF pH4 | 23H11-F02-385247 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | 23K02-H08-00941 | 5 |
| | SyrSpend® SF pH4 neo (Mai… | 23K14-H10-00947 | 2 |
| | SyrSpend® SF pH4 neo (Mai… | 23L01-H01-00941 | 2 |
| | Corn starch | 24001513001 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Corn starch | 24001906002 | 2 |
| | SyrSpend® SF pH4 neo (Mai… | 24A09-HD7-00941 | 1 |
| | SyrSpend® SF Alka | 24F10-M01-006979 | 3 |
| | SyrSpend® SF pH4 neo (Mai… | 24G10-H12-0094001 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | 24H06-H07-00941 | 1 |
| | SyrSpend® SF Alka | 24J16-M01-005862 | 2 |
| | SyrSpend® SF pH4 neo (Mai… | 25C20-H11-00941 | 2 |
| | Corn starch | 30502-01 | 2 |
| | Corn starch | 64a230502-01 | 1 |
| | Rice starch | 84A180522 | 1 |
| | SyrSpend® SF Alka | F01-3847703 | 1 |
| | SyrSpend® SF Alka | F01-5269903 | 1 |
| | SyrSpend® SF pH4 | F02-2845309 | 1 |
| | SyrSpend® SF Alka | F0238363009 | 1 |
| | SyrSpend® SF pH4 | F05-3811006 | 1 |
| | SyrSpend® SF Alka | F07-3819306 | 1 |
| | SyrSpend® SF Alka | FO1-3847703 | 1 |
| | SyrSpend® SF Alka | FO5-3810302 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | H01-0094001 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | H03-0094001 | 4 |
| | SyrSpend® SF pH4 neo (Mai… | H04-0094001 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | H07-0094001 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | H09-0094001 | 1 |
| | SyrSpend® SF pH4 neo (Mai… | H12-0094001 | 1 |
| AEP | SyrSpend® SF Alka | 23A18-F07-384725 | 1 |
| AHD | SyrSpend® SF Alka | 22J04-F06-383652 | 2 |
| AHD | SyrSpend® SF Alka | 22K17-F05-384376 | 1 |
| AHD | SyrSpend® SF Alka | 23A18-F07-384725 | 1 |
| AHD | Corn starch | 64A170123 | 1 |
| AHD | Corn starch | 64A230502-01 | 1 |
| Alliance Healthcare | SyrSpend® SF Alka | 20G03-F12-374282 | 1 |
| Alliance | Wheat starch | 192516005 | 1 |
| Anzag 05.03.13 ek: 9,65EUR | Wheat starch | 104A120621 | 2 |
| Anzag | SyrSpend® SF pH4 | 23E22-F01-384947 | 1 |
| Anzag | SyrSpend® SF pH4 | 23E22-F02-384949 | 1 |
| Anzag | SyrSpend® SF pH4 | 23E22-F03-384948 | 1 |
| Bombastus | Potato starch | 12214303 | 2 |
| Bombastus | Corn starch | 15310902 | 1 |
| Bombastus | SyrSpend® SF pH4 | 18I16-B01-357703 | 1 |
| Caelo | Rice starch | 10061134 | 2 |
| Caelo | Corn starch | 10061146 | 1 |
| Caelo | Rice starch | 10177507 | 1 |
| Caelo | Rice starch | 10177515 | 1 |
| Caelo | Rice starch | 104A120621 | 1 |
| Caelo | Rice starch | 104A141114 | 3 |
| Caelo | Wheat starch | 104A160512 | 1 |
| Caelo | Wheat starch | 104A171122 | 1 |
| Caelo | Rice starch | 11132406 | 1 |
| Caelo | Wheat starch | 11145011 | 1 |
| Caelo | Wheat starch | 11146011 | 1 |
| Caelo | Wheat starch | 1114611 | 1 |
| Caelo | Corn starch | 11179307 | 2 |
| Caelo | Rice starch | 11186026 | 1 |
| Caelo | Potato starch | 11301012 | 2 |
| Caelo | Wheat starch | 11350907 | 1 |
| Caelo | Wheat starch | 11350911 | 2 |
| Caelo | Rice starch | 12166007 | 3 |
| Caelo | Rice starch | 12214303 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Corn starch | 12238705 | 1 |
| Caelo | Rice starch | 12238714 | 1 |
| Caelo | Corn starch | 12238715 | 2 |
| Caelo | Rice starch | 12238719 | 1 |
| Caelo | SyrSpend® SF Alka | 12B23-B07-305668 | 1 |
| Caelo | Rice starch | 13005905 | 2 |
| Caelo | Rice starch | 13005908 | 1 |
| Caelo | Rice starch | 13154904 | 3 |
| Caelo | Corn starch | 13154914 | 2 |
| Caelo | Rice starch | 13305103 | 3 |
| Caelo | Rice starch | 13305108 | 1 |
| Caelo | Rice starch | 14011612 | 3 |
| Caelo | Rice starch | 14011621 | 1 |
| Caelo | Rice starch | 14011630 | 2 |
| Caelo | Rice starch | 14023203 | 3 |
| Caelo | Rice starch | 14025710 | 1 |
| Caelo | Rice starch | 14025733 | 1 |
| Caelo | Rice starch | 14025734 | 1 |
| Caelo | Potato starch | 14033815 | 1 |
| Caelo | Corn starch | 14111701 | 1 |
| Caelo | Wheat starch | 14301214 | 3 |
| Caelo | Potato starch | 15062912 | 2 |
| Caelo | Potato starch | 15062915 | 1 |
| Caelo | Rice starch | 15118607 | 1 |
| Caelo | Corn starch | 15119011 | 6 |
| Caelo | Wheat starch | 15124707 | 3 |
| Caelo | Wheat starch | 15124710 | 1 |
| Caelo | Wheat starch | 1512477 | 1 |
| Caelo | Corn starch | 15210908 | 2 |
| Caelo | Corn starch | 15310902 | 5 |
| Caelo | Corn starch | 15310903 | 3 |
| Caelo | Corn starch | 15310904 | 1 |
| Caelo | Corn starch | 15310908 | 3 |
| Caelo | Corn starch | 15310909 | 2 |
| Caelo | Corn starch | 15310914 | 6 |
| Caelo | Wheat starch | 15421507 | 2 |
| Caelo | Rice starch | 16101401 | 1 |
| Caelo | Corn starch | 16138505 | 5 |
| Caelo | Corn starch | 16138507 | 4 |
| Caelo | Rice starch | 16144506 | 1 |
| Caelo | Wheat starch | 16162905 | 3 |
| Caelo | Rice starch | 16218002 | 2 |
| Caelo | Rice starch | 16218009 | 1 |
| Caelo | Rice starch | 16218013 | 1 |
| Caelo | SyrSpend® SF pH4 | 16J10-B03-330757 | 1 |
| Caelo | Potato starch | 17037404 | 1 |
| Caelo | Corn starch | 17047404 | 12 |
| Caelo | Rice starch | 17173501 | 2 |
| Caelo | Wheat starch | 17183201 | 1 |
| Caelo | Corn starch | 17287302 | 7 |
| Caelo | Corn starch | 17287305 | 2 |
| Caelo | Corn starch | 17287306 | 1 |
| Caelo | Potato starch | 17327201 | 3 |
| Caelo | Rice starch | 17327502 | 1 |
| Caelo | Rice starch | 17327503 | 2 |
| Caelo | Rice starch | 17327506 | 2 |
| Caelo | Corn starch | 17327601 | 2 |
| Caelo | Wheat starch | 18120004 | 2 |
| Caelo | Wheat starch | 18120012 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | SyrSpend® SF Alka | 18125-B15-357803 | 1 |
| Caelo | Potato starch | 182059005 | 2 |
| Caelo | Potato starch | 18205905 | 3 |
| Caelo | Corn starch | 18274802 | 11 |
| Caelo | Corn starch | 18274804 | 11 |
| Caelo | Corn starch | 18274808 | 2 |
| Caelo | SyrSpend® SF Alka | 18871B06 | 1 |
| Caelo | SyrSpend® SF pH4 | 18A22_B05_346147 | 1 |
| Caelo | SyrSpend® SF Alka | 18B21-B08 | 1 |
| Caelo | SyrSpend® SF Alka | 18C13-B11-350851 | 1 |
| Caelo | SyrSpend® SF Alka | 18H01-B12-353473 | 1 |
| Caelo | SyrSpend® SF pH4 | 18H30-B02 | 1 |
| Caelo | SyrSpend® SF pH4 | 18H30-B02-355226 | 2 |
| Caelo | SyrSpend® SF Alka | 18J25-B15-357803 | 8 |
| Caelo | Rice starch | 190168001 | 1 |
| Caelo | Rice starch | 190168003 | 5 |
| Caelo | Rice starch | 190168004 | 3 |
| Caelo | Rice starch | 19016801 | 1 |
| Caelo | Rice starch | 19016803 | 8 |
| Caelo | Rice starch | 19016805 | 1 |
| Caelo | Corn starch | 1918702 | 1 |
| Caelo | Corn starch | 191878005 | 3 |
| Caelo | Corn starch | 19187802 | 7 |
| Caelo | Corn starch | 19187803 | 1 |
| Caelo | Wheat starch | 192516001 | 3 |
| Caelo | Wheat starch | 192516005 | 4 |
| Caelo | Corn starch | 20000573002 | 6 |
| Caelo | Potato starch | 20003937003 | 1 |
| Caelo | Corn starch | 20004426002 | 1 |
| Caelo | Corn starch | 20004426005 | 6 |
| Caelo | Corn starch | 20004426010 | 1 |
| Caelo | Corn starch | 20004426013 | 1 |
| Caelo | Corn starch | 2000442602 | 1 |
| Caelo | Rice starch | 20004428002 | 2 |
| Caelo | Rice starch | 20004428003 | 1 |
| Caelo | Rice starch | 20004428022 | 1 |
| Caelo | Rice starch | 200613K3 | 1 |
| Caelo | SyrSpend® SF pH4 | 20A09-F03-369540 | 1 |
| Caelo | Wheat starch | 21002057001 | 3 |
| Caelo | Wheat starch | 21002057006 | 1 |
| Caelo | Wheat starch | 21002057007 | 1 |
| Caelo | Rice starch | 2212M-01115 | 1 |
| Caelo | Rice starch | 23001380004 | 1 |
| Caelo | SyrSpend® SF Alka | 353473 | 1 |
| Caelo | Corn starch | 64A130304 | 6 |
| Caelo | Corn starch | 64A170123 | 1 |
| Caelo | Corn starch | 64A200427-01 | 1 |
| Caelo | SyrSpend® SF Alka | 720026-000 | 1 |
| Caelo | Rice starch | 9352108 | 1 |
| Caelo | Potato starch | 94A18091901 | 1 |
| Caesar & Loretz GmbH... | Corn starch | 18274804 | 2 |
| Caesar & Loretz GmbH/AHD | Corn starch | 20000573002 | 1 |
| Caesar & Loretz GmbH... | Wheat starch | 192516001 | 1 |
| Caesar & Loretz GmbH/Gehe | Corn starch | 18274808 | 1 |
| Caesar & Loretz GmbH/Gehe | Corn starch | 19187802 | 2 |
| Caesar & Loretz GmbH/Sana | Wheat starch | 21002057001 | 1 |
| Caesar & Loretz GmbH | Wheat starch | 16162908 | 2 |
| Caesar & Loretz GmbH | Rice starch | 17327510 | 1 |
| Caesar & Loretz GmbH | Wheat starch | 18120012 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Rice starch | 190168004 | 5 |
| Caesar & Loretz GmbH | Wheat starch | 192516005 | 1 |
| Caesar & Loretz GmbH | Corn starch | 20000573002 | 2 |
| Caesar & Loretz GmbH | Corn starch | 20004426006 | 2 |
| Caesar & Loretz GmbH | Corn starch | 20004426013 | 1 |
| Caesar & Loretz GmbH | Wheat starch | 21000570005 | 1 |
| Caesar & Loretz GmbH | Wheat starch | 21002057001 | 1 |
| Caesar & Loretz/Geil... | Corn starch | 19187802 | 1 |
| Cealo/Sanacorp | Corn starch | 17287302 | 1 |
| Cealo/Sanacorp | Corn starch | 20000573002 | 1 |
| Cealo | Rice starch | 13305103 | 1 |
| Cealo | Wheat starch | 15421507 | 1 |
| Euro OTC | Wheat starch | 104A171122 | 1 |
| Euro OTC | SyrSpend® SF pH4 | 18A22-B05-347899 | 1 |
| Euro OTC | SyrSpend® SF pH4 | 20F18-F13-379343 | 1 |
| Euro OTC | Corn starch | 64A170123 | 1 |
| Fa.Phönix | Wheat starch | 104a171122 | 1 |
| Fagon/Novatis | SyrSpend® SF pH4 | 20F08-f03 | 1 |
| Fagron | SyrSpend® SF Alka | | 2 |
| Fagron | SyrSpend® SF pH4 | 11111346 | 1 |
| Fagron | Rice starch | 12L19-N06 | 1 |
| Fagron | Corn starch | 14011627 | 1 |
| Fagron | Rice starch | 14F18-B04-301616 | 1 |
| Fagron | SyrSpend® SF Alka | 14I22-B40-311723 | 1 |
| Fagron | SyrSpend® SF Alka | 14J22-B40-311723 | 2 |
| Fagron | Corn starch | 15310902 | 1 |
| Fagron | SyrSpend® SF pH4 | 15A26-B04-305667 | 1 |
| Fagron | SyrSpend® SF Alka | 15K03-B01-525173 | 1 |
| Fagron | SyrSpend® SF pH4 | 16/10-B03 | 1 |
| Fagron | SyrSpend® SF pH4 | 16710-B03 | 1 |
| Fagron | SyrSpend® SF Alka | 16B03-B07-525234 | 1 |
| Fagron | SyrSpend® SF pH4 | 16J10_B03_330757 | 1 |
| Fagron | SyrSpend® SF pH4 | 16J10B03 | 1 |
| Fagron | SyrSpend® SF pH4 | 16J10-B03 | 3 |
| Fagron | SyrSpend® SF pH4 | 16j10-b03-330757 | 1 |
| Fagron | SyrSpend® SF pH4 | 16J10B03330757 | 1 |
| Fagron | SyrSpend® SF pH4 | 16J10-B03-330757 | 8 |
| Fagron | Corn starch | 17287302 | 1 |
| Fagron | SyrSpend® SF Alka | 17D11-804-332593 | 1 |
| Fagron | SyrSpend® SF Alka | 17D11-B04 | 2 |
| Fagron | SyrSpend® SF Alka | 17D11-B04-332593 | 7 |
| Fagron | SyrSpend® SF Alka | 17D11-bo4-332593 | 1 |
| Fagron | SyrSpend® SF Alka | 17D29-B11 | 1 |
| Fagron | SyrSpend® SF Alka | 17F14802-335945 | 1 |
| Fagron | SyrSpend® SF Alka | 17F14B02-335945 | 1 |
| Fagron | SyrSpend® SF Alka | 17F14-B02-335945 | 5 |
| Fagron | SyrSpend® SF Alka | 17F14-B05 | 1 |
| Fagron | SyrSpend® SF Alka | 17F14-B05-525556 | 2 |
| Fagron | SyrSpend® SF pH4 | 18/16-B01-357703 | 1 |
| Fagron | SyrSpend® SF Alka | 18/25-B15-357803 | 1 |
| Fagron | SyrSpend® SF Alka | 18125-B15-357803 | 1 |
| Fagron | SyrSpend® SF Alka | 181C13-B11-350851 | 1 |
| Fagron | SyrSpend® SF Alka | 18821-808-147192 | 1 |
| Fagron | SyrSpend® SF Alka | 18821-b08-347192 | 1 |
| Fagron | SyrSpend® SF Alka | 18821-B08-347192 | 5 |
| Fagron | SyrSpend® SF pH4 | 18A22_B04_346147 | 1 |
| Fagron | SyrSpend® SF pH4 | 18A22-B05 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | SyrSpend® SF pH4 | 18A22-B05-346147 | 6 |
| Fagron | SyrSpend® SF pH4 | 18A22-B05-347899 | 5 |
| Fagron | SyrSpend® SF Alka | 18A26-B05 | 1 |
| Fagron | SyrSpend® SF Alka | 18a26b05346410 | 1 |
| Fagron | SyrSpend® SF Alka | 18A26-B05-346410 | 4 |
| Fagron | SyrSpend® SF Alka | 18A26-Bo5-346410 | 1 |
| Fagron | SyrSpend® SF Alka | 18B21-B08 | 2 |
| Fagron | SyrSpend® SF Alka | 18B21-B08-347192 | 3 |
| Fagron | SyrSpend® SF Alka | 18C13_B11_350851 | 1 |
| Fagron | SyrSpend® SF Alka | 18C13-B11 | 5 |
| Fagron | SyrSpend® SF Alka | 18C13-B11-350851 | 8 |
| Fagron | SyrSpend® SF Alka | 18C-B11-350851 | 1 |
| Fagron | SyrSpend® SF Alka | 18H01-812353473 | 1 |
| Fagron | SyrSpend® SF Alka | 18H01-b12 | 1 |
| Fagron | SyrSpend® SF Alka | 18H01-B12 | 7 |
| Fagron | SyrSpend® SF Alka | 18h01b12353473 | 1 |
| Fagron | SyrSpend® SF Alka | 18H01-B12353473 | 1 |
| Fagron | SyrSpend® SF Alka | 18H01-B12-353473 | 24 |
| Fagron | SyrSpend® SF Alka | 18H13-B12-353473 | 1 |
| Fagron | SyrSpend® SF pH4 | 18H30_B02_355226 | 2 |
| Fagron | SyrSpend® SF pH4 | 18H30-355226 | 1 |
| Fagron | SyrSpend® SF pH4 | 18H30-B02 | 8 |
| Fagron | SyrSpend® SF pH4 | 18H30B02355226 | 1 |
| Fagron | SyrSpend® SF pH4 | 18H30-B02-355226 | 7 |
| Fagron | SyrSpend® SF Alka | 18I25-B15-357803 | 1 |
| Fagron | SyrSpend® SF pH4 | 18J16_B01_357703 | 1 |
| Fagron | SyrSpend® SF pH4 | 18J16-B01 | 2 |
| Fagron | SyrSpend® SF pH4 | 18J16B01357703 | 1 |
| Fagron | SyrSpend® SF pH4 | 18J16-B01-357703 | 12 |
| Fagron | SyrSpend® SF Alka | 18J21B113659901 | 1 |
| Fagron | SyrSpend® SF Alka | 18j25-B15 | 1 |
| Fagron | SyrSpend® SF Alka | 18J25B15 | 1 |
| Fagron | SyrSpend® SF Alka | 18J25-B15 | 6 |
| Fagron | SyrSpend® SF Alka | 18j25b15357803 | 1 |
| Fagron | SyrSpend® SF Alka | 18J25-B15357803 | 1 |
| Fagron | SyrSpend® SF Alka | 18J25-B15-357803 | 15 |
| Fagron | SyrSpend® SF Alka | 18L21-B11 | 11 |
| Fagron | SyrSpend® SF Alka | 18l21-b11-359901 | 2 |
| Fagron | SyrSpend® SF Alka | 18L21B11359901 | 1 |
| Fagron | SyrSpend® SF Alka | 18L21-B11-359901 | 16 |
| Fagron | SyrSpend® SF Alka | 18L21-B113659901 | 1 |
| Fagron | SyrSpend® SF Alka | 18L25-B15-357803 | 1 |
| Fagron | SyrSpend® SF pH4 | 19/10-F09-367004 | 1 |
| Fagron | SyrSpend® SF Alka | 19029-B07-362182 | 1 |
| Fagron | SyrSpend® SF pH4 | 19A14-B07 | 3 |
| Fagron | SyrSpend® SF pH4 | 19A14-B07_362431 | 1 |
| Fagron | SyrSpend® SF pH4 | 19A14-B07-362431 | 5 |
| Fagron | SyrSpend® SF Alka | 19D29-807 | 1 |
| Fagron | SyrSpend® SF Alka | 19D29807362182 | 1 |
| Fagron | SyrSpend® SF Alka | 19D29B07 | 1 |
| Fagron | SyrSpend® SF Alka | 19D29-B07 | 1 |
| Fagron | SyrSpend® SF Alka | 19d29b07362182 | 1 |
| Fagron | SyrSpend® SF Alka | 19D29-B07-362182 | 19 |
| Fagron | SyrSpend® SF Alka | 19D29-B11-363786 | 5 |
| Fagron | SyrSpend® SF Alka | 19D29-Bo7-362182 | 1 |
| Fagron | SyrSpend® SF Alka | 19F06-B002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | SyrSpend® SF Alka | 19F06-B02 | 7 |
| Fagron | SyrSpend® SF Alka | 19F06-B02_363789 | 1 |
| Fagron | SyrSpend® SF Alka | 19F06-b02-363789 | 2 |
| Fagron | SyrSpend® SF Alka | 19F06-B02-363789 | 29 |
| Fagron | SyrSpend® SF Alka | 19F12 | 1 |
| Fagron | SyrSpend® SF Alka | 19F12-804-364057 | 1 |
| Fagron | SyrSpend® SF Alka | 19F12-B04 | 6 |
| Fagron | SyrSpend® SF Alka | 19-F12-B04 | 1 |
| Fagron | SyrSpend® SF Alka | 19F12-B04-364057 | 13 |
| Fagron | SyrSpend® SF Alka | 19F12-B04-36-4057 | 1 |
| Fagron | SyrSpend® SF Alka | 19F12-B07 | 2 |
| Fagron | SyrSpend® SF Alka | 19F12-B07-526149 | 8 |
| Fagron | SyrSpend® SF Alka | 19F12-BO4-364057 | 3 |
| Fagron | SyrSpend® SF pH4 | 19J10-F08 | 8 |
| Fagron | SyrSpend® SF pH4 | 19J10-F08-3669903 | 1 |
| Fagron | SyrSpend® SF pH4 | 19j10-F08-366992 | 1 |
| Fagron | SyrSpend® SF pH4 | 19J10-F08-366992 | 2 |
| Fagron | SyrSpend® SF pH4 | 19J10-f08366993 | 1 |
| Fagron | SyrSpend® SF pH4 | 19J10-F08-366993 | 7 |
| Fagron | SyrSpend® SF pH4 | 19j10F09 | 1 |
| Fagron | SyrSpend® SF pH4 | 19J10-F09 | 5 |
| Fagron | SyrSpend® SF pH4 | 19j10-f09-364007 | 1 |
| Fagron | SyrSpend® SF pH4 | 19J10-F09-366992 | 1 |
| Fagron | SyrSpend® SF pH4 | 19j10-f09-367004 | 2 |
| Fagron | SyrSpend® SF pH4 | 19j10-F09-367004 | 1 |
| Fagron | SyrSpend® SF pH4 | 19J10-F09-367004 | 6 |
| Fagron | SyrSpend® SF pH4 | 19J10-FO8-366992 | 1 |
| Fagron | SyrSpend® SF Alka | 19K007-F04 | 1 |
| Fagron | SyrSpend® SF Alka | 19K07-F04 | 4 |
| Fagron | SyrSpend® SF Alka | 19K07F04367548 | 1 |
| Fagron | SyrSpend® SF Alka | 19K07-F04-367548 | 5 |
| Fagron | SyrSpend® SF Alka | 19k07fo4 | 1 |
| Fagron | SyrSpend® SF Alka | 19K07-FO4-367548 | 6 |
| Fagron | SyrSpend® SF Alka | 19Ko7-F04-367548 | 1 |
| Fagron | SyrSpend® SF pH4 | 19L05-F10 | 5 |
| Fagron | SyrSpend® SF pH4 | 19L05-F10-3688704 | 1 |
| Fagron | SyrSpend® SF pH4 | 19L05-f10-368874 | 1 |
| Fagron | SyrSpend® SF pH4 | 19L05-F10-368874 | 14 |
| Fagron | SyrSpend® SF pH4 | 19L05-F1O-368874 | 1 |
| Fagron | SyrSpend® SF pH4 | 19LO5-F10-368874 | 1 |
| Fagron | SyrSpend® SF pH4 | 1BL21-B11 | 1 |
| Fagron | SyrSpend® SF Alka | 20817-F03 | 1 |
| Fagron | SyrSpend® SF Alka | 20818F03 | 1 |
| Fagron | SyrSpend® SF Alka | 20818-F03-369574 | 3 |
| Fagron | SyrSpend® SF Alka | 20825f0625F06 | 1 |
| Fagron | SyrSpend® SF Alka | 20825-F06-369913 | 3 |
| Fagron | SyrSpend® SF Alka | 20825-F07 | 1 |
| Fagron | SyrSpend® SF Alka | 20825-F07-3669914 | 2 |
| Fagron | SyrSpend® SF Alka | 20825-F07369914 | 2 |
| Fagron | SyrSpend® SF Alka | 20825-F07-369914 | 2 |
| Fagron | SyrSpend® SF Alka | 20825-O6-3669913 | 1 |
| Fagron | SyrSpend® SF Alka | 2085-F06 | 1 |
| Fagron | SyrSpend® SF pH4 | 20A09-F03 | 11 |
| Fagron | SyrSpend® SF pH4 | 20A09-F03-369540 | 7 |
| Fagron | SyrSpend® SF pH4 | 20A09-F03-3695400 | 1 |
| Fagron | SyrSpend® SF Alka | 20B18-F03 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | SyrSpend® SF Alka | 20B18-F03-369574 | 10 |
| Fagron | SyrSpend® SF Alka | 20B25-F06 | 5 |
| Fagron | SyrSpend® SF Alka | 20B25-F06_369913 | 1 |
| Fagron | SyrSpend® SF Alka | 20B25-F06-369913 | 29 |
| Fagron | SyrSpend® SF Alka | 20B25-F07 | 8 |
| Fagron | SyrSpend® SF Alka | 20B25-F07-369914 | 9 |
| Fagron | SyrSpend® SF Alka | 20B25-F07-369914 | 1 |
| Fagron | SyrSpend® SF Alka | 20B818-F03-369574 | 2 |
| Fagron | SyrSpend® SF pH4 | 20c24-F02 | 1 |
| Fagron | SyrSpend® SF pH4 | 20C24-F02 | 8 |
| Fagron | SyrSpend® SF pH4 | 20c24-f02-372398 | 1 |
| Fagron | SyrSpend® SF pH4 | 20c24-F02-372398 | 1 |
| Fagron | SyrSpend® SF pH4 | 20C24-F02-372398 | 18 |
| Fagron | SyrSpend® SF pH4 | 20C24-F09 | 1 |
| Fagron | SyrSpend® SF pH4 | 20C24-FO2 | 2 |
| Fagron | SyrSpend® SF Alka | 20D15-F08 | 1 |
| Fagron | SyrSpend® SF Alka | 20D15-F08-371028 | 3 |
| Fagron | SyrSpend® SF Alka | 20D16-F01 | 1 |
| Fagron | SyrSpend® SF Alka | 20D16-F06 | 1 |
| Fagron | SyrSpend® SF Alka | 20D16-F06-371034 | 1 |
| Fagron | SyrSpend® SF pH4 | 20F08_F03_372517 | 1 |
| Fagron | SyrSpend® SF pH4 | 20F08-F03 | 5 |
| Fagron | SyrSpend® SF pH4 | 20F08-F03-0000 | 1 |
| Fagron | SyrSpend® SF pH4 | 20F08-F03-372517 | 19 |
| Fagron | SyrSpend® SF pH4 | 20F08-F04-372518 | 1 |
| Fagron | SyrSpend® SF pH4 | 20F18-F13 | 1 |
| Fagron | SyrSpend® SF pH4 | 20F18-F13-379343 | 22 |
| Fagron | SyrSpend® SF pH4 | 20F18-F-13-379343 | 2 |
| Fagron | SyrSpend® SF pH4 | 20F18-F14 | 2 |
| Fagron | SyrSpend® SF pH4 | 20F18-F14379344 | 1 |
| Fagron | SyrSpend® SF pH4 | 20F18-F14-379344 | 11 |
| Fagron | SyrSpend® SF Alka | 20G03-F09-526400 | 2 |
| Fagron | SyrSpend® SF Alka | 20G03-F11 | 3 |
| Fagron | SyrSpend® SF Alka | 20G03-F11-374279 | 20 |
| Fagron | SyrSpend® SF Alka | 20G03-F12 | 2 |
| Fagron | SyrSpend® SF Alka | 20G03-F12-374282 | 7 |
| Fagron | SyrSpend® SF Alka | 20Go3-f12-374282 | 1 |
| Fagron | SyrSpend® SF Alka | 21101_F-02 | 1 |
| Fagron | SyrSpend® SF Alka | 21101-F02 | 1 |
| Fagron | SyrSpend® SF Alka | 21101-F02-380031 | 5 |
| Fagron | SyrSpend® SF pH4 | 211021-01 | 1 |
| Fagron | SyrSpend® SF Alka | 21826-F08 | 1 |
| Fagron | SyrSpend® SF Alka | 21826-F08-379141 | 2 |
| Fagron | SyrSpend® SF Alka | 21926-F07-378133 | 1 |
| Fagron | SyrSpend® SF Alka | 21A21-376829 | 3 |
| Fagron | SyrSpend® SF Alka | 21A21-F01 | 6 |
| Fagron | SyrSpend® SF Alka | 21A21-F01-376829 | 18 |
| Fagron | SyrSpend® SF Alka | 21A21-FO1 | 1 |
| Fagron | SyrSpend® SF Alka | 21B26-F06 | 2 |
| Fagron | SyrSpend® SF Alka | 21B26-F06-5264809 | 1 |
| Fagron | SyrSpend® SF Alka | 21B26-F07_378830 | 1 |
| Fagron | SyrSpend® SF Alka | 21B26-F07-378133 | 9 |
| Fagron | SyrSpend® SF Alka | 21B26-F08 | 2 |
| Fagron | SyrSpend® SF Alka | 21B26-F08-379141 | 10 |
| Fagron | SyrSpend® SF Alka | 21B26-FO6 | 1 |
| Fagron | SyrSpend® SF Alka | 21B26-FO7378133 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | SyrSpend® SF pH4 | 21F02-F01-378237 | 1 |
| Fagron | SyrSpend® SF Alka | 21F08-F03 | 3 |
| Fagron | SyrSpend® SF Alka | 21F08F03378828 | 1 |
| Fagron | SyrSpend® SF Alka | 21F08-F03-378828 | 20 |
| Fagron | SyrSpend® SF Alka | 21F08-F04 | 1 |
| Fagron | SyrSpend® SF Alka | 21F08-F04-378832 | 5 |
| Fagron | SyrSpend® SF Alka | 21F24F01379228 | 1 |
| Fagron | SyrSpend® SF Alka | 21F24-F01-379228 | 17 |
| Fagron | SyrSpend® SF Alka | 21F24-F01-37928 | 1 |
| Fagron | SyrSpend® SF Alka | 21F24-F03-379228 | 1 |
| Fagron | SyrSpend® SF Alka | 21F24-F03526598 | 1 |
| Fagron | SyrSpend® SF Alka | 21F24-F03-526598 | 5 |
| Fagron | SyrSpend® SF Alka | 21F24-F04 | 2 |
| Fagron | SyrSpend® SF Alka | 21F24-F04-379672 | 6 |
| Fagron | SyrSpend® SF Alka | 21F24-F01 | 1 |
| Fagron | SyrSpend® SF Alka | 21F08-F03-378828 | 1 |
| Fagron | SyrSpend® SF Alka | 21H16-F06 | 1 |
| Fagron | SyrSpend® SF Alka | 21H16-F06-0000 | 1 |
| Fagron | SyrSpend® SF Alka | 21H16F06379894 | 1 |
| Fagron | SyrSpend® SF Alka | 21H16-F06-379894 | 33 |
| Fagron | SyrSpend® SF Alka | 21H16-F06 | 1 |
| Fagron | SyrSpend® SF pH4 | 21H20-F02 | 2 |
| Fagron | SyrSpend® SF pH4 | 21H20-F02-380674 | 9 |
| Fagron | SyrSpend® SF Alka | 21I01-F02 | 1 |
| Fagron | SyrSpend® SF Alka | 21I01-F02-280031 | 1 |
| Fagron | SyrSpend® SF Alka | 21i01-F02-380031 | 1 |
| Fagron | SyrSpend® SF Alka | 21I01-F02-380031 | 31 |
| Fagron | SyrSpend® SF Alka | 21IL07-F05-381032 | 1 |
| Fagron | SyrSpend® SF pH4 | 21K22-F06 | 1 |
| Fagron | SyrSpend® SF Alka | 21l01-F02-380031 | 1 |
| Fagron | SyrSpend® SF Alka | 21L07-F04-381033 | 3 |
| Fagron | SyrSpend® SF Alka | 21L07-F05 | 5 |
| Fagron | SyrSpend® SF Alka | 21L07F05381032 | 1 |
| Fagron | SyrSpend® SF Alka | 21L07-F05-381032 | 46 |
| Fagron | SyrSpend® SF Alka | 21L-07-F05-381032 | 1 |
| Fagron | SyrSpend® SF Alka | 21L0-F04-381033 | 1 |
| Fagron | SyrSpend® SF Alka | 21LO7-F05-381032 | 1 |
| Fagron | SyrSpend® SF Alka | 21LO7-FO5-381032 | 1 |
| Fagron | SyrSpend® SF pH4 | 22007-F04 | 1 |
| Fagron | SyrSpend® SF pH4 | 22109-F01-383384 | 1 |
| Fagron | SyrSpend® SF pH4 | 22109-F02 | 1 |
| Fagron | SyrSpend® SF pH4 | 22109-F02-383489 | 1 |
| Fagron | SyrSpend® SF pH4 | 22109-F03-383490 | 2 |
| Fagron | SyrSpend® SF Alka | 22804-F05-381975 | 1 |
| Fagron | SyrSpend® SF Alka | 22804-F06 | 1 |
| Fagron | SyrSpend® SF Alka | 22804-F06-381564 | 2 |
| Fagron | SyrSpend® SF Alka | 22A12F20381408 | 1 |
| Fagron | SyrSpend® SF Alka | 22A12-F20-381408 | 8 |
| Fagron | SyrSpend® SF Alka | 22A12-F21 | 1 |
| Fagron | SyrSpend® SF Alka | 22A12F21526828 | 1 |
| Fagron | SyrSpend® SF Alka | 22A12-F21-526828 | 3 |
| Fagron | SyrSpend® SF Alka | 22A12-F22101/22P | 1 |
| Fagron | SyrSpend® SF Alka | 22A12F223821295 | 1 |
| Fagron | SyrSpend® SF Alka | 22A12-F22-382195 | 14 |
| Fagron | SyrSpend® SF Alka | 22A12-F24-382104 | 5 |
| Fagron | SyrSpend® SF Alka | 22B04-F04-381555 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | SyrSpend® SF Alka | 22B04F05-3819009 | 1 |
| Fagron | SyrSpend® SF Alka | 22B04-F05-381909 | 2 |
| Fagron | SyrSpend® SF Alka | 22B04-F05-381975 | 2 |
| Fagron | SyrSpend® SF Alka | 22B04-F06 | 2 |
| Fagron | SyrSpend® SF Alka | 22B04F06-381564 | 1 |
| Fagron | SyrSpend® SF Alka | 22B04-F06-381564 | 14 |
| Fagron | SyrSpend® SF Alka | 22B04-F07-381936 | 4 |
| Fagron | SyrSpend® SF pH4 | 22BO4-F02381139 | 1 |
| Fagron | SyrSpend® SF Alka | 22BO4-F06-381564 | 1 |
| Fagron | SyrSpend® SF pH4 | 22C07-F03 | 2 |
| Fagron | SyrSpend® SF pH4 | 22C07-F03-382305 | 6 |
| Fagron | SyrSpend® SF pH4 | 22C07-F04 | 1 |
| Fagron | SyrSpend® SF pH4 | 22C07-F04-0000 | 1 |
| Fagron | SyrSpend® SF pH4 | 22C07-F04-32813 | 1 |
| Fagron | SyrSpend® SF pH4 | 22C07F04382813 | 1 |
| Fagron | SyrSpend® SF pH4 | 22C07-F04-382813 | 14 |
| Fagron | SyrSpend® SF pH4 | 22G07-H08 | 1 |
| Fagron | SyrSpend® SF pH4 | 22I09-F01-383384 | 4 |
| Fagron | SyrSpend® SF pH4 | 22I09-F02-383489 | 10 |
| Fagron | SyrSpend® SF Alka | 22J04-F02-383639 | 12 |
| Fagron | SyrSpend® SF Alka | 22J04-F0-2383639 | 1 |
| Fagron | SyrSpend® SF Alka | 22J04-F06-383652 | 12 |
| Fagron | SyrSpend® SF Alka | 22J31-F01-383842 | 1 |
| Fagron | SyrSpend® SF Alka | 22J31-F01-526993 | 2 |
| Fagron | SyrSpend® SF Alka | 22J4-F06-383652 | 1 |
| Fagron | SyrSpend® SF Alka | 22J-F08-383658 | 1 |
| Fagron | SyrSpend® SF Alka | 22JO4-F11-383746 | 1 |
| Fagron | SyrSpend® SF Alka | 22JO4-FO2-383639 | 1 |
| Fagron | SyrSpend® SF pH4 | 22JO4-FO6-383652 | 1 |
| Fagron | SyrSpend® SF pH4 | 22K01-H01 | 1 |
| Fagron | SyrSpend® SF pH4 | 22K08F02-383826 | 1 |
| Fagron | SyrSpend® SF pH4 | 22K08-F02-383826 | 6 |
| Fagron | SyrSpend® SF Alka | 22K17-F04-384631 | 1 |
| Fagron | SyrSpend® SF Alka | 22K17-FO4-384631 | 1 |
| Fagron | SyrSpend® SF pH4 | 22l09-F01-383384 | 1 |
| Fagron | SyrSpend® SF pH4 | 22l09-F03-383490 | 1 |
| Fagron | SyrSpend® SF pH4 | 22L2O-F03-384076 | 1 |
| Fagron | SyrSpend® SF pH4 | 23A03-F10-384538 | 1 |
| Fagron | SyrSpend® SF pH4 | 23B13-F02-384539 | 1 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23C21-H01-00941 | 1 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23J11-H01-00941 | 1 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 23K002-H08-00941 | 1 |
| Fagron | SyrSpend® SF pH4 neo (Mai… | 24B28-H08-00941 | 1 |
| Fagron | SyrSpend® SF Alka | 2IF24-F04-379672 | 2 |
| Fagron | SyrSpend® SF Alka | 2IL07-F05 | 1 |
| Fagron | SyrSpend® SF Alka | 2IL07-F05-381032 | 1 |
| Fagron | SyrSpend® SF Alka | 2OB18F03369574 | 1 |
| Fagron | SyrSpend® SF pH4 | 2OF18-F13-379343 | 1 |
| Fagron | SyrSpend® SF Alka | 318828 | 1 |
| Fagron | SyrSpend® SF Alka | 379672 | 1 |
| Fagron | SyrSpend® SF Alka | 6369913 | 1 |
| Fagron | SyrSpend® SF Alka | 720026-0000 | 2 |
| Fagron | SyrSpend® SF Alka | 7-378133 | 1 |
| Fagron | SyrSpend® SF Alka | 802-3637809 | 1 |
| Fagron | SyrSpend® SF Alka | B02-3637809 | 4 |
| Fagron | SyrSpend® SF Alka | B04-3640507 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | SyrSpend® SF Alka | B07-5261409 | 3 |
| Fagron | SyrSpend® SF Alka | F01-3768209 | 2 |
| Fagron | SyrSpend® SF Alka | F01-376829 | 2 |
| Fagron | SyrSpend® SF pH4 | F02-3723908 | 4 |
| Fagron | SyrSpend® SF Alka | F02-3800301 | 1 |
| Fagron | SyrSpend® SF pH4 | F02-3834809 | 3 |
| Fagron | SyrSpend® SF pH4 | F03-3695400 | 1 |
| Fagron | SyrSpend® SF Alka | F03-3695704 | 2 |
| Fagron | SyrSpend® SF pH4 | F03-3725107 | 1 |
| Fagron | SyrSpend® SF Alka | F03-3788208 | 1 |
| Fagron | SyrSpend® SF pH4 | F03-3834900 | 1 |
| Fagron | SyrSpend® SF Alka | F03-5265908 | 1 |
| Fagron | SyrSpend® SF Alka | F04-3815505 | 1 |
| Fagron | SyrSpend® SF Alka | F0538103002 | 1 |
| Fagron | SyrSpend® SF Alka | F06-3699103 | 3 |
| Fagron | SyrSpend® SF Alka | F06-369913 | 1 |
| Fagron | SyrSpend® SF Alka | F06-3815604 | 1 |
| Fagron | SyrSpend® SF Alka | F07-3699104 | 3 |
| Fagron | SyrSpend® SF Alka | F07-3781303 | 1 |
| Fagron | SyrSpend® SF Alka | F07-3788300 | 2 |
| Fagron | SyrSpend® SF pH4 | F08-3669902 | 1 |
| Fagron | SyrSpend® SF pH4 | F08-3669903 | 2 |
| Fagron | SyrSpend® SF Alka | F08-3791401 | 2 |
| Fagron | SyrSpend® SF pH4 | F09-3670004 | 1 |
| Fagron | SyrSpend® SF pH4 | F10-3688704 | 2 |
| Fagron | SyrSpend® SF Alka | F1137427009 | 3 |
| Fagron | SyrSpend® SF Alka | F11-3742709 | 3 |
| Fagron | SyrSpend® SF Alka | F12-3748002 | 1 |
| Fagron | SyrSpend® SF Alka | F21-5268208 | 1 |
| Fagron | SyrSpend® SF pH4 | F03-3725107 | 1 |
| Fagron | SyrSpend® SF Alka | F04-3815505 | 1 |
| Fagron | SyrSpend® SF Alka | F06-3798904 | 1 |
| Fargon / AHD | SyrSpend® SF Alka | 20G03-F09-526400 | 1 |
| Fargon/AHD | SyrSpend® SF Alka | 18C13-B11 | 1 |
| Fargon/Phönix | SyrSpend® SF Alka | 20B25-F06-369913 | 2 |
| Fargon | SyrSpend® SF Alka | 19F12-B04-364057 | 1 |
| Fargon | SyrSpend® SF Alka | 21A21-F01-376829 | 1 |
| Fargon | SyrSpend® SF Alka | 21B26F07378133 | 1 |
| Fiebig 16.01.13 ek: 4,18EUR | Wheat starch | 11350911 | 1 |
| Fiebig | Wheat starch | 104A201028-01 | 1 |
| Fiebig | Wheat starch | 104A221027-01 | 1 |
| Fiebig | SyrSpend® SF pH4 | 20F08-F03 | 1 |
| Fiebig | Corn starch | 64A170123 | 1 |
| Fiebig | Corn starch | 64A230502-01 | 1 |
| Fischar/Gehe | SyrSpend® SF Alka | 18L21-B11-359901 | 1 |
| Fragon/ Noweda | SyrSpend® SF Alka | 19F12-B04-364057 | 2 |
| Fragron / Gehe | SyrSpend® SF Alka | 20G03-F11-374279 | 1 |
| Fresenius | Wheat starch | 13305103 | 1 |
| Gehe | Wheat starch | 1028-01 | 1 |
| gehe | Wheat starch | 104a221027-01 | 1 |
| Gehe | Corn starch | 16138505 | 1 |
| Gehe | Corn starch | 17287302 | 1 |
| Gehe | Corn starch | 17287305 | 1 |
| Gehe | Corn starch | 18274802 | 2 |
| Gehe | SyrSpend® SF Alka | 18A26-B05-346410 | 1 |
| Gehe | SyrSpend® SF Alka | 18H01-B12-353473 | 1 |
| Gehe | SyrSpend® SF pH4 | 18J16-B01-357703 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | SyrSpend® SF Alka | 18L21-B11 | 1 |
| Gehe | Corn starch | 19187802 | 1 |
| Gehe | SyrSpend® SF pH4 | 19A14-B07-362431 | 1 |
| Gehe | SyrSpend® SF Alka | 22J04-F08-383658 | 1 |
| Gehe | Corn starch | 64A130304 | 1 |
| Gutenberg-Apotheke | Rice starch | 12360216 | 1 |
| Jenne | SyrSpend® SF Alka | 22K21-F03-385074 | 1 |
| Kehr | Wheat starch | 104A160512 | 1 |
| Kehr | SyrSpend® SF pH4 | 22L20-F03-384076 | 1 |
| Kehr | SyrSpend® SF pH4 | 23E22-F01-384947 | 1 |
| Klemk | Wheat starch | 104A160512 | 1 |
| Klenk | Wheat starch | 101A201028-01 | 1 |
| Klenk | Wheat starch | 1028-01 | 1 |
| Klenk | Wheat starch | 104A101116 | 1 |
| Klenk | Rice starch | 104A120621 | 5 |
| Klenk | Rice starch | 104A130304 | 8 |
| Klenk | Wheat starch | 104a141114 | 1 |
| Klenk | Wheat starch | 104A141114 | 9 |
| Klenk | Wheat starch | 104a160512 | 1 |
| Klenk | Wheat starch | 104A160512 | 8 |
| Klenk | Wheat starch | 104a171122 | 1 |
| Klenk | Wheat starch | 104A171122 | 12 |
| Klenk | Wheat starch | 104A19100101 | 1 |
| Klenk | Wheat starch | 104A191001-01 | 3 |
| Klenk | Wheat starch | 104A200107-01 | 2 |
| Klenk | Wheat starch | 104A201028-01 | 4 |
| Klenk | Wheat starch | 104A210720-01 | 2 |
| Klenk | Wheat starch | 10720-01 | 1 |
| Klenk | Corn starch | 10816-01 | 1 |
| Klenk | Wheat starch | 10A160512 | 1 |
| Klenk | Wheat starch | 10A201028-01 | 1 |
| Klenk | Wheat starch | 191001-001 | 1 |
| Klenk | Corn starch | 200427-001 | 2 |
| Klenk | Rice starch | 200921-002 | 1 |
| Klenk | Corn starch | 220328A | 1 |
| Klenk | Corn starch | 4263535 | 1 |
| Klenk | Corn starch | 427-01 | 1 |
| Klenk | Rice starch | 64A080218 | 5 |
| Klenk | Rice starch | 64a130304 | 1 |
| Klenk | Corn starch | 64A130304 | 18 |
| Klenk | Corn starch | 64A170123 | 31 |
| Klenk | Corn starch | 64A181203 | 15 |
| Klenk | Corn starch | 64A20042701 | 2 |
| Klenk | Corn starch | 64A200427-01 | 17 |
| Klenk | Corn starch | 64-A-200427-01 | 1 |
| Klenk | Corn starch | 64A21081601 | 1 |
| Klenk | Corn starch | 64A210816-01 | 2 |
| Klenk | Corn starch | 6A181203 | 1 |
| Klenk | Potato starch | 80919-01 | 1 |
| Klenk | Rice starch | 84A130304 | 1 |
| Klenk | Rice starch | 84A141114 | 4 |
| Klenk | Rice starch | 84A180522 | 2 |
| Klenk | Wheat starch | 91001-01 | 1 |
| Klenk | Rice starch | 94A100122 | 1 |
| Klenk | Potato starch | 94A110512 | 1 |
| Klenk | Potato starch | 94A130304 | 5 |
| Klenk | Potato starch | 94a170123 | 1 |
| Klenk | Potato starch | 94A170123 | 4 |
| Klenk | Potato starch | 94A180919 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Potato starch | 94A180919-01 | 3 |
| Klosterring | Wheat starch | 15421507 | 1 |
| Koisser | Rice starch | WE07032013 | 1 |
| Krieger | SyrSpend® SF Alka | 22B04-F06-381564 | 1 |
| Nachprüfung | Wheat starch | 3082019-1 | 1 |
| Nachprüfung | Rice starch | 3709E01116 | 1 |
| Nachprüfung | Corn starch | AP200525-12 | 1 |
| Noweda/Hedinger | SyrSpend® SF pH4 | 18J16-B01-357703 | 1 |
| Noweda | Wheat starch | 104A221027-01 | 1 |
| Noweda | Rice starch | 14011621 | 1 |
| Noweda | Rice starch | 14023203 | 1 |
| noweda | SyrSpend® SF pH4 | 15I22-B02-52176 | 1 |
| Noweda | SyrSpend® SF pH4 | 16J10-B03-330757 | 3 |
| Noweda | SyrSpend® SF Alka | 18L21-B11-359901 | 1 |
| Noweda | Corn starch | 20004426006 | 1 |
| Noweda | Corn starch | 20004426018 | 2 |
| Noweda | Rice starch | 20004428009 | 1 |
| Noweda | SyrSpend® SF Alka | 20B25-F07 | 1 |
| Noweda | SyrSpend® SF pH4 | 2209-F03-383490 | 1 |
| Noweda | SyrSpend® SF Alka | 22A12-F22-382195 | 1 |
| Noweda | SyrSpend® SF pH4 | 22I09-F01-383384 | 2 |
| Noweda | SyrSpend® SF pH4 | 22I09-F02-383489 | 1 |
| Noweda | SyrSpend® SF pH4 | 22I09-F03-383490 | 6 |
| Noweda | SyrSpend® SF Alka | 22J04-F02-383639 | 1 |
| Noweda | SyrSpend® SF Alka | 22J31-F01-526993 | 3 |
| Noweda | SyrSpend® SF Alka | 22J04-F06-383652 | 1 |
| Noweda | SyrSpend® SF pH4 | 22K08-F02-383826 | 1 |
| Noweda | SyrSpend® SF Alka | 23A18-F07-384725 | 1 |
| Noweda | SyrSpend® SF pH4 | 23E23-F04-385081 | 1 |
| Phoenix | SyrSpend® SF Alka | 18H01-B12-353473 | 9 |
| Phoenix | SyrSpend® SF pH4 | 18H30-B02-355226 | 9 |
| Phoenix | SyrSpend® SF pH4 | 18J25-B15-357803 | 1 |
| Phoenix | SyrSpend® SF pH4 | 18L21-B11-359901 | 6 |
| Phoenix | SyrSpend® SF Alka | 19D29-B07-362182 | 4 |
| Phoenix | SyrSpend® SF Alka | 19D29-B11-363786 | 3 |
| Phoenix | SyrSpend® SF pH4 | 23E22-F02-384949 | 1 |
| Phoenix | SyrSpend® SF pH4 | 23E23-F05-385178 | 1 |
| Phoenix | SyrSpend® SF Alka | F03-3788208 | 1 |
| Phönix/Fagon | SyrSpend® SF Alka | 17D11-B04-332593 | 1 |
| Phönix/Noweda | Corn starch | 20004426006 | 1 |
| Phönix | Wheat starch | 104A191001-01 | 1 |
| PHönix | Wheat starch | 104A210720-01 | 1 |
| PHÖNIX | Wheat starch | 16162905 | 1 |
| Phönix | SyrSpend® SF Alka | 18B13-B11-350851 | 1 |
| Phönix | SyrSpend® SF Alka | 19F12-B04-364057 | 1 |
| Phönix | SyrSpend® SF Alka | 21F08-F03378828 | 1 |
| Phönix | SyrSpend® SF Alka | 21L07-F05 | 3 |
| Phönix | SyrSpend® SF Alka | 22B04-F04-381555 | 8 |
| Phönix | SyrSpend® SF Alka | 22J04-F06-383652 | 1 |
| phönix | Rice starch | 84a141114 | 1 |
| Phönix | Rice starch | 84A141114 | 2 |
| Sanacorp | Corn starch | 18274808 | 1 |
| Sanacorp | SyrSpend® SF Alka | 21F08-F03-378828 | 1 |
| Sanacorp | SyrSpend® SF Alka | 21F08-F03-378828210166 | 1 |
| Sanacorp | SyrSpend® SF Alka | 22804-F07 | 1 |
| Sanacorp | SyrSpend® SF Alka | 23A18-F07-384725 | 2 |
| Sanacorp | SyrSpend® SF pH4 | 23E22-F02-384949 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | SyrSpend® SF pH4 neo (Mai… | 24H06-H07-00941 | 1 |
| Sanacorp | Corn starch | 64A181203 | 1 |
| Sanacorp | Rice starch | 84A141114 | 1 |
| sanacorp | Rice starch | 94A130304 | 1 |
| Spinnrad GmbH | Corn starch | 519408192 | 1 |
| VDL;03.03.15;3,04EUR | Rice starch | 14011627 | 1 |
| VDL;3,03EUR;11.06.15 | Rice starch | 14011630 | 1 |

- 254 719 spectra from 1666 *Apo-Ident* customers from a total of 51 533 batches from a further 718 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Starch* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Starch* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 1860 | 0 | 156 466 |
| **Type B** | 0 | 1670 | 0 | 211 270 |
| **Type C** | 0 | 2120 | 47 | 254 689 |

The substance/substance group *Starch* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.6774 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6407 %) |
| **Type C** | 100.0000 % (> 99.9025 %) | 97.8311 % (> 97.6927 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20790 | 22450 | 8.48 | 56.18 |
| 20996 | 20996 | 0.00 | 70.71 |
| 21447 | 21447 | 0.00 | 52.16 |
| 21827 | 22450 | 5.89 | 59.18 |
| 21965 | 22449 | 6.80 | 74.35 |
| 21973 | 22450 | 8.03 | 58.17 |
| 22246 | 22450 | 11.33 | 56.01 |
| 22449 | 22449 | 0.00 | 69.68 |
| 22450 | 22450 | 0.00 | 60.54 |
| 22496 | 22496 | 0.00 | 41.42 |
| 22497 | 22496 | 2.07 | 41.58 |
| 22585 | 25767 | 8.47 | 53.49 |
| 22719 | 22719 | 0.00 | 32.61 |
| 23219 | 23220 | 7.25 | 39.02 |
| 23220 | 23220 | 0.00 | 46.27 |
| 23448 | 24112 | 17.26 | 51.31 |
| 23449 | 24112 | 16.61 | 50.80 |
| 23510 | 21447 | 12.95 | 58.71 |
| 23750 | 23750 | 0.00 | 52.95 |
| 23923 | 22449 | 7.18 | 71.94 |
| 24112 | 24112 | 0.00 | 61.69 |
| 24290 | 24112 | 7.50 | 59.77 |
| 24361 | 24361 | 0.00 | 60.55 |
| 25080 | 25080 | 0.00 | 30.05 |
| 25363 | 24112 | 18.33 | 46.99 |
| 25369 | 22496 | 10.21 | 38.50 |
| 25382 | 22449 | 9.83 | 68.99 |
| 25383 | 22450 | 9.37 | 49.57 |
| 25534 | 25534 | 0.00 | 34.36 |
| 25755 | 25755 | 0.00 | 41.41 |
| 25767 | 25767 | 0.00 | 51.32 |
| 26568 | 22496 | 15.75 | 34.67 |
| 26613 | 22496 | 5.71 | 39.68 |
| 26677 | 22496 | 9.76 | 36.41 |
| 27029 | 24112 | 25.44 | 44.85 |
| 27030 | 22496 | 18.23 | 37.34 |
| 27056 | 22496 | 14.16 | 43.62 |
| 27107 | 27107 | 0.00 | 55.90 |
| 27180 | 22496 | 11.68 | 38.60 |
| 27192 | 22496 | 14.52 | 44.15 |
| 27321 | 27321 | 0.00 | 72.25 |
| 27324 | 27324 | 0.00 | 57.04 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Stearic acid 50** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20869-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Stearic acid 50; Acidum stearicum

### Special notes

When selecting the *Stearic acid 50* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Stearic acid 50 | 6 | 5 | 38 |

### Second-stage model

For differentiation of the substance/substance group *Stearic acid 50* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Stearic acid 50* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Hard fat | 93.47 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Stearic acid 50* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Stearic acid 50*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Stearic acid 50 | 12241910 | 20869 | 40 | AR-15-FG-007284-01 |
| Caelo | Stearic acid 50 | 14359310 | 21793 | 60 | 20150126 |
| Caelo | Stearic acid 50 | 14359310 | 21928 | 60 | AR-16-FG-004044-01 |
| Caelo | Stearic acid 50 | 14359314 | 22274 | 60 | 20150126 |
| Caelo | Stearic acid 50 | 170810 | 23294 | 40 | 20170426* |
| Caelo | Stearic acid 50 | 170810 | 23667 | 40 | 20170426* |
| Caelo | Stearic acid 50 | 192910 | 25066 | 40 | 20191128* |
| Caelo | Stearic acid 50 | 22000750 | 26125 | 30 | 20220429* |
| Caelo | Stearic acid 50 | 22000750 | 26125SI | 20 | 20220429* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 390 spectra of 9 reference samples from the substance/substance group *Stearic acid 50*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 936 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 250 spectra of 7 reference samples from the substance/substance group *Stearic acid 50*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Stearic acid 50 | 163469 | 23032 | 40 |
| Caelo | Stearic acid 50 | 180809 | 24036 | 40 |
| Caelo | Stearic acid 50 | 20003933010 | 25731 | 50 |
| Caelo | Stearic acid 50 | 23001610 | 26833 | 40 |
| Caelo | Stearic acid 50 | 24003028 | 27549 | 40 |
| Caelo | Stearic acid 50 | 23001610 | 26833SI | 20 |
| Caelo | Stearic acid 50 | 24003028 | 27549SI | 20 |

- 212 690 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 90 spectra from 43 *Apo-Ident* customers from 41 batches from the substance/substance group *Stearic acid 50*.

- Among them are spectra of independent samples from 38 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Stearic acid 50 | 22000750007 | 1 |
| | Stearic acid 50 | 23001610002 | 1 |
| | Stearic acid 50 | 24001939005 | 1 |
| Caelo | Stearic acid 50 | 11103706 | 1 |
| Caelo | Stearic acid 50 | 11308505 | 1 |
| Caelo | Stearic acid 50 | 11308514 | 1 |
| Caelo | Stearic acid 50 | 12241911 | 2 |
| Caelo | Stearic acid 50 | 12241914 | 1 |
| Caelo | Stearic acid 50 | 12241915 | 2 |
| Caelo | Stearic acid 50 | 12241930 | 3 |
| Caelo | Stearic acid 50 | 14359314 | 4 |
| Caelo | Stearic acid 50 | 1609611 | 1 |
| Caelo | Stearic acid 50 | 16096301 | 2 |
| Caelo | Stearic acid 50 | 16096311 | 1 |
| Caelo | Stearic acid 50 | 1617081006 | 1 |
| Caelo | Stearic acid 50 | 17081003 | 1 |
| Caelo | Stearic acid 50 | 17081006 | 5 |
| Caelo | Stearic acid 50 | 1808013 | 1 |
| Caelo | Stearic acid 50 | 18080901 | 4 |
| Caelo | Stearic acid 50 | 18080913 | 4 |
| Caelo | Stearic acid 50 | 18238002 | 1 |
| Caelo | Stearic acid 50 | 18238004 | 5 |
| Caelo | Stearic acid 50 | 18238006 | 2 |
| Caelo | Stearic acid 50 | 18238010 | 4 |
| Caelo | Stearic acid 50 | 192910002 | 1 |
| Caelo | Stearic acid 50 | 192910005 | 2 |
| Caelo | Stearic acid 50 | 192910010 | 1 |
| Caelo | Stearic acid 50 | 192910012 | 1 |
| Caelo | Stearic acid 50 | 2000393001 | 1 |
| Caelo | Stearic acid 50 | 20003933002 | 1 |
| Caelo | Stearic acid 50 | 21003445001 | 1 |
| Caelo | Stearic acid 50 | 21003445002 | 1 |
| Caelo | Stearic acid 50 | 22000750004 | 4 |
| Caelo | Stearic acid 50 | 23933002 | 1 |
| Caesar & Loretz GmbH… | Stearic acid 50 | 18238010 | 1 |
| Caesar & Loretz GmbH… | Stearic acid 50 | 20003933002 | 1 |
| Caesar & Loretz GmbH… | Stearic acid 50 | 18238006 | 1 |
| Caesar & Loretz GmbH… | Stearic acid 50 | 192910 | 1 |
| Caesar & Loretz GmbH… | Stearic acid 50 | 18238006 | 1 |
| Caesar & Loretz GmbH | Stearic acid 50 | 18238010 | 1 |
| Caesar & Loretz GmbH | Stearic acid 50 | 192910005 | 5 |
| Caesar & Loretz GmbH | Stearic acid 50 | 20003933001 | 3 |
| Caesar & Loretz GmbH | Stearic acid 50 | 20003933010 | 1 |
| Caesar & Loretz GmbH | Stearic acid 50 | 21003445002 | 1 |
| Caesar & Loretz | Stearic acid 50 | 14359310 | 1 |
| Caesar&Loretz GmbH/Anzag | Stearic acid 50 | 11308505 | 1 |
| Caleo | Stearic acid 50 | 16096301 | 1 |
| GEHE | Stearic acid 50 | 18238006 | 1 |
| Jenne | Stearic acid 50 | 18080901 | 1 |
| Kehr | Stearic acid 50 | 16346902 | 1 |
| Phoenix | Stearic acid 50 | 12241915 | 1 |
| Phönix | Stearic acid 50 | 1224915 | 1 |
| Phönix | Stearic acid 50 | 18080901 | 1 |
| ROHA | Stearic acid 50 | 130240 | 1 |

- 256 796 spectra from 1666 *Apo-Ident* customers from a total of 52 112 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be


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identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Stearic acid 50* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Stearic acid 50* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 390 | 0 | 157 936 |
| **Type B** | 0 | 250 | 0 | 212 690 |
| **Type C** | 0 | 88 | 2 | 256 796 |

The substance/substance group *Stearic acid 50* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4615 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.7778 % (> 94.4444 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20869 | 20869 | 0.00 | 125.74 |
| 21793 | 21928 | 7.19 | 123.99 |
| 21928 | 21928 | 0.00 | 129.69 |
| 22274 | 25066 | 6.93 | 121.18 |
| 23294 | 23294 | 0.00 | 121.72 |
| 23667 | 23667 | 0.00 | 120.59 |
| 25066 | 25066 | 0.00 | 121.70 |
| 26125 | 26125 | 0.00 | 130.10 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,

thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sucrose** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20372-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sucrose; Saccharum

### Special notes

When selecting the *Sucrose* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sucrose | 13 | 8 | 707 |

### Second-stage model

For differentiation of the substance/substance group *Sucrose* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sucrose* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 46.03 | – |
| Sodium cromoglicate | 57.92 | – |
| ⋮ | ⋮ | ⋮ |
| Sodium citrate | >50 | 76.37 |
| Heparin sodium | >50 | 124.79 |
| Capsaicin | >50 | 262.07 |
| Amifampridine | >50 | 423.54 |
| Quinine hydrochloride dihydrate | >50 | 462.94 |
| Oxybutynin hydrochloride | >50 | 513.40 |
| Levocarnitine | >50 | 554.28 |
| Prednicarbate | >50 | 596.83 |
| Pyridoxal-5-phosphate hydrate | >50 | 716.35 |
| Ciprofloxacin hydrochloride | >50 | 817.82 |
| Methoxsalen | >50 | 903.06 |
| Triclosan | >50 | 911.25 |
| Alfatradiol | >50 | 975.04 |
| Tetracaine | >50 | 1087.55 |
| Cyproterone acetate | >50 | 1478.10 |
| Norethisterone acetate | >50 | 1536.25 |
| Amitriptyline hydrochloride | >50 | 2938.32 |
| Valine | >50 | 3801.94 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sucrose* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sucrose*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sucrose | 13352909 | 21484 | 40 | 1410501 |
| Caelo | Sucrose | 14340003 | 21736 | 60 | 20141114 |
| Caelo | Sucrose | 161999 | 22615 | 40 | 20160714* |
| Caelo | Sucrose | 162060 | 22643 | 40 | 20160808* |
| Caelo | Sucrose | 163286 | 23057 | 40 | 20161219* |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sucrose | 163081 | 23058 | 40 | 20161115* |
| Caelo | Sucrose | 171066 | 23297 | 40 | 20170511* |
| Caelo | Sucrose | 172133 | 23666 | 40 | 20170817* |
| Caelo | Sucrose | 173247 | 23833 | 40 | 20180117* |
| Caelo | Sucrose | 181582 | 24217 | 40 | 20180605* |
| Caelo | Sucrose | 21000656 | 25651 | 40 | 20210406* |
| Caelo | Sucrose | 22002704 | 26630 | 40 | 20220909* |
| Caelo | Sucrose | 22002704 | 26630SI | 20 | 20220909* |
| Caelo | Sucrose | 23000893 | 26723 | 40 | 20230601* |
| Caelo | Sucrose | 23000893 | 26723SI | 20 | 20230601* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 580 spectra of 15 reference samples from the substance/substance group *Sucrose*. These samples are listed above in the *calibration samples* section. The reference samples come from 13 different batches.

- 157 746 spectra from a total of 2944 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 340 spectra of 9 reference samples from the substance/substance group *Sucrose*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sucrose | 12146801 | 20909 | 40 |
| Caelo | Sucrose | 181546 | 24237 | 40 |
| Caelo | Sucrose | 182574 | 24353 | 40 |
| Caelo | Sucrose | 182818 | 24359 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sucrose | 192839 | 25235 | 40 |
| Caelo | Sucrose | 190627 | 25236 | 40 |
| Caelo | Sucrose | 24000032 | 27134 | 40 |
| Caelo | Sucrose | 24002338 | 27447 | 40 |
| Caelo | Sucrose | 24000032 | 27134SI | 20 |

- 212 600 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1867 spectra from 534 *Apo-Ident* customers from 711 batches from the substance/substance group *Sucrose*.
- Among them are spectra of independent samples from 706 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sucrose | | 1 |
| | Sucrose | 13352908 | 1 |
| | Sucrose | 18024407 | 4 |
| | Sucrose | 181023/13 | 1 |
| | Sucrose | 20004028003 | 1 |
| | Sucrose | 21003804004 | 7 |
| | Sucrose | 21003804006 | 1 |
| | Sucrose | 21003804007 | 2 |
| | Sucrose | 21003804011 | 1 |
| | Sucrose | 21003804012 | 10 |
| | Sucrose | 22002704004 | 18 |
| | Sucrose | 22002704005 | 3 |
| | Sucrose | 22002704009 | 1 |
| | Sucrose | 2202704004 | 1 |
| | Sucrose | 222704004 | 1 |
| | Sucrose | 23000893001 | 1 |
| | Sucrose | 23000893002 | 14 |
| | Sucrose | 23003269002 | 1 |
| | Sucrose | 23003269003 | 1 |
| | Sucrose | 23003269004 | 20 |
| | Sucrose | 23003269010 | 1 |
| | Sucrose | 24000032005 | 7 |
| | Sucrose | 24000032009 | 2 |
| 250,0 | Sucrose | 22002704004 | 1 |
| AHD | Sucrose | 15182805 | 1 |
| AHD | Sucrose | 18154602 | 1 |
| AHD | Sucrose | 18154603 | 2 |
| Anzag | Sucrose | 22002704004 | 1 |
| Anzag | Sucrose | 23003269004 | 1 |
| Anzag | Sucrose | 24000032005 | 2 |
| apomix | Sucrose | 13352909 | 1 |
| Audor Pharma | Sucrose | 16206102 | 1 |
| Bombastus | Sucrose | 15156008 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sucrose | | 1 |
| Caelo | Sucrose | 1(192839004) | 1 |
| Caelo | Sucrose | 11246306 | 1 |
| Caelo | Sucrose | 11246313 | 2 |
| Caelo | Sucrose | 12107805 | 1 |
| Caelo | Sucrose | 12107806 | 2 |
| Caelo | Sucrose | 12241801 | 1 |
| Caelo | Sucrose | 12241803 | 2 |
| Caelo | Sucrose | 12241804 | 2 |
| Caelo | Sucrose | 12241808 | 5 |
| Caelo | Sucrose | 12241817 | 2 |
| Caelo | Sucrose | 12280309 | 1 |
| Caelo | Sucrose | 130031417 | 1 |
| Caelo | Sucrose | 13031405 | 3 |
| Caelo | Sucrose | 13031406 | 2 |
| Caelo | Sucrose | 13031409 | 1 |
| Caelo | Sucrose | 13031410 | 2 |
| Caelo | Sucrose | 13031414 | 1 |
| Caelo | Sucrose | 13031417 | 2 |
| Caelo | Sucrose | 13063907 | 1 |
| Caelo | Sucrose | 13111706 | 1 |
| Caelo | Sucrose | 13352901 | 2 |
| Caelo | Sucrose | 13352902 | 13 |
| Caelo | Sucrose | 13352905 | 1 |
| Caelo | Sucrose | 13352908 | 1 |
| Caelo | Sucrose | 13352909 | 4 |
| Caelo | Sucrose | 13352911 | 1 |
| Caelo | Sucrose | 13352916 | 3 |
| Caelo | Sucrose | 13352920 | 7 |
| Caelo | Sucrose | 1352920 | 1 |
| Caelo | Sucrose | 14197301 | 4 |
| Caelo | Sucrose | 14197302 | 3 |
| Caelo | Sucrose | 14197313 | 1 |
| Caelo | Sucrose | 1430009 | 1 |
| Caelo | Sucrose | 14340003 | 4 |
| Caelo | Sucrose | 14340004 | 5 |
| Caelo | Sucrose | 14340005 | 1 |
| Caelo | Sucrose | 14340006 | 1 |
| Caelo | Sucrose | 14340008 | 5 |
| Caelo | Sucrose | 14340009 | 4 |
| Caelo | Sucrose | 15028801 | 14 |
| Caelo | Sucrose | 15028802 | 7 |
| Caelo | Sucrose | 15156008 | 1 |
| Caelo | Sucrose | 15182804 | 28 |
| Caelo | Sucrose | 15182805 | 3 |
| Caelo | Sucrose | 154460 | 1 |
| Caelo | Sucrose | 15446002 | 11 |
| Caelo | Sucrose | 15446003 | 7 |
| Caelo | Sucrose | 15446007 | 1 |
| Caelo | Sucrose | 160499 | 1 |
| Caelo | Sucrose | 16049902 | 3 |
| Caelo | Sucrose | 16049907 | 17 |
| Caelo | Sucrose | 16051301 | 1 |
| Caelo | Sucrose | 16051304 | 1 |
| Caelo | Sucrose | 16051305 | 2 |
| Caelo | Sucrose | 16166003 | 1 |
| Caelo | Sucrose | 162061 | 1 |
| Caelo | Sucrose | 16206102 | 13 |
| Caelo | Sucrose | 16206103 | 6 |
| Caelo | Sucrose | 1628603 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sucrose | 16305501 | 1 |
| Caelo | Sucrose | 16325605 | 1 |
| Caelo | Sucrose | 16328603 | 13 |
| Caelo | Sucrose | 16328605 | 22 |
| Caelo | Sucrose | 16328606 | 7 |
| Caelo | Sucrose | 16328607 | 22 |
| Caelo | Sucrose | 16351702 | 1 |
| Caelo | Sucrose | 1649902 | 1 |
| Caelo | Sucrose | 17021620306 | 1 |
| Caelo | Sucrose | 17042103 | 4 |
| Caelo | Sucrose | 17106601 | 1 |
| Caelo | Sucrose | 17106603 | 55 |
| Caelo | Sucrose | 17106604 | 22 |
| Caelo | Sucrose | 17247203 | 1 |
| Caelo | Sucrose | 17288702 | 1 |
| Caelo | Sucrose | 17354506 | 20 |
| Caelo | Sucrose | 18024405 | 42 |
| Caelo | Sucrose | 1802445 | 1 |
| Caelo | Sucrose | 18154602 | 15 |
| Caelo | Sucrose | 18154603 | 28 |
| Caelo | Sucrose | 18257401 | 16 |
| Caelo | Sucrose | 18257402 | 45 |
| Caelo | Sucrose | 18260801 | 1 |
| Caelo | Sucrose | 18281803 | 4 |
| Caelo | Sucrose | 18281804 | 24 |
| Caelo | Sucrose | 18281810 | 2 |
| Caelo | Sucrose | 18329702 | 29 |
| Caelo | Sucrose | 18329703 | 9 |
| Caelo | Sucrose | 19060320648 | 1 |
| Caelo | Sucrose | 19060320649 | 1 |
| Caelo | Sucrose | 19060320650 | 1 |
| Caelo | Sucrose | 190627001 | 3 |
| Caelo | Sucrose | 190627002 | 21 |
| Caelo | Sucrose | 19062701 | 41 |
| Caelo | Sucrose | 19062702 | 4 |
| Caelo | Sucrose | 19132301 | 2 |
| Caelo | Sucrose | 1928339004 | 1 |
| Caelo | Sucrose | 192839001 | 1 |
| Caelo | Sucrose | 192839002 | 5 |
| Caelo | Sucrose | 192839004 | 34 |
| Caelo | Sucrose | 192839006 | 4 |
| Caelo | Sucrose | 192839007 | 26 |
| Caelo | Sucrose | 1928839004 | 1 |
| Caelo | Sucrose | 19329702 | 1 |
| Caelo | Sucrose | 2(192839007) | 1 |
| Caelo | Sucrose | 20001028003 | 1 |
| Caelo | Sucrose | 20002000004 | 1 |
| Caelo | Sucrose | 20003141002 | 1 |
| Caelo | Sucrose | 20003432001 | 1 |
| Caelo | Sucrose | 20004028001 | 3 |
| Caelo | Sucrose | 20004028003 | 19 |
| Caelo | Sucrose | 20011401 | 1 |
| Caelo | Sucrose | 20031515 | 1 |
| Caelo | Sucrose | 2100065004 | 1 |
| Caelo | Sucrose | 2100065006 | 1 |
| Caelo | Sucrose | 2100065007 | 1 |
| Caelo | Sucrose | 210006560001 | 1 |
| Caelo | Sucrose | 21000656001 | 24 |
| Caelo | Sucrose | 21000656004 | 4 |
| Caelo | Sucrose | 21000656006 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sucrose | 21000656007 | 4 |
| Caelo | Sucrose | 21000656010 | 16 |
| Caelo | Sucrose | 21003804003 | 4 |
| Caelo | Sucrose | 21003804004 | 20 |
| Caelo | Sucrose | 21003804007 | 8 |
| Caelo | Sucrose | 21003804008 | 3 |
| Caelo | Sucrose | 21003804011 | 1 |
| Caelo | Sucrose | 21003804012 | 4 |
| Caelo | Sucrose | 21003804013 | 2 |
| Caelo | Sucrose | 2100380412 | 1 |
| Caelo | Sucrose | 21003B | 1 |
| Caelo | Sucrose | 22002704004 | 1 |
| Caelo | Sucrose | 24061502 | 1 |
| Caelo | Sucrose | 27111802 | 1 |
| Caelo | Sucrose | 28041504 | 1 |
| Caelo | Sucrose | 28081308 | 1 |
| Caelo | Sucrose | 29081502 | 1 |
| Caelo | Sucrose | 4028003 | 1 |
| Caelo | Sucrose | 8024405 | 1 |
| Caelo | Sucrose | 81172478 | 2 |
| Caelo | Sucrose | 8704717 | 1 |
| Caelo | Sucrose | Caelo14197301 | 1 |
| Caeol/ Sanacorp | Sucrose | 21000656001 | 1 |
| Caeol/Sanacorp | Sucrose | 18154603 | 1 |
| Caeolo/Gehe | Sucrose | 15446002 | 1 |
| Caeolo/NOWEDA | Sucrose | 21003804008 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 16049907 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 192839006 | 2 |
| Caesar & Loretz GmbH... | Sucrose | 21000656007 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 192839006 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 192839007 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 190627002 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 20004028003 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 20004028003 | 2 |
| Caesar & Loretz GmbH... | Sucrose | 21000656010 | 1 |
| Caesar & Loretz GmbH/AHD | Sucrose | 192839004 | 1 |
| Caesar & Loretz GmbH/G | Sucrose | 18257402 | 1 |
| Caesar & Loretz GmbH/Gehe | Sucrose | 192839007 | 1 |
| Caesar & Loretz GmbH/Gehe | Sucrose | 20004028003 | 1 |
| Caesar & Loretz GmbH/Gehe | Sucrose | 21000656001 | 1 |
| Caesar & Loretz GmbH/Gehe | Sucrose | 21003804004 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 192839006 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 21000656007 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 18281804 | 2 |
| Caesar & Loretz GmbH... | Sucrose | 190627002 | 3 |
| Caesar & Loretz GmbH... | Sucrose | 18329703 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 192839004 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 21000656001 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 21003804007 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 21003804012 | 1 |
| Caesar & Loretz GmbH/Sana | Sucrose | 20004028001 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 17354506 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 190627002 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 19062701 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 192839007 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 21000656001 | 1 |
| Caesar & Loretz GmbH... | Sucrose | 21000656006 | 1 |
| Caesar & Loretz GmbH | Sucrose | 16328605 | 1 |
| Caesar & Loretz GmbH | Sucrose | 18154601 | 1 |
| Caesar & Loretz GmbH | Sucrose | 18154603 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Sucrose | 18257401 | 4 |
| Caesar & Loretz GmbH | Sucrose | 18257402 | 14 |
| Caesar & Loretz GmbH | Sucrose | 18281803 | 1 |
| Caesar & Loretz GmbH | Sucrose | 18281804 | 8 |
| Caesar & Loretz GmbH | Sucrose | 18329702 | 10 |
| Caesar & Loretz GmbH | Sucrose | 18329703 | 2 |
| Caesar & Loretz GmbH | Sucrose | 190627001 | 2 |
| Caesar & Loretz GmbH | Sucrose | 190627002 | 10 |
| Caesar & Loretz GmbH | Sucrose | 19062701 | 13 |
| Caesar & Loretz GmbH | Sucrose | 19062706 | 1 |
| Caesar & Loretz GmbH | Sucrose | 192839001 | 3 |
| Caesar & Loretz GmbH | Sucrose | 192839002 | 5 |
| Caesar & Loretz GmbH | Sucrose | 192839004 | 8 |
| Caesar & Loretz GmbH | Sucrose | 192839006 | 2 |
| Caesar & Loretz GmbH | Sucrose | 192839007 | 13 |
| Caesar & Loretz GmbH | Sucrose | 20004028003 | 14 |
| Caesar & Loretz GmbH | Sucrose | 21000656001 | 12 |
| Caesar & Loretz GmbH | Sucrose | 21000656006 | 4 |
| Caesar & Loretz GmbH | Sucrose | 21000656007 | 1 |
| Caesar & Loretz GmbH | Sucrose | 21000656010 | 6 |
| Caesar & Loretz GmbH | Sucrose | 21003804004 | 4 |
| Caesar & Loretz GmbH | Sucrose | 21003804007 | 11 |
| Caesar & Loretz GmbH | Sucrose | 21003804012 | 1 |
| Caesar & Loretz GmbH | Sucrose | 21003804013 | 1 |
| Caesar & Loretz Hilden | Sucrose | 18257402 | 1 |
| Caesar & Loretz/Noweda | Sucrose | 18329702 | 1 |
| Caesar und Loretz | Sucrose | 18329702 | 1 |
| Caleo/ Noweda | Sucrose | 17106603 | 1 |
| Calo, Hilden/ Phönix | Sucrose | 190627002 | 1 |
| Cealo | Sucrose | 15446002 | 1 |
| Cealo | Sucrose | 16206102 | 1 |
| DHU | Sucrose | 7020407 | 1 |
| DHU | Sucrose | 9010709 | 1 |
| DHU | Sucrose | 9010710 | 1 |
| DHU | Sucrose | 9020110 | 1 |
| DHU | Sucrose | 9020510 | 1 |
| DHU | Sucrose | 9050610 | 1 |
| Diamant | Sucrose | L24223 | 1 |
| Euro OTC | Sucrose | 12345 | 2 |
| Euro OTC | Sucrose | 16328605 | 1 |
| Euro OTC | Sucrose | 17106603 | 1 |
| Euro OTC | Sucrose | 17354506 | 1 |
| Euro OTC | Sucrose | 18024405 | 2 |
| Fagron | Sucrose | 1011208731 | 2 |
| Fagron | Sucrose | 11/16-N01 | 1 |
| Fagron | Sucrose | 11/16-NO1 | 1 |
| Fagron | Sucrose | 11/20-N05 | 1 |
| Fagron | Sucrose | 11E19-N04 | 1 |
| Fagron | Sucrose | 11I16-N01 | 1 |
| Fagron | Sucrose | 11L09-N16 | 2 |
| Fagron | Sucrose | 12-E03-M01 | 1 |
| Fagron | Sucrose | 12E29-N04 | 1 |
| Fagron | Sucrose | 12G26-N01 | 2 |
| Fagron | Sucrose | 13A07-N03 | 1 |
| Fagron | Sucrose | 13D29-N08 | 1 |
| Fagron | Sucrose | 13G03-N16 | 1 |
| Fagron | Sucrose | 13G04-N01 | 1 |
| Fagron | Sucrose | 13I30-N05 | 1 |
| Fagron | Sucrose | 15446002 | 1 |
| Fagron | Sucrose | 16206102 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Sucrose | 18082014D | 1 |
| Fagron | Sucrose | 18257402 | 1 |
| Fagron | Sucrose | 2102308731 | 1 |
| Fagron | Sucrose | 5071201 | 1 |
| Fagron | Sucrose | 5112I-02207 | 1 |
| Fargon | Sucrose | 19I30-T05-079071 | 1 |
| Gehe Weiterstadt | Sucrose | 21003804012 | 1 |
| Gehe | Sucrose | 1434006 | 1 |
| Gehe | Sucrose | 15028802 | 1 |
| Gehe | Sucrose | 15446003 | 2 |
| Gehe | Sucrose | 16328607 | 1 |
| GEHE | Sucrose | 16328607 | 1 |
| Gehe | Sucrose | 17106603 | 2 |
| Gehe | Sucrose | 18281804 | 1 |
| Gehe | Sucrose | 18329702 | 2 |
| Gehe | Sucrose | 192839007 | 1 |
| Gehe | Sucrose | 21000656001 | 1 |
| Gehe | Sucrose | 21000656004 | 2 |
| GEHE | Sucrose | 21003804012 | 1 |
| Hanns G.Werner GmbH | Sucrose | 8731158 | 1 |
| Haushalt | Sucrose | 123456 | 1 |
| Jenne | Sucrose | 15182804 | 1 |
| Jenne | Sucrose | 18257402 | 2 |
| Jenne | Sucrose | 24000032005 | 1 |
| Jenne | Sucrose | 240703(23003269004) | 1 |
| Kaufland | Sucrose | L24475 | 1 |
| Kaufland | Sucrose | L24494 | 2 |
| Kehr | Sucrose | 16328606 | 1 |
| Kehr | Sucrose | 190627002 | 1 |
| L12 | Sucrose | 18154603 | 1 |
| L30 | Sucrose | 17106603 | 2 |
| Lebensmittelware (Edeka) | Sucrose | | 1 |
| Noweda | Sucrose | 16328603 | 1 |
| Noweda | Sucrose | 16328607 | 1 |
| Noweda | Sucrose | 18154603 | 1 |
| Noweda | Sucrose | 21003804004 | 1 |
| Noweda | Sucrose | 210038044007 | 1 |
| Noweda | Sucrose | 220002704004 | 1 |
| Noweda | Sucrose | 22002704005 | 1 |
| Penny Markt | Sucrose | 201L113530100 | 3 |
| Penny Markt | Sucrose | L120325600 | 2 |
| Penny Markt | Sucrose | L120404100 | 3 |
| Penny Markt | Sucrose | L120612100 | 3 |
| Penny Markt | Sucrose | L120628000 | 3 |
| Penny | Sucrose | L12513800 | 3 |
| Pfeifer/Langen | Sucrose | L03144N | 1 |
| Pharmachem | Sucrose | 7878 | 1 |
| pharm-a-speres | Sucrose | 8731003 | 1 |
| pharm-a-spheres/sana... | Sucrose | 8731306 | 1 |
| Phoenix | Sucrose | 18257402 | 1 |
| Phoenix | Sucrose | 192839004 | 1 |
| phoenix | Sucrose | 2100656001 | 1 |
| Phoenix | Sucrose | 22002704004 | 1 |
| Phönix | Sucrose | 15446002 | 1 |
| phönix | Sucrose | 16351701 | 1 |
| PHÖNIX | Sucrose | 17106603 | 1 |
| Phönix | Sucrose | 192839004 | 2 |
| Phönix | Sucrose | 22002704004 | 2 |
| ROHA | Sucrose | 130090 | 1 |
| Salvator Apotheke | Sucrose | R2229455M | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp/Caela | Sucrose | 17106603 | 1 |
| Sanacorp | Sucrose | 14197301 | 1 |
| Sanacorp | Sucrose | 14340005 | 1 |
| Sanacorp | Sucrose | 17106603 | 1 |
| Sanacorp | Sucrose | 192839007 | 1 |
| Sanacorp | Sucrose | 22002704004 | 1 |
| Sanacorp | Sucrose | 23000893002 | 1 |
| Sanacorp | Sucrose | AKD5 | 1 |
| Sanarcorp | Sucrose | 21000656007 | 1 |
| Soldan | Sucrose | | 1 |
| Soldan | Sucrose | 232027 | 1 |
| Soldan | Sucrose | 243983 | 1 |
| Spagyra Österreich | Sucrose | 15112321097 | 1 |
| Spagyra Österreich | Sucrose | 21102920359 | 1 |
| Spagyra/Österreich | Sucrose | 10070521044 | 1 |
| Spagyra/Österreich | Sucrose | 12112721050 | 1 |
| Spagyra/Österreich | Sucrose | 13021920149 | 1 |
| Spagyra/Österreich | Sucrose | 13050621774 | 1 |
| Spagyra/Österreich | Sucrose | 13070420936 | 2 |
| Spagyra/Österreich | Sucrose | 13070420937 | 2 |
| Spagyra/Österreich | Sucrose | 13091920456 | 1 |
| Spagyra/Österreich | Sucrose | 13102520353 | 1 |
| Spagyra/Österreich | Sucrose | 13111121193 | 1 |
| Spagyra/Österreich | Sucrose | 14010721509 | 1 |
| Spagyra/Österreich | Sucrose | 14012420377 | 1 |
| Spagyra/Österreich | Sucrose | 14041421810 | 1 |
| Spagyra/Österreich | Sucrose | 14050621091 | 1 |
| Spagyra/Österreich | Sucrose | 14060353342 | 1 |
| Spagyra/Österreich | Sucrose | 14060353343 | 1 |
| Spagyra/Österreich | Sucrose | 14070721041 | 1 |
| Spagyra/Österreich | Sucrose | 14071421137 | 2 |
| Spagyra/Österreich | Sucrose | 16122820921 | 1 |
| Spagyra/Österreich | Sucrose | 1624 | 1 |
| Spagyra/Österreich | Sucrose | 17020820810 | 1 |
| Spagyra/Österreich | Sucrose | 17020820816 | 1 |
| Spagyra/Österreich | Sucrose | 17021620307 | 1 |
| Spagyra/Österreich | Sucrose | 17021620309 | 1 |
| Spagyra/Österreich | Sucrose | 17022022188 | 1 |
| Spagyra/Österreich | Sucrose | 17032120927 | 1 |
| Spagyra/Österreich | Sucrose | 17032321132 | 1 |
| Spagyra/Österreich | Sucrose | 17032820797 | 1 |
| Spagyra/Österreich | Sucrose | 17041821026 | 1 |
| Spagyra/Österreich | Sucrose | 17041821027 | 1 |
| Spagyra/Österreich | Sucrose | 17070320627 | 1 |
| Spagyra/Österreich | Sucrose | 17091520139 | 1 |
| Spagyra/Österreich | Sucrose | 17092620773 | 1 |
| Spagyra/Österreich | Sucrose | 17121420710 | 1 |
| Spagyra/Österreich | Sucrose | 1721420709 | 1 |
| Spagyra/Österreich | Sucrose | 18021921250 | 1 |
| Spagyra/Österreich | Sucrose | 18032320385 | 1 |
| Spagyra/Österreich | Sucrose | 18032320386 | 1 |
| Spagyra/Österreich | Sucrose | 18032320387 | 1 |
| Spagyra/Österreich | Sucrose | 18032320388 | 1 |
| Spagyra/Österreich | Sucrose | 18041120712 | 1 |
| Spagyra/Österreich | Sucrose | 18041180714 | 1 |
| Spagyra/Österreich | Sucrose | 18042720542 | 1 |
| Spagyra/Österreich | Sucrose | 18042720555 | 2 |
| Spagyra/Österreich | Sucrose | 18051421069 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spagyra/Österreich | Sucrose | 18051421071 | 1 |
| Spagyra/Österreich | Sucrose | 18072420037 | 1 |
| Spagyra/Österreich | Sucrose | 18090520787 | 3 |
| Spagyra/Österreich | Sucrose | 18090520788 | 1 |
| Spagyra/Österreich | Sucrose | 18090520789 | 1 |
| Spagyra/Österreich | Sucrose | 18091020640 | 1 |
| Spagyra/Österreich | Sucrose | 18092720503 | 1 |
| Spagyra/Österreich | Sucrose | 1809272503 | 1 |
| Spagyra/Österreich | Sucrose | 18111921057 | 1 |
| Spagyra/Österreich | Sucrose | 18112920404 | 1 |
| Spagyra/Österreich | Sucrose | 18120520314 | 1 |
| Spagyra/Österreich | Sucrose | 18120720497 | 1 |
| Spagyra/Österreich | Sucrose | 18121320236 | 1 |
| Spagyra/Österreich | Sucrose | 18121320237 | 1 |
| Spagyra/Österreich | Sucrose | 19010320203 | 1 |
| Spagyra/Österreich | Sucrose | 19010320204 | 1 |
| Spagyra/Österreich | Sucrose | 19010320205 | 1 |
| Spagyra/Österreich | Sucrose | 19010320207 | 1 |
| Spagyra/Österreich | Sucrose | 19010320208 | 1 |
| Spagyra/Österreich | Sucrose | 19010320209 | 1 |
| Spagyra/Österreich | Sucrose | 19011421251 | 1 |
| Spagyra/Österreich | Sucrose | 19020521071 | 1 |
| Spagyra/Österreich | Sucrose | 19020521072 | 1 |
| Spagyra/Österreich | Sucrose | 19043020816 | 1 |
| Spagyra/Österreich | Sucrose | 19060620656 | 1 |
| Spagyra/Österreich | Sucrose | 19060720528 | 1 |
| Spagyra/Österreich | Sucrose | 19060720530 | 1 |
| Spagyra/Österreich | Sucrose | 19060720880 | 1 |
| Spagyra/Österreich | Sucrose | 19062120093 | 1 |
| Spagyra/Österreich | Sucrose | 19071020656 | 1 |
| Spagyra/Österreich | Sucrose | 19071020657 | 1 |
| Spagyra/Österreich | Sucrose | 19071020658 | 1 |
| Spagyra/Österreich | Sucrose | 19071020659 | 1 |
| Spagyra/Österreich | Sucrose | 19080520520 | 1 |
| Spagyra/Österreich | Sucrose | 19080720443 | 1 |
| Spagyra/Österreich | Sucrose | 19082621169 | 1 |
| Spagyra/Österreich | Sucrose | 19082621170 | 1 |
| Spagyra/Österreich | Sucrose | 19082621174 | 1 |
| Spagyra/Österreich | Sucrose | 19082621175 | 1 |
| Spagyra/Österreich | Sucrose | 1910320206 | 1 |
| Spagyra/Österreich | Sucrose | 19110420478 | 1 |
| Spagyra/Österreich | Sucrose | 19110720552 | 1 |
| Spagyra/Österreich | Sucrose | 19112220556 | 1 |
| Spagyra/Österreich | Sucrose | 20012420378 | 1 |
| Spagyra/Österreich | Sucrose | 20012420379 | 1 |
| Spagyra/Österreich | Sucrose | 2001290835 | 1 |
| Spagyra/Österreich | Sucrose | 20021120369 | 1 |
| Spagyra/Österreich | Sucrose | 20021120370 | 1 |
| Spagyra/Österreich | Sucrose | 200220020125 | 1 |
| Spagyra/Österreich | Sucrose | 20022620346 | 1 |
| Spagyra/Österreich | Sucrose | 20022620347 | 1 |
| Spagyra/Österreich | Sucrose | 20030220903 | 1 |
| Spagyra/Österreich | Sucrose | 20030220904 | 1 |
| Spagyra/Österreich | Sucrose | 20030520349 | 1 |
| Spagyra/Österreich | Sucrose | 20030520350 | 1 |
| Spagyra/Österreich | Sucrose | 20031120315 | 1 |
| Spagyra/Österreich | Sucrose | 20031120316 | 1 |
| Spagyra/Österreich | Sucrose | 20031820569 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spagyra/Österreich | Sucrose | 20032321824 | 1 |
| Spagyra/Österreich | Sucrose | 20032420357 | 1 |
| Spagyra/Österreich | Sucrose | 20032420358 | 1 |
| Spagyra/Österreich | Sucrose | 20032420359 | 1 |
| Spagyra/Österreich | Sucrose | 20032520757 | 1 |
| Spagyra/Österreich | Sucrose | 20032520824 | 1 |
| Spagyra/Österreich | Sucrose | 20032520825 | 1 |
| Spagyra/Österreich | Sucrose | 20032520826 | 1 |
| Spagyra/Österreich | Sucrose | 20032520827 | 1 |
| Spagyra/Österreich | Sucrose | 20033120462 | 1 |
| Spagyra/Österreich | Sucrose | 20040120719 | 1 |
| Spagyra/Österreich | Sucrose | 20040820313 | 1 |
| Spagyra/Österreich | Sucrose | 20040820315 | 1 |
| Spagyra/Österreich | Sucrose | 20042020392 | 2 |
| Spagyra/Österreich | Sucrose | 20042020394 | 1 |
| Spagyra/Österreich | Sucrose | 20042020395 | 1 |
| Spagyra/Österreich | Sucrose | 20042020398 | 1 |
| Spagyra/Österreich | Sucrose | 20042020399 | 1 |
| Spagyra/Österreich | Sucrose | 20042020400 | 1 |
| Spagyra/Österreich | Sucrose | 20042020401 | 1 |
| Spagyra/Österreich | Sucrose | 20042020402 | 1 |
| Spagyra/Österreich | Sucrose | 20050520188 | 1 |
| Spagyra/Österreich | Sucrose | 20050520189 | 1 |
| Spagyra/Österreich | Sucrose | 20050520190 | 1 |
| Spagyra/Österreich | Sucrose | 20050520191 | 1 |
| Spagyra/Österreich | Sucrose | 20050520193 | 1 |
| Spagyra/Österreich | Sucrose | 20050520194 | 1 |
| Spagyra/Österreich | Sucrose | 20050720449 | 1 |
| Spagyra/Österreich | Sucrose | 20052520367 | 1 |
| Spagyra/Österreich | Sucrose | 20052520368 | 1 |
| Spagyra/Österreich | Sucrose | 20061720426 | 1 |
| Spagyra/Österreich | Sucrose | 20061720427 | 1 |
| Spagyra/Österreich | Sucrose | 20061720428 | 1 |
| Spagyra/Österreich | Sucrose | 20061720480 | 1 |
| Spagyra/Österreich | Sucrose | 20062620145 | 1 |
| Spagyra/Österreich | Sucrose | 20070720637 | 1 |
| Spagyra/Österreich | Sucrose | 20072920245 | 1 |
| Spagyra/Österreich | Sucrose | 20082620273 | 1 |
| Spagyra/Österreich | Sucrose | 20082620274 | 1 |
| Spagyra/Österreich | Sucrose | 20082820224 | 1 |
| Spagyra/Österreich | Sucrose | 20082820225 | 1 |
| Spagyra/Österreich | Sucrose | 20082820226 | 1 |
| Spagyra/Österreich | Sucrose | 20090120367 | 1 |
| Spagyra/Österreich | Sucrose | 20090120368 | 1 |
| Spagyra/Österreich | Sucrose | 20091020538 | 1 |
| Spagyra/Österreich | Sucrose | 20091020539 | 1 |
| Spagyra/Österreich | Sucrose | 20091720367 | 1 |
| Spagyra/Österreich | Sucrose | 20091720374 | 1 |
| Spagyra/Österreich | Sucrose | 20091720375 | 1 |
| Spagyra/Österreich | Sucrose | 20092821146 | 1 |
| Spagyra/Österreich | Sucrose | 20092821147 | 1 |
| Spagyra/Österreich | Sucrose | 20092821149 | 1 |
| Spagyra/Österreich | Sucrose | 20092821152 | 1 |
| Spagyra/Österreich | Sucrose | 20092821153 | 1 |
| Spagyra/Österreich | Sucrose | 20092821154 | 1 |
| Spagyra/Österreich | Sucrose | 20092821155 | 1 |
| Spagyra/Österreich | Sucrose | 20092821156 | 1 |
| Spagyra/Österreich | Sucrose | 20093020124 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spagyra/Österreich | Sucrose | 20102320364 | 1 |
| Spagyra/Österreich | Sucrose | 20102320365 | 1 |
| Spagyra/Österreich | Sucrose | 20102320366 | 1 |
| Spagyra/Österreich | Sucrose | 20102720460 | 1 |
| Spagyra/Österreich | Sucrose | 20111720437 | 1 |
| Spagyra/Österreich | Sucrose | 20111720439 | 1 |
| Spagyra/Österreich | Sucrose | 20112321275 | 1 |
| Spagyra/Österreich | Sucrose | 20112321277 | 1 |
| Spagyra/Österreich | Sucrose | 20112321278 | 1 |
| Spagyra/Österreich | Sucrose | 20112321279 | 1 |
| Spagyra/Österreich | Sucrose | 20112520599 | 1 |
| Spagyra/Österreich | Sucrose | 20112520600 | 1 |
| Spagyra/Österreich | Sucrose | 20112520601 | 1 |
| Spagyra/Österreich | Sucrose | 20112520602 | 1 |
| Spagyra/Österreich | Sucrose | 20112520603 | 1 |
| Spagyra/Österreich | Sucrose | 20112520604 | 1 |
| Spagyra/Österreich | Sucrose | 20112520605 | 1 |
| Spagyra/Österreich | Sucrose | 20112520606 | 1 |
| Spagyra/Österreich | Sucrose | 20112520607 | 1 |
| Spagyra/Österreich | Sucrose | 20112520608 | 1 |
| Spagyra/Österreich | Sucrose | 20112520609 | 1 |
| Spagyra/Österreich | Sucrose | 20112720457 | 1 |
| Spagyra/Österreich | Sucrose | 20112720459 | 1 |
| Spagyra/Österreich | Sucrose | 20112720460 | 1 |
| Spagyra/Österreich | Sucrose | 20112720461 | 1 |
| Spagyra/Österreich | Sucrose | 20122320203 | 1 |
| Spagyra/Österreich | Sucrose | 20122320204 | 1 |
| Spagyra/Österreich | Sucrose | 2042220600 | 1 |
| Spagyra/Österreich | Sucrose | 2042220601 | 1 |
| Spagyra/Österreich | Sucrose | 2042220602 | 1 |
| Spagyra/Österreich | Sucrose | 20881420115 | 1 |
| Spagyra/Österreich | Sucrose | 21011120754 | 1 |
| Spagyra/Österreich | Sucrose | 21011120755 | 1 |
| Spagyra/Österreich | Sucrose | 21011120756 | 1 |
| Spagyra/Österreich | Sucrose | 21012120262 | 1 |
| Spagyra/Österreich | Sucrose | 21022220519 | 1 |
| Spagyra/Österreich | Sucrose | 21022220531 | 1 |
| Spagyra/Österreich | Sucrose | 21022220532 | 1 |
| Spagyra/Österreich | Sucrose | 21022420250 | 1 |
| Spagyra/Österreich | Sucrose | 21030320285 | 1 |
| Spagyra/Österreich | Sucrose | 21030320286 | 1 |
| Spagyra/Österreich | Sucrose | 21030320289 | 1 |
| Spagyra/Österreich | Sucrose | 21031520864 | 1 |
| Spagyra/Österreich | Sucrose | 21031920545 | 1 |
| Spagyra/Österreich | Sucrose | 21033020089 | 1 |
| Spagyra/Österreich | Sucrose | 21042221787 | 1 |
| Spagyra/Österreich | Sucrose | 21042820617 | 1 |
| Spagyra/Österreich | Sucrose | 21050420503 | 1 |
| Spagyra/Österreich | Sucrose | 21051720779 | 1 |
| Spagyra/Österreich | Sucrose | 21051720780 | 1 |
| Spagyra/Österreich | Sucrose | 21051720781 | 1 |
| Spagyra/Österreich | Sucrose | 21051720782 | 1 |
| Spagyra/Österreich | Sucrose | 21051720783 | 1 |
| Spagyra/Österreich | Sucrose | 21051720785 | 1 |
| Spagyra/Österreich | Sucrose | 21051720786 | 1 |
| Spagyra/Österreich | Sucrose | 21061020532 | 1 |
| Spagyra/Österreich | Sucrose | 21061020535 | 1 |
| Spagyra/Österreich | Sucrose | 21072320083 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spagyra/Österreich | Sucrose | 21072320084 | 2 |
| Spagyra/Österreich | Sucrose | 21090920173 | 1 |
| Spagyra/Österreich | Sucrose | 21090920174 | 1 |
| Spagyra/Österreich | Sucrose | 21090920176 | 2 |
| Spagyra/Österreich | Sucrose | 21090920177 | 2 |
| Spagyra/Österreich | Sucrose | 21101520263 | 1 |
| Spagyra/Österreich | Sucrose | 2307 | 2 |
| Spagyra/Österreich | Sucrose | 2382 | 1 |
| Spagyra/Österreich | Sucrose | 2506 | 1 |
| Spagyra/Österreich | Sucrose | 2516 | 1 |
| Spagyra/Österreich | Sucrose | 2963 | 1 |
| Spagyra/Österreich | Sucrose | 3071 | 1 |
| Spagyra/Österreich | Sucrose | 3082 | 1 |
| Spagyra/Österreich | Sucrose | 3183 | 1 |
| Spagyra/Österreich | Sucrose | 3303 | 1 |
| Spagyra/Österreich | Sucrose | 3802 | 1 |
| Spagyra/Österreich | Sucrose | 3988 | 1 |
| Spagyra/Österreich | Sucrose | 4087 | 1 |
| Spagyra/Österreich | Sucrose | 4153 | 1 |
| Spagyra/Österreich | Sucrose | 4159 | 1 |
| Spagyra/Österreich | Sucrose | 4251 | 1 |
| Spagyra/Österreich | Sucrose | 4255 | 1 |
| Spagyra/Österreich | Sucrose | 4338 | 1 |
| Spagyra/Österreich | Sucrose | 4417 | 1 |
| Spagyra/Österreich | Sucrose | 4504 | 1 |
| Spagyra/Österreich | Sucrose | 4941 | 1 |
| Spagyra/Österreich | Sucrose | 4965 | 1 |
| Spagyra/Österreich | Sucrose | 5009 | 1 |
| Spagyra/Österreich | Sucrose | 5030920991 | 1 |
| Spagyra/Österreich | Sucrose | 5030920993 | 1 |
| Spagyra/Österreich | Sucrose | 5030921008 | 1 |
| Spagyra/Österreich | Sucrose | 5030921018 | 1 |
| Spagyra/Österreich | Sucrose | 5031 | 1 |
| Spagyra/Österreich | Sucrose | 5156 | 1 |
| Spagyra/Österreich | Sucrose | 5329 | 1 |
| Spagyra/Österreich | Sucrose | 5520 | 2 |
| Spagyra/Österreich | Sucrose | 5545 | 1 |
| Spagyra/Österreich | Sucrose | 5660 | 1 |
| Spagyra/Österreich | Sucrose | 5699 | 1 |
| Spagyra/Österreich | Sucrose | 5743 | 1 |
| Spagyra/Österreich | Sucrose | 5899 | 1 |
| Spagyra/Österreich | Sucrose | 5998 | 1 |
| Spagyra/Österreich | Sucrose | 6019 | 1 |
| Spagyra/Österreich | Sucrose | 6032 | 2 |
| Spagyra/Österreich | Sucrose | 6047 | 1 |
| Spagyra/Österreich | Sucrose | 6079 | 1 |
| Spagyra/Österreich | Sucrose | 6091 | 2 |
| Spagyra/Österreich | Sucrose | 6106 | 1 |
| Spagyra/Österreich | Sucrose | 6128 | 1 |
| Spagyra/Österreich | Sucrose | 6201 | 1 |
| Spagyra/Österreich | Sucrose | 6243 | 1 |
| Spagyra/Österreich | Sucrose | 6285 | 1 |
| Spagyra/Österreich | Sucrose | 6327 | 1 |
| Spagyra/Österreich | Sucrose | 6340 | 1 |
| Spagyra/Österreich | Sucrose | 6371 | 1 |
| Spagyra/Österreich | Sucrose | 6409 | 1 |
| Spagyra/Österreich | Sucrose | 6415 | 1 |
| Spagyra/Österreich | Sucrose | 6562 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spagyra/Österreich | Sucrose | H17-0047 | 1 |
| Spagyra/Österreich | Sucrose | H18-0021 | 1 |
| Spagyra/Österreich | Sucrose | H18-0210 | 1 |
| Spagyra/Österreich | Sucrose | H18-0235 | 1 |
| Spagyra/Österreich | Sucrose | H18-0252 | 1 |
| Spagyra/Österreich | Sucrose | H18-0327 | 1 |
| Spagyra/Österreich | Sucrose | H19-0130 | 1 |
| Spagyra/Österreich | Sucrose | H19-0270 | 1 |
| Spagyra | Sucrose | 10032921256 | 1 |
| Spagyra | Sucrose | 10073020385 | 1 |
| Spagyra | Sucrose | 12082320717 | 1 |
| Spagyra | Sucrose | 12103020975 | 1 |
| Spagyra | Sucrose | 13012920302 | 1 |
| Spagyra | Sucrose | 13020620240 | 1 |
| Spagyra | Sucrose | 13030621373 | 1 |
| Spagyra | Sucrose | 13040921424 | 1 |
| Spagyra | Sucrose | 13040921427 | 1 |
| Spagyra | Sucrose | 13040921430 | 1 |
| Spagyra | Sucrose | 13040921431 | 1 |
| Spagyra | Sucrose | 13041920152 | 2 |
| Spagyra | Sucrose | 13041920154 | 1 |
| Spagyra | Sucrose | 13050621773 | 2 |
| Spagyra | Sucrose | 13051520939 | 1 |
| Spagyra | Sucrose | 13051520941 | 1 |
| Spagyra | Sucrose | 13061020524 | 1 |
| Spagyra | Sucrose | 13061020525 | 1 |
| Spagyra | Sucrose | 13061020526 | 1 |
| Spagyra | Sucrose | 13061020528 | 1 |
| Spagyra | Sucrose | 13061020529 | 1 |
| Spagyra | Sucrose | 13061220385 | 2 |
| Spagyra | Sucrose | 13070420938 | 1 |
| Spagyra | Sucrose | 13072620834 | 1 |
| Spagyra | Sucrose | 15032620414 | 1 |
| Spagyra | Sucrose | 15082720411 | 1 |
| Spagyra | Sucrose | 16032920732 | 1 |
| Spagyra | Sucrose | 16042522126 | 1 |
| Spagyra | Sucrose | 16050220821 | 1 |
| Spagyra | Sucrose | 16050421023 | 1 |
| Spagyra | Sucrose | 16051820801 | 1 |
| Spagyra | Sucrose | 16053020827 | 1 |
| Spagyra | Sucrose | 16070421669 | 1 |
| Spagyra | Sucrose | 16083120745 | 1 |
| Spagyra | Sucrose | 16102120418 | 1 |
| Spagyra | Sucrose | 16110320884 | 1 |
| Spagyra | Sucrose | 1691 | 1 |
| Spagyra | Sucrose | 17070420968 | 1 |
| Spagyra | Sucrose | 17072120536 | 1 |
| Spagyra | Sucrose | 17072120537 | 1 |
| Spagyra | Sucrose | 17072120538 | 1 |
| Spagyra | Sucrose | 17080920574 | 1 |
| Spagyra | Sucrose | 17082320366 | 1 |
| Spagyra | Sucrose | 17090620617 | 1 |
| Spagyra | Sucrose | 18081720533 | 1 |
| Spagyra | Sucrose | 19043020815 | 1 |
| Spagyra | Sucrose | 1905 | 1 |
| Spagyra | Sucrose | 1911 | 1 |
| Spagyra | Sucrose | 1918 | 1 |
| Spagyra | Sucrose | 2007 | 2 |
| Spagyra | Sucrose | 20102720461 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spagyra | Sucrose | 20102720462 | 1 |
| Spagyra | Sucrose | 2923 | 1 |
| Spagyra | Sucrose | 3750 | 1 |
| Spagyra | Sucrose | 5030920873 | 1 |
| Spagyra | Sucrose | 5030920881 | 1 |
| Spagyra | Sucrose | 5030920883 | 1 |
| Spagyra | Sucrose | 5030920885 | 1 |
| Spagyra | Sucrose | 5030920893 | 1 |
| Spagyra | Sucrose | 5030920895 | 1 |
| Spagyra | Sucrose | 5030920908 | 1 |
| Spagyra | Sucrose | 5030920922 | 1 |
| Spagyra | Sucrose | 5030920923 | 1 |
| Spagyra | Sucrose | 5030920924 | 1 |
| Spagyra | Sucrose | 5030920989 | 1 |
| Spagyra | Sucrose | 5030920995 | 1 |
| Spagyra | Sucrose | 5030920996 | 1 |
| Spagyra | Sucrose | 5030920997 | 1 |
| Spagyra | Sucrose | 5030920998 | 1 |
| Spagyra | Sucrose | 5030920999 | 1 |
| Spagyra | Sucrose | 5030921002 | 1 |
| Spagyra | Sucrose | 5030921004 | 1 |
| Spagyra | Sucrose | 5030921006 | 1 |
| Spagyra | Sucrose | 5030921010 | 1 |
| Spagyra | Sucrose | 5030921012 | 1 |
| Spagyra | Sucrose | 5030921014 | 1 |
| Spagyra | Sucrose | 5030921015 | 1 |
| Spagyra | Sucrose | 5030921016 | 1 |
| Spagyra | Sucrose | 5030921019 | 1 |
| Spagyra | Sucrose | 5030921020 | 1 |
| Spagyra | Sucrose | 5030921024 | 1 |
| Spagyra | Sucrose | 5030921026 | 1 |
| Spagyra | Sucrose | 5030921028 | 1 |
| Spagyra | Sucrose | 5030921030 | 1 |
| Spagyra | Sucrose | 5030921031 | 1 |
| Spagyra | Sucrose | 5030921032 | 1 |
| Spagyra | Sucrose | 5030921036 | 1 |
| Spagyra | Sucrose | 5030921037 | 1 |
| Spagyra | Sucrose | 5030921038 | 1 |
| Spagyra | Sucrose | 5030921039 | 1 |
| Spagyra | Sucrose | 5030921040 | 1 |
| Spagyra | Sucrose | 5030921041 | 1 |
| Spagyra | Sucrose | 5030921042 | 1 |
| Spagyra | Sucrose | 5030921043 | 1 |
| Spagyra | Sucrose | 5030921053 | 1 |
| Spagyra | Sucrose | 5030921054 | 1 |
| Spagyra | Sucrose | 5030921056 | 1 |
| Spagyra | Sucrose | 5030921060 | 1 |
| Spagyra | Sucrose | 5030921064 | 1 |
| Spagyra | Sucrose | 5030921065 | 1 |
| Spagyra | Sucrose | 5030921067 | 1 |
| Spagyra | Sucrose | 5030921072 | 1 |
| Spagyra | Sucrose | 5030921075 | 1 |
| Spagyra | Sucrose | 5030921078 | 1 |
| Spagyra | Sucrose | 5030921080 | 1 |
| Spagyra | Sucrose | 5030921081 | 1 |
| Spagyra | Sucrose | 5030921082 | 1 |
| Spagyra | Sucrose | 5030921090 | 1 |
| Spagyra | Sucrose | 5030921094 | 1 |
| Spagyra | Sucrose | 5030921096 | 1 |
| Spagyra | Sucrose | 5030921100 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Spagyra | Sucrose | 5030921101 | 1 |
| Spagyra | Sucrose | 5030921122 | 1 |
| Spagyra | Sucrose | 5030921152 | 1 |
| Spagyra | Sucrose | 5030921221 | 1 |
| Spagyra | Sucrose | 7062220875 | 1 |
| SpagyraÖsterreich | Sucrose | 21112620135 | 1 |
| SpagyraÖsterreich | Sucrose | 21112620136 | 1 |
| SpagyraÖsterreich | Sucrose | 21112620137 | 1 |
| SpagyraÖsterreich | Sucrose | 21112620138 | 1 |
| SpagyraÖsterreich | Sucrose | 21112620139 | 1 |
| SpagyraÖsterreich | Sucrose | 21112620140 | 1 |
| SpagyraÖsterreich | Sucrose | 21112620141 | 1 |
| SpagyraÖsterreich | Sucrose | 21120220394 | 1 |
| SpagyraÖsterreich | Sucrose | 21120220395 | 1 |
| SpagyraÖsterreich | Sucrose | 22010420102 | 1 |
| SpagyraÖsterreich | Sucrose | 22010420103 | 1 |
| SpagyraÖsterreich | Sucrose | 22010420104 | 1 |
| SpagyraÖsterreich | Sucrose | 22010420105 | 1 |
| SpagyraÖsterreich | Sucrose | 22010420106 | 1 |
| SpagyraÖsterreich | Sucrose | 22010420107 | 1 |
| SpagyraÖsterreich | Sucrose | 22012520412 | 1 |
| SpagyraÖsterreich | Sucrose | 22020820910 | 1 |
| SpagyraÖsterreich | Sucrose | 22020820911 | 1 |
| SpagyraÖsterreich | Sucrose | 22020821013 | 1 |
| SpagyraÖsterreich | Sucrose | 22020821014 | 1 |
| SpagyraÖsterreich | Sucrose | 22020821015 | 1 |
| SpagyraÖsterreich | Sucrose | 22020821016 | 1 |
| SpagyraÖsterreich | Sucrose | 22021020386 | 1 |
| SpagyraÖsterreich | Sucrose | 22021020387 | 1 |
| SpagyraÖsterreich | Sucrose | 22030000141 | 2 |
| SpagyraÖsterreich | Sucrose | 22031720088 | 1 |
| SpagyraÖsterreich | Sucrose | 22042020195 | 1 |
| SpagyraÖsterreich | Sucrose | 22042020199 | 1 |
| SpagyraÖsterreich | Sucrose | 22042720155 | 1 |
| SpagyraÖsterreich | Sucrose | 22050620618 | 1 |
| SpagyraÖsterreich | Sucrose | 22050620621 | 2 |
| SpagyraÖsterreich | Sucrose | 22050620622 | 1 |
| SpagyraÖsterreich | Sucrose | 22060220035 | 1 |
| SpagyraÖsterreich | Sucrose | 22060220038 | 1 |
| SpagyraÖsterreich | Sucrose | 22060920061 | 1 |
| SpagyraÖsterreich | Sucrose | 22060920062 | 1 |
| SpagyraÖsterreich | Sucrose | 22060920063 | 1 |
| SpagyraÖsterreich | Sucrose | 22060920064 | 1 |
| SpagyraÖsterreich | Sucrose | 22060920065 | 1 |
| SpagyraÖsterreich | Sucrose | 22062020221 | 1 |
| SpagyraÖsterreich | Sucrose | 22070420262 | 1 |
| SpagyraÖsterreich | Sucrose | 22070820291 | 1 |
| SpagyraÖsterreich | Sucrose | 22080220229 | 1 |
| SpagyraÖsterreich | Sucrose | 22080220230 | 1 |
| SpagyraÖsterreich | Sucrose | 22081620115 | 1 |
| SpagyraÖsterreich | Sucrose | 22081620117 | 1 |
| SpagyraÖsterreich | Sucrose | 22083020318 | 1 |
| SpagyraÖsterreich | Sucrose | 22083020323 | 2 |
| SpagyraÖsterreich | Sucrose | 22083020326 | 1 |
| SpagyraÖsterreich | Sucrose | 22090220218 | 1 |
| SpagyraÖsterreich | Sucrose | 22090620388 | 1 |
| SpagyraÖsterreich | Sucrose | 6083 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| SpagyraÖsterreich | Sucrose | 6116 | 1 |
| SpagyraÖsterreich | Sucrose | 6553 | 1 |
| SpagyraÖsterreich | Sucrose | 6807 | 1 |
| SpagyraÖsterreich | Sucrose | 680722021720173 | 1 |
| SpagyraÖsterreich | Sucrose | 680722021720174 | 1 |
| SpagyraÖsterreich | Sucrose | 680722021720175 | 1 |
| SpagyraÖsterreich | Sucrose | 680722021720176 | 1 |
| SpagyraÖsterreich | Sucrose | 680722021720177 | 1 |
| SpagyraÖsterreich | Sucrose | 680722021720178 | 1 |
| SpagyraÖsterreich | Sucrose | 7056 | 1 |
| SpagyraÖsterreich | Sucrose | 7075 | 1 |
| SpagyraÖsterreich | Sucrose | 7206 | 1 |
| SpagyraÖsterreich | Sucrose | 7237 | 1 |
| SpagyraÖsterreich | Sucrose | 7263 | 2 |
| SpagyraÖsterreich | Sucrose | 7318 | 2 |
| SpagyraÖsterreich | Sucrose | 7340 | 1 |
| SpagyraÖsterreich | Sucrose | 7377 | 1 |
| SpagyraÖsterreich | Sucrose | 7447 | 1 |
| SpagyraÖsterreich | Sucrose | 7656 | 1 |
| SpagyraÖsterreich | Sucrose | 7660 | 1 |
| SpagyraÖsterreich | Sucrose | H20-0298 | 1 |
| St. Erhard Apotheke | Sucrose | 1809052072 | 1 |
| St. Erhard Apotheke | Sucrose | 18090520790 | 1 |
| St. Erhard Apotheke | Sucrose | 18090520791 | 1 |
| St. Erhard Apotheke | Sucrose | 18090520792 | 1 |
| St. Erhard Apotheke | Sucrose | 18090520793 | 1 |
| St. Erhard Apotheke | Sucrose | 18090520794 | 1 |
| St. Erhard Apotheke | Sucrose | 18090520795 | 1 |
| St. Erhard Apotheke | Sucrose | 19060720878 | 1 |
| St. Erhard Apotheke | Sucrose | 19061720787 | 1 |
| St. Erhard Apotheke | Sucrose | 19061721186 | 1 |
| St. Erhard Apotheke | Sucrose | 20032321403 | 1 |
| St. Erhard Apotheke | Sucrose | 20032321827 | 1 |
| St. Erhard Apotheke | Sucrose | 20100920507 | 1 |
| St. Erhard Apotheke | Sucrose | 21020520525 | 1 |
| St. Erhard Apotheke | Sucrose | 21020520526 | 1 |
| St. Erhard Apotheke | Sucrose | 21020520527 | 1 |
| St. Erhard Apotheke | Sucrose | 32520757 | 1 |
| Staufen-Pharma | Sucrose | 161112 | 2 |
| Staufenpharma | Sucrose | 3314E-01586 | 1 |
| südzucker | Sucrose | | 1 |
| südzucker | Sucrose | L120031600 | 1 |
| Wepa | Sucrose | LOTAP-SP0005 | 1 |
| Werner | Sucrose | 1901208731 | 2 |

- 255 019 spectra from 1666 *Apo-Ident* customers from a total of 51 449 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sucrose* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sucrose* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table


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breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 580 | 0 | 157 746 |
| **Type B** | 0 | 321 | 19 | 212 600 |
| **Type C** | 0 | 1867 | 0 | 255 019 |

The substance/substance group *Sucrose* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.9655 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 94.4118 % (> 93.5294 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 99.6786 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21484 | 21484 | 0.00 | 51.56 |
| 21736 | 21484 | 4.19 | 54.45 |
| 22615 | 22615 | 0.00 | 53.93 |
| 22643 | 22643 | 0.00 | 57.17 |
| 23057 | 23057 | 0.00 | 55.13 |
| 23058 | 23058 | 0.00 | 56.32 |
| 23297 | 23297 | 0.00 | 54.59 |
| 23666 | 23666 | 0.00 | 57.67 |
| 23833 | 23833 | 0.00 | 53.21 |
| 24217 | 24217 | 0.00 | 57.97 |
| 25651 | 25651 | 0.00 | 79.80 |
| 26630 | 26630 | 0.00 | 58.45 |
| 26723 | 26723 | 0.00 | 63.91 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sulfacetamide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20695-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sulfacetamide; Sulfacetamidum

### Special notes

When selecting the *Sulfacetamide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sulfacetamide | 6 | 3 | 38 |

### Second-stage model

For differentiation of the substance/substance group *Sulfacetamide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sulfacetamide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 165.41 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sulfacetamide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sulfacetamide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sulfacetamide | 11085910 | 20695 | 40 | 1402651 |
| Caelo | Sulfacetamide | 15445901 | 23251 | 40 | 20160126 |
| Caelo | Sulfacetamide | 15445901 | 23456 | 40 | 20160126 |
| Caelo | Sulfacetamide | 20002794001 | 25515 | 40 | 20201022 |
| Euro OTC | Sulfacetamide | 1312012-01 | 21633 | 60 | 20140117 |
| Euro OTC | Sulfacetamide | 1509018 | 21902 | 60 | 20150929* |
| Euro OTC | Sulfacetamide | 2101027 | 25546 | 40 | 20210127* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 320 spectra of 7 reference samples from the substance/substance group *Sulfacetamide*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 3 reference samples from the substance/substance group *Sulfacetamide*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Sulfacetamide | 1702006 | 23157 | 40 |
| Euro OTC | Sulfacetamide | 1808035 | 24193 | 40 |
| Euro OTC | Sulfacetamide | 1907026 | 24804 | 40 |

- 212 820 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 187 spectra from 84 *Apo-Ident* customers from 43 batches from the substance/substance group *Sulfacetamide*.

- Among them are spectra of independent samples from 38 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Sulfacetamide | 2101027-02 | 1 |
| AHC 12.08.13 EK9,31 | Sulfacetamide | 11085912 | 1 |
| Apo-ident/Alliance | Sulfacetamide | 1702006-02 | 1 |
| Caelo | Sulfacetamide | 10145802 | 1 |
| Caelo | Sulfacetamide | 10145811 | 1 |
| Caelo | Sulfacetamide | 11085909 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sulfacetamide | 11085911 | 3 |
| Caelo | Sulfacetamide | 11085912 | 4 |
| Caelo | Sulfacetamide | 11085913 | 2 |
| Caelo | Sulfacetamide | 11085914 | 2 |
| Caelo | Sulfacetamide | 11095912 | 1 |
| Caelo | Sulfacetamide | 1509018-02 | 2 |
| Caelo | Sulfacetamide | 15445901 | 2 |
| Caelo | Sulfacetamide | 15445902 | 2 |
| Caelo | Sulfacetamide | 15445904 | 1 |
| Caelo | Sulfacetamide | 15445905 | 2 |
| Caelo | Sulfacetamide | 1702006-01 | 1 |
| Caelo | Sulfacetamide | 20002794001 | 1 |
| Caelo | Sulfacetamide | 20002794002 | 1 |
| Caelo | Sulfacetamide | 21003927003 | 1 |
| Caesar & Loretz GmbH... | Sulfacetamide | 20002794002 | 1 |
| Caesar & Loretz GmbH | Sulfacetamide | 15445902 | 2 |
| Caesar & Loretz GmbH | Sulfacetamide | 20002794001 | 2 |
| Caesar & Loretz GmbH | Sulfacetamide | 20002794002 | 2 |
| Caesar & Loretz | Sulfacetamide | 15445902 | 1 |
| EuRho/Jenne | Sulfacetamide | 2101027-01 | 1 |
| EuRho/Noweda | Sulfacetamide | 1702006-04 | 1 |
| EuRho/Phönix | Sulfacetamide | 1702006-02 | 1 |
| EuRho | Sulfacetamide | 210102701 | 1 |
| Euro OTC | Sulfacetamide | 1112032-01 | 3 |
| Euro OTC | Sulfacetamide | 1112032-02 | 4 |
| Euro OTC | Sulfacetamide | 1312012-01 | 4 |
| Euro OTC | Sulfacetamide | 1312012-02 | 2 |
| Euro OTC | Sulfacetamide | 1509018-01 | 5 |
| Euro OTC | Sulfacetamide | 1509018-02 | 5 |
| Euro OTC | Sulfacetamide | 1509018-03 | 3 |
| Euro OTC | Sulfacetamide | 1702006-01 | 3 |
| Euro OTC | Sulfacetamide | 1702006-02 | 3 |
| Euro OTC | Sulfacetamide | 170200604 | 1 |
| Euro OTC | Sulfacetamide | 1702006-04 | 3 |
| Euro OTC | Sulfacetamide | 1808035-01 | 2 |
| Euro OTC | Sulfacetamide | 1907026 | 1 |
| Euro OTC | Sulfacetamide | 190702601 | 3 |
| Euro OTC | Sulfacetamide | 1907026-01 | 31 |
| Euro OTC | Sulfacetamide | 2101027 | 1 |
| Euro OTC | Sulfacetamide | 2101027-01 | 25 |
| Euro OTC | Sulfacetamide | 2101027-02 | 1 |
| Euro OTC | Sulfacetamide | 5119E01073 | 1 |
| Euro OTC | Sulfacetamide | AP210205-03 | 1 |
| Euro OTC | Sulfacetamide | AP220721-02 | 1 |
| Gehe/EuRho | Sulfacetamide | 2101027-02 | 1 |
| Gehe | Sulfacetamide | 11085904 | 1 |
| Gehe | Sulfacetamide | 1112032-01 | 4 |
| Gehe | Sulfacetamide | 1312012-01 | 2 |
| Gehe | Sulfacetamide | 1312012-02 | 1 |
| Gehe | Sulfacetamide | 1505025-01 | 1 |
| Gehe | Sulfacetamide | 190702601 | 1 |
| Gehe | Sulfacetamide | 1907026-01 | 2 |
| Gehe | Sulfacetamide | 2101027-01 | 1 |
| Ge-Hh | Sulfacetamide | 20002794002 | 2 |
| Industrias GmbH / Ph | Sulfacetamide | 64518 | 1 |
| Katwijk Chemie B.V. | Sulfacetamide | 15445902 | 3 |
| Katwijk Chemie | Sulfacetamide | 1702006-01 | 1 |
| Noweda | Sulfacetamide | 15445904 | 1 |
| Noweda | Sulfacetamide | 1702006-02 | 1 |
| Noweda | Sulfacetamide | 2101027-01 | 2 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda200002794001 | Sulfacetamide | 200002794001 | 1 |
| Phoenix 07.02.2014 | Sulfacetamide | 1112032-02 | 2 |
| Phoenix | Sulfacetamide | 15445904 | 1 |
| Phönix 17.02.2015 | Sulfacetamide | 1312012-02 | 2 |
| Phönix 23.06.2014 | Sulfacetamide | 1312012-01 | 1 |
| Phönix Gotha | Sulfacetamide | 11085911 | 1 |
| Phönix Gotha | Sulfacetamide | 1312012-02 | 1 |
| Phönix | Sulfacetamide | 11085910 | 1 |
| Phönix | Sulfacetamide | 1509018-02 | 1 |
| Phönix | Sulfacetamide | 15445905 | 1 |
| Phönix | Sulfacetamide | 1907026-01 | 3 |
| Spangropharm | Sulfacetamide | 11085915 | 1 |

- 256 699 spectra from 1666 *Apo-Ident* customers from a total of 52 110 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sulfacetamide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sulfacetamide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 184 | 3 | 256 699 |

The substance/substance group *Sulfacetamide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.3957 % (> 96.7914 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20695 | 20695 | 0.00 | 357.11 |
| 21633 | 21902 | 9.83 | 360.30 |
| 21902 | 21902 | 0.00 | 361.22 |
| 23251 | 21902 | 9.63 | 354.53 |
| 23456 | 21902 | 7.78 | 357.94 |
| 25515 | 21902 | 12.34 | 356.92 |
| 25546 | 25546 | 0.00 | 359.10 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sulfadiazine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20753-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sulfadiazine; Sulfadiazinum

### Special notes

When selecting the *Sulfadiazine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sulfadiazine | 7 | 6 | 23 |

### Second-stage model

For differentiation of the substance/substance group *Sulfadiazine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sulfadiazine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 215.03 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sulfadiazine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sulfadiazine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sulfadiazine | 12164101 | 20753 | 40 | 1402053 |
| Caelo | Sulfadiazine | 13150011 | 21744 | 60 | 20130708 |
| Caelo | Sulfadiazine | 170566 | 23319 | 40 | 20170330* |
| Caelo | Sulfadiazine | 17056602 | 23374 | 40 | 20170330 |
| Caelo | Sulfadiazine | 17056602 | 23447 | 40 | 20170330 |
| Caelo | Sulfadiazine | 191850 | 24735 | 40 | 20190730* |
| Caelo | Sulfadiazine | 20000240002 | 25513 | 40 | 20200430 |
| Caelo | Sulfadiazine | 23003071 | 27233 | 40 | 20240220* |
| Caelo | Sulfadiazine | 23003071 | 27233SI | 20 | 20240220* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *Sulfadiazine*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 966 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 260 spectra of 8 reference samples from the substance/substance group *Sulfadiazine*.

- Among them are spectra of independent samples from 6 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sulfadiazine | 172222 | 23630 | 30 |
| Caelo | Sulfadiazine | 190683 | 24523 | 40 |
| Caelo | Sulfadiazine | 21002176001 | 26412 | 40 |
| Caelo | Sulfadiazine | 24001426 | 27325 | 40 |
| Fagron | Sulfadiazine | 21G10-B22-216650 | 26061 | 40 |
| Fagron | Sulfadiazine | 23G05-B11-231251 | 27064 | 40 |
| Fagron | Sulfadiazine | 21G10-B22-216650 | 26061SI | 10 |
| Fagron | Sulfadiazine | 23G05-B11-231251 | 27064SI | 20 |

- 212 680 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 51 spectra from 25 *Apo-Ident* customers from 24 batches from the substance/substance group *Sulfadiazine*.

- Among them are spectra of independent samples from 23 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sulfadiazine | 11194204 | 1 |
| Caelo | Sulfadiazine | 13150004 | 1 |
| Caelo | Sulfadiazine | 17358901 | 1 |
| Caelo | Sulfadiazine | 17358905 | 2 |
| Caelo | Sulfadiazine | 17358906 | 1 |
| Caelo | Sulfadiazine | 17358910 | 4 |
| Caelo | Sulfadiazine | 17358913 | 1 |
| Caelo | Sulfadiazine | 17358917 | 1 |
| Caelo | Sulfadiazine | 19068302 | 3 |
| Caelo | Sulfadiazine | 191850001 | 2 |
| Caelo | Sulfadiazine | 191850002 | 2 |
| Caelo | Sulfadiazine | 200000240005 | 1 |
| Caelo | Sulfadiazine | 20000240002 | 5 |
| Caelo | Sulfadiazine | 20000240003 | 6 |
| Caelo | Sulfadiazine | 2000024002 | 2 |
| Caelo | Sulfadiazine | 200024003 | 1 |
| Caelo | Sulfadiazine | 20003569003 | 5 |
| Caelo | Sulfadiazine | 21002176001 | 1 |
| Caelo | Sulfadiazine | 21002176002 | 1 |
| Caelo | Sulfadiazine | 240002 | 1 |
| Caesar & Loretz GmbH | Sulfadiazine | 19068301 | 1 |
| Caesar & Loretz GmbH | Sulfadiazine | 19068302 | 1 |
| Caesar & Loretz GmbH | Sulfadiazine | 20000240005 | 2 |
| Caesar & Loretz GmbH | Sulfadiazine | 20000240006 | 1 |
| Caesar & Loretz GmbH | Sulfadiazine | 20003569002 | 1 |
| Caesar & Loretz GmbH | Sulfadiazine | 20003569003 | 3 |

- 256 835 spectra from 1666 *Apo-Ident* customers from a total of 52 129 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sulfadiazine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sulfadiazine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 260 | 0 | 212 680 |
| **Type C** | 0 | 51 | 0 | 256 835 |

The substance/substance group *Sulfadiazine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6923 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 88.2353 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20753 | 20753 | 0.00 | 426.56 |
| 21744 | 23319 | 7.02 | 431.14 |
| 23319 | 23319 | 0.00 | 431.11 |
| 23374 | 23319 | 6.10 | 429.92 |
| 23447 | 23319 | 4.74 | 430.77 |
| 24735 | 24735 | 0.00 | 431.68 |
| 25513 | 20753 | 8.55 | 430.58 |
| 27233 | 27233 | 0.00 | 429.35 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sulfogaiacol hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20327-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sulfogaiacol hydrate; Potassium guaiacolsulfonate; Sulfoguaiacolum hydricum

### Special notes

When selecting the *Sulfogaiacol hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sulfogaiacol hydrate | 6 | 2 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Sulfogaiacol hydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sulfogaiacol hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 71.79 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sulfogaiacol hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sulfogaiacol hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Sulfogaiacol hydrate | 13405805 | 21696 | 45 | 20140108 |
| Caelo | Sulfogaiacol hydrate | 190303 | 24495 | 40 | 20190222* |
| Caelo | Sulfogaiacol hydrate | 20001657 | 25191 | 40 | 20200619* |
| Gatt-Koller | Sulfogaiacol hydrate | 1156/04152115 | 21843 | 60 | 20150410 |
| Gatt-Koller | Sulfogaiacol hydrate | 4543/01170317 | 23113 | 40 | AR-17-FG-012520-01 |
| Gatt-Koller | Sulfogaiacol hydrate | 23J00290 | 26680 | 40 | 20230314 |
| Gatt-Koller | Sulfogaiacol hydrate | 23J00290 | 26680SI | 20 | 20230314 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 285 spectra of 7 reference samples from the substance/substance group *Sulfogaiacol hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 041 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 120 spectra of 3 reference samples from the substance/substance group *Sulfogaiacol hydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Sulfogaiacol hydrate | 170919 | 23300 | 40 |
| Caelo | Sulfogaiacol hydrate | 190921 | 24732 | 40 |
| Caelo | Sulfogaiacol hydrate | 170919 | 23306 | 40 |

- 212 820 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 12 spectra from 4 *Apo-Ident* customers from 1 batches from the substance/substance group *Sulfogaiacol hydrate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sulfogaiacol hydrate | 15343912 | 12 |

- 256 874 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are docu-

mented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sulfogaiacol hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sulfogaiacol hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 285 | 0 | 158 041 |
| **Type B** | 0 | 120 | 0 | 212 820 |
| **Type C** | 0 | 12 | 0 | 256 874 |

The substance/substance group *Sulfogaiacol hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8947 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.0000 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21696 | 23113 | 22.68 | 202.65 |
| 21843 | 23113 | 27.03 | 198.20 |
| 23113 | 23113 | 0.00 | 212.65 |
| 24495 | 24495 | 0.00 | 206.66 |
| 25191 | 25191 | 0.00 | 220.94 |
| 26680 | 25191 | 25.77 | 213.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Sulpiride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005288-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Sulpiride; Sulpiridum

### Special notes

When selecting the *Sulpiride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Sulpiride | 2 | 3 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Sulpiride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Sulpiride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Tetracaine hydrochloride | 107.70 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Sulpiride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Sulpiride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Sulpiride | 20I16-F01-374539 | 26320 | 40 | 230502387 |
| Fagron | Sulpiride | 20I16-F01-374539 | 26320SI | 20 | 230502387 |
| Pharma Che… | Sulpiride | 21F16-1226 | 26318 | 40 | 20210616 |
| Pharma Che… | Sulpiride | 21F16-1226 | 26318SI | 20 | 20210616 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 120 spectra of 4 reference samples from the substance/substance group *Sulpiride*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.
- 158 206 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by


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this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 4 reference samples from the substance/substance group *Sulpiride*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Sulpiride | 18H09-B08-355949 | 25692 | 50 |
| FSA Chemicals | Sulpiride | 19G29-APR90102 | 25693 | 50 |
| FSA Chemicals | Sulpiride | 21G16-APR21165 | 26319 | 40 |
| FSA Chemicals | Sulpiride | 21G16-APR21165 | 26319SI | 20 |

- 212 780 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Sulpiride*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Sulpiride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Sulpiride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 120 | 0 | 158 206 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Sulpiride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26318 | 26320 | 36.12 | 235.95 |
| 26320 | 26320 | 0.00 | 236.53 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tacrolimus monohydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10005936-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tacrolimus monohydrate ; Tacrolimusum monohydricum

### Special notes

When selecting the *Tacrolimus monohydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tacrolimus monohydrate | 6 | 3 | 2 |

### Second-stage model

For differentiation of the substance/substance group *Tacrolimus monohydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tacrolimus monohydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 71.40 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tacrolimus monohydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tacrolimus monohydrate* :

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Tacrolimus monohydrate | 2201007 | 25941 | 40 | 20220301* |
| Euro OTC | Tacrolimus monohydrate | 2205032 | 26417 | 30 | 20221110* |
| Euro OTC | Tacrolimus monohydrate | 2502003 | 27617 | 41 | 20250328* |
| Fagron | Tacrolimus monohydrate | 21I24-B12-215778 | 26147 | 40 | 20211223 |
| Fagron | Tacrolimus monohydrate | 21I24-B12-215778 | 26147SI | 20 | 20211223 |
| Fagron | Tacrolimus monohydrate | 23K23-B05-223469 | 27048 | 40 | 20231229 |
| Fagron | Tacrolimus monohydrate | 24D29-B09-003494 | 27473 | 40 | 20240829 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 251 spectra of 7 reference samples from the substance/substance group *Tacrolimus monohydrate* . These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 075 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 150 spectra of 5 reference samples from the substance/substance group *Tacrolimus monohydrate* .

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Tacrolimus monohydrate | 1904015 | 24605 | 40 |
| Euro OTC | Tacrolimus monohydrate | 2304013 | 26762 | 40 |
| Euro OTC | Tacrolimus monohydrate | 2405003 | 27360 | 40 |
| Euro OTC | Tacrolimus monohydrate | 2201007 | 25941SI† | 10 |
| Euro OTC | Tacrolimus monohydrate | 2304013 | 26762SI | 20 |

- 212 790 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 7 spectra from 3 *Apo-Ident* customers from 2 batches from the substance/substance group *Tacrolimus monohydrate* .

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tacrolimus monohydrate | 2205032-01 | 2 |
| | Tacrolimus monohydrate | 2304013-01 | 4 |
| Euro OTC | Tacrolimus monohydrate | 2304013-01 | 1 |

- 256 879 spectra from 1666 *Apo-Ident* customers from a total of 52 151 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tacrolimus monohydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tacrolimus monohydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 251 | 0 | 158 075 |
| **Type B** | 0 | 150 | 0 | 212 790 |
| **Type C** | 0 | 6 | 1 | 256 879 |

The substance/substance group *Tacrolimus monohydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6096 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.0000 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 25941 | 25941 | 0.00 | 144.97 |
| 26147 | 27617 | 19.93 | 147.95 |
| 26417 | 26417 | 0.00 | 149.12 |
| 27048 | 26417 | 21.01 | 149.75 |
| 27473 | 25941 | 27.35 | 149.57 |
| 27617 | 27617 | 0.00 | 149.50 |


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The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tannin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20018-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tannin; Tanninum

### Special notes

When selecting the *Tannin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tannin | 6 | 3 | 165 |

### Second-stage model

For differentiation of the substance/substance group *Tannin* the following second-stage model is used:

- Submodel 09

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tannin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 54.92 | – |
| ⋮ | ⋮ | ⋮ |
| Dequalinium chloride | >50 | 48.63 |
| Oxytetracycline hydrochloride | >50 | 72.35 |
| Levothyroxin sodium | >50 | 95.27 |
| Eosin Y | >50 | 95.87 |
| Dithranol | >50 | 489.15 |
| Acetylsalicylic acid | >50 | 539.60 |
| Sodium salicylate | >50 | 709.01 |
| Benzoic acid | >50 | 1074.05 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tannin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tannin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Tannin | 12336016 | 21608 | 60 | 20121127 |
| Caelo | Tannin | 172092 | 23631 | 40 | 20170829* |
| Caelo | Tannin | 20002512002 | 25516 | 40 | 20200904 |
| Caelo | Tannin | 22001643 | 26254 | 40 | 20220613* |
| Fagron | Tannin | 13H30-B03-287645 | 21653 | 60 | 1711482 |
| Fagron | Tannin | 16D08-B04-328410 | 23211 | 40 | AR-17-FG-015963-01 |
| Fagron | Tannin | 16D08-B04-328410 | 23501 | 40 | 20160425 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 7 reference samples from the substance/substance group *Tannin*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 190 spectra of 5 reference samples from the substance/substance group *Tannin*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Tannin | 16074504 | 23205 | 40 |
| Fagron | Tannin | 20F16-B04-203751 | 25751 | 50 |
| Fagron | Tannin | 21C15-B08-210552 | 25902 | 40 |
| Caelo | Tannin | 22001643 | 26254SI† | 20 |
| Fagron | Tannin | 21C15-B08-210552 | 25902SI | 40 |

- 212 750 spectra from a total of 4283 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 673 spectra from 403 *Apo-Ident* customers from 171 batches from the substance/substance group *Tannin*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 164 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tannin | 20004500007 | 1 |
| | Tannin | 2000450001170/23P | 1 |
| | Tannin | 20F16-B04-203751 | 1 |
| | Tannin | 21C15-B08210552 | 1 |
| | Tannin | 21C15-B08-210552 | 2 |
| | Tannin | 22001643003 | 3 |
| | Tannin | 22001643005 | 1 |
| | Tannin | 22001643006 | 1 |
| | Tannin | 22001643011 | 11 |
| | Tannin | 23000395001 | 1 |
| | Tannin | 23000395002 | 10 |
| | Tannin | 24000028005 | 2 |
| | Tannin | 2DF16-B04-203751 | 2 |
| A.H.D. | Tannin | 13E27-N08 | 1 |
| AHC | Tannin | 20004500007 | 1 |
| ALH | Tannin | 14031919 | 1 |
| ALH | Tannin | 15091515 | 1 |
| Alliance Healthcare | Tannin | 12336001 | 1 |
| Alliance Healthcare | Tannin | 20F16-B04-203751 | 1 |
| Alliance | Tannin | 200004500002 | 1 |
| Caelo | Tannin | | 1 |
| Caelo | Tannin | 10019007 | 1 |
| Caelo | Tannin | 10315107 | 2 |
| Caelo | Tannin | 10315110 | 2 |
| Caelo | Tannin | 1091503 | 1 |
| Caelo | Tannin | 11302307 | 5 |
| Caelo | Tannin | 12171101 | 4 |
| Caelo | Tannin | 12171103 | 2 |
| Caelo | Tannin | 12171106 | 7 |
| Caelo | Tannin | 1217112263904 | 1 |
| Caelo | Tannin | 12336001 | 11 |
| Caelo | Tannin | 12336005 | 2 |
| Caelo | Tannin | 12336007 | 2 |
| Caelo | Tannin | 12336009 | 10 |
| Caelo | Tannin | 12336011 | 1 |
| Caelo | Tannin | 12336013 | 6 |
| Caelo | Tannin | 12336014 | 5 |
| Caelo | Tannin | 12336016 | 7 |
| Caelo | Tannin | 1236001 | 1 |
| Caelo | Tannin | 12A27-N01 | 1 |
| Caelo | Tannin | 13031401 | 1 |
| Caelo | Tannin | 14031901 | 2 |
| Caelo | Tannin | 14031903 | 5 |
| Caelo | Tannin | 14031905 | 3 |
| Caelo | Tannin | 14031912 | 4 |
| Caelo | Tannin | 14031913 | 2 |
| Caelo | Tannin | 14031915 | 2 |
| Caelo | Tannin | 14031918 | 4 |
| Caelo | Tannin | 14031919 | 7 |
| Caelo | Tannin | 14031920 | 2 |
| Caelo | Tannin | 15091503 | 3 |
| Caelo | Tannin | 15091504 | 4 |
| Caelo | Tannin | 15091506 | 1 |
| Caelo | Tannin | 15091509 | 18 |
| Caelo | Tannin | 15091511 | 2 |
| Caelo | Tannin | 15091512 | 1 |
| Caelo | Tannin | 15091515 | 15 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tannin | 1509509 | 1 |
| Caelo | Tannin | 1524308 | 1 |
| Caelo | Tannin | 15243801 | 11 |
| Caelo | Tannin | 15243802 | 3 |
| Caelo | Tannin | 15F23-B01-326357 | 1 |
| Caelo | Tannin | 16074501 | 1 |
| Caelo | Tannin | 16074504 | 15 |
| Caelo | Tannin | 16074505 | 1 |
| Caelo | Tannin | 16074507 | 1 |
| Caelo | Tannin | 16074509 | 8 |
| Caelo | Tannin | 16074509/171027T | 1 |
| Caelo | Tannin | 16074516 | 13 |
| Caelo | Tannin | 16074517 | 1 |
| Caelo | Tannin | 16074518 | 8 |
| Caelo | Tannin | 16D08-B04-328410 | 1 |
| Caelo | Tannin | 16D08-B04-334834 | 1 |
| Caelo | Tannin | 16D08-B04-354470 | 1 |
| Caelo | Tannin | 17343502 | 1 |
| Caelo | Tannin | 17343503 | 1 |
| Caelo | Tannin | 17343504 | 13 |
| Caelo | Tannin | 17343505 | 1 |
| Caelo | Tannin | 17343509 | 8 |
| Caelo | Tannin | 17343511 | 3 |
| Caelo | Tannin | 17343515 | 13 |
| Caelo | Tannin | 17343518 | 1 |
| Caelo | Tannin | 17343519 | 1 |
| Caelo | Tannin | 17343520 | 12 |
| Caelo | Tannin | 1734515 | 1 |
| Caelo | Tannin | 18017701 | 6 |
| Caelo | Tannin | 191382001 | 1 |
| Caelo | Tannin | 191382002 | 2 |
| Caelo | Tannin | 191382003 | 1 |
| Caelo | Tannin | 191382006 | 19 |
| Caelo | Tannin | 191382007 | 2 |
| Caelo | Tannin | 19138202 | 7 |
| Caelo | Tannin | 19138203 | 16 |
| Caelo | Tannin | 19138204 | 1 |
| Caelo | Tannin | 20002512002 | 23 |
| Caelo | Tannin | 20004500002 | 19 |
| Caelo | Tannin | 20004500007 | 9 |
| Caelo | Tannin | 20004500011 | 3 |
| Caelo | Tannin | 20045000007 | 1 |
| Caelo | Tannin | 21101305 | 1 |
| Caelo | Tannin | 22001643002 | 1 |
| Caelo | Tannin | 22001643003 | 6 |
| Caelo | Tannin | 22001643011 | 1 |
| Caelo | Tannin | 2211Q-01052 | 1 |
| Caelo | Tannin | 23000395002 | 1 |
| Caelo | Tannin | 28011502 | 1 |
| Caelo | Tannin | 318E-01052 | 1 |
| Caelo | Tannin | 32(191382006) | 1 |
| Caelo | Tannin | 320E01052 | 1 |
| Caelo | Tannin | 3513A-01052 | 1 |
| Caelo | Tannin | 41161-01052 | 1 |
| Caelo | Tannin | 4413I1052 | 1 |
| Caelo | Tannin | 5015A-01052 | 1 |
| Caelo | Tannin | 70132238 | 1 |
| Caelo | Tannin | 9128608 | 1 |
| Caelo | Tannin | 91382031 | 1 |
| Caelo | Tannin | B01-326357 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tannin | B04-1976109 | 1 |
| Caelo | Tannin | B04-2037501 | 1 |
| Caelo | Tannin | Tannin20004500002 | 1 |
| Caeol/ Noweda | Tannin | 16074505 | 1 |
| Caesar & Loretz GmbH… | Tannin | 19138203 | 1 |
| Caesar & Loretz GmbH… | Tannin | 191382006 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20004500002 | 1 |
| Caesar & Loretz GmbH… | Tannin | 191382006 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20004500003 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20004500002 | 1 |
| Caesar & Loretz GmbH… | Tannin | 191382006 | 1 |
| Caesar & Loretz GmbH… | Tannin | 17343520 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20002512002 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20002512003 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20004500002 | 1 |
| Caesar & Loretz GmbH/Otto | Tannin | 20002512002 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20004500002 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20004500002 | 1 |
| Caesar & Loretz GmbH… | Tannin | 200004500001 | 1 |
| Caesar & Loretz GmbH… | Tannin | 20004500002 | 1 |
| Caesar & Loretz GmbH | Tannin | 16D08-B04 | 1 |
| Caesar & Loretz GmbH | Tannin | 17343509 | 1 |
| Caesar & Loretz GmbH | Tannin | 17343515 | 2 |
| Caesar & Loretz GmbH | Tannin | 17343520 | 6 |
| Caesar & Loretz GmbH | Tannin | 191382006 | 5 |
| Caesar & Loretz GmbH | Tannin | 191382007 | 1 |
| Caesar & Loretz GmbH | Tannin | 19138202 | 1 |
| Caesar & Loretz GmbH | Tannin | 19138203 | 3 |
| Caesar & Loretz GmbH | Tannin | 20002512001 | 1 |
| Caesar & Loretz GmbH | Tannin | 20002512002 | 7 |
| Caesar & Loretz GmbH | Tannin | 20004500002 | 15 |
| Caesar & Loretz GmbH | Tannin | 20F16-B04-197619 | 1 |
| Caesar & Loretz | Tannin | 16074504 | 1 |
| Caesar Loretz | Tannin | 20002512002 | 1 |
| Caesar/Lorenz | Tannin | 11302307 | 1 |
| Caleo/Phoenix | Tannin | 14K17-B08-306993 | 1 |
| Ebert u. Jacobi 1… | Tannin | 15091509 | 1 |
| Euro OTC | Tannin | 15091509 | 1 |
| Euro OTC | Tannin | 16074501 | 1 |
| Euro OTC | Tannin | 16074509 | 1 |
| Euro OTC | Tannin | 18017701 | 1 |
| Euro OTC | Tannin | 4117I-01052 | 1 |
| Fagron | Tannin | 1014A-01052 | 1 |
| Fagron | Tannin | 11C09-N05 | 1 |
| Fagron | Tannin | 12A27-N01 | 1 |
| Fagron | Tannin | 12E21-N04 | 4 |
| Fagron | Tannin | 12H14N05 | 1 |
| Fagron | Tannin | 12H14-N05 | 5 |
| Fagron | Tannin | 13B28-N08 | 1 |
| Fagron | Tannin | 13E27-N08 | 1 |
| Fagron | Tannin | 13H30-B03287645 | 1 |
| Fagron | Tannin | 13H30-B03-287645 | 2 |
| Fagron | Tannin | 14A07-B01-293468 | 5 |
| Fagron | Tannin | 14e07-b03-298480 | 1 |
| Fagron | Tannin | 14E07-B03-298480 | 2 |
| Fagron | Tannin | 14J06-B04 | 1 |
| Fagron | Tannin | 14J06-B04-0858 | 1 |
| Fagron | Tannin | 14J06B04299398 | 2 |
| Fagron | Tannin | 14J06-B04-299398 | 2 |
| Fagron | Tannin | 14K17-B08-306993 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tannin | 15F23-B01 | 1 |
| Fagron | Tannin | 15F23-B01-322984 | 3 |
| Fagron | Tannin | 15F23B01326357 | 1 |
| Fagron | Tannin | 15F23-B01-326357 | 1 |
| Fagron | Tannin | 160300029 | 1 |
| Fagron | Tannin | 160300126 | 1 |
| Fagron | Tannin | 160300146 | 2 |
| Fagron | Tannin | 1603001788 | 1 |
| Fagron | Tannin | 160300178B | 4 |
| Fagron | Tannin | 163001788 | 1 |
| Fagron | Tannin | 16D08-b04 | 1 |
| Fagron | Tannin | 16D08B04 | 2 |
| Fagron | Tannin | 16D08-B04 | 2 |
| Fagron | Tannin | 16D08-B04-328410 | 2 |
| Fagron | Tannin | 16D08-B04-334834 | 3 |
| Fagron | Tannin | 16D08B04335787 | 1 |
| Fagron | Tannin | 16D08-B04-335787 | 2 |
| Fagron | Tannin | 16D08-B04-337161 | 1 |
| Fagron | Tannin | 16D08-B04-352128 | 3 |
| Fagron | Tannin | 16D08-B04-354470 | 3 |
| Fagron | Tannin | 16D08B04354470 | 1 |
| Fagron | Tannin | 20F16-B04 | 1 |
| Fagron | Tannin | 20F16-B04-197619 | 8 |
| Fagron | Tannin | 20F16-B04-2033751 | 2 |
| Fagron | Tannin | 20F16-B04-203751 | 10 |
| Fagron | Tannin | 20F16-bo4-203751 | 1 |
| Fagron | Tannin | 21C15-B08 | 1 |
| Fagron | Tannin | 21C15-B08-210552 | 5 |
| Fagron | Tannin | 21C5-B08-210552 | 1 |
| Fagron | Tannin | 2212M-01052 | 1 |
| Fagron | Tannin | 3518M-01052 | 1 |
| Fagron | Tannin | 4-20375001 | 1 |
| Fagron | Tannin | B04-2037501 | 2 |
| Fiebig | Tannin | 16074518 | 1 |
| Frago/Gehe | Tannin | 15F23-B01 | 1 |
| Gatt-Koller / Phoenix | Tannin | 3335/08134613 | 1 |
| Gatt-Koller / Phoenix | Tannin | 333508134613 | 2 |
| Gehe | Tannin | 12171106 | 1 |
| Gehe | Tannin | 12336016 | 2 |
| Gehe | Tannin | 12H14-N05 | 1 |
| Gehe | Tannin | 15091506 | 1 |
| Gehe | Tannin | 16074504 | 1 |
| Gehe | Tannin | 20002512002 | 1 |
| Gehe | Tannin | 20004500002 | 2 |
| Gehe | Tannin | 21C15-B08-210552 | 1 |
| Hirsch | Tannin | 1811209 | 1 |
| INTERN-DROGEN | Tannin | 20004500002 | 1 |
| Jenne | Tannin | 250310(24000028005) | 1 |
| Kehr | Tannin | 22001643011 | 1 |
| L10 | Tannin | 17343509 | 1 |
| Nachprüfung vom 31.0… | Tannin | 9128607 | 2 |
| Nachprüfung | Tannin | 5210A-01052 | 1 |
| Noweda | Tannin | 16074509 | 1 |
| Noweda | Tannin | 17343520 | 1 |
| Noweda | Tannin | 191382006 | 1 |
| Noweda | Tannin | 24000028005 | 1 |
| Phoenix | Tannin | 12336013 | 1 |
| Phoenix | Tannin | 16074509 | 1 |
| Phönix | Tannin | 10313107Retest | 1 |
| Phönix | Tannin | 10315110 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| phönix | Tannin | 14E07-B03-293744 | 1 |
| phönix | Tannin | 15/AKD65 | 1 |
| Phönix | Tannin | 17343520 | 1 |
| Sanacorp WE: 26.01.1… | Tannin | 14031912 | 1 |
| Sanacorp | Tannin | | 1 |
| Sanacorp | Tannin | 12171102 | 1 |
| Sanacorp | Tannin | 12336011 | 1 |
| Sanacorp | Tannin | 12336014 | 1 |
| Sanacorp | Tannin | 14031912 | 1 |
| Sanacorp | Tannin | 16D08-B04 | 1 |
| Sanacorp | Tannin | 21C15-B08-210552 | 1 |
| Sanacorp | Tannin | 22001613011 | 2 |
| Sanacorp | Tannin | 22001643003 | 1 |
| Synopharm/Anzag | Tannin | 3411I-01052 | 1 |

- 256 213 spectra from 1666 *Apo-Ident* customers from a total of 51 984 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tannin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tannin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 190 | 0 | 212 750 |
| **Type C** | 0 | 657 | 16 | 256 213 |

The substance/substance group *Tannin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.8421 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.6226 % (> 97.1768 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21608 | 23211 | 46.68 | 129.11 |
| 21653 | 21653 | 0.00 | 121.53 |
| 23211 | 23211 | 0.00 | 134.49 |
| 23501 | 23211 | 8.86 | 131.50 |
| 23631 | 23631 | 0.00 | 113.65 |
| 25516 | 23211 | 21.81 | 136.88 |
| 26254 | 26254 | 0.00 | 118.25 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tartaric acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20014-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tartaric acid; Acidum tartaricum

### Special notes

When selecting the *Tartaric acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tartaric acid | 10 | 5 | 180 |

### Second-stage model

For differentiation of the substance/substance group *Tartaric acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tartaric acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 87.33 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tartaric acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tartaric acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Tartaric acid | 15130201 | 22383 | 60 | 20150416 |
| Caelo | Tartaric acid | 15164001 | 22384 | 60 | 1704461 |
| Caelo | Tartaric acid | 161468 | 22613 | 40 | 20160607* |
| Caelo | Tartaric acid | 21000301 | 25628 | 40 | 20210301* |
| Caelo | Tartaric acid | 21000938 | 25699 | 50 | 20210430* |
| Caelo | Tartaric acid | 24001998 | 27307 | 40 | 20240906* |
| Caelo | Tartaric acid | 24001998 | 27307SI | 20 | 20240906* |
| Euro OTC | Tartaric acid | 1907022 | 24806 | 40 | 20190813* |
| Fagron | Tartaric acid | 13I25-B01-294093 | 22391 | 60 | 1711509 |
| Fagron | Tartaric acid | 14G07-B02-308554 | 22501 | 40 | 20140827 |
| Fagron | Tartaric acid | 21J15-B03-220487 | 26397 | 40 | 20220126 |
| Fagron | Tartaric acid | 21J15-B03-220487 | 26397SI | 20 | 20220126 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 510 spectra of 12 reference samples from the substance/substance group *Tartaric acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 10 different batches.

- 157 816 spectra from a total of 2947 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 250 spectra of 6 reference samples from the substance/substance group *Tartaric acid*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Tartaric acid | 13217803 | 21457 | 60 |
| Caelo | Tartaric acid | 181212 | 24015 | 40 |
| Caelo | Tartaric acid | 21002221 | 25799 | 50 |
| Caelo | Tartaric acid | 24002743 | 27543 | 40 |
| Fagron | Tartaric acid | 14G07-B02-322976 | 23527 | 40 |
| Caelo | Tartaric acid | 24002743 | 27543SI | 20 |

- 212 690 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 461 spectra from 219 *Apo-Ident* customers from 188 batches from the substance/substance group *Tartaric acid*.

- Among them are spectra of independent samples from 179 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tartaric acid | 1000301002 | 1 |
| | Tartaric acid | 20J05B01202754 | 1 |
| | Tartaric acid | 21000301006 | 1 |
| | Tartaric acid | 21J15B03224308 | 1 |
| | Tartaric acid | 23000312002 | 1 |
| | Tartaric acid | 23000312004 | 3 |
| | Tartaric acid | 24001998002 | 1 |
| | Tartaric acid | 700061 | 1 |
| | Tartaric acid | 702121 | 1 |
| apomix | Tartaric acid | | 1 |
| apomix | Tartaric acid | 1111 | 1 |
| Caelo | Tartaric acid | | 1 |
| Caelo | Tartaric acid | 10073105 | 1 |
| Caelo | Tartaric acid | 10180708 | 2 |
| Caelo | Tartaric acid | 10180713 | 2 |
| Caelo | Tartaric acid | 10180714 | 1 |
| Caelo | Tartaric acid | 10199713 | 1 |
| Caelo | Tartaric acid | 11169406 | 2 |
| Caelo | Tartaric acid | 1169406 | 1 |
| Caelo | Tartaric acid | 11k10-n07 | 1 |
| Caelo | Tartaric acid | 1204102 | 1 |
| Caelo | Tartaric acid | 12044101 | 2 |
| Caelo | Tartaric acid | 12044102 | 3 |
| Caelo | Tartaric acid | 12044103 | 4 |
| Caelo | Tartaric acid | 12044119 | 3 |
| Caelo | Tartaric acid | 12240402 | 1 |
| Caelo | Tartaric acid | 12240413 | 1 |
| Caelo | Tartaric acid | 12240415 | 1 |
| Caelo | Tartaric acid | 12286903 | 2 |
| Caelo | Tartaric acid | 12286904 | 2 |
| Caelo | Tartaric acid | 12286906 | 4 |
| Caelo | Tartaric acid | 12286911 | 1 |
| Caelo | Tartaric acid | 12286924 | 1 |
| Caelo | Tartaric acid | 12286932 | 1 |
| Caelo | Tartaric acid | 12286934 | 1 |
| Caelo | Tartaric acid | 12286939 | 1 |
| Caelo | Tartaric acid | 12H02-n07 | 1 |
| Caelo | Tartaric acid | 13116306 | 1 |
| Caelo | Tartaric acid | 13116307 | 1 |
| Caelo | Tartaric acid | 13116308 | 2 |
| Caelo | Tartaric acid | 13217803 | 1 |
| Caelo | Tartaric acid | 13217806 | 2 |
| Caelo | Tartaric acid | 13217807 | 1 |
| Caelo | Tartaric acid | 13B15-N01 | 2 |
| Caelo | Tartaric acid | 13125-B01-294093 | 1 |
| Caelo | Tartaric acid | 14054521 | 1 |
| Caelo | Tartaric acid | 14186211 | 1 |
| Caelo | Tartaric acid | 14186213 | 4 |
| Caelo | Tartaric acid | 14G07-B02-308555 | 2 |
| Caelo | Tartaric acid | 14G07-B02-330640 | 1 |
| Caelo | Tartaric acid | 15045303 | 1 |
| Caelo | Tartaric acid | 15045304 | 1 |
| Caelo | Tartaric acid | 151302 | 1 |
| Caelo | Tartaric acid | 15130201 | 6 |
| Caelo | Tartaric acid | 15130205 | 2 |
| Caelo | Tartaric acid | 15130206 | 1 |
| Caelo | Tartaric acid | 15130207 | 1 |
| Caelo | Tartaric acid | 15164001 | 5 |
| Caelo | Tartaric acid | 15164002 | 3 |
| Caelo | Tartaric acid | 15164008 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tartaric acid | 15164010 | 1 |
| Caelo | Tartaric acid | 15349101 | 5 |
| Caelo | Tartaric acid | 15349102 | 7 |
| Caelo | Tartaric acid | 15349105 | 9 |
| Caelo | Tartaric acid | 15349106 | 6 |
| Caelo | Tartaric acid | 15349109 | 5 |
| Caelo | Tartaric acid | 15349110 | 2 |
| Caelo | Tartaric acid | 16146806 | 2 |
| Caelo | Tartaric acid | 16146809 | 1 |
| Caelo | Tartaric acid | 16146811 | 1 |
| Caelo | Tartaric acid | 16260403 | 5 |
| Caelo | Tartaric acid | 16260404 | 5 |
| Caelo | Tartaric acid | 16260405 | 1 |
| Caelo | Tartaric acid | 16260406 | 6 |
| Caelo | Tartaric acid | 17091402 | 1 |
| Caelo | Tartaric acid | 17098101 | 1 |
| Caelo | Tartaric acid | 17337504 | 2 |
| Caelo | Tartaric acid | 17337505 | 3 |
| Caelo | Tartaric acid | 17337506 | 2 |
| Caelo | Tartaric acid | 17347103 | 5 |
| Caelo | Tartaric acid | 17347104 | 4 |
| Caelo | Tartaric acid | 1812104 | 1 |
| Caelo | Tartaric acid | 18121201 | 1 |
| Caelo | Tartaric acid | 18121204 | 6 |
| Caelo | Tartaric acid | 18121205 | 1 |
| Caelo | Tartaric acid | 18121208 | 6 |
| Caelo | Tartaric acid | 18121210 | 5 |
| Caelo | Tartaric acid | 18121211 | 9 |
| Caelo | Tartaric acid | 18121212 | 4 |
| Caelo | Tartaric acid | 18121214 | 9 |
| Caelo | Tartaric acid | 18121215 | 1 |
| Caelo | Tartaric acid | 182394004 | 1 |
| Caelo | Tartaric acid | 18239403 | 1 |
| Caelo | Tartaric acid | 18239405 | 1 |
| Caelo | Tartaric acid | 18239406 | 3 |
| Caelo | Tartaric acid | 18239407 | 3 |
| Caelo | Tartaric acid | 18239407/P-04121921 | 1 |
| Caelo | Tartaric acid | 191825002 | 11 |
| Caelo | Tartaric acid | 191825003 | 13 |
| Caelo | Tartaric acid | 191825004 | 2 |
| Caelo | Tartaric acid | 191825006 | 2 |
| Caelo | Tartaric acid | 19182502 | 1 |
| Caelo | Tartaric acid | 19825005 | 1 |
| Caelo | Tartaric acid | 21000301001 | 2 |
| Caelo | Tartaric acid | 21000938002 | 3 |
| Caelo | Tartaric acid | 21000938004 | 1 |
| Caelo | Tartaric acid | 21000938006 | 1 |
| Caelo | Tartaric acid | 21000938007 | 2 |
| Caelo | Tartaric acid | 21000938008 | 2 |
| Caelo | Tartaric acid | 21002221001 | 1 |
| Caelo | Tartaric acid | 2717I-01053 | 1 |
| Caelo | Tartaric acid | 4110N-01053 | 1 |
| Caelo | Tartaric acid | 708061 | 2 |
| Caelo | Tartaric acid | 8051809 | 1 |
| Caelo | Tartaric acid | 9041703 | 1 |
| Caelo | Tartaric acid | 9494239 | 1 |
| Caesar & Loretz GmbH... | Tartaric acid | 17337504 | 2 |
| Caesar & Loretz GmbH... | Tartaric acid | 18239405 | 1 |
| Caesar & Loretz GmbH... | Tartaric acid | 191825003 | 3 |
| Caesar & Loretz GmbH... | Tartaric acid | 18121211 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Tartaric acid | 191825003 | 1 |
| Caesar & Loretz GmbH/Gehe | Tartaric acid | 18121211 | 1 |
| Caesar & Loretz GmbH/Gehe | Tartaric acid | 18121214 | 1 |
| Caesar & Loretz GmbH/Gehe | Tartaric acid | 9494222 | 1 |
| Caesar & Loretz GmbH... | Tartaric acid | 191825004 | 1 |
| Caesar & Loretz GmbH... | Tartaric acid | 182394004 | 1 |
| Caesar & Loretz GmbH... | Tartaric acid | 18239405 | 1 |
| Caesar & Loretz GmbH... | Tartaric acid | 17337505 | 1 |
| Caesar & Loretz GmbH... | Tartaric acid | 18121212 | 1 |
| Caesar & Loretz GmbH | Tartaric acid | 18121204 | 1 |
| Caesar & Loretz GmbH | Tartaric acid | 18121208 | 3 |
| Caesar & Loretz GmbH | Tartaric acid | 18121210 | 1 |
| Caesar & Loretz GmbH | Tartaric acid | 18121211 | 1 |
| Caesar & Loretz GmbH | Tartaric acid | 18239405 | 1 |
| Caesar & Loretz GmbH | Tartaric acid | 18239406 | 1 |
| Caesar & Loretz GmbH | Tartaric acid | 191825002 | 8 |
| Caesar & Loretz GmbH | Tartaric acid | 191825003 | 4 |
| Caesar & Loretz GmbH | Tartaric acid | 191825004 | 3 |
| Caesar & Loretz GmbH | Tartaric acid | 191825005 | 2 |
| Caesar & Loretz GmbH | Tartaric acid | 19182501 | 1 |
| Caesar & Loretz GmbH | Tartaric acid | 21000938003 | 3 |
| Caesar & Loretz/ Noweda | Tartaric acid | 12044103 | 1 |
| canea, anzag | Tartaric acid | 12286906 | 1 |
| Distillerie Mazzari/... | Tartaric acid | 13405 | 1 |
| E-plus | Tartaric acid | 15349107 | 1 |
| Euro OTC | Tartaric acid | 1604046-02 | 1 |
| Euro OTC | Tartaric acid | 17347103 | 1 |
| Euro OTC | Tartaric acid | 702265 | 1 |
| Fagron | Tartaric acid | 1106211053 | 1 |
| Fagron | Tartaric acid | 11E24-N06 | 1 |
| Fagron | Tartaric acid | 11E24-N060752/764 | 1 |
| Fagron | Tartaric acid | 11G19-N08 | 2 |
| Fagron | Tartaric acid | 12131 | 2 |
| Fagron | Tartaric acid | 12225 | 1 |
| Fagron | Tartaric acid | 12F18-N02 | 1 |
| Fagron | Tartaric acid | 12F18-No2 | 1 |
| Fagron | Tartaric acid | 12H02-N07 | 3 |
| Fagron | Tartaric acid | 12K16-N02 | 1 |
| Fagron | Tartaric acid | 12K29-B01-285247 | 1 |
| Fagron | Tartaric acid | 13/25-B01 | 1 |
| Fagron | Tartaric acid | 13/25-B01-285487 | 1 |
| Fagron | Tartaric acid | 13/25-B01-285488 | 2 |
| Fagron | Tartaric acid | 13/25-B01-294094 | 1 |
| Fagron | Tartaric acid | 1325-B01-294093 | 1 |
| Fagron | Tartaric acid | 1325-B01-294094 | 1 |
| Fagron | Tartaric acid | 13B15N01 | 1 |
| Fagron | Tartaric acid | 13B15-N01 | 8 |
| Fagron | Tartaric acid | 13G03-N14 | 3 |
| Fagron | Tartaric acid | 13I25-B01 | 1 |
| Fagron | Tartaric acid | 13I25-B01-285487 | 1 |
| Fagron | Tartaric acid | 13I25-B01-285488 | 2 |
| Fagron | Tartaric acid | 13I25-b01-294093 | 1 |
| Fagron | Tartaric acid | 13I25-B01-294093 | 3 |
| Fagron | Tartaric acid | 13I25-B01-294094 | 5 |
| Fagron | Tartaric acid | 13I25-B01-294095 | 1 |
| Fagron | Tartaric acid | 13l25-B01-285488 | 1 |
| Fagron | Tartaric acid | 14186212 | 1 |
| Fagron | Tartaric acid | 14519 | 1 |
| Fagron | Tartaric acid | 14G07-802 | 1 |
| Fagron | Tartaric acid | 14G07-B02 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tartaric acid | 14G07-B02-308554 | 3 |
| Fagron | Tartaric acid | 14G07-B02-308555 | 2 |
| Fagron | Tartaric acid | 14G07-B02-322976 | 2 |
| Fagron | Tartaric acid | 14G07-B02-322977 | 1 |
| Fagron | Tartaric acid | 14G07-B02-330640 | 4 |
| Fagron | Tartaric acid | 15045303 | 1 |
| Fagron | Tartaric acid | 18G17-B01-351824 | 1 |
| Fagron | Tartaric acid | 20151112-2 | 1 |
| Fagron | Tartaric acid | 20A17-B04-196364 | 1 |
| Fagron | Tartaric acid | 20A17-B04-200531 | 1 |
| Fagron | Tartaric acid | 20A17-B04-200532 | 2 |
| Fagron | Tartaric acid | 20J05-B01-202753 | 1 |
| Fagron | Tartaric acid | 2414E1053 | 1 |
| Fagron | Tartaric acid | 2513M01053 | 1 |
| Fagron | Tartaric acid | B04-2005302 | 1 |
| Fagron | Tartaric acid | P161019AT09/18 | 1 |
| Fagron | Tartaric acid | xxxxxxx | 1 |
| fischar, Gehe | Tartaric acid | 700061 | 1 |
| Fischar/Gehe | Tartaric acid | 705061 | 1 |
| Fischar/PH | Tartaric acid | 700061 | 1 |
| Fischar/Phönix 05.07... | Tartaric acid | 700061 | 1 |
| Fischar/Phönix | Tartaric acid | 704021 | 1 |
| Fischar | Tartaric acid | 704061 | 2 |
| Fischar | Tartaric acid | 705061 | 1 |
| Fischar | Tartaric acid | 709041 | 1 |
| Fischer/AHD | Tartaric acid | 700061 | 1 |
| Gatt-Koller / Phoenix | Tartaric acid | 3334/08131514 | 1 |
| GEHE 07.05.2014 | Tartaric acid | 13G03-N14 | 2 |
| GEHE 14.04.2014 | Tartaric acid | 12H02-N07 | 1 |
| Gehe/Fischer | Tartaric acid | 706061 | 1 |
| Gehe/Henry Lamotte | Tartaric acid | 17/12 | 1 |
| Gehe | Tartaric acid | 1325-B01-285487 | 1 |
| Gehe | Tartaric acid | 16146806 | 1 |
| Gehe | Tartaric acid | 21000938008 | 1 |
| Gehe | Tartaric acid | 703061 | 1 |
| Gehe | Tartaric acid | 7284696 | 1 |
| Hänseler | Tartaric acid | | 1 |
| Klenk | Tartaric acid | 13405 | 1 |
| L12 | Tartaric acid | 14G07-B02-308555 | 1 |
| Max Jenne | Tartaric acid | 21000301002 | 1 |
| Max Jenne | Tartaric acid | 23000312004 | 1 |
| Nachprüfung | Tartaric acid | 2082019-13 | 1 |
| Noweda 20.7.19 | Tartaric acid | 18121212 | 1 |
| Noweda/ Fischar | Tartaric acid | 702061 | 1 |
| Noweda | Tartaric acid | 7284696 | 1 |
| Otto Fischar/ Gehe | Tartaric acid | 709041 | 1 |
| Otto Fischar | Tartaric acid | 705061 | 2 |
| Otto Fischer GmbH | Tartaric acid | 705061 | 1 |
| Phoenix | Tartaric acid | 12044115 | 1 |
| Phoenix | Tartaric acid | 12Ho2-N07 | 1 |
| Phoenix | Tartaric acid | 12K29B01 | 1 |
| Phoenix | Tartaric acid | 13116308 | 1 |
| Phönix Gotha | Tartaric acid | 704021 | 1 |
| Phönix | Tartaric acid | 11e24-n06 | 1 |
| Phönix | Tartaric acid | 12286904 | 1 |
| Phönix | Tartaric acid | 13/25-B01-294094 | 1 |
| Phönix | Tartaric acid | 18121208 | 1 |
| Sanacorp WE: 19.0518... | Tartaric acid | 16260406 | 1 |
| Sanacorp | Tartaric acid | 17347104 | 2 |
| Sanacorp | Tartaric acid | 191825005 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Tartaric acid | 21000301006 | 1 |
| Sanacorp | Tartaric acid | 23000312004 | 1 |
| schubert / Phoenix | Tartaric acid | 1014PLV-755 | 1 |
| Spangropharm | Tartaric acid | 10073111 | 1 |

- 256 425 spectra from 1666 *Apo-Ident* customers from a total of 51 968 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tartaric acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tartaric acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 510 | 0 | 157 816 |
| **Type B** | 0 | 250 | 0 | 212 690 |
| **Type C** | 0 | 461 | 0 | 256 425 |

The substance/substance group *Tartaric acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8235 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 98.6985 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22383 | 22613 | 8.64 | 219.99 |
| 22384 | 22384 | 0.00 | 217.30 |

*continued on the next page*


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*continued from previous page*

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22391 | 22391 | 0.00 | 220.47 |
| 22501 | 22391 | 3.77 | 222.05 |
| 22613 | 22613 | 0.00 | 222.64 |
| 24806 | 24806 | 0.00 | 219.17 |
| 25628 | 25628 | 0.00 | 224.39 |
| 25699 | 25699 | 0.00 | 224.32 |
| 26397 | 22391 | 5.36 | 224.34 |
| 27307 | 27307 | 0.00 | 228.82 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Taurine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20403-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Taurine; Taurinum

### Special notes

When selecting the *Taurine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Taurine | 9 | 8 | 15 |

### Second-stage model

For differentiation of the substance/substance group *Taurine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Taurine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 126.15 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Taurine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Taurine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Taurine | 1306024-01 | 21108 | 50 | 20130822 |
| Euro OTC | Taurine | 1504032-01 | 21893 | 60 | 20150430 |
| Euro OTC | Taurine | 1504032-01 | 21992 | 60 | 9167 |
| Euro OTC | Taurine | 1602011 | 22370 | 60 | 20160218* |
| Euro OTC | Taurine | 1607035 | 22795 | 40 | 20160819* |
| Euro OTC | Taurine | 1704001 | 23177 | 40 | 20170426* |
| Euro OTC | Taurine | 1904003 | 24632 | 40 | 20190425* |
| Euro OTC | Taurine | 2004002 | 25406 | 40 | 20200615* |
| Euro OTC | Taurine | 2206003 | 26222 | 40 | 20220629* |
| Euro OTC | Taurine | 2206003 | 26222SI | 20 | 20220629* |
| Euro OTC | Taurine | 2301048 | 26749 | 40 | 20230511* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 490 spectra of 11 reference samples from the substance/substance group *Taurine*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 836 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 420 spectra of 13 reference samples from the substance/substance group *Taurine*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Taurine | 1711006 | 23739 | 40 |
| Euro OTC | Taurine | 1810006 | 24310 | 40 |
| Euro OTC | Taurine | 1910017 | 24977 | 40 |
| Euro OTC | Taurine | 2309005 | 26927 | 40 |
| Euro OTC | Taurine | 2310009 | 26991 | 40 |
| Fagron | Taurine | 25C13-B031 | BR20136 | 40 |
| Fagron | Taurine | 24I18-B013 | BR20137 | 40 |
| Fagron | Taurine | 25G01-B076 | BR20138 | 40 |
| Euro OTC | Taurine | 2301048 | 26749SI† | 20 |
| Euro OTC | Taurine | 2309005 | 26927SI | 20 |
| Fagron | Taurine | 25C13-B031 | BR20136SI | 20 |
| Fagron | Taurine | 24I18-B013 | BR20137SI | 20 |
| Fagron | Taurine | 25G01-B076 | BR20138SI | 20 |

- 212 520 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 32 spectra from 11 *Apo-Ident* customers from 15 batches from the substance/substance group *Taurine*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Taurine | 123456 | 1 |
| Caelo | Taurine | 1704001-01 | 2 |
| el compra import | Taurine | 1609025 | 1 |
| elcompra | Taurine | xp17013244 | 1 |
| Euro OTC | Taurine | 1704001-01 | 1 |
| Euro OTC | Taurine | 1904003-01 | 1 |
| Euro OTC | Taurine | 1910017-01 | 1 |
| Euro OTC | Taurine | 2004002-01 | 7 |
| Euro OTC | Taurine | 2008013-01 | 6 |
| Euro OTC | Taurine | 2008013-02 | 2 |
| Euro OTC | Taurine | 2008013-03 | 1 |
| Euro OTC | Taurine | 2206003-01 | 4 |
| Euro OTC | Taurine | 2301048-01 | 1 |
| Euro OTC | Taurine | XP16023196 | 1 |
| Gall Pharma / Phoenix | Taurine | | 1 |
| hannes | Taurine | 1202125 | 1 |

- 256 854 spectra from 1666 *Apo-Ident* customers from a total of 52 139 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Taurine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Taurine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 490 | 0 | 157 836 |
| **Type B** | 0 | 420 | 0 | 212 520 |
| **Type C** | 0 | 32 | 0 | 256 854 |

The substance/substance group *Taurine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7755 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5714 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 81.2500 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to


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exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21108 | 22370 | 4.14 | 122.08 |
| 21893 | 22370 | 3.88 | 121.50 |
| 21992 | 21992 | 0.00 | 121.97 |
| 22370 | 22370 | 0.00 | 121.31 |
| 22795 | 22795 | 0.00 | 121.95 |
| 23177 | 23177 | 0.00 | 121.20 |
| 24632 | 24632 | 0.00 | 121.57 |
| 25406 | 25406 | 0.00 | 122.65 |
| 26222 | 26222 | 0.00 | 121.64 |
| 26749 | 26749 | 0.00 | 122.24 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Testosterone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20961-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Testosterone; Testosteronum

### Special notes

When selecting the *Testosterone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Testosterone | 15 | 21 | 119 |

### Second-stage model

For differentiation of the substance/substance group *Testosterone* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Testosterone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prasterone | 68.15 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Testosterone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Testosterone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Testosterone | 13406004 | 21370 | 50 | 20131219 |
| Caelo | Testosterone | 13406004 | 21371 | 50 | 20131219 |
| Caelo | Testosterone | 15244906 | 21987 | 60 | 20150814 |
| Caelo | Testosterone | 15244906 | 21987SI | 38 | 20150814 |
| Caelo | Testosterone | 16311506 | 23244 | 40 | 20161123 |
| Euro OTC | Testosterone | 1307001-01 | 20961 | 40 | 1402309 |
| Euro OTC | Testosterone | 1511005 | 22232 | 60 | 20151119* |
| Euro OTC | Testosterone | 1511005 | 22232SI | 35 | 20151119* |
| Euro OTC | Testosterone | 1604049 | 22561 | 40 | 20160510* |
| Euro OTC | Testosterone | 1604049 | 22561SI | 34 | 20160510* |
| Euro OTC | Testosterone | 1910001 | 24963 | 40 | 20191024* |
| Euro OTC | Testosterone | 1912017 | 25104 | 40 | 20191216* |
| Euro OTC | Testosterone | 2005006 | 25160 | 40 | 20200519* |
| Euro OTC | Testosterone | 2005006 | 25160SI | 27 | 20200519* |
| Euro OTC | Testosterone | 2403002 | 27212 | 40 | 20240502* |
| Euro OTC | Testosterone | 2411009 | 27521 | 40 | 20241218* |
| Fagron | Testosterone | 12F13-N02 | 20729 | 40 | 20120628 |
| Fagron | Testosterone | 15E18-B08-307772 | 21970 | 60 | 20150526 |
| Fagron | Testosterone | 15E18-B08-307772 | 21970SI | 54 | 20150526 |
| Fagron | Testosterone | 17J26-B01-342032 | 23764 | 40 | 20171205 |
| Fagron | Testosterone | 22H08-B02-222389 | 26392 | 40 | 20220905 |
| Fagron | Testosterone | 22H08-B02-222389 | 26392SI | 40 | 20220905 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 948 spectra of 22 reference samples from the substance/substance group *Testosterone*. These samples are listed above in the *calibration samples* section. The reference samples come from 15 different batches.

- 157 378 spectra from a total of 2942 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1917 spectra of 50 reference samples from the substance/substance group *Testosterone*.

- Among them are spectra of independent samples from 21 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Testosterone | 171199 | 23347 | 40 |
| Caelo | Testosterone | 181478 | 24265 | 40 |
| Caelo | Testosterone | 191113 | 24520 | 40 |
| Caelo | Testosterone | 21002048 | 25794 | 40 |
| Caelo | Testosterone | 24001237002 | 27581 | 40 |
| Euro OTC | Testosterone | 1511005-01 | 21994 | 60 |
| Euro OTC | Testosterone | 1607013 | 22707 | 40 |
| Euro OTC | Testosterone | 1702017 | 23146 | 40 |
| Euro OTC | Testosterone | 1802015 | 23948 | 40 |
| Euro OTC | Testosterone | 1805006 | 24131 | 40 |
| Euro OTC | Testosterone | 1805021 | 24132 | 40 |
| Euro OTC | Testosterone | 1808033 | 24201 | 40 |
| Euro OTC | Testosterone | 1811027 | 24422 | 40 |
| Euro OTC | Testosterone | 1912014 | 24964 | 40 |
| Euro OTC | Testosterone | 2008038 | 25308 | 40 |
| Euro OTC | Testosterone | 2008032 | 25327 | 40 |
| Euro OTC | Testosterone | 2106009 | 25705 | 50 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Testosterone | 2110010 | 25877 | 50 |
| Euro OTC | Testosterone | 2206013 | 26215 | 40 |
| Euro OTC | Testosterone | 2311029 | 27004 | 40 |
| Euro OTC | Testosterone | 2407002 | 27341 | 40 |
| Caelo | Testosterone | 16311506 | 23244SI† | 30 |
| Caelo | Testosterone | 171199 | 23347SI | 28 |
| Caelo | Testosterone | 171199 | 23670 | 40 |
| Caelo | Testosterone | 171199 | 23670SI | 30 |
| Caelo | Testosterone | 181478 | 24265SI | 40 |
| Caelo | Testosterone | 191113 | 24520SI | 40 |
| Caelo | Testosterone | 21002048 | 25794SI | 40 |
| Caelo | Testosterone | 24001237002 | 27581SI | 30 |
| Euro OTC | Testosterone | 1511005-01 | 21994SI | 32 |
| Euro OTC | Testosterone | 1607013 | 22707SI | 40 |
| Euro OTC | Testosterone | 1702017 | 23146SI | 21 |
| Euro OTC | Testosterone | 1802015 | 23948SI | 40 |
| Euro OTC | Testosterone | 1805006 | 24131SI | 40 |
| Euro OTC | Testosterone | 1805021 | 24132SI | 40 |
| Euro OTC | Testosterone | 1808033 | 24201SI | 40 |
| Euro OTC | Testosterone | 1811027 | 24422SI | 26 |
| Euro OTC | Testosterone | 1910001 | 24963SI† | 39 |
| Euro OTC | Testosterone | 1912014 | 24964SI | 30 |
| Euro OTC | Testosterone | 1912017 | 25104SI† | 40 |
| Euro OTC | Testosterone | 2008038 | 25308SI | 36 |
| Euro OTC | Testosterone | 2008032 | 25327SI | 40 |
| Euro OTC | Testosterone | 2106009 | 25705SI | 49 |
| Euro OTC | Testosterone | 2110010 | 25877SI | 50 |
| Euro OTC | Testosterone | 2206013 | 26215SI | 40 |
| Euro OTC | Testosterone | 2311029 | 27004SI | 32 |
| Euro OTC | Testosterone | 2403002 | 27212SI† | 30 |
| Euro OTC | Testosterone | 2407002 | 27341SI | 32 |
| Euro OTC | Testosterone | 2411009 | 27521SI† | 32 |
| Fagron | Testosterone | 17J26-B01-342032 | 23764SI† | 30 |

- 211 023 spectra from a total of 4260 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 380 spectra from 113 *Apo-Ident* customers from 127 batches from the substance/substance group *Testosterone*.
- Among them are spectra of independent samples from 119 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Testosterone | 2206013-02 | 4 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Testosterone | 23000429003 | 1 |
| | Testosterone | 23000429004 | 2 |
| | Testosterone | 23000429008 | 1 |
| | Testosterone | 2311029-01 | 1 |
| | Testosterone | 23K14-B10230723 | 1 |
| | Testosterone | 23K14-B10-230723 | 1 |
| | Testosterone | 24001237002 | 3 |
| | Testosterone | 2403002 | 1 |
| | Testosterone | 24F05-B05-238727 | 1 |
| Audor Pharma | Testosterone | AP5106061T | 5 |
| Audor Pharma | Testosterone | APZTST16001-M1T | 1 |
| Audor Pharma | Testosterone | APZTSTG18003T | 8 |
| Audor Pharma | Testosterone | apztstg18004t | 2 |
| Audor Pharma | Testosterone | APZTSTG18004T | 3 |
| Caelo | Testosterone | | 1 |
| Caelo | Testosterone | 11/07-N12 | 1 |
| Caelo | Testosterone | 12176301 | 1 |
| Caelo | Testosterone | 12176305 | 3 |
| Caelo | Testosterone | 13134804 | 1 |
| Caelo | Testosterone | 13134806 | 4 |
| Caelo | Testosterone | 13134808 | 1 |
| Caelo | Testosterone | 13406004 | 2 |
| Caelo | Testosterone | 14201105 | 1 |
| Caelo | Testosterone | 14355605 | 1 |
| Caelo | Testosterone | 15195802 | 1 |
| Caelo | Testosterone | 15195803 | 1 |
| Caelo | Testosterone | 15244906 | 1 |
| Caelo | Testosterone | 15412201 | 5 |
| Caelo | Testosterone | 15412202 | 3 |
| Caelo | Testosterone | 1604049-01 | 1 |
| Caelo | Testosterone | 16225804 | 3 |
| Caelo | Testosterone | 16225807 | 2 |
| Caelo | Testosterone | 16311506 | 1 |
| Caelo | Testosterone | 17119902 | 2 |
| Caelo | Testosterone | 17119903 | 1 |
| Caelo | Testosterone | 17119911 | 1 |
| Caelo | Testosterone | 1805021-01 | 2 |
| Caelo | Testosterone | 1811027-01 | 1 |
| Caelo | Testosterone | 18147803 | 7 |
| Caelo | Testosterone | 18147810 | 1 |
| Caelo | Testosterone | 19111302 | 1 |
| Caelo | Testosterone | 192738003 | 1 |
| Caelo | Testosterone | 192738006 | 5 |
| Caelo | Testosterone | 192738009 | 1 |
| Caelo | Testosterone | 19273803 | 2 |
| Caelo | Testosterone | 20004205001 | 1 |
| Caelo | Testosterone | 20004205002 | 1 |
| Caelo | Testosterone | 20004205004 | 1 |
| Caelo | Testosterone | 21002048002 | 3 |
| Caelo | Testosterone | 21002048003 | 1 |
| Caelo | Testosterone | 21002048004 | 2 |
| Caelo | Testosterone | 21002048008 | 1 |
| Caelo | Testosterone | 21002048009 | 7 |
| Caelo | Testosterone | 21002048010 | 1 |
| Caelo | Testosterone | 23000429004 | 1 |
| Caelo | Testosterone | AP5106061T | 1 |
| Caelo | Testosterone | APL00034466T | 1 |
| Caelo | Testosterone | APZTSTG18003T | 2 |
| Caelo | Testosterone | APZTSTG18004T | 1 |
| Caesar & Loretz GmbH... | Testosterone | 21002048002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Testosterone | 18147803 | 1 |
| Caesar & Loretz GmbH | Testosterone | 19273804 | 2 |
| Caesar & Loretz GmbH | Testosterone | 20004205002 | 1 |
| Caesar & Loretz GmbH | Testosterone | 20004205007 | 1 |
| Caesar & Loretz GmbH | Testosterone | 21002048002 | 1 |
| Caesar & Loretz GmbH | Testosterone | 21002048010 | 1 |
| erou | Testosterone | 2110010-02 | 1 |
| EuRho | Testosterone | 1106011-03 | 2 |
| EuRho | Testosterone | 1811027 | 1 |
| Euro OTC | Testosterone | 1106011-01 | 1 |
| Euro OTC | Testosterone | 1106011-03 | 2 |
| Euro OTC | Testosterone | 11o6011-03 | 1 |
| Euro OTC | Testosterone | 1207005-02 | 1 |
| Euro OTC | Testosterone | 130700101 | 1 |
| Euro OTC | Testosterone | 1307001-01 | 5 |
| Euro OTC | Testosterone | 140400201 | 1 |
| Euro OTC | Testosterone | 1404002-01 | 3 |
| Euro OTC | Testosterone | 1404002-1 | 1 |
| Euro OTC | Testosterone | 1511005-01 | 6 |
| Euro OTC | Testosterone | 1604049-01 | 17 |
| Euro OTC | Testosterone | 1607013-01 | 1 |
| Euro OTC | Testosterone | 1607013-02 | 9 |
| Euro OTC | Testosterone | 1702017-01 | 41 |
| Euro OTC | Testosterone | 1802015 | 1 |
| Euro OTC | Testosterone | 180500601 | 1 |
| Euro OTC | Testosterone | 1805006-01 | 1 |
| Euro OTC | Testosterone | 1805021-01 | 9 |
| Euro OTC | Testosterone | 180506-01 | 1 |
| Euro OTC | Testosterone | 1808033-01 | 3 |
| Euro OTC | Testosterone | 1811027 | 1 |
| Euro OTC | Testosterone | 1811027-01 | 10 |
| Euro OTC | Testosterone | 1811027-02 | 1 |
| Euro OTC | Testosterone | 18147813 | 2 |
| Euro OTC | Testosterone | 1910001-01 | 5 |
| Euro OTC | Testosterone | 1912014-01 | 5 |
| Euro OTC | Testosterone | 1912017-01 | 1 |
| Euro OTC | Testosterone | 2005006-01 | 2 |
| Euro OTC | Testosterone | 2008032-01 | 10 |
| Euro OTC | Testosterone | 2008038-01 | 14 |
| Euro OTC | Testosterone | 2008038-02 | 1 |
| Euro OTC | Testosterone | 2106009-01 | 9 |
| Euro OTC | Testosterone | 2106009-02 | 4 |
| Euro OTC | Testosterone | 2110010-01 | 7 |
| Euro OTC | Testosterone | 2110010-02 | 1 |
| Euro OTC | Testosterone | 2403002-01 | 1 |
| Euro OTC | Testosterone | 3x1106011-03 | 1 |
| Euro OTC | Testosterone | APZTSTG18003T | 1 |
| Euro OTC | Testosterone | ZTSTy18004 | 1 |
| Euro TOC | Testosterone | 1811027-02 | 1 |
| EUro/AHD | Testosterone | 1106011-03 | 1 |
| Euroo/Phoenix | Testosterone | 1307001-01 | 1 |
| Fagron | Testosterone | 11/07-N12 | 1 |
| Fagron | Testosterone | 12F13-N02 | 1 |
| Fagron | Testosterone | 13g10n03 | 1 |
| Fagron | Testosterone | 13G10-N03 | 2 |
| Fagron | Testosterone | 13I26-N08 | 1 |
| Fagron | Testosterone | 13L09-B03-294148 | 1 |
| Fagron | Testosterone | 13l09b03294149 | 1 |
| Fagron | Testosterone | 13l09b03298118 | 1 |
| Fagron | Testosterone | 15E18-B08 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Testosterone | 16A20-B11-318899 | 7 |
| Fagron | Testosterone | 1712-B05 | 1 |
| Fagron | Testosterone | 17A12-B05-331496 | 1 |
| Fagron | Testosterone | 17J26-B01-342033 | 2 |
| Fagron | Testosterone | 17J26-B01-342637 | 4 |
| Fagron | Testosterone | 18A25-B03-350800 | 2 |
| Fagron | Testosterone | 19B12-B01 | 5 |
| Fagron | Testosterone | 19J04-F04_365938 | 1 |
| Fagron | Testosterone | 19J04-F04-365936 | 1 |
| Fagron | Testosterone | 20804-F03-370229 | 3 |
| Fagron | Testosterone | 20B04-F03 | 1 |
| Fagron | Testosterone | 23K14-B10-233057 | 1 |
| Fagron | Testosterone | 24B26-B07-237509 | 1 |
| Fagron | Testosterone | F03-3702209 | 1 |
| Fagron | Testosterone | GTJ151103 | 1 |
| Gatt-Koller | Testosterone | 22J00592 | 1 |
| Gehe | Testosterone | 1805021-01 | 1 |
| GEHE | Testosterone | 1912014-01 | 1 |
| Geilenkirchen | Testosterone | 16225803 | 1 |
| Haihang Industry | Testosterone | 20140114-1 | 1 |
| Haihang Industry | Testosterone | 20140114-2 | 1 |
| Hubei Zhuxi Humanwell | Testosterone | 2005006-01 | 1 |
| Noweda | Testosterone | 1702017-01 | 1 |
| Noweda | Testosterone | 1811027-01 | 3 |
| Noweda | Testosterone | 19111303 | 1 |
| Noweda | Testosterone | 23000429008 | 1 |
| Noweda | Testosterone | 2311029-01 | 1 |
| NWM CHina | Testosterone | TE150402 | 1 |
| Pharbil Waltrop GmbH | Testosterone | 9542100/228178-0 | 1 |
| Phönix Gotha | Testosterone | 1106011-03 | 1 |
| Phönix Gotha | Testosterone | 1408015-01 | 1 |
| Sanacorp | Testosterone | 2110010-01 | 1 |
| Sanacorp | Testosterone | 23000429006 | 1 |
| Shandong Northwest M… | Testosterone | GTJ160510 | 1 |
| Spirig | Testosterone | 13406003 | 1 |

- 256 506 spectra from 1666 *Apo-Ident* customers from a total of 52 029 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Testosterone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Testosterone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 948 | 0 | 157 378 |
| **Type B** | 0 | 1917 | 0 | 211 023 |
| **Type C** | 0 | 378 | 2 | 256 506 |

The substance/substance group *Testosterone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.3671 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6870 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.4737 % (> 98.6842 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20729 | 24963 | 14.44 | 132.28 |
| 20961 | 20961 | 0.00 | 133.58 |
| 21370 | 22232 | 7.79 | 132.32 |
| 21371 | 22232 | 8.93 | 132.72 |
| 21970 | 22232 | 4.05 | 132.36 |
| 21987 | 22232 | 3.36 | 133.19 |
| 22232 | 22232 | 0.00 | 133.48 |
| 22561 | 22561 | 0.00 | 125.52 |
| 23244 | 22232 | 6.27 | 133.46 |
| 23764 | 22232 | 6.34 | 133.99 |
| 24963 | 24963 | 0.00 | 132.79 |
| 25104 | 25104 | 0.00 | 136.33 |
| 25160 | 25160 | 0.00 | 131.69 |
| 26392 | 25104 | 15.04 | 135.03 |
| 27212 | 27212 | 0.00 | 135.27 |
| 27521 | 27521 | 0.00 | 127.88 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Testosterone propionate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20880-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Testosterone propionate; Testosteroni propionas

### Special notes

When selecting the *Testosterone propionate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Testosterone propionate | 6 | 11 | 282 |

### Second-stage model

For differentiation of the substance/substance group *Testosterone propionate* the following second-stage model is used:

- Submodel 05

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Testosterone propionate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Progesterone | 37.24 | 48.83 |
| Spironolactone | 50.27 | 49.76 |
| ⋮ | ⋮ | ⋮ |
| Povidone iodine | >50 | 83.00 |
| Povidone | >50 | 84.80 |
| Fusidic acid | >50 | 105.08 |
| Ubidecarenone | >50 | 125.49 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Testosterone propionate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Testosterone propionate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Testosterone propionate | 12163607 | 20880 | 40 | AR-15-FG-000623-01 |
| Caelo | Testosterone propionate | 15444709 | 23170 | 40 | 1707612 |
| Euro OTC | Testosterone propionate | 1109024-02 | 21644 | 60 | 1503607 |
| Euro OTC | Testosterone propionate | 1511003 | 22230 | 60 | 20151111* |
| Euro OTC | Testosterone propionate | 1511003 | 22230SI | 43 | 20151111* |
| Euro OTC | Testosterone propionate | 1512023 | 22288 | 45 | 20151230* |
| Euro OTC | Testosterone propionate | 1512023 | 22288SI | 45 | 20151230* |
| Euro OTC | Testosterone propionate | 2003011 | 25116 | 40 | 20200408* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 373 spectra of 8 reference samples from the substance/substance group *Testosterone propionate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 953 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 939 spectra of 24 reference samples from the substance/substance group *Testosterone propionate*.

- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Testosterone propionate | 170963 | 23334 | 40 |
| Caelo | Testosterone propionate | 191986 | 24759 | 40 |
| Caelo | Testosterone propionate | 22003581 | 26494 | 40 |
| Caelo | Testosterone propionate | 23001951 | 26952 | 40 |
| Euro OTC | Testosterone propionate | 1710027 | 23734 | 40 |
| Euro OTC | Testosterone propionate | 1811040 | 24413 | 40 |
| Euro OTC | Testosterone propionate | 2010004 | 25476 | 40 |
| Euro OTC | Testosterone propionate | 2206019 | 26205 | 40 |
| Euro OTC | Testosterone propionate | 2309024 | 26925 | 40 |
| Fagron | Testosterone propionate | 22F07-F03-382822 | 26373 | 40 |
| Fagron | Testosterone propionate | 24E02-B03-241020 | 27411 | 40 |
| Caelo | Testosterone propionate | 15444709 | 23170SI† | 30 |
| Caelo | Testosterone propionate | 170963 | 23334SI | 29 |
| Caelo | Testosterone propionate | 191986 | 24759SI | 40 |
| Caelo | Testosterone propionate | 22003581 | 26494SI | 40 |
| Caelo | Testosterone propionate | 23001951 | 26952SI | 40 |
| Euro OTC | Testosterone propionate | 1710027 | 23734SI | 40 |
| Euro OTC | Testosterone propionate | 1811040 | 24413SI | 40 |
| Euro OTC | Testosterone propionate | 2003011 | 25116SI† | 40 |
| Euro OTC | Testosterone propionate | 2010004 | 25476SI | 40 |
| Euro OTC | Testosterone propionate | 2206019 | 26205SI | 40 |
| Euro OTC | Testosterone propionate | 2309024 | 26925SI | 40 |
| Fagron | Testosterone propionate | 22F07-F03-382822 | 26373SI | 40 |
| Fagron | Testosterone propionate | 24E02-B03-241020 | 27411SI | 40 |

- 212 001 spectra from a total of 4274 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 973 spectra from 454 *Apo-Ident* customers from 298 batches from the substance/substance group *Testosterone propionate*.
- Among them are spectra of independent samples from 282 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Testosterone propionate | 2010004-02 | 1 |
| | Testosterone propionate | 22003581002 | 3 |
| | Testosterone propionate | 22003581003 | 1 |
| | Testosterone propionate | 2206019 | 1 |
| | Testosterone propionate | 2206019-01 | 2 |
| | Testosterone propionate | 2206019-02 | 8 |
| | Testosterone propionate | 22K07-B09 | 2 |
| | Testosterone propionate | 22K07-B09-223645 | 2 |
| | Testosterone propionate | 22K07-b09-223647 | 1 |
| | Testosterone propionate | 22K07-B09-223647 | 6 |
| | Testosterone propionate | 22K07-B09-228637 | 11 |
| | Testosterone propionate | 22K07-B09-229120 | 1 |
| | Testosterone propionate | 2309024-01 | 2 |
| | Testosterone propionate | 23J09-B10-233051 | 7 |
| | Testosterone propionate | 24L10-B09-005566 | 1 |
| | Testosterone propionate | f03-3828201 | 1 |
| | Testosterone propionate | TSP103/0322 | 2 |
| AHD | Testosterone propionate | 17325712 | 1 |
| AHD | Testosterone propionate | 19K11-F05 | 1 |
| AHD | Testosterone propionate | AP12E04-N01TP | 1 |
| AHL | Testosterone propionate | APZTSP15003-MTP | 2 |
| Alliance | Testosterone propionate | 2206019-02 | 1 |
| Alliance | Testosterone propionate | 22k07-b09-223645 | 1 |
| allianz | Testosterone propionate | 15444704 | 1 |
| Andor | Testosterone propionate | 1109024-03TP | 1 |
| Anzag | Testosterone propionate | 14L31-B02-304721 | 2 |
| Anzag | Testosterone propionate | 14L31-B02-304722 | 1 |
| Anzag | Testosterone propionate | 20K26-F06-375792 | 1 |
| Apo-ident / AH | Testosterone propionate | 2003011-01 | 1 |
| apomix | Testosterone propionate | 13K25-B05-287648 | 1 |
| apomix | Testosterone propionate | 40/14 | 1 |
| Audor Pharma | Testosterone propionate | AP1109024-03 | 2 |
| Audor Pharma | Testosterone propionate | AP1109024-03TP | 4 |
| Audor Pharma | Testosterone propionate | AP12E04N01TP | 2 |
| Audor Pharma | Testosterone propionate | AP12J10-N08TP | 2 |
| Audor Pharma | Testosterone propionate | AP13K25-B05-287643T | 1 |
| Audor Pharma | Testosterone propionate | AP13K25-B05-287643TP | 1 |
| Audor Pharma | Testosterone propionate | APZTSP15003-MTP | 16 |

*continued on the next page*

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Testosterone propionate | APZTSP1503-MTP | 1 |
| Caelo | Testosterone propionate | 10235809 | 1 |
| Caelo | Testosterone propionate | 103004 | 1 |
| Caelo | Testosterone propionate | 106212376 | 1 |
| Caelo | Testosterone propionate | 1108212376 | 1 |
| Caelo | Testosterone propionate | 1109024-02 | 1 |
| Caelo | Testosterone propionate | 12060102 | 2 |
| Caelo | Testosterone propionate | 12163605 | 2 |
| Caelo | Testosterone propionate | 12163607 | 1 |
| Caelo | Testosterone propionate | 12163610 | 2 |
| Caelo | Testosterone propionate | 12163612 | 6 |
| Caelo | Testosterone propionate | 12163613 | 1 |
| Caelo | Testosterone propionate | 12163615 | 2 |
| Caelo | Testosterone propionate | 12163616 | 4 |
| Caelo | Testosterone propionate | 12163617 | 4 |
| Caelo | Testosterone propionate | 12163619 | 2 |
| Caelo | Testosterone propionate | 12163621 | 1 |
| Caelo | Testosterone propionate | 1263607 | 1 |
| Caelo | Testosterone propionate | 12A02-N05 | 1 |
| Caelo | Testosterone propionate | 12J10-N08 | 2 |
| Caelo | Testosterone propionate | 13C08-N02 | 1 |
| Caelo | Testosterone propionate | 13F05-N04 | 1 |
| Caelo | Testosterone propionate | 13K25-B05-291974 | 1 |
| Caelo | Testosterone propionate | 14D15-B03-296959 | 1 |
| Caelo | Testosterone propionate | 14L31-B02-304722 | 2 |
| Caelo | Testosterone propionate | 15003002 | 8 |
| Caelo | Testosterone propionate | 15003004 | 3 |
| Caelo | Testosterone propionate | 15003008 | 2 |
| Caelo | Testosterone propionate | 151100301 | 1 |
| Caelo | Testosterone propionate | 1511003-01 | 1 |
| Caelo | Testosterone propionate | 15169504 | 1 |
| Caelo | Testosterone propionate | 15444702 | 11 |
| Caelo | Testosterone propionate | 15444703 | 16 |
| Caelo | Testosterone propionate | 15444705 | 4 |
| Caelo | Testosterone propionate | 15444706 | 3 |
| Caelo | Testosterone propionate | 15444707 | 4 |
| Caelo | Testosterone propionate | 15444709 | 1 |
| Caelo | Testosterone propionate | 15444710 | 5 |
| Caelo | Testosterone propionate | 15444711 | 1 |
| Caelo | Testosterone propionate | 15444712 | 1 |
| Caelo | Testosterone propionate | 15444713 | 2 |
| Caelo | Testosterone propionate | 15444714 | 3 |
| Caelo | Testosterone propionate | 15444717 | 1 |
| Caelo | Testosterone propionate | 15444718 | 2 |
| Caelo | Testosterone propionate | 15444719 | 1 |
| Caelo | Testosterone propionate | 15444721 | 2 |
| Caelo | Testosterone propionate | 15444723 | 1 |
| Caelo | Testosterone propionate | 1544717 | 1 |
| Caelo | Testosterone propionate | 16E24-B01-324711 | 2 |
| Caelo | Testosterone propionate | 16H22-B05-326483 | 1 |
| Caelo | Testosterone propionate | 1710027-01 | 4 |
| Caelo | Testosterone propionate | 17325707 | 10 |
| Caelo | Testosterone propionate | 17325709 | 2 |
| Caelo | Testosterone propionate | 17325711 | 2 |
| Caelo | Testosterone propionate | 17325712 | 2 |
| Caelo | Testosterone propionate | 17325712P-190312-8 | 1 |
| Caelo | Testosterone propionate | 17325716 | 1 |
| Caelo | Testosterone propionate | 17325717 | 9 |
| Caelo | Testosterone propionate | 17325719 | 2 |
| Caelo | Testosterone propionate | 17B09B03332376 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Testosterone propionate | 17B09-B03-332376 | 1 |
| Caelo | Testosterone propionate | 17J16-B03-341320 | 1 |
| Caelo | Testosterone propionate | 18b06-B04 | 1 |
| Caelo | Testosterone propionate | 18b06-b04-351510 | 1 |
| Caelo | Testosterone propionate | 18B14-B02-353456 | 1 |
| Caelo | Testosterone propionate | 18I12-B03-355137 | 1 |
| Caelo | Testosterone propionate | 191986001 | 3 |
| Caelo | Testosterone propionate | 191986003 | 1 |
| Caelo | Testosterone propionate | 191986007 | 2 |
| Caelo | Testosterone propionate | 19198603 | 6 |
| Caelo | Testosterone propionate | 19198603P-200319-13 | 1 |
| Caelo | Testosterone propionate | 19198604 | 8 |
| Caelo | Testosterone propionate | 19k11-f05-366325 | 1 |
| Caelo | Testosterone propionate | 2013U-02376 | 1 |
| Caelo | Testosterone propionate | 20H19-F07-373643 | 1 |
| Caelo | Testosterone propionate | 21000430001 | 1 |
| Caelo | Testosterone propionate | 21000430002 | 3 |
| Caelo | Testosterone propionate | 21000430006 | 3 |
| Caelo | Testosterone propionate | 21000430010 | 3 |
| Caelo | Testosterone propionate | 22003581002 | 1 |
| Caelo | Testosterone propionate | 22K07-B09-223647 | 1 |
| Caelo | Testosterone propionate | 23051816 | 1 |
| Caelo | Testosterone propionate | 2910030-02 | 1 |
| Caelo | Testosterone propionate | 36814m1 | 1 |
| Caelo | Testosterone propionate | 36814M1 | 2 |
| Caelo | Testosterone propionate | 612212376 | 1 |
| Caelo | Testosterone propionate | 614E2376 | 1 |
| Caelo | Testosterone propionate | 903312376 | 1 |
| Caesar & Loretz GmbH... | Testosterone propionate | 21000430009 | 1 |
| Caesar & Loretz GmbH... | Testosterone propionate | 17325719 | 1 |
| Caesar & Loretz GmbH... | Testosterone propionate | 19198603 | 1 |
| Caesar & Loretz GmbH... | Testosterone propionate | 21000430006 | 2 |
| Caesar & Loretz GmbH... | Testosterone propionate | 17325722 | 1 |
| Caesar & Loretz GmbH... | Testosterone propionate | 19198604 | 2 |
| Caesar & Loretz GmbH | Testosterone propionate | 17325716 | 1 |
| Caesar & Loretz GmbH | Testosterone propionate | 17325717 | 2 |
| Caesar & Loretz GmbH | Testosterone propionate | 191986003 | 2 |
| Caesar & Loretz GmbH | Testosterone propionate | 191986006 | 1 |
| Caesar & Loretz GmbH | Testosterone propionate | 19198603 | 2 |
| Caesar & Loretz GmbH | Testosterone propionate | 19198604 | 5 |
| Caesar & Loretz GmbH | Testosterone propionate | 21000430002 | 1 |
| Caesar & Loretz GmbH | Testosterone propionate | 21000430006 | 1 |
| Caesar & Loretz GmbH | Testosterone propionate | 21000430009 | 3 |
| Caesar & Loretz GmbH | Testosterone propionate | 21000430010 | 2 |
| Caesar & Loretz GmbH | Testosterone propionate | 21000430012 | 2 |
| Caesar & Loretz GmbH | Testosterone propionate | 22003581003 | 1 |
| Ebert 17.08.16 | Testosterone propionate | 15444703 | 1 |
| EuRho / Gehe | Testosterone propionate | 2010004-01 | 2 |
| EURHO/Anzag | Testosterone propionate | 1811040-01 | 1 |
| EuRho/Krieger | Testosterone propionate | 1811040-01 | 3 |
| EuRho | Testosterone propionate | 17100271 | 1 |
| EuRho | Testosterone propionate | 1811040-01 | 1 |
| EuRho | Testosterone propionate | 2003011-01 | 1 |
| Euro OTC | Testosterone propionate | 101/0218 | 1 |
| Euro OTC | Testosterone propionate | 1103010-01 | 1 |
| Euro OTC | Testosterone propionate | 1103010-02 | 1 |
| Euro OTC | Testosterone propionate | 1109024-02 | 1 |
| Euro OTC | Testosterone propionate | 1109024-03 | 1 |
| Euro OTC | Testosterone propionate | 1409037-01 | 2 |
| Euro OTC | Testosterone propionate | 1504023-01 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Testosterone propionate | 1511003-01 | 10 |
| Euro OTC | Testosterone propionate | 1512023-01 | 2 |
| Euro OTC | Testosterone propionate | 15444718 | 2 |
| Euro OTC | Testosterone propionate | 1710027-01 | 6 |
| Euro OTC | Testosterone propionate | 181040-01 | 1 |
| Euro OTC | Testosterone propionate | 181104001 | 2 |
| Euro OTC | Testosterone propionate | 1811040-01 | 16 |
| Euro OTC | Testosterone propionate | 18111709 | 1 |
| Euro OTC | Testosterone propionate | 18114001 | 1 |
| Euro OTC | Testosterone propionate | 2003011-01 | 10 |
| Euro OTC | Testosterone propionate | 2010004-01 | 12 |
| Euro OTC | Testosterone propionate | 2010004-02 | 1 |
| Euro OTC | Testosterone propionate | 710027-01 | 1 |
| Euro OTC | Testosterone propionate | 970116/1 | 1 |
| Euro OTC | Testosterone propionate | F07-3736403 | 1 |
| Euro/Lui | Testosterone propionate | 1811040-01 | 1 |
| euro | Testosterone propionate | 2010004-01 | 1 |
| Fagro/Noweda | Testosterone propionate | 16H22-B05-326483 | 2 |
| Fagron | Testosterone propionate | | 2 |
| Fagron | Testosterone propionate | 10L03-N16 | 3 |
| Fagron | Testosterone propionate | 11/12-N03 | 1 |
| Fagron | Testosterone propionate | 11C21-N09 | 1 |
| Fagron | Testosterone propionate | 11G15-N07 | 3 |
| Fagron | Testosterone propionate | 11K18-N04 | 4 |
| Fagron | Testosterone propionate | 12/10-N08 | 1 |
| Fagron | Testosterone propionate | 12163616 | 2 |
| Fagron | Testosterone propionate | 12A02-N05 | 2 |
| Fagron | Testosterone propionate | 12C01-N01 | 1 |
| Fagron | Testosterone propionate | 12C01-NO1 | 1 |
| Fagron | Testosterone propionate | 12E04-N01 | 3 |
| Fagron | Testosterone propionate | 12E29-N02 | 1 |
| Fagron | Testosterone propionate | 12J10N-08 | 1 |
| Fagron | Testosterone propionate | 12J10-N08 | 4 |
| Fagron | Testosterone propionate | 13/03-N02 | 2 |
| Fagron | Testosterone propionate | 13C08N02 | 1 |
| Fagron | Testosterone propionate | 13C08-N02 | 15 |
| Fagron | Testosterone propionate | 13F05-N04 | 16 |
| Fagron | Testosterone propionate | 13I03-N02 | 1 |
| Fagron | Testosterone propionate | 13K25-B05 | 1 |
| Fagron | Testosterone propionate | 13K25-B05-287647 | 10 |
| Fagron | Testosterone propionate | 13K25B05287648 | 1 |
| Fagron | Testosterone propionate | 13K25-B05-287648 | 5 |
| Fagron | Testosterone propionate | 13K25-B05-291974 | 2 |
| Fagron | Testosterone propionate | 14A28-B12 | 2 |
| Fagron | Testosterone propionate | 14A28-B12-291977 | 1 |
| Fagron | Testosterone propionate | 14A28B12296958 | 1 |
| Fagron | Testosterone propionate | 14A28-B12-296958 | 2 |
| Fagron | Testosterone propionate | 14A28-B12-296960 | 2 |
| Fagron | Testosterone propionate | 14D15-B03-296959 | 4 |
| Fagron | Testosterone propionate | 14I31-B02 | 1 |
| Fagron | Testosterone propionate | 14L31-B02 | 4 |
| Fagron | Testosterone propionate | 14L31B02-304721 | 1 |
| Fagron | Testosterone propionate | 14L31-B02-304721 | 9 |
| Fagron | Testosterone propionate | 14L31B02304722 | 1 |
| Fagron | Testosterone propionate | 14L31-B02-304722 | 11 |
| Fagron | Testosterone propionate | 15/01-B09 | 1 |
| Fagron | Testosterone propionate | 15/01-B09-312867 | 1 |
| Fagron | Testosterone propionate | 15/01-B09-318371 | 2 |
| Fagron | Testosterone propionate | 1501-B09-312867 | 1 |
| Fagron | Testosterone propionate | 1511003-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Testosterone propionate | 15444717 | 1 |
| Fagron | Testosterone propionate | 15D03-B02-310694 | 1 |
| Fagron | Testosterone propionate | 15I01-B01-318371 | 1 |
| Fagron | Testosterone propionate | 15I01-B09-312867 | 2 |
| Fagron | Testosterone propionate | 15I01-B09-318371 | 2 |
| Fagron | Testosterone propionate | 15k03-b03 | 1 |
| Fagron | Testosterone propionate | 15K03-B03-315218 | 7 |
| Fagron | Testosterone propionate | 15K03-B-03-315218 | 1 |
| Fagron | Testosterone propionate | 15l01-B09-312867 | 1 |
| Fagron | Testosterone propionate | 16C24B04320784 | 1 |
| Fagron | Testosterone propionate | 16C24-B04-320784 | 6 |
| Fagron | Testosterone propionate | 16E24-B01 | 1 |
| Fagron | Testosterone propionate | 16E24-B01-322593 | 7 |
| Fagron | Testosterone propionate | 16E24B01322938 | 1 |
| Fagron | Testosterone propionate | 16E24B01324711 | 1 |
| Fagron | Testosterone propionate | 16E24-B01-324711 | 2 |
| Fagron | Testosterone propionate | 16E24-B01-325476 | 1 |
| Fagron | Testosterone propionate | 16E24-Bo1-322938 | 1 |
| Fagron | Testosterone propionate | 16H22-B05 | 2 |
| Fagron | Testosterone propionate | 16H22-B05-326482 | 4 |
| Fagron | Testosterone propionate | 16h22-b05-326483 | 1 |
| Fagron | Testosterone propionate | 16H22B05326483 | 1 |
| Fagron | Testosterone propionate | 16H22-B05-326483 | 12 |
| Fagron | Testosterone propionate | 16K24B03330544 | 1 |
| Fagron | Testosterone propionate | 16K24-B03-330544 | 1 |
| Fagron | Testosterone propionate | 17116-B04-346529 | 1 |
| Fagron | Testosterone propionate | 17B09-B03 | 1 |
| Fagron | Testosterone propionate | 17B09B03332376 | 1 |
| Fagron | Testosterone propionate | 17B09-B03-332376 | 6 |
| Fagron | Testosterone propionate | 17B09-B04-335269 | 2 |
| Fagron | Testosterone propionate | 17E22-B09 | 1 |
| Fagron | Testosterone propionate | 17E22-B09-338592 | 4 |
| Fagron | Testosterone propionate | 17H25-B02-341321 | 4 |
| Fagron | Testosterone propionate | 17J16-B03 | 1 |
| Fagron | Testosterone propionate | 17j16-B03-341320 | 1 |
| Fagron | Testosterone propionate | 17J16B03-341320 | 2 |
| Fagron | Testosterone propionate | 17J16-B03-341320 | 1 |
| Fagron | Testosterone propionate | 17J16-B03-343010 | 4 |
| Fagron | Testosterone propionate | 17J16-B03-344243 | 2 |
| Fagron | Testosterone propionate | 17J16B04346529 | 1 |
| Fagron | Testosterone propionate | 17J16-B04-346529 | 7 |
| Fagron | Testosterone propionate | 18/12-B03 | 1 |
| Fagron | Testosterone propionate | 18/12-B03-355296 | 4 |
| Fagron | Testosterone propionate | 18/12-B03-3567 | 1 |
| Fagron | Testosterone propionate | 18/12-B03-356702 | 4 |
| Fagron | Testosterone propionate | 18/12-B03-356703 | 4 |
| Fagron | Testosterone propionate | 18/12-B03-3596 | 1 |
| Fagron | Testosterone propionate | 18B06-B04 | 2 |
| Fagron | Testosterone propionate | 18B06-B04-348557 | 4 |
| Fagron | Testosterone propionate | 18B06B04350560 | 1 |
| Fagron | Testosterone propionate | 18B06-B04-350560 | 1 |
| Fagron | Testosterone propionate | 18B06-B04-351510 | 7 |
| Fagron | Testosterone propionate | 18B06-B04-352492 | 4 |
| Fagron | Testosterone propionate | 18B06-B04-352493 | 6 |
| Fagron | Testosterone propionate | 18b14-b02-353456 | 1 |
| Fagron | Testosterone propionate | 18B14-B02-353456 | 2 |
| Fagron | Testosterone propionate | 18I12-B03 | 1 |
| Fagron | Testosterone propionate | 18I12-B03-355137 | 2 |
| Fagron | Testosterone propionate | 18I12-B03-355296 | 2 |
| Fagron | Testosterone propionate | 18I12-B03-356702 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Testosterone propionate | 18I12-B03-356703 | 2 |
| Fagron | Testosterone propionate | 18I22-B03-356703 | 1 |
| Fagron | Testosterone propionate | 18l12-B03-356703 | 1 |
| Fagron | Testosterone propionate | 19H16-F03-364849 | 4 |
| Fagron | Testosterone propionate | 19H16-F03-364850 | 7 |
| Fagron | Testosterone propionate | 19H22-B05-326483 | 1 |
| Fagron | Testosterone propionate | 19K11-F05-366324 | 9 |
| Fagron | Testosterone propionate | 19K11-F05-366325 | 11 |
| Fagron | Testosterone propionate | 20121012-3 | 1 |
| Fagron | Testosterone propionate | 20A27-F08 | 2 |
| Fagron | Testosterone propionate | 20A27-F08-368802 | 6 |
| Fagron | Testosterone propionate | 20A27-F08-368803 | 1 |
| Fagron | Testosterone propionate | 20A27-F08-368803 | 2 |
| Fagron | Testosterone propionate | 20A27F08369542 | 1 |
| Fagron | Testosterone propionate | 20A27-F08-369542 | 2 |
| Fagron | Testosterone propionate | 20F24-F02 | 1 |
| Fagron | Testosterone propionate | 20F24-F02-371915 | 7 |
| Fagron | Testosterone propionate | 20F24-F02-371916 | 10 |
| Fagron | Testosterone propionate | 20F24-FO2-371915 | 1 |
| Fagron | Testosterone propionate | 20H19-F07 | 2 |
| Fagron | Testosterone propionate | 20H19-F07-3736403 | 1 |
| Fagron | Testosterone propionate | 20H19-F07-373642 | 7 |
| Fagron | Testosterone propionate | 20H19-F07-373643 | 10 |
| Fagron | Testosterone propionate | 20H19-F07-373643 | 1 |
| Fagron | Testosterone propionate | 20H19-F07-375282 | 4 |
| Fagron | Testosterone propionate | 20K26-F06 | 3 |
| Fagron | Testosterone propionate | 20K26-F06-375792 | 7 |
| Fagron | Testosterone propionate | 20K26-F06-375793 | 7 |
| Fagron | Testosterone propionate | 21J04-F03 | 2 |
| Fagron | Testosterone propionate | 21J04F03-380627 | 1 |
| Fagron | Testosterone propionate | 21J04-F03-380627 | 11 |
| Fagron | Testosterone propionate | 21J04-F03-380628 | 14 |
| Fagron | Testosterone propionate | 21JO4-F03-380627 | 1 |
| Fagron | Testosterone propionate | 22F07-03F-382821 | 1 |
| Fagron | Testosterone propionate | 22F07-F03-382821 | 8 |
| Fagron | Testosterone propionate | 22K07-B09 | 1 |
| Fagron | Testosterone propionate | 22K07-B09-223647 | 5 |
| Fagron | Testosterone propionate | 24411M1 | 1 |
| Fagron | Testosterone propionate | 2OF24-FO2-371915 | 1 |
| Fagron | Testosterone propionate | 2OK26-F06-375792 | 1 |
| Fagron | Testosterone propionate | 2OK26-FO6-375792 | 1 |
| Fagron | Testosterone propionate | 32012M1 | 1 |
| Fagron | Testosterone propionate | 3380627 | 1 |
| Fagron | Testosterone propionate | 3613M-02376 | 1 |
| Fagron | Testosterone propionate | 36513M1 | 3 |
| Fagron | Testosterone propionate | 36814M1 | 2 |
| Fagron | Testosterone propionate | 6081201 | 1 |
| Fagron | Testosterone propionate | APZTSP15003-MTP | 2 |
| Fagron | Testosterone propionate | F02-3719105 | 2 |
| Fagron | Testosterone propionate | F02-3719106 | 1 |
| Fagron | Testosterone propionate | F03-3648500 | 1 |
| Fagron | Testosterone propionate | F06-3757902 | 7 |
| Fagron | Testosterone propionate | F06-3757903 | 1 |
| Fagron | Testosterone propionate | F07-3736402 | 2 |
| Fagron | Testosterone propionate | F07-3736403 | 2 |
| Fagron | Testosterone propionate | F07-3752802 | 2 |
| Fagron | Testosterone propionate | F08-3688002 | 1 |
| Fagron | Testosterone propionate | F08-3688003 | 2 |
| Fagron | Testosterone propionate | T009/07109 | 2 |
| Fagron | Testosterone propionate | t011/072000 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Testosterone propionate | TSP101/0720 | 1 |
| Fagron | Testosterone propionate | TSP102/0720 | 1 |
| Fagron | Testosterone propionate | TSP-BLT008/0719 | 1 |
| Fagron | Testosterone propionate | TSP-BLT011/0720 | 1 |
| Fargon - Alliance He... | Testosterone propionate | 18/12-B03-356703 | 1 |
| Fargon /Max Jenne | Testosterone propionate | 18I12-B03-355296 | 1 |
| Fargon/ Phönix | Testosterone propionate | 16H22-B05-326483 | 3 |
| Fargon/ Phönix | Testosterone propionate | 18I12-B03-356703 | 1 |
| Fargon/Kehr | Testosterone propionate | 17B09-B04-335269 | 1 |
| Fargon | Testosterone propionate | 19K11-F05_366324 | 1 |
| Fiebig | Testosterone propionate | 20F24-F02-371915 | 1 |
| Fragon | Testosterone propionate | 21j04-F03-380628 | 1 |
| Galderma | Testosterone propionate | 15K03-B03-315218 | 1 |
| Gatt-Koller | Testosterone propionate | 1803006 | 1 |
| Gatt-Koller | Testosterone propionate | 3478/09153915 | 1 |
| Gatt-Koller | Testosterone propionate | 606213811 | 1 |
| Gehe/Euro | Testosterone propionate | 1200318/151100301 | 1 |
| Gehe/Fragon | Testosterone propionate | 17B09B03332376 | 1 |
| Gehe | Testosterone propionate | 14A28B12296958 | 1 |
| Gehe | Testosterone propionate | 15444706 | 1 |
| Gehe | Testosterone propionate | 16H22-B05 | 1 |
| GEHE | Testosterone propionate | 17325709 | 1 |
| GEHE | Testosterone propionate | 17325712 | 1 |
| Gehe | Testosterone propionate | 19H16-F03 | 1 |
| Gehe | Testosterone propionate | 19H16-F03-364849 | 1 |
| Gehe | Testosterone propionate | 19K11-F05-366325 | 1 |
| Gehe | Testosterone propionate | 20K26-F06-375792 | 1 |
| Gehe | Testosterone propionate | 22K07-B09-228637 | 1 |
| Infectopharm/Phönix | Testosterone propionate | 18B06-B04-352493 | 1 |
| Jenne | Testosterone propionate | 22003581003 | 1 |
| Jenne | Testosterone propionate | 22K07-B09-228637 | 1 |
| Kehr/Fargon | Testosterone propionate | 17J16-B03-344243 | 1 |
| Kehr | Testosterone propionate | 2206019-01 | 1 |
| Noweda | Testosterone propionate | 12163610 | 1 |
| Noweda | Testosterone propionate | 1511003 | 1 |
| Noweda | Testosterone propionate | 17B09-B03-332376 | 1 |
| Noweda | Testosterone propionate | 2206019-01 | 2 |
| Noweda | Testosterone propionate | 22F07-F03-382821 | 1 |
| Noweda | Testosterone propionate | 22K07-B09-223647 | 1 |
| Noweda | Testosterone propionate | 22K07-B09-228637 | 1 |
| Noweda | Testosterone propionate | 22K07-B09-229120 | 1 |
| Phoenix/Cealo | Testosterone propionate | 36814M1 | 1 |
| Phoenix | Testosterone propionate | 1109024-02 | 1 |
| phoenix | Testosterone propionate | 12163615 | 1 |
| Phönix WE:25.04.16 E... | Testosterone propionate | 14L31-B02-304722 | 1 |
| Phönix/ Fargon | Testosterone propionate | 19H16-F03-364850 | 1 |
| Phönix/Euro | Testosterone propionate | 110301002 | 1 |
| Phönix | Testosterone propionate | 12163613 | 1 |
| Phönix | Testosterone propionate | 12163617 | 1 |
| Phönix | Testosterone propionate | 12J10-N08 | 1 |
| Phönix | Testosterone propionate | 13C08-N02 | 1 |
| Phönix | Testosterone propionate | 13K25-B05 | 1 |
| Phönix | Testosterone propionate | 14L31-B02-304722 | 1 |
| Phönix | Testosterone propionate | 15444702 | 1 |
| Phönix | Testosterone propionate | 15444707 | 1 |
| Phönix | Testosterone propionate | 15444710 | 1 |
| PHÖNIX | Testosterone propionate | 15444720 | 1 |
| Phönix | Testosterone propionate | 17325704 | 1 |
| Phönix | Testosterone propionate | 20H19-F07-373643 | 1 |
| Sanacorp 12.06.2019 6,70EUR | Testosterone propionate | 1710027-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Testosterone propionate | 13K25-B05 | 1 |
| Sanacorp | Testosterone propionate | 18B06-B0 | 1 |
| Sanacorp | Testosterone propionate | 18I12-B03 | 1 |
| Sanacorp | Testosterone propionate | 19H16-F03 | 1 |
| Sanacorp | Testosterone propionate | 20A27-F09 | 1 |
| Sanacorp | Testosterone propionate | 21J04-F03 | 1 |
| Sanacorp | Testosterone propionate | 22003581003 | 1 |
| Sanacorp | Testosterone propionate | 22Fo7-F03-382822 | 1 |
| Sanacorp | Testosterone propionate | TSP103/0322 | 2 |
| symbiotec | Testosterone propionate | APZTSP15003-MTP | 1 |
| Symbiotica Speciality | Testosterone propionate | 15444702 | 2 |

- 255 913 spectra from 1666 *Apo-Ident* customers from a total of 51 857 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Testosterone propionate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Testosterone propionate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 373 | 0 | 157 953 |
| **Type B** | 0 | 939 | 0 | 212 001 |
| **Type C** | 0 | 887 | 86 | 255 913 |

The substance/substance group *Testosterone propionate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3914 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3610 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 91.1614 % (> 90.8530 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20880 | 20880 | 0.00 | 39.95 |
| 21644 | 21644 | 0.00 | 38.04 |
| 22230 | 22230 | 0.00 | 38.40 |
| 22288 | 22288 | 0.00 | 38.43 |
| 23170 | 23170 | 0.00 | 37.24 |
| 25116 | 25116 | 0.00 | 42.04 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tetracaine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20947-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tetracaine; Tetracainum

### Special notes

When selecting the *Tetracaine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tetracaine | 9 | 14 | 166 |

### Second-stage model

For differentiation of the substance/substance group *Tetracaine* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tetracaine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 151.37 | – |
| ⋮ | ⋮ | ⋮ |
| Capsaicin | >50 | 108.75 |
| Prednicarbate | >50 | 137.55 |
| Cyproterone acetate | >50 | 179.47 |
| Oxybutynin hydrochloride | >50 | 195.89 |
| Levocarnitine | >50 | 225.89 |
| Alfatradiol | >50 | 235.20 |
| Sodium citrate | >50 | 240.60 |
| Amitriptyline hydrochloride | >50 | 254.42 |
| Norethisterone acetate | >50 | 344.96 |
| Heparin sodium | >50 | 415.20 |
| Quinine hydrochloride dihydrate | >50 | 537.39 |
| Pyridoxal-5-phosphate hydrate | >50 | 546.39 |
| Methoxsalen | >50 | 586.45 |
| Ciprofloxacin hydrochloride | >50 | 777.41 |
| Valine | >50 | 1019.00 |
| Amifampridine | >50 | 1522.18 |
| Triclosan | >50 | 1761.66 |
| Sucrose | >50 | 2175.21 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tetracaine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tetracaine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Tetracaine | 171117 | 23321 | 40 | 20170512* |
| Caelo | Tetracaine | 181249 | 24255 | 40 | 20180605* |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Tetracaine | 1405025-01 | 21603 | 60 | AR-14-FG-012475-01 |
| Euro OTC | Tetracaine | 1512022 | 22299 | 45 | 20160128* |
| Euro OTC | Tetracaine | 2304012 | 26661 | 40 | 20230508* |
| Fagron | Tetracaine | 12L19-N10 | 20947 | 40 | 20130108 |
| Fagron | Tetracaine | 14A16-B04-292915 | 21650 | 60 | 20140205 |
| Fagron | Tetracaine | 14A16-B04-292916 | 21659 | 60 | 20140205 |
| Fagron | Tetracaine | 21L22-B01-216874 | 26081 | 40 | 20220315 |
| Fagron | Tetracaine | 21L22-B01-216874 | 26081SI | 20 | 20220315 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 445 spectra of 10 reference samples from the substance/substance group *Tetracaine*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 881 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 620 spectra of 17 reference samples from the substance/substance group *Tetracaine*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Tetracaine | 24002763 | 27561 | 40 |
| Euro OTC | Tetracaine | 1606009 | 22717 | 40 |
| Euro OTC | Tetracaine | 1609010 | 22858 | 40 |
| Euro OTC | Tetracaine | 1701035 | 23149 | 40 |
| Euro OTC | Tetracaine | 1708024 | 23736 | 40 |
| Euro OTC | Tetracaine | 1803002 | 24066 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Tetracaine | 1805019 | 24135 | 40 |
| Euro OTC | Tetracaine | 1811021 | 24427 | 40 |
| Euro OTC | Tetracaine | 1903004 | 24451 | 40 |
| Euro OTC | Tetracaine | 1909021 | 24961 | 40 |
| Euro OTC | Tetracaine | 2107010 | 25883 | 50 |
| Euro OTC | Tetracaine | 2203018 | 26046 | 40 |
| Euro OTC | Tetracaine | 2308016 | 27071 | 40 |
| Euro OTC | Tetracaine | 2401016 | 27161 | 40 |
| Euro OTC | Tetracaine | 2107010 | 25883SI | 10 |
| Euro OTC | Tetracaine | 2203018 | 26046SI | 20 |
| Euro OTC | Tetracaine | 2304012 | 26661SI[†] | 20 |

- 212 320 spectra from a total of 4272 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 663 spectra from 242 *Apo-Ident* customers from 180 batches from the substance/substance group *Tetracaine*.
- Among them are spectra of independent samples from 165 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tetracaine | 1811021-01 | 1 |
| | Tetracaine | 21L22-B01-215564 | 2 |
| | Tetracaine | 21L22-B01-216874 | 1 |
| | Tetracaine | 2203018-02 | 6 |
| | Tetracaine | 2302016-01 | 1 |
| | Tetracaine | 2304012-01 | 7 |
| | Tetracaine | 2304012-02 | 2 |
| | Tetracaine | 2401016-01 | 6 |
| | Tetracaine | 2401016-03 | 1 |
| Alliance | Tetracaine | 2203018-02 | 1 |
| Anzag | Tetracaine | 2304012-01 | 1 |
| Anzag | Tetracaine | 2304012-02 | 1 |
| Caelo | Tetracaine | 14A16-B04 | 1 |
| Caelo | Tetracaine | 14A16-B04-290207 | 1 |
| Caelo | Tetracaine | 14A16-B04-292916 | 1 |
| Caelo | Tetracaine | 1512022-01 | 1 |
| Caelo | Tetracaine | 1516B06312783 | 1 |
| Caelo | Tetracaine | 160004 | 1 |
| Caelo | Tetracaine | 1606009-01 | 1 |
| Caelo | Tetracaine | 16a13-b07-318736 | 1 |
| Caelo | Tetracaine | 16A13-B07-318736 | 5 |
| Caelo | Tetracaine | 16E23-B04 | 1 |
| Caelo | Tetracaine | 1701035-01 | 1 |
| Caelo | Tetracaine | 171111706 | 1 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tetracaine | 17111705 | 1 |
| Caelo | Tetracaine | 17111706 | 5 |
| Caelo | Tetracaine | 17111713 | 2 |
| Caelo | Tetracaine | 17111713P-190909-1 | 1 |
| Caelo | Tetracaine | 17111714 | 3 |
| Caelo | Tetracaine | 17K13-B02-344448 | 1 |
| Caelo | Tetracaine | 17K13-B02-347172 | 2 |
| Caelo | Tetracaine | 1803002-01 | 1 |
| Caelo | Tetracaine | 1805019-01 | 2 |
| Caelo | Tetracaine | 1811021-01 | 2 |
| Caelo | Tetracaine | 18124097 | 1 |
| Caelo | Tetracaine | 18124905 | 1 |
| Caelo | Tetracaine | 19106602 | 5 |
| Caelo | Tetracaine | 19106605 | 1 |
| Caelo | Tetracaine | 192737004 | 3 |
| Caelo | Tetracaine | 192737006 | 1 |
| Caelo | Tetracaine | 192737008 | 1 |
| Caelo | Tetracaine | 20000160003 | 1 |
| Caelo | Tetracaine | 20000160009 | 2 |
| Caelo | Tetracaine | 20000160011 | 1 |
| Caelo | Tetracaine | 20003786004 | 14 |
| Caelo | Tetracaine | 20003786007 | 1 |
| Caelo | Tetracaine | 20003786012 | 8 |
| Caelo | Tetracaine | T-290413-1 | 1 |
| Caelo | Tetracaine | TC130621 | 1 |
| Caeolo/Alliance | Tetracaine | 20000160009 | 1 |
| Caesar & Loretz GmbH... | Tetracaine | 17111714 | 1 |
| Caesar & Loretz GmbH... | Tetracaine | 20000160003 | 1 |
| Caesar & Loretz GmbH... | Tetracaine | 17111706 | 1 |
| Caesar & Loretz GmbH... | Tetracaine | 20000160003 | 2 |
| Caesar & Loretz GmbH | Tetracaine | 18124906 | 1 |
| Caesar & Loretz GmbH | Tetracaine | 19106602 | 1 |
| Caesar & Loretz GmbH | Tetracaine | 192737004 | 1 |
| Caesar & Loretz GmbH | Tetracaine | 192737006 | 1 |
| Caesar & Loretz GmbH | Tetracaine | 20000160009 | 1 |
| Caesar & Loretz GmbH | Tetracaine | 20003786007 | 1 |
| Caesar & Loretz/Noweda | Tetracaine | 17111714 | 1 |
| Ebert-Jacobi | Tetracaine | 16J12-B06-327371 | 1 |
| EuRho/ NOWEDA | Tetracaine | 1811021-01 | 1 |
| EuRho/ NOWEDA | Tetracaine | 1903004-01 | 2 |
| EuRho/ Phoenix | Tetracaine | 1805019-01 | 1 |
| EuRho/ Phoenix | Tetracaine | TC0090717 | 1 |
| EuRho/AHD | Tetracaine | 1811021-01 | 1 |
| EuRho/GEHE | Tetracaine | 1803002-01 | 1 |
| EuRho/Jenne | Tetracaine | 1909021-02 | 1 |
| Eurho/noweda | Tetracaine | 220301801 | 1 |
| euRho/Noweda | Tetracaine | 2203018-02 | 1 |
| EuRho/Phoenix | Tetracaine | 1909021-02 | 1 |
| Eurho/Phönix | Tetracaine | 1909021-01 | 1 |
| EuRho/Sanacorp | Tetracaine | 2203018-02 | 3 |
| EuRho | Tetracaine | 220301801 | 1 |
| EuRho | Tetracaine | 2203018-02 | 1 |
| EuRho | Tetracaine | 519Q-04004 | 1 |
| Euro OTC | Tetracaine | 10887133 | 1 |
| Euro OTC | Tetracaine | 12081501 | 1 |
| Euro OTC | Tetracaine | 1312034-01 | 6 |
| Euro OTC | Tetracaine | 1405025-01 | 1 |
| Euro OTC | Tetracaine | 1405025-02 | 1 |
| Euro OTC | Tetracaine | 151022-01 | 1 |
| Euro OTC | Tetracaine | 1512022-01 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Tetracaine | 160600-01 | 1 |
| Euro OTC | Tetracaine | 1606009-01 | 7 |
| Euro OTC | Tetracaine | 160901 | 1 |
| Euro OTC | Tetracaine | 1609010-01 | 15 |
| Euro OTC | Tetracaine | 1701035-01 | 10 |
| Euro OTC | Tetracaine | 170802401 | 3 |
| Euro OTC | Tetracaine | 1708024-01 | 12 |
| Euro OTC | Tetracaine | 1803002-01 | 16 |
| Euro OTC | Tetracaine | 18041809 | 1 |
| Euro OTC | Tetracaine | 180501901 | 2 |
| Euro OTC | Tetracaine | 1805019-01 | 10 |
| Euro OTC | Tetracaine | 1805019-02 | 2 |
| Euro OTC | Tetracaine | 181102101 | 8 |
| Euro OTC | Tetracaine | 1811021-01 | 29 |
| Euro OTC | Tetracaine | 19009021-02 | 1 |
| Euro OTC | Tetracaine | 1903001-02 | 1 |
| Euro OTC | Tetracaine | 1903004 | 2 |
| Euro OTC | Tetracaine | 190300401 | 1 |
| Euro OTC | Tetracaine | 1903004-01 | 22 |
| Euro OTC | Tetracaine | 1903004-02 | 3 |
| Euro OTC | Tetracaine | 1903004-03 | 2 |
| Euro OTC | Tetracaine | 1909021-01 | 31 |
| Euro OTC | Tetracaine | 1909021-02 | 1 |
| Euro OTC | Tetracaine | 1909021-21 | 2 |
| Euro OTC | Tetracaine | 19K04-F07 | 1 |
| Euro OTC | Tetracaine | 19K04-F07-368617 | 1 |
| Euro OTC | Tetracaine | 2107010-01 | 26 |
| Euro OTC | Tetracaine | 2107070-01 | 2 |
| Euro OTC | Tetracaine | 2203018-01 | 30 |
| Euro OTC | Tetracaine | 2203018-02 | 24 |
| Euro OTC | Tetracaine | 2203018-16 | 1 |
| Euro OTC | Tetracaine | 2304012-01 | 2 |
| Euro OTC | Tetracaine | 2304012-02 | 1 |
| Euro OTC | Tetracaine | 2401016-01 | 1 |
| Euro OTC | Tetracaine | 2401016-02 | 1 |
| Euro OTC | Tetracaine | 3081701 | 1 |
| Euro OTC | Tetracaine | TC0010118 | 1 |
| Euro OTC | Tetracaine | TC0041018 | 1 |
| Euro OTC | Tetracaine | TC0091115 | 1 |
| Euro/Noweda | Tetracaine | 1805019-01 | 2 |
| Euro/Phönix | Tetracaine | 1903004-02 | 1 |
| Fag | Tetracaine | 16A13-B07-322947 | 1 |
| Fagro/Noweda | Tetracaine | 19A15-B01-361269 | 1 |
| Fagron | Tetracaine | | 2 |
| Fagron | Tetracaine | 11D07-N20 | 1 |
| Fagron | Tetracaine | 11G12-N13 | 3 |
| Fagron | Tetracaine | 11l01-N09 | 1 |
| Fagron | Tetracaine | 11L09-N03 | 3 |
| Fagron | Tetracaine | 12F26-NO5 | 1 |
| Fagron | Tetracaine | 12f29-n05 | 1 |
| Fagron | Tetracaine | 12F29-N05 | 7 |
| Fagron | Tetracaine | 12H23-N07 | 1 |
| Fagron | Tetracaine | 12L19-N10 | 5 |
| Fagron | Tetracaine | 13D30-N11 | 2 |
| Fagron | Tetracaine | 14A16-B04 | 1 |
| Fagron | Tetracaine | 14A16-B04-2490207 | 1 |
| Fagron | Tetracaine | 14a16-b04-290208 | 1 |
| Fagron | Tetracaine | 14A16-B04-290208 | 3 |
| Fagron | Tetracaine | 14A16-B04-290209 | 1 |
| Fagron | Tetracaine | 14A16-B04-292916 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tetracaine | 14G30-B08 | 2 |
| Fagron | Tetracaine | 14g30-b08-297305 | 1 |
| Fagron | Tetracaine | 14G30-B08-297305 | 1 |
| Fagron | Tetracaine | 14g30-b08-297306 | 1 |
| Fagron | Tetracaine | 14G30-B08-297306 | 2 |
| Fagron | Tetracaine | 14G30-B08-297307 | 1 |
| Fagron | Tetracaine | 14K03-B02 | 1 |
| Fagron | Tetracaine | 14k03-b02-303178 | 1 |
| Fagron | Tetracaine | 14K03B02303178 | 1 |
| Fagron | Tetracaine | 14K03-B02-303178 | 1 |
| Fagron | Tetracaine | 14K03-B02-303179 | 2 |
| Fagron | Tetracaine | 15/16-B06-312783 | 2 |
| Fagron | Tetracaine | 15/16-B06-316260 | 1 |
| Fagron | Tetracaine | 1516-B06-316259 | 1 |
| Fagron | Tetracaine | 1516-B06-316260 | 1 |
| Fagron | Tetracaine | 15D01-B03-306258 | 3 |
| Fagron | Tetracaine | 15G30-B04-312060 | 1 |
| Fagron | Tetracaine | 16A13-B07-318736 | 5 |
| Fagron | Tetracaine | 16A13-B07-322947 | 2 |
| Fagron | Tetracaine | 16E23-B04-323269 | 1 |
| Fagron | Tetracaine | 16G29-B02-325569 | 4 |
| Fagron | Tetracaine | 16G29B02325570 | 2 |
| Fagron | Tetracaine | 16G29-B02-325570 | 1 |
| Fagron | Tetracaine | 16J12-B06 | 1 |
| Fagron | Tetracaine | 16J12-B06-327371 | 1 |
| Fagron | Tetracaine | 16J12-B06-329087 | 2 |
| Fagron | Tetracaine | 17184083 | 2 |
| Fagron | Tetracaine | 17E18-B02-337216 | 3 |
| Fagron | Tetracaine | 17E18-B02-337217 | 2 |
| Fagron | Tetracaine | 17K13-B02 | 1 |
| Fagron | Tetracaine | 17K13-B02-34172 | 1 |
| Fagron | Tetracaine | 17K13-B02-344448 | 7 |
| Fagron | Tetracaine | 17K13-B02-347172 | 7 |
| Fagron | Tetracaine | 18104050 | 1 |
| Fagron | Tetracaine | 18C26-B01-350472 | 1 |
| Fagron | Tetracaine | 19A15-B01 | 2 |
| Fagron | Tetracaine | 19A15-B010 | 2 |
| Fagron | Tetracaine | 19A15-B01-361263 | 2 |
| Fagron | Tetracaine | 19A15-B01-361269 | 5 |
| Fagron | Tetracaine | 19K04-F0-366996 | 1 |
| Fagron | Tetracaine | 19K04-F07 | 2 |
| Fagron | Tetracaine | 19K04-F07-0366996 | 1 |
| Fagron | Tetracaine | 19K04-F07-366996 | 4 |
| Fagron | Tetracaine | 19K04-F07-3669966 | 1 |
| Fagron | Tetracaine | 19K04-F07-368617 | 2 |
| Fagron | Tetracaine | 19K04-F07-369725 | 2 |
| Fagron | Tetracaine | 20E20-F06 | 3 |
| Fagron | Tetracaine | 20E20-F06-371444 | 3 |
| Fagron | Tetracaine | 20H28-U01-009031 | 1 |
| Fagron | Tetracaine | 20K16-F03-376067 | 1 |
| Fagron | Tetracaine | 21G10-B23-213654 | 1 |
| Fagron | Tetracaine | 21G10-B23-216782 | 5 |
| Fagron | Tetracaine | 21L22-B01-215564 | 3 |
| Fagron | Tetracaine | 21L22-B01-216874 | 1 |
| Fagron | Tetracaine | 2913Q-07165 | 1 |
| Fagron | Tetracaine | 3465093 | 1 |
| Fagron | Tetracaine | 5111202 | 1 |
| Fagron | Tetracaine | 9K04-F07-369725 | 1 |
| Fagron | Tetracaine | F07-3697205 | 1 |
| Fagron | Tetracaine | TC0041018 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tetracaine | TC0070716 | 1 |
| Fagron | Tetracaine | TC0090913 | 2 |
| Fagron | Tetracaine | TC0140719 | 2 |
| Fargon/AHD | Tetracaine | 17K13-B02-347172 | 1 |
| Fargon/Gehe | Tetracaine | 18C26-B01-350472 | 1 |
| Fargon/Gehe | Tetracaine | 18c26-B01-355789 | 1 |
| Fragon/ Gehe | Tetracaine | 18C26-B01-350472 | 1 |
| Fragon/ Phönix | Tetracaine | 19a15b01361263 | 1 |
| GEHE 02.05.2014 | Tetracaine | 14A16-B04-290208 | 2 |
| GEHE 04.05 | Tetracaine | 1405025-01 | 1 |
| GEHE | Tetracaine | 16G29-B02-325569 | 1 |
| Gehe | Tetracaine | 170103501 | 1 |
| Gehe | Tetracaine | 1805019-01 | 2 |
| Gehe | Tetracaine | 1811021-01 | 1 |
| GEHE | Tetracaine | 18C26-B01 | 1 |
| Gehe | Tetracaine | 21L22-B01-222760 | 1 |
| gehe | Tetracaine | 21L22-B01-222760 | 2 |
| Gehe | Tetracaine | 2304012-01 | 1 |
| Gehe-Berlin | Tetracaine | 2401016-01 | 2 |
| Geilenkirchen | Tetracaine | 1805019-01 | 2 |
| Hepart | Tetracaine | 15G30-B04-310590 | 1 |
| Jenne | Tetracaine | 2203018-02 | 1 |
| Noweda, EuRho | Tetracaine | 2203018-01 | 1 |
| Noweda/Fargon | Tetracaine | 16/12-B06-329087 | 1 |
| Noweda | Tetracaine | 21G10-B23-221083 | 1 |
| Noweda | Tetracaine | 2304012-02 | 1 |
| Phoenix 07.10.14 | Tetracaine | 14A16-B04-292916 | 1 |
| Phoenix Goettin | Tetracaine | 14G30-B08-297306 | 1 |
| phoenix | Tetracaine | 14A16B04290207 | 2 |
| Phoenix | Tetracaine | 1811021-01 | 1 |
| Phoenix | Tetracaine | 1909021-01 | 2 |
| Phoenix | Tetracaine | 19A15-B01-361269 | 3 |
| Phoenix | Tetracaine | 19k04-f07366996 | 1 |
| Phoenix | Tetracaine | 19k04-f07-366996 | 1 |
| Phoenix | Tetracaine | 19k04-f07369725 | 1 |
| Phoenix | Tetracaine | 20e20-f06-371444 | 1 |
| Phoenix | Tetracaine | 3118 | 1 |
| Phönix Gotha | Tetracaine | 10F11N04 | 1 |
| Phönix | Tetracaine | 11g12-n13 | 1 |
| Phönix | Tetracaine | 1303018-01 | 1 |
| Phönix | Tetracaine | 1312034-01 | 2 |
| Phönix | Tetracaine | 1708024-01 | 2 |
| PHÖNIX | Tetracaine | 20003786004 | 1 |
| Phönix | Tetracaine | 2203018 | 1 |
| Phönix | Tetracaine | 2304012-01 | 1 |
| Phönix | Tetracaine | 3465093 | 1 |
| Rondell Apotheke | Tetracaine | 1312034-01 | 1 |
| Sanacorp | Tetracaine | 1803002-01 | 1 |
| Sanacorp | Tetracaine | 1805019-01 | 1 |
| sanacorp | Tetracaine | 2203018-02 | 1 |
| Sanacorp | Tetracaine | 2304012-01 | 2 |
| Sanacorp | Tetracaine | 2308016-01 | 2 |
| Sanacorp | Tetracaine | 2401016-01 | 2 |
| Sanacorp | Tetracaine | 2401016-02 | 1 |
| Sanacorp | Tetracaine | F07-3669906 | 1 |
| Sanacorp | Tetracaine | TC0040123 | 2 |
| Siegfried / Gehe | Tetracaine | 18C26-B01-350472 | 1 |
| siehe Lennartz | Tetracaine | sieheLennartz | 1 |
| tetracain | Tetracaine | 1903004-03 | 1 |



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- 256 223 spectra from 1666 *Apo-Ident* customers from a total of 51 976 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tetracaine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tetracaine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 445 | 0 | 157 881 |
| **Type B** | 0 | 620 | 0 | 212 320 |
| **Type C** | 0 | 663 | 0 | 256 223 |

The substance/substance group *Tetracaine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6517 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0323 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 99.0950 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20947 | 21603 | 10.05 | 162.98 |
| 21603 | 21603 | 0.00 | 161.46 |
| 21650 | 22299 | 6.25 | 164.52 |
| 21659 | 21603 | 7.08 | 164.85 |
| 22299 | 22299 | 0.00 | 164.59 |
| 23321 | 23321 | 0.00 | 164.69 |
| 24255 | 24255 | 0.00 | 163.95 |
| 26081 | 24255 | 10.79 | 164.03 |
| 26661 | 26661 | 0.00 | 161.72 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tetracaine hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20037-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tetracaine hydrochloride; Tetracaini hydrochloridum

### Special notes

When selecting the *Tetracaine hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tetracaine hydrochloride | 9 | 20 | 407 |

### Second-stage model

For differentiation of the substance/substance group *Tetracaine hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tetracaine hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 167.50 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tetracaine hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tetracaine hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Tetracaine hydrochloride | 12019822 | 20924 | 40 | 20120228 |
| Caelo | Tetracaine hydrochloride | 15437108 | 23163 | 40 | 20160211 |
| Caelo | Tetracaine hydrochloride | 24003019 | 27559 | 40 | 20250228* |
| Euro OTC | Tetracaine hydrochloride | 1506040 | 21845 | 60 | 20150713* |
| Euro OTC | Tetracaine hydrochloride | 1512019 | 22285 | 45 | 20151228* |
| Euro OTC | Tetracaine hydrochloride | 1612005 | 22912 | 40 | 20170112* |
| Euro OTC | Tetracaine hydrochloride | 1807017 | 24141 | 40 | 20180730* |
| Fagron | Tetracaine hydrochloride | 15K04-B03-322151 | 23162 | 40 | 20160112 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-327368 | 23500 | 40 | 20160826 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 385 spectra of 9 reference samples from the substance/substance group *Tetracaine hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 941 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 930 spectra of 27 reference samples from the substance/substance group *Tetracaine hydrochloride*.

- Among them are spectra of independent samples from 20 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Tetracaine hydrochloride | 190119 | 24561 | 40 |
| Caelo | Tetracaine hydrochloride | 22001496 | 26239 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1607031 | 22708 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1706018 | 23558 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1712012 | 23886 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1310006 | 23910 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1803001 | 24079 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1812006 | 24448 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1902015 | 24452 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1907007 | 24783 | 40 |
| Euro OTC | Tetracaine hydrochloride | 1909024 | 24974 | 40 |
| Euro OTC | Tetracaine hydrochloride | 2001011 | 25105 | 40 |
| Euro OTC | Tetracaine hydrochloride | 2003053 | 25267 | 40 |
| Euro OTC | Tetracaine hydrochloride | 2010019 | 25470 | 40 |
| Euro OTC | Tetracaine hydrochloride | 2110008 | 25885 | 50 |
| Euro OTC | Tetracaine hydrochloride | 2207015 | 26267 | 40 |
| Euro OTC | Tetracaine hydrochloride | 2307022 | 26879 | 30 |
| Euro OTC | Tetracaine hydrochloride | 2405009 | 27347 | 40 |
| Fagron | Tetracaine hydrochloride | 22J19-B01-221586 | 26551 | 40 |
| Fagron | Tetracaine hydrochloride | 24H26-B01-002406 | 27384 | 40 |
| Caelo | Tetracaine hydrochloride | 22001496 | 26239SI | 20 |
| Caelo | Tetracaine hydrochloride | 24003019 | 27559SI† | 20 |
| Euro OTC | Tetracaine hydrochloride | 2110008 | 25885SI | 10 |
| Euro OTC | Tetracaine hydrochloride | 2207015 | 26267SI | 20 |
| Euro OTC | Tetracaine hydrochloride | 2405009 | 27347SI | 20 |
| Fagron | Tetracaine hydrochloride | 22J19-B01-221586 | 26551SI | 20 |
| Fagron | Tetracaine hydrochloride | 24H26-B01-002406 | 27384SI | 20 |

- 212 010 spectra from a total of 4266 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 2230 spectra from 769 *Apo-Ident* customers from 417 batches from the substance/substance group *Tetracaine hydrochloride*.

- Among them are spectra of independent samples from 404 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tetracaine hydrochloride | 1902015-01 | 1 |
| | Tetracaine hydrochloride | 1909024-01 | 1 |
| | Tetracaine hydrochloride | 191023/6 | 1 |
| | Tetracaine hydrochloride | 2110008-01 | 3 |
| | Tetracaine hydrochloride | 21120-B04-225868 | 1 |
| | Tetracaine hydrochloride | 22001496004 | 2 |
| | Tetracaine hydrochloride | 22001496010 | 2 |
| | Tetracaine hydrochloride | 22001496014 | 1 |
| | Tetracaine hydrochloride | 22001496015 | 8 |
| | Tetracaine hydrochloride | 2201496015 | 1 |
| | Tetracaine hydrochloride | 2207015-01 | 11 |
| | Tetracaine hydrochloride | 2207015-02 | 6 |
| | Tetracaine hydrochloride | 2207015-03 | 4 |
| | Tetracaine hydrochloride | 221630 | 1 |
| | Tetracaine hydrochloride | 22J19-B01-217468 | 1 |
| | Tetracaine hydrochloride | 22J19-B01-221586 | 5 |
| | Tetracaine hydrochloride | 2307022-01 | 13 |
| | Tetracaine hydrochloride | 2307022-02 | 2 |
| | Tetracaine hydrochloride | 230702203 | 1 |
| | Tetracaine hydrochloride | 2307022-03 | 1 |
| | Tetracaine hydrochloride | 24003019003 | 2 |
| | Tetracaine hydrochloride | 2405009-01 | 13 |
| | Tetracaine hydrochloride | 2405009-01TH0080423 | 1 |
| | Tetracaine hydrochloride | 2405009-02 | 6 |
| | Tetracaine hydrochloride | 24H26-B01-002406 | 3 |
| | Tetracaine hydrochloride | 2501021-01 | 3 |
| | Tetracaine hydrochloride | TH0060322 | 1 |
| | Tetracaine hydrochloride | TH00804232405009-01 | 2 |
| | Tetracaine hydrochloride | TH0140922 | 1 |
| AHD/EuRho | Tetracaine hydrochloride | 1902015-01 | 1 |
| AHD | Tetracaine hydrochloride | 15437121 | 1 |
| AHD | Tetracaine hydrochloride | 15A12-B03-308857 | 1 |
| AHD | Tetracaine hydrochloride | 18060602 | 1 |
| AHD | Tetracaine hydrochloride | 18060614 | 1 |
| AHD | Tetracaine hydrochloride | 2307022-01 | 1 |
| AHD | Tetracaine hydrochloride | 2405009-01 | 1 |
| Alliance healfcare | Tetracaine hydrochloride | 17g03-b07-351509 | 1 |
| Alliance Health 05.0... | Tetracaine hydrochloride | 13H21-B02-286559 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance Health 22.0... | Tetracaine hydrochloride | 1303012-01 | 2 |
| Alliance Health 22.0... | Tetracaine hydrochloride | 6093549 | 1 |
| Alliance Health | Tetracaine hydrochloride | 14C18-B03-293967 | 1 |
| Alliance Healthcare | Tetracaine hydrochloride | 12H24-N05 | 1 |
| Alliance | Tetracaine hydrochloride | 20004176020 | 1 |
| Alliance | Tetracaine hydrochloride | 220715-02 | 1 |
| Anzag | Tetracaine hydrochloride | 1411019-01 | 1 |
| Anzag | Tetracaine hydrochloride | 14710369 | 1 |
| Anzag | Tetracaine hydrochloride | 1607031-01 | 3 |
| Anzag | Tetracaine hydrochloride | 17256705 | 1 |
| Anzag | Tetracaine hydrochloride | 2405009-01 | 1 |
| apo-ident | Tetracaine hydrochloride | 1706018-01 | 1 |
| Apolda/Gehe | Tetracaine hydrochloride | 1909024 | 1 |
| BASF Fine Chemicals ... | Tetracaine hydrochloride | 13155714 | 1 |
| BASF Pharma S.A. | Tetracaine hydrochloride | 1310006-01 | 1 |
| BASF Pharma S.A. | Tetracaine hydrochloride | 1409026-02 | 1 |
| BASF Pharma | Tetracaine hydrochloride | 1411019-01 | 1 |
| BASF | Tetracaine hydrochloride | 13K25-B04-290277 | 1 |
| BASF | Tetracaine hydrochloride | 14C18-B03-293967 | 1 |
| Bombastus | Tetracaine hydrochloride | 13H21-B02-286558 | 1 |
| Bombastus | Tetracaine hydrochloride | 1712012-01 | 2 |
| cae | Tetracaine hydrochloride | 17256703 | 4 |
| Caelo | Tetracaine hydrochloride | 10118210 | 2 |
| Caelo | Tetracaine hydrochloride | 10118211 | 1 |
| Caelo | Tetracaine hydrochloride | 10118225 | 4 |
| Caelo | Tetracaine hydrochloride | 1110010-01 | 1 |
| Caelo | Tetracaine hydrochloride | 1110010-02 | 2 |
| Caelo | Tetracaine hydrochloride | 1110010-07 | 1 |
| Caelo | Tetracaine hydrochloride | 12019802 | 5 |
| Caelo | Tetracaine hydrochloride | 12019810 | 5 |
| Caelo | Tetracaine hydrochloride | 12019812 | 3 |
| Caelo | Tetracaine hydrochloride | 12019815 | 1 |
| Caelo | Tetracaine hydrochloride | 12019816 | 9 |
| Caelo | Tetracaine hydrochloride | 12019820 | 1 |
| Caelo | Tetracaine hydrochloride | 12019822 | 6 |
| Caelo | Tetracaine hydrochloride | 1207001-01 | 1 |
| Caelo | Tetracaine hydrochloride | 1260917/15437119 | 1 |
| Caelo | Tetracaine hydrochloride | 12H24-N05 | 3 |
| Caelo | Tetracaine hydrochloride | 1303012-01 | 3 |
| Caelo | Tetracaine hydrochloride | 1310006-01 | 1 |
| Caelo | Tetracaine hydrochloride | 1310006-02 | 1 |
| Caelo | Tetracaine hydrochloride | 1313012-01 | 1 |
| Caelo | Tetracaine hydrochloride | 13155703 | 1 |
| Caelo | Tetracaine hydrochloride | 13155705 | 3 |
| Caelo | Tetracaine hydrochloride | 13155706 | 10 |
| Caelo | Tetracaine hydrochloride | 13155711 | 7 |
| Caelo | Tetracaine hydrochloride | 13155714 | 2 |
| Caelo | Tetracaine hydrochloride | 13155716 | 2 |
| Caelo | Tetracaine hydrochloride | 13155720 | 2 |
| Caelo | Tetracaine hydrochloride | 13155724 | 4 |
| Caelo | Tetracaine hydrochloride | 13155727 | 6 |
| Caelo | Tetracaine hydrochloride | 13K25-B04-290276 | 1 |
| Caelo | Tetracaine hydrochloride | 1405026-01 | 1 |
| Caelo | Tetracaine hydrochloride | 1409026-01 | 2 |
| Caelo | Tetracaine hydrochloride | 1409026-02 | 1 |
| Caelo | Tetracaine hydrochloride | 1411019-01 | 4 |
| Caelo | Tetracaine hydrochloride | 14c18-b03-293966 | 1 |
| Caelo | Tetracaine hydrochloride | 14C18-B03-300199 | 1 |
| Caelo | Tetracaine hydrochloride | 14C18-B03-300200 | 4 |
| Caelo | Tetracaine hydrochloride | 14G14-B08 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tetracaine hydrochloride | 14G14-B08-300198 | 1 |
| Caelo | Tetracaine hydrochloride | 15/16-B06-312783 | 1 |
| Caelo | Tetracaine hydrochloride | 150604001 | 1 |
| Caelo | Tetracaine hydrochloride | 1506040-01 | 2 |
| Caelo | Tetracaine hydrochloride | 150604002 | 1 |
| Caelo | Tetracaine hydrochloride | 15079501 | 2 |
| Caelo | Tetracaine hydrochloride | 15079507 | 1 |
| Caelo | Tetracaine hydrochloride | 1508040-01 | 1 |
| Caelo | Tetracaine hydrochloride | 1512019-01 | 5 |
| Caelo | Tetracaine hydrochloride | 1512019-02 | 1 |
| Caelo | Tetracaine hydrochloride | 15196102 | 5 |
| Caelo | Tetracaine hydrochloride | 15196103 | 6 |
| Caelo | Tetracaine hydrochloride | 15196104 | 2 |
| Caelo | Tetracaine hydrochloride | 15356902 | 2 |
| Caelo | Tetracaine hydrochloride | 1537109 | 1 |
| Caelo | Tetracaine hydrochloride | 15437102 | 1 |
| Caelo | Tetracaine hydrochloride | 15437104 | 14 |
| Caelo | Tetracaine hydrochloride | 15437106 | 3 |
| Caelo | Tetracaine hydrochloride | 15437107 | 2 |
| Caelo | Tetracaine hydrochloride | 15437108 | 4 |
| Caelo | Tetracaine hydrochloride | 15437109 | 12 |
| Caelo | Tetracaine hydrochloride | 15437114 | 12 |
| Caelo | Tetracaine hydrochloride | 15437117 | 6 |
| Caelo | Tetracaine hydrochloride | 15437118 | 2 |
| Caelo | Tetracaine hydrochloride | 15437119 | 18 |
| Caelo | Tetracaine hydrochloride | 15437120 | 2 |
| Caelo | Tetracaine hydrochloride | 15437121 | 10 |
| Caelo | Tetracaine hydrochloride | 15437122 | 3 |
| Caelo | Tetracaine hydrochloride | 15H24-B03-311450 | 3 |
| Caelo | Tetracaine hydrochloride | 15K04-B03-318368 | 2 |
| Caelo | Tetracaine hydrochloride | 15K04-B03-318369 | 1 |
| Caelo | Tetracaine hydrochloride | 15K04-B03-322151 | 2 |
| Caelo | Tetracaine hydrochloride | 15K04-B03-328163 | 1 |
| Caelo | Tetracaine hydrochloride | 1607031-01 | 6 |
| Caelo | Tetracaine hydrochloride | 161200501 | 1 |
| Caelo | Tetracaine hydrochloride | 1612005-01 | 3 |
| Caelo | Tetracaine hydrochloride | 16G25-B03-332099 | 1 |
| Caelo | Tetracaine hydrochloride | 16G28-B03-327368 | 4 |
| Caelo | Tetracaine hydrochloride | 16G28-B03-332099 | 2 |
| Caelo | Tetracaine hydrochloride | 170601801 | 1 |
| Caelo | Tetracaine hydrochloride | 1706018-01 | 1 |
| Caelo | Tetracaine hydrochloride | 17114181 | 1 |
| Caelo | Tetracaine hydrochloride | 171201201 | 1 |
| Caelo | Tetracaine hydrochloride | 1712012-01 | 3 |
| Caelo | Tetracaine hydrochloride | 17256703 | 2 |
| Caelo | Tetracaine hydrochloride | 17256704 | 5 |
| Caelo | Tetracaine hydrochloride | 17256705 | 9 |
| Caelo | Tetracaine hydrochloride | 17G03-B07 | 1 |
| Caelo | Tetracaine hydrochloride | 17G03-B07-338538 | 2 |
| Caelo | Tetracaine hydrochloride | 17G03-B07-345008 | 2 |
| Caelo | Tetracaine hydrochloride | 17G03-B07-346693 | 1 |
| Caelo | Tetracaine hydrochloride | 1803001-01 | 11 |
| Caelo | Tetracaine hydrochloride | 1805019-01 | 1 |
| Caelo | Tetracaine hydrochloride | 18060602 | 20 |
| Caelo | Tetracaine hydrochloride | 18060603 | 6 |
| Caelo | Tetracaine hydrochloride | 18060604 | 4 |
| Caelo | Tetracaine hydrochloride | 18060606 | 1 |
| Caelo | Tetracaine hydrochloride | 18060609 | 2 |
| Caelo | Tetracaine hydrochloride | 18060610 | 1 |
| Caelo | Tetracaine hydrochloride | 18060612 | 11 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tetracaine hydrochloride | 18060613 | 1 |
| Caelo | Tetracaine hydrochloride | 18060614 | 5 |
| Caelo | Tetracaine hydrochloride | 18060619 | 2 |
| Caelo | Tetracaine hydrochloride | 18060620 | 8 |
| Caelo | Tetracaine hydrochloride | 18060621 | 3 |
| Caelo | Tetracaine hydrochloride | 18120006-01 | 1 |
| Caelo | Tetracaine hydrochloride | 1812006-01 | 3 |
| Caelo | Tetracaine hydrochloride | 18J03-B05 | 2 |
| Caelo | Tetracaine hydrochloride | 18J03-B05-361978 | 2 |
| Caelo | Tetracaine hydrochloride | 1901190002 | 1 |
| Caelo | Tetracaine hydrochloride | 190119001 | 9 |
| Caelo | Tetracaine hydrochloride | 190119002 | 3 |
| Caelo | Tetracaine hydrochloride | 190119003 | 1 |
| Caelo | Tetracaine hydrochloride | 19011901 | 7 |
| Caelo | Tetracaine hydrochloride | 19011903 | 8 |
| Caelo | Tetracaine hydrochloride | 19011903P-190909-2 | 1 |
| Caelo | Tetracaine hydrochloride | 19011906 | 3 |
| Caelo | Tetracaine hydrochloride | 19011907 | 10 |
| Caelo | Tetracaine hydrochloride | 19011908 | 9 |
| Caelo | Tetracaine hydrochloride | 20000156001 | 5 |
| Caelo | Tetracaine hydrochloride | 20000156002 | 1 |
| Caelo | Tetracaine hydrochloride | 20000156003 | 5 |
| Caelo | Tetracaine hydrochloride | 20000156005 | 7 |
| Caelo | Tetracaine hydrochloride | 20000156006 | 4 |
| Caelo | Tetracaine hydrochloride | 20000156008 | 7 |
| Caelo | Tetracaine hydrochloride | 200004176002 | 1 |
| Caelo | Tetracaine hydrochloride | 2000156003 | 1 |
| Caelo | Tetracaine hydrochloride | 2000156005 | 1 |
| Caelo | Tetracaine hydrochloride | 2000156008 | 1 |
| Caelo | Tetracaine hydrochloride | 20004176003 | 9 |
| Caelo | Tetracaine hydrochloride | 20004176004 | 8 |
| Caelo | Tetracaine hydrochloride | 20004176006 | 4 |
| Caelo | Tetracaine hydrochloride | 20004176007 | 1 |
| Caelo | Tetracaine hydrochloride | 20004176008 | 9 |
| Caelo | Tetracaine hydrochloride | 20004176011 | 2 |
| Caelo | Tetracaine hydrochloride | 20004176012 | 3 |
| Caelo | Tetracaine hydrochloride | 20004176013 | 3 |
| Caelo | Tetracaine hydrochloride | 20004176015 | 4 |
| Caelo | Tetracaine hydrochloride | 20004176016 | 2 |
| Caelo | Tetracaine hydrochloride | 20004176019 | 3 |
| Caelo | Tetracaine hydrochloride | 20004176020 | 4 |
| Caelo | Tetracaine hydrochloride | 20004176021 | 2 |
| Caelo | Tetracaine hydrochloride | 200047176004 | 1 |
| Caelo | Tetracaine hydrochloride | 2003053-01 | 1 |
| Caelo | Tetracaine hydrochloride | 20G10F07373352 | 1 |
| Caelo | Tetracaine hydrochloride | 2110008-01 | 1 |
| Caelo | Tetracaine hydrochloride | 22001496003 | 7 |
| Caelo | Tetracaine hydrochloride | 22001496004 | 4 |
| Caelo | Tetracaine hydrochloride | 22001496005 | 2 |
| Caelo | Tetracaine hydrochloride | 22001496010 | 6 |
| Caelo | Tetracaine hydrochloride | 2200701501 | 1 |
| Caelo | Tetracaine hydrochloride | 2201496004 | 1 |
| Caelo | Tetracaine hydrochloride | 221496003 | 1 |
| Caelo | Tetracaine hydrochloride | 259/22 | 1 |
| Caelo | Tetracaine hydrochloride | 27111305 | 1 |
| Caelo | Tetracaine hydrochloride | 4176002 | 1 |
| Caelo | Tetracaine hydrochloride | 6093549 | 1 |
| Caelo | Tetracaine hydrochloride | 700216-0001 | 1 |
| Caelo | Tetracaine hydrochloride | 9070003 | 2 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 20004176003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 22001496010 | 2 |
| Caesar & Loretz GmbH/E | Tetracaine hydrochloride | 20004176003 | 1 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | F10-3708006 | 1 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | TH0060219 | 1 |
| Caesar & Loretz GmbH/Gehe | Tetracaine hydrochloride | 190119001 | 1 |
| Caesar & Loretz GmbH/Gehe | Tetracaine hydrochloride | 1909024-02 | 2 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 19011901 | 4 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 19011908 | 2 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 18060614 | 1 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 18060621 | 1 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 20000156002 | 1 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 18060619 | 1 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 18060620 | 1 |
| Caesar & Loretz GmbH... | Tetracaine hydrochloride | 190119002 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 17G03-B07-351509 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 18060604 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 18060610 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 18060612 | 4 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 18060619 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 18060621 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 190119001 | 3 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 190119002 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 190119003 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 19011901 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 19011902 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 19011903 | 5 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 19011906 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 19011907 | 5 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 19011908 | 5 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20000156001 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20000156002 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20000156005 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20000156006 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20000156008 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176003 | 5 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176004 | 6 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176006 | 4 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176007 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176011 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176012 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176013 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176015 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176019 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 20004176020 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 22001496004 | 1 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | 22001496010 | 2 |
| Caesar & Loretz GmbH | Tetracaine hydrochloride | TH0100718 | 1 |
| Caesar & Loretz | Tetracaine hydrochloride | 1803001-01 | 1 |
| Caesar & Loretz | Tetracaine hydrochloride | 18060609 | 1 |
| Caesar Loretz | Tetracaine hydrochloride | 190229001 | 1 |
| Caesar Loretz | Tetracaine hydrochloride | 20000156006 | 1 |
| Calo/AHD | Tetracaine hydrochloride | 13155727 | 1 |
| Ebert-Jacobi | Tetracaine hydrochloride | 15K04-B03-328163 | 1 |
| Ebert-Jacobi | Tetracaine hydrochloride | 1612005-01 | 1 |
| EuRho / Fiebig | Tetracaine hydrochloride | 2010019-01 | 1 |
| EuRho Anzag | Tetracaine hydrochloride | 1207001-01 | 1 |
| EuRho/ NOWEDA | Tetracaine hydrochloride | 14G14-B08-300198 | 1 |
| EuRho/ Noweda | Tetracaine hydrochloride | 1803001-01 | 3 |
| EuRho/ Phönix | Tetracaine hydrochloride | 1612002-01 | 1 |
| EuRho/AHD | Tetracaine hydrochloride | 1909024-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho/AHD | Tetracaine hydrochloride | 2010019-02 | 1 |
| EuRho/Alliance | Tetracaine hydrochloride | 2001011-01 | 1 |
| EuRho/Gehe | Tetracaine hydrochloride | 1909024-01 | 1 |
| EuRho/Noweda | Tetracaine hydrochloride | 1706018-01 | 1 |
| euRho/Noweda | Tetracaine hydrochloride | 2010019-02 | 1 |
| EuRho/Phoenix | Tetracaine hydrochloride | 2110008-01 | 2 |
| Eurho/Phönix | Tetracaine hydrochloride | 2003053-01 | 1 |
| Eurho/Phönix | Tetracaine hydrochloride | 2010019-01 | 1 |
| Eurho/Phönix | Tetracaine hydrochloride | 211000801 | 1 |
| EuRho/Sanacorp | Tetracaine hydrochloride | 1909024-02 | 1 |
| EuRho/Sanacorp | Tetracaine hydrochloride | 2001011-01 | 1 |
| EuRho | Tetracaine hydrochloride | 1106035-01 | 2 |
| EuRho | Tetracaine hydrochloride | 1110010-01 | 2 |
| EuRho | Tetracaine hydrochloride | 1110010-02 | 1 |
| EuRho | Tetracaine hydrochloride | 1615I-02039 | 1 |
| EuRho | Tetracaine hydrochloride | 1712012-01 | 2 |
| euRho | Tetracaine hydrochloride | 1803001-01 | 1 |
| EuRho | Tetracaine hydrochloride | 1803001-01 | 1 |
| EuRho | Tetracaine hydrochloride | 1902015-01 | 1 |
| EuRho | Tetracaine hydrochloride | 1909024-02 | 2 |
| EuRho | Tetracaine hydrochloride | 2001011-01 | 1 |
| EuRho | Tetracaine hydrochloride | 2003053-01 | 3 |
| EuRho | Tetracaine hydrochloride | 2010019-01 | 3 |
| Eurho | Tetracaine hydrochloride | 2110008-01 | 1 |
| EuRho | Tetracaine hydrochloride | 2207015-01 | 1 |
| EuRho | Tetracaine hydrochloride | 2906009V-04 | 1 |
| EuRho | Tetracaine hydrochloride | TH0060219 | 1 |
| Euro CT Phönix | Tetracaine hydrochloride | 1207001-02 | 1 |
| Euro ETC / Phönix | Tetracaine hydrochloride | 2110008-01 | 1 |
| Euro OT/Phönix | Tetracaine hydrochloride | TH0030315 | 1 |
| Euro OTC | Tetracaine hydrochloride | | 1 |
| Euro OTC | Tetracaine hydrochloride | 1011-012 | 1 |
| Euro OTC | Tetracaine hydrochloride | 10416THCL | 1 |
| Euro OTC | Tetracaine hydrochloride | 1106035 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1106035-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1110010-01 | 5 |
| Euro OTC | Tetracaine hydrochloride | 1110010-02 | 6 |
| Euro OTC | Tetracaine hydrochloride | 11110010-02 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1207001-01 | 8 |
| Euro OTC | Tetracaine hydrochloride | 1207001-02 | 8 |
| Euro OTC | Tetracaine hydrochloride | 130301201 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1303012-01 | 19 |
| Euro OTC | Tetracaine hydrochloride | 1310006-01 | 18 |
| Euro OTC | Tetracaine hydrochloride | 1310006-02 | 2 |
| Euro OTC | Tetracaine hydrochloride | 13155710 | 4 |
| Euro OTC | Tetracaine hydrochloride | 13509155 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1404026-02 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1405025-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 140502601 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1405026-01 | 18 |
| Euro OTC | Tetracaine hydrochloride | 1405026-02 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1405026-04 | 6 |
| Euro OTC | Tetracaine hydrochloride | 1409026 | 1 |
| Euro OTC | Tetracaine hydrochloride | 14090-26 | 1 |
| Euro OTC | Tetracaine hydrochloride | 140902601 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1409026-01 | 10 |
| Euro OTC | Tetracaine hydrochloride | 140902602 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1409026-02 | 14 |
| Euro OTC | Tetracaine hydrochloride | 1411019 | 1 |
| Euro OTC | Tetracaine hydrochloride | 141101901 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Tetracaine hydrochloride | 1411019-01 | 26 |
| Euro OTC | Tetracaine hydrochloride | 14G14-B08-300202 | 1 |
| Euro OTC | Tetracaine hydrochloride | 150604001 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1506040-01 | 29 |
| Euro OTC | Tetracaine hydrochloride | 1506040-02 | 7 |
| Euro OTC | Tetracaine hydrochloride | 15120019-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 151201901 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1512019-01 | 30 |
| Euro OTC | Tetracaine hydrochloride | 151-2019-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1512019-02 | 2 |
| Euro OTC | Tetracaine hydrochloride | 1603026-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1607031 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1607031_01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 160703101 | 2 |
| Euro OTC | Tetracaine hydrochloride | 1607031-01 | 38 |
| Euro OTC | Tetracaine hydrochloride | 1607032-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 161200501 | 4 |
| Euro OTC | Tetracaine hydrochloride | 1612005-01 | 38 |
| Euro OTC | Tetracaine hydrochloride | 1612005-015445 | 1 |
| Euro OTC | Tetracaine hydrochloride | 170323181 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1706018-01 | 22 |
| Euro OTC | Tetracaine hydrochloride | 17081503 | 1 |
| Euro OTC | Tetracaine hydrochloride | 17114181 | 1 |
| Euro OTC | Tetracaine hydrochloride | 171201201 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1712012-01 | 28 |
| Euro OTC | Tetracaine hydrochloride | 171212-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 18003001-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1803001 | 1 |
| Euro OTC | Tetracaine hydrochloride | 180300101 | 10 |
| Euro OTC | Tetracaine hydrochloride | 1803001-01 | 50 |
| Euro OTC | Tetracaine hydrochloride | 1803001-1 | 1 |
| Euro OTC | Tetracaine hydrochloride | 180701701 | 2 |
| Euro OTC | Tetracaine hydrochloride | 1807017-01 | 8 |
| Euro OTC | Tetracaine hydrochloride | 18120006-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1812006 | 2 |
| Euro OTC | Tetracaine hydrochloride | 181200601 | 2 |
| Euro OTC | Tetracaine hydrochloride | 1812006-01 | 33 |
| Euro OTC | Tetracaine hydrochloride | 18701701 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1902012-01 | 2 |
| Euro OTC | Tetracaine hydrochloride | 1902015 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1902015-01 | 33 |
| Euro OTC | Tetracaine hydrochloride | 1907007 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1907007-01 | 14 |
| Euro OTC | Tetracaine hydrochloride | 1909024_01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1909024-0 | 1 |
| Euro OTC | Tetracaine hydrochloride | 190902401 | 1 |
| Euro OTC | Tetracaine hydrochloride | 1909024-01 | 74 |
| Euro OTC | Tetracaine hydrochloride | 1909024-02 | 17 |
| Euro OTC | Tetracaine hydrochloride | 1909024-21 | 1 |
| Euro OTC | Tetracaine hydrochloride | 19909024-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 20010019-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2001011-01 | 16 |
| Euro OTC | Tetracaine hydrochloride | 2003053 | 1 |
| Euro OTC | Tetracaine hydrochloride | 200305301 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2003053-01 | 39 |
| Euro OTC | Tetracaine hydrochloride | 2003053-02 | 4 |
| Euro OTC | Tetracaine hydrochloride | 2003053-03 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2010010-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2010019-01 | 47 |
| Euro OTC | Tetracaine hydrochloride | 2010019-02 | 21 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Tetracaine hydrochloride | 2010091-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 201019-02 | 1 |
| Euro OTC | Tetracaine hydrochloride | 20160812-2 | 1 |
| Euro OTC | Tetracaine hydrochloride | 21071807 | 1 |
| Euro OTC | Tetracaine hydrochloride | 21100008-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2110008-01 | 32 |
| Euro OTC | Tetracaine hydrochloride | 211008-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2207015-01 | 5 |
| Euro OTC | Tetracaine hydrochloride | 2207015-02 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2307022-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 2405009-01 | 1 |
| Euro OTC | Tetracaine hydrochloride | 24102014A | 1 |
| Euro OTC | Tetracaine hydrochloride | 2906009V-03 | 1 |
| Euro OTC | Tetracaine hydrochloride | 3071716 | 1 |
| Euro OTC | Tetracaine hydrochloride | 3113M-02039 | 1 |
| Euro OTC | Tetracaine hydrochloride | 4811A-02039 | 1 |
| Euro OTC | Tetracaine hydrochloride | 5016Y-02039 | 1 |
| Euro OTC | Tetracaine hydrochloride | 6093547 | 1 |
| Euro OTC | Tetracaine hydrochloride | Euro-OTC | 1 |
| Euro OTC | Tetracaine hydrochloride | TH0030315 | 1 |
| Euro OTC | Tetracaine hydrochloride | TH00602019 | 1 |
| Euro OTC | Tetracaine hydrochloride | TH0070816 | 1 |
| Euro OTC | Tetracaine hydrochloride | TH0100718 | 2 |
| Euro OTC | Tetracaine hydrochloride | TH0121219 | 2 |
| Euro OTG Pharma | Tetracaine hydrochloride | 1409026-02 | 1 |
| Euro OTG/ AHD | Tetracaine hydrochloride | 1706018-01 | 2 |
| Euro OTG | Tetracaine hydrochloride | 1207001-01 | 1 |
| Euro/Phönix | Tetracaine hydrochloride | 1506040-01 | 1 |
| Euro | Tetracaine hydrochloride | 1506040-01 | 1 |
| euroct/gehe | Tetracaine hydrochloride | 1405026-01 | 1 |
| Europharm | Tetracaine hydrochloride | 1409026-02 | 1 |
| EuroTOC / Noweda | Tetracaine hydrochloride | 131000601 | 2 |
| EurRho/Noweda | Tetracaine hydrochloride | 1712012-01 | 2 |
| Fa.Phönix | Tetracaine hydrochloride | 13155706 | 1 |
| Fa.Phönix | Tetracaine hydrochloride | 2110008-01 | 2 |
| fag | Tetracaine hydrochloride | 20G10-F07-373354 | 1 |
| Fagreo / Sanacorp | Tetracaine hydrochloride | 20A17F10370805 | 1 |
| Fagro/Gehe | Tetracaine hydrochloride | 15K04-B03-322151 | 5 |
| Fagron | Tetracaine hydrochloride | | 1 |
| Fagron | Tetracaine hydrochloride | 10330837 | 1 |
| Fagron | Tetracaine hydrochloride | 10990834 | 3 |
| Fagron | Tetracaine hydrochloride | 10990837 | 3 |
| Fagron | Tetracaine hydrochloride | 10990841 | 3 |
| Fagron | Tetracaine hydrochloride | 10A29-N12 | 2 |
| Fagron | Tetracaine hydrochloride | 11/15-N12 | 1 |
| Fagron | Tetracaine hydrochloride | 11A31-N15 | 1 |
| Fagron | Tetracaine hydrochloride | 11C22-N04 | 1 |
| Fagron | Tetracaine hydrochloride | 12C22-N04 | 5 |
| Fagron | Tetracaine hydrochloride | 12H24-N05 | 10 |
| Fagron | Tetracaine hydrochloride | 12H24-N050696/1050 | 1 |
| Fagron | Tetracaine hydrochloride | 12H-N05 | 1 |
| Fagron | Tetracaine hydrochloride | 12K01-N04 | 7 |
| Fagron | Tetracaine hydrochloride | 1303012-01 | 1 |
| Fagron | Tetracaine hydrochloride | 13155711 | 1 |
| Fagron | Tetracaine hydrochloride | 13509149 | 2 |
| Fagron | Tetracaine hydrochloride | 13509155 | 1 |
| Fagron | Tetracaine hydrochloride | 13D11-N01 | 1 |
| Fagron | Tetracaine hydrochloride | 13D11-N07 | 12 |
| Fagron | Tetracaine hydrochloride | 13G02-N01 | 1 |
| Fagron | Tetracaine hydrochloride | 13H21-B02 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tetracaine hydrochloride | 13H21-B02-286558 | 3 |
| Fagron | Tetracaine hydrochloride | 13H21-B02-286559 | 1 |
| Fagron | Tetracaine hydrochloride | 13K25-B04 | 1 |
| Fagron | Tetracaine hydrochloride | 13k25-b04-290276 | 1 |
| Fagron | Tetracaine hydrochloride | 13K25-B04290276 | 1 |
| Fagron | Tetracaine hydrochloride | 13K25-B04-290276 | 3 |
| Fagron | Tetracaine hydrochloride | 13K25B04290277 | 1 |
| Fagron | Tetracaine hydrochloride | 13K25-B04-290278 | 1 |
| Fagron | Tetracaine hydrochloride | 13K25-Bo4-290276 | 1 |
| Fagron | Tetracaine hydrochloride | 1411019-01 | 2 |
| Fagron | Tetracaine hydrochloride | 1418-03-300199 | 1 |
| Fagron | Tetracaine hydrochloride | 14710369 | 1 |
| Fagron | Tetracaine hydrochloride | 14C18-B03 | 1 |
| Fagron | Tetracaine hydrochloride | 14C18-B03-293966 | 7 |
| Fagron | Tetracaine hydrochloride | 14C18-B03-293967 | 1 |
| Fagron | Tetracaine hydrochloride | 14C18-B03-300199 | 6 |
| Fagron | Tetracaine hydrochloride | 14C18-B03-300200 | 1 |
| Fagron | Tetracaine hydrochloride | 14C18-Bo3-300200 | 1 |
| Fagron | Tetracaine hydrochloride | 14c18d03300199 | 1 |
| Fagron | Tetracaine hydrochloride | 14G14B08300198 | 1 |
| Fagron | Tetracaine hydrochloride | 14G14-B08-300198 | 8 |
| Fagron | Tetracaine hydrochloride | 1506040-02 | 1 |
| Fagron | Tetracaine hydrochloride | 15A12B03308857 | 1 |
| Fagron | Tetracaine hydrochloride | 15A12-B03-308857 | 8 |
| Fagron | Tetracaine hydrochloride | 15H24-B03 | 3 |
| Fagron | Tetracaine hydrochloride | 15H24-B03-311450 | 4 |
| Fagron | Tetracaine hydrochloride | 15h24-b03-313594 | 1 |
| Fagron | Tetracaine hydrochloride | 15H24-B03-313594 | 6 |
| Fagron | Tetracaine hydrochloride | 15H24-B03-314243 | 1 |
| Fagron | Tetracaine hydrochloride | 15K04-B03 | 2 |
| Fagron | Tetracaine hydrochloride | 15K04-B03_322151 | 1 |
| Fagron | Tetracaine hydrochloride | 15K04-B03-318368 | 3 |
| Fagron | Tetracaine hydrochloride | 15K04B03318369 | 1 |
| Fagron | Tetracaine hydrochloride | 15K04-B03-318369 | 3 |
| Fagron | Tetracaine hydrochloride | 15K04-B03-321567 | 1 |
| Fagron | Tetracaine hydrochloride | 15K04-B03-321568 | 1 |
| Fagron | Tetracaine hydrochloride | 15K04-B03-322151 | 12 |
| Fagron | Tetracaine hydrochloride | 15K04-B03-328163 | 1 |
| Fagron | Tetracaine hydrochloride | 15K04-bo3-312151 | 1 |
| Fagron | Tetracaine hydrochloride | 1607031-01 | 1 |
| Fagron | Tetracaine hydrochloride | 16G28-B03 | 1 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-327368 | 14 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-327369 | 2 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-328913 | 1 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-330362 | 5 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-330363 | 1 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-332099 | 3 |
| Fagron | Tetracaine hydrochloride | 16G28-B03-334124 | 2 |
| Fagron | Tetracaine hydrochloride | 16G2-B03-327368 | 1 |
| Fagron | Tetracaine hydrochloride | 16G8-B03-327368 | 1 |
| Fagron | Tetracaine hydrochloride | 17114181 | 12 |
| Fagron | Tetracaine hydrochloride | 17G03_B07-351508 | 1 |
| Fagron | Tetracaine hydrochloride | 17G03-B07 | 8 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-338538 | 7 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-338539 | 4 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-338540 | 1 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-341319 | 1 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-341853 | 4 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-345008 | 7 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-345009 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tetracaine hydrochloride | 17G03-B07-349367 | 5 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-349368 | 2 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-3515009 | 1 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-351508 | 2 |
| Fagron | Tetracaine hydrochloride | 17G03-B07-351509 | 2 |
| Fagron | Tetracaine hydrochloride | 17G05-B04-341204 | 1 |
| Fagron | Tetracaine hydrochloride | 17Go3-B07-341853 | 1 |
| Fagron | Tetracaine hydrochloride | 1803001-01 | 1 |
| Fagron | Tetracaine hydrochloride | 1812006-01 | 1 |
| Fagron | Tetracaine hydrochloride | 18J03-B05 | 5 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-356329 | 5 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-356330 | 2 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-358079 | 1 |
| Fagron | Tetracaine hydrochloride | 18J03B05358080 | 1 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-358080 | 6 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-359813 | 5 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-359814 | 2 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-359815 | 2 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-361978 | 4 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-361979 | 5 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-362469 | 8 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-362470 | 2 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-362471 | 4 |
| Fagron | Tetracaine hydrochloride | 18J03-B05-58079 | 1 |
| Fagron | Tetracaine hydrochloride | 18j0-b05-358079 | 1 |
| Fagron | Tetracaine hydrochloride | 192021003 | 1 |
| Fagron | Tetracaine hydrochloride | 2003053-01 | 1 |
| Fagron | Tetracaine hydrochloride | 20A17-F10 | 3 |
| Fagron | Tetracaine hydrochloride | 20A17-F1008581264 | 1 |
| Fagron | Tetracaine hydrochloride | 20A17-F10-3708007 | 1 |
| Fagron | Tetracaine hydrochloride | 20A17-F10-370805 | 3 |
| Fagron | Tetracaine hydrochloride | 20A17-F10-370806 | 2 |
| Fagron | Tetracaine hydrochloride | 20A17-F10-370807 | 3 |
| Fagron | Tetracaine hydrochloride | 20G10-07-373352 | 1 |
| Fagron | Tetracaine hydrochloride | 20G10-F07 | 3 |
| Fagron | Tetracaine hydrochloride | 20G10-F07-372358 | 1 |
| Fagron | Tetracaine hydrochloride | 20G10-F07-373352 | 6 |
| Fagron | Tetracaine hydrochloride | 20G10F07373353 | 1 |
| Fagron | Tetracaine hydrochloride | 20G10-F07-373353 | 6 |
| Fagron | Tetracaine hydrochloride | 20G10-F07-373354 | 1 |
| Fagron | Tetracaine hydrochloride | 20G10-F07-374915 | 1 |
| Fagron | Tetracaine hydrochloride | 20G10-F07-374916 | 1 |
| Fagron | Tetracaine hydrochloride | 20L03-F02-377430 | 2 |
| Fagron | Tetracaine hydrochloride | 21120-B04-213603 | 1 |
| Fagron | Tetracaine hydrochloride | 212131/221630-0002 | 1 |
| Fagron | Tetracaine hydrochloride | 218I-02039 | 1 |
| Fagron | Tetracaine hydrochloride | 21I20-B04-213603 | 3 |
| Fagron | Tetracaine hydrochloride | 21I20-B04-213604 | 4 |
| Fagron | Tetracaine hydrochloride | 21l20-B04-213604 | 1 |
| Fagron | Tetracaine hydrochloride | 221I20-B04-213603 | 1 |
| Fagron | Tetracaine hydrochloride | 2OA17-F10-370807 | 2 |
| Fagron | Tetracaine hydrochloride | 3413U02039 | 1 |
| Fagron | Tetracaine hydrochloride | 3913I-02039 | 1 |
| Fagron | Tetracaine hydrochloride | 4118A-02039 | 1 |
| Fagron | Tetracaine hydrochloride | 4313E-02039 | 1 |
| Fagron | Tetracaine hydrochloride | 6093547 | 2 |
| Fagron | Tetracaine hydrochloride | 6093549 | 1 |
| Fagron | Tetracaine hydrochloride | 715Q-02039 | 1 |
| Fagron | Tetracaine hydrochloride | B05-3619708 | 2 |
| Fagron | Tetracaine hydrochloride | F07-3733502 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tetracaine hydrochloride | F10-3708005 | 1 |
| Fagron | Tetracaine hydrochloride | F10-3708006 | 1 |
| Fagron | Tetracaine hydrochloride | F10-3708007 | 1 |
| Fagron | Tetracaine hydrochloride | TH0050520 | 2 |
| Fagron | Tetracaine hydrochloride | TH0060721 | 1 |
| Fagron | Tetracaine hydrochloride | TH0100718 | 6 |
| Fargon / GEIBO | Tetracaine hydrochloride | 21120-B04-213604 | 1 |
| Fargon/AllianceH. | Tetracaine hydrochloride | 17G03-B07-338538 | 1 |
| Fargon/Noweda | Tetracaine hydrochloride | 17G03-B07-345008 | 1 |
| Fargron/ Sanacorp | Tetracaine hydrochloride | 14C18-B03-300200 | 1 |
| Fiebig/Calo | Tetracaine hydrochloride | 17256704 | 1 |
| Finze | Tetracaine hydrochloride | 2906009-02 | 1 |
| Gatt-Koller / Phoenix | Tetracaine hydrochloride | 80/02140614 | 2 |
| Gatt-Koller | Tetracaine hydrochloride | 1803034 | 2 |
| Gatt-Koller | Tetracaine hydrochloride | KNC1825J18 | 1 |
| Gehe 07.07.2014 | Tetracaine hydrochloride | 13155706 | 1 |
| Gehe amax | Tetracaine hydrochloride | 1812006-01 | 1 |
| gehe europharm | Tetracaine hydrochloride | 201001901 | 1 |
| Gehe | Tetracaine hydrochloride | 1310006-01 | 1 |
| Gehe | Tetracaine hydrochloride | 13155711 | 2 |
| Gehe | Tetracaine hydrochloride | 15437119 | 1 |
| Gehe | Tetracaine hydrochloride | 15A12-B03-308857 | 1 |
| Gehe | Tetracaine hydrochloride | 15K04-B03-322151 | 1 |
| GEHE | Tetracaine hydrochloride | 1612005-01 | 1 |
| GEHE | Tetracaine hydrochloride | 1706018-01 | 1 |
| GEHE | Tetracaine hydrochloride | 17G03-B07-338540 | 1 |
| Gehe | Tetracaine hydrochloride | 1803001-01 | 1 |
| GEHE | Tetracaine hydrochloride | 18060602 | 2 |
| GEHE | Tetracaine hydrochloride | 18060614 | 2 |
| Gehe | Tetracaine hydrochloride | 1812006-01 | 1 |
| Gehe | Tetracaine hydrochloride | 1902015-01 | 1 |
| Gehe | Tetracaine hydrochloride | 1907007-01 | 1 |
| Gehe | Tetracaine hydrochloride | 1909024-01 | 1 |
| Gehe | Tetracaine hydrochloride | 200041 | 1 |
| Gehe | Tetracaine hydrochloride | 20004176008 | 1 |
| Gehe | Tetracaine hydrochloride | 2010019-02 | 1 |
| Gehe | Tetracaine hydrochloride | 2207015-02 | 1 |
| Geibo/ Fargron | Tetracaine hydrochloride | 15H24-B03-313594 | 1 |
| Geibo/ Fargron | Tetracaine hydrochloride | 17G03-B07-338538 | 1 |
| Geibo | Tetracaine hydrochloride | 2003053-01 | 1 |
| Geibo | Tetracaine hydrochloride | 22001496003 | 1 |
| Geilenkirchen | Tetracaine hydrochloride | 1812006-01 | 1 |
| Geilenkirchen | Tetracaine hydrochloride | 1902015-01 | 2 |
| Geilenkirchen | Tetracaine hydrochloride | 1909024-01 | 1 |
| Gutenberg-Apotheke | Tetracaine hydrochloride | 13D11-N07 | 1 |
| Hänseler | Tetracaine hydrochloride | | 4 |
| Hänseler | Tetracaine hydrochloride | 2018060021 | 1 |
| Ichthyol-Gesellschaf... | Tetracaine hydrochloride | 12019816 | 2 |
| Jenne | Tetracaine hydrochloride | 13D11-No7 | 1 |
| Kehr | Tetracaine hydrochloride | 22001496010 | 1 |
| Kehr | Tetracaine hydrochloride | 22001496014 | 1 |
| kehr | Tetracaine hydrochloride | 220701501 | 1 |
| Kehr | Tetracaine hydrochloride | 2405009-01 | 1 |
| KÖGL | Tetracaine hydrochloride | 1900461 | 6 |
| Lamotte/3 | Tetracaine hydrochloride | 13155720 | 1 |
| Noveda | Tetracaine hydrochloride | 12H24-N05 | 1 |
| Noweda 06.02.19 EK:7,84 | Tetracaine hydrochloride | 1807017-01 | 1 |
| Noweda Taucha | Tetracaine hydrochloride | 2110008-01 | 1 |
| Noweda/ BASF Pharma ... | Tetracaine hydrochloride | 12H24-N05 | 1 |
| Noweda | Tetracaine hydrochloride | 1106035-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Tetracaine hydrochloride | 120700-02 | 1 |
| Noweda | Tetracaine hydrochloride | 1310006-01 | 1 |
| Noweda | Tetracaine hydrochloride | 1405026-04 | 2 |
| Noweda | Tetracaine hydrochloride | 14G14-B08 | 1 |
| Noweda | Tetracaine hydrochloride | 17G03-B07-351508 | 2 |
| Noweda | Tetracaine hydrochloride | 1812006-01 | 1 |
| Noweda | Tetracaine hydrochloride | 18J03-B05-359814 | 1 |
| Noweda | Tetracaine hydrochloride | 19011908 | 1 |
| Noweda | Tetracaine hydrochloride | 1909024-1 | 1 |
| Noweda | Tetracaine hydrochloride | 20004176012 | 1 |
| Noweda | Tetracaine hydrochloride | 211008-01 | 2 |
| Noweda | Tetracaine hydrochloride | 22001496004 | 1 |
| Noweda | Tetracaine hydrochloride | 22001496010 | 1 |
| Noweda | Tetracaine hydrochloride | 2207015-01 | 1 |
| Noweda | Tetracaine hydrochloride | 2207015-02 | 1 |
| Noweda | Tetracaine hydrochloride | 22J19-B01-221586 | 1 |
| Noweda | Tetracaine hydrochloride | 2307022-01 | 1 |
| Noweda | Tetracaine hydrochloride | 2405009-01 | 2 |
| Noweda | Tetracaine hydrochloride | 24H26-B01-002395 | 1 |
| Noweda | Tetracaine hydrochloride | TH0050520 | 1 |
| Noweda30.08.2027 | Tetracaine hydrochloride | 2307022-01 | 1 |
| Nutra / Noweda | Tetracaine hydrochloride | 1803001-01 | 1 |
| Orgamol Pharma | Tetracaine hydrochloride | 6093547 | 1 |
| Pala | Tetracaine hydrochloride | 18J03-B05-356329 | 1 |
| Phoenix 04.11.16 Pho… | Tetracaine hydrochloride | 1607031-01 | 1 |
| Phoenix 27.07.2019 6,98EUR | Tetracaine hydrochloride | 1712012-01 | 1 |
| Phoenix am 30.04.2014 | Tetracaine hydrochloride | 1310006-01 | 1 |
| Phoenix Goettin | Tetracaine hydrochloride | 1409026-01 | 1 |
| Phoenix | Tetracaine hydrochloride | 15437104 | 2 |
| Phoenix | Tetracaine hydrochloride | 1803001-01 | 4 |
| Phoenix | Tetracaine hydrochloride | 20004176004 | 1 |
| Phoenix | Tetracaine hydrochloride | 2003053-01 | 2 |
| Phoenix | Tetracaine hydrochloride | 2010019-01 | 1 |
| Phoenix | Tetracaine hydrochloride | 2110008-01 | 1 |
| Phoenix | Tetracaine hydrochloride | 2207015-01 | 3 |
| Phoenix | Tetracaine hydrochloride | 3058 | 1 |
| Phönix /euro | Tetracaine hydrochloride | 2003053-01 | 1 |
| Phönix | Tetracaine hydrochloride | 130301201 | 1 |
| Phönix | Tetracaine hydrochloride | 1310006-01 | 1 |
| Phönix | Tetracaine hydrochloride | 1405026-01 | 1 |
| PHÖNIX | Tetracaine hydrochloride | 15437109 | 1 |
| phönix | Tetracaine hydrochloride | 15437121 | 1 |
| Phönix | Tetracaine hydrochloride | 1612005-01 | 1 |
| Phönix | Tetracaine hydrochloride | 171201201 | 1 |
| Phönix | Tetracaine hydrochloride | 1812006-01 | 1 |
| Phönix | Tetracaine hydrochloride | 1902015-01 | 1 |
| Phönix | Tetracaine hydrochloride | 1909024-01 | 1 |
| PHÖNIX | Tetracaine hydrochloride | 2003053-02 | 1 |
| Phönix | Tetracaine hydrochloride | 2010019-01 | 1 |
| PHönix | Tetracaine hydrochloride | 2010019-01 | 1 |
| Phönix | Tetracaine hydrochloride | 2015E-02039 | 1 |
| Phönix | Tetracaine hydrochloride | 2207015-01 | 1 |
| Phönix | Tetracaine hydrochloride | 2207015-03 | 1 |
| Phönix | Tetracaine hydrochloride | 22J19-B01-221586 | 1 |
| Phönix | Tetracaine hydrochloride | TH0060322 | 1 |
| Sana 20.12.17 7.99 | Tetracaine hydrochloride | 1612005-01 | 2 |
| Sanacorp, 21.02.17, … | Tetracaine hydrochloride | 1607031-01 | 1 |
| Sanacorp/EuRho | Tetracaine hydrochloride | 18060604 | 1 |
| Sanacorp | Tetracaine hydrochloride | 1207001-02 | 1 |
| Sanacorp | Tetracaine hydrochloride | 1303012-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Tetracaine hydrochloride | 1409026-01 | 1 |
| Sanacorp | Tetracaine hydrochloride | 15/AKD1 | 1 |
| Sanacorp | Tetracaine hydrochloride | 17G03-B07-341318 | 1 |
| Sanacorp | Tetracaine hydrochloride | 17G03-B07-341853 | 1 |
| Sanacorp | Tetracaine hydrochloride | 1803001-01 | 2 |
| Sanacorp | Tetracaine hydrochloride | 19011903 | 2 |
| Sanacorp | Tetracaine hydrochloride | 1902015-01 | 1 |
| Sanacorp | Tetracaine hydrochloride | 2001011-01 | 1 |
| Sanacorp | Tetracaine hydrochloride | 20A17-F10 | 2 |
| Sanacorp | Tetracaine hydrochloride | 20A17-F10-370806 | 1 |
| Sanacorp | Tetracaine hydrochloride | 20G10-F07-373352 | 2 |
| Sanacorp | Tetracaine hydrochloride | 2110008-01 | 1 |
| Sanacorp | Tetracaine hydrochloride | 21I20-B04-213603 | 1 |
| Sanacorp | Tetracaine hydrochloride | 22001496004 | 1 |
| sanacorp | Tetracaine hydrochloride | 2207015-02 | 1 |
| Sanacorp | Tetracaine hydrochloride | 2207015-02 | 1 |
| Sanacorp | Tetracaine hydrochloride | 2207015-03 | 3 |
| Sanacorp | Tetracaine hydrochloride | 2307022-03 | 2 |
| Sanacorp | Tetracaine hydrochloride | 2405009-01 | 1 |
| Sanacorp | Tetracaine hydrochloride | F07-3733502 | 1 |
| Sino Phyto | Tetracaine hydrochloride | 12019816 | 1 |
| Synopharm/Anzag | Tetracaine hydrochloride | 2712Q-02039 | 1 |
| VDl 26.09.14 12,00 euro | Tetracaine hydrochloride | 1405026-01 | 1 |
| Venkata NA / Gehe | Tetracaine hydrochloride | 190119002 | 2 |
| Venkata Narayana / Gehe | Tetracaine hydrochloride | 1907007-01 | 1 |
| Venkata/Noweda | Tetracaine hydrochloride | TH00602019 | 1 |
| Venkata/Noweda | Tetracaine hydrochloride | TH0060219 | 1 |
| Venkata/phoenix | Tetracaine hydrochloride | TH0100718 | 1 |

- 254 656 spectra from 1666 *Apo-Ident* customers from a total of 51 751 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tetracaine hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tetracaine hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 385 | 0 | 157 941 |
| **Type B** | 0 | 930 | 0 | 212 010 |
| **Type C** | 0 | 2227 | 3 | 254 656 |

The substance/substance group *Tetracaine hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4416 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.3548 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8655 % (> 99.7309 %) |


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In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20924 | 21845 | 7.39 | 208.52 |
| 21845 | 21845 | 0.00 | 206.92 |
| 22285 | 22285 | 0.00 | 208.74 |
| 22912 | 22912 | 0.00 | 206.99 |
| 23162 | 21845 | 7.58 | 207.29 |
| 23163 | 21845 | 8.91 | 208.26 |
| 23500 | 21845 | 7.04 | 206.18 |
| 24141 | 24141 | 0.00 | 204.98 |
| 27559 | 27559 | 0.00 | 205.90 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tetracycline hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20044-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tetracycline hydrochloride; Tetracyclini hydrochloridum

### Special notes

When selecting the *Tetracycline hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tetracycline hydrochloride | 9 | 7 | 196 |

### Second-stage model

For differentiation of the substance/substance group *Tetracycline hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tetracycline hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Chlortetracycline hydrochloride | 55.25 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tetracycline hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tetracycline hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Tetracycline hydrochloride | 13201303 | 21427 | 60 | 20130807 |
| Caelo | Tetracycline hydrochloride | 13201303 | 21428 | 60 | 20130807 |
| Caelo | Tetracycline hydrochloride | 161167 | 22468 | 60 | 20160504* |
| Caelo | Tetracycline hydrochloride | 15230712 | 22833 | 40 | 20150819 |
| Caelo | Tetracycline hydrochloride | 20003996010 | 26301 | 30 | 20201127 |
| Caelo | Tetracycline hydrochloride | 20003996010 | 26301SI | 20 | 20201127 |
| Euro OTC | Tetracycline hydrochloride | 1302012-01 | 21079 | 40 | 1411585 |
| Euro OTC | Tetracycline hydrochloride | 1506012 | 21835 | 60 | 20150707* |
| Euro OTC | Tetracycline hydrochloride | 2004023 | 25279 | 40 | 20200721* |
| Euro OTC | Tetracycline hydrochloride | 2103015 | 25686 | 50 | 20210525* |
| Fagron | Tetracycline hydrochloride | 24J01-B02-005133 | 27569 | 40 | 20241213 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 500 spectra of 11 reference samples from the substance/substance group *Tetracycline hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 826 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 320 spectra of 9 reference samples from the substance/substance group *Tetracycline hydrochloride*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Tetracycline hydrochloride | 172858 | 23847 | 40 |
| Caelo | Tetracycline hydrochloride | 181986 | 24256 | 40 |
| Caelo | Tetracycline hydrochloride | 183083 | 24394 | 40 |
| Euro OTC | Tetracycline hydrochloride | 1603026 | 22545 | 40 |
| Euro OTC | Tetracycline hydrochloride | 1706020 | 23691 | 30 |
| Euro OTC | Tetracycline hydrochloride | 1811031 | 24450 | 40 |
| Euro OTC | Tetracycline hydrochloride | 2203017 | 26099 | 40 |
| Euro OTC | Tetracycline hydrochloride | 2103015 | 25686SI† | 10 |
| Euro OTC | Tetracycline hydrochloride | 2203017 | 26099SI | 40 |

- 212 620 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1145 spectra from 551 *Apo-Ident* customers from 201 batches from the substance/substance group *Tetracycline hydrochloride*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 195 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tetracycline hydrochloride | 21003348003 | 1 |
| | Tetracycline hydrochloride | 21003348008 | 1 |
| | Tetracycline hydrochloride | 21003348011 | 4 |
| | Tetracycline hydrochloride | 21003348015 | 1 |
| | Tetracycline hydrochloride | 21003348017 | 5 |
| | Tetracycline hydrochloride | 2103015-02 | 5 |
| | Tetracycline hydrochloride | 2103348011 | 1 |
| | Tetracycline hydrochloride | 2202017-01 | 1 |
| | Tetracycline hydrochloride | 2203017-01 | 5 |
| | Tetracycline hydrochloride | 23000427002 | 3 |
| | Tetracycline hydrochloride | 23000427003 | 6 |
| | Tetracycline hydrochloride | 23000427005 | 11 |
| | Tetracycline hydrochloride | 23000427009 | 9 |
| | Tetracycline hydrochloride | 24000509003 | 5 |
| | Tetracycline hydrochloride | 24000509004 | 5 |
| | Tetracycline hydrochloride | 24000509005 | 6 |
| | Tetracycline hydrochloride | 24000509009 | 9 |
| | Tetracycline hydrochloride | 24000509013 | 3 |
| | Tetracycline hydrochloride | 24002486005 | 7 |
| | Tetracycline hydrochloride | 2400509004 | 1 |
| | Tetracycline hydrochloride | AP220324-04 | 1 |
| AHD | Tetracycline hydrochloride | 21003348003 | 1 |
| AHD | Tetracycline hydrochloride | 23000427005 | 1 |
| AHD | Tetracycline hydrochloride | 23000427009 | 1 |
| Aliance am 10.03.2014 | Tetracycline hydrochloride | 1302012-02 | 1 |
| Alliance Health 22.0... | Tetracycline hydrochloride | 13201307 | 1 |
| Alliance Healthcare | Tetracycline hydrochloride | 192021008 | 1 |
| Anzag/euRho | Tetracycline hydrochloride | | 1 |
| Bombastus | Tetracycline hydrochloride | 1204039-02 | 1 |
| Bombastus | Tetracycline hydrochloride | 1603026-01 | 2 |
| Bombastus | Tetracycline hydrochloride | 1811031-01 | 1 |
| Caeli / Phönix | Tetracycline hydrochloride | 21003348002 | 1 |
| Caelo | Tetracycline hydrochloride | 1017A-02378 | 1 |
| Caelo | Tetracycline hydrochloride | 103201301 | 1 |
| Caelo | Tetracycline hydrochloride | 111002901 | 1 |
| Caelo | Tetracycline hydrochloride | 1160117 | 1 |
| Caelo | Tetracycline hydrochloride | 1204039 | 2 |
| Caelo | Tetracycline hydrochloride | 12138104 | 1 |
| Caelo | Tetracycline hydrochloride | 12138106 | 2 |
| Caelo | Tetracycline hydrochloride | 12353602 | 1 |
| Caelo | Tetracycline hydrochloride | 12353603 | 6 |
| Caelo | Tetracycline hydrochloride | 12353609 | 1 |
| Caelo | Tetracycline hydrochloride | 12353612 | 1 |
| Caelo | Tetracycline hydrochloride | 12353613 | 1 |
| Caelo | Tetracycline hydrochloride | 1302012-01 | 1 |
| Caelo | Tetracycline hydrochloride | 13201301 | 3 |
| Caelo | Tetracycline hydrochloride | 13201302 | 1 |
| Caelo | Tetracycline hydrochloride | 13201307 | 1 |
| Caelo | Tetracycline hydrochloride | 13201309 | 2 |
| Caelo | Tetracycline hydrochloride | 13F17-N03 | 1 |
| Caelo | Tetracycline hydrochloride | 13L10B02296956 | 1 |
| Caelo | Tetracycline hydrochloride | 1402030-01 | 1 |
| Caelo | Tetracycline hydrochloride | 14080605 | 2 |
| Caelo | Tetracycline hydrochloride | 14080606 | 4 |
| Caelo | Tetracycline hydrochloride | 1412007-01 | 2 |
| Caelo | Tetracycline hydrochloride | 1412007-03 | 3 |
| Caelo | Tetracycline hydrochloride | 14364601 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tetracycline hydrochloride | 14364604 | 3 |
| Caelo | Tetracycline hydrochloride | 14364612 | 3 |
| Caelo | Tetracycline hydrochloride | 14364614 | 1 |
| Caelo | Tetracycline hydrochloride | 14364616 | 2 |
| Caelo | Tetracycline hydrochloride | 14H06-B05-313591 | 1 |
| Caelo | Tetracycline hydrochloride | 1506012-01 | 2 |
| Caelo | Tetracycline hydrochloride | 151018-61 | 1 |
| Caelo | Tetracycline hydrochloride | 15230703 | 4 |
| Caelo | Tetracycline hydrochloride | 15230707 | 2 |
| Caelo | Tetracycline hydrochloride | 15230711 | 1 |
| Caelo | Tetracycline hydrochloride | 15230714 | 1 |
| Caelo | Tetracycline hydrochloride | 15230715 | 5 |
| Caelo | Tetracycline hydrochloride | 15230717 | 3 |
| Caelo | Tetracycline hydrochloride | 15230720 | 3 |
| Caelo | Tetracycline hydrochloride | 1603026-01 | 3 |
| Caelo | Tetracycline hydrochloride | 1611617 | 1 |
| Caelo | Tetracycline hydrochloride | 16116701 | 3 |
| Caelo | Tetracycline hydrochloride | 16116704 | 1 |
| Caelo | Tetracycline hydrochloride | 16116706 | 6 |
| Caelo | Tetracycline hydrochloride | 16116708 | 1 |
| Caelo | Tetracycline hydrochloride | 16116709 | 5 |
| Caelo | Tetracycline hydrochloride | 16116714 | 2 |
| Caelo | Tetracycline hydrochloride | 16116715 | 8 |
| Caelo | Tetracycline hydrochloride | 16116720 | 2 |
| Caelo | Tetracycline hydrochloride | 16116721 | 9 |
| Caelo | Tetracycline hydrochloride | 166116709 | 1 |
| Caelo | Tetracycline hydrochloride | 170602001 | 3 |
| Caelo | Tetracycline hydrochloride | 1706020-01 | 6 |
| Caelo | Tetracycline hydrochloride | 172855809 | 1 |
| Caelo | Tetracycline hydrochloride | 17285801 | 12 |
| Caelo | Tetracycline hydrochloride | 17285802 | 1 |
| Caelo | Tetracycline hydrochloride | 17285803 | 9 |
| Caelo | Tetracycline hydrochloride | 17285808 | 8 |
| Caelo | Tetracycline hydrochloride | 17285809 | 5 |
| Caelo | Tetracycline hydrochloride | 1811031/01 | 1 |
| Caelo | Tetracycline hydrochloride | 1811031-01 | 2 |
| Caelo | Tetracycline hydrochloride | 18198602 | 8 |
| Caelo | Tetracycline hydrochloride | 18198603 | 9 |
| Caelo | Tetracycline hydrochloride | 18198604 | 2 |
| Caelo | Tetracycline hydrochloride | 18198608 | 12 |
| Caelo | Tetracycline hydrochloride | 18198612 | 4 |
| Caelo | Tetracycline hydrochloride | 18300213 | 1 |
| Caelo | Tetracycline hydrochloride | 18308302 | 4 |
| Caelo | Tetracycline hydrochloride | 18308303 | 2 |
| Caelo | Tetracycline hydrochloride | 18308305 | 12 |
| Caelo | Tetracycline hydrochloride | 18308306 | 2 |
| Caelo | Tetracycline hydrochloride | 18308313 | 4 |
| Caelo | Tetracycline hydrochloride | 18308314 | 3 |
| Caelo | Tetracycline hydrochloride | 192021003 | 11 |
| Caelo | Tetracycline hydrochloride | 192021004 | 11 |
| Caelo | Tetracycline hydrochloride | 192021008 | 4 |
| Caelo | Tetracycline hydrochloride | 192021011 | 27 |
| Caelo | Tetracycline hydrochloride | 1920221011 | 1 |
| Caelo | Tetracycline hydrochloride | 200003996008 | 1 |
| Caelo | Tetracycline hydrochloride | 20001708003 | 3 |
| Caelo | Tetracycline hydrochloride | 20001708004 | 10 |
| Caelo | Tetracycline hydrochloride | 20001708005 | 2 |
| Caelo | Tetracycline hydrochloride | 2000178003 | 1 |
| Caelo | Tetracycline hydrochloride | 20003996002 | 4 |
| Caelo | Tetracycline hydrochloride | 20003996003 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tetracycline hydrochloride | 20003996004 | 4 |
| Caelo | Tetracycline hydrochloride | 20003996006 | 6 |
| Caelo | Tetracycline hydrochloride | 20003996010 | 7 |
| Caelo | Tetracycline hydrochloride | 20003996011 | 6 |
| Caelo | Tetracycline hydrochloride | 20003996017 | 4 |
| Caelo | Tetracycline hydrochloride | 2000399606 | 1 |
| Caelo | Tetracycline hydrochloride | 2003996010 | 1 |
| Caelo | Tetracycline hydrochloride | 21003348002 | 7 |
| Caelo | Tetracycline hydrochloride | 21003348003 | 10 |
| Caelo | Tetracycline hydrochloride | 21003348004 | 2 |
| Caelo | Tetracycline hydrochloride | 21003348008 | 4 |
| Caelo | Tetracycline hydrochloride | 21003348011 | 9 |
| Caelo | Tetracycline hydrochloride | 21003348033 | 1 |
| Caelo | Tetracycline hydrochloride | 23000427005 | 1 |
| Caelo | Tetracycline hydrochloride | 2714U-02378 | 1 |
| Caelo | Tetracycline hydrochloride | 2883 | 1 |
| Caelo | Tetracycline hydrochloride | 3314 | 1 |
| Caelo | Tetracycline hydrochloride | 3341 | 1 |
| Caelo | Tetracycline hydrochloride | 4012Q-02378 | 1 |
| Caelo | Tetracycline hydrochloride | 4117I-02378 | 1 |
| Caelo | Tetracycline hydrochloride | 4315I-02378 | 1 |
| Caelo | Tetracycline hydrochloride | 5091202 | 1 |
| Caelo | Tetracycline hydrochloride | 8682 | 1 |
| Caelo | Tetracycline hydrochloride | 9248704 | 1 |
| Caesar & Lorenz GmbH | Tetracycline hydrochloride | 18308312 | 1 |
| Caesar & Lorenz GmbH | Tetracycline hydrochloride | 20001708005 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 18308312 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 192021010 | 2 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 20001708005 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 20003996008 | 2 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 21003348004 | 2 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 18308306 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 21003348011 | 1 |
| Caesar & Loretz GmbH /E | Tetracycline hydrochloride | 18308305 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 20003996010 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 192021004 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 192021011 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 20001708005 | 3 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 18308302 | 1 |
| Caesar & Loretz GmbH/Kehr | Tetracycline hydrochloride | 18198612 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 18308313 | 1 |
| Caesar & Loretz GmbH/Phoe | Tetracycline hydrochloride | 20003996004 | 1 |
| Caesar & Loretz GmbH... | Tetracycline hydrochloride | 20001708004 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 102021011 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 18198612 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 18308302 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 18308303 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 18308305 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 18308306 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 18308313 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 192021003 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 192021008 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 192021011 | 6 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20001708004 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20001708005 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20003996002 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20003996003 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20003996004 | 3 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20003996006 | 4 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20003996010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20003996011 | 3 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 20003996017 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 21003348002 | 2 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 21003348003 | 4 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 21003348010 | 1 |
| Caesar & Loretz GmbH | Tetracycline hydrochloride | 21003348011 | 2 |
| Caesar / Gehe | Tetracycline hydrochloride | 16116706 | 1 |
| Celo/Kehr | Tetracycline hydrochloride | 13201307 | 1 |
| EuRho / 107 | Tetracycline hydrochloride | 1811031-01 | 1 |
| EuRho/AHD | Tetracycline hydrochloride | | 1 |
| Eurho/Phoenix | Tetracycline hydrochloride | 1204039-02 | 1 |
| EuRho/Phoenix | Tetracycline hydrochloride | 1811031-01 | 1 |
| EuRho/Phoenix | Tetracycline hydrochloride | 2004023-01 | 1 |
| EuRho/Sanacorp | Tetracycline hydrochloride | 2004023-01 | 1 |
| EuRho | Tetracycline hydrochloride | 1302012-02 | 1 |
| EuRho | Tetracycline hydrochloride | 1402030-02 | 1 |
| EuRho | Tetracycline hydrochloride | 1811031-01 | 3 |
| euRho | Tetracycline hydrochloride | 2004023-01 | 1 |
| EuRho | Tetracycline hydrochloride | 2004023-01 | 1 |
| EuRho | Tetracycline hydrochloride | 2203017-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 100518-62 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1103003-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1110029-01 | 2 |
| Euro OTC | Tetracycline hydrochloride | 12040390 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1204039-01 | 5 |
| Euro OTC | Tetracycline hydrochloride | 120403902 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1204039-02 | 14 |
| Euro OTC | Tetracycline hydrochloride | 1302012-01 | 7 |
| Euro OTC | Tetracycline hydrochloride | 1302012-02 | 16 |
| Euro OTC | Tetracycline hydrochloride | 13042015C | 1 |
| Euro OTC | Tetracycline hydrochloride | 140203001 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1402030-01 | 9 |
| Euro OTC | Tetracycline hydrochloride | 1402030-02 | 9 |
| Euro OTC | Tetracycline hydrochloride | 140410-62 | 1 |
| Euro OTC | Tetracycline hydrochloride | 14120007-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 141200701 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1412007-01 | 12 |
| Euro OTC | Tetracycline hydrochloride | 1412007-03 | 12 |
| Euro OTC | Tetracycline hydrochloride | 150601201 | 2 |
| Euro OTC | Tetracycline hydrochloride | 1506012-01 | 31 |
| Euro OTC | Tetracycline hydrochloride | 1506012-02 | 6 |
| Euro OTC | Tetracycline hydrochloride | 1506012-02Eur | 1 |
| Euro OTC | Tetracycline hydrochloride | 150612-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 151018-61 | 1 |
| Euro OTC | Tetracycline hydrochloride | 160302 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1603026 | 2 |
| Euro OTC | Tetracycline hydrochloride | 1603026_01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 160302601 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1603026-01 | 43 |
| Euro OTC | Tetracycline hydrochloride | 16032026-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 160621TCH | 1 |
| Euro OTC | Tetracycline hydrochloride | 1706020 | 2 |
| Euro OTC | Tetracycline hydrochloride | 170602001 | 4 |
| Euro OTC | Tetracycline hydrochloride | 1706020-01 | 68 |
| Euro OTC | Tetracycline hydrochloride | 1706020-02 | 2 |
| Euro OTC | Tetracycline hydrochloride | 17060201-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 180306T/1412007-03 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1811031 | 2 |
| Euro OTC | Tetracycline hydrochloride | 181103101 | 1 |
| Euro OTC | Tetracycline hydrochloride | 1811031-01 | 86 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Tetracycline hydrochloride | 1811031-02 | 4 |
| Euro OTC | Tetracycline hydrochloride | 18308314 | 1 |
| Euro OTC | Tetracycline hydrochloride | 20004023-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | 2004023 | 3 |
| Euro OTC | Tetracycline hydrochloride | 200402301 | 3 |
| Euro OTC | Tetracycline hydrochloride | 2004023-01 | 59 |
| Euro OTC | Tetracycline hydrochloride | 2004023-02 | 5 |
| Euro OTC | Tetracycline hydrochloride | 210301501 | 1 |
| Euro OTC | Tetracycline hydrochloride | 2103015-01 | 14 |
| Euro OTC | Tetracycline hydrochloride | 2103015-02 | 3 |
| Euro OTC | Tetracycline hydrochloride | 21031702 | 1 |
| Euro OTC | Tetracycline hydrochloride | 21111404 | 1 |
| Euro OTC | Tetracycline hydrochloride | 22(1706020-01) | 1 |
| Euro OTC | Tetracycline hydrochloride | 2203017-01 | 4 |
| Euro OTC | Tetracycline hydrochloride | 2301001 | 1 |
| Euro OTC | Tetracycline hydrochloride | 27101708 | 1 |
| Euro OTC | Tetracycline hydrochloride | 28021315 | 1 |
| Euro OTC | Tetracycline hydrochloride | 29052001 | 1 |
| Euro OTC | Tetracycline hydrochloride | 411682 | 1 |
| Euro OTC | Tetracycline hydrochloride | 80111031-01 | 1 |
| Euro OTC | Tetracycline hydrochloride | RetestCharge20219/3 | 1 |
| Euro OTG/ AHD | Tetracycline hydrochloride | 1706020-01 | 1 |
| EUro/AHD | Tetracycline hydrochloride | 1302012-01 | 1 |
| Euro/Anzag | Tetracycline hydrochloride | 1603026-01 | 1 |
| EuRo/Noweda | Tetracycline hydrochloride | 1603026-01 | 1 |
| EuRo/Noweda | Tetracycline hydrochloride | 1706020-01 | 1 |
| euro/phönix | Tetracycline hydrochloride | 1506012-01 | 2 |
| Euro/Phönix | Tetracycline hydrochloride | 200402302 | 1 |
| EuRoh/ Gehe | Tetracycline hydrochloride | 1811031 | 1 |
| Europh/An | Tetracycline hydrochloride | 2004023-01 | 1 |
| Europharm/Otto | Tetracycline hydrochloride | 1204039-01 | 1 |
| Fagron | Tetracycline hydrochloride | 12E10-N015 | 1 |
| Fagron | Tetracycline hydrochloride | 12E10-N05 | 1 |
| Fagron | Tetracycline hydrochloride | 12J15-N05 | 1 |
| Fagron | Tetracycline hydrochloride | 13201301 | 1 |
| Fagron | Tetracycline hydrochloride | 13F17-N03 | 4 |
| Fagron | Tetracycline hydrochloride | 13J22-N04 | 1 |
| Fagron | Tetracycline hydrochloride | 13L10-B02-294454 | 1 |
| Fagron | Tetracycline hydrochloride | 13L10-B02-294455 | 2 |
| Fagron | Tetracycline hydrochloride | 1402030-02 | 2 |
| Fagron | Tetracycline hydrochloride | 14H06-B05 | 1 |
| Fagron | Tetracycline hydrochloride | 14H06-B05-299498 | 1 |
| Fagron | Tetracycline hydrochloride | 14H06-B05-303911 | 1 |
| Fagron | Tetracycline hydrochloride | 14H06-B05-303912 | 7 |
| Fagron | Tetracycline hydrochloride | 14H06-B05-311707 | 1 |
| Fagron | Tetracycline hydrochloride | 14H06-B05-314870 | 1 |
| Fagron | Tetracycline hydrochloride | 14H06-Bo5-303912 | 1 |
| Fagron | Tetracycline hydrochloride | 1506012-01 | 1 |
| Fagron | Tetracycline hydrochloride | 18308305 | 1 |
| Fargon/Noweda | Tetracycline hydrochloride | 1811031-01 | 1 |
| Gatt-Koller | Tetracycline hydrochloride | 1700729 | 1 |
| Gehe Rostock | Tetracycline hydrochloride | 192021010 | 1 |
| Gehe | Tetracycline hydrochloride | 1110029-01 | 1 |
| Gehe | Tetracycline hydrochloride | 15230703 | 1 |
| Gehe | Tetracycline hydrochloride | 16116706 | 1 |
| Gehe | Tetracycline hydrochloride | 1706020-01 | 1 |
| Gehe | Tetracycline hydrochloride | 18198603 | 1 |
| GEHE | Tetracycline hydrochloride | 18198612 | 1 |
| Gehe | Tetracycline hydrochloride | 2000178003 | 1 |
| Gehe | Tetracycline hydrochloride | 2004023-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Tetracycline hydrochloride | 2103015-01 | 3 |
| Gehe | Tetracycline hydrochloride | 2103015-02 | 1 |
| GEHE | Tetracycline hydrochloride | 2203017-01 | 1 |
| Hoff/ Noweda | Tetracycline hydrochloride | 14364604 | 1 |
| Ichthyol/Phönix | Tetracycline hydrochloride | 1603026-01 | 1 |
| Ichthyol-Gesellschaft | Tetracycline hydrochloride | 1603026-01 | 1 |
| Jenne | Tetracycline hydrochloride | 1506012-02 | 1 |
| Jenne | Tetracycline hydrochloride | 18198602 | 1 |
| Jenne | Tetracycline hydrochloride | 21003348011 | 1 |
| Kehr Holdermann | Tetracycline hydrochloride | 24002486005 | 1 |
| Kehr.22.04.2020 | Tetracycline hydrochloride | 192021004 | 1 |
| Kehr | Tetracycline hydrochloride | 23000427003 | 2 |
| Kehr | Tetracycline hydrochloride | 23000427005 | 1 |
| Ningxia / Caesar & L... | Tetracycline hydrochloride | 17285801 | 1 |
| Ningxia Qiyuan Pharm... | Tetracycline hydrochloride | 21003348002 | 1 |
| Ningxia Qiyuan Pharm... | Tetracycline hydrochloride | 1811031-01 | 1 |
| ningxia | Tetracycline hydrochloride | 1412007-01 | 1 |
| Ningxia | Tetracycline hydrochloride | 1603026-01 | 3 |
| Noweda | Tetracycline hydrochloride | 13201307 | 1 |
| Noweda | Tetracycline hydrochloride | 1412007-03 | 1 |
| Noweda | Tetracycline hydrochloride | 1506012-01 | 1 |
| Noweda | Tetracycline hydrochloride | 17285801 | 1 |
| Noweda | Tetracycline hydrochloride | 17285802 | 1 |
| Noweda | Tetracycline hydrochloride | 18198603 | 1 |
| Noweda | Tetracycline hydrochloride | 210033448008 | 1 |
| Noweda | Tetracycline hydrochloride | 21003348011 | 1 |
| Noweda | Tetracycline hydrochloride | 21003348015 | 1 |
| Noweda | Tetracycline hydrochloride | 2203017-01 | 1 |
| Noweda | Tetracycline hydrochloride | 24000509004 | 1 |
| Noweda | Tetracycline hydrochloride | 24000509013 | 1 |
| Ph.Eur/Sanacorp | Tetracycline hydrochloride | 1811031-01 | 1 |
| Phoenix | Tetracycline hydrochloride | 170602001 | 3 |
| Phoenix | Tetracycline hydrochloride | 18198612 | 1 |
| Phoenix | Tetracycline hydrochloride | 3428 | 1 |
| Phönix Gotha | Tetracycline hydrochloride | 1302012-01 | 1 |
| Phönix | Tetracycline hydrochloride | 16116715 | 1 |
| PHÖNIX | Tetracycline hydrochloride | 16116721 | 1 |
| Phönix | Tetracycline hydrochloride | 1706020-01 | 1 |
| PHÖNIX | Tetracycline hydrochloride | 192021004 | 1 |
| phönix | Tetracycline hydrochloride | 2103015-01 | 1 |
| phönix | Tetracycline hydrochloride | 2203017-01 | 1 |
| Röntgen | Tetracycline hydrochloride | 17285801 | 1 |
| s. Protokol | Tetracycline hydrochloride | | 1 |
| Sanacorp | Tetracycline hydrochloride | 100403401 | 1 |
| Sanacorp | Tetracycline hydrochloride | 1402030-01 | 1 |
| Sanacorp | Tetracycline hydrochloride | 1603026-01 | 1 |
| Sanacorp | Tetracycline hydrochloride | 192021011 | 1 |
| Sanacorp | Tetracycline hydrochloride | 204023-01 | 1 |
| Sanacorp | Tetracycline hydrochloride | 21003348008 | 1 |
| Sanacorp | Tetracycline hydrochloride | 2203017-01 | 1 |
| Sanacorp | Tetracycline hydrochloride | 23000427009 | 1 |
| yinchuan Ningxia | Tetracycline hydrochloride | 1811031-01 | 1 |

- 255 741 spectra from 1666 *Apo-Ident* customers from a total of 51 959 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tetracycline hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tetracycline hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 500 | 0 | 157 826 |
| **Type B** | 0 | 320 | 0 | 212 620 |
| **Type C** | 0 | 1140 | 5 | 255 741 |

The substance/substance group *Tetracycline hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.1250 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.5633 % (> 99.3013 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21079 | 21079 | 0.00 | 164.23 |
| 21427 | 21835 | 11.79 | 130.12 |
| 21428 | 21835 | 8.46 | 116.48 |
| 21835 | 21835 | 0.00 | 99.26 |
| 22468 | 22468 | 0.00 | 245.71 |
| 22833 | 25686 | 8.88 | 182.98 |
| 25279 | 25279 | 0.00 | 202.48 |
| 25686 | 25686 | 0.00 | 166.64 |
| 26301 | 21079 | 8.09 | 162.55 |
| 27569 | 21835 | 20.74 | 138.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Theophylline** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20723-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Theophylline; Theophyllinum

### Special notes

When selecting the *Theophylline* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Theophylline | 6 | 3 | 15 |

### Second-stage model

For differentiation of the substance/substance group *Theophylline* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Theophylline* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Midazolam hydrochloride | 112.52 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Theophylline* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Theophylline*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Theophylline | 12166316 | 20723 | 40 | 1402055 |
| Caelo | Theophylline | 12341101 | 21740 | 60 | 20121115 |
| Caelo | Theophylline | 192563 | 24902 | 40 | 20191120* |
| Caelo | Theophylline | 22001229002 | 26236 | 40 | 20220505 |
| Caelo | Theophylline | 24001902 | 27317 | 40 | 20240819* |
| Gatt-Koller | Theophylline | 23J01412 | 27095 | 30 | 20230809 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 250 spectra of 6 reference samples from the substance/substance group *Theophylline*. These

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 076 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 180 spectra of 6 reference samples from the substance/substance group *Theophylline*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Theophylline | 15203018 | 23253 | 40 |
| Caelo | Theophylline | 171962 | 23854 | 40 |
| Caelo | Theophylline | 23001176 | 26838 | 40 |
| Caelo | Theophylline | 22001229002 | 26236SI† | 20 |
| Caelo | Theophylline | 23001176 | 26838SI | 20 |
| Gatt-Koller | Theophylline | 23J01412 | 27095SI† | 20 |

- 212 760 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 26 spectra from 23 *Apo-Ident* customers from 17 batches from the substance/substance group *Theophylline*.
- Among them are spectra of independent samples from 15 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Theophylline | 22001229007 | 1 |
| | Theophylline | 22001229009 | 1 |
| | Theophylline | 24001902002 | 1 |
| Alliance Healthcare | Theophylline | 192563003 | 1 |
| Caelo | Theophylline | 12166305 | 2 |
| Caelo | Theophylline | 12166306 | 1 |
| Caelo | Theophylline | 12166311 | 1 |
| Caelo | Theophylline | 12166312 | 3 |
| Caelo | Theophylline | 12166315 | 1 |
| Caelo | Theophylline | 12341101 | 2 |
| Caelo | Theophylline | 12341104 | 1 |
| Caelo | Theophylline | 15203010 | 1 |
| Caelo | Theophylline | 17196203 | 2 |
| Caelo | Theophylline | 18097508 | 1 |
| Caelo | Theophylline | 22001229002 | 1 |
| Caelo | Theophylline | 22001229006 | 1 |
| Caesar & Loretz GmbH | Theophylline | 21000106001 | 1 |
| Caesar & Loretz GmbH | Theophylline | 22001229002 | 1 |
| Caesar&loretz,Phoenix | Theophylline | 12166315 | 1 |
| Caeser und Loretz GmbH | Theophylline | 18097508 | 1 |
| Noweda | Theophylline | 12166305 | 1 |

- 256 860 spectra from 1666 *Apo-Ident* customers from a total of 52 136 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Theophylline* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Theophylline* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 250 | 0 | 158 076 |
| **Type B** | 0 | 180 | 0 | 212 760 |
| **Type C** | 0 | 26 | 0 | 256 860 |

The substance/substance group *Theophylline* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.6000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.6667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 76.9231 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20723 | 20723 | 0.00 | 261.54 |
| 21740 | 20723 | 16.36 | 275.47 |
| 24902 | 24902 | 0.00 | 260.62 |
| 26236 | 24902 | 7.83 | 259.74 |
| 27095 | 20723 | 13.28 | 250.45 |
| 27317 | 27317 | 0.00 | 254.67 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Theophylline-ethylenediamine hydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20831-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Theophylline-ethylenediamine hydrate; Theophyllinum et ethylendiaminum hydricum

### Special notes

When selecting the *Theophylline-ethylenediamine hydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Theophylline-ethylenediamine hydrate | 7 | 5 | 2 |

### Second-stage model

For differentiation of the substance/substance group *Theophylline-ethylenediamine hydrate* the following second-stage model is used:

- Submodel 12

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Theophylline-ethylenediamine hydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycine | 105.94 | – |
| ⋮ | ⋮ | ⋮ |
| Clioquinol | >50 | 20.49 |
| Mesalazine | >50 | 46.19 |
| Miconazole nitrate | >50 | 49.72 |
| Nicotinic acid | >50 | 112.58 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Theophylline-ethylenediamine hydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Theophylline-ethylenediamine hydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Theophylline-ethylenediam… | 12145301 | 20831 | 40 | 20120628 |
| Caelo | Theophylline-ethylenediam… | 12363708 | 20992 | 40 | 20130116 |
| Caelo | Theophylline-ethylenediam… | 13268609 | 21549 | 40 | 1412133 |
| Caelo | Theophylline-ethylenediam… | 15380302 | 22589 | 40 | 20160211 |
| Caelo | Theophylline-ethylenediam… | 17073707 | 23564 | 30 | 20170323 |
| Caelo | Theophylline-ethylenediam… | 192220 | 24903 | 40 | 20191204* |
| Caelo | Theophylline-ethylenediam… | 20004052 | 25510 | 40 | 20201201 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 270 spectra of 7 reference samples from the substance/substance group *Theophylline-ethylenediamine hydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 158 056 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 250 spectra of 8 reference samples from the substance/substance group *Theophylline-ethylenediamine hydrate*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Theophylline-ethylenediam… | 172999 | 23823 | 40 |
| Caelo | Theophylline-ethylenediam… | 182738 | 24383 | 40 |
| Caelo | Theophylline-ethylenediam… | 22000118006 | 25974 | 40 |
| Caelo | Theophylline-ethylenediam… | 22003464 | 26499 | 40 |
| Caelo | Theophylline-ethylenediam… | 23003143 | 27237 | 40 |
| Caelo | Theophylline-ethylenediam… | 22000118006 | 25974SI | 10 |
| Caelo | Theophylline-ethylenediam… | 22003464 | 26499SI | 20 |
| Caelo | Theophylline-ethylenediam… | 23003143 | 27237SI | 20 |

- 212 690 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 4 spectra from 4 *Apo-Ident* customers from 3 batches from the substance/substance group *Theophylline-ethylenediamine hydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| ACM / Phoenix | Theophylline-ethylenediam… | KNC0896J14 | 1 |
| Caelo | Theophylline-ethylenediam… | 15380302 | 1 |
| Caelo | Theophylline-ethylenediam… | 20003320003 | 1 |
| Caesar & Loretz GmbH | Theophylline-ethylenediam… | 20003320003 | 1 |

- 256 882 spectra from 1666 *Apo-Ident* customers from a total of 52 150 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Theophylline-ethylenediamine hydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Theophylline-ethylenediamine hydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 270 | 0 | 158 056 |
| **Type B** | 0 | 250 | 0 | 212 690 |
| **Type C** | 0 | 4 | 0 | 256 882 |

The substance/substance group *Theophylline-ethylenediamine hydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.7778 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.6000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20831 | 21549 | 9.66 | 161.62 |
| 20992 | 21549 | 5.50 | 160.53 |
| 21549 | 21549 | 0.00 | 158.99 |
| 22589 | 24903 | 7.57 | 166.51 |
| 23564 | 24903 | 9.71 | 170.09 |
| 24903 | 24903 | 0.00 | 165.26 |
| 25510 | 21549 | 14.56 | 166.97 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Thiamine chloride hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20566-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Thiamine chloride hydrochloride; Thiamini hydrochloridum

### Special notes

When selecting the *Thiamine chloride hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Thiamine chloride hydrochloride | 9 | 13 | 43 |

### Second-stage model

For differentiation of the substance/substance group *Thiamine chloride hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Thiamine chloride hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 88.78 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Thiamine chloride hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Thiamine chloride hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Thiamine chloride hydroch… | 14069502 | 21478 | 60 | 20140321 |
| Caelo | Thiamine chloride hydroch… | 14069502 | 21511 | 60 | 8986 |
| Caelo | Thiamine chloride hydroch… | 160156 | 22477 | 60 | 20160316* |
| Caelo | Thiamine chloride hydroch… | 192567 | 25095 | 40 | 20191216* |
| Caelo | Thiamine chloride hydroch… | 20001173 | 25193 | 40 | 20200724* |
| Euro OTC | Thiamine chloride hydroch… | 1211008-02 | 21647 | 60 | 20121122 |
| Euro OTC | Thiamine chloride hydroch… | 1612004 | 22919 | 40 | 20170117* |
| Euro OTC | Thiamine chloride hydroch… | 2004007 | 25274 | 40 | 20200618* |
| Euro OTC | Thiamine chloride hydroch… | 2007034 | 25332 | 40 | 20200909* |
| Euro OTC | Thiamine chloride hydroch… | 2309008 | 26928 | 40 | 20231006* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 480 spectra of 10 reference samples from the substance/substance group *Thiamine chloride hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 846 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 555 spectra of 16 reference samples from the substance/substance group *Thiamine chloride hydrochloride*.

- Among them are spectra of independent samples from 13 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Thiamine chloride hydroch… | 170976 | 23368 | 40 |
| Caelo | Thiamine chloride hydroch… | 21002868002 | 26416 | 30 |
| Caelo | Thiamine chloride hydroch… | 22003533 | 26482 | 40 |
| Caelo | Thiamine chloride hydroch… | 23001172 | 26835 | 40 |
| Euro OTC | Thiamine chloride hydroch… | 1705034 | 23439 | 40 |
| Euro OTC | Thiamine chloride hydroch… | 1712013 | 23911 | 40 |
| Euro OTC | Thiamine chloride hydroch… | 1807001 | 24146 | 40 |
| Euro OTC | Thiamine chloride hydroch… | 2201045 | 25961 | 40 |
| Euro OTC | Thiamine chloride hydroch… | 2207008 | 26211 | 40 |
| Euro OTC | Thiamine chloride hydroch… | 2501017 | 27514 | 40 |
| Fagron | Thiamine chloride hydroch… | 22I22-B05-223757 | 26536 | 40 |
| Fagron | Thiamine chloride hydroch… | 23G04-B12-239937 | 27191 | 40 |
| Fagron | Thiamine chloride hydroch… | 24J08-B09-007103 | 27613 | 40 |
| Caelo | Thiamine chloride hydroch… | 22003533 | 26482SI | 20 |
| Euro OTC | Thiamine chloride hydroch… | 2201045 | 25961SI | 5 |
| Euro OTC | Thiamine chloride hydroch… | 2207008 | 26211SI | 20 |

- 212 385 spectra from a total of 4274 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 75 spectra from 30 *Apo-Ident* customers from 45 batches from the substance/substance group *Thiamine chloride hydrochloride*.

- Among them are spectra of independent samples from 43 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Thiamine chloride hydroch… | 22001226008 | 1 |
| | Thiamine chloride hydroch… | 22001226009 | 2 |
| | Thiamine chloride hydroch… | 22001226012 | 3 |
| | Thiamine chloride hydroch… | 2201045-01 | 2 |
| | Thiamine chloride hydroch… | 23003557002 | 5 |
| Caelo | Thiamine chloride hydroch… | | 1 |
| Caelo | Thiamine chloride hydroch… | 11061401 | 1 |
| Caelo | Thiamine chloride hydroch… | 11371309 | 2 |
| Caelo | Thiamine chloride hydroch… | 11371313 | 1 |
| Caelo | Thiamine chloride hydroch… | 11371319 | 3 |
| Caelo | Thiamine chloride hydroch… | 12091407 | 1 |
| Caelo | Thiamine chloride hydroch… | 12340712 | 1 |
| Caelo | Thiamine chloride hydroch… | 13296610 | 4 |
| Caelo | Thiamine chloride hydroch… | 14069502 | 1 |
| Caelo | Thiamine chloride hydroch… | 15003201 | 1 |
| Caelo | Thiamine chloride hydroch… | 15199009 | 2 |
| Caelo | Thiamine chloride hydroch… | 15199099 | 1 |
| Caelo | Thiamine chloride hydroch… | 15269613 | 1 |
| Caelo | Thiamine chloride hydroch… | 16015607 | 1 |
| Caelo | Thiamine chloride hydroch… | 16015609 | 1 |
| Caelo | Thiamine chloride hydroch… | 17097602 | 1 |
| Caelo | Thiamine chloride hydroch… | 171201301 | 1 |
| Caelo | Thiamine chloride hydroch… | 18163717 | 2 |
| Caelo | Thiamine chloride hydroch… | 20001173002 | 2 |
| Caelo | Thiamine chloride hydroch… | 20004527005 | 1 |
| Caelo | Thiamine chloride hydroch… | 4071402 | 1 |
| Caelo | Thiamine chloride hydroch… | 5122 | 1 |
| Caelo | Thiamine chloride hydroch… | 8121405 | 1 |
| Caesar & Loretz GmbH | Thiamine chloride hydroch… | 18163705 | 1 |
| Caesar & Loretz GmbH | Thiamine chloride hydroch… | 18163709 | 2 |
| Caesar & Loretz GmbH | Thiamine chloride hydroch… | 18163717 | 1 |
| Caesar & Loretz GmbH | Thiamine chloride hydroch… | 20004527005 | 5 |
| Euro OTC | Thiamine chloride hydroch… | 1211008-01 | 1 |
| Euro OTC | Thiamine chloride hydroch… | 161200401 | 1 |
| Euro OTC | Thiamine chloride hydroch… | 1705034-01 | 2 |
| Euro OTC | Thiamine chloride hydroch… | 1712013-01 | 1 |
| Euro OTC | Thiamine chloride hydroch… | 1807001-01 | 3 |
| Euro OTC | Thiamine chloride hydroch… | 2004007-01 | 1 |
| Euro OTC | Thiamine chloride hydroch… | 2007034-01 | 1 |
| Euro OTC | Thiamine chloride hydroch… | 2207008-01 | 1 |
| Fagron | Thiamine chloride hydroch… | 10111401 | 1 |
| Fagron | Thiamine chloride hydroch… | 13E22-No8 | 1 |
| Fagron | Thiamine chloride hydroch… | 17F23-B02-340810 | 1 |
| Fagron | Thiamine chloride hydroch… | 190115006 | 1 |
| Fagron | Thiamine chloride hydroch… | 20A13-B08-196821 | 1 |
| Fagron | Thiamine chloride hydroch… | 20F16-B09-201351 | 2 |
| Finze | Thiamine chloride hydroch… | 9216114 | 1 |
| Jiangxi Tianxin | Thiamine chloride hydroch… | 1807001-01 | 1 |
| Sanacorp | Thiamine chloride hydroch… | 12340712 | 1 |

- 256 811 spectra from 1666 *Apo-Ident* customers from a total of 52 109 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,


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the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Thiamine chloride hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Thiamine chloride hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 555 | 0 | 212 385 |
| **Type C** | 0 | 75 | 0 | 256 811 |

The substance/substance group *Thiamine chloride hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.9189 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 92.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21478 | 25274 | 12.04 | 174.01 |
| 21511 | 21511 | 0.00 | 181.89 |
| 21647 | 22477 | 10.60 | 191.28 |
| 22477 | 22477 | 0.00 | 201.44 |
| 22919 | 22919 | 0.00 | 181.33 |
| 25095 | 25095 | 0.00 | 180.46 |
| 25193 | 25193 | 0.00 | 186.53 |
| 25274 | 25274 | 0.00 | 177.43 |
| 25332 | 25332 | 0.00 | 169.64 |
| 26928 | 26928 | 0.00 | 160.28 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by

laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Thiomersal** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20702-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Thiomersal; Thiomersalum

### Special notes

When selecting the *Thiomersal* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Thiomersal | 3 | 1 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Thiomersal* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Thiomersal* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prilocaine hydrochloride | 98.80 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Thiomersal* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Thiomersal*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Thiomersal | 172173 | 23679 | 30 | 20170919* |
| Caelo | Thiomersal | 22003780 | 27219 | 40 | 20230404* |
| Caelo | Thiomersal | 22003780 | 27219SI | 20 | 20230404* |
| Fagron | Thiomersal | 11K01-N03 | 20702 | 40 | 1401417 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 130 spectra of 4 reference samples from the substance/substance group *Thiomersal*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 196 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 40 spectra of 1 reference samples from the substance/substance group *Thiomersal*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Thiomersal | 193090 | 25198 | 40 |

- 212 900 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 27 spectra from 16 *Apo-Ident* customers from 17 batches from the substance/substance group *Thiomersal*.
- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Thiomersal | 20004306007 | 1 |
| | Thiomersal | 22003780001 | 1 |
| | Thiomersal | 22003780002 | 4 |
| | Thiomersal | 23003535001 | 2 |
| | Thiomersal | 23003535002 | 1 |
| Caelo | Thiomersal | 10296413 | 1 |
| Caelo | Thiomersal | 13577020 | 1 |
| Caelo | Thiomersal | 20004306001 | 1 |
| Caelo | Thiomersal | 20004306002 | 1 |
| Caelo | Thiomersal | 20004306003 | 2 |
| Caelo | Thiomersal | 20004306005 | 1 |
| Caelo | Thiomersal | 21051507 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Thiomersal | 12275218 | 1 |
| Caesar & Loretz GmbH | Thiomersal | 193090002 | 1 |
| Caesar & Loretz GmbH | Thiomersal | 20004306003 | 3 |
| Caesar & Loretz GmbH | Thiomersal | 20004306005 | 2 |
| Fagron | Thiomersal | | 1 |
| Fagron | Thiomersal | 12F19-N11 | 1 |
| Fagron | Thiomersal | 12J17-N02 | 1 |

- 256 859 spectra from 1666 *Apo-Ident* customers from a total of 52 136 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Thiomersal* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Thiomersal* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 130 | 0 | 158 196 |
| **Type B** | 0 | 40 | 0 | 212 900 |
| **Type C** | 0 | 27 | 0 | 256 859 |

The substance/substance group *Thiomersal* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.3846 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 85.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 77.7778 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20702 | 20702 | 0.00 | 134.98 |
| 23679 | 23679 | 0.00 | 139.95 |
| 27219 | 27219 | 0.00 | 133.98 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Thymol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20003-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Thymol; Thymolum

### Special notes

When selecting the *Thymol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Thymol | 8 | 9 | 82 |

### Second-stage model

For differentiation of the substance/substance group *Thymol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Thymol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 79.74 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Thymol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Thymol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Thymol | 14025805 | 21469 | 60 | 20140127 |
| Caelo | Thymol | 16144101 | 23160 | 40 | 20160606 |
| Caelo | Thymol | 173407 | 23837 | 40 | 20180110* |
| Caelo | Thymol | 21000880 | 25650 | 40 | 20210401* |
| Caelo | Thymol | 23001568 | 26840 | 40 | 20230622* |
| Caelo | Thymol | 23001568 | 26840SI | 40 | 20230622* |
| Euro OTC | Thymol | 1312022-02 | 21639 | 60 | 20131219 |
| Euro OTC | Thymol | 1510004 | 21943 | 60 | 20151016* |
| Fagron | Thymol | 15H13-B05-328912 | 23499 | 40 | 20151118 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 420 spectra of 9 reference samples from the substance/substance group *Thymol*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 906 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 409 spectra of 11 reference samples from the substance/substance group *Thymol*.

- Among them are spectra of independent samples from 9 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Thymol | 181424 | 24231 | 40 |
| Caelo | Thymol | 190342 | 24552 | 40 |
| Caelo | Thymol | 21002863 | 25862 | 50 |
| Caelo | Thymol | 22002344 | 26245 | 40 |
| Caelo | Thymol | 22002044 | 26258 | 40 |
| Caelo | Thymol | 24000390 | 27122 | 40 |
| Caelo | Thymol | 24001437 | 27313 | 39 |
| Euro OTC | Thymol | 1710037 | 23773 | 40 |
| Euro OTC | Thymol | 1808014 | 24299 | 40 |
| Caelo | Thymol | 22002344 | 26245SI | 20 |
| Caelo | Thymol | 22002044 | 26258SI | 20 |

- 212 531 spectra from a total of 4278 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 244 spectra from 189 *Apo-Ident* customers from 85 batches from the substance/substance group *Thymol*.

- Among them are spectra of independent samples from 82 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Thymol | 14025802 | 1 |
| | Thymol | 22002044004 | 3 |
| | Thymol | 23000600003 | 1 |
| | Thymol | 23003216001 | 1 |
| | Thymol | 23003216003 | 2 |
| | Thymol | 23003216008 | 1 |
| ACM / Herba | Thymol | KNC1166J14 | 1 |
| AHD | Thymol | 22002044004 | 1 |
| Alliance Healthcare | Thymol | 20003672009 | 1 |
| apo-ident | Thymol | 1808014-01 | 1 |
| Caelo | Thymol | 11178718 | 1 |
| Caelo | Thymol | 11358607 | 2 |
| Caelo | Thymol | 11358608 | 1 |
| Caelo | Thymol | 11358616 | 2 |
| Caelo | Thymol | 13147502 | 2 |
| Caelo | Thymol | 13288802 | 4 |
| Caelo | Thymol | 13288806 | 1 |
| Caelo | Thymol | 14025802 | 2 |
| Caelo | Thymol | 14025805 | 1 |
| Caelo | Thymol | 14025807 | 1 |
| Caelo | Thymol | 14025809 | 2 |
| Caelo | Thymol | 14025815 | 1 |
| Caelo | Thymol | 14025816 | 1 |
| Caelo | Thymol | 14302401 | 1 |
| Caelo | Thymol | 14310601 | 2 |
| Caelo | Thymol | 14310605 | 1 |
| Caelo | Thymol | 15130101 | 2 |
| Caelo | Thymol | 15130106 | 3 |
| Caelo | Thymol | 15362901 | 5 |
| Caelo | Thymol | 15362908 | 4 |
| Caelo | Thymol | 16144101 | 6 |
| Caelo | Thymol | 16144105 | 7 |
| Caelo | Thymol | 16144108 | 7 |
| Caelo | Thymol | 161441108 | 1 |
| Caelo | Thymol | 1730711 | 1 |
| Caelo | Thymol | 17324203 | 4 |
| Caelo | Thymol | 17340708 | 1 |
| Caelo | Thymol | 17340711 | 7 |
| Caelo | Thymol | 17340716 | 2 |
| Caelo | Thymol | 18221907 | 1 |
| Caelo | Thymol | 19034203 | 5 |
| Caelo | Thymol | 19034205 | 4 |
| Caelo | Thymol | 19061303 | 1 |
| Caelo | Thymol | 192437003 | 3 |
| Caelo | Thymol | 19243701 | 10 |
| Caelo | Thymol | 20001482001 | 6 |
| Caelo | Thymol | 20001482003 | 5 |
| Caelo | Thymol | 20003672003 | 3 |
| Caelo | Thymol | 20003672006 | 6 |
| Caelo | Thymol | 20003672007 | 5 |
| Caelo | Thymol | 20003750002 | 1 |
| Caelo | Thymol | 2031503 | 1 |
| Caelo | Thymol | 21000880002 | 2 |
| Caelo | Thymol | 21000880007 | 2 |
| Caelo | Thymol | 2100088002 | 1 |
| Caelo | Thymol | 21042 | 1 |
| Caelo | Thymol | 4364887223 | 1 |
| Caesar & Loretz GmbH... | Thymol | 19034205 | 1 |
| Caesar & Loretz GmbH... | Thymol | 21000880009 | 1 |
| Caesar & Loretz GmbH... | Thymol | 19034203 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Thymol | 192437003 | 1 |
| Caesar & Loretz GmbH... | Thymol | 18221907 | 1 |
| Caesar & Loretz GmbH... | Thymol | 20003672009 | 1 |
| Caesar & Loretz GmbH | Thymol | 16144101 | 1 |
| Caesar & Loretz GmbH | Thymol | 17340711 | 1 |
| Caesar & Loretz GmbH | Thymol | 17340716 | 2 |
| Caesar & Loretz GmbH | Thymol | 19034203 | 1 |
| Caesar & Loretz GmbH | Thymol | 19034205 | 1 |
| Caesar & Loretz GmbH | Thymol | 192437003 | 1 |
| Caesar & Loretz GmbH | Thymol | 19243701 | 3 |
| Caesar & Loretz GmbH | Thymol | 20001482001 | 2 |
| Caesar & Loretz GmbH | Thymol | 20003672003 | 3 |
| Caesar & Loretz GmbH | Thymol | 20003672006 | 2 |
| Caesar & Loretz GmbH | Thymol | 20003672007 | 2 |
| Caesar & Loretz GmbH | Thymol | 20003750002 | 1 |
| Caesar & Loretz GmbH | Thymol | 21000880005 | 1 |
| Caesar & Loretz GmbH | Thymol | 21000880007 | 1 |
| Caesar & Loretz GmbH | Thymol | 21000880009 | 1 |
| Caesar & Loretz GmbH | Thymol | 22002044004 | 1 |
| Caesar § Lorenz GmbH | Thymol | 13288806 | 1 |
| Ebert & Jacobi 02... | Thymol | 15362901 | 1 |
| Euro OTC | Thymol | 1107021-01 | 1 |
| Euro OTC | Thymol | 11358603 | 1 |
| Euro OTC | Thymol | 1202028-01 | 1 |
| Euro OTC | Thymol | 1312022-01 | 1 |
| Euro OTC | Thymol | 1410007-01 | 5 |
| Euro OTC | Thymol | 15100004-03 | 1 |
| Euro OTC | Thymol | 1510004-01 | 2 |
| Euro OTC | Thymol | 1510004-02 | 9 |
| Euro OTC | Thymol | 1510004-03 | 1 |
| Euro OTC | Thymol | 1710037-01 | 5 |
| Euro OTC | Thymol | 1808014-01 | 3 |
| Euro OTC | Thymol | 20151012-1 | 1 |
| Euro/ Phönix | Thymol | 1510004-02 | 1 |
| Euro/Phönix | Thymol | 180801401 | 1 |
| Fagron | Thymol | 12B06-N11 | 1 |
| Fagron | Thymol | 12E30-N11 | 1 |
| Fagron | Thymol | 12H29-N02 | 2 |
| Fagron | Thymol | 12K01-N02 | 2 |
| Fagron | Thymol | 12M29-N02 | 1 |
| Fagron | Thymol | 713575 | 1 |
| Fagron | Thymol | 8G23-N09 | 2 |
| Frey+Lau GmbH/Phönix | Thymol | 1312022-01 | 1 |
| Gehe Kassel | Thymol | 1312022-01 | 1 |
| gehe | Thymol | 1808014-01 | 1 |
| Gehe | Thymol | 19243701 | 1 |
| gehe | Thymol | 20003672003 | 1 |
| gehe | Thymol | 5112139 | 1 |
| L12 | Thymol | 15172002 | 1 |
| L30 | Thymol | 1510004-03 | 1 |
| Noweda | Thymol | 12k01-no2 | 1 |
| Noweda | Thymol | 16144105 | 1 |
| Noweda | Thymol | 20003750007 | 2 |
| PHOENIX 26.03.2014 | Thymol | 14025802 | 2 |
| Phoenix | Thymol | 19034205 | 1 |
| Phoenix | Thymol | 20001482003 | 1 |
| Phönix | Thymol | 11358610 | 1 |
| Phönix | Thymol | 1510004-01 | 1 |
| Phönix | Thymol | 20001482003 | 1 |
| Sanacorp | Thymol | 1135816 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Thymol | 9E14-N16 | 1 |
| xxxxx | Thymol | | 1 |
| xxxxx | Thymol | RT1211 | 1 |

- 256 642 spectra from 1666 *Apo-Ident* customers from a total of 52 069 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Thymol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Thymol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 420 | 0 | 157 906 |
| **Type B** | 0 | 409 | 0 | 212 531 |
| **Type C** | 0 | 244 | 0 | 256 642 |

The substance/substance group *Thymol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5714 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5330 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 97.5410 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21469 | 23837 | 13.97 | 123.70 |
| 21639 | 23837 | 11.02 | 123.29 |
| 21943 | 21943 | 0.00 | 128.39 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 23160 | 23837 | 17.56 | 123.14 |
| 23499 | 23837 | 7.32 | 124.95 |
| 23837 | 23837 | 0.00 | 123.92 |
| 25650 | 25650 | 0.00 | 123.11 |
| 26840 | 26840 | 0.00 | 118.89 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Thyroid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10007125-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Thyroid; Thyreoidum; Thyroid powder

### Special notes

When selecting the *Thyroid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Thyroid | 2 | 1 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Thyroid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Thyroid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 44.41 | – |
| Lactose monohydrate | 52.47 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Thyroid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Thyroid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Bioiberica... | Thyroid | 24/0002 | 27531 | 40 | 20240708* |
| Bioiberica... | Thyroid | 24/0002 | 27531SI | 20 | 20240708* |
| Bioiberica... | Thyroid | 24/0006 | 27533 | 40 | 20240708* |
| Bioiberica... | Thyroid | 24/0006 | 27533SI | 20 | 20240708* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 120 spectra of 4 reference samples from the substance/substance group *Thyroid*. These samples are listed above in the *calibration samples* section. The reference samples come from 2 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 206 spectra from a total of 2955 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 2 reference samples from the substance/substance group *Thyroid*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Bioiberica S.A.U. | Thyroid | 24/0004 | 27532 | 40 |
| Bioiberica S.A.U. | Thyroid | 24/0004 | 27532SI | 20 |

- 212 880 spectra from a total of 4286 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Thyroid*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Thyroid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Thyroid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 120 | 0 | 158 206 |
| **Type B** | 0 | 60 | 0 | 212 682 |
| **Type C** | 0 | 0 | 0 | 256 884 |

The substance/substance group *Thyroid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9033 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 27531 | 27531 | 0.00 | 81.66 |
| 27533 | 27533 | 0.00 | 92.94 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tobramycin sulfate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20951-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tobramycin sulfate; Tobramycin sulphate; Tobramycini sulfas

### Special notes

When selecting the *Tobramycin sulfate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tobramycin sulfate | 15 | 4 | 19 |

### Second-stage model

For differentiation of the substance/substance group *Tobramycin sulfate* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tobramycin sulfate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Neomycin sulfate | 20.82 | 16.38 |
| Polymyxin B sulfate | 52.47 | – |
| ⋮ | ⋮ | ⋮ |
| Riboflavin sodium phosphate hydrate | >50 | 69.66 |
| Mg-Ca-K colamine phosphate | >50 | 70.60 |
| Zinc gluconate | >50 | 87.82 |
| Carbomers | >50 | 109.13 |
| Gentamicin sulfate | >50 | 127.67 |
| Magnesium citrate | >50 | 136.08 |
| Sodium tetraborate | >50 | 473.06 |
| Finasteride | >50 | 1279.29 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tobramycin sulfate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tobramycin sulfate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Tobramycin sulfate | AP15061047002T | 22393 | 40 | 1608462 |
| Audor Pharma | Tobramycin sulfate | AP15061047002T | 23502 | 40 | 20160322 |
| Euro OTC | Tobramycin sulfate | 1301011-02 | 21624 | 60 | 1508071 |
| Euro OTC | Tobramycin sulfate | 1505015-01 | 21832 | 60 | 8963 |
| Euro OTC | Tobramycin sulfate | 1510035-01 | 22240 | 60 | 9202 |
| Euro OTC | Tobramycin sulfate | 1510035 | 22252 | 60 | 20151208* |
| Euro OTC | Tobramycin sulfate | 1807045 | 24321 | 40 | 20180917* |
| Euro OTC | Tobramycin sulfate | 2001010 | 25100 | 40 | 20200113* |
| Euro OTC | Tobramycin sulfate | 2202013 | 26045 | 40 | 20220324* |
| Euro OTC | Tobramycin sulfate | 2404002 | 27371 | 40 | 20240904* |
| Fagron | Tobramycin sulfate | 12G03-N03 | 20951 | 40 | 1404541 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Tobramycin sulfate | 15I17-B04-315697 | 22359 | 45 | 20150928 |
| Fagron | Tobramycin sulfate | 16B05-B03-336397 | 23515 | 40 | 1801385 |
| Fagron | Tobramycin sulfate | 20H13-F05-373631 | 25506 | 40 | 2105375 |
| Fagron | Tobramycin sulfate | 20F18-F05-376114 | 25507 | 40 | 2105376 |
| Fagron | Tobramycin sulfate | 23K07-B16-233773 | 27050 | 40 | 20231215 |
| Fagron | Tobramycin sulfate | 23K07-B16-233773 | 27050SI | 20 | 20231215 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 745 spectra of 17 reference samples from the substance/substance group *Tobramycin sulfate*. These samples are listed above in the *calibration samples* section. The reference samples come from 15 different batches.

- 157 581 spectra from a total of 2942 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 190 spectra of 6 reference samples from the substance/substance group *Tobramycin sulfate*.

- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Tobramycin sulfate | 1710029 | 23870 | 40 |
| Euro OTC | Tobramycin sulfate | 1910008 | 25085 | 40 |
| Euro OTC | Tobramycin sulfate | 2211003 | 26569 | 40 |
| Fagron | Tobramycin sulfate | 20A14-F02-368920 | 25184 | 40 |
| Euro OTC | Tobramycin sulfate | 2202013 | 26045SI† | 10 |
| Euro OTC | Tobramycin sulfate | 2211003 | 26569SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 750 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 33 spectra from 14 *Apo-Ident* customers from 22 batches from the substance/substance group *Tobramycin sulfate*.
- Among them are spectra of independent samples from 19 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tobramycin sulfate | 22E06-B02-224488 | 2 |
| | Tobramycin sulfate | B02-2283406 | 1 |
| EuRho/VDL01 | Tobramycin sulfate | 1710029-01 | 1 |
| Euro OCT/Noweda | Tobramycin sulfate | 1510035-01 | 1 |
| Euro OTC | Tobramycin sulfate | 1505015-01 | 1 |
| Euro OTC | Tobramycin sulfate | 15I17-B04-315697 | 1 |
| Euro OTC | Tobramycin sulfate | 1807045-01 | 3 |
| Fagron | Tobramycin sulfate | 13H09-N09 | 1 |
| Fagron | Tobramycin sulfate | 15/17-B04-315697 | 1 |
| Fagron | Tobramycin sulfate | 16b-03-319433 | 1 |
| Fagron | Tobramycin sulfate | 16B05-B03 | 4 |
| Fagron | Tobramycin sulfate | 16B05-B03-317988 | 2 |
| Fagron | Tobramycin sulfate | 16B05-B03-319433 | 1 |
| Fagron | Tobramycin sulfate | 16B05-B03-330974 | 2 |
| Fagron | Tobramycin sulfate | 17E05-B03-338122 | 2 |
| Fagron | Tobramycin sulfate | 17J12-B04-341324 | 2 |
| Fagron | Tobramycin sulfate | 20A14-F02-368920 | 2 |
| Fagron | Tobramycin sulfate | 20H13-F05-373633 | 1 |
| Fagron | Tobramycin sulfate | 21A04-F02 | 1 |
| Fagron | Tobramycin sulfate | 21H30-B02-213664 | 1 |
| Fagron | Tobramycin sulfate | 21H30-B02-213666 | 1 |
| PHOENIX 31.01.2014 | Tobramycin sulfate | 1202006-01 | 1 |

- 256 853 spectra from 1666 *Apo-Ident* customers from a total of 52 131 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tobramycin sulfate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tobramycin sulfate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 745 | 0 | 157 581 |
| **Type B** | 0 | 190 | 0 | 212 750 |
| **Type C** | 0 | 32 | 1 | 256 853 |

The substance/substance group *Tobramycin sulfate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1946 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.8421 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 96.9697 % (> 87.8788 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20951 | 20951 | 0.00 | 113.12 |
| 21624 | 21624 | 0.00 | 96.84 |
| 21832 | 21832 | 0.00 | 90.35 |
| 22240 | 22240 | 0.00 | 122.46 |
| 22252 | 22252 | 0.00 | 89.99 |
| 22359 | 23515 | 20.12 | 103.08 |
| 22393 | 22393 | 0.00 | 55.55 |
| 23502 | 25100 | 16.10 | 70.62 |
| 23515 | 23515 | 0.00 | 100.27 |
| 24321 | 24321 | 0.00 | 70.13 |
| 25100 | 25100 | 0.00 | 85.33 |
| 25506 | 25506 | 0.00 | 175.28 |
| 25507 | 25507 | 0.00 | 165.74 |
| 26045 | 26045 | 0.00 | 105.07 |
| 27050 | 22240 | 33.59 | 160.74 |
| 27371 | 27371 | 0.00 | 54.95 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tosylchloramide sodium** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20133-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tosylchloramide sodium; Tosylchloramidum natricum

### Special notes

When selecting the *Tosylchloramide sodium* substance/substance group, the following information is displayed to the user:

- Advice: Currently no longer available from major pharmaceutical manufacturers. Therefore, batch maintenance is currently not possible.

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tosylchloramide sodium | 4 | 3 | 36 |

### Second-stage model

For differentiation of the substance/substance group *Tosylchloramide sodium* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tosylchloramide sodium* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 67.06 | – |
| ⋮ | ⋮ | ⋮ |
| Riboflavin | >50 | 26.14 |
| Polymyxin B sulfate | >50 | 49.81 |
| Hyoscine hydrobromide | >50 | 63.60 |
| Bacitracin | >50 | 65.19 |
| Cyanocobalamin | >50 | 68.63 |
| Colistin sulfate | >50 | 73.93 |
| Calcium pantothenate | >50 | 95.80 |
| Nystatin | >50 | 115.41 |
| Amphotericin B | >50 | 118.76 |
| Estradiol hemihydrate | >50 | 120.01 |
| Calcium glycerophosphate | >50 | 127.38 |
| Triamcinolone | >50 | 144.22 |
| Estriol | >50 | 156.40 |
| alpha-tocopheryl acetate dry concentrate | >50 | 167.42 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 169.82 |
| Methylcobalamin | >50 | 176.80 |
| Gelatine, white | >50 | 192.28 |
| Oxalic acid | >50 | 197.90 |
| SyrSpend® SF Alka | >50 | 199.92 |
| Rice starch | >50 | 219.28 |
| Carmellose sodium | >50 | 266.29 |
| Wheat starch | >50 | 282.14 |
| Fructose | >50 | 295.83 |
| SyrSpend® SF pH4 | >50 | 309.79 |
| Potato starch | >50 | 325.46 |
| Corn starch | >50 | 370.14 |
| Acacia, dried dispersion | >50 | 378.33 |
| Maltodextrin | >50 | 422.65 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tosylchloramide sodium* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tosylchloramide sodium*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Tosylchloramide sodium | 13103201 | 20864 | 40 | 20130424 |
| Caelo | Tosylchloramide sodium | 13361602 | 21115 | 40 | 1407634 |
| Caelo | Tosylchloramide sodium | 16236603 | 23562 | 40 | 20160819 |
| Caelo | Tosylchloramide sodium | 172265 | 24238 | 40 | 20170906* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 160 spectra of 4 reference samples from the substance/substance group *Tosylchloramide sodium*. These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.
- 158 166 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 160 spectra of 4 reference samples from the substance/substance group *Tosylchloramide sodium*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Tosylchloramide sodium | 13361606 | 21480 | 60 |
| Caelo | Tosylchloramide sodium | 162366 | 22773 | 40 |
| Caelo | Tosylchloramide sodium | 23000577 | 27114 | 40 |
| Caelo | Tosylchloramide sodium | 23000577 | 27114SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 780 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 96 spectra from 60 *Apo-Ident* customers from 38 batches from the substance/substance group *Tosylchloramide sodium*.

- Among them are spectra of independent samples from 36 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tosylchloramide sodium | | 1 |
| | Tosylchloramide sodium | 89539524 | 2 |
| Anzag | Tosylchloramide sodium | 12H09-N01 | 1 |
| Caelo | Tosylchloramide sodium | 11116708 | 1 |
| Caelo | Tosylchloramide sodium | 12277005 | 3 |
| Caelo | Tosylchloramide sodium | 12323605 | 1 |
| Caelo | Tosylchloramide sodium | 12323606 | 1 |
| Caelo | Tosylchloramide sodium | 12323607 | 1 |
| Caelo | Tosylchloramide sodium | 12323609 | 2 |
| Caelo | Tosylchloramide sodium | 1310206 | 1 |
| Caelo | Tosylchloramide sodium | 13103206 | 6 |
| Caelo | Tosylchloramide sodium | 13103207 | 1 |
| Caelo | Tosylchloramide sodium | 13103210 | 2 |
| Caelo | Tosylchloramide sodium | 13361606 | 4 |
| Caelo | Tosylchloramide sodium | 13361607 | 3 |
| Caelo | Tosylchloramide sodium | 14183504 | 1 |
| Caelo | Tosylchloramide sodium | 14183509 | 1 |
| Caelo | Tosylchloramide sodium | 15039603 | 5 |
| Caelo | Tosylchloramide sodium | 15183905 | 1 |
| Caelo | Tosylchloramide sodium | 15370501 | 5 |
| Caelo | Tosylchloramide sodium | 15370505 | 2 |
| Caelo | Tosylchloramide sodium | 16236603 | 11 |
| Caelo | Tosylchloramide sodium | 16236603/1180117 | 1 |
| Caelo | Tosylchloramide sodium | 16236607 | 6 |
| Caelo | Tosylchloramide sodium | 16236611 | 3 |
| Caelo | Tosylchloramide sodium | 17061503 | 3 |
| Caelo | Tosylchloramide sodium | 17061511 | 1 |
| Caelo | Tosylchloramide sodium | 17226502 | 2 |
| Caelo | Tosylchloramide sodium | 17226503 | 4 |
| Caelo | Tosylchloramide sodium | 71051187 | 2 |
| Caelo | Tosylchloramide sodium | 72215377 | 2 |
| Caeolo | Tosylchloramide sodium | 16236607 | 1 |
| EuRho | Tosylchloramide sodium | 133610607 | 1 |
| Euro OTC | Tosylchloramide sodium | 13361607 | 3 |
| Fagron | Tosylchloramide sodium | 11L08-N04 | 1 |
| Fagron | Tosylchloramide sodium | 14B27-B03-291967 | 1 |
| Fagron | Tosylchloramide sodium | 14L12-B01-301915 | 1 |
| Hydra International Ltd | Tosylchloramide sodium | 91020132 | 1 |
| L10 | Tosylchloramide sodium | 16236607 | 2 |
| Lysoform | Tosylchloramide sodium | K-09-2019 | 1 |
| PHOENIX am 22.01.2014 | Tosylchloramide sodium | 13103206 | 2 |
| Sanacorp | Tosylchloramide sodium | 12H09-N01 | 1 |
| Taoasis | Tosylchloramide sodium | 1623607 | 1 |


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- 256 790 spectra from 1666 *Apo-Ident* customers from a total of 52 117 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tosylchloramide sodium* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tosylchloramide sodium* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 160 | 0 | 158 166 |
| **Type B** | 0 | 160 | 0 | 212 780 |
| **Type C** | 0 | 96 | 0 | 256 790 |

The substance/substance group *Tosylchloramide sodium* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.2500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 96.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 93.7500 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20864 | 21115 | 21.03 | 153.53 |
| 21115 | 21115 | 0.00 | 145.72 |
| 23562 | 21115 | 16.89 | 151.69 |
| 24238 | 24238 | 0.00 | 152.75 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all

substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tranexamic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20397-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tranexamic acid; Acidum tranexamicum

### Special notes

When selecting the *Tranexamic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tranexamic acid | 9 | 5 | 46 |

### Second-stage model

For differentiation of the substance/substance group *Tranexamic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tranexamic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 75.94 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tranexamic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tranexamic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Tranexamic acid | APX1508016MT | 23504 | 40 | 20170224 |
| Audor Pharma | Tranexamic acid | APX1803027MT | 24708 | 40 | 20180430 |
| Euro OTC | Tranexamic acid | 2002005 | 25078 | 40 | 20200219* |
| Euro OTC | Tranexamic acid | 2001034 | 25099 | 40 | 20200218* |
| Euro OTC | Tranexamic acid | 2304017 | 26652 | 40 | 20230508* |
| Euro OTC | Tranexamic acid | 2304017 | 26652SI | 20 | 20230508* |
| Euro OTC | Tranexamic acid | 2312001 | 27140 | 40 | 20240313* |
| Euro OTC | Tranexamic acid | 2312001 | 27140SI | 20 | 20240313* |
| Fagron | Tranexamic acid | 14C21-B08-292225 | 21654 | 60 | AR-17-FG-016394-01 |
| Fagron | Tranexamic acid | 14L15-B06-3000036 | 21727 | 60 | AR-15-FG-008937-02 |
| Fagron | Tranexamic acid | 20H24-F02-373687 | 25586 | 40 | 20200923 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 440 spectra of 11 reference samples from the substance/substance group *Tranexamic acid*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 886 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 280 spectra of 7 reference samples from the substance/substance group *Tranexamic acid*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Tranexamic acid | 2006030 | 25247 | 40 |
| Euro OTC | Tranexamic acid | 2203031 | 26098 | 40 |
| Fagron | Tranexamic acid | 16E31-B07-331591 | 23503 | 50 |
| Fagron | Tranexamic acid | 21B05-F03-377271 | 25745 | 50 |
| Fagron | Tranexamic acid | 24I05-B05-007025 | 27633 | 40 |
| Euro OTC | Tranexamic acid | 2203031 | 26098SI | 20 |
| Fagron | Tranexamic acid | 16E31-B07-331591 | 23505 | 40 |

- 212 660 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 147 spectra from 89 *Apo-Ident* customers from 53 batches from the substance/substance group *Tranexamic acid*.

- Among them are spectra of independent samples from 46 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tranexamic acid | 21B05-F03-377271 | 19 |
| | Tranexamic acid | 2304017-01 | 8 |
| | Tranexamic acid | 2304017-02 | 2 |
| | Tranexamic acid | 2312001-01 | 4 |
| | Tranexamic acid | 2312001-02 | 3 |
| | Tranexamic acid | X2012306M | 1 |
| AHD | Tranexamic acid | 21B05-F03-377271 | 2 |
| AHD | Tranexamic acid | APX1712011MT | 2 |
| Alliance | Tranexamic acid | 2304017-01 | 1 |
| Audor Pharma | Tranexamic acid | 1508016MT | 1 |
| Audor Pharma | Tranexamic acid | APX1508016MT | 4 |
| Audor Pharma | Tranexamic acid | APX1611013MT | 6 |
| Audor Pharma | Tranexamic acid | APX17112011MT | 1 |
| Audor Pharma | Tranexamic acid | APX1712011MT | 8 |
| Audor Pharma | Tranexamic acid | ApX1803027MT | 1 |
| Audor Pharma | Tranexamic acid | APX1803027MT | 6 |
| Audor Pharma | Tranexamic acid | X1611013M | 2 |
| Audor Pharma | Tranexamic acid | X1706014M | 1 |
| Audor Pharma | Tranexamic acid | X1712011M | 1 |
| Audor Pharma | Tranexamic acid | X1803027M | 1 |
| Caelo | Tranexamic acid | 15J29-B04 | 1 |
| Caelo | Tranexamic acid | 16E31-B07-331591 | 1 |
| Caelo | Tranexamic acid | 18/25-B05-354991 | 1 |
| Caelo | Tranexamic acid | 18A17-B05-345037 | 1 |
| Caelo | Tranexamic acid | 2006030-02 | 1 |
| Caelo | Tranexamic acid | APX1712011MT | 1 |
| Euro OTC | Tranexamic acid | | 1 |
| Euro OTC | Tranexamic acid | 2002005-01 | 1 |
| Euro OTC | Tranexamic acid | 2006030-01 | 13 |
| Euro OTC | Tranexamic acid | 2006030-02 | 1 |
| Euro OTC | Tranexamic acid | 2203031-01 | 1 |
| Euro OTC | Tranexamic acid | TXAA200005 | 1 |
| Fagron | Tranexamic acid | | 1 |
| Fagron | Tranexamic acid | 1197-18-8 | 1 |
| Fagron | Tranexamic acid | 12D11-N02 | 1 |
| Fagron | Tranexamic acid | 13D08-N24 | 1 |
| Fagron | Tranexamic acid | 13D08-N240002/40 | 1 |
| Fagron | Tranexamic acid | 13Do8-N24 | 1 |
| Fagron | Tranexamic acid | 13G24-N21 | 1 |
| Fagron | Tranexamic acid | 13K08-B04-287966 | 1 |
| Fagron | Tranexamic acid | 15J29-B04 | 1 |
| Fagron | Tranexamic acid | 15J29-B04-312372 | 1 |
| Fagron | Tranexamic acid | 16B03-B02-319617 | 2 |
| Fagron | Tranexamic acid | 16J29-B04-312372 | 1 |
| Fagron | Tranexamic acid | 18A17-B05-345037 | 1 |
| Fagron | Tranexamic acid | 18A17-B05-345038 | 1 |
| Fagron | Tranexamic acid | 18F20-B01 | 1 |
| Fagron | Tranexamic acid | 18F20-B01-351691 | 3 |
| Fagron | Tranexamic acid | 18F20-B01-351693 | 1 |
| Fagron | Tranexamic acid | 18J25-B05 | 1 |
| Fagron | Tranexamic acid | 18J25-B05-354991 | 4 |
| Fagron | Tranexamic acid | 20H24-F02 | 1 |
| Fagron | Tranexamic acid | 20H24F02373687 | 1 |
| Fagron | Tranexamic acid | 20H24-F02-373687 | 5 |
| Fagron | Tranexamic acid | 21B05-F03-377271 | 3 |
| Fagron | Tranexamic acid | 5041804 | 1 |
| Fagron | Tranexamic acid | F02-3736807 | 1 |
| Fagron | Tranexamic acid | F03_3772701 | 1 |
| Fagron | Tranexamic acid | X1712011M | 1 |
| Fagron | Tranexamic acid | X19D25-B01-361249 | 1 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tranexamic acid | X2012306M | 1 |
| Noweda | Tranexamic acid | 18a17-b05-345037 | 1 |
| Sanacorp | Tranexamic acid | 16E31-B07-331591 | 1 |
| Sanacorp | Tranexamic acid | 2002005-02 | 1 |
| Sanacorp | Tranexamic acid | 2006030-01 | 1 |
| Sanacorp | Tranexamic acid | 2304017-01 | 2 |
| Sanacorp | Tranexamic acid | 2312001-01 | 2 |

- 256 739 spectra from 1666 *Apo-Ident* customers from a total of 52 102 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tranexamic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tranexamic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 280 | 0 | 212 660 |
| **Type C** | 0 | 147 | 0 | 256 739 |

The substance/substance group *Tranexamic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.8571 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 95.9184 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21654 | 21654 | 0.00 | 121.74 |
| 21727 | 21727 | 0.00 | 115.56 |
| 23504 | 25099 | 4.11 | 114.52 |
| 24708 | 25099 | 4.42 | 120.18 |
| 25078 | 25078 | 0.00 | 112.67 |
| 25099 | 25099 | 0.00 | 117.66 |
| 25586 | 25078 | 9.28 | 122.51 |
| 26652 | 26652 | 0.00 | 122.19 |
| 27140 | 27140 | 0.00 | 125.57 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tretinoin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20474-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tretinoin; Tretinoinum

### Special notes

When selecting the *Tretinoin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tretinoin | 7 | 18 | 358 |

### Second-stage model

For differentiation of the substance/substance group *Tretinoin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tretinoin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Mepivacaine hydrochloride | 68.82 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tretinoin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tretinoin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Tretinoin | 15028403 | 21757 | 60 | 1507086 |
| Caelo | Tretinoin | 15028403 | 21757SI | 60 | 1507086 |
| Caelo | Tretinoin | 15239503 | 21878 | 60 | 20150717 |
| Caelo | Tretinoin | 15239503 | 21878SI | 60 | 20150717 |
| Euro OTC | Tretinoin | 1402007-02 | 21747 | 60 | 1507085 |
| Euro OTC | Tretinoin | 1402007-02 | 21747SI | 60 | 1507085 |
| Euro OTC | Tretinoin | 1510007 | 21940 | 60 | 20151102* |
| Euro OTC | Tretinoin | 1510007 | 21940SI | 60 | 20151102* |
| Euro OTC | Tretinoin | 1604059 | 22574 | 40 | 20160603* |
| Euro OTC | Tretinoin | 2501038 | 27496 | 40 | 20250227* |
| Fagron | Tretinoin | 15F01-B06-317884 | 22936 | 40 | 20150619 |
| Fagron | Tretinoin | 15F01-B06-317884 | 22936SI | 40 | 20150619 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 640 spectra of 12 reference samples from the substance/substance group *Tretinoin*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 686 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1500 spectra of 38 reference samples from the substance/substance group *Tretinoin*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Tretinoin | 162915 | 22779 | 40 |
| Caelo | Tretinoin | 162171 | 22780 | 40 |
| Caelo | Tretinoin | 172731 | 23680 | 40 |
| Caelo | Tretinoin | 173057 | 23843 | 40 |
| Caelo | Tretinoin | 181673 | 24251 | 40 |
| Caelo | Tretinoin | 181674 | 24258 | 40 |
| Euro OTC | Tretinoin | 1612010 | 22911 | 40 |
| Euro OTC | Tretinoin | 1804005 | 24061 | 40 |
| Euro OTC | Tretinoin | 1901001 | 24456 | 40 |
| Euro OTC | Tretinoin | 1907014 | 24855 | 40 |
| Euro OTC | Tretinoin | 2004014 | 25283 | 40 |
| Euro OTC | Tretinoin | 2106017 | 25779 | 40 |
| Euro OTC | Tretinoin | 2205021 | 26228 | 40 |
| Euro OTC | Tretinoin | 2303017 | 26655 | 40 |
| Euro OTC | Tretinoin | 2311013 | 27198 | 40 |
| Euro OTC | Tretinoin | 2406007 | 27407 | 40 |
| Fagron | Tretinoin | 18J30-B02-358547 | 24824 | 40 |
| Fagron | Tretinoin | 22F28-B05-221065 | 26606 | 40 |
| Caelo | Tretinoin | 162915 | 22779SI | 40 |
| Caelo | Tretinoin | 162171 | 22780SI | 40 |
| Caelo | Tretinoin | 172731 | 23680SI | 40 |
| Caelo | Tretinoin | 173057 | 23843SI | 40 |
| Caelo | Tretinoin | 181673 | 24251SI | 20 |
| Caelo | Tretinoin | 181674 | 24258SI | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Tretinoin | 1604059 | 22574SI† | 40 |
| Euro OTC | Tretinoin | 1612010 | 22911SI | 40 |
| Euro OTC | Tretinoin | 1804005 | 24061SI | 40 |
| Euro OTC | Tretinoin | 1901001 | 24456SI | 40 |
| Euro OTC | Tretinoin | 1907014 | 24855SI | 40 |
| Euro OTC | Tretinoin | 2004014 | 25283SI | 40 |
| Euro OTC | Tretinoin | 2106017 | 25779SI | 40 |
| Euro OTC | Tretinoin | 2205021 | 26228SI | 40 |
| Euro OTC | Tretinoin | 2303017 | 26655SI | 40 |
| Euro OTC | Tretinoin | 2311013 | 27198SI | 40 |
| Euro OTC | Tretinoin | 2406007 | 27407SI | 40 |
| Euro OTC | Tretinoin | 2501038 | 27496SI† | 40 |
| Fagron | Tretinoin | 18J30-B02-358547 | 24824SI | 40 |
| Fagron | Tretinoin | 22F28-B05-221065 | 26606SI | 40 |

- 211 440 spectra from a total of 4267 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1800 spectra from 793 *Apo-Ident* customers from 366 batches from the substance/substance group *Tretinoin*.
- Among them are spectra of independent samples from 357 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tretinoin | 2004014-01 | 1 |
| | Tretinoin | 2004014-02 | 1 |
| | Tretinoin | 2100421009 | 1 |
| | Tretinoin | 21004211007 | 1 |
| | Tretinoin | 2106017-02 | 4 |
| | Tretinoin | 2106017-03 | 5 |
| | Tretinoin | 21G10-B08-213327 | 1 |
| | Tretinoin | 22002262001 | 1 |
| | Tretinoin | 2205021 | 1 |
| | Tretinoin | 220502101 | 1 |
| | Tretinoin | 2205021-01 | 8 |
| | Tretinoin | 2205021-02 | 13 |
| | Tretinoin | 2205321-02 | 1 |
| | Tretinoin | 22082114 | 1 |
| | Tretinoin | 22120002 | 1 |
| | Tretinoin | 22F28-B05-221065 | 1 |
| | Tretinoin | 2303017 | 5 |
| | Tretinoin | 230301701 | 1 |
| | Tretinoin | 2303017-01 | 35 |
| | Tretinoin | 230317-01 | 1 |
| | Tretinoin | 231101301 | 1 |

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†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tretinoin | 2311013-01 | 17 |
| | Tretinoin | 234508 | 1 |
| | Tretinoin | 23A23-B12-225240 | 4 |
| | Tretinoin | 23g06-b05-230224 | 1 |
| | Tretinoin | 23G06-B05-230224 | 1 |
| | Tretinoin | 23L01-B04-2023901 | 1 |
| | Tretinoin | 23L01-B04234508 | 1 |
| | Tretinoin | 23L01-B04-234508 | 5 |
| | Tretinoin | 24000848003 | 2 |
| | Tretinoin | 24000848004 | 2 |
| | Tretinoin | 2406007 | 1 |
| | Tretinoin | 240600701 | 1 |
| | Tretinoin | 2406007-01 | 10 |
| | Tretinoin | 24E15-B07-238345 | 1 |
| | Tretinoin | 8806694 | 1 |
| | Tretinoin | B04-2345008 | 1 |
| AHC | Tretinoin | 2205021-02 | 1 |
| AHD | Tretinoin | 16070002 | 1 |
| AHD | Tretinoin | 1901001-01 | 1 |
| AHD | Tretinoin | 1907014-02 | 1 |
| AHD | Tretinoin | 2205021-02 | 1 |
| AHD | Tretinoin | 2303017-01 | 1 |
| AHD | Tretinoin | 2311013-01 | 1 |
| Alliance Healthcare | Tretinoin | 20000490002 | 1 |
| Alliance Healthcare | Tretinoin | 2205021-01 | 1 |
| Allianz Healthcare | Tretinoin | 1907014-01 | 1 |
| Anzag/Henry Lamotte | Tretinoin | 15078303 | 1 |
| Anzag | Tretinoin | 14L24B01303157 | 1 |
| Anzag | Tretinoin | 15078305 | 1 |
| Apo Ident/ Noweda | Tretinoin | 1804005-01 | 1 |
| apo-ident | Tretinoin | 1804005-01 | 1 |
| Apo-ident | Tretinoin | 2004014-01 | 1 |
| apomix | Tretinoin | 8806694 | 1 |
| BASF / Phönix | Tretinoin | 1604059-02 | 1 |
| BASF/Phönix | Tretinoin | 1304028-02 | 2 |
| BASF | Tretinoin | 1402007-03 | 1 |
| Bombastus | Tretinoin | 1402007-03 | 1 |
| Caelo | Tretinoin | | 1 |
| Caelo | Tretinoin | 10003050032 | 1 |
| Caelo | Tretinoin | 1109014-02 | 1 |
| Caelo | Tretinoin | 11225504 | 1 |
| Caelo | Tretinoin | 11225506 | 1 |
| Caelo | Tretinoin | 11225511 | 1 |
| Caelo | Tretinoin | 11284703 | 1 |
| Caelo | Tretinoin | 12023302 | 9 |
| Caelo | Tretinoin | 12023303 | 1 |
| Caelo | Tretinoin | 12023309 | 1 |
| Caelo | Tretinoin | 12102902 | 1 |
| Caelo | Tretinoin | 12102903 | 2 |
| Caelo | Tretinoin | 12102904 | 2 |
| Caelo | Tretinoin | 12320201 | 2 |
| Caelo | Tretinoin | 12320203 | 2 |
| Caelo | Tretinoin | 12320204 | 1 |
| Caelo | Tretinoin | 12320205 | 5 |
| Caelo | Tretinoin | 12320207 | 1 |
| Caelo | Tretinoin | 12320209 | 6 |
| Caelo | Tretinoin | 12320301 | 1 |
| Caelo | Tretinoin | 12320303 | 1 |
| Caelo | Tretinoin | 12367101 | 2 |
| Caelo | Tretinoin | 12367103 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tretinoin | 12367104 | 1 |
| Caelo | Tretinoin | 12959AX20 | 1 |
| Caelo | Tretinoin | 12D05-N08 | 1 |
| Caelo | Tretinoin | 12I06-N01 | 1 |
| Caelo | Tretinoin | 1304028-02 | 3 |
| Caelo | Tretinoin | 131950002 | 1 |
| Caelo | Tretinoin | 13195002 | 14 |
| Caelo | Tretinoin | 13195003 | 1 |
| Caelo | Tretinoin | 13195008 | 1 |
| Caelo | Tretinoin | 13278101 | 1 |
| Caelo | Tretinoin | 13278102 | 4 |
| Caelo | Tretinoin | 13278104 | 2 |
| Caelo | Tretinoin | 13278105 | 2 |
| Caelo | Tretinoin | 13308003 | 1 |
| Caelo | Tretinoin | 13308004 | 4 |
| Caelo | Tretinoin | 13B05-B02-287360 | 1 |
| Caelo | Tretinoin | 14040504 | 5 |
| Caelo | Tretinoin | 14040507 | 1 |
| Caelo | Tretinoin | 14093502 | 4 |
| Caelo | Tretinoin | 14093503 | 1 |
| Caelo | Tretinoin | 1411016-01 | 2 |
| Caelo | Tretinoin | 14252702 | 5 |
| Caelo | Tretinoin | 14252706 | 2 |
| Caelo | Tretinoin | 14252710 | 2 |
| Caelo | Tretinoin | 14252801 | 1 |
| Caelo | Tretinoin | 1452802 | 1 |
| Caelo | Tretinoin | 14L24-B01-303157 | 2 |
| Caelo | Tretinoin | 15078301 | 1 |
| Caelo | Tretinoin | 15078302 | 2 |
| Caelo | Tretinoin | 15078303 | 2 |
| Caelo | Tretinoin | 15078305 | 2 |
| Caelo | Tretinoin | 15078307 | 3 |
| Caelo | Tretinoin | 15078308 | 1 |
| Caelo | Tretinoin | 151000701 | 1 |
| Caelo | Tretinoin | 1510007-02 | 2 |
| Caelo | Tretinoin | 1517E-02563 | 1 |
| Caelo | Tretinoin | 15239501 | 2 |
| Caelo | Tretinoin | 15239502 | 6 |
| Caelo | Tretinoin | 15239503 | 2 |
| Caelo | Tretinoin | 15437301 | 1 |
| Caelo | Tretinoin | 15437303 | 14 |
| Caelo | Tretinoin | 15F01-B06-308722 | 3 |
| Caelo | Tretinoin | 15F01-B06-308856 | 1 |
| Caelo | Tretinoin | 15H31-B01 | 1 |
| Caelo | Tretinoin | 160405901 | 1 |
| Caelo | Tretinoin | 1604059-02 | 1 |
| Caelo | Tretinoin | 16070001 | 1 |
| Caelo | Tretinoin | 16070002 | 2 |
| Caelo | Tretinoin | 16070003 | 1 |
| Caelo | Tretinoin | 1612010-01 | 4 |
| Caelo | Tretinoin | 1612010-02 | 4 |
| Caelo | Tretinoin | 16217107 | 1 |
| Caelo | Tretinoin | 16217108 | 3 |
| Caelo | Tretinoin | 16217112 | 2 |
| Caelo | Tretinoin | 16217120 | 1 |
| Caelo | Tretinoin | 16217122 | 3 |
| Caelo | Tretinoin | 16291502 | 6 |
| Caelo | Tretinoin | 16291503 | 8 |
| Caelo | Tretinoin | 16357602 | 1 |
| Caelo | Tretinoin | 16F14-B04 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tretinoin | 16F14-B04-324636 | 1 |
| Caelo | Tretinoin | 16F14-B04-326181 | 1 |
| Caelo | Tretinoin | 16K03-806328-388 | 1 |
| Caelo | Tretinoin | 16K03-B06-328388 | 2 |
| Caelo | Tretinoin | 17106101 | 4 |
| Caelo | Tretinoin | 17106102 | 15 |
| Caelo | Tretinoin | 171061025343 | 1 |
| Caelo | Tretinoin | 17106103 | 1 |
| Caelo | Tretinoin | 1723102 | 1 |
| Caelo | Tretinoin | 17273102 | 1 |
| Caelo | Tretinoin | 17273103 | 1 |
| Caelo | Tretinoin | 172773102 | 1 |
| Caelo | Tretinoin | 17305701 | 10 |
| Caelo | Tretinoin | 17305702 | 7 |
| Caelo | Tretinoin | 17305704 | 6 |
| Caelo | Tretinoin | 17305705 | 1 |
| Caelo | Tretinoin | 17305707 | 6 |
| Caelo | Tretinoin | 173057075597 | 1 |
| Caelo | Tretinoin | 17305708 | 1 |
| Caelo | Tretinoin | 17305709 | 2 |
| Caelo | Tretinoin | 17305710 | 2 |
| Caelo | Tretinoin | 17305711 | 1 |
| Caelo | Tretinoin | 17357001 | 11 |
| Caelo | Tretinoin | 17357002 | 7 |
| Caelo | Tretinoin | 17357004 | 1 |
| Caelo | Tretinoin | 17357005 | 2 |
| Caelo | Tretinoin | 17357007 | 7 |
| Caelo | Tretinoin | 17357008 | 4 |
| Caelo | Tretinoin | 17357009 | 5 |
| Caelo | Tretinoin | 1735707 | 1 |
| Caelo | Tretinoin | 17K01-B05-0005 | 1 |
| Caelo | Tretinoin | 17K01-B05-345784 | 1 |
| Caelo | Tretinoin | 1804005-01 | 7 |
| Caelo | Tretinoin | 18157410 | 1 |
| Caelo | Tretinoin | 18167301 | 3 |
| Caelo | Tretinoin | 18167301P-190314-2 | 1 |
| Caelo | Tretinoin | 18167302 | 9 |
| Caelo | Tretinoin | 18167307 | 5 |
| Caelo | Tretinoin | 18167309 | 22 |
| Caelo | Tretinoin | 18167401 | 3 |
| Caelo | Tretinoin | 18167402 | 4 |
| Caelo | Tretinoin | 18167403 | 2 |
| Caelo | Tretinoin | 18167405 | 2 |
| Caelo | Tretinoin | 18167407 | 1 |
| Caelo | Tretinoin | 18167408 | 1 |
| Caelo | Tretinoin | 18167409 | 3 |
| Caelo | Tretinoin | 18167410 | 3 |
| Caelo | Tretinoin | 1901001-01 | 4 |
| Caelo | Tretinoin | 1903084002 | 1 |
| Caelo | Tretinoin | 190500003 | 1 |
| Caelo | Tretinoin | 19050001 | 14 |
| Caelo | Tretinoin | 19050003 | 16 |
| Caelo | Tretinoin | 1907014-01 | 1 |
| Caelo | Tretinoin | 1907014-02 | 1 |
| Caelo | Tretinoin | 191001-01 | 1 |
| Caelo | Tretinoin | 19185802 | 5 |
| Caelo | Tretinoin | 19185803 | 3 |
| Caelo | Tretinoin | 19185805 | 12 |
| Caelo | Tretinoin | 19185808 | 1 |
| Caelo | Tretinoin | 192571001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tretinoin | 192571002 | 1 |
| Caelo | Tretinoin | 192571003 | 1 |
| Caelo | Tretinoin | 192571005 | 1 |
| Caelo | Tretinoin | 19257102 | 6 |
| Caelo | Tretinoin | 19257103 | 6 |
| Caelo | Tretinoin | 193084002 | 12 |
| Caelo | Tretinoin | 193084003 | 12 |
| Caelo | Tretinoin | 20000490001 | 5 |
| Caelo | Tretinoin | 20000490002 | 8 |
| Caelo | Tretinoin | 20000490005 | 5 |
| Caelo | Tretinoin | 20001881004 | 7 |
| Caelo | Tretinoin | 20004135001 | 7 |
| Caelo | Tretinoin | 20004135002 | 2 |
| Caelo | Tretinoin | 2004014-0 | 1 |
| Caelo | Tretinoin | 2004014-01 | 2 |
| Caelo | Tretinoin | 2004014-02 | 1 |
| Caelo | Tretinoin | 2004135001 | 1 |
| Caelo | Tretinoin | 20120601 | 1 |
| Caelo | Tretinoin | 20A28-F01-368810 | 1 |
| Caelo | Tretinoin | 210000305002 | 1 |
| Caelo | Tretinoin | 21000305002 | 11 |
| Caelo | Tretinoin | 21000305003 | 7 |
| Caelo | Tretinoin | 21000703001 | 7 |
| Caelo | Tretinoin | 21000703002 | 4 |
| Caelo | Tretinoin | 21000703004 | 4 |
| Caelo | Tretinoin | 21004211002 | 5 |
| Caelo | Tretinoin | 21004211003 | 12 |
| Caelo | Tretinoin | 21004211005 | 1 |
| Caelo | Tretinoin | 21004211007 | 3 |
| Caelo | Tretinoin | 2100421107 | 1 |
| Caelo | Tretinoin | 2106017-02 | 2 |
| Caelo | Tretinoin | 2205021-01 | 1 |
| Caelo | Tretinoin | 3041302 | 1 |
| Caelo | Tretinoin | 5012I-02563 | 1 |
| Caelo | Tretinoin | 5015A-02563 | 1 |
| Caelo | Tretinoin | 711212563 | 1 |
| Caeol/Noweda | Tretinoin | 15437303 | 1 |
| Caesar & Loretz /Gehe | Tretinoin | 193084003 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 21004211002 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 12023302 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 21004211005 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 193084003 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 19050001 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 20000490005 | 1 |
| Caesar & Loretz GmbH/AHD | Tretinoin | 19257103 | 1 |
| Caesar & Loretz GmbH/AHD | Tretinoin | 20000490002 | 1 |
| Caesar & Loretz GmbH/AHD | Tretinoin | 21000305002 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 19185802 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 20000490001 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 21000305002 | 2 |
| Caesar & Loretz GmbH… | Tretinoin | 193084002 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 193084002 | 1 |
| Caesar & Loretz GmbH/gehe | Tretinoin | 19257102 | 1 |
| Caesar & Loretz GmbH/Gehe | Tretinoin | 21000305003 | 3 |
| Caesar & Loretz GmbH… | Tretinoin | 21000703002 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 19185803 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 193084002 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 21000302002 | 1 |
| Caesar & Loretz GmbH… | Tretinoin | 21000305002 | 2 |
| Caesar & Loretz GmbH… | Tretinoin | 19257103 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Sana | Tretinoin | 193084003 | 1 |
| Caesar & Loretz GmbH... | Tretinoin | 21004211006 | 1 |
| Caesar & Loretz GmbH... | Tretinoin | 22002262001 | 1 |
| Caesar & Loretz GmbH... | Tretinoin | 193084002 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 11225515 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 12320211 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 18167302 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 18167309 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 18167401 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 18167408 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 18167410 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 19050001 | 2 |
| Caesar & Loretz GmbH | Tretinoin | 19050003 | 6 |
| Caesar & Loretz GmbH | Tretinoin | 19185801 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 19185802 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 19185803 | 2 |
| Caesar & Loretz GmbH | Tretinoin | 19185805 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 192571001 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 19257102 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 19257103 | 4 |
| Caesar & Loretz GmbH | Tretinoin | 193084002 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 193084003 | 6 |
| Caesar & Loretz GmbH | Tretinoin | 20000490001 | 2 |
| Caesar & Loretz GmbH | Tretinoin | 20000490002 | 4 |
| Caesar & Loretz GmbH | Tretinoin | 20000490004 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 20000490005 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 20001881004 | 2 |
| Caesar & Loretz GmbH | Tretinoin | 20001881005 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 21000305001 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 21000305002 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 21000305003 | 9 |
| Caesar & Loretz GmbH | Tretinoin | 21000703001 | 5 |
| Caesar & Loretz GmbH | Tretinoin | 21000703002 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 21000703004 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 21004211002 | 2 |
| Caesar & Loretz GmbH | Tretinoin | 21004211003 | 3 |
| Caesar & Loretz GmbH | Tretinoin | 21004211005 | 3 |
| Caesar & Loretz GmbH | Tretinoin | 21004211007 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 21004211009 | 1 |
| Caesar & Loretz GmbH | Tretinoin | 22002262001 | 1 |
| Cealo/Phoenix | Tretinoin | 19050003 | 1 |
| cealo | Tretinoin | 13195002 | 1 |
| Ceasar & Lorenz | Tretinoin | 19185805 | 2 |
| Celo/Kehr | Tretinoin | 16217122 | 1 |
| Celo | Tretinoin | 15437303 | 1 |
| Eu Rho | Tretinoin | 1612010-02 | 1 |
| Eur Rho | Tretinoin | 200401402 | 1 |
| EuRho / AHD | Tretinoin | 2106017-02 | 1 |
| EuRho / Phoenix | Tretinoin | 2205021-01 | 1 |
| EuRho- Phoenix | Tretinoin | 2106017-01 | 1 |
| EURho/ Noweda | Tretinoin | 1901001-01 | 1 |
| EuRho/ Fiebig | Tretinoin | 2004014-01 | 1 |
| EuRho/ Gehe | Tretinoin | 1907014-02 | 1 |
| EuRho/ NOWEDA | Tretinoin | 1804005-01 | 2 |
| EuRho/ Noweda | Tretinoin | 1907014-02 | 1 |
| Eurho/Noweda | Tretinoin | 2004014-02 | 1 |
| EuRho/Noweda | Tretinoin | 2106017-02 | 1 |
| euRho/Noweda | Tretinoin | 2205021-01 | 1 |
| EURho/Phoenix | Tretinoin | 1907014-01 | 1 |
| Eurho/Phönix | Tretinoin | 2205021 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho/Sanacorp | Tretinoin | 130402802 | 1 |
| EuRho/Sanacorp | Tretinoin | 210601703 | 1 |
| EuRho/Spangro | Tretinoin | 1901001-01 | 1 |
| EuRho | Tretinoin | 151007-01 | 1 |
| EuRho | Tretinoin | 1804005-01 | 1 |
| EuRho | Tretinoin | 19042068 | 1 |
| EuRho | Tretinoin | 1907014-01 | 1 |
| EuRho | Tretinoin | 190701402 | 1 |
| EuRho | Tretinoin | 1907014-02 | 1 |
| EuRho | Tretinoin | 200401402 | 1 |
| EuRho | Tretinoin | 2004014-02 | 4 |
| Eurho | Tretinoin | 2205021-01 | 1 |
| EuRho | Tretinoin | 2205021-01 | 1 |
| Eurimpharm | Tretinoin | 1411016-01 | 1 |
| Euro OCT Pharma/Fiebig | Tretinoin | 1604059-01 | 2 |
| Euro OT/ Gehe | Tretinoin | 1901001-01 | 2 |
| Euro OTC | Tretinoin | 1008021-02 | 1 |
| Euro OTC | Tretinoin | 10429AX21 | 1 |
| Euro OTC | Tretinoin | 1109014-02 | 2 |
| Euro OTC | Tretinoin | 12059AX20 | 2 |
| Euro OTC | Tretinoin | 12959AX20 | 3 |
| Euro OTC | Tretinoin | 130102802 | 1 |
| Euro OTC | Tretinoin | 1304028-01 | 7 |
| Euro OTC | Tretinoin | 130402802 | 1 |
| Euro OTC | Tretinoin | 1304028-02 | 4 |
| Euro OTC | Tretinoin | 13041028-01 | 1 |
| Euro OTC | Tretinoin | 140007-02 | 1 |
| Euro OTC | Tretinoin | 14020007-01 | 1 |
| Euro OTC | Tretinoin | 1402007 | 1 |
| Euro OTC | Tretinoin | 140200701 | 1 |
| Euro OTC | Tretinoin | 1402007-01 | 5 |
| Euro OTC | Tretinoin | 1402007-02 | 9 |
| Euro OTC | Tretinoin | 140200703 | 1 |
| Euro OTC | Tretinoin | 1402007-03 | 3 |
| Euro OTC | Tretinoin | 14101602 | 1 |
| Euro OTC | Tretinoin | 1411016-01 | 12 |
| Euro OTC | Tretinoin | 141101602 | 1 |
| Euro OTC | Tretinoin | 1411016-02 | 12 |
| Euro OTC | Tretinoin | 141107602 | 1 |
| Euro OTC | Tretinoin | 151000 | 1 |
| Euro OTC | Tretinoin | 1510007-01 | 13 |
| Euro OTC | Tretinoin | 151000702 | 1 |
| Euro OTC | Tretinoin | 1510007-02 | 17 |
| Euro OTC | Tretinoin | 16004059-02 | 1 |
| Euro OTC | Tretinoin | 160405901 | 1 |
| Euro OTC | Tretinoin | 1604059-01 | 23 |
| Euro OTC | Tretinoin | 160405902 | 2 |
| Euro OTC | Tretinoin | 1604059-02 | 21 |
| Euro OTC | Tretinoin | 16052905 | 1 |
| Euro OTC | Tretinoin | 161201001 | 2 |
| Euro OTC | Tretinoin | 1612010-01 | 30 |
| Euro OTC | Tretinoin | 1612010-02 | 15 |
| Euro OTC | Tretinoin | 161210-01 | 1 |
| Euro OTC | Tretinoin | 162010-02 | 1 |
| Euro OTC | Tretinoin | 16217108 | 1 |
| Euro OTC | Tretinoin | 165070002 | 1 |
| Euro OTC | Tretinoin | 17273103 | 1 |
| Euro OTC | Tretinoin | 17357001 | 2 |
| Euro OTC | Tretinoin | 17Ko1-Bo5-345784 | 1 |
| Euro OTC | Tretinoin | 180400501 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Tretinoin | 1804005-01 | 55 |
| Euro OTC | Tretinoin | 1804008-01 | 1 |
| Euro OTC | Tretinoin | 18062082 | 2 |
| Euro OTC | Tretinoin | 18167302 | 1 |
| Euro OTC | Tretinoin | 18167401 | 3 |
| Euro OTC | Tretinoin | 18167405 | 1 |
| Euro OTC | Tretinoin | 184005-01 | 1 |
| Euro OTC | Tretinoin | 18432003 | 3 |
| Euro OTC | Tretinoin | 18J30-B02-359836 | 1 |
| Euro OTC | Tretinoin | 190100-01 | 1 |
| Euro OTC | Tretinoin | 190100101 | 2 |
| Euro OTC | Tretinoin | 1901001-01 | 46 |
| Euro OTC | Tretinoin | 190100102 | 1 |
| Euro OTC | Tretinoin | 1901001-02 | 20 |
| Euro OTC | Tretinoin | 19042068 | 3 |
| Euro OTC | Tretinoin | 19042092 | 3 |
| Euro OTC | Tretinoin | 1907014 | 1 |
| Euro OTC | Tretinoin | 190701401 | 4 |
| Euro OTC | Tretinoin | 1907014-01 | 22 |
| Euro OTC | Tretinoin | 190701402 | 1 |
| Euro OTC | Tretinoin | 1907014-02 | 43 |
| Euro OTC | Tretinoin | 190714-02 | 2 |
| Euro OTC | Tretinoin | 2001014-01 | 1 |
| Euro OTC | Tretinoin | 2001014-02 | 2 |
| Euro OTC | Tretinoin | 2004014 | 2 |
| Euro OTC | Tretinoin | 2004014-01 | 46 |
| Euro OTC | Tretinoin | 200401402 | 1 |
| Euro OTC | Tretinoin | 2004014-02 | 44 |
| Euro OTC | Tretinoin | 2004014-021 | 1 |
| Euro OTC | Tretinoin | 20332110 | 1 |
| Euro OTC | Tretinoin | 2105017-01 | 1 |
| Euro OTC | Tretinoin | 2106017 | 1 |
| Euro OTC | Tretinoin | 2106017_03 | 1 |
| Euro OTC | Tretinoin | 210601701 | 2 |
| Euro OTC | Tretinoin | 2106017-01 | 18 |
| Euro OTC | Tretinoin | 2106017-02 | 28 |
| Euro OTC | Tretinoin | 2106017-03 | 11 |
| Euro OTC | Tretinoin | 2205021-01 | 12 |
| Euro OTC | Tretinoin | 230301701 | 1 |
| Euro OTC | Tretinoin | 2303017-01 | 2 |
| Euro OTC | Tretinoin | 230313(2205021-01) | 1 |
| Euro OTC | Tretinoin | 2311013-01 | 2 |
| Euro OTC | Tretinoin | 2994014-02 | 1 |
| Euro OTC | Tretinoin | 30042014A | 1 |
| Euro OTC | Tretinoin | 5219Q-02563 | 1 |
| Euro OTC | Tretinoin | 67(1804005-01) | 1 |
| Euro OTC | Tretinoin | 819081-16 | 1 |
| Euro OTC | Tretinoin | 99999999 | 1 |
| Euro/ Sanacorp | Tretinoin | 1901001-01 | 1 |
| Euro/Gehe | Tretinoin | 1604059-01 | 1 |
| Euro/Noweda | Tretinoin | 1612010-01 | 1 |
| Euro/Phoenix | Tretinoin | 1907014-01 | 1 |
| Euro/Phönix | Tretinoin | 18J30B02359836 | 1 |
| Euro/Phönix | Tretinoin | 1907014-01 | 1 |
| Euro/Sanacorp | Tretinoin | 1604059-02 | 1 |
| Euro | Tretinoin | 14111016-01 | 1 |
| Euroo/Phönix | Tretinoin | 210601703 | 1 |
| EuroPharm/ Sanacorp | Tretinoin | 1804005-01 | 1 |
| Fa.Phönix | Tretinoin | 21e17-03 | 1 |
| Fagron | Tretinoin | 11K29-N01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tretinoin | 12I06-N01 | 2 |
| Fagron | Tretinoin | 12l06-N01 | 1 |
| Fagron | Tretinoin | 13B05-B02-287360 | 4 |
| Fagron | Tretinoin | 13B05-B02-287361 | 2 |
| Fagron | Tretinoin | 13C11-N06 | 2 |
| Fagron | Tretinoin | 13D30N14 | 1 |
| Fagron | Tretinoin | 13D30-N14 | 2 |
| Fagron | Tretinoin | 13D30-N14-3365319091 | 1 |
| Fagron | Tretinoin | 14009-804 | 1 |
| Fagron | Tretinoin | 14040504 | 1 |
| Fagron | Tretinoin | 14093505 | 1 |
| Fagron | Tretinoin | 1410001594 | 1 |
| Fagron | Tretinoin | 1411016-01 | 1 |
| Fagron | Tretinoin | 1440104 | 1 |
| Fagron | Tretinoin | 14D09-B04 | 1 |
| Fagron | Tretinoin | 14D09-B04-293224 | 1 |
| Fagron | Tretinoin | 14D09-B04-293225 | 1 |
| Fagron | Tretinoin | 14D09-B04-293594 | 1 |
| Fagron | Tretinoin | 14D09-B04-295551 | 1 |
| Fagron | Tretinoin | 14L24-B01 | 1 |
| Fagron | Tretinoin | 14L24-B01-303152 | 1 |
| Fagron | Tretinoin | 14L24-B01-303157 | 4 |
| Fagron | Tretinoin | 1510007-01 | 1 |
| Fagron | Tretinoin | 1510007-02 | 1 |
| Fagron | Tretinoin | 15F01-B06-308722 | 4 |
| Fagron | Tretinoin | 15F01-B06-308856 | 4 |
| Fagron | Tretinoin | 15F01-B06-313216 | 2 |
| Fagron | Tretinoin | 15F01-B06-315491 | 1 |
| Fagron | Tretinoin | 15F01-B06-317884 | 1 |
| Fagron | Tretinoin | 1604059-01 | 1 |
| Fagron | Tretinoin | 16052905 | 4 |
| Fagron | Tretinoin | 16F14-B04 | 3 |
| Fagron | Tretinoin | 16F14-B04-324636 | 2 |
| Fagron | Tretinoin | 16f14-b04-325560 | 1 |
| Fagron | Tretinoin | 16F14B04325560 | 1 |
| Fagron | Tretinoin | 16F14-B04-325560 | 2 |
| Fagron | Tretinoin | 16F-14-B04-325560 | 1 |
| Fagron | Tretinoin | 16F14-B04-325567 | 1 |
| Fagron | Tretinoin | 16F14-B04-326181 | 2 |
| Fagron | Tretinoin | 16F14B04325560 | 1 |
| Fagron | Tretinoin | 16K03-B06 | 3 |
| Fagron | Tretinoin | 16K03-B06-328388 | 4 |
| Fagron | Tretinoin | 170706TTRER-20151004 | 1 |
| Fagron | Tretinoin | 17273102 | 1 |
| Fagron | Tretinoin | 17357007 | 1 |
| Fagron | Tretinoin | 17K01-B05 | 2 |
| Fagron | Tretinoin | 17K01-B05-341936 | 8 |
| Fagron | Tretinoin | 17K01-B05-341941 | 2 |
| Fagron | Tretinoin | 17K01-B05-345784 | 4 |
| Fagron | Tretinoin | 17K01-B05-347435 | 3 |
| Fagron | Tretinoin | 17K01-B05-347436 | 1 |
| Fagron | Tretinoin | 17K01B05349946 | 1 |
| Fagron | Tretinoin | 17K01-B05-349946 | 4 |
| Fagron | Tretinoin | 18167404 | 1 |
| Fagron | Tretinoin | 18A10-B03-344364 | 1 |
| Fagron | Tretinoin | 18J30-B02 | 2 |
| Fagron | Tretinoin | 18J30-B02_359836 | 1 |
| Fagron | Tretinoin | 18j30B02358540 | 1 |
| Fagron | Tretinoin | 18J30-B02-358540 | 4 |
| Fagron | Tretinoin | 18J30-B02-358546 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tretinoin | 18J30-B02-358547 | 1 |
| Fagron | Tretinoin | 18J30-B02-359836 | 1 |
| Fagron | Tretinoin | 18J30-B02-362110 | 5 |
| Fagron | Tretinoin | 18J30-B02-362120 | 1 |
| Fagron | Tretinoin | 19K07-06-366648 | 1 |
| Fagron | Tretinoin | 19K07-F06 | 4 |
| Fagron | Tretinoin | 19K07-F06-366648 | 13 |
| Fagron | Tretinoin | 20000490002 | 2 |
| Fagron | Tretinoin | 20110004 | 1 |
| Fagron | Tretinoin | 20120601 | 1 |
| Fagron | Tretinoin | 20A28-F01-368810 | 2 |
| Fagron | Tretinoin | 20A28-F01-368813 | 1 |
| Fagron | Tretinoin | 21E17-F03-378623 | 2 |
| Fagron | Tretinoin | 21E17-F03-678623 | 1 |
| Fagron | Tretinoin | 21G10-B08 | 1 |
| Fagron | Tretinoin | 21G10-B08-213327 | 3 |
| Fagron | Tretinoin | 22080001 | 1 |
| Fagron | Tretinoin | 231115T | 1 |
| Fagron | Tretinoin | 23A23-B12-225240 | 1 |
| Fagron | Tretinoin | 6366648 | 1 |
| Fagron | Tretinoin | F01-3688100 | 2 |
| Fagron | Tretinoin | TRER-20180703 | 2 |
| Fargon | Tretinoin | 16K03-B06-328388 | 1 |
| Fargron/ Sanacorp | Tretinoin | 17k01-b05-341936 | 1 |
| Fargron | Tretinoin | 1402007-01 | 1 |
| Fargron | Tretinoin | 14D09-B04-293225 | 1 |
| FEJ | Tretinoin | 15F01-B06-308856 | 1 |
| Fiebig | Tretinoin | 1612010-01 | 1 |
| Gatt-Koller | Tretinoin | 1702180 | 1 |
| Gatt-Koller | Tretinoin | 1804193 | 1 |
| Gatt-Koller | Tretinoin | 606210909 | 1 |
| Gehe am 11.10.2017 | Tretinoin | 17106102 | 1 |
| Gehe amax | Tretinoin | 1604059-02 | 1 |
| Gehe | Tretinoin | 15078307 | 1 |
| Gehe | Tretinoin | 1510007-01 | 1 |
| Gehe | Tretinoin | 15437303 | 1 |
| Gehe | Tretinoin | 1604059-02 | 1 |
| Gehe | Tretinoin | 1612010-01 | 2 |
| Gehe | Tretinoin | 1901001-01 | 1 |
| Gehe | Tretinoin | 1901001-02 | 1 |
| Gehe | Tretinoin | 19050001 | 1 |
| GEHE | Tretinoin | 19050001 | 1 |
| Gehe | Tretinoin | 1907014-01 | 2 |
| Gehe | Tretinoin | 1907014-02 | 1 |
| Gehe | Tretinoin | 2106017-01 | 1 |
| Gehe | Tretinoin | 21G10B08213327 | 1 |
| gehe | Tretinoin | 2205021-01 | 1 |
| Gehe | Tretinoin | 2205021-02 | 1 |
| GEHE | Tretinoin | 2205021-02 | 1 |
| Gehe | Tretinoin | 2406007-01 | 2 |
| Gehe-Eurho 22.11.2017 | Tretinoin | 2171127Ma7 | 1 |
| Geibo | Tretinoin | 17K01-B05-341936 | 1 |
| JENNE | Tretinoin | 17K01-B05-341941 | 1 |
| Jenne | Tretinoin | 1901001-01 | 1 |
| Kehr | Tretinoin | 1604059-01 | 1 |
| Kehr | Tretinoin | 2311013-01 | 1 |
| Kehr | Tretinoin | 24E15-B07-238345 | 1 |
| Krieger am 17.08.2018 | Tretinoin | 17K01-B05-345784 | 1 |
| Krieger | Tretinoin | 2205021-02 | 1 |
| Krieger | Tretinoin | 23A23-B12-225240 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| L10 | Tretinoin | 1612010-01 | 2 |
| Nachprüfung | Tretinoin | | 1 |
| Nachprüfung | Tretinoin | 2605001-01 | 1 |
| Noweda/EuRho 06.05.2… | Tretinoin | 2004014-01 | 1 |
| Noweda/EuRho | Tretinoin | 2106017-02 | 1 |
| Noweda | Tretinoin | 12023302 | 2 |
| Noweda | Tretinoin | 13D30-N14 | 1 |
| Noweda | Tretinoin | 15078307 | 1 |
| Noweda | Tretinoin | 15F01-B06-315491 | 1 |
| Noweda | Tretinoin | 17305701 | 1 |
| Noweda | Tretinoin | 18167402 | 1 |
| Noweda | Tretinoin | 19257103 | 1 |
| Noweda | Tretinoin | 200401402 | 1 |
| Noweda | Tretinoin | 2004014-02 | 1 |
| Noweda | Tretinoin | 2106017-02 | 1 |
| Noweda | Tretinoin | 2205021-01 | 2 |
| Noweda | Tretinoin | 2205021-02 | 1 |
| Noweda | Tretinoin | 2303017-01 | 1 |
| Phoenix | Tretinoin | 12367103 | 1 |
| Phoenix | Tretinoin | 15F01-B06-317884 | 1 |
| Phoenix | Tretinoin | 190701402 | 1 |
| Phoenix | Tretinoin | 19K07-F06-366648 | 1 |
| Phoenix | Tretinoin | 200401401 | 3 |
| Phoenix | Tretinoin | 2004014-01 | 3 |
| Phoenix | Tretinoin | 2106017-03 | 1 |
| Phoenix | Tretinoin | 2205021-02 | 1 |
| Phönix WE:04.01.18 … | Tretinoin | 17273102 | 1 |
| phönix/Siegfried Pha… | Tretinoin | 2004014-02 | 2 |
| Phönix | Tretinoin | 1109014-02 | 1 |
| Phönix | Tretinoin | 1402007-02 | 1 |
| Phönix | Tretinoin | 14D09-B04 | 2 |
| Phönix | Tretinoin | 14D09-B04-293224 | 1 |
| phönix | Tretinoin | 1612010-01 | 1 |
| phönix | Tretinoin | 17273102 | 1 |
| Phönix | Tretinoin | 17k01-b05-349946 | 1 |
| Phönix | Tretinoin | 18167302 | 1 |
| Phönix | Tretinoin | 1901001-01 | 1 |
| Phönix | Tretinoin | 200831409 | 1 |
| Phönix | Tretinoin | 200931709 | 1 |
| Phönix | Tretinoin | 2205021-01 | 2 |
| Phönix | Tretinoin | 2303017-01 | 1 |
| Phönix | Tretinoin | 3144 | 1 |
| Sana | Tretinoin | 21G10-B08-213327 | 1 |
| Sanacorp/EuRho | Tretinoin | 1604059-02 | 1 |
| Sanacorp | Tretinoin | 12/06-N01 | 1 |
| Sanacorp | Tretinoin | 12320302 | 1 |
| Sanacorp | Tretinoin | 13308004 | 1 |
| Sanacorp | Tretinoin | 1411016-01 | 1 |
| Sanacorp | Tretinoin | 1411016-02 | 1 |
| Sanacorp | Tretinoin | 14L24-B01 | 1 |
| Sanacorp | Tretinoin | 16217122 | 1 |
| Sanacorp | Tretinoin | 17357001 | 1 |
| Sanacorp | Tretinoin | 1804005-01 | 1 |
| Sanacorp | Tretinoin | 18167309 | 1 |
| Sanacorp | Tretinoin | 1907014-02 | 1 |
| Sanacorp | Tretinoin | 19185805 | 1 |
| Sanacorp | Tretinoin | 193084003 | 1 |
| Sanacorp | Tretinoin | 21000305001 | 1 |
| Sanacorp | Tretinoin | 2205021-01 | 3 |
| Sanacorp | Tretinoin | 2205021-02 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Tretinoin | 2303017-01 | 1 |
| Sanacorp | Tretinoin | 2311013-01 | 1 |
| Sanacorp | Tretinoin | 24000848004 | 1 |
| Siegfried Chemikalie… | Tretinoin | 1804005 | 1 |
| Siegfried Pharamchikalien | Tretinoin | 2004014-01 | 1 |
| Siegfried Pharm. Che… | Tretinoin | 17K01-B05-345784 | 1 |
| Siegfried Pharma / Gehe | Tretinoin | 1907014-01 | 1 |
| Siegfried Pharma / Gehe | Tretinoin | 1907014-02 | 1 |
| siegfried pharma che… | Tretinoin | 2106017-01 | 1 |
| Siegfried PharmaChem… | Tretinoin | 1907014-02 | 1 |
| Siegfried PharmaChem… | Tretinoin | 1907014-02 | 1 |
| Siegfried Pharmachem… | Tretinoin | 2004014-01 | 1 |
| Siegfried Pharmachem… | Tretinoin | 19042092 | 1 |
| Siegfried Pharmachem… | Tretinoin | 2004014-01 | 1 |
| Siegfried Pharmachem… | Tretinoin | 2004014-02 | 1 |
| Siegfried PharmaChem… | Tretinoin | 18432003 | 1 |
| Siegfried PharmaChem… | Tretinoin | 19042092 | 1 |
| Synthetisch/GEIBO | Tretinoin | 2106017-03 | 1 |
| synthetisch | Tretinoin | 2106017-02 | 1 |
| WE:Phönix 20.08.201… | Tretinoin | 1510007-02 | 1 |
| WE:Phönix 02.11..201… | Tretinoin | 1604059-01 | 1 |

- 255 086 spectra from 1666 *Apo-Ident* customers from a total of 51 794 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tretinoin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tretinoin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 640 | 0 | 157 686 |
| **Type B** | 0 | 1500 | 0 | 211 440 |
| **Type C** | 0 | 1710 | 90 | 255 086 |

The substance/substance group *Tretinoin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.0625 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 95.0000 % (> 94.8333 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to

exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21747 | 21747 | 0.00 | 126.98 |
| 21757 | 21757 | 0.00 | 105.88 |
| 21878 | 21747 | 22.63 | 119.31 |
| 21940 | 21940 | 0.00 | 118.44 |
| 22574 | 22574 | 0.00 | 108.50 |
| 22936 | 21940 | 7.09 | 112.32 |
| 27496 | 27496 | 0.00 | 105.94 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Triamcinolone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20564-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Triamcinolone; Triamcinolonum

### Special notes

When selecting the *Triamcinolone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Triamcinolone | 9 | 3 | 62 |

### Second-stage model

For differentiation of the substance/substance group *Triamcinolone* the following second-stage model is used:

- Submodel 03

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Triamcinolone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Riboflavin sodium phosphate hydrate | 66.28 | – |
| ⋮ | ⋮ | ⋮ |
| Polymyxin B sulfate | 66.92 | 35.32 |
| Cyanocobalamin | >50 | 36.50 |
| Bacitracin | >50 | 41.30 |
| Amphotericin B | >50 | 50.81 |
| Riboflavin | >50 | 55.17 |
| Colistin sulfate | >50 | 57.72 |
| Methylcobalamin | >50 | 64.13 |
| Calcium pantothenate | >50 | 64.60 |
| Nystatin | >50 | 79.91 |
| Estradiol hemihydrate | >50 | 88.27 |
| Estriol | >50 | 95.17 |
| Gelatine, white | >50 | 103.26 |
| Hyoscine hydrobromide | >50 | 103.51 |
| Tosylchloramide sodium | >50 | 115.59 |
| Calcium glycerophosphate | >50 | 126.16 |
| alpha-tocopheryl acetate dry concentrate | >50 | 142.27 |
| SyrSpend® SF pH4 neo (Maize starch) | >50 | 180.07 |
| SyrSpend® SF Alka | >50 | 191.83 |
| Oxalic acid | >50 | 219.38 |
| Rice starch | >50 | 243.06 |
| Carmellose sodium | >50 | 253.79 |
| Corn starch | >50 | 322.17 |
| SyrSpend® SF pH4 | >50 | 343.58 |
| Acacia, dried dispersion | >50 | 384.87 |
| Wheat starch | >50 | 403.16 |
| Potato starch | >50 | 451.95 |
| Maltodextrin | >50 | 456.83 |
| Fructose | >50 | 457.82 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Triamcinolone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.


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### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Triamcinolone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Triamcinolone | 15106905 | 22273 | 45 | 20150527 |
| Caelo | Triamcinolone | 15106905 | 22605 | 40 | 20150527 |
| Caelo | Triamcinolone | 20001706 | 25555 | 40 | 20200902* |
| Caelo | Triamcinolone | 20001706 | 25555SI | 35 | 20200902* |
| Fagron | Triamcinolone | 12A03-N09 | 20730 | 40 | 20120117 |
| Fagron | Triamcinolone | 12K07-N13 | 20936 | 80 | AR-15-FG-003373-01 |
| Fagron | Triamcinolone | 14B13-B30-316101 | 22840 | 40 | 20140311 |
| Fagron | Triamcinolone | 18A19-B05-351174 | 24182 | 40 | 1811263 |
| Fagron | Triamcinolone | 18A19-B05-351174 | 24182SI | 32 | 1811263 |
| Fagron | Triamcinolone | 18E09-B04-353921 | 24446 | 40 | 1907730 |
| Fagron | Triamcinolone | 18J01-B05-364078 | 24944 | 40 | 2004435 |
| Fagron | Triamcinolone | 22A17-B05-216480 | 26140 | 40 | 20220421 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 512 spectra of 12 reference samples from the substance/substance group *Triamcinolone*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.
- 157 814 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 400 spectra of 10 reference samples from the substance/substance group *Triamcinolone*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Triamcinolone | 15106911 | 23508 | 40 |
| Fagron | Triamcinolone | 17G03-B04-343670 | 24097 | 40 |
| Fagron | Triamcinolone | 21H13-B19-215838 | 25938 | 40 |
| Fagron | Triamcinolone | 17G03-B04-343670 | 24097SI | 40 |
| Fagron | Triamcinolone | 17G03-B04-343670 | 24107 | 40 |
| Fagron | Triamcinolone | 17G03-B04-343670 | 24107SI | 40 |
| Fagron | Triamcinolone | 18E09-B04-353921 | 24446SI† | 40 |
| Fagron | Triamcinolone | 18J01-B05-364078 | 24944SI† | 40 |
| Fagron | Triamcinolone | 21H13-B19-215838 | 25938SI | 40 |
| Fagron | Triamcinolone | 22A17-B05-216480 | 26140SI† | 40 |

- 212 540 spectra from a total of 4281 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 103 spectra from 62 *Apo-Ident* customers from 66 batches from the substance/substance group *Triamcinolone*.

- Among them are spectra of independent samples from 62 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Triamcinolone | 20K25-F03-377107 | 1 |
| | Triamcinolone | 21001467008 | 1 |
| | Triamcinolone | 21001467010 | 4 |
| | Triamcinolone | 22A17-B05-222384 | 1 |
| | Triamcinolone | 22J05B05227276 | 1 |
| | Triamcinolone | 22J05-B05-227276 | 2 |
| | Triamcinolone | 24C11-B03-000852 | 1 |
| | Triamcinolone | B05_2223804 | 1 |
| AHD | Triamcinolone | 22A17-B05-216480 | 3 |
| Caelo | Triamcinolone | 12295207 | 3 |
| Caelo | Triamcinolone | 12295210 | 1 |
| Caelo | Triamcinolone | 13J07-N08 | 2 |
| Caelo | Triamcinolone | 14B13-B30-293474 | 1 |
| Caelo | Triamcinolone | 14B13-B30312868 | 1 |
| Caelo | Triamcinolone | 15106902 | 1 |
| Caelo | Triamcinolone | 15106912 | 1 |
| Caelo | Triamcinolone | 15106960 | 1 |
| Caelo | Triamcinolone | 180921002 | 3 |
| Caelo | Triamcinolone | 18092104 | 3 |
| Caesar & Loretz GmbH... | Triamcinolone | 21001467001 | 1 |
| Caesar & Loretz GmbH | Triamcinolone | 21001467001 | 1 |
| Fagron | Triamcinolone | 11D28-N04 | 1 |
| Fagron | Triamcinolone | 11G26-N04 | 1 |
| Fagron | Triamcinolone | 12A03-N09 | 1 |
| Fagron | Triamcinolone | 12D02-N14 | 1 |

*continued on the next page*

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triamcinolone | 12Do2-N14 | 1 |
| Fagron | Triamcinolone | 12F01-N19 | 3 |
| Fagron | Triamcinolone | 13C26-N04 | 1 |
| Fagron | Triamcinolone | 13D30-N15 | 2 |
| Fagron | Triamcinolone | 13J07-N08 | 1 |
| Fagron | Triamcinolone | 14A14-B01 | 1 |
| Fagron | Triamcinolone | 14B13-B30 | 1 |
| Fagron | Triamcinolone | 14B13-B30-293473 | 1 |
| Fagron | Triamcinolone | 14B13-B30-312868 | 1 |
| Fagron | Triamcinolone | 14B13-B30-316102 | 1 |
| Fagron | Triamcinolone | 15B13-B30-312868 | 1 |
| Fagron | Triamcinolone | 16A13-B06 | 2 |
| Fagron | Triamcinolone | 18A19-B05-352984 | 3 |
| Fagron | Triamcinolone | 18E09-B04-355656 | 1 |
| Fagron | Triamcinolone | 18J01-B05 | 2 |
| Fagron | Triamcinolone | 18J01-B05-364078 | 2 |
| Fagron | Triamcinolone | 18J01B05364080 | 1 |
| Fagron | Triamcinolone | 18J01-B05-364080 | 1 |
| Fagron | Triamcinolone | 20k25-f03 | 1 |
| Fagron | Triamcinolone | 20K25-F03 | 2 |
| Fagron | Triamcinolone | 20K25-F03-376111 | 2 |
| Fagron | Triamcinolone | 20K25-F03-376112 | 4 |
| Fagron | Triamcinolone | 20K25-F03-377107 | 1 |
| Fagron | Triamcinolone | 21I03-B01-216482 | 1 |
| Fagron | Triamcinolone | 21l03-B01_216482 | 1 |
| Fagron | Triamcinolone | 21l03-B01-216482 | 1 |
| Fagron | Triamcinolone | 22A17-B05 | 1 |
| Fagron | Triamcinolone | F03-3761102 | 1 |
| Fagron | Triamcinolone | NT1484M | 1 |
| Fagron | Triamcinolone | NTL171102 | 1 |
| Fagron | Triamcinolone | NTL200702 | 2 |
| Fargon/Gehe | Triamcinolone | B04-3539201 | 1 |
| Fargon/Gehe | Triamcinolone | B05-3640708 | 1 |
| Fargon | Triamcinolone | 18J01-B05-364078 | 1 |
| Gehe | Triamcinolone | 16F07-B01-331398 | 1 |
| Gehe | Triamcinolone | NTL180603 | 1 |
| L12 | Triamcinolone | 17359001 | 1 |
| Noweda 24.08.2015 | Triamcinolone | 14B13-B30-293474 | 1 |
| Noweda | Triamcinolone | 21/03-B01-216482 | 2 |
| Noweda | Triamcinolone | 22A17-B05-222384 | 1 |
| Noweda | Triamcinolone | 22J05-B05-227276 | 1 |
| Phönix | Triamcinolone | 18A19B05-352890 | 1 |
| Phönix | Triamcinolone | NS0608M | 1 |
| Sanacorp | Triamcinolone | 100/AKD6 | 1 |
| Sanacorp | Triamcinolone | 15106907 | 1 |
| Sanacorp | Triamcinolone | 15106916 | 1 |
| Sanacorp | Triamcinolone | 23F26-B02-229454 | 2 |
| Tianjin Tianyao Phar... | Triamcinolone | 18J01-B05-364080 | 1 |
| Tianjin Tianyao Phar... | Triamcinolone | 21I03-B01-216482 | 1 |

- 256 783 spectra from 1666 *Apo-Ident* customers from a total of 52 088 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Triamcinolone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Triamcinolone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 512 | 0 | 157 814 |
| **Type B** | 0 | 385 | 15 | 212 540 |
| **Type C** | 0 | 96 | 7 | 256 783 |

The substance/substance group *Triamcinolone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8281 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 96.2500 % (> 95.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 93.2039 % (> 90.2913 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20730 | 20936 | 51.26 | 151.18 |
| 20936 | 20936 | 0.00 | 179.08 |
| 22273 | 25555 | 12.60 | 186.19 |
| 22605 | 25555 | 9.29 | 181.25 |
| 22840 | 25555 | 12.56 | 174.39 |
| 24182 | 24182 | 0.00 | 113.54 |
| 24446 | 24446 | 0.00 | 128.45 |
| 24944 | 24944 | 0.00 | 103.88 |
| 25555 | 25555 | 0.00 | 183.15 |
| 26140 | 24182 | 42.87 | 110.55 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Triamcinolone acetonide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20765-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Triamcinolone acetonide; Triamcinoloni acetonidum

### Special notes

When selecting the *Triamcinolone acetonide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Triamcinolone acetonide | 12 | 25 | 868 |

### Second-stage model

For differentiation of the substance/substance group *Triamcinolone acetonide* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Triamcinolone acetonide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Prednisolon dihydrogen phosphate di… | 63.13 | – |
| ⋮ | ⋮ | ⋮ |
| Fluocinolone acetonide | 74.53 | 34.92 |
| Prednisolone | >50 | 61.12 |
| Betamethasone | >50 | 63.08 |
| Methylprednisolone | >50 | 77.88 |
| Tyrothricin | >50 | 90.87 |
| Dexamethasone | >50 | 96.52 |
| Gramicidin | >50 | 136.76 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Triamcinolone acetonide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Triamcinolone acetonide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Triamcinolone acetonide | 13256607 | 21061 | 100 | AR-15-FG-003755-01 |
| Caelo | Triamcinolone acetonide | 13379921 | 21587 | 60 | 1503634 |
| Caelo | Triamcinolone acetonide | 20002630 | 25560 | 40 | 20200902* |
| Caelo | Triamcinolone acetonide | 20002630 | 25560SI | 31 | 20200902* |
| Euro OTC | Triamcinolone acetonide | 1303001-02 | 20910 | 40 | 20130815 |
| Euro OTC | Triamcinolone acetonide | 1211013-02 | 21072 | 30 | 20130417 |
| Euro OTC | Triamcinolone acetonide | 1508008 | 21883 | 60 | 20150902* |
| Euro OTC | Triamcinolone acetonide | 1601021 | 22313 | 45 | 20160119* |
| Euro OTC | Triamcinolone acetonide | 1605010 | 22572 | 40 | 20160531* |
| Euro OTC | Triamcinolone acetonide | 1605010 | 22572SI | 25 | 20160531* |
| Euro OTC | Triamcinolone acetonide | 1608005 | 22752 | 40 | 20160906* |
| Euro OTC | Triamcinolone acetonide | 1608005 | 22752SI | 22 | 20160906* |
| Euro OTC | Triamcinolone acetonide | 2006002 | 25339 | 40 | 2011401 |

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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Triamcinolone acetonide | 2006002 | 25339SI | 29 | 2011401 |
| Fagron | Triamcinolone acetonide | 12E15-N03 | 20765 | 60 | 1412051 |
| Fagron | Triamcinolone acetonide | 15C19-B06-308572 | 21962 | 60 | 20150402 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 722 spectra of 16 reference samples from the substance/substance group *Triamcinolone acetonide*. These samples are listed above in the *calibration samples* section. The reference samples come from 12 different batches.

- 157 604 spectra from a total of 2945 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1759 spectra of 52 reference samples from the substance/substance group *Triamcinolone acetonide*.

- Among them are spectra of independent samples from 25 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Triamcinolone acetonide | 12301505 | 20769 | 60 |
| Caelo | Triamcinolone acetonide | 160945 | 22473 | 60 |
| Caelo | Triamcinolone acetonide | 171206 | 23330 | 40 |
| Caelo | Triamcinolone acetonide | 181002 | 24016 | 40 |
| Caelo | Triamcinolone acetonide | 190619 | 24509 | 40 |
| Caelo | Triamcinolone acetonide | 23002617 | 26965 | 40 |
| Euro OTC | Triamcinolone acetonide | 1612014 | 22978 | 40 |
| Euro OTC | Triamcinolone acetonide | 1703037 | 23393 | 40 |
| Euro OTC | Triamcinolone acetonide | 1706013 | 23557 | 40 |
| Euro OTC | Triamcinolone acetonide | 1710002 | 23694 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Triamcinolone acetonide | 1801020 | 23883 | 40 |
| Euro OTC | Triamcinolone acetonide | 1805001-01 | 24191 | 40 |
| Euro OTC | Triamcinolone acetonide | 1810015 | 24333 | 40 |
| Euro OTC | Triamcinolone acetonide | 1903015 | 24629 | 40 |
| Euro OTC | Triamcinolone acetonide | 1907044 | 24842 | 40 |
| Euro OTC | Triamcinolone acetonide | 2001017 | 25115 | 40 |
| Euro OTC | Triamcinolone acetonide | 2002047 | 25117 | 40 |
| Euro OTC | Triamcinolone acetonide | 2006032 | 25456 | 40 |
| Euro OTC | Triamcinolone acetonide | 2012006 | 25526 | 40 |
| Euro OTC | Triamcinolone acetonide | 2109004 | 25832 | 50 |
| Euro OTC | Triamcinolone acetonide | 2208004 | 26261 | 40 |
| Euro OTC | Triamcinolone acetonide | 2308018 | 26930 | 40 |
| Euro OTC | Triamcinolone acetonide | 2410004 | 27520 | 40 |
| Fagron | Triamcinolone acetonide | 13C13-N20 | 21043 | 60 |
| Fagron | Triamcinolone acetonide | 22A22-B02-221452 | 26131 | 40 |
| Caelo | Triamcinolone acetonide | 160945 | 22473SI | 40 |
| Caelo | Triamcinolone acetonide | 171206 | 23330SI | 20 |
| Caelo | Triamcinolone acetonide | 171206 | 23343 | 40 |
| Caelo | Triamcinolone acetonide | 171206 | 23343SI | 20 |
| Caelo | Triamcinolone acetonide | 181002 | 24016SI | 20 |
| Caelo | Triamcinolone acetonide | 190619 | 24509SI | 20 |
| Caelo | Triamcinolone acetonide | 23002617 | 26965SI | 30 |
| Euro OTC | Triamcinolone acetonide | 1508008 | 21883SI† | 30 |
| Euro OTC | Triamcinolone acetonide | 1612014 | 22978SI | 29 |
| Euro OTC | Triamcinolone acetonide | 1703037 | 23393SI | 20 |
| Euro OTC | Triamcinolone acetonide | 1706013 | 23557SI | 20 |
| Euro OTC | Triamcinolone acetonide | 1710002 | 23694SI | 20 |
| Euro OTC | Triamcinolone acetonide | 1801020 | 23883SI | 20 |
| Euro OTC | Triamcinolone acetonide | 1805001-01 | 24191SI | 20 |
| Euro OTC | Triamcinolone acetonide | 1810015 | 24333SI | 20 |
| Euro OTC | Triamcinolone acetonide | 1903015 | 24629SI | 20 |
| Euro OTC | Triamcinolone acetonide | 1907044 | 24842SI | 20 |
| Euro OTC | Triamcinolone acetonide | 2001017 | 25115SI | 40 |
| Euro OTC | Triamcinolone acetonide | 2002047 | 25117SI | 20 |
| Euro OTC | Triamcinolone acetonide | 2006032 | 25456SI | 20 |
| Euro OTC | Triamcinolone acetonide | 2012006 | 25526SI | 20 |
| Euro OTC | Triamcinolone acetonide | 2109004 | 25832SI | 30 |
| Euro OTC | Triamcinolone acetonide | 2208004 | 26261SI | 30 |
| Euro OTC | Triamcinolone acetonide | 2308018 | 26930SI | 31 |
| Euro OTC | Triamcinolone acetonide | 2410004 | 27520SI | 40 |
| Fagron | Triamcinolone acetonide | 15C19-B06-308572 | 21962SI† | 19 |
| Fagron | Triamcinolone acetonide | 22A22-B02-221452 | 26131SI | 30 |

- 211 181 spectra from a total of 4260 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6054 spectra from 1408 *Apo-Ident* customers from 900 batches from the substance/substance group *Triamcinolone acetonide*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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- Among them are spectra of independent samples from 864 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Triamcinolone acetonide | 12E30-No7 | 1 |
| | Triamcinolone acetonide | 1403009-01 | 1 |
| | Triamcinolone acetonide | 2006023-01 | 1 |
| | Triamcinolone acetonide | 2012006-01 | 1 |
| | Triamcinolone acetonide | 21000116001 | 1 |
| | Triamcinolone acetonide | 21000116008 | 1 |
| | Triamcinolone acetonide | 21000116011 | 1 |
| | Triamcinolone acetonide | 21003093011 | 3 |
| | Triamcinolone acetonide | 21003093012 | 1 |
| | Triamcinolone acetonide | 21003093013 | 4 |
| | Triamcinolone acetonide | 2109004-01 | 2 |
| | Triamcinolone acetonide | 2109004-03 | 4 |
| | Triamcinolone acetonide | 21H25-F03 | 1 |
| | Triamcinolone acetonide | 21H25-F03-379863 | 2 |
| | Triamcinolone acetonide | 21H25-F03-379875 | 2 |
| | Triamcinolone acetonide | 21J20-B03-218184 | 1 |
| | Triamcinolone acetonide | 2200004-01 | 1 |
| | Triamcinolone acetonide | 220000902012 | 1 |
| | Triamcinolone acetonide | 22000902001 | 5 |
| | Triamcinolone acetonide | 22000902002 | 4 |
| | Triamcinolone acetonide | 22000902004 | 1 |
| | Triamcinolone acetonide | 22000902005 | 4 |
| | Triamcinolone acetonide | 22000902008 | 11 |
| | Triamcinolone acetonide | 22000902009 | 12 |
| | Triamcinolone acetonide | 22000902010 | 23 |
| | Triamcinolone acetonide | 22000902012 | 12 |
| | Triamcinolone acetonide | 2200090201274/23P | 1 |
| | Triamcinolone acetonide | 22000902013 | 1 |
| | Triamcinolone acetonide | 22000902014 | 2 |
| | Triamcinolone acetonide | 22000902015 | 7 |
| | Triamcinolone acetonide | 22000902016 | 17 |
| | Triamcinolone acetonide | 22000902018 | 20 |
| | Triamcinolone acetonide | 22000902019 | 11 |
| | Triamcinolone acetonide | 2200090212 | 1 |
| | Triamcinolone acetonide | 2200090218 | 3 |
| | Triamcinolone acetonide | 2208004-01 | 46 |
| | Triamcinolone acetonide | 2208004-02 | 13 |
| | Triamcinolone acetonide | 22A22_B01 | 1 |
| | Triamcinolone acetonide | 22A22-B01 | 1 |
| | Triamcinolone acetonide | 22A22-B01-218005 | 11 |
| | Triamcinolone acetonide | 22A22-B01218-218005 | 1 |
| | Triamcinolone acetonide | 22A22-B02-218066 | 2 |
| | Triamcinolone acetonide | 22A22-B02-221452 | 2 |
| | Triamcinolone acetonide | 22A2-BO1-218005 | 1 |
| | Triamcinolone acetonide | 22D15-B01-220144 | 3 |
| | Triamcinolone acetonide | 22D15-B01-222391 | 3 |
| | Triamcinolone acetonide | 22D15-B01-222393 | 2 |
| | Triamcinolone acetonide | 23002018-02 | 1 |
| | Triamcinolone acetonide | 23002073004 | 1 |
| | Triamcinolone acetonide | 23002073005 | 24 |
| | Triamcinolone acetonide | 23002617001 | 1 |
| | Triamcinolone acetonide | 23003235001 | 4 |
| | Triamcinolone acetonide | 23003235002 | 1 |
| | Triamcinolone acetonide | 23003235003 | 7 |
| | Triamcinolone acetonide | 23003235004 | 10 |
| | Triamcinolone acetonide | 23003235005 | 1 |
| | Triamcinolone acetonide | 23003235006 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Triamcinolone acetonide | 23003235011 | 1 |
| | Triamcinolone acetonide | 2300325001 | 1 |
| | Triamcinolone acetonide | 2305018-01 | 1 |
| | Triamcinolone acetonide | 23080-02 | 1 |
| | Triamcinolone acetonide | 23080180-03 | 1 |
| | Triamcinolone acetonide | 2308018-01 | 20 |
| | Triamcinolone acetonide | 2308018-02 | 11 |
| | Triamcinolone acetonide | 2308018-03 | 14 |
| | Triamcinolone acetonide | 23080-18-03 | 1 |
| | Triamcinolone acetonide | 2308018-04 | 2 |
| | Triamcinolone acetonide | 230818-02 | 1 |
| | Triamcinolone acetonide | 23C28-B04-227509 | 3 |
| | Triamcinolone acetonide | 23F13-B09-236124 | 1 |
| | Triamcinolone acetonide | 2410004-01 | 5 |
| | Triamcinolone acetonide | 24C23-B01-238732 | 1 |
| | Triamcinolone acetonide | FO3-3798603 | 1 |
| | Triamcinolone acetonide | NB0601M | 2 |
| | Triamcinolone acetonide | NB3123M | 2 |
| | Triamcinolone acetonide | NB314M | 1 |
| | Triamcinolone acetonide | ND1896M | 1 |
| 08582421 | Triamcinolone acetonide | 20B28-F04-371546 | 1 |
| 08582421 | Triamcinolone acetonide | F01-3766508 | 1 |
| 16804-B07 | Triamcinolone acetonide | 16B04/B07 | 1 |
| 17270001 | Triamcinolone acetonide | 17120610 | 2 |
| 2001017-0 | Triamcinolone acetonide | 2001017-01 | 1 |
| A.H. 07.05.13 ek: 7,25EUR | Triamcinolone acetonide | 1211013-02 | 1 |
| A.H.D. | Triamcinolone acetonide | 12301508 | 1 |
| AEP | Triamcinolone acetonide | 22000902019 | 1 |
| AHD 03.03.2015 | Triamcinolone acetonide | NT1430M | 1 |
| AHD 06.03.15 9,47 | Triamcinolone acetonide | 14355102 | 2 |
| AHD 17.07.2020 | Triamcinolone acetonide | NA0088M | 1 |
| AHD 22.12.16 EK 29,74 | Triamcinolone acetonide | 16D14B11322136 | 1 |
| AHD/Hedinger | Triamcinolone acetonide | 15233902 | 1 |
| AHD | Triamcinolone acetonide | 14355711 | 1 |
| AHD | Triamcinolone acetonide | 17057905 | 4 |
| AHD | Triamcinolone acetonide | 20B28-F04-371546 | 1 |
| AHD | Triamcinolone acetonide | 21003093001 | 1 |
| AHD | Triamcinolone acetonide | 22000902009 | 1 |
| AHD | Triamcinolone acetonide | 22000902018 | 1 |
| AHD | Triamcinolone acetonide | 22000902019 | 1 |
| AHD | Triamcinolone acetonide | 2208004-01 | 2 |
| AHD | Triamcinolone acetonide | 2208004-02 | 2 |
| AHD | Triamcinolone acetonide | 23003235006 | 1 |
| ahd | Triamcinolone acetonide | 2308018-03 | 1 |
| AHD | Triamcinolone acetonide | APU0544/315240T | 1 |
| AhHD | Triamcinolone acetonide | 22000902016 | 1 |
| Alliance Healthcare | Triamcinolone acetonide | 13C13-N20 | 2 |
| Alliance Healthcare | Triamcinolone acetonide | 21000116001 | 1 |
| Alliance Healthcare | Triamcinolone acetonide | 22000902016 | 1 |
| Alliance Healthcare | Triamcinolone acetonide | 2308018-03 | 2 |
| Alliance | Triamcinolone acetonide | 21003093001 | 1 |
| Alliance | Triamcinolone acetonide | 22000902009 | 1 |
| Alliance | Triamcinolone acetonide | 22000902012 | 1 |
| Alliance | Triamcinolone acetonide | 2208004-01 | 2 |
| Allianz Healthcare | Triamcinolone acetonide | 16080005-01 | 1 |
| Anzag | Triamcinolone acetonide | 1303001-02 | 1 |
| Anzag | Triamcinolone acetonide | 14355103 | 1 |
| Anzag | Triamcinolone acetonide | 14355711 | 1 |
| Anzag | Triamcinolone acetonide | 1605010-01 | 1 |
| Anzag | Triamcinolone acetonide | 17120605 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag | Triamcinolone acetonide | 20002630005 | 1 |
| Anzag | Triamcinolone acetonide | 201200601 | 1 |
| Anzag | Triamcinolone acetonide | 2012006-01 | 1 |
| Anzag | Triamcinolone acetonide | 22000902008 | 1 |
| Anzag | Triamcinolone acetonide | 2208004-01 | 1 |
| Anzag | Triamcinolone acetonide | 22A22B01-218005 | 1 |
| Anzag | Triamcinolone acetonide | 23003235006 | 1 |
| Anzag | Triamcinolone acetonide | 250409(23003235006) | 1 |
| apo ident | Triamcinolone acetonide | 1612014-01 | 1 |
| apo ident | Triamcinolone acetonide | 1710002-01 | 2 |
| Apo Ident | Triamcinolone acetonide | 1907044-01 | 1 |
| APO III | Triamcinolone acetonide | 21003093005 | 1 |
| apoident | Triamcinolone acetonide | 1508008-01 | 1 |
| apo-ident | Triamcinolone acetonide | 1608005-01 | 1 |
| apo-ident | Triamcinolone acetonide | 1801020-01 | 1 |
| apo-ident | Triamcinolone acetonide | 1810015-01 | 1 |
| Apotheke Mildenau | Triamcinolone acetonide | 13C13-N20 | 1 |
| Audor Pharma | Triamcinolone acetonide | 15240T | 1 |
| Audor Pharma | Triamcinolone acetonide | APNET180403T | 3 |
| Audor Pharma | Triamcinolone acetonide | APU0544/315240T | 3 |
| Audor Pharma | Triamcinolone acetonide | APU0544/3162705 | 1 |
| Audor Pharma | Triamcinolone acetonide | APU0544/316270T | 2 |
| Audor Pharma | Triamcinolone acetonide | APU0544/317171T | 1 |
| Audor Pharma | Triamcinolone acetonide | APU0544/31524T | 1 |
| Audor Pharma | Triamcinolone acetonide | U0544/315240T | 1 |
| Beiersdorf | Triamcinolone acetonide | 18F14-B01-351889 | 1 |
| Berkel AHK | Triamcinolone acetonide | 14355101 | 3 |
| Bombas/Sanac | Triamcinolone acetonide | 16094506 | 1 |
| Bombastus | Triamcinolone acetonide | 13124804 | 2 |
| Bombastus | Triamcinolone acetonide | 17120610 | 1 |
| Bombastus | Triamcinolone acetonide | 1810015-01 | 1 |
| Cael/Sanacorp | Triamcinolone acetonide | 171002-01 | 1 |
| Caelo | Triamcinolone acetonide | 100/AKD2 | 1 |
| Caelo | Triamcinolone acetonide | 10220341 | 1 |
| Caelo | Triamcinolone acetonide | 1040417 | 1 |
| Caelo | Triamcinolone acetonide | 11022021-02 | 1 |
| Caelo | Triamcinolone acetonide | 1107212516 | 1 |
| Caelo | Triamcinolone acetonide | 1110005-01 | 1 |
| Caelo | Triamcinolone acetonide | 1120717/16094502 | 1 |
| Caelo | Triamcinolone acetonide | 11267704 | 1 |
| Caelo | Triamcinolone acetonide | 11267705 | 1 |
| Caelo | Triamcinolone acetonide | 11267707 | 4 |
| Caelo | Triamcinolone acetonide | 11267710 | 2 |
| Caelo | Triamcinolone acetonide | 11267720 | 1 |
| Caelo | Triamcinolone acetonide | 11267721 | 2 |
| Caelo | Triamcinolone acetonide | 116D14B11325479 | 1 |
| Caelo | Triamcinolone acetonide | 12/10-N09 | 5 |
| Caelo | Triamcinolone acetonide | 1201506 | 1 |
| Caelo | Triamcinolone acetonide | 12031601 | 1 |
| Caelo | Triamcinolone acetonide | 1206008-01 | 1 |
| Caelo | Triamcinolone acetonide | 1209040-01 | 1 |
| Caelo | Triamcinolone acetonide | 120904002 | 1 |
| Caelo | Triamcinolone acetonide | 1210-n09 | 1 |
| Caelo | Triamcinolone acetonide | 1211013-01 | 1 |
| Caelo | Triamcinolone acetonide | 12173701 | 5 |
| Caelo | Triamcinolone acetonide | 12173703 | 1 |
| Caelo | Triamcinolone acetonide | 12173704 | 2 |
| Caelo | Triamcinolone acetonide | 12173705 | 2 |
| Caelo | Triamcinolone acetonide | 12173707 | 5 |
| Caelo | Triamcinolone acetonide | 12173710 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triamcinolone acetonide | 12301501 | 4 |
| Caelo | Triamcinolone acetonide | 12301502 | 1 |
| Caelo | Triamcinolone acetonide | 12301503 | 1 |
| Caelo | Triamcinolone acetonide | 12301504 | 1 |
| Caelo | Triamcinolone acetonide | 12301505 | 1 |
| Caelo | Triamcinolone acetonide | 12301506 | 1 |
| Caelo | Triamcinolone acetonide | 12301507 | 8 |
| Caelo | Triamcinolone acetonide | 12301508 | 4 |
| Caelo | Triamcinolone acetonide | 12301509 | 4 |
| Caelo | Triamcinolone acetonide | 12301510 | 4 |
| Caelo | Triamcinolone acetonide | 12301515 | 12 |
| Caelo | Triamcinolone acetonide | 12301518 | 4 |
| Caelo | Triamcinolone acetonide | 1230517/16094502 | 1 |
| Caelo | Triamcinolone acetonide | 1257952 | 1 |
| Caelo | Triamcinolone acetonide | 12E15-N03 | 1 |
| Caelo | Triamcinolone acetonide | 1303001-02 | 1 |
| Caelo | Triamcinolone acetonide | 1307043-01 | 2 |
| Caelo | Triamcinolone acetonide | 1312407 | 1 |
| Caelo | Triamcinolone acetonide | 13124801 | 6 |
| Caelo | Triamcinolone acetonide | 13124803 | 2 |
| Caelo | Triamcinolone acetonide | 13124804 | 12 |
| Caelo | Triamcinolone acetonide | 13124805 | 7 |
| Caelo | Triamcinolone acetonide | 13124806 | 2 |
| Caelo | Triamcinolone acetonide | 13124807 | 12 |
| Caelo | Triamcinolone acetonide | 13124808 | 13 |
| Caelo | Triamcinolone acetonide | 13124809 | 1 |
| Caelo | Triamcinolone acetonide | 13124810 | 2 |
| Caelo | Triamcinolone acetonide | 13124811 | 4 |
| Caelo | Triamcinolone acetonide | 13256603 | 1 |
| Caelo | Triamcinolone acetonide | 13256604 | 6 |
| Caelo | Triamcinolone acetonide | 13256607 | 5 |
| Caelo | Triamcinolone acetonide | 13256608 | 2 |
| Caelo | Triamcinolone acetonide | 13379901 | 1 |
| Caelo | Triamcinolone acetonide | 13379903 | 2 |
| Caelo | Triamcinolone acetonide | 13379904 | 6 |
| Caelo | Triamcinolone acetonide | 13379905 | 19 |
| Caelo | Triamcinolone acetonide | 13379906 | 6 |
| Caelo | Triamcinolone acetonide | 13379911 | 1 |
| Caelo | Triamcinolone acetonide | 13379912 | 10 |
| Caelo | Triamcinolone acetonide | 13379913 | 4 |
| Caelo | Triamcinolone acetonide | 13379914 | 6 |
| Caelo | Triamcinolone acetonide | 13379919 | 1 |
| Caelo | Triamcinolone acetonide | 13379921 | 1 |
| Caelo | Triamcinolone acetonide | 13379922 | 1 |
| Caelo | Triamcinolone acetonide | 1355101 | 1 |
| Caelo | Triamcinolone acetonide | 13C13-N20 | 2 |
| Caelo | Triamcinolone acetonide | 13e15-n03 | 1 |
| Caelo | Triamcinolone acetonide | 13E15-N03 | 2 |
| Caelo | Triamcinolone acetonide | 13I26-N11 | 1 |
| Caelo | Triamcinolone acetonide | 13K14-B04-289032 | 1 |
| Caelo | Triamcinolone acetonide | 13K14-B04-289033 | 2 |
| Caelo | Triamcinolone acetonide | 13K15-B31-289027 | 2 |
| Caelo | Triamcinolone acetonide | 13K15-B31-289029 | 1 |
| Caelo | Triamcinolone acetonide | 13K15-B31-289031 | 1 |
| Caelo | Triamcinolone acetonide | 14188302 | 5 |
| Caelo | Triamcinolone acetonide | 14188303 | 4 |
| Caelo | Triamcinolone acetonide | 14188304 | 4 |
| Caelo | Triamcinolone acetonide | 14233904 | 1 |
| Caelo | Triamcinolone acetonide | 14255104 | 1 |
| Caelo | Triamcinolone acetonide | 14355101 | 12 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triamcinolone acetonide | 14355102 | 18 |
| Caelo | Triamcinolone acetonide | 14355103 | 12 |
| Caelo | Triamcinolone acetonide | 14355104 | 2 |
| Caelo | Triamcinolone acetonide | 14355701 | 1 |
| Caelo | Triamcinolone acetonide | 14355702 | 11 |
| Caelo | Triamcinolone acetonide | 14355703 | 3 |
| Caelo | Triamcinolone acetonide | 14355704 | 3 |
| Caelo | Triamcinolone acetonide | 14355706 | 1 |
| Caelo | Triamcinolone acetonide | 14355708 | 11 |
| Caelo | Triamcinolone acetonide | 14355709 | 2 |
| Caelo | Triamcinolone acetonide | 14355711 | 9 |
| Caelo | Triamcinolone acetonide | 14355712 | 7 |
| Caelo | Triamcinolone acetonide | 14G23_B07_2976618 | 1 |
| Caelo | Triamcinolone acetonide | 14G23-B07-297619 | 1 |
| Caelo | Triamcinolone acetonide | 1504007-01 | 1 |
| Caelo | Triamcinolone acetonide | 1504007-02 | 1 |
| Caelo | Triamcinolone acetonide | 1504007-2 | 1 |
| Caelo | Triamcinolone acetonide | 1508008-01 | 2 |
| Caelo | Triamcinolone acetonide | 1508008-02 | 1 |
| Caelo | Triamcinolone acetonide | 1514Q2516 | 1 |
| Caelo | Triamcinolone acetonide | 15233901 | 15 |
| Caelo | Triamcinolone acetonide | 15233902 | 29 |
| Caelo | Triamcinolone acetonide | 15233903 | 27 |
| Caelo | Triamcinolone acetonide | 15233903-20160615Ma9 | 1 |
| Caelo | Triamcinolone acetonide | 15233904 | 14 |
| Caelo | Triamcinolone acetonide | 15233905 | 7 |
| Caelo | Triamcinolone acetonide | 15233906 | 17 |
| Caelo | Triamcinolone acetonide | 15233908 | 3 |
| Caelo | Triamcinolone acetonide | 15233909 | 1 |
| Caelo | Triamcinolone acetonide | 1530102 | 1 |
| Caelo | Triamcinolone acetonide | 15308613 | 1 |
| Caelo | Triamcinolone acetonide | 15430102 | 4 |
| Caelo | Triamcinolone acetonide | 15430102I-300916/1 | 1 |
| Caelo | Triamcinolone acetonide | 15430103 | 7 |
| Caelo | Triamcinolone acetonide | 15430105 | 7 |
| Caelo | Triamcinolone acetonide | 15430106 | 5 |
| Caelo | Triamcinolone acetonide | 15430107 | 15 |
| Caelo | Triamcinolone acetonide | 15430108 | 13 |
| Caelo | Triamcinolone acetonide | 15C19/B06 | 1 |
| Caelo | Triamcinolone acetonide | 15C19-B06-308571 | 1 |
| Caelo | Triamcinolone acetonide | 15C19-B06-308573 | 1 |
| Caelo | Triamcinolone acetonide | 15G31-B07-313597 | 1 |
| Caelo | Triamcinolone acetonide | 15G31-B07-314045 | 1 |
| Caelo | Triamcinolone acetonide | 15L21-B03-316123 | 1 |
| Caelo | Triamcinolone acetonide | 15L21-B03-318663 | 1 |
| Caelo | Triamcinolone acetonide | 160102101 | 1 |
| Caelo | Triamcinolone acetonide | 1601021-01 | 1 |
| Caelo | Triamcinolone acetonide | 160501001 | 1 |
| Caelo | Triamcinolone acetonide | 1605010-01 | 1 |
| Caelo | Triamcinolone acetonide | 16079502 | 1 |
| Caelo | Triamcinolone acetonide | 160800501 | 1 |
| Caelo | Triamcinolone acetonide | 1608005-01 | 8 |
| Caelo | Triamcinolone acetonide | 16092504 | 22 |
| Caelo | Triamcinolone acetonide | 16094501 | 10 |
| Caelo | Triamcinolone acetonide | 16094502 | 2 |
| Caelo | Triamcinolone acetonide | 16094504 | 6 |
| Caelo | Triamcinolone acetonide | 16094505 | 2 |
| Caelo | Triamcinolone acetonide | 16094506 | 8 |
| Caelo | Triamcinolone acetonide | 16094507 | 5 |
| Caelo | Triamcinolone acetonide | 16094511 | 17 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triamcinolone acetonide | 16094512 | 5 |
| Caelo | Triamcinolone acetonide | 16094513 | 1 |
| Caelo | Triamcinolone acetonide | 16094514 | 28 |
| Caelo | Triamcinolone acetonide | 1612014 | 1 |
| Caelo | Triamcinolone acetonide | 1612014-01 | 8 |
| Caelo | Triamcinolone acetonide | 16B04-B07-318957 | 1 |
| Caelo | Triamcinolone acetonide | 16D14-B11 | 1 |
| Caelo | Triamcinolone acetonide | 16D14-B11-321318 | 1 |
| Caelo | Triamcinolone acetonide | 16D14-B11-325482 | 4 |
| Caelo | Triamcinolone acetonide | 16D14-B11-328167 | 1 |
| Caelo | Triamcinolone acetonide | 16D16-B11-325482 | 1 |
| Caelo | Triamcinolone acetonide | 16K07-B06-329447 | 1 |
| Caelo | Triamcinolone acetonide | 16K07-B06-332102 | 1 |
| Caelo | Triamcinolone acetonide | 16K07-B06-333438 | 3 |
| Caelo | Triamcinolone acetonide | 17030347-01 | 1 |
| Caelo | Triamcinolone acetonide | 1703037 | 1 |
| Caelo | Triamcinolone acetonide | 170303701 | 2 |
| Caelo | Triamcinolone acetonide | 1703037-01 | 2 |
| Caelo | Triamcinolone acetonide | 170324T1612014-01 | 1 |
| Caelo | Triamcinolone acetonide | 170547902 | 1 |
| Caelo | Triamcinolone acetonide | 17057901 | 10 |
| Caelo | Triamcinolone acetonide | 17057902 | 19 |
| Caelo | Triamcinolone acetonide | 17057903 | 2 |
| Caelo | Triamcinolone acetonide | 17057905 | 18 |
| Caelo | Triamcinolone acetonide | 17057906 | 16 |
| Caelo | Triamcinolone acetonide | 17057907 | 9 |
| Caelo | Triamcinolone acetonide | 17057908 | 19 |
| Caelo | Triamcinolone acetonide | 17057909 | 2 |
| Caelo | Triamcinolone acetonide | 17057910 | 1 |
| Caelo | Triamcinolone acetonide | 1705797 | 1 |
| Caelo | Triamcinolone acetonide | 1706013-01 | 7 |
| Caelo | Triamcinolone acetonide | 17060131 | 1 |
| Caelo | Triamcinolone acetonide | 1706601-01 | 1 |
| Caelo | Triamcinolone acetonide | 1710002-01 | 1 |
| Caelo | Triamcinolone acetonide | 17100201 | 1 |
| Caelo | Triamcinolone acetonide | 1710610 | 1 |
| Caelo | Triamcinolone acetonide | 17120603 | 25 |
| Caelo | Triamcinolone acetonide | 17120604 | 7 |
| Caelo | Triamcinolone acetonide | 17120605 | 11 |
| Caelo | Triamcinolone acetonide | 17120606 | 23 |
| Caelo | Triamcinolone acetonide | 17120606/1211117 | 1 |
| Caelo | Triamcinolone acetonide | 17120607 | 13 |
| Caelo | Triamcinolone acetonide | 17120608 | 17 |
| Caelo | Triamcinolone acetonide | 17120609 | 1 |
| Caelo | Triamcinolone acetonide | 17120610 | 16 |
| Caelo | Triamcinolone acetonide | 17120611 | 35 |
| Caelo | Triamcinolone acetonide | 17120618 | 6 |
| Caelo | Triamcinolone acetonide | 17120619 | 7 |
| Caelo | Triamcinolone acetonide | 17120620 | 11 |
| Caelo | Triamcinolone acetonide | 17128606 | 1 |
| Caelo | Triamcinolone acetonide | 1720606 | 1 |
| Caelo | Triamcinolone acetonide | 1720608 | 1 |
| Caelo | Triamcinolone acetonide | 1735302 | 1 |
| Caelo | Triamcinolone acetonide | 17356306 | 1 |
| Caelo | Triamcinolone acetonide | 1735802 | 1 |
| Caelo | Triamcinolone acetonide | 1735805 | 1 |
| Caelo | Triamcinolone acetonide | 17358302 | 48 |
| Caelo | Triamcinolone acetonide | 17358302-T20181115Ma | 1 |
| Caelo | Triamcinolone acetonide | 17358303 | 8 |
| Caelo | Triamcinolone acetonide | 17358304 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triamcinolone acetonide | 17358305 | 40 |
| Caelo | Triamcinolone acetonide | 17358309 | 2 |
| Caelo | Triamcinolone acetonide | 1738305 | 1 |
| Caelo | Triamcinolone acetonide | 17C09-B01-340173 | 1 |
| Caelo | Triamcinolone acetonide | 17c09-b01-340174 | 1 |
| Caelo | Triamcinolone acetonide | 17C09-B01-340174 | 2 |
| Caelo | Triamcinolone acetonide | 17H03-B12-343457 | 1 |
| Caelo | Triamcinolone acetonide | 17H03-B12-343459 | 1 |
| Caelo | Triamcinolone acetonide | 17H03-B12-345552 | 1 |
| Caelo | Triamcinolone acetonide | 17H03B12346697 | 1 |
| Caelo | Triamcinolone acetonide | 180102001 | 2 |
| Caelo | Triamcinolone acetonide | 1801020-01 | 6 |
| Caelo | Triamcinolone acetonide | 18010202-01 | 1 |
| Caelo | Triamcinolone acetonide | 1805001-01 | 5 |
| Caelo | Triamcinolone acetonide | 180500102 | 1 |
| Caelo | Triamcinolone acetonide | 1805001-02 | 2 |
| Caelo | Triamcinolone acetonide | 1810015-01 | 2 |
| Caelo | Triamcinolone acetonide | 18100203 | 11 |
| Caelo | Triamcinolone acetonide | 18100204 | 18 |
| Caelo | Triamcinolone acetonide | 18100205 | 14 |
| Caelo | Triamcinolone acetonide | 18100206 | 9 |
| Caelo | Triamcinolone acetonide | 18100207 | 3 |
| Caelo | Triamcinolone acetonide | 18100208 | 10 |
| Caelo | Triamcinolone acetonide | 18100209 | 10 |
| Caelo | Triamcinolone acetonide | 18100210 | 30 |
| Caelo | Triamcinolone acetonide | 18100213 | 28 |
| Caelo | Triamcinolone acetonide | 18100215 | 1 |
| Caelo | Triamcinolone acetonide | 18100217 | 5 |
| Caelo | Triamcinolone acetonide | 18100218 | 4 |
| Caelo | Triamcinolone acetonide | 18100220 | 21 |
| Caelo | Triamcinolone acetonide | 18100221 | 30 |
| Caelo | Triamcinolone acetonide | 18100222 | 21 |
| Caelo | Triamcinolone acetonide | 18100225 | 3 |
| Caelo | Triamcinolone acetonide | 18100226 | 22 |
| Caelo | Triamcinolone acetonide | 1810207 | 1 |
| Caelo | Triamcinolone acetonide | 1810299 | 1 |
| Caelo | Triamcinolone acetonide | 1811211 | 1 |
| Caelo | Triamcinolone acetonide | 18C15-B05-347275 | 1 |
| Caelo | Triamcinolone acetonide | 18C15-B05-349087 | 1 |
| Caelo | Triamcinolone acetonide | 18F14-B01-351889 | 1 |
| Caelo | Triamcinolone acetonide | 18F14-B01-352343 | 1 |
| Caelo | Triamcinolone acetonide | 18F14B01355979 | 1 |
| Caelo | Triamcinolone acetonide | 18F14-B01-355979 | 1 |
| Caelo | Triamcinolone acetonide | 18F14-B01-356853 | 1 |
| Caelo | Triamcinolone acetonide | 1903015_01 | 1 |
| Caelo | Triamcinolone acetonide | 1903015-01 | 1 |
| Caelo | Triamcinolone acetonide | 1907044-01 | 2 |
| Caelo | Triamcinolone acetonide | 1912005 | 1 |
| Caelo | Triamcinolone acetonide | 191202003 | 2 |
| Caelo | Triamcinolone acetonide | 191202005 | 28 |
| Caelo | Triamcinolone acetonide | 191202006 | 22 |
| Caelo | Triamcinolone acetonide | 191202007 | 8 |
| Caelo | Triamcinolone acetonide | 19120205 | 1 |
| Caelo | Triamcinolone acetonide | 19120205P-191111-2 | 1 |
| Caelo | Triamcinolone acetonide | 19120206 | 12 |
| Caelo | Triamcinolone acetonide | 19120207 | 35 |
| Caelo | Triamcinolone acetonide | 19120208 | 27 |
| Caelo | Triamcinolone acetonide | 19120209 | 39 |
| Caelo | Triamcinolone acetonide | 19120210 | 20 |
| Caelo | Triamcinolone acetonide | 1912021007 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triamcinolone acetonide | 19120211 | 23 |
| Caelo | Triamcinolone acetonide | 1912208 | 1 |
| Caelo | Triamcinolone acetonide | 19J11-F02-367962 | 1 |
| Caelo | Triamcinolone acetonide | 200000461003 | 1 |
| Caelo | Triamcinolone acetonide | 200002630005 | 1 |
| Caelo | Triamcinolone acetonide | 200002630006 | 2 |
| Caelo | Triamcinolone acetonide | 20000461003 | 19 |
| Caelo | Triamcinolone acetonide | 20000461004 | 22 |
| Caelo | Triamcinolone acetonide | 20000461005 | 20 |
| Caelo | Triamcinolone acetonide | 20000461006 | 9 |
| Caelo | Triamcinolone acetonide | 20000461007 | 18 |
| Caelo | Triamcinolone acetonide | 20000461010 | 1 |
| Caelo | Triamcinolone acetonide | 20002360006 | 1 |
| Caelo | Triamcinolone acetonide | 20002630001 | 4 |
| Caelo | Triamcinolone acetonide | 20002630002 | 7 |
| Caelo | Triamcinolone acetonide | 20002630003 | 1 |
| Caelo | Triamcinolone acetonide | 20002630004 | 1 |
| Caelo | Triamcinolone acetonide | 20002630005 | 37 |
| Caelo | Triamcinolone acetonide | 20002630006 | 12 |
| Caelo | Triamcinolone acetonide | 2000263005 | 1 |
| Caelo | Triamcinolone acetonide | 20004422002 | 2 |
| Caelo | Triamcinolone acetonide | 2000461006 | 1 |
| Caelo | Triamcinolone acetonide | 2000461007 | 1 |
| Caelo | Triamcinolone acetonide | 2000464005 | 1 |
| Caelo | Triamcinolone acetonide | 2001017-01 | 1 |
| Caelo | Triamcinolone acetonide | 2006002-01 | 4 |
| Caelo | Triamcinolone acetonide | 2006032-01 | 2 |
| Caelo | Triamcinolone acetonide | 201200601 | 1 |
| Caelo | Triamcinolone acetonide | 2012006-01 | 7 |
| Caelo | Triamcinolone acetonide | 20B28-F04-371546 | 3 |
| Caelo | Triamcinolone acetonide | 20L18-F01-376650 | 1 |
| Caelo | Triamcinolone acetonide | 210000116002 | 1 |
| Caelo | Triamcinolone acetonide | 210000116014 | 1 |
| Caelo | Triamcinolone acetonide | 21000116001 | 52 |
| Caelo | Triamcinolone acetonide | 21000116002 | 15 |
| Caelo | Triamcinolone acetonide | 21000116003 | 2 |
| Caelo | Triamcinolone acetonide | 21000116004 | 1 |
| Caelo | Triamcinolone acetonide | 21000116005 | 19 |
| Caelo | Triamcinolone acetonide | 21000116006 | 4 |
| Caelo | Triamcinolone acetonide | 21000116008 | 8 |
| Caelo | Triamcinolone acetonide | 21000116010 | 4 |
| Caelo | Triamcinolone acetonide | 21000116011 | 14 |
| Caelo | Triamcinolone acetonide | 21000116014 | 30 |
| Caelo | Triamcinolone acetonide | 21000116016 | 1 |
| Caelo | Triamcinolone acetonide | 21000116018 | 2 |
| Caelo | Triamcinolone acetonide | 21000116019 | 18 |
| Caelo | Triamcinolone acetonide | 21000116021 | 2 |
| Caelo | Triamcinolone acetonide | 21000116022 | 5 |
| Caelo | Triamcinolone acetonide | 21000118001 | 1 |
| Caelo | Triamcinolone acetonide | 21000166001 | 1 |
| Caelo | Triamcinolone acetonide | 21000428001 | 1 |
| Caelo | Triamcinolone acetonide | 2100116014 | 1 |
| Caelo | Triamcinolone acetonide | 2100303011 | 1 |
| Caelo | Triamcinolone acetonide | 2100309001 | 1 |
| Caelo | Triamcinolone acetonide | 21003090310 | 1 |
| Caelo | Triamcinolone acetonide | 21003093001 | 29 |
| Caelo | Triamcinolone acetonide | 21003093003 | 11 |
| Caelo | Triamcinolone acetonide | 21003093008 | 7 |
| Caelo | Triamcinolone acetonide | 21003093009 | 1 |
| Caelo | Triamcinolone acetonide | 21003093010 | 10 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triamcinolone acetonide | 21003093011 | 18 |
| Caelo | Triamcinolone acetonide | 21003093013 | 2 |
| Caelo | Triamcinolone acetonide | 2109004-02 | 1 |
| Caelo | Triamcinolone acetonide | 22000302001 | 1 |
| Caelo | Triamcinolone acetonide | 22000902001 | 20 |
| Caelo | Triamcinolone acetonide | 22000902002 | 14 |
| Caelo | Triamcinolone acetonide | 22000902003 | 1 |
| Caelo | Triamcinolone acetonide | 22000902004 | 6 |
| Caelo | Triamcinolone acetonide | 22000902005 | 12 |
| Caelo | Triamcinolone acetonide | 22000902007 | 1 |
| Caelo | Triamcinolone acetonide | 22000902008 | 4 |
| Caelo | Triamcinolone acetonide | 22000902010 | 3 |
| Caelo | Triamcinolone acetonide | 22000902014 | 2 |
| Caelo | Triamcinolone acetonide | 2208004-01 | 1 |
| Caelo | Triamcinolone acetonide | 2211171 | 1 |
| Caelo | Triamcinolone acetonide | 2449210001161 | 1 |
| Caelo | Triamcinolone acetonide | 2513M02516 | 1 |
| Caelo | Triamcinolone acetonide | 29091806 | 1 |
| Caelo | Triamcinolone acetonide | 3041206 | 1 |
| Caelo | Triamcinolone acetonide | 310320161 | 1 |
| Caelo | Triamcinolone acetonide | 3110120 | 2 |
| Caelo | Triamcinolone acetonide | 31117-1/16094502 | 1 |
| Caelo | Triamcinolone acetonide | 3282 | 1 |
| Caelo | Triamcinolone acetonide | 3340 | 1 |
| Caelo | Triamcinolone acetonide | 42(18100213) | 1 |
| Caelo | Triamcinolone acetonide | 4613E2516 | 1 |
| Caelo | Triamcinolone acetonide | 5430105 | 1 |
| Caelo | Triamcinolone acetonide | 6051401 | 1 |
| Caelo | Triamcinolone acetonide | 618E-02516 | 1 |
| Caelo | Triamcinolone acetonide | 8681 | 1 |
| Caelo | Triamcinolone acetonide | 9081305 | 1 |
| Caelo | Triamcinolone acetonide | 912020061 | 1 |
| Caelo | Triamcinolone acetonide | 93/AD1 | 1 |
| Caelo | Triamcinolone acetonide | 9364429 | 2 |
| Caelo | Triamcinolone acetonide | 95/AKD34 | 1 |
| Caelo | Triamcinolone acetonide | I270715-1 | 1 |
| Caelo | Triamcinolone acetonide | NA0088M | 1 |
| Caelo | Triamcinolone acetonide | NS0571M | 1 |
| Caelo | Triamcinolone acetonide | NZ0071M | 1 |
| Caesar & Loretz / Noweda | Triamcinolone acetonide | 191202006 | 1 |
| Caesar & Loretz /Phönix | Triamcinolone acetonide | 21000116014 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 19120207 | 2 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 19120210 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 21003093010 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 19120208 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 20002630005 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 21000116001 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 21003093001 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 22000902002 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 18100221 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 20000461005 | 2 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 13379905 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 20000461003 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 21003093001 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 17358309 | 2 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 20002630006 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 21000116011 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 19120208 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 22000902009 | 1 |
| Caesar & Loretz GmbH… | Triamcinolone acetonide | 19120208 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20000461005 | 1 |
| Caesar & Loretz GmbH/AEP | Triamcinolone acetonide | 21003093001 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 22000902004 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116014 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 191202005 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116002 | 1 |
| Caesar & Loretz GmbH/Gehe | Triamcinolone acetonide | 18100210 | 1 |
| Caesar & Loretz GmbH/Gehe | Triamcinolone acetonide | 18100220 | 1 |
| Caesar & Loretz GmbH/GEHE | Triamcinolone acetonide | 21000116002 | 1 |
| Caesar & Loretz GmbH/Gehe | Triamcinolone acetonide | 22000902016 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 19120207 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116002 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21003093003 | 2 |
| Caesar & Loretz GmbH/Gö | Triamcinolone acetonide | 21003093011 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 19120210 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 19120211 | 5 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20000461007 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116005 | 2 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116019 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21003093010 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 22000902005 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 18100222 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 191202006 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20000461006 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20002630006 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20002630005 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116001 | 2 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116022 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21003093003 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 22000902001 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 18100209 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20000461005 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 18100210 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 18100222 | 2 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 19120211 | 2 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20000461006 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20000461007 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116008 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 18100210 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 19120207 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21003093011 | 1 |
| Caesar & Loretz GmbH/P | Triamcinolone acetonide | 19120206 | 2 |
| Caesar & Loretz GmbH/Ph | Triamcinolone acetonide | 19120208 | 1 |
| Caesar & Loretz GmbH/phö | Triamcinolone acetonide | 20000461003 | 2 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20002630006 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116019 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 18100213 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20000461007 | 2 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 20002630005 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116002 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116014 | 2 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 19120207 | 1 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21000116001 | 3 |
| Caesar & Loretz GmbH... | Triamcinolone acetonide | 21003093001 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 17057906 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 17057907 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 17120610 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 17358302 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 17358305 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 17358309 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Triamcinolone acetonide | 175358305 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100203 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100206 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100209 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100210 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100213 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100218 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100220 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100221 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100222 | 5 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 18100226 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 1907044-01 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 191202005 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 191202006 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 19120206 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 19120207 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 19120208 | 8 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 19120209 | 8 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 19120210 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 19120211 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20000461003 | 6 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20000461004 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20000461005 | 8 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20000461006 | 7 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20000461007 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20002630001 | 5 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20002630002 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20002630005 | 6 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20002630006 | 9 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 20004422002 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 2002047-01 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 2012006-01 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116001 | 21 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116002 | 14 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116005 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116006 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116008 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116011 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116012 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116013 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116014 | 15 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116018 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116019 | 6 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21000116022 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21003093001 | 10 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21003093003 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21003093008 | 9 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21003093009 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21003093010 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21003093011 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 21003093012 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 22000902001 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 22000902002 | 1 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 22000902004 | 3 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 22000902005 | 2 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 22000902009 | 4 |
| Caesar & Loretz GmbH | Triamcinolone acetonide | 3695669 | 1 |
| Caesar & Loretz | Triamcinolone acetonide | 17057906 | 1 |
| Caesar & Loretz | Triamcinolone acetonide | 18100204 | 1 |
| Caesar Loretz | Triamcinolone acetonide | 17057907 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar&loretz,Phoenix | Triamcinolone acetonide | 11267705 | 1 |
| Caesar&loretz,Phoenix | Triamcinolone acetonide | 12173703 | 1 |
| Caesar&loretz,Phoenix | Triamcinolone acetonide | 12301502 | 1 |
| Caleo/ Noweda | Triamcinolone acetonide | 16092504 | 1 |
| Caleo/ Noweda | Triamcinolone acetonide | 18100213 | 1 |
| Caleo/Phönix | Triamcinolone acetonide | 21003093010 | 2 |
| Calo, Hilden/ Phönix | Triamcinolone acetonide | 19120208 | 1 |
| Calo/Sanacorp | Triamcinolone acetonide | 16092504 | 1 |
| Cealo / Phönix / 22... | Triamcinolone acetonide | 18100225 | 1 |
| Cealo/ AHD | Triamcinolone acetonide | 18100221 | 1 |
| Cealo/Jenne | Triamcinolone acetonide | 220826(21003093001) | 1 |
| Cealo/Phönix | Triamcinolone acetonide | 17057901 | 1 |
| Cealo | Triamcinolone acetonide | 1907044-01 | 1 |
| Cealo | Triamcinolone acetonide | 20000461006 | 1 |
| Cealo | Triamcinolone acetonide | 21000116005 | 1 |
| cesar&lorentz/Phönix | Triamcinolone acetonide | 13124801 | 1 |
| Christal Pharma/Ober... | Triamcinolone acetonide | U0544/113530 | 1 |
| Crystal pharma/ Ober... | Triamcinolone acetonide | U0544/113530 | 1 |
| Crystal Pharma/Oberl... | Triamcinolone acetonide | B0544/114010 | 2 |
| Dr. Wolff | Triamcinolone acetonide | 1612014-01 | 1 |
| Ebert & Jacobi | Triamcinolone acetonide | 16K07-B06-329445 | 1 |
| Ebert/Euo | Triamcinolone acetonide | 1612014-01 | 1 |
| Eigen/Defektur | Triamcinolone acetonide | U0544/113530 | 1 |
| E-plus | Triamcinolone acetonide | 17120610 | 2 |
| EuRho / 11 | Triamcinolone acetonide | 2006032-01 | 1 |
| EuRho / Alliance | Triamcinolone acetonide | 2012006-01 | 1 |
| Eurho / Alliance | Triamcinolone acetonide | 2109004-01 | 1 |
| EuRho / Phoenix | Triamcinolone acetonide | 1612014-01 | 1 |
| EuRho- Phoenix | Triamcinolone acetonide | 1710002-01 | 1 |
| EuRho- Phoenix | Triamcinolone acetonide | 1810015-01 | 2 |
| EuRho/ AHD | Triamcinolone acetonide | 1710002-01 | 1 |
| EuRho/ Phönix | Triamcinolone acetonide | 1907044-01 | 1 |
| EuRho/ Sanacorp | Triamcinolone acetonide | 1703037-01 | 1 |
| EuRho/ Sanacorp | Triamcinolone acetonide | 2109004-01 | 1 |
| EuRho/Noweda | Triamcinolone acetonide | 1601021-01 | 1 |
| EuRho/Noweda | Triamcinolone acetonide | 1706013-01 | 1 |
| EuRho/Noweda | Triamcinolone acetonide | 1710002-01 | 1 |
| Eurho/Noweda | Triamcinolone acetonide | 2012006-01 | 1 |
| EuRho/Noweda | Triamcinolone acetonide | 2109004-01 | 1 |
| EuRho/Phoenix | Triamcinolone acetonide | 1403009-02 | 1 |
| EuRho/Phoenix | Triamcinolone acetonide | 2109004-03 | 1 |
| EuRho/Phönix | Triamcinolone acetonide | 1211013-01 | 1 |
| EuRho/Phönix | Triamcinolone acetonide | 1307043-02 | 1 |
| EuRho/Phönix | Triamcinolone acetonide | 1407044-01 | 1 |
| Eurho/Phönix | Triamcinolone acetonide | 2002047-01 | 1 |
| Eurho/Phönix | Triamcinolone acetonide | 201200601 | 1 |
| EuRho/Px | Triamcinolone acetonide | 219004-02 | 1 |
| Eurho/Sanacorp | Triamcinolone acetonide | 1710002-01 | 1 |
| EuRho/Sanacorp | Triamcinolone acetonide | 2006002-01 | 1 |
| EuRho | Triamcinolone acetonide | 110015-01 | 1 |
| EuRho | Triamcinolone acetonide | 1403009-02 | 1 |
| EuRho | Triamcinolone acetonide | 1407044-02 | 1 |
| EuRho | Triamcinolone acetonide | 150800-08-02 | 1 |
| EuRho | Triamcinolone acetonide | 1508008-02 | 2 |
| EuRho | Triamcinolone acetonide | 1703037-01 | 2 |
| EuRho | Triamcinolone acetonide | 17100002-01 | 1 |
| EuRho | Triamcinolone acetonide | 171000201 | 1 |
| EuRho | Triamcinolone acetonide | 17100201 | 1 |
| EuRho | Triamcinolone acetonide | 180500101 | 1 |
| Eurho | Triamcinolone acetonide | 1805001-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| EuRho | Triamcinolone acetonide | 1810015-01 | 1 |
| EuRho | Triamcinolone acetonide | 1905015-01 | 1 |
| EuRho | Triamcinolone acetonide | 1907044-01 | 2 |
| euRho | Triamcinolone acetonide | 2006032-01 | 2 |
| EuRho | Triamcinolone acetonide | 2006032-01 | 2 |
| EuRho | Triamcinolone acetonide | 2012006-01 | 1 |
| EuRho | Triamcinolone acetonide | 2012006-02 | 1 |
| EuRho | Triamcinolone acetonide | 2109004-01 | 1 |
| euRho | Triamcinolone acetonide | 2208004-01 | 2 |
| EuRho | Triamcinolone acetonide | NW2518M | 1 |
| Euro / Noweda | Triamcinolone acetonide | 1612014-01 | 1 |
| Euro OCT / Krieger | Triamcinolone acetonide | 2002047-01 | 1 |
| Euro OCT / Krieger | Triamcinolone acetonide | 2006032-01 | 1 |
| Euro OTC | Triamcinolone acetonide | | 5 |
| Euro OTC | Triamcinolone acetonide | 1/10002-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1013I-02516 | 1 |
| Euro OTC | Triamcinolone acetonide | 1110005-01 | 2 |
| Euro OTC | Triamcinolone acetonide | 111005-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1112023-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1112023-02 | 6 |
| Euro OTC | Triamcinolone acetonide | 112014-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 11801020-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1206008-01 | 5 |
| Euro OTC | Triamcinolone acetonide | 1209040-01 | 4 |
| Euro OTC | Triamcinolone acetonide | 1209040-02 | 2 |
| Euro OTC | Triamcinolone acetonide | 1211013-01 | 4 |
| Euro OTC | Triamcinolone acetonide | 1211013-02 | 9 |
| Euro OTC | Triamcinolone acetonide | 121113-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 1234567 | 1 |
| Euro OTC | Triamcinolone acetonide | 12G6008-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 13030001-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1303001-01 | 5 |
| Euro OTC | Triamcinolone acetonide | 1303001-02 | 8 |
| Euro OTC | Triamcinolone acetonide | 130704301 | 1 |
| Euro OTC | Triamcinolone acetonide | 1307043-01 | 15 |
| Euro OTC | Triamcinolone acetonide | 130704302 | 1 |
| Euro OTC | Triamcinolone acetonide | 1307043-02 | 14 |
| Euro OTC | Triamcinolone acetonide | 1307043-03 | 1 |
| Euro OTC | Triamcinolone acetonide | 14030009-01 | 2 |
| Euro OTC | Triamcinolone acetonide | 14030009-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 1403009-01 | 7 |
| Euro OTC | Triamcinolone acetonide | 1403009-02 | 13 |
| Euro OTC | Triamcinolone acetonide | 1407044-01 | 9 |
| Euro OTC | Triamcinolone acetonide | 1407044-02 | 15 |
| Euro OTC | Triamcinolone acetonide | 140744-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 14120130 | 1 |
| Euro OTC | Triamcinolone acetonide | 141201301 | 1 |
| Euro OTC | Triamcinolone acetonide | 1412013-01 | 13 |
| Euro OTC | Triamcinolone acetonide | 141201302 | 4 |
| Euro OTC | Triamcinolone acetonide | 1412013-02 | 9 |
| Euro OTC | Triamcinolone acetonide | 141213-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 14188304 | 1 |
| Euro OTC | Triamcinolone acetonide | 150008-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 150400701 | 2 |
| Euro OTC | Triamcinolone acetonide | 1504007-01 | 10 |
| Euro OTC | Triamcinolone acetonide | 1504007-02 | 17 |
| Euro OTC | Triamcinolone acetonide | 15041007-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 15042014A | 1 |
| Euro OTC | Triamcinolone acetonide | 1508008 | 1 |
| Euro OTC | Triamcinolone acetonide | 1508008-01 | 17 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Triamcinolone acetonide | 150800802 | 2 |
| Euro OTC | Triamcinolone acetonide | 1508008-02 | 16 |
| Euro OTC | Triamcinolone acetonide | 15081701 | 1 |
| Euro OTC | Triamcinolone acetonide | 15111740 | 1 |
| Euro OTC | Triamcinolone acetonide | 15121806 | 1 |
| Euro OTC | Triamcinolone acetonide | 15233904 | 1 |
| Euro OTC | Triamcinolone acetonide | 15233906 | 2 |
| Euro OTC | Triamcinolone acetonide | 15404007-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 15430103 | 1 |
| Euro OTC | Triamcinolone acetonide | 15121-b03-316123 | 1 |
| Euro OTC | Triamcinolone acetonide | 15L21-B03-316123 | 2 |
| Euro OTC | Triamcinolone acetonide | 1601021-01 | 32 |
| Euro OTC | Triamcinolone acetonide | 1602005-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 160501001 | 3 |
| Euro OTC | Triamcinolone acetonide | 1605010-01 | 42 |
| Euro OTC | Triamcinolone acetonide | 160510-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1608005 | 1 |
| Euro OTC | Triamcinolone acetonide | 1608005-01 | 44 |
| Euro OTC | Triamcinolone acetonide | 161006T | 1 |
| Euro OTC | Triamcinolone acetonide | 1612014-01 | 64 |
| Euro OTC | Triamcinolone acetonide | 1612014-014 | 1 |
| Euro OTC | Triamcinolone acetonide | 161214-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 16D14-B11 | 1 |
| Euro OTC | Triamcinolone acetonide | 16D14-B11-322136 | 1 |
| Euro OTC | Triamcinolone acetonide | 170060013-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 17030307-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1703037 | 3 |
| Euro OTC | Triamcinolone acetonide | 1703037_01 | 1 |
| Euro OTC | Triamcinolone acetonide | 170303701 | 3 |
| Euro OTC | Triamcinolone acetonide | 1703037-01 | 58 |
| Euro OTC | Triamcinolone acetonide | 1706013 | 1 |
| Euro OTC | Triamcinolone acetonide | 170601301 | 5 |
| Euro OTC | Triamcinolone acetonide | 1706013-01 | 73 |
| Euro OTC | Triamcinolone acetonide | 1706079-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 17061406 | 1 |
| Euro OTC | Triamcinolone acetonide | 171000-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 17100002-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1710002-01 | 68 |
| Euro OTC | Triamcinolone acetonide | 1710002-1 | 1 |
| Euro OTC | Triamcinolone acetonide | 171002-01 | 2 |
| Euro OTC | Triamcinolone acetonide | 171212T/1703037-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 171302-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 171613-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1801020 | 3 |
| Euro OTC | Triamcinolone acetonide | 180102001 | 3 |
| Euro OTC | Triamcinolone acetonide | 1801020-01 | 80 |
| Euro OTC | Triamcinolone acetonide | 1801020-1 | 1 |
| Euro OTC | Triamcinolone acetonide | 1805001 | 1 |
| Euro OTC | Triamcinolone acetonide | 180500101 | 3 |
| Euro OTC | Triamcinolone acetonide | 1805001-01 | 45 |
| Euro OTC | Triamcinolone acetonide | 180500102 | 1 |
| Euro OTC | Triamcinolone acetonide | 1805001-02 | 24 |
| Euro OTC | Triamcinolone acetonide | 18100115-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1810015001 | 1 |
| Euro OTC | Triamcinolone acetonide | 181001501 | 5 |
| Euro OTC | Triamcinolone acetonide | 1810015-01 | 93 |
| Euro OTC | Triamcinolone acetonide | 181016181 | 1 |
| Euro OTC | Triamcinolone acetonide | 181020-1 | 1 |
| Euro OTC | Triamcinolone acetonide | 190301501 | 1 |
| Euro OTC | Triamcinolone acetonide | 1903015-01 | 65 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Triamcinolone acetonide | 1903015-15 | 1 |
| Euro OTC | Triamcinolone acetonide | 19030156-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 190601206 | 1 |
| Euro OTC | Triamcinolone acetonide | 190704401 | 5 |
| Euro OTC | Triamcinolone acetonide | 1907044-01 | 83 |
| Euro OTC | Triamcinolone acetonide | 19070744-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 19074401 | 1 |
| Euro OTC | Triamcinolone acetonide | 190744-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 1912014-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 19120209 | 1 |
| Euro OTC | Triamcinolone acetonide | 20006032-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 2001017 | 1 |
| Euro OTC | Triamcinolone acetonide | 2001017-01 | 7 |
| Euro OTC | Triamcinolone acetonide | 2002047 | 3 |
| Euro OTC | Triamcinolone acetonide | 200204701 | 5 |
| Euro OTC | Triamcinolone acetonide | 2002047-01 | 49 |
| Euro OTC | Triamcinolone acetonide | 20024047-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 200600201 | 1 |
| Euro OTC | Triamcinolone acetonide | 2006002-01 | 54 |
| Euro OTC | Triamcinolone acetonide | 2006002-1 | 1 |
| Euro OTC | Triamcinolone acetonide | 200603201 | 1 |
| Euro OTC | Triamcinolone acetonide | 2006032-01 | 52 |
| Euro OTC | Triamcinolone acetonide | 2006032-31 | 1 |
| Euro OTC | Triamcinolone acetonide | 2012 | 1 |
| Euro OTC | Triamcinolone acetonide | 2012003-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 2012006 | 2 |
| Euro OTC | Triamcinolone acetonide | 2012006_01 | 1 |
| Euro OTC | Triamcinolone acetonide | 201200601 | 8 |
| Euro OTC | Triamcinolone acetonide | 2012006-01 | 67 |
| Euro OTC | Triamcinolone acetonide | 2012006-02 | 38 |
| Euro OTC | Triamcinolone acetonide | 2012006-04 | 1 |
| Euro OTC | Triamcinolone acetonide | 2012006-1 | 1 |
| Euro OTC | Triamcinolone acetonide | 20130912-5 | 1 |
| Euro OTC | Triamcinolone acetonide | 2015006-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 20212006-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 2108004-03 | 1 |
| Euro OTC | Triamcinolone acetonide | 21090004-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 2109001-03 | 1 |
| Euro OTC | Triamcinolone acetonide | 2109004_01 | 1 |
| Euro OTC | Triamcinolone acetonide | 21090040-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 2109004-01 | 57 |
| Euro OTC | Triamcinolone acetonide | 2109004-02 | 25 |
| Euro OTC | Triamcinolone acetonide | 2109004-03 | 23 |
| Euro OTC | Triamcinolone acetonide | 220800401 | 1 |
| Euro OTC | Triamcinolone acetonide | 2208004-01 | 19 |
| Euro OTC | Triamcinolone acetonide | 2208004-02 | 2 |
| Euro OTC | Triamcinolone acetonide | 23061808 | 1 |
| Euro OTC | Triamcinolone acetonide | 2308018-01 | 1 |
| Euro OTC | Triamcinolone acetonide | 2308018-02 | 1 |
| Euro OTC | Triamcinolone acetonide | 26011804 | 1 |
| Euro OTC | Triamcinolone acetonide | 26081405 | 1 |
| Euro OTC | Triamcinolone acetonide | 2772 | 1 |
| Euro OTC | Triamcinolone acetonide | 28041728 | 1 |
| Euro OTC | Triamcinolone acetonide | 2898 | 1 |
| Euro OTC | Triamcinolone acetonide | 29011503 | 1 |
| Euro OTC | Triamcinolone acetonide | 29081501 | 1 |
| Euro OTC | Triamcinolone acetonide | 3022015A | 1 |
| Euro OTC | Triamcinolone acetonide | 3051402 | 1 |
| Euro OTC | Triamcinolone acetonide | 31101414 | 1 |
| Euro OTC | Triamcinolone acetonide | 5051816 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Triamcinolone acetonide | 6702020004 | 1 |
| Euro OTC | Triamcinolone acetonide | 6702020010 | 2 |
| Euro OTC | Triamcinolone acetonide | 6702021007 | 3 |
| Euro OTC | Triamcinolone acetonide | 700124 | 1 |
| Euro OTC | Triamcinolone acetonide | 8031803 | 1 |
| Euro OTC | Triamcinolone acetonide | 80616-5 | 1 |
| Euro OTC | Triamcinolone acetonide | 8700 | 1 |
| Euro OTC | Triamcinolone acetonide | APB0544/112020T | 1 |
| Euro OTC | Triamcinolone acetonide | B0544/111404 | 1 |
| Euro OTC | Triamcinolone acetonide | NV0635M | 1 |
| Euro OTC | Triamcinolone acetonide | NW2518M | 1 |
| Euro OTC | Triamcinolone acetonide | NX2518M | 1 |
| Euro OTC | Triamcinolone acetonide | NZ032211 | 1 |
| Euro OTC | Triamcinolone acetonide | PT49 | 1 |
| Euro/ Anzag | Triamcinolone acetonide | 2012006-02 | 1 |
| euro/ Anzag | Triamcinolone acetonide | 3315I02516 | 1 |
| Euro/Gehe | Triamcinolone acetonide | 1612014-01 | 1 |
| Euro/Gehe | Triamcinolone acetonide | 1703037-01 | 1 |
| Euro/gehe | Triamcinolone acetonide | 2012006-01 | 1 |
| Euro/Krieger | Triamcinolone acetonide | 1907044-01 | 1 |
| Euro/Noweda | Triamcinolone acetonide | 161201401 | 1 |
| Euro/Phönix | Triamcinolone acetonide | 1805401 | 1 |
| Euro/Phönix | Triamcinolone acetonide | 1907044 | 1 |
| Euro/Sanacorp | Triamcinolone acetonide | 2006002-01 | 1 |
| Euro/Sanacorp | Triamcinolone acetonide | 2008032-01 | 1 |
| euro | Triamcinolone acetonide | 1211013-02 | 1 |
| Euro | Triamcinolone acetonide | 1303001-02 | 1 |
| Euro | Triamcinolone acetonide | 2006002-01 | 3 |
| euroct/gehe | Triamcinolone acetonide | 1403009 | 1 |
| euroct/gehe | Triamcinolone acetonide | 1403009-02 | 1 |
| EuroOCT/Gehe | Triamcinolone acetonide | 1710002-01 | 2 |
| Europharm/Otto | Triamcinolone acetonide | 1206008-01 | 1 |
| Europharm/Otto | Triamcinolone acetonide | 1209040-02 | 1 |
| Europharm/Sanacorp | Triamcinolone acetonide | 1211013-01 | 3 |
| Europharm/Sanacorp | Triamcinolone acetonide | B0544/111040 | 2 |
| Fa.Phönix | Triamcinolone acetonide | 17120611 | 1 |
| Fa.Phönix | Triamcinolone acetonide | 18100213 | 1 |
| Fa.Phönix | Triamcinolone acetonide | 19120208 | 1 |
| Fa.Phönix | Triamcinolone acetonide | 20000461004 | 1 |
| Fa.Phönix | Triamcinolone acetonide | 20002630005 | 1 |
| Fa.Phönix | Triamcinolone acetonide | 21000116001 | 1 |
| Fa.Phönix | Triamcinolone acetonide | 22000902001 | 1 |
| Fagron | Triamcinolone acetonide | | 3 |
| Fagron | Triamcinolone acetonide | 11B22-N05 | 1 |
| Fagron | Triamcinolone acetonide | 11E24-N04 | 1 |
| Fagron | Triamcinolone acetonide | 11K11-N10 | 6 |
| Fagron | Triamcinolone acetonide | 11N11-N10 | 1 |
| Fagron | Triamcinolone acetonide | 12/10-N09 | 4 |
| Fagron | Triamcinolone acetonide | 12/-N09 | 1 |
| Fagron | Triamcinolone acetonide | 120600801 | 1 |
| Fagron | Triamcinolone acetonide | 1210-N09 | 1 |
| Fagron | Triamcinolone acetonide | 12301503 | 1 |
| Fagron | Triamcinolone acetonide | 12B08N01 | 1 |
| Fagron | Triamcinolone acetonide | 12B08-N01 | 8 |
| Fagron | Triamcinolone acetonide | 12E15/N03 | 1 |
| Fagron | Triamcinolone acetonide | 12E15-N03 | 21 |
| Fagron | Triamcinolone acetonide | 12I10-N09 | 4 |
| Fagron | Triamcinolone acetonide | 12l10-N09 | 3 |
| Fagron | Triamcinolone acetonide | 13/26-N11 | 10 |
| Fagron | Triamcinolone acetonide | 13021408 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triamcinolone acetonide | 13121201 | 1 |
| Fagron | Triamcinolone acetonide | 13126-N11 | 1 |
| Fagron | Triamcinolone acetonide | 1326-N11 | 1 |
| Fagron | Triamcinolone acetonide | 13C13-20 | 1 |
| Fagron | Triamcinolone acetonide | 13c13-n20 | 1 |
| Fagron | Triamcinolone acetonide | 13C13-N20 | 14 |
| Fagron | Triamcinolone acetonide | 13C13-N200217/412 | 1 |
| Fagron | Triamcinolone acetonide | 13e15-n03 | 1 |
| Fagron | Triamcinolone acetonide | 13E15N03 | 3 |
| Fagron | Triamcinolone acetonide | 13E15-N03 | 44 |
| Fagron | Triamcinolone acetonide | 13E15-NO3 | 1 |
| Fagron | Triamcinolone acetonide | 13i26-N11 | 1 |
| Fagron | Triamcinolone acetonide | 13I26N11 | 1 |
| Fagron | Triamcinolone acetonide | 13I26-N11 | 13 |
| Fagron | Triamcinolone acetonide | 13I26-N26 | 1 |
| Fagron | Triamcinolone acetonide | 13K14-b04 | 1 |
| Fagron | Triamcinolone acetonide | 13K14-B04 | 4 |
| Fagron | Triamcinolone acetonide | 13k14-B04-289032 | 1 |
| Fagron | Triamcinolone acetonide | 13K14-B04-289032 | 6 |
| Fagron | Triamcinolone acetonide | 13K14-B04-289033 | 10 |
| Fagron | Triamcinolone acetonide | 13K15-B31 | 9 |
| Fagron | Triamcinolone acetonide | 13K15-B31-289025 | 1 |
| Fagron | Triamcinolone acetonide | 13K15-B31-289027 | 6 |
| Fagron | Triamcinolone acetonide | 13k15-b31-289029 | 2 |
| Fagron | Triamcinolone acetonide | 13K15B31289029 | 1 |
| Fagron | Triamcinolone acetonide | 13K15-B31-289029 | 3 |
| Fagron | Triamcinolone acetonide | 13k15-b31-289030 | 1 |
| Fagron | Triamcinolone acetonide | 13K15-B31-289031 | 6 |
| Fagron | Triamcinolone acetonide | 1407044-01 | 1 |
| Fagron | Triamcinolone acetonide | 1412013-01 | 1 |
| Fagron | Triamcinolone acetonide | 14355104 | 1 |
| Fagron | Triamcinolone acetonide | 14355709 | 1 |
| Fagron | Triamcinolone acetonide | 14F30B01 | 1 |
| Fagron | Triamcinolone acetonide | 14F30-B01 | 2 |
| Fagron | Triamcinolone acetonide | 14F30-B01-296287 | 4 |
| Fagron | Triamcinolone acetonide | 14F30-B021-296287 | 1 |
| Fagron | Triamcinolone acetonide | 14G23-B07 | 1 |
| Fagron | Triamcinolone acetonide | 14G23-B07-297618 | 5 |
| Fagron | Triamcinolone acetonide | 14G23-B07-297619 | 2 |
| Fagron | Triamcinolone acetonide | 14G23-B07-297620 | 7 |
| Fagron | Triamcinolone acetonide | 14G23-BO7-297620 | 1 |
| Fagron | Triamcinolone acetonide | 14k14-B05-302887 | 1 |
| Fagron | Triamcinolone acetonide | 14K14-B05-302887 | 2 |
| Fagron | Triamcinolone acetonide | 14K24N-N01 | 1 |
| Fagron | Triamcinolone acetonide | 1508008-02 | 1 |
| Fagron | Triamcinolone acetonide | 1531-07-313596 | 1 |
| Fagron | Triamcinolone acetonide | 15B02-B03 | 5 |
| Fagron | Triamcinolone acetonide | 15B02-B03-303827 | 2 |
| Fagron | Triamcinolone acetonide | 15B02-B03-303828 | 5 |
| Fagron | Triamcinolone acetonide | 15B02-B03-303830 | 8 |
| Fagron | Triamcinolone acetonide | 15BO2-B03-303828 | 1 |
| Fagron | Triamcinolone acetonide | 15C19-B06 | 2 |
| Fagron | Triamcinolone acetonide | 15C19-B06-308571 | 1 |
| Fagron | Triamcinolone acetonide | 15C19-B06-308572 | 7 |
| Fagron | Triamcinolone acetonide | 15C19-B06-308573 | 10 |
| Fagron | Triamcinolone acetonide | 15C19-B06-309194 | 2 |
| Fagron | Triamcinolone acetonide | 15G31B07 | 2 |
| Fagron | Triamcinolone acetonide | 15G31-B07 | 2 |
| Fagron | Triamcinolone acetonide | 15G31-B07-313596 | 6 |
| Fagron | Triamcinolone acetonide | 15G31B07313597 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triamcinolone acetonide | 15G31-B07-313597 | 6 |
| Fagron | Triamcinolone acetonide | 15G31-B07-314045 | 6 |
| Fagron | Triamcinolone acetonide | 15g31-b07-314046 | 1 |
| Fagron | Triamcinolone acetonide | 15G31-B07-314046 | 4 |
| Fagron | Triamcinolone acetonide | 15G31-B07-314047 | 3 |
| Fagron | Triamcinolone acetonide | 15L21-B03 | 1 |
| Fagron | Triamcinolone acetonide | 15L21-B03-316123 | 9 |
| Fagron | Triamcinolone acetonide | 15L21-B03-318663 | 4 |
| Fagron | Triamcinolone acetonide | 16011407 | 1 |
| Fagron | Triamcinolone acetonide | 16014-B12-3231318 | 1 |
| Fagron | Triamcinolone acetonide | 1608005-01 | 1 |
| Fagron | Triamcinolone acetonide | 1612014-01 | 1 |
| Fagron | Triamcinolone acetonide | 16B04 | 1 |
| Fagron | Triamcinolone acetonide | 16B04-B07 | 4 |
| Fagron | Triamcinolone acetonide | 16B04-B07318664 | 1 |
| Fagron | Triamcinolone acetonide | 16B04-B07-318664 | 7 |
| Fagron | Triamcinolone acetonide | 16B04-B07-318957 | 6 |
| Fagron | Triamcinolone acetonide | 16B04-B07-319471 | 4 |
| Fagron | Triamcinolone acetonide | 16B04-Bo7-318664 | 1 |
| Fagron | Triamcinolone acetonide | 16-B07-318664 | 1 |
| Fagron | Triamcinolone acetonide | 16D04-B11-325479 | 1 |
| Fagron | Triamcinolone acetonide | 16D14_B11_328167 | 2 |
| Fagron | Triamcinolone acetonide | 16D14-B11 | 2 |
| Fagron | Triamcinolone acetonide | 16D14-B11_322158 | 1 |
| Fagron | Triamcinolone acetonide | 16D14-B11-321318 | 3 |
| Fagron | Triamcinolone acetonide | 16D14-B11-322135 | 4 |
| Fagron | Triamcinolone acetonide | 16D14-B11-322136 | 10 |
| Fagron | Triamcinolone acetonide | 16D14-B11-322158 | 10 |
| Fagron | Triamcinolone acetonide | 16D14B11325479 | 1 |
| Fagron | Triamcinolone acetonide | 16D14-B11-325479 | 6 |
| Fagron | Triamcinolone acetonide | 16D14-B11-325480 | 3 |
| Fagron | Triamcinolone acetonide | 16D14-B11-325481 | 1 |
| Fagron | Triamcinolone acetonide | 16D14-B11-325482 | 6 |
| Fagron | Triamcinolone acetonide | 16D14-B11-328167 | 15 |
| Fagron | Triamcinolone acetonide | 16K07-B06 | 3 |
| Fagron | Triamcinolone acetonide | 16K07-B060921 | 1 |
| Fagron | Triamcinolone acetonide | 16K07B06329445 | 1 |
| Fagron | Triamcinolone acetonide | 16K07-B06-329445 | 5 |
| Fagron | Triamcinolone acetonide | 16K07-B06-329446 | 1 |
| Fagron | Triamcinolone acetonide | 16K07-B06-329447 | 1 |
| Fagron | Triamcinolone acetonide | 16K07-B06-332101 | 7 |
| Fagron | Triamcinolone acetonide | 16K07-B06-332102 | 4 |
| Fagron | Triamcinolone acetonide | 16k07-b06332103 | 1 |
| Fagron | Triamcinolone acetonide | 16K07B06332103 | 1 |
| Fagron | Triamcinolone acetonide | 16K07-B06-332103 | 2 |
| Fagron | Triamcinolone acetonide | 16K07-B06-333438 | 4 |
| Fagron | Triamcinolone acetonide | 16l07-b06-332102 | 1 |
| Fagron | Triamcinolone acetonide | 1703-B12-345553 | 1 |
| Fagron | Triamcinolone acetonide | 17C09_B01_337464 | 1 |
| Fagron | Triamcinolone acetonide | 17C09-B01 | 3 |
| Fagron | Triamcinolone acetonide | 17C09-B01_337464 | 1 |
| Fagron | Triamcinolone acetonide | 17C09-B01-334196 | 6 |
| Fagron | Triamcinolone acetonide | 17C09-B01-334197 | 4 |
| Fagron | Triamcinolone acetonide | 17C-09-B01-334197 | 1 |
| Fagron | Triamcinolone acetonide | 17C09-B01-336881 | 2 |
| Fagron | Triamcinolone acetonide | 17C09-B01-337464 | 3 |
| Fagron | Triamcinolone acetonide | 17C09-B01-340173 | 10 |
| Fagron | Triamcinolone acetonide | 17c09-b01-340174 | 1 |
| Fagron | Triamcinolone acetonide | 17C09-B01-340174 | 10 |
| Fagron | Triamcinolone acetonide | 17C-B01-336881 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triamcinolone acetonide | 17D9-B01-334197 | 1 |
| Fagron | Triamcinolone acetonide | 17F14-B01-352343 | 1 |
| Fagron | Triamcinolone acetonide | 17H03-812-346697 | 1 |
| Fagron | Triamcinolone acetonide | 17H03-B12 | 6 |
| Fagron | Triamcinolone acetonide | 17H03-B12-343457 | 6 |
| Fagron | Triamcinolone acetonide | 17H03-B12343458 | 1 |
| Fagron | Triamcinolone acetonide | 17H03-B12-343458 | 6 |
| Fagron | Triamcinolone acetonide | 17H03-B12-343459 | 3 |
| Fagron | Triamcinolone acetonide | 17h03-b12-343672 | 1 |
| Fagron | Triamcinolone acetonide | 17H03-B12-343672 | 6 |
| Fagron | Triamcinolone acetonide | 17H03-B12-345552 | 10 |
| Fagron | Triamcinolone acetonide | 17H03-B12-345553 | 2 |
| Fagron | Triamcinolone acetonide | 17H03-B12-346697 | 2 |
| Fagron | Triamcinolone acetonide | 17H03-B12-672 | 1 |
| Fagron | Triamcinolone acetonide | 1810015-01 | 1 |
| Fagron | Triamcinolone acetonide | 18100205 | 1 |
| Fagron | Triamcinolone acetonide | 18100221 | 1 |
| Fagron | Triamcinolone acetonide | 18C15-B05 | 7 |
| Fagron | Triamcinolone acetonide | 18C15-B05_348063 | 1 |
| Fagron | Triamcinolone acetonide | 18C15B05347275 | 2 |
| Fagron | Triamcinolone acetonide | 18C15-B05-347275 | 6 |
| Fagron | Triamcinolone acetonide | 18C15-B05-348063 | 6 |
| Fagron | Triamcinolone acetonide | 18c15-b05-348064 | 2 |
| Fagron | Triamcinolone acetonide | 18C15-B05-348064 | 3 |
| Fagron | Triamcinolone acetonide | 18c15-b05-349087 | 1 |
| Fagron | Triamcinolone acetonide | 18C15-B05-349087 | 9 |
| Fagron | Triamcinolone acetonide | 18c15-b05-350263 | 1 |
| Fagron | Triamcinolone acetonide | 18C15-B05-350263 | 4 |
| Fagron | Triamcinolone acetonide | 18C15-B05-348063 | 1 |
| Fagron | Triamcinolone acetonide | 18F14 | 1 |
| Fagron | Triamcinolone acetonide | 18F14_B01_352343 | 1 |
| Fagron | Triamcinolone acetonide | 18F14_B01_352630 | 1 |
| Fagron | Triamcinolone acetonide | 18F14-B01 | 3 |
| Fagron | Triamcinolone acetonide | 18F14-B01_356853 | 1 |
| Fagron | Triamcinolone acetonide | 18f14b01351889 | 1 |
| Fagron | Triamcinolone acetonide | 18F14-B01-351889 | 7 |
| Fagron | Triamcinolone acetonide | 18F14-B01-352343 | 10 |
| Fagron | Triamcinolone acetonide | 18F14-B01-352630 | 5 |
| Fagron | Triamcinolone acetonide | 18F14-B01-353255 | 9 |
| Fagron | Triamcinolone acetonide | 18F14-B01-355724 | 4 |
| Fagron | Triamcinolone acetonide | 18F14-B01-355979 | 5 |
| Fagron | Triamcinolone acetonide | 18F14-B01-356853 | 13 |
| Fagron | Triamcinolone acetonide | 18f14-b01-357073 | 1 |
| Fagron | Triamcinolone acetonide | 18F14-B01-357073 | 6 |
| Fagron | Triamcinolone acetonide | 18F14-B-351889 | 1 |
| Fagron | Triamcinolone acetonide | 18F14-B01-357073 | 1 |
| Fagron | Triamcinolone acetonide | 18F-B01-355979 | 1 |
| Fagron | Triamcinolone acetonide | 18I216-B05-361518 | 1 |
| Fagron | Triamcinolone acetonide | 18k16-B05 | 1 |
| Fagron | Triamcinolone acetonide | 18K16-B05 | 5 |
| Fagron | Triamcinolone acetonide | 18K-16-B05 | 1 |
| Fagron | Triamcinolone acetonide | 18K16-B05_367959 | 1 |
| Fagron | Triamcinolone acetonide | 18K16-B05-357775 | 5 |
| Fagron | Triamcinolone acetonide | 18K16-B05-35969 | 1 |
| Fagron | Triamcinolone acetonide | 18K16-B05-359867 | 7 |
| Fagron | Triamcinolone acetonide | 18K16-B05-359868 | 6 |
| Fagron | Triamcinolone acetonide | 18K16-B05-359869 | 4 |
| Fagron | Triamcinolone acetonide | 18K16-B05-359871 | 8 |
| Fagron | Triamcinolone acetonide | 18K16-B05-361518 | 6 |
| Fagron | Triamcinolone acetonide | 18K16-B05-361521 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triamcinolone acetonide | 18K16-B05-361522 | 2 |
| Fagron | Triamcinolone acetonide | 18K-16-B05-361522 | 1 |
| Fagron | Triamcinolone acetonide | 18k16b05361523 | 1 |
| Fagron | Triamcinolone acetonide | 18k16-b05-361523 | 1 |
| Fagron | Triamcinolone acetonide | 18K16-B05-361523 | 3 |
| Fagron | Triamcinolone acetonide | 18K16-B05-367959 | 5 |
| Fagron | Triamcinolone acetonide | 18K16-B06-357775 | 1 |
| Fagron | Triamcinolone acetonide | 19J11-F02 | 3 |
| Fagron | Triamcinolone acetonide | 19J11-F02-367958 | 1 |
| Fagron | Triamcinolone acetonide | 19J11-F02367961 | 1 |
| Fagron | Triamcinolone acetonide | 19J11-F02-367961 | 2 |
| Fagron | Triamcinolone acetonide | 19J11-F02-367962 | 7 |
| Fagron | Triamcinolone acetonide | 19J11-F02-368619 | 1 |
| Fagron | Triamcinolone acetonide | 19J11-F02-367958 | 1 |
| Fagron | Triamcinolone acetonide | 19J-F02-367962 | 1 |
| Fagron | Triamcinolone acetonide | 20031302 | 1 |
| Fagron | Triamcinolone acetonide | 20828-F04-371546 | 1 |
| Fagron | Triamcinolone acetonide | 20B28-F04 | 6 |
| Fagron | Triamcinolone acetonide | 20B28-F04-0005 | 1 |
| Fagron | Triamcinolone acetonide | 20B28-F04-3715406 | 1 |
| Fagron | Triamcinolone acetonide | 20B28-F04-371541 | 7 |
| Fagron | Triamcinolone acetonide | 20B28-F04-371542 | 1 |
| Fagron | Triamcinolone acetonide | 20B28F04-371544 | 1 |
| Fagron | Triamcinolone acetonide | 20B28-F04-371544 | 1 |
| Fagron | Triamcinolone acetonide | 20b28-f04-371546 | 1 |
| Fagron | Triamcinolone acetonide | 20b28-F04-371546 | 1 |
| Fagron | Triamcinolone acetonide | 20B28-F04-371546 | 15 |
| Fagron | Triamcinolone acetonide | 20L18-F01 | 3 |
| Fagron | Triamcinolone acetonide | 20L-18-F01 | 1 |
| Fagron | Triamcinolone acetonide | 20l18-f01-376647 | 1 |
| Fagron | Triamcinolone acetonide | 20L18-F01-376647 | 7 |
| Fagron | Triamcinolone acetonide | 20L18-F01-376649 | 2 |
| Fagron | Triamcinolone acetonide | 20L18-F01-376650 | 9 |
| Fagron | Triamcinolone acetonide | 20L18-F01-376653 | 1 |
| Fagron | Triamcinolone acetonide | 20L18F01-376658 | 1 |
| Fagron | Triamcinolone acetonide | 20L18-F01-376658 | 3 |
| Fagron | Triamcinolone acetonide | 20L18F01376658 | 1 |
| Fagron | Triamcinolone acetonide | 21H04-B13-21363 | 1 |
| Fagron | Triamcinolone acetonide | 21H04-B13-213632 | 1 |
| Fagron | Triamcinolone acetonide | 21H04-B13-213633 | 3 |
| Fagron | Triamcinolone acetonide | 21H25-F03-379863 | 5 |
| Fagron | Triamcinolone acetonide | 21H25-F03-379867 | 7 |
| Fagron | Triamcinolone acetonide | 21H25-F03-379871 | 3 |
| Fagron | Triamcinolone acetonide | 21H25-F03-379874 | 17 |
| Fagron | Triamcinolone acetonide | 21H25-F03-379875 | 16 |
| Fagron | Triamcinolone acetonide | 21H25-F03-379871 | 1 |
| Fagron | Triamcinolone acetonide | 21J20-B03 | 2 |
| Fagron | Triamcinolone acetonide | 21j20-b03-217884 | 1 |
| Fagron | Triamcinolone acetonide | 21J20-B03-217884 | 8 |
| Fagron | Triamcinolone acetonide | 21J20-B03-218184 | 1 |
| Fagron | Triamcinolone acetonide | 21J20-Bo3-217884 | 1 |
| Fagron | Triamcinolone acetonide | 21J20-BO3-217884 | 1 |
| Fagron | Triamcinolone acetonide | 22A22-B01-218005 | 3 |
| Fagron | Triamcinolone acetonide | 22A22-B01-218005/NB3123M | 1 |
| Fagron | Triamcinolone acetonide | 22D15-B01-220144 | 3 |
| Fagron | Triamcinolone acetonide | 22D15-B01-222391 | 2 |
| Fagron | Triamcinolone acetonide | 23C28-B04-227509 | 1 |
| Fagron | Triamcinolone acetonide | 289027 | 1 |
| Fagron | Triamcinolone acetonide | 3212U-02516(NP) | 1 |
| Fagron | Triamcinolone acetonide | 355724 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triamcinolone acetonide | 411082-1-P | 1 |
| Fagron | Triamcinolone acetonide | 4111408 | 1 |
| Fagron | Triamcinolone acetonide | 5061205 | 1 |
| Fagron | Triamcinolone acetonide | 5061303 | 1 |
| Fagron | Triamcinolone acetonide | 5121302 | 1 |
| Fagron | Triamcinolone acetonide | 7041501 | 1 |
| Fagron | Triamcinolone acetonide | 9041305 | 1 |
| Fagron | Triamcinolone acetonide | B05-3480603 | 1 |
| Fagron | Triamcinolone acetonide | B05-3598607 | 1 |
| Fagron | Triamcinolone acetonide | B053679509 | 1 |
| Fagron | Triamcinolone acetonide | C22H25CIN209 | 1 |
| Fagron | Triamcinolone acetonide | F01_3766500 | 1 |
| Fagron | Triamcinolone acetonide | F01-3766407 | 1 |
| Fagron | Triamcinolone acetonide | F01-3766409 | 1 |
| Fagron | Triamcinolone acetonide | F01-3766507 | 1 |
| Fagron | Triamcinolone acetonide | F01-3766508 | 1 |
| Fagron | Triamcinolone acetonide | F01-376653 | 1 |
| Fagron | Triamcinolone acetonide | F02-3679508 | 1 |
| Fagron | Triamcinolone acetonide | F02-3679602 | 1 |
| Fagron | Triamcinolone acetonide | F03-3798603 | 1 |
| Fagron | Triamcinolone acetonide | F03-3798704 | 1 |
| Fagron | Triamcinolone acetonide | F04-3715401 | 1 |
| Fagron | Triamcinolone acetonide | F04-3715406 | 5 |
| Fagron | Triamcinolone acetonide | F08-3679508 | 1 |
| Fagron | Triamcinolone acetonide | FO1-3766507 | 1 |
| Fagron | Triamcinolone acetonide | NA0087M | 3 |
| Fagron | Triamcinolone acetonide | NA3552M | 6 |
| Fagron | Triamcinolone acetonide | NB0601M | 4 |
| Fagron | Triamcinolone acetonide | NBO601M | 2 |
| Fagron | Triamcinolone acetonide | NS0571M | 5 |
| Fagron | Triamcinolone acetonide | NS0996M | 2 |
| Fagron | Triamcinolone acetonide | NS2236M | 1 |
| Fagron | Triamcinolone acetonide | NSO571M | 1 |
| Fagron | Triamcinolone acetonide | NT0487M | 1 |
| Fagron | Triamcinolone acetonide | NT0770M | 1 |
| Fagron | Triamcinolone acetonide | NT077oM | 1 |
| Fagron | Triamcinolone acetonide | NT1094M | 1 |
| Fagron | Triamcinolone acetonide | NT1430M | 3 |
| Fagron | Triamcinolone acetonide | NU0930M | 1 |
| Fagron | Triamcinolone acetonide | NVO262M | 1 |
| Fagron | Triamcinolone acetonide | Nw0635M | 1 |
| Fagron | Triamcinolone acetonide | NW2261M | 2 |
| Fagron | Triamcinolone acetonide | NW2518M | 1 |
| Fagron | Triamcinolone acetonide | NX0241M | 1 |
| Fagron | Triamcinolone acetonide | NX1540M | 2 |
| Fagron | Triamcinolone acetonide | ny0485m | 1 |
| Fagron | Triamcinolone acetonide | NY0485M | 5 |
| Fagron | Triamcinolone acetonide | NY1271M | 6 |
| Fagron | Triamcinolone acetonide | NY2097M | 3 |
| Fargon / AHD | Triamcinolone acetonide | 18C15-B05-350263 | 1 |
| Fargon/Alliance HC | Triamcinolone acetonide | 15B02-B03-303830 | 1 |
| Fargon/Gehe | Triamcinolone acetonide | 16D14-B11 | 1 |
| Fargon/Phoenix | Triamcinolone acetonide | 18K16-B05-359871 | 1 |
| fargon | Triamcinolone acetonide | 13C13-N20 | 1 |
| Fargon | Triamcinolone acetonide | 15C19-B06-308572 | 2 |
| Fargon | Triamcinolone acetonide | 15C19-B06-308573 | 1 |
| Fargon | Triamcinolone acetonide | Nu2526M | 1 |
| Fargron | Triamcinolone acetonide | 13/26-N11 | 1 |
| Farmabios / Gehe | Triamcinolone acetonide | 15233905 | 1 |
| Farmabios S.p.A. IT | Triamcinolone acetonide | 18100213 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Farmabios S.p.A./Cae... | Triamcinolone acetonide | 15233901 | 1 |
| Fiebig | Triamcinolone acetonide | 15C19-B06-308571 | 1 |
| Fiebig | Triamcinolone acetonide | 16B04-B07-318957 | 1 |
| Fiebig | Triamcinolone acetonide | 17057902 | 1 |
| Fiebig | Triamcinolone acetonide | 1805001-02 | 1 |
| Fiebig | Triamcinolone acetonide | 20000461004 | 1 |
| Fiebig | Triamcinolone acetonide | 22000902018 | 1 |
| fiebig | Triamcinolone acetonide | 23002673005 | 1 |
| Finteler Apotheke | Triamcinolone acetonide | 17057910 | 1 |
| fragon/phonix | Triamcinolone acetonide | 18K16-B05-357636 | 1 |
| Fragon | Triamcinolone acetonide | 21H25-F03-379867 | 1 |
| Fragron/ Alliance | Triamcinolone acetonide | 20L-18-F01-376658 | 1 |
| Gehe amax | Triamcinolone acetonide | 17C09-B01-340174 | 1 |
| Gehe amax | Triamcinolone acetonide | 1801020-01 | 1 |
| Gehe amax | Triamcinolone acetonide | 1903015-01 | 1 |
| Gehe Apo-ident | Triamcinolone acetonide | 201200601 | 1 |
| Gehe Berlin | Triamcinolone acetonide | 23003235001 | 1 |
| Gehe Rostock | Triamcinolone acetonide | 19120211 | 1 |
| Gehe Rostock | Triamcinolone acetonide | 21000116019 | 1 |
| Gehe Rostock | Triamcinolone acetonide | 2100016019 | 1 |
| Gehe/EuRo | Triamcinolone acetonide | 1605010-01 | 1 |
| Gehe/EuRo | Triamcinolone acetonide | 1801020-01 | 1 |
| Gehe/EuRoh | Triamcinolone acetonide | 2006002-01 | 1 |
| Gehe/Fragon | Triamcinolone acetonide | 16D14-B11-325479 | 1 |
| Gehe/Phönix | Triamcinolone acetonide | 1209040-02 | 1 |
| Gehe | Triamcinolone acetonide | 12301510 | 2 |
| Gehe | Triamcinolone acetonide | 12E15-N03 | 1 |
| Gehe | Triamcinolone acetonide | 13124805 | 1 |
| Gehe | Triamcinolone acetonide | 13E15-N03 | 1 |
| Gehe | Triamcinolone acetonide | 13I26-N11 | 1 |
| Gehe | Triamcinolone acetonide | 1504007-01 | 1 |
| Gehe | Triamcinolone acetonide | 1508008-02 | 1 |
| Gehe | Triamcinolone acetonide | 15430102 | 2 |
| Gehe | Triamcinolone acetonide | 15B02-B03-303827 | 1 |
| GEHE | Triamcinolone acetonide | 1605010-01 | 1 |
| Gehe | Triamcinolone acetonide | 160800501 | 1 |
| Gehe | Triamcinolone acetonide | 1608005-01 | 1 |
| Gehe | Triamcinolone acetonide | 16094501 | 1 |
| Gehe | Triamcinolone acetonide | 1612014-01 | 1 |
| GEHE | Triamcinolone acetonide | 16K07-B06-332103 | 1 |
| Gehe | Triamcinolone acetonide | 1703037 | 1 |
| Gehe | Triamcinolone acetonide | 17057906 | 1 |
| Gehe | Triamcinolone acetonide | 17057908 | 2 |
| Gehe | Triamcinolone acetonide | 170601301 | 1 |
| Gehe | Triamcinolone acetonide | 1706013-01 | 2 |
| GEHE | Triamcinolone acetonide | 1706013-01 | 1 |
| Gehe | Triamcinolone acetonide | 1710002-01 | 1 |
| GEHE | Triamcinolone acetonide | 1710002-01 | 1 |
| Gehe | Triamcinolone acetonide | 17120606 | 2 |
| Gehe | Triamcinolone acetonide | 17120610 | 1 |
| GEHE | Triamcinolone acetonide | 17358303 | 1 |
| Gehe | Triamcinolone acetonide | 1801020-01 | 1 |
| Gehe | Triamcinolone acetonide | 1805001-01 | 1 |
| Gehe | Triamcinolone acetonide | 1805001-02 | 1 |
| Gehe | Triamcinolone acetonide | 1810015-01 | 2 |
| GEHE | Triamcinolone acetonide | 1810015-01 | 1 |
| Gehe | Triamcinolone acetonide | 18100203 | 1 |
| Gehe | Triamcinolone acetonide | 18100206 | 1 |
| GEHE | Triamcinolone acetonide | 18100206 | 1 |
| Gehe | Triamcinolone acetonide | 18100208 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Triamcinolone acetonide | 18100222 | 1 |
| GEHE | Triamcinolone acetonide | 18100225 | 2 |
| Gehe | Triamcinolone acetonide | 18C15-B05 | 1 |
| Gehe | Triamcinolone acetonide | 18K16-B05-367959 | 1 |
| Gehe | Triamcinolone acetonide | 1903015-01 | 3 |
| Gehe | Triamcinolone acetonide | 1903018-01 | 1 |
| Gehe | Triamcinolone acetonide | 19J11-F02 | 1 |
| Gehe | Triamcinolone acetonide | 20000461003 | 1 |
| Gehe | Triamcinolone acetonide | 20000461004 | 1 |
| Gehe | Triamcinolone acetonide | 2001017-01 | 1 |
| Gehe | Triamcinolone acetonide | 2012006-01 | 1 |
| Gehe | Triamcinolone acetonide | 20B28F04371542 | 1 |
| Gehe | Triamcinolone acetonide | 21000116001 | 2 |
| Gehe | Triamcinolone acetonide | 21000116005 | 1 |
| Gehe | Triamcinolone acetonide | 21000116008 | 3 |
| Gehe | Triamcinolone acetonide | 21000116014 | 1 |
| Gehe | Triamcinolone acetonide | 2109004-03 | 1 |
| Gehe | Triamcinolone acetonide | 21H25-F03-379875 | 1 |
| Gehe | Triamcinolone acetonide | 22000902005 | 1 |
| GEHE | Triamcinolone acetonide | 22000902012 | 1 |
| Gehe | Triamcinolone acetonide | 22000902016 | 1 |
| Gehe | Triamcinolone acetonide | 22000902018 | 1 |
| gehe | Triamcinolone acetonide | 22000902019 | 1 |
| Gehe | Triamcinolone acetonide | 22000902019 | 1 |
| gehe | Triamcinolone acetonide | 2200902019 | 1 |
| Gehe | Triamcinolone acetonide | 2208004-01 | 3 |
| GEHE | Triamcinolone acetonide | 2208004-02 | 1 |
| Gehe | Triamcinolone acetonide | 22A22-B01-218005 | 3 |
| Gehe | Triamcinolone acetonide | 230032235004 | 1 |
| Gehe | Triamcinolone acetonide | 23003235001 | 1 |
| Gehe | Triamcinolone acetonide | 23003235004 | 1 |
| Gehe | Triamcinolone acetonide | 2308018-01 | 1 |
| Gehe | Triamcinolone acetonide | 6702020010 | 1 |
| Gehe | Triamcinolone acetonide | 700124-0007 | 1 |
| Geibo/ Fargron | Triamcinolone acetonide | 16D14-B11-322158 | 1 |
| Geilenkirchen | Triamcinolone acetonide | 18K16-B05-357775 | 1 |
| Geilenkirchen | Triamcinolone acetonide | 20000461007 | 1 |
| Geilenkirchen | Triamcinolone acetonide | 21000116008 | 1 |
| Hirsch | Triamcinolone acetonide | 12I10-N09 | 2 |
| Holdermann | Triamcinolone acetonide | 2308018-03 | 2 |
| Jenne | Triamcinolone acetonide | 1805001-01 | 2 |
| Jenne | Triamcinolone acetonide | 18C15-B05-347275 | 1 |
| Jenne | Triamcinolone acetonide | 2012006-01 | 1 |
| Jenne | Triamcinolone acetonide | 21000116001 | 1 |
| Jenne | Triamcinolone acetonide | 21003093001 | 2 |
| Jenne | Triamcinolone acetonide | 2109004-01 | 2 |
| Jenne | Triamcinolone acetonide | 22000902019 | 2 |
| Jenne | Triamcinolone acetonide | 2208004-01 | 1 |
| Jenne | Triamcinolone acetonide | 23002073005 | 1 |
| Kehr | Triamcinolone acetonide | 1057902 | 1 |
| Kehr | Triamcinolone acetonide | 21003093005 | 1 |
| Kehr | Triamcinolone acetonide | 22000902005 | 1 |
| Kehr | Triamcinolone acetonide | 22000902019 | 1 |
| Kehr | Triamcinolone acetonide | 2200902014 | 1 |
| Kehr | Triamcinolone acetonide | 22A22-B01-218005 | 1 |
| Kehr | Triamcinolone acetonide | 23003235002 | 1 |
| Kehr | Triamcinolone acetonide | 23003235009 | 1 |
| Kehr-Holdermann | Triamcinolone acetonide | | 1 |
| Klenk | Triamcinolone acetonide | 1504007-02 | 1 |
| Klenk | Triamcinolone acetonide | NS1680M | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Krieger | Triamcinolone acetonide | 22000902019 | 1 |
| L10 Gehe | Triamcinolone acetonide | 22000902016 | 1 |
| Lamotte | Triamcinolone acetonide | 19120207 | 1 |
| Martinus-Apotheke | Triamcinolone acetonide | 13379905 | 1 |
| Midas Göttingen | Triamcinolone acetonide | 16094504 | 1 |
| Midas | Triamcinolone acetonide | 16094511 | 1 |
| Midas | Triamcinolone acetonide | 17H03-B12-343457 | 1 |
| new Chem | Triamcinolone acetonide | 22A22-B01-218005 | 1 |
| Newchem / Gehe | Triamcinolone acetonide | 18F14-B01-355979 | 1 |
| Newchem / Gehe | Triamcinolone acetonide | 191202005 | 1 |
| Newchem / Gehe | Triamcinolone acetonide | B05-3598701 | 1 |
| Newchem / Gehe | Triamcinolone acetonide | NV2998M | 1 |
| NEWCHEM / Sanacorp | Triamcinolone acetonide | 15040007-01 | 1 |
| Newchem S. p. A. / Noweda | Triamcinolone acetonide | 17120608 | 1 |
| Newchem S.P.A. / Noweda | Triamcinolone acetonide | 2002047-01 | 1 |
| Newchem S.p.A./Caesa... | Triamcinolone acetonide | 1543015 | 1 |
| NEWCHEM S.P.A. | Triamcinolone acetonide | NV0994M | 1 |
| Newchem S.P.A/Allian... | Triamcinolone acetonide | 2006032-01 | 1 |
| Newchem S.P.A | Triamcinolone acetonide | 1508008-02 | 1 |
| Newchem Spa (site) | Triamcinolone acetonide | 16K07-B06-332102 | 1 |
| Newchem Spa | Triamcinolone acetonide | 191202006 | 1 |
| Newchem Spa | Triamcinolone acetonide | 19J11-F02-367962 | 1 |
| Newchem/ Jenne | Triamcinolone acetonide | 18F14-B01-356853 | 1 |
| Newchem/ Noweda | Triamcinolone acetonide | 1403009-01 | 1 |
| Newchem/AHD | Triamcinolone acetonide | 1407044-02 | 1 |
| Newchem/Fiebig | Triamcinolone acetonide | 1605010-01 | 1 |
| Newchem/Kehr | Triamcinolone acetonide | 1407044-01 | 1 |
| Newchem/Noweda | Triamcinolone acetonide | 15C19-B06-308573 | 1 |
| Newchem/Noweda | Triamcinolone acetonide | NA3551M | 1 |
| Newchem/Noweda | Triamcinolone acetonide | NZ0071M | 2 |
| Newchem/Noweda | Triamcinolone acetonide | NZ3279M | 1 |
| Newchem/Phönix | Triamcinolone acetonide | 1810015-01 | 1 |
| Newchem | Triamcinolone acetonide | 1303001-02 | 1 |
| Neweda | Triamcinolone acetonide | 23003235004 | 1 |
| Noveda | Triamcinolone acetonide | 12301518 | 1 |
| Noweda/ NEWCHEM | Triamcinolone acetonide | 1211013-02 | 1 |
| Noweda/Fargon | Triamcinolone acetonide | 18K16-B05-359868 | 1 |
| Noweda | Triamcinolone acetonide | 1112023-02 | 1 |
| Noweda | Triamcinolone acetonide | 12301501 | 1 |
| Noweda | Triamcinolone acetonide | 12301509 | 1 |
| Noweda | Triamcinolone acetonide | 12E15-N03 | 1 |
| noweda | Triamcinolone acetonide | 13256604 | 1 |
| Noweda | Triamcinolone acetonide | 13K15-B31-289029 | 1 |
| Noweda | Triamcinolone acetonide | 1407044-01 | 1 |
| Noweda | Triamcinolone acetonide | 14355103 | 1 |
| Noweda | Triamcinolone acetonide | 14355708 | 1 |
| Noweda | Triamcinolone acetonide | 15233902 | 1 |
| Noweda | Triamcinolone acetonide | 15233903 | 1 |
| Noweda | Triamcinolone acetonide | 1605010-01 | 1 |
| Noweda | Triamcinolone acetonide | 1608005-01 | 1 |
| Noweda | Triamcinolone acetonide | 16092504 | 2 |
| Noweda | Triamcinolone acetonide | 16094514 | 1 |
| Noweda | Triamcinolone acetonide | 1703037-01 | 2 |
| Noweda | Triamcinolone acetonide | 17057905 | 2 |
| Noweda | Triamcinolone acetonide | 17057908 | 1 |
| Noweda | Triamcinolone acetonide | 1706013-01 | 1 |
| Noweda | Triamcinolone acetonide | 17120603 | 1 |
| Noweda | Triamcinolone acetonide | 17120606 | 2 |
| Noweda | Triamcinolone acetonide | 17120611 | 1 |
| Noweda | Triamcinolone acetonide | 17358305 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Triamcinolone acetonide | 17H03-B12-343457 | 1 |
| Noweda | Triamcinolone acetonide | 1805001-01 | 1 |
| Noweda | Triamcinolone acetonide | 181000226 | 1 |
| Noweda | Triamcinolone acetonide | 1810015-01 | 2 |
| Noweda | Triamcinolone acetonide | 18100210 | 2 |
| Noweda | Triamcinolone acetonide | 18100213 | 1 |
| Noweda | Triamcinolone acetonide | 18100221 | 1 |
| Noweda | Triamcinolone acetonide | 18100222 | 2 |
| Noweda | Triamcinolone acetonide | 18K16B05359867 | 1 |
| Noweda | Triamcinolone acetonide | 1903015-01 | 1 |
| Noweda | Triamcinolone acetonide | 1907044-01 | 1 |
| Noweda | Triamcinolone acetonide | 191202005 | 1 |
| Noweda | Triamcinolone acetonide | 19120211 | 1 |
| Noweda | Triamcinolone acetonide | 2006002-01 | 1 |
| Noweda | Triamcinolone acetonide | 2006032-01 | 1 |
| Noweda | Triamcinolone acetonide | 2012006-01 | 1 |
| Noweda | Triamcinolone acetonide | 21000116014 | 1 |
| Noweda | Triamcinolone acetonide | 21000116022 | 1 |
| Noweda | Triamcinolone acetonide | 21003093001 | 1 |
| Noweda | Triamcinolone acetonide | 2109004-02 | 1 |
| Noweda | Triamcinolone acetonide | 21H25-F03-379863 | 1 |
| Noweda | Triamcinolone acetonide | 22000902002 | 1 |
| Noweda | Triamcinolone acetonide | 22000902009 | 1 |
| Noweda | Triamcinolone acetonide | 22000902010 | 2 |
| Noweda | Triamcinolone acetonide | 22000902019 | 1 |
| Noweda | Triamcinolone acetonide | 2200902018 | 1 |
| Noweda | Triamcinolone acetonide | 2208004-01 | 6 |
| Noweda | Triamcinolone acetonide | 22D15-B01-220144 | 1 |
| Noweda | Triamcinolone acetonide | 23002073005 | 2 |
| Noweda | Triamcinolone acetonide | 23003235004 | 1 |
| Noweda | Triamcinolone acetonide | 23003235011 | 1 |
| Noweda | Triamcinolone acetonide | 2308018-01 | 2 |
| Noweda | Triamcinolone acetonide | 23080185_03 | 1 |
| Noweda | Triamcinolone acetonide | 23C28-B04-227509 | 1 |
| Noweda | Triamcinolone acetonide | 2410004-01 | 1 |
| Noweda | Triamcinolone acetonide | 702022005 | 1 |
| Noweda | Triamcinolone acetonide | F04-3715401 | 1 |
| Noweda | Triamcinolone acetonide | FO4-3715401 | 1 |
| Noweda | Triamcinolone acetonide | NZ1748M | 1 |
| Oberlinden Apotheke | Triamcinolone acetonide | B0544/114010 | 1 |
| Oberlinden- Apotheke | Triamcinolone acetonide | U0544/113530 | 1 |
| Oberlinden-Apotheke | Triamcinolone acetonide | U0544/1 | 1 |
| Parthe Apotheke | Triamcinolone acetonide | 55/21 | 1 |
| Pharmachem/Phönix | Triamcinolone acetonide | 1907044-01 | 1 |
| Phoenix /Eu Rho | Triamcinolone acetonide | 2006002-01 | 1 |
| Phoenix 07.03.2017 11,62EUR | Triamcinolone acetonide | 16D14-B11-325480 | 1 |
| Phoenix 12.03.2019 11,43EUR | Triamcinolone acetonide | 18F14-B01-352630 | 1 |
| Phoenix WE 16.03.17 ... | Triamcinolone acetonide | 1612014-01 | 1 |
| Phoenix | Triamcinolone acetonide | 13126-N11 | 2 |
| Phoenix | Triamcinolone acetonide | 14355708 | 1 |
| Phoenix | Triamcinolone acetonide | 14355709 | 1 |
| Phoenix | Triamcinolone acetonide | 1703037 | 1 |
| Phoenix | Triamcinolone acetonide | 1703037-01 | 1 |
| Phoenix | Triamcinolone acetonide | 1706013-01 | 2 |
| Phoenix | Triamcinolone acetonide | 17120603 | 2 |
| Phoenix | Triamcinolone acetonide | 1805001-01 | 1 |
| Phoenix | Triamcinolone acetonide | 18100221 | 1 |
| Phoenix | Triamcinolone acetonide | 2006032-01 | 2 |
| Phoenix | Triamcinolone acetonide | 2012006-01 | 1 |
| Phoenix | Triamcinolone acetonide | 2012006-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Triamcinolone acetonide | 2109004-01 | 1 |
| Phoenix | Triamcinolone acetonide | 2109004-02 | 1 |
| Phoenix | Triamcinolone acetonide | 21H25-F03_379875 | 1 |
| Phoenix | Triamcinolone acetonide | 22000902005 | 1 |
| Phoenix | Triamcinolone acetonide | 22000902008 | 1 |
| Phoenix | Triamcinolone acetonide | 22000902018 | 1 |
| Phoenix | Triamcinolone acetonide | 22000902019 | 2 |
| Phoenix | Triamcinolone acetonide | 23003235004 | 1 |
| Phoenix | Triamcinolone acetonide | 2308018-01 | 3 |
| Phoenix | Triamcinolone acetonide | 2308018-02 | 1 |
| Phoenix | Triamcinolone acetonide | 3064 | 1 |
| Phoenix | Triamcinolone acetonide | 3129 | 1 |
| Phoenix | Triamcinolone acetonide | 3219 | 1 |
| Phoenix | Triamcinolone acetonide | 3424 | 1 |
| Phoenix_25.01.2019 | Triamcinolone acetonide | 1810015-01 | 2 |
| phoenix-06.11.18 | Triamcinolone acetonide | 1801020-01 | 1 |
| Phönix Gotha | Triamcinolone acetonide | 14355711 | 1 |
| Phönix Gotha | Triamcinolone acetonide | 17120610 | 1 |
| Phönix Gotha | Triamcinolone acetonide | 191202005 | 1 |
| Phönix W.E: 16.04.20... | Triamcinolone acetonide | 1710002-01 | 1 |
| Phönix/Apo-Ident | Triamcinolone acetonide | 6702021007 | 1 |
| Phönix/Caesar&Lorenz... | Triamcinolone acetonide | 21003093001 | 1 |
| Phönix | Triamcinolone acetonide | 12E15-N03 | 1 |
| Phönix | Triamcinolone acetonide | 13379902 | 1 |
| Phönix | Triamcinolone acetonide | 13E15-N03 | 1 |
| Phönix | Triamcinolone acetonide | 13K15-B31-289027 | 1 |
| Phönix | Triamcinolone acetonide | 1403009-01 | 1 |
| Phönix | Triamcinolone acetonide | 1407044-01 | 1 |
| phönix | Triamcinolone acetonide | 15233906 | 1 |
| phönix | Triamcinolone acetonide | 15430107 | 1 |
| phönix | Triamcinolone acetonide | 1605010-01 | 1 |
| Phönix | Triamcinolone acetonide | 1608005-01 | 1 |
| Phönix | Triamcinolone acetonide | 17057908 | 2 |
| Phönix | Triamcinolone acetonide | 1706013-01 | 1 |
| Phönix | Triamcinolone acetonide | 1801020-01 | 1 |
| Phönix | Triamcinolone acetonide | 1805001-02 | 1 |
| Phönix | Triamcinolone acetonide | 1810015-01 | 2 |
| Phönix | Triamcinolone acetonide | 18100204 | 1 |
| Phönix | Triamcinolone acetonide | 18F14-B01-032343 | 1 |
| Phönix | Triamcinolone acetonide | 18K16-B05-359871 | 2 |
| Phönix | Triamcinolone acetonide | 18K16-B05-361521 | 1 |
| Phönix | Triamcinolone acetonide | 1903015 | 1 |
| Phönix | Triamcinolone acetonide | 1907044-01 | 1 |
| Phönix | Triamcinolone acetonide | 19120207 | 1 |
| Phönix | Triamcinolone acetonide | 19120209 | 1 |
| Phönix | Triamcinolone acetonide | 19120210 | 3 |
| PHÖNIX | Triamcinolone acetonide | 19120210 | 1 |
| Phönix | Triamcinolone acetonide | 19120211 | 2 |
| Phönix | Triamcinolone acetonide | 20000461003 | 1 |
| Phönix | Triamcinolone acetonide | 20002630001 | 1 |
| Phönix | Triamcinolone acetonide | 20002630005 | 2 |
| Phönix | Triamcinolone acetonide | 2001017-01 | 1 |
| Phönix | Triamcinolone acetonide | 2006002-01 | 2 |
| Phönix | Triamcinolone acetonide | 200850209 | 2 |
| PHÖNIX | Triamcinolone acetonide | 21000116008 | 1 |
| Phönix | Triamcinolone acetonide | 21000116011 | 1 |
| Phönix | Triamcinolone acetonide | 220000902008 | 1 |
| Phönix | Triamcinolone acetonide | 220004-01 | 1 |
| Phönix | Triamcinolone acetonide | 22000902001 | 1 |
| Phönix | Triamcinolone acetonide | 22000902008 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Triamcinolone acetonide | 22000902010 | 2 |
| Phönix | Triamcinolone acetonide | 22000902012 | 1 |
| Phönix | Triamcinolone acetonide | 22000902018 | 8 |
| Phönix | Triamcinolone acetonide | 22000902019 | 1 |
| Phönix | Triamcinolone acetonide | 2200902018 | 1 |
| Phönix | Triamcinolone acetonide | 2208004-002 | 1 |
| Phönix | Triamcinolone acetonide | 2208004-01 | 6 |
| Phönix | Triamcinolone acetonide | 23002073005 | 5 |
| Phönix | Triamcinolone acetonide | 23003235004 | 2 |
| Phönix | Triamcinolone acetonide | TAC7 | 1 |
| Raben-Apotheke Mildenau | Triamcinolone acetonide | 13E15-N03 | 2 |
| Röntgen | Triamcinolone acetonide | 1903015-01 | 1 |
| Sa / EuRho | Triamcinolone acetonide | 2012006-01 | 1 |
| Sanacorp | Triamcinolone acetonide | | 1 |
| Sanacorp | Triamcinolone acetonide | 100/AKD4 | 1 |
| Sanacorp | Triamcinolone acetonide | 12301506 | 1 |
| Sanacorp | Triamcinolone acetonide | 13124807 | 2 |
| Sanacorp | Triamcinolone acetonide | 1326N11 | 1 |
| Sanacorp | Triamcinolone acetonide | 13379905 | 1 |
| Sanacorp | Triamcinolone acetonide | 13E15-N03 | 1 |
| sanacorp | Triamcinolone acetonide | 15233902 | 1 |
| Sanacorp | Triamcinolone acetonide | 15430108 | 1 |
| Sanacorp | Triamcinolone acetonide | 1710002-01 | 1 |
| Sanacorp | Triamcinolone acetonide | 17120605 | 1 |
| Sanacorp | Triamcinolone acetonide | 17120610 | 1 |
| Sanacorp | Triamcinolone acetonide | 17358302 | 1 |
| Sanacorp | Triamcinolone acetonide | 17358305 | 1 |
| Sanacorp | Triamcinolone acetonide | 17H03-B12-345553 | 1 |
| Sanacorp | Triamcinolone acetonide | 18100220 | 1 |
| Sanacorp | Triamcinolone acetonide | 18100221 | 3 |
| Sanacorp | Triamcinolone acetonide | 18fB01355724 | 1 |
| Sanacorp | Triamcinolone acetonide | 18K16-B05-359867 | 1 |
| Sanacorp | Triamcinolone acetonide | 191202005 | 1 |
| Sanacorp | Triamcinolone acetonide | 19120208 | 3 |
| Sanacorp | Triamcinolone acetonide | 19120209 | 1 |
| Sanacorp | Triamcinolone acetonide | 2006002-01 | 1 |
| Sanacorp | Triamcinolone acetonide | 20B28-F04-371546 | 1 |
| Sanacorp | Triamcinolone acetonide | 20L18-F01 | 1 |
| Sanacorp | Triamcinolone acetonide | 20L18-F01-376658 | 1 |
| Sanacorp | Triamcinolone acetonide | 210001604 | 1 |
| Sanacorp | Triamcinolone acetonide | 2100309093004 | 1 |
| Sanacorp | Triamcinolone acetonide | 21003093013 | 1 |
| Sanacorp | Triamcinolone acetonide | 2109004-02 | 1 |
| Sanacorp | Triamcinolone acetonide | 21H25-F03-379874 | 1 |
| Sanacorp | Triamcinolone acetonide | 22000902002 | 1 |
| Sanacorp | Triamcinolone acetonide | 22000902012 | 1 |
| Sanacorp | Triamcinolone acetonide | 22000902018 | 1 |
| Sanacorp | Triamcinolone acetonide | 2208004-01 | 1 |
| Sanacorp | Triamcinolone acetonide | 2208004-02 | 1 |
| Sanacorp | Triamcinolone acetonide | 22A22-B01-218005 | 1 |
| Sanacorp | Triamcinolone acetonide | 22D15-B01-222391 | 1 |
| Sanacorp | Triamcinolone acetonide | 23003235004 | 1 |
| Sanacorp | Triamcinolone acetonide | 23003235009 | 1 |
| Sanacorp | Triamcinolone acetonide | 2308018-01 | 1 |
| Sanacorp | Triamcinolone acetonide | NY0485M | 2 |
| Schulzendorfer Apotheke | Triamcinolone acetonide | 2208004-02 | 1 |
| Sittig | Triamcinolone acetonide | 1508008-02 | 1 |
| Spangro 15.1.2014 | Triamcinolone acetonide | 1303001-02 | 1 |
| Spangro 27.03.18 | Triamcinolone acetonide | 17030337-01 | 1 |
| Spangropharm | Triamcinolone acetonide | 1209040-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Tiarnyao/Gehe | Triamcinolone acetonide | 2001017-01 | 1 |
| VDL | Triamcinolone acetonide | 13379903 | 1 |
| WE: 08.12.2015 | Triamcinolone acetonide | 14K14-B05-302887 | 1 |

- 250 832 spectra from 1666 *Apo-Ident* customers from a total of 51 271 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Triamcinolone acetonide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Triamcinolone acetonide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 722 | 0 | 157 604 |
| **Type B** | 0 | 1759 | 0 | 211 181 |
| **Type C** | 0 | 5993 | 61 | 250 832 |

The substance/substance group *Triamcinolone acetonide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1690 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.6589 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 98.9924 % (> 98.9428 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20765 | 20765 | 0.00 | 79.84 |
| 20910 | 21061 | 4.07 | 79.11 |
| 21061 | 21061 | 0.00 | 76.87 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21072 | 21061 | 4.09 | 78.96 |
| 21587 | 21587 | 0.00 | 79.34 |
| 21883 | 21883 | 0.00 | 76.38 |
| 21962 | 21587 | 14.41 | 80.42 |
| 22313 | 22313 | 0.00 | 76.13 |
| 22572 | 22572 | 0.00 | 80.21 |
| 22752 | 22752 | 0.00 | 73.81 |
| 25339 | 25339 | 0.00 | 157.77 |
| 25560 | 25560 | 0.00 | 77.92 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Triclosan** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20005-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Triclosan; Triclosanum

### Special notes

When selecting the *Triclosan* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Triclosan | 8 | 18 | 728 |

### Second-stage model

For differentiation of the substance/substance group *Triclosan* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Triclosan* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Oxytetracycline hydrochloride | 105.13 | – |
| ⋮ | ⋮ | ⋮ |
| Sodium citrate | >50 | 211.73 |
| Capsaicin | >50 | 281.74 |
| Methoxsalen | >50 | 320.88 |
| Quinine hydrochloride dihydrate | >50 | 412.92 |
| Levocarnitine | >50 | 425.17 |
| Heparin sodium | >50 | 457.68 |
| Oxybutynin hydrochloride | >50 | 458.63 |
| Prednicarbate | >50 | 536.78 |
| Pyridoxal-5-phosphate hydrate | >50 | 598.22 |
| Ciprofloxacin hydrochloride | >50 | 644.22 |
| Tetracaine | >50 | 833.67 |
| Alfatradiol | >50 | 850.01 |
| Cyproterone acetate | >50 | 948.29 |
| Amifampridine | >50 | 982.73 |
| Sucrose | >50 | 1028.05 |
| Norethisterone acetate | >50 | 1688.95 |
| Amitriptyline hydrochloride | >50 | 2047.99 |
| Valine | >50 | 2794.96 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Triclosan* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Triclosan*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Triclosan | 13391808 | 21509 | 60 | 20131211 |
| Caelo | Triclosan | 14121209 | 21591 | 45 | 20140718 |

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| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Triclosan | 1406032-01 | 21615 | 60 | 20140710 |
| Euro OTC | Triclosan | 1507041 | 21856 | 60 | 20150804* |
| Euro OTC | Triclosan | 1510045 | 22227 | 60 | 20150511* |
| Euro OTC | Triclosan | 1602003 | 22373 | 45 | 20160204* |
| Euro OTC | Triclosan | 1701032 | 22987 | 40 | 20170207* |
| Fagron | Triclosan | 17K02-B06-343548 | 23915 | 40 | 20180105 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 410 spectra of 8 reference samples from the substance/substance group *Triclosan*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.

- 157 916 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 800 spectra of 21 reference samples from the substance/substance group *Triclosan*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Triclosan | 160846 | 22453 | 60 |
| Caelo | Triclosan | 162808 | 22775 | 40 |
| Caelo | Triclosan | 171498 | 23315 | 40 |
| Caelo | Triclosan | 180814 | 24048 | 40 |
| Caelo | Triclosan | 182537 | 24387 | 40 |
| Caelo | Triclosan | 192709 | 25221 | 40 |
| Caelo | Triclosan | 23002009 | 27331 | 40 |
| Caelo | Triclosan | 25000677 | 27665 | 40 |

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*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Triclosan | 1607002 | 22674 | 40 |
| Euro OTC | Triclosan | 1705011 | 23425 | 40 |
| Euro OTC | Triclosan | 1708025 | 23699 | 40 |
| Euro OTC | Triclosan | 1801049 | 23964 | 40 |
| Euro OTC | Triclosan | 1901006 | 24466 | 40 |
| Euro OTC | Triclosan | 1912002 | 24927 | 40 |
| Euro OTC | Triclosan | 2001027 | 25097 | 40 |
| Euro OTC | Triclosan | 2101029 | 25578 | 40 |
| Euro OTC | Triclosan | 2206016 | 26217 | 40 |
| Fagron | Triclosan | 21B25-B02-203360 | 26284 | 40 |
| Caelo | Triclosan | 23002009 | 27331SI | 20 |
| Euro OTC | Triclosan | 2206016 | 26217SI | 20 |
| Fagron | Triclosan | 21B25-B02-203360 | 26284SI | 20 |

- 212 140 spectra from a total of 4269 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6942 spectra from 1372 *Apo-Ident* customers from 765 batches from the substance/substance group *Triclosan*.

- Among them are spectra of independent samples from 709 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Triclosan | | 1 |
| | Triclosan | /20/11/6107 | 1 |
| | Triclosan | 1901006-02 | 1 |
| | Triclosan | 20J30-B03-204648 | 1 |
| | Triclosan | 20J30-B03-204649 | 1 |
| | Triclosan | 210000427015 | 1 |
| | Triclosan | 21000427001 | 2 |
| | Triclosan | 21000427002 | 3 |
| | Triclosan | 21000427003 | 10 |
| | Triclosan | 21000427005 | 6 |
| | Triclosan | 21000427006 | 9 |
| | Triclosan | 21000427007 | 5 |
| | Triclosan | 21000427008 | 9 |
| | Triclosan | 21000427009 | 6 |
| | Triclosan | 21000427010 | 3 |
| | Triclosan | 21000427011 | 20 |
| | Triclosan | 21000427014 | 31 |
| | Triclosan | 21000427015 | 23 |
| | Triclosan | 2100042701511/24P | 1 |
| | Triclosan | 21000427016 | 6 |
| | Triclosan | 21000427017 | 18 |
| | Triclosan | 21000428009 | 5 |
| | Triclosan | 21000428015 | 3 |
| | Triclosan | 21000428016 | 1 |
| | Triclosan | 21000428017 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Triclosan | 21000428019 | 1 |
| | Triclosan | 21000428020 | 15 |
| | Triclosan | 21000428021 | 8 |
| | Triclosan | 21000428022 | 14 |
| | Triclosan | 2100042802272/23P | 1 |
| | Triclosan | 2100427011 | 1 |
| | Triclosan | 2100428022 | 1 |
| | Triclosan | 2101029-02 | 5 |
| | Triclosan | 2101029-04 | 6 |
| | Triclosan | 2101029-05 | 2 |
| | Triclosan | 21B25-B02-203359 | 2 |
| | Triclosan | 21B25-B02-203363 | 1 |
| | Triclosan | 21B25-B02-203393 | 1 |
| | Triclosan | 22006016-01 | 1 |
| | Triclosan | 2206016 | 1 |
| | Triclosan | 220601601 | 1 |
| | Triclosan | 2206016-01 | 20 |
| | Triclosan | 220601602 | 1 |
| | Triclosan | 2206016-02 | 15 |
| | Triclosan | 2206016-03 | 3 |
| | Triclosan | 22060616-02 | 1 |
| | Triclosan | 2208016-02 | 1 |
| | Triclosan | 23002009001 | 34 |
| | Triclosan | 23002009003 | 35 |
| | Triclosan | 23002009005 | 16 |
| | Triclosan | 23002009006 | 4 |
| | Triclosan | 23002009009 | 1 |
| | Triclosan | 23002009010 | 10 |
| | Triclosan | 2300200901030/25P | 1 |
| | Triclosan | 23002009013 | 6 |
| | Triclosan | 23002009014 | 5 |
| | Triclosan | 241219(23002009005) | 1 |
| | Triclosan | 72071176107 | 1 |
| 18253716 | Triclosan | | 1 |
| 30.01.2019 Phoenix | Triclosan | 18081415 | 1 |
| 73681 Indien / Gehe | Triclosan | 1912002-01 | 1 |
| 73681 Indien / Gehe | Triclosan | 1912002-03 | 1 |
| A.H.D. | Triclosan | 12L06-N01 | 1 |
| AEP | Triclosan | 18253722 | 1 |
| AEP | Triclosan | 2302009010 | 1 |
| agron/ Noweda | Triclosan | 13A11-N03 | 1 |
| AHC 02.09.13 EK9,04 | Triclosan | 13D02-N02 | 1 |
| AHD 17.01.15 | Triclosan | 13L18-B35-289992 | 1 |
| AHD Frankfurt | Triclosan | 23002009010 | 2 |
| AHD | Triclosan | 17081723 | 1 |
| AHD | Triclosan | 18081417 | 2 |
| AHD | Triclosan | 18253705 | 1 |
| AHD | Triclosan | 21000427006 | 1 |
| AHD | Triclosan | 21000427007 | 1 |
| AHD | Triclosan | 21000427008 | 1 |
| ahd | Triclosan | 21000427011 | 1 |
| ahd | Triclosan | 21000427014 | 1 |
| AHD | Triclosan | 21000427017 | 1 |
| AHD | Triclosan | 21000428021 | 1 |
| AHD | Triclosan | 21000428022 | 2 |
| AHD | Triclosan | 2206016-02 | 1 |
| AHD | Triclosan | 23002009003 | 1 |
| AHD | Triclosan | 23002009013 | 1 |
| AHL | Triclosan | 1801049-01 | 2 |
| ALH | Triclosan | 1607002-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alli | Triclosan | 21000427015 | 1 |
| Alliance healfcare | Triclosan | 17149821 | 1 |
| Alliance Health 26.1... | Triclosan | 13L18-B35-289995 | 1 |
| Alliance Healthcare/... | Triclosan | 13H09-N01 | 1 |
| Alliance Healthcare | Triclosan | 12G09-N09 | 1 |
| Alliance Healthcare | Triclosan | 12L06-N01 | 1 |
| Alliance Healthcare | Triclosan | 13D02-N02 | 1 |
| Alliance Healthcare | Triclosan | 13L-18-835 | 1 |
| Alliance Healthcare | Triclosan | 16084608 | 1 |
| Alliance Healthcare | Triclosan | 21000427015 | 1 |
| Alliance/EuRho | Triclosan | 1912002-03 | 3 |
| Alliance | Triclosan | 1912002-003 | 1 |
| Alliance | Triclosan | 192709018 | 1 |
| Alliance | Triclosan | 21000427008 | 1 |
| Alliance | Triclosan | 21000427011 | 1 |
| Alliance | Triclosan | 21000428005 | 1 |
| alliance | Triclosan | 21000428022 | 2 |
| Alliance | Triclosan | 2101029-02 | 1 |
| Alliance | Triclosan | 220601602 | 1 |
| Alliance | Triclosan | 23002009003 | 2 |
| Allianz | Triclosan | 1801049-01 | 1 |
| anzag 20.11.2013 | Triclosan | 12359114 | 1 |
| Anzag 4.12.12 ek:8,89 | Triclosan | 12G17-N04 | 1 |
| Anzag | Triclosan | 12G09-N09 | 2 |
| Anzag | Triclosan | 12G17-N04 | 3 |
| Anzag | Triclosan | 13L18-B35-289995 | 1 |
| Anzag | Triclosan | 1607002-01 | 2 |
| Anzag | Triclosan | 1701032-02 | 1 |
| Anzag | Triclosan | 192709004 | 2 |
| Anzag | Triclosan | 192709015 | 1 |
| Anzag | Triclosan | 192709022 | 1 |
| Anzag | Triclosan | 21000427017 | 1 |
| Anzag | Triclosan | 2100427015 | 1 |
| Anzag | Triclosan | 240118(21000427015) | 1 |
| Anzag | Triclosan | 5846205 | 1 |
| Anzag06. | Triclosan | 14F23-B02-295758 | 1 |
| apo-ident/sana | Triclosan | 2101029-01 | 1 |
| apo-ident | Triclosan | | 1 |
| apo-ident | Triclosan | 1708025-01 | 1 |
| apo-ident | Triclosan | 2101029-01 | 1 |
| apomix | Triclosan | 14F23-B02-295760 | 1 |
| apomix | Triclosan | 17149813 | 1 |
| Audor Pharma | Triclosan | | 2 |
| BASF Chem trade GmbH... | Triclosan | 5846205 | 1 |
| BASF Grenzach GmbH/Phönix | Triclosan | 10006226 | 1 |
| BASF Grenzach GmbH/Phönix | Triclosan | 13A11-N03 | 1 |
| BASF Grenzach GmbH/Phönix | Triclosan | 13A11-No3 | 1 |
| BASF Grenzach GmbH/Phönix | Triclosan | 13D02-N02 | 1 |
| BASF Grenzach GmbH/Phönix | Triclosan | 13H09-N01 | 1 |
| BASF Grenzach/Noweda | Triclosan | 5900346 | 1 |
| BASF | Triclosan | 1505009-01 | 1 |
| BASF | Triclosan | 1708025-01 | 1 |
| BASF | Triclosan | 4486611 | 2 |
| Beiersdorf | Triclosan | 14F23-B02-295764 | 1 |
| Bionorica/Phönix | Triclosan | 1708025-01 | 1 |
| Bombastus | Triclosan | 12359111 | 1 |
| Bombastus | Triclosan | 12L06-N01 | 2 |
| Bombastus | Triclosan | 13L18-35-289984 | 1 |
| Bombastus | Triclosan | 1408024-01 | 1 |
| Bombastus | Triclosan | 14f23-b02-300219 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Triclosan | 15203603 | 2 |
| Bombastus | Triclosan | 17081726 | 1 |
| Bombastus | Triclosan | 17149809 | 1 |
| Cael | Triclosan | 182537002 | 1 |
| Caeleo/ Kehr | Triclosan | 192709025 | 1 |
| Caelo | Triclosan | | 5 |
| Caelo | Triclosan | 10206240 | 1 |
| Caelo | Triclosan | 108144416 | 1 |
| Caelo | Triclosan | 11076716 | 1 |
| Caelo | Triclosan | 11076717 | 2 |
| Caelo | Triclosan | 11238003 | 2 |
| Caelo | Triclosan | 11238004 | 1 |
| Caelo | Triclosan | 11238009 | 2 |
| Caelo | Triclosan | 11238011 | 1 |
| Caelo | Triclosan | 1125204 | 1 |
| Caelo | Triclosan | 1149806 | 1 |
| Caelo | Triclosan | 11777748 | 3 |
| Caelo | Triclosan | 12003201 | 3 |
| Caelo | Triclosan | 12003202 | 1 |
| Caelo | Triclosan | 12003205 | 7 |
| Caelo | Triclosan | 12003210 | 5 |
| Caelo | Triclosan | 12145901 | 6 |
| Caelo | Triclosan | 12145902 | 5 |
| Caelo | Triclosan | 12145906 | 6 |
| Caelo | Triclosan | 12145907 | 9 |
| Caelo | Triclosan | 12145908 | 7 |
| Caelo | Triclosan | 12145909 | 11 |
| Caelo | Triclosan | 12145910 | 11 |
| Caelo | Triclosan | 12145917 | 1 |
| Caelo | Triclosan | 12276827 | 1 |
| Caelo | Triclosan | 12359104 | 6 |
| Caelo | Triclosan | 12359105 | 7 |
| Caelo | Triclosan | 12359106 | 11 |
| Caelo | Triclosan | 12359107 | 1 |
| Caelo | Triclosan | 12359108 | 13 |
| Caelo | Triclosan | 12359109 | 3 |
| Caelo | Triclosan | 12359110 | 5 |
| Caelo | Triclosan | 12359111 | 7 |
| Caelo | Triclosan | 12359112 | 8 |
| Caelo | Triclosan | 12359114 | 1 |
| Caelo | Triclosan | 12537002 | 1 |
| Caelo | Triclosan | 12680801 | 1 |
| Caelo | Triclosan | 1280801 | 1 |
| Caelo | Triclosan | 12c21-n05 | 1 |
| Caelo | Triclosan | 12G17-N04 | 2 |
| Caelo | Triclosan | 12l06-n01 | 1 |
| Caelo | Triclosan | 12L06-N01 | 2 |
| Caelo | Triclosan | 12L06-N01/0005900346 | 1 |
| Caelo | Triclosan | 13247805 | 1 |
| Caelo | Triclosan | 13247903 | 1 |
| Caelo | Triclosan | 13247904 | 11 |
| Caelo | Triclosan | 13247905 | 10 |
| Caelo | Triclosan | 13247908 | 2 |
| Caelo | Triclosan | 13391801 | 2 |
| Caelo | Triclosan | 13391802 | 4 |
| Caelo | Triclosan | 13391804 | 10 |
| Caelo | Triclosan | 13391807 | 3 |
| Caelo | Triclosan | 13391808 | 9 |
| Caelo | Triclosan | 13A11-N03 | 2 |
| Caelo | Triclosan | 13D02-N02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triclosan | 13D02-No2 | 1 |
| Caelo | Triclosan | 13H08-N10 | 2 |
| Caelo | Triclosan | 13H09-N01 | 7 |
| Caelo | Triclosan | 13L18-B35-289984 | 1 |
| Caelo | Triclosan | 13L18B35289986 | 1 |
| Caelo | Triclosan | 13L18-B35-289987 | 1 |
| Caelo | Triclosan | 13L18-B35-289992 | 2 |
| Caelo | Triclosan | 13L18B35289993 | 1 |
| Caelo | Triclosan | 13L18-B35-289995 | 1 |
| Caelo | Triclosan | 14052101 | 5 |
| Caelo | Triclosan | 14052102 | 11 |
| Caelo | Triclosan | 14052103 | 14 |
| Caelo | Triclosan | 14052105 | 1 |
| Caelo | Triclosan | 1412109 | 1 |
| Caelo | Triclosan | 14121203 | 10 |
| Caelo | Triclosan | 14121204 | 9 |
| Caelo | Triclosan | 14121207 | 10 |
| Caelo | Triclosan | 14121209 | 6 |
| Caelo | Triclosan | 14121210 | 11 |
| Caelo | Triclosan | 14121211 | 10 |
| Caelo | Triclosan | 14121214 | 13 |
| Caelo | Triclosan | 14121215 | 16 |
| Caelo | Triclosan | 14121220 | 1 |
| Caelo | Triclosan | 1418E-03402 | 1 |
| Caelo | Triclosan | 14205901 | 7 |
| Caelo | Triclosan | 14205902 | 9 |
| Caelo | Triclosan | 14205903 | 15 |
| Caelo | Triclosan | 14205904 | 6 |
| Caelo | Triclosan | 14205905 | 6 |
| Caelo | Triclosan | 14211207 | 1 |
| Caelo | Triclosan | 14211211 | 1 |
| Caelo | Triclosan | 14F23-B02 | 1 |
| Caelo | Triclosan | 14F23B02293859 | 1 |
| Caelo | Triclosan | 14F23-B02-295758 | 1 |
| Caelo | Triclosan | 14F23-B02-295760 | 1 |
| Caelo | Triclosan | 14F23-B02-295765 | 1 |
| Caelo | Triclosan | 150103201 | 1 |
| Caelo | Triclosan | 1501032-02 | 1 |
| Caelo | Triclosan | 1503603 | 1 |
| Caelo | Triclosan | 1505009 | 1 |
| Caelo | Triclosan | 150704101 | 1 |
| Caelo | Triclosan | 1507041-01 | 2 |
| Caelo | Triclosan | 15121202 | 1 |
| Caelo | Triclosan | 15203603 | 16 |
| Caelo | Triclosan | 15203604 | 14 |
| Caelo | Triclosan | 15203606 | 7 |
| Caelo | Triclosan | 15203607 | 17 |
| Caelo | Triclosan | 15203608 | 11 |
| Caelo | Triclosan | 1520603 | 1 |
| Caelo | Triclosan | 1530105 | 1 |
| Caelo | Triclosan | 15301501 | 1 |
| Caelo | Triclosan | 15301502 | 13 |
| Caelo | Triclosan | 15301503 | 12 |
| Caelo | Triclosan | 15301504 | 12 |
| Caelo | Triclosan | 15301505 | 12 |
| Caelo | Triclosan | 15301506 | 16 |
| Caelo | Triclosan | 15301510 | 2 |
| Caelo | Triclosan | 15301511 | 9 |
| Caelo | Triclosan | 15301512 | 6 |
| Caelo | Triclosan | 15301513 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triclosan | 15301514 | 1 |
| Caelo | Triclosan | 15c10-b06 | 1 |
| Caelo | Triclosan | 15C10-B06-310031 | 3 |
| Caelo | Triclosan | 15C10-B06-310031 | 1 |
| Caelo | Triclosan | 15C10-B06-311161 | 1 |
| Caelo | Triclosan | 15C10-B06-312981 | 3 |
| Caelo | Triclosan | 15C10-B06-312982 | 3 |
| Caelo | Triclosan | 15G07-B03-30039 | 1 |
| Caelo | Triclosan | 15G07-B03-310035 | 1 |
| Caelo | Triclosan | 15G07-B03-310035/201 | 1 |
| Caelo | Triclosan | 15G07-B03-310037 | 2 |
| Caelo | Triclosan | 15G07-B03-310038 | 2 |
| Caelo | Triclosan | 15G07-B03-310040 | 1 |
| Caelo | Triclosan | 160084601 | 1 |
| Caelo | Triclosan | 1602003-01 | 2 |
| Caelo | Triclosan | 16021306 | 1 |
| Caelo | Triclosan | 160280811 | 1 |
| Caelo | Triclosan | 16064616 | 1 |
| Caelo | Triclosan | 1607002-01 | 2 |
| Caelo | Triclosan | 16071801 | 1 |
| Caelo | Triclosan | 160846 | 1 |
| Caelo | Triclosan | 16084601 | 7 |
| Caelo | Triclosan | 160846018 | 1 |
| Caelo | Triclosan | 16084602 | 10 |
| Caelo | Triclosan | 16084603 | 15 |
| Caelo | Triclosan | 16084606 | 6 |
| Caelo | Triclosan | 16084607 | 11 |
| Caelo | Triclosan | 16084608 | 17 |
| Caelo | Triclosan | 16084609 | 3 |
| Caelo | Triclosan | 16084610 | 11 |
| Caelo | Triclosan | 16084611 | 17 |
| Caelo | Triclosan | 16084614 | 20 |
| Caelo | Triclosan | 16084617 | 1 |
| Caelo | Triclosan | 16084618 | 16 |
| Caelo | Triclosan | 16084620 | 1 |
| Caelo | Triclosan | 16084621 | 1 |
| Caelo | Triclosan | 16084622 | 1 |
| Caelo | Triclosan | 1609005 | 1 |
| Caelo | Triclosan | 1609005-01 | 2 |
| Caelo | Triclosan | 1609005-02 | 2 |
| Caelo | Triclosan | 1620809 | 1 |
| Caelo | Triclosan | 16253716 | 1 |
| Caelo | Triclosan | 162808 | 1 |
| Caelo | Triclosan | 16280801 | 28 |
| Caelo | Triclosan | 16280802 | 23 |
| Caelo | Triclosan | 16280802-30417/1 | 1 |
| Caelo | Triclosan | 16280803 | 5 |
| Caelo | Triclosan | 16280805 | 2 |
| Caelo | Triclosan | 16280808 | 21 |
| Caelo | Triclosan | 16280809 | 8 |
| Caelo | Triclosan | 16280810 | 1 |
| Caelo | Triclosan | 16280811 | 19 |
| Caelo | Triclosan | 16280816 | 17 |
| Caelo | Triclosan | 16280817 | 17 |
| Caelo | Triclosan | 16280818 | 7 |
| Caelo | Triclosan | 16280819 | 7 |
| Caelo | Triclosan | 1628082 | 1 |
| Caelo | Triclosan | 16280820 | 13 |
| Caelo | Triclosan | 16280821 | 2 |
| Caelo | Triclosan | 16280824 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triclosan | 16280874 | 1 |
| Caelo | Triclosan | 162820817 | 1 |
| Caelo | Triclosan | 16293901 | 1 |
| Caelo | Triclosan | 1701032 | 1 |
| Caelo | Triclosan | 1701032-01 | 3 |
| Caelo | Triclosan | 170501101 | 2 |
| Caelo | Triclosan | 1705011-01 | 5 |
| Caelo | Triclosan | 170802-01 | 1 |
| Caelo | Triclosan | 170802501 | 1 |
| Caelo | Triclosan | 1708025-01 | 4 |
| Caelo | Triclosan | 170817 | 1 |
| Caelo | Triclosan | 17081702 | 1 |
| Caelo | Triclosan | 17081703 | 11 |
| Caelo | Triclosan | 17081704 | 1 |
| Caelo | Triclosan | 17081705 | 13 |
| Caelo | Triclosan | 17081706 | 4 |
| Caelo | Triclosan | 17081707 | 29 |
| Caelo | Triclosan | 170817075274 | 1 |
| Caelo | Triclosan | 17081709 | 20 |
| Caelo | Triclosan | 17081710 | 19 |
| Caelo | Triclosan | 17081711 | 17 |
| Caelo | Triclosan | 17081712 | 19 |
| Caelo | Triclosan | 17081713 | 9 |
| Caelo | Triclosan | 17081714 | 12 |
| Caelo | Triclosan | 17081716 | 17 |
| Caelo | Triclosan | 17081716-T20180112Ma | 1 |
| Caelo | Triclosan | 17081717 | 8 |
| Caelo | Triclosan | 17081720 | 31 |
| Caelo | Triclosan | 17081721 | 24 |
| Caelo | Triclosan | 17081722 | 30 |
| Caelo | Triclosan | 17081723 | 10 |
| Caelo | Triclosan | 17081724 | 23 |
| Caelo | Triclosan | 17081725 | 19 |
| Caelo | Triclosan | 17081726 | 16 |
| Caelo | Triclosan | 170817265507 | 1 |
| Caelo | Triclosan | 1708173 | 1 |
| Caelo | Triclosan | 170919Di | 1 |
| Caelo | Triclosan | 1710025 | 2 |
| Caelo | Triclosan | 171449809 | 1 |
| Caelo | Triclosan | 1714819 | 1 |
| Caelo | Triclosan | 17148927 | 1 |
| Caelo | Triclosan | 1714926 | 1 |
| Caelo | Triclosan | 1714930 | 1 |
| Caelo | Triclosan | 17149621 | 1 |
| Caelo | Triclosan | 171498 | 1 |
| Caelo | Triclosan | 17149801 | 5 |
| Caelo | Triclosan | 17149805 | 10 |
| Caelo | Triclosan | 17149806 | 13 |
| Caelo | Triclosan | 17149807 | 17 |
| Caelo | Triclosan | 17149808 | 40 |
| Caelo | Triclosan | 171498085598 | 1 |
| Caelo | Triclosan | 17149809 | 51 |
| Caelo | Triclosan | 17149810P-190531-3 | 1 |
| Caelo | Triclosan | 17149812 | 16 |
| Caelo | Triclosan | 17149812-20180619Ma4 | 1 |
| Caelo | Triclosan | 17149813 | 19 |
| Caelo | Triclosan | 17149813-T20181115Ma | 1 |
| Caelo | Triclosan | 17149814 | 23 |
| Caelo | Triclosan | 17149815 | 14 |
| Caelo | Triclosan | 17149817 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triclosan | 17149818 | 1 |
| Caelo | Triclosan | 17149819 | 32 |
| Caelo | Triclosan | 17149820 | 20 |
| Caelo | Triclosan | 17149821 | 39 |
| Caelo | Triclosan | 17149822 | 15 |
| Caelo | Triclosan | 17149824 | 9 |
| Caelo | Triclosan | 17149825 | 26 |
| Caelo | Triclosan | 17149826 | 1 |
| Caelo | Triclosan | 17149827 | 22 |
| Caelo | Triclosan | 171499808 | 1 |
| Caelo | Triclosan | 171499815 | 1 |
| Caelo | Triclosan | 171549805 | 1 |
| Caelo | Triclosan | 1719809 | 1 |
| Caelo | Triclosan | 1719814 | 1 |
| Caelo | Triclosan | 1748912 | 1 |
| Caelo | Triclosan | 1749825 | 1 |
| Caelo | Triclosan | 17801712 | 1 |
| Caelo | Triclosan | 1781720 | 1 |
| Caelo | Triclosan | 17K02-B06_343544 | 2 |
| Caelo | Triclosan | 17K02-B06-343543 | 1 |
| Caelo | Triclosan | 180081408 | 1 |
| Caelo | Triclosan | 1801417 | 1 |
| Caelo | Triclosan | 18061407 | 1 |
| Caelo | Triclosan | 180811401 | 1 |
| Caelo | Triclosan | 18081401 | 8 |
| Caelo | Triclosan | 18081402 | 21 |
| Caelo | Triclosan | 18081403 | 15 |
| Caelo | Triclosan | 18081405 | 43 |
| Caelo | Triclosan | 18081406 | 33 |
| Caelo | Triclosan | 18081407 | 37 |
| Caelo | Triclosan | 18081408 | 55 |
| Caelo | Triclosan | 18081409 | 1 |
| Caelo | Triclosan | 18081410 | 14 |
| Caelo | Triclosan | 18081411 | 1 |
| Caelo | Triclosan | 18081413 | 39 |
| Caelo | Triclosan | 18081414 | 30 |
| Caelo | Triclosan | 18081415 | 42 |
| Caelo | Triclosan | 18081416 | 37 |
| Caelo | Triclosan | 18081417 | 50 |
| Caelo | Triclosan | 1808414 | 1 |
| Caelo | Triclosan | 18243726 | 1 |
| Caelo | Triclosan | 18253/06 | 1 |
| Caelo | Triclosan | 18253078 | 1 |
| Caelo | Triclosan | 182533722 | 1 |
| Caelo | Triclosan | 182537001 | 63 |
| Caelo | Triclosan | 182537002 | 52 |
| Caelo | Triclosan | 18253701 | 6 |
| Caelo | Triclosan | 18253702 | 12 |
| Caelo | Triclosan | 18253703 | 3 |
| Caelo | Triclosan | 18253705 | 50 |
| Caelo | Triclosan | 182537052 | 1 |
| Caelo | Triclosan | 18253706 | 44 |
| Caelo | Triclosan | 18253707 | 38 |
| Caelo | Triclosan | 18253708 | 40 |
| Caelo | Triclosan | 18253709 | 34 |
| Caelo | Triclosan | 18253710 | 11 |
| Caelo | Triclosan | 18253711 | 30 |
| Caelo | Triclosan | 18253712 | 28 |
| Caelo | Triclosan | 18253713P-200116-1 | 1 |
| Caelo | Triclosan | 18253714 | 11 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triclosan | 18253715 | 3 |
| Caelo | Triclosan | 18253716 | 60 |
| Caelo | Triclosan | 18253717 | 19 |
| Caelo | Triclosan | 18253718 | 21 |
| Caelo | Triclosan | 18253721 | 28 |
| Caelo | Triclosan | 18253722 | 35 |
| Caelo | Triclosan | 18253724 | 6 |
| Caelo | Triclosan | 182537247 | 1 |
| Caelo | Triclosan | 18253726 | 19 |
| Caelo | Triclosan | 18253729 | 1 |
| Caelo | Triclosan | 18253731 | 2 |
| Caelo | Triclosan | 1825717 | 1 |
| Caelo | Triclosan | 182597001 | 1 |
| Caelo | Triclosan | 185237002 | 1 |
| Caelo | Triclosan | 18523716 | 1 |
| Caelo | Triclosan | 1852537001 | 1 |
| Caelo | Triclosan | 185253711 | 1 |
| Caelo | Triclosan | 1901006-01 | 1 |
| Caelo | Triclosan | 1901006-02 | 1 |
| Caelo | Triclosan | 1901006-03 | 1 |
| Caelo | Triclosan | 190709021 | 1 |
| Caelo | Triclosan | 1912002-01 | 3 |
| Caelo | Triclosan | 1912002-03 | 3 |
| Caelo | Triclosan | 192109015 | 1 |
| Caelo | Triclosan | 1922709021 | 1 |
| Caelo | Triclosan | 1927009013 | 1 |
| Caelo | Triclosan | 192708022 | 1 |
| Caelo | Triclosan | 192709002 | 25 |
| Caelo | Triclosan | 192709003 | 10 |
| Caelo | Triclosan | 192709004 | 22 |
| Caelo | Triclosan | 192709006 | 1 |
| Caelo | Triclosan | 192709007 | 13 |
| Caelo | Triclosan | 192709008 | 1 |
| Caelo | Triclosan | 192709009 | 8 |
| Caelo | Triclosan | 192709010 | 16 |
| Caelo | Triclosan | 192709011 | 30 |
| Caelo | Triclosan | 192709012 | 32 |
| Caelo | Triclosan | 192709013 | 20 |
| Caelo | Triclosan | 192709014 | 35 |
| Caelo | Triclosan | 192709014/4720 | 1 |
| Caelo | Triclosan | 192709015 | 32 |
| Caelo | Triclosan | 192709016 | 32 |
| Caelo | Triclosan | 192709018 | 8 |
| Caelo | Triclosan | 192709020 | 44 |
| Caelo | Triclosan | 192709021 | 49 |
| Caelo | Triclosan | 192709022 | 32 |
| Caelo | Triclosan | 192709023 | 11 |
| Caelo | Triclosan | 192709025 | 32 |
| Caelo | Triclosan | 19270913 | 1 |
| Caelo | Triclosan | 1927099021 | 1 |
| Caelo | Triclosan | 19709007 | 1 |
| Caelo | Triclosan | 2000428001 | 1 |
| Caelo | Triclosan | 20021304 | 1 |
| Caelo | Triclosan | 200701407 | 1 |
| Caelo | Triclosan | 200870409 | 1 |
| Caelo | Triclosan | 210000427007 | 1 |
| Caelo | Triclosan | 210000427017 | 1 |
| Caelo | Triclosan | 21000427 | 1 |
| Caelo | Triclosan | 21000427001 | 17 |
| Caelo | Triclosan | 21000427002 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Triclosan | 21000427003 | 2 |
| Caelo | Triclosan | 21000427005 | 5 |
| Caelo | Triclosan | 21000427006 | 2 |
| Caelo | Triclosan | 21000427007 | 14 |
| Caelo | Triclosan | 21000427008 | 1 |
| Caelo | Triclosan | 21000427009 | 1 |
| Caelo | Triclosan | 21000427011 | 3 |
| Caelo | Triclosan | 21000427015 | 2 |
| Caelo | Triclosan | 21000427017 | 2 |
| Caelo | Triclosan | 21000428001 | 34 |
| Caelo | Triclosan | 21000428002 | 1 |
| Caelo | Triclosan | 21000428003 | 23 |
| Caelo | Triclosan | 21000428004 | 23 |
| Caelo | Triclosan | 21000428005 | 7 |
| Caelo | Triclosan | 21000428008 | 26 |
| Caelo | Triclosan | 21000428009 | 21 |
| Caelo | Triclosan | 2100042801 | 1 |
| Caelo | Triclosan | 21000428010 | 24 |
| Caelo | Triclosan | 21000428011 | 16 |
| Caelo | Triclosan | 21000428012 | 20 |
| Caelo | Triclosan | 21000428013 | 7 |
| Caelo | Triclosan | 21000428015 | 19 |
| Caelo | Triclosan | 2100042801575/22P | 1 |
| Caelo | Triclosan | 21000428016 | 15 |
| Caelo | Triclosan | 21000428017 | 16 |
| Caelo | Triclosan | 21000428020 | 1 |
| Caelo | Triclosan | 21000428021 | 11 |
| Caelo | Triclosan | 2100042811 | 1 |
| Caelo | Triclosan | 2100042812 | 1 |
| Caelo | Triclosan | 21000828001 | 1 |
| Caelo | Triclosan | 2100427001 | 1 |
| Caelo | Triclosan | 2100428001 | 4 |
| Caelo | Triclosan | 2100428011 | 1 |
| Caelo | Triclosan | 228711-514 | 1 |
| Caelo | Triclosan | 23121409 | 1 |
| Caelo | Triclosan | 2317I-03402 | 1 |
| Caelo | Triclosan | 28011 | 1 |
| Caelo | Triclosan | 3041408 | 1 |
| Caelo | Triclosan | 39(192709020) | 1 |
| Caelo | Triclosan | 5012E-03402 | 1 |
| Caelo | Triclosan | 517E-03402 | 1 |
| Caelo | Triclosan | 5203607 | 1 |
| Caelo | Triclosan | 6121711 | 1 |
| Caelo | Triclosan | 8081401 | 1 |
| Caelo | Triclosan | 8253718 | 1 |
| Caelo | Triclosan | 87767 | 1 |
| Caelo | Triclosan | AKD12 | 1 |
| Caelo | Triclosan | bhfdd | 1 |
| Caelo | Triclosan | Caelo | 2 |
| Caeo/Noweda | Triclosan | 15301505 | 1 |
| Caeo/Sanacorp | Triclosan | 18081405 | 1 |
| Caeolo/Noweda | Triclosan | 13247905 | 1 |
| Caeolo/Phönix | Triclosan | 18081416 | 1 |
| Caeolo | Triclosan | 17149809 | 1 |
| Caesar & Lorenz GmbH | Triclosan | 192709016 | 1 |
| Caesar & Lorenz | Triclosan | 21000428020 | 1 |
| Caesar & Loretz GmbH… | Triclosan | 18253721 | 1 |
| Caesar & Loretz GmbH… | Triclosan | 21000428015 | 1 |
| Caesar & Loretz GmbH… | Triclosan | 18081413 | 2 |
| Caesar & Loretz GmbH… | Triclosan | 18081414 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Triclosan | 182537001 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253708 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253717 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000427002 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000427011 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 192709015 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 17149813 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18081416 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000427001 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 18253705 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709013 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709022 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428015 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000428016 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253730 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18081417 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253709 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 18253710 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253707 | 1 |
| Caesar & Loretz GmbH/ AHD | Triclosan | 18081416 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 182537002 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 192709016 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000428008 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709022 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 192709020 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000427003 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709022 | 1 |
| Caesar & Loretz GmbH/AHD | Triclosan | 192709011 | 1 |
| Caesar & Loretz GmbH/AHD | Triclosan | 21000427011 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709020 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 18081408 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709025 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18081417 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709016 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709021 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428011 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 18253708 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 192709012 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 192709013 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 192709014 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 192709016 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 192709021 | 2 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 192709025 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 21000427002 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 21000428010 | 1 |
| Caesar & Loretz GmbH/Gehe | Triclosan | 21000428011 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 18253707 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709002 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709009 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709012 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709022 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428001 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428009 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428010 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428011 | 1 |
| Caesar & Loretz GmbH... | Triclosan | AP210406-01 | 1 |
| Caesar & Loretz GmbH/Kehr | Triclosan | 18253707 | 1 |
| Caesar & Loretz GmbH/Kehr | Triclosan | 18253712 | 1 |
| Caesar & Loretz GmbH/Kehr | Triclosan | 18253721 | 1 |
| Caesar & Loretz GmbH/Kehr | Triclosan | 192709014 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Kehr | Triclosan | 21000427002 | 1 |
| Caesar & Loretz GmbH/Kehr | Triclosan | 21000428003 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18081413 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253721 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253708 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18081407 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 182537002 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253711 | 3 |
| Caesar & Loretz GmbH... | Triclosan | 192709003 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709018 | 4 |
| Caesar & Loretz GmbH... | Triclosan | 192709020 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000428004 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428015 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000428017 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000427007 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000428003 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428010 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253718 | 4 |
| Caesar & Loretz GmbH... | Triclosan | 18253712 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 182537002 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 18253706 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253711 | 4 |
| Caesar & Loretz GmbH... | Triclosan | 18253714 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253722 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709016 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709021 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709025 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000427001 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428001 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000428003 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428005 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428011 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253711 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 18253721 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 18253722 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709011 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709013 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 192709021 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 192709021 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428009 | 3 |
| Caesar & Loretz GmbH... | Triclosan | 21000428012 | 2 |
| Caesar & Loretz GmbH... | Triclosan | 21000428015 | 1 |
| Caesar & Loretz GmbH... | Triclosan | 21000428017 | 1 |
| Caesar & Loretz GmbH | Triclosan | 15081416 | 1 |
| Caesar & Loretz GmbH | Triclosan | 1609005-01 | 1 |
| Caesar & Loretz GmbH | Triclosan | 16280811 | 1 |
| Caesar & Loretz GmbH | Triclosan | 17149806 | 1 |
| Caesar & Loretz GmbH | Triclosan | 17149813 | 1 |
| Caesar & Loretz GmbH | Triclosan | 17149821 | 1 |
| Caesar & Loretz GmbH | Triclosan | 18081403 | 1 |
| Caesar & Loretz GmbH | Triclosan | 18081410 | 1 |
| Caesar & Loretz GmbH | Triclosan | 18081413 | 1 |
| Caesar & Loretz GmbH | Triclosan | 18081414 | 1 |
| Caesar & Loretz GmbH | Triclosan | 18081416 | 4 |
| Caesar & Loretz GmbH | Triclosan | 18081417 | 4 |
| Caesar & Loretz GmbH | Triclosan | 182537001 | 13 |
| Caesar & Loretz GmbH | Triclosan | 182537002 | 9 |
| Caesar & Loretz GmbH | Triclosan | 18253702 | 2 |
| Caesar & Loretz GmbH | Triclosan | 18253705 | 7 |
| Caesar & Loretz GmbH | Triclosan | 18253706 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Triclosan | 18253707 | 5 |
| Caesar & Loretz GmbH | Triclosan | 18253708 | 7 |
| Caesar & Loretz GmbH | Triclosan | 18253709 | 9 |
| Caesar & Loretz GmbH | Triclosan | 18253710 | 3 |
| Caesar & Loretz GmbH | Triclosan | 18253711 | 3 |
| Caesar & Loretz GmbH | Triclosan | 18253712 | 4 |
| Caesar & Loretz GmbH | Triclosan | 18253714 | 2 |
| Caesar & Loretz GmbH | Triclosan | 18253716 | 17 |
| Caesar & Loretz GmbH | Triclosan | 18253717 | 4 |
| Caesar & Loretz GmbH | Triclosan | 18253718 | 9 |
| Caesar & Loretz GmbH | Triclosan | 18253721 | 7 |
| Caesar & Loretz GmbH | Triclosan | 18253722 | 2 |
| Caesar & Loretz GmbH | Triclosan | 18253724 | 2 |
| Caesar & Loretz GmbH | Triclosan | 18253726 | 6 |
| Caesar & Loretz GmbH | Triclosan | 190100602 | 1 |
| Caesar & Loretz GmbH | Triclosan | 1912002-01 | 1 |
| Caesar & Loretz GmbH | Triclosan | 1912002-04 | 1 |
| Caesar & Loretz GmbH | Triclosan | 192709002 | 7 |
| Caesar & Loretz GmbH | Triclosan | 192709003 | 1 |
| Caesar & Loretz GmbH | Triclosan | 192709004 | 3 |
| Caesar & Loretz GmbH | Triclosan | 192709009 | 1 |
| Caesar & Loretz GmbH | Triclosan | 192709010 | 2 |
| Caesar & Loretz GmbH | Triclosan | 192709011 | 7 |
| Caesar & Loretz GmbH | Triclosan | 192709012 | 8 |
| Caesar & Loretz GmbH | Triclosan | 192709013 | 9 |
| Caesar & Loretz GmbH | Triclosan | 192709014 | 5 |
| Caesar & Loretz GmbH | Triclosan | 192709015 | 12 |
| Caesar & Loretz GmbH | Triclosan | 192709016 | 10 |
| Caesar & Loretz GmbH | Triclosan | 192709018 | 5 |
| Caesar & Loretz GmbH | Triclosan | 192709020 | 14 |
| Caesar & Loretz GmbH | Triclosan | 192709021 | 19 |
| Caesar & Loretz GmbH | Triclosan | 192709022 | 14 |
| Caesar & Loretz GmbH | Triclosan | 192709023 | 3 |
| Caesar & Loretz GmbH | Triclosan | 192709024 | 1 |
| Caesar & Loretz GmbH | Triclosan | 192709025 | 6 |
| Caesar & Loretz GmbH | Triclosan | 19279003 | 2 |
| Caesar & Loretz GmbH | Triclosan | 20003964012 | 1 |
| Caesar & Loretz GmbH | Triclosan | 2001027-01 | 1 |
| Caesar & Loretz GmbH | Triclosan | 21000427001 | 8 |
| Caesar & Loretz GmbH | Triclosan | 21000427002 | 1 |
| Caesar & Loretz GmbH | Triclosan | 21000427003 | 3 |
| Caesar & Loretz GmbH | Triclosan | 21000427005 | 1 |
| Caesar & Loretz GmbH | Triclosan | 21000427006 | 1 |
| Caesar & Loretz GmbH | Triclosan | 21000427007 | 4 |
| Caesar & Loretz GmbH | Triclosan | 21000427008 | 1 |
| Caesar & Loretz GmbH | Triclosan | 21000427011 | 3 |
| Caesar & Loretz GmbH | Triclosan | 21000428001 | 9 |
| Caesar & Loretz GmbH | Triclosan | 21000428003 | 8 |
| Caesar & Loretz GmbH | Triclosan | 21000428004 | 4 |
| Caesar & Loretz GmbH | Triclosan | 21000428005 | 1 |
| Caesar & Loretz GmbH | Triclosan | 21000428008 | 9 |
| Caesar & Loretz GmbH | Triclosan | 21000428009 | 7 |
| Caesar & Loretz GmbH | Triclosan | 21000428010 | 8 |
| Caesar & Loretz GmbH | Triclosan | 21000428011 | 18 |
| Caesar & Loretz GmbH | Triclosan | 21000428012 | 8 |
| Caesar & Loretz GmbH | Triclosan | 21000428013 | 5 |
| Caesar & Loretz GmbH | Triclosan | 21000428015 | 3 |
| Caesar & Loretz GmbH | Triclosan | 21000428016 | 6 |
| Caesar & Loretz GmbH | Triclosan | 21000428017 | 5 |
| Caesar & Loretz GmbH | Triclosan | 21000428018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Triclosan | 21000428020 | 3 |
| Caesar & Loretz GmbH | Triclosan | 21000428021 | 3 |
| Caesar & Loretz GmbH | Triclosan | AP210205-02 | 1 |
| Caesar & Loretz Hild... | Triclosan | 192709013 | 1 |
| Caesar & Loretz Hild... | Triclosan | 182537001 | 2 |
| Caesar & Loretz Hilden | Triclosan | 18081408 | 1 |
| Caesar & Loretz Hilden | Triclosan | 18081413 | 1 |
| Caesar & Loretz Hilden | Triclosan | 18081414 | 1 |
| Caesar & Loretz Hilden | Triclosan | 18081417 | 2 |
| Caesar & Loretz Hilden | Triclosan | 18253707 | 1 |
| Caesar & Loretz Hilden | Triclosan | 18253709 | 1 |
| Caesar & Loretz Hilden | Triclosan | 18253710 | 1 |
| Caesar & Loretz Hilden | Triclosan | 18253717 | 1 |
| Caesar & Loretz Hilden | Triclosan | 18253726 | 1 |
| Caesar & Loretz Hilden | Triclosan | 192709002 | 1 |
| Caesar & Loretz Hilden | Triclosan | 192709011 | 1 |
| Caesar & Loretz/ Noweda | Triclosan | 17149812 | 1 |
| Caesar & Loretz/AHD | Triclosan | 14121209 | 1 |
| Caesar & Loretz | Triclosan | 17081705 | 1 |
| Caesar / Ebert | Triclosan | 17081716 | 1 |
| Caesar / Gehe | Triclosan | 18253709 | 1 |
| Caesar Loretz | Triclosan | 18253706 | 1 |
| Caesar u Loretz | Triclosan | 15301503 | 1 |
| Caesar und Loretz GmbH | Triclosan | 17149808 | 1 |
| Caesar und Loretz | Triclosan | 15301502 | 1 |
| Caesar&Lorenz / Gehe | Triclosan | 18253716 | 1 |
| Caesar&Lorenz / Gehe | Triclosan | 18253722 | 1 |
| Caesar&Lorenz | Triclosan | 17081707 | 1 |
| Caesar&Lorenz | Triclosan | 21000428001 | 1 |
| Caesar&Lorenz | Triclosan | 21000428010 | 1 |
| Caesar&Loretz GmbH/ ... | Triclosan | 16084603 | 2 |
| Caesar&Loretz GmbH/S... | Triclosan | 15301505 | 1 |
| Caesar&Loretz GmbH | Triclosan | 16084609 | 1 |
| Caesar&Loretz GmbH | Triclosan | 16280808 | 1 |
| Caesar&Loretz GmbH | Triclosan | 192709002 | 1 |
| Caesar&Loretz GmbH | Triclosan | 192709025 | 1 |
| Caesar&Loretz,AHC,12... | Triclosan | 16084618 | 1 |
| Caesar&loretz,Phönix | Triclosan | 15203606 | 1 |
| caesar&loretz,Phönix | Triclosan | 15203607 | 1 |
| Caesar/Lorenz | Triclosan | 12145910 | 1 |
| Caesar/Lorenz | Triclosan | 12359104 | 1 |
| Caesar/Lorenz | Triclosan | 13247904 | 1 |
| Caleo/Phönix | Triclosan | 17081711 | 1 |
| Carlo/Phönix/23,50 | Triclosan | 1901006-01 | 1 |
| Cealo/AHD | Triclosan | 14F23-B02-295947 | 1 |
| Cealo/Anzag | Triclosan | 182537002 | 1 |
| Cealo/Gehe | Triclosan | 17149807 | 1 |
| Cealo/Phoenix | Triclosan | 192709015 | 1 |
| Cealo/Sanacorp | Triclosan | 192709025 | 1 |
| Cealo | Triclosan | 16280801 | 1 |
| Cealo | Triclosan | 17081723 | 1 |
| Cealo | Triclosan | 17149809 | 1 |
| Cealo | Triclosan | 18081403 | 1 |
| Cealo | Triclosan | 18081405 | 1 |
| Cealo | Triclosan | 18081416 | 1 |
| Cealo | Triclosan | 192709016 | 1 |
| Cealo | Triclosan | 21000428003 | 1 |
| Cealo | Triclosan | 71215/1Gie | 1 |
| Celo/Phonix | Triclosan | 16084611 | 1 |
| Crystal pharma/ Ober... | Triclosan | 15203603 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| DAC 2006 | Triclosan | 12003201 | 2 |
| Delta Apotheke | Triclosan | 17149822 | 1 |
| E Plus | Triclosan | 16280808 | 1 |
| E Plus | Triclosan | 17081705 | 1 |
| Easy Höchst | Triclosan | 17149822 | 1 |
| ebe a | Triclosan | 14121207 | 1 |
| Eigenproduktion | Triclosan | 13A11-N03 | 1 |
| EuRho / 30 | Triclosan | 1401038-01 | 1 |
| EuRho / fiebig | Triclosan | 1705011-01 | 1 |
| EuRho / Fiebig | Triclosan | 2001027 | 1 |
| EuRho /11 | Triclosan | 1912002-01 | 1 |
| EuRho Gehe | Triclosan | 1801049-01 | 1 |
| EuRho Pharma | Triclosan | 2206016-02 | 3 |
| EuRho/ Noweda | Triclosan | 1901006-02 | 4 |
| EuRho/ Phoenix | Triclosan | 2101029-01 | 1 |
| Eurho/A | Triclosan | 2101029-01 | 2 |
| eurho/AHC | Triclosan | 2001027-01 | 1 |
| EuRho/Gehe | Triclosan | 1912002-02 | 1 |
| EuRho/Gehe | Triclosan | 2001027-01 | 1 |
| EuRho/Noweda | Triclosan | 1708025-01 | 2 |
| EuRho/Noweda | Triclosan | 1901006-03 | 1 |
| EuRho/Noweda | Triclosan | 2101029-02 | 1 |
| EuRho/Noweda | Triclosan | 2101029-03 | 3 |
| euRho/Noweda | Triclosan | 2101029-04 | 2 |
| EuRho/Phoenix | Triclosan | 1401038-01 | 1 |
| EuRho/Phönix | Triclosan | 1307050-01 | 2 |
| EuRho/Phönix | Triclosan | 1912002-01 | 1 |
| EuRho/Phönix | Triclosan | 1912002-02 | 1 |
| Eurho/Phönix | Triclosan | 210102901 | 1 |
| Eurho/S | Triclosan | 2101029-02 | 1 |
| Eurho/Sanacorp | Triclosan | 2101029-01 | 1 |
| Eurho/Sanacorp | Triclosan | 2206016 | 1 |
| EuRho | Triclosan | 1107030-01 | 2 |
| EuRho | Triclosan | 1202018-01 | 1 |
| EuRho | Triclosan | 1206034-02 | 2 |
| EuRho | Triclosan | 1408024-01 | 1 |
| EuRho | Triclosan | 151004501 | 1 |
| EuRho | Triclosan | 1705011-01 | 1 |
| EuRho | Triclosan | 1708025-01 | 1 |
| EuRho | Triclosan | 1901006-01 | 1 |
| euRho | Triclosan | 190100602 | 1 |
| EuRho | Triclosan | 1901006-03 | 1 |
| EuRho | Triclosan | 1912002-01 | 3 |
| euRho | Triclosan | 1912002-02 | 1 |
| euRho | Triclosan | 191200204 | 1 |
| euRho | Triclosan | 2001027-01 | 1 |
| euRho | Triclosan | 2101029-01 | 1 |
| EuRho | Triclosan | 2101029-01 | 1 |
| Eurho | Triclosan | 2101029-02 | 1 |
| EuRho | Triclosan | 2101029-02 | 4 |
| EuRho | Triclosan | 2206016-01 | 1 |
| EuRho | Triclosan | k0011 | 1 |
| EuRhoNoweda | Triclosan | 1602003-01 | 1 |
| Euro OCT/Noweda | Triclosan | 1501032-02 | 1 |
| Euro OCT | Triclosan | 1912002-01 | 1 |
| Euro OTC | Triclosan | | 13 |
| Euro OTC | Triclosan | /19/07/3301 | 1 |
| Euro OTC | Triclosan | /20/11/6107 | 2 |
| Euro OTC | Triclosan | 1107030-01 | 3 |
| Euro OTC | Triclosan | 1202018-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Triclosan | 1202018-02 | 2 |
| Euro OTC | Triclosan | 120203-02 | 1 |
| Euro OTC | Triclosan | 1206034-01 | 1 |
| Euro OTC | Triclosan | 120603402 | 1 |
| Euro OTC | Triclosan | 1206034-02 | 3 |
| Euro OTC | Triclosan | 1211025-01 | 11 |
| Euro OTC | Triclosan | 12276023 | 2 |
| Euro OTC | Triclosan | 12276024 | 1 |
| Euro OTC | Triclosan | 12276027 | 3 |
| Euro OTC | Triclosan | 12276028 | 5 |
| Euro OTC | Triclosan | 1245 | 1 |
| Euro OTC | Triclosan | 130301101 | 1 |
| Euro OTC | Triclosan | 1303011-01 | 5 |
| Euro OTC | Triclosan | 1307050-01 | 6 |
| Euro OTC | Triclosan | 13247904 | 1 |
| Euro OTC | Triclosan | 13H08-N10 | 1 |
| Euro OTC | Triclosan | 140103801 | 1 |
| Euro OTC | Triclosan | 1401038-01 | 10 |
| Euro OTC | Triclosan | 140603201 | 1 |
| Euro OTC | Triclosan | 1406032-01 | 12 |
| Euro OTC | Triclosan | 1408024-01 | 6 |
| Euro OTC | Triclosan | 14121204 | 1 |
| Euro OTC | Triclosan | 14F23-B02-295948 | 1 |
| Euro OTC | Triclosan | 1501032-01 | 10 |
| Euro OTC | Triclosan | 1501032-02 | 4 |
| Euro OTC | Triclosan | 150500901 | 1 |
| Euro OTC | Triclosan | 1505009-01 | 12 |
| Euro OTC | Triclosan | 15058946 | 2 |
| Euro OTC | Triclosan | 1507041-01 | 7 |
| Euro OTC | Triclosan | 151004501 | 1 |
| Euro OTC | Triclosan | 1510045-01 | 19 |
| Euro OTC | Triclosan | 15150229 | 2 |
| Euro OTC | Triclosan | 15203606 | 2 |
| Euro OTC | Triclosan | 15203607 | 1 |
| Euro OTC | Triclosan | 1550229 | 1 |
| Euro OTC | Triclosan | 15C10-B06-312981 | 1 |
| Euro OTC | Triclosan | 15C10-B06-312982 | 1 |
| Euro OTC | Triclosan | 15G07-B03-310036 | 1 |
| Euro OTC | Triclosan | 15G07-B03-310040 | 1 |
| Euro OTC | Triclosan | 1602003 | 2 |
| Euro OTC | Triclosan | 160200301 | 1 |
| Euro OTC | Triclosan | 1602003-01 | 29 |
| Euro OTC | Triclosan | 16047002-01 | 1 |
| Euro OTC | Triclosan | 160531T | 1 |
| Euro OTC | Triclosan | 160700201 | 1 |
| Euro OTC | Triclosan | 1607002-01 | 34 |
| Euro OTC | Triclosan | 160702-01 | 1 |
| Euro OTC | Triclosan | 16084614 | 1 |
| Euro OTC | Triclosan | 160900-02 | 1 |
| Euro OTC | Triclosan | 16090005-02 | 1 |
| Euro OTC | Triclosan | 1609005-01 | 28 |
| Euro OTC | Triclosan | 160900502 | 1 |
| Euro OTC | Triclosan | 1609005-02 | 27 |
| Euro OTC | Triclosan | 16280820 | 1 |
| Euro OTC | Triclosan | 169005-02 | 1 |
| Euro OTC | Triclosan | 1701032 | 1 |
| Euro OTC | Triclosan | 1701032_01 | 1 |
| Euro OTC | Triclosan | 1701032-01 | 17 |
| Euro OTC | Triclosan | 170103202 | 1 |
| Euro OTC | Triclosan | 1701032-02 | 14 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Triclosan | 1701037-01 | 1 |
| Euro OTC | Triclosan | 170113T1609005-01 | 1 |
| Euro OTC | Triclosan | 170132-01 | 1 |
| Euro OTC | Triclosan | 170501101 | 2 |
| Euro OTC | Triclosan | 1705011-01 | 53 |
| Euro OTC | Triclosan | 170511-01 | 1 |
| Euro OTC | Triclosan | 170511-010012276028 | 1 |
| Euro OTC | Triclosan | 170526T/1701032-02 | 1 |
| Euro OTC | Triclosan | 17080-01 | 1 |
| Euro OTC | Triclosan | 1708025 | 1 |
| Euro OTC | Triclosan | 1708025_01 | 1 |
| Euro OTC | Triclosan | 170802501 | 2 |
| Euro OTC | Triclosan | 1708025-01 | 47 |
| Euro OTC | Triclosan | 1708025-01P-181001-3 | 1 |
| Euro OTC | Triclosan | 1708025-01P181129-4 | 1 |
| Euro OTC | Triclosan | 17081703 | 1 |
| Euro OTC | Triclosan | 17081722 | 1 |
| Euro OTC | Triclosan | 170825-01 | 1 |
| Euro OTC | Triclosan | 171121T/1705011-01 | 1 |
| Euro OTC | Triclosan | 17149806 | 1 |
| Euro OTC | Triclosan | 17149808 | 1 |
| Euro OTC | Triclosan | 17149812 | 1 |
| Euro OTC | Triclosan | 17149815 | 1 |
| Euro OTC | Triclosan | 1801049 | 1 |
| Euro OTC | Triclosan | 1801049-01 | 12 |
| Euro OTC | Triclosan | 1801049-21 | 1 |
| Euro OTC | Triclosan | 180149-01 | 1 |
| Euro OTC | Triclosan | 1805001-01 | 1 |
| Euro OTC | Triclosan | 18253706 | 2 |
| Euro OTC | Triclosan | 1901006 | 1 |
| Euro OTC | Triclosan | 1901006-002 | 1 |
| Euro OTC | Triclosan | 190100601 | 2 |
| Euro OTC | Triclosan | 1901006-01 | 58 |
| Euro OTC | Triclosan | 190100602 | 2 |
| Euro OTC | Triclosan | 1901006-02 | 34 |
| Euro OTC | Triclosan | 1901006-03 | 17 |
| Euro OTC | Triclosan | 1901006-1 | 3 |
| Euro OTC | Triclosan | 1901006-1P-190506-2 | 1 |
| Euro OTC | Triclosan | 191006-02 | 1 |
| Euro OTC | Triclosan | 19120002-02 | 1 |
| Euro OTC | Triclosan | 19120003 | 1 |
| Euro OTC | Triclosan | 1912001-01 | 1 |
| Euro OTC | Triclosan | 1912002 | 3 |
| Euro OTC | Triclosan | 1912002-001 | 1 |
| Euro OTC | Triclosan | 191200201 | 4 |
| Euro OTC | Triclosan | 1912002-01 | 45 |
| Euro OTC | Triclosan | 1912002-02 | 19 |
| Euro OTC | Triclosan | 191200203 | 2 |
| Euro OTC | Triclosan | 1912002-03 | 42 |
| Euro OTC | Triclosan | 1912002-04 | 21 |
| Euro OTC | Triclosan | 19122002-03 | 1 |
| Euro OTC | Triclosan | 20001027-01 | 1 |
| Euro OTC | Triclosan | 2001027-01 | 29 |
| Euro OTC | Triclosan | 2101025-01 | 1 |
| Euro OTC | Triclosan | 2101029 | 2 |
| Euro OTC | Triclosan | 210102901 | 1 |
| Euro OTC | Triclosan | 2101029-01 | 52 |
| Euro OTC | Triclosan | 2101029-02 | 21 |
| Euro OTC | Triclosan | 2101029-03 | 8 |
| Euro OTC | Triclosan | 21011029-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Triclosan | 220601601 | 1 |
| Euro OTC | Triclosan | 2206016-01 | 16 |
| Euro OTC | Triclosan | 2206016-02 | 3 |
| Euro OTC | Triclosan | 2206016-03 | 1 |
| Euro OTC | Triclosan | 220616-02 | 1 |
| Euro OTC | Triclosan | 226016-02 | 1 |
| Euro OTC | Triclosan | 3078439 | 1 |
| Euro OTC | Triclosan | 5860088 | 1 |
| Euro OTC | Triclosan | 700228 | 1 |
| Euro OTC | Triclosan | CHB1303011-01 | 1 |
| Euro OTC | Triclosan | K/00111809334 | 1 |
| Euro UTC | Triclosan | 1510045-01 | 1 |
| Euro/Anzag | Triclosan | 1607002-01 | 1 |
| Euro/Gehe | Triclosan | 1602003-01 | 1 |
| Euro/Noweda | Triclosan | 1607002-01 | 1 |
| Euro/Phoenix | Triclosan | 1912002-04 | 1 |
| Euro/Phönix | Triclosan | 160900502 | 1 |
| Euro/Phönix | Triclosan | 170103201 | 1 |
| Euro/Phönix | Triclosan | 1901006 | 2 |
| Euro/Phönix | Triclosan | 1912002-02 | 1 |
| Euro/Sanacorp | Triclosan | 1701032-01 | 1 |
| Euro/Sanacorp | Triclosan | 1912002-01 | 1 |
| Euro | Triclosan | 2001027-01 | 1 |
| Euroct/Gehe | Triclosan | 1510045-01 | 2 |
| EuRoh/ Gehe | Triclosan | 17149821 | 1 |
| EuRoh/ Gehe | Triclosan | 1901006-02 | 1 |
| EuRoh/ Gehe | Triclosan | 191200202 | 1 |
| EuRoh | Triclosan | | 1 |
| Euroo/direkt | Triclosan | 1705011-01 | 1 |
| EuroOCT/Sanacorp | Triclosan | 1609005-02 | 1 |
| Europ Ots Pharma | Triclosan | 13D02-N02 | 1 |
| EurRho/Gehe | Triclosan | | 1 |
| EurRho/Noweda | Triclosan | 1912002-04 | 1 |
| Fa.Phönix | Triclosan | 17081720 | 1 |
| Fa.Phönix | Triclosan | 17149827 | 1 |
| Fa.Phönix | Triclosan | 21000428012 | 1 |
| Fagro/Gehe | Triclosan | 13H08-N10 | 1 |
| Fagro/Sanacorp | Triclosan | TCS0214037 | 1 |
| Fagron | Triclosan | | 5 |
| Fagron | Triclosan | 10006226 | 2 |
| Fagron | Triclosan | 1006226 | 1 |
| Fagron | Triclosan | 10112014C | 1 |
| Fagron | Triclosan | 10666066 | 2 |
| Fagron | Triclosan | 106666066 | 1 |
| Fagron | Triclosan | 10J18-N01 | 2 |
| Fagron | Triclosan | 11238004 | 1 |
| Fagron | Triclosan | 11777748 | 4 |
| Fagron | Triclosan | 11A05-N13 | 2 |
| Fagron | Triclosan | 11c21-n05 | 1 |
| Fagron | Triclosan | 11D20-N10 | 1 |
| Fagron | Triclosan | 11h09-n02 | 1 |
| Fagron | Triclosan | 11H09-N02 | 6 |
| Fagron | Triclosan | 11J28-n02 | 1 |
| Fagron | Triclosan | 11J28-N02 | 4 |
| Fagron | Triclosan | 11L19-N11 | 7 |
| Fagron | Triclosan | 1209213402 | 1 |
| Fagron | Triclosan | 1214I03402 | 1 |
| Fagron | Triclosan | 12c21-n05 | 3 |
| Fagron | Triclosan | 12C21-N05 | 23 |
| Fagron | Triclosan | 12G09-N09 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triclosan | 12G09-no9 | 1 |
| Fagron | Triclosan | 12g17-n04 | 2 |
| Fagron | Triclosan | 12G17-n04 | 2 |
| Fagron | Triclosan | 12G17N04 | 1 |
| Fagron | Triclosan | 12G17-N04 | 30 |
| Fagron | Triclosan | 12l06-n01 | 1 |
| Fagron | Triclosan | 12L06-n01 | 1 |
| Fagron | Triclosan | 12L06-N01 | 40 |
| Fagron | Triclosan | 13092012C | 1 |
| Fagron | Triclosan | 13a11n03 | 1 |
| Fagron | Triclosan | 13A11N03 | 1 |
| Fagron | Triclosan | 13A11-N03 | 10 |
| Fagron | Triclosan | 13A11-NO3 | 1 |
| Fagron | Triclosan | 13C10-B06-312981 | 1 |
| Fagron | Triclosan | 13d02-n02 | 1 |
| Fagron | Triclosan | 13d02-N02 | 1 |
| Fagron | Triclosan | 13D02N02 | 1 |
| Fagron | Triclosan | 13D02-N02 | 73 |
| Fagron | Triclosan | 13D02-N-02 | 1 |
| Fagron | Triclosan | 13Do2-N02 | 1 |
| Fagron | Triclosan | 13DO2-NO2 | 1 |
| Fagron | Triclosan | 13h08-n10 | 1 |
| Fagron | Triclosan | 13H08N10 | 2 |
| Fagron | Triclosan | 13H08-N10 | 30 |
| Fagron | Triclosan | 13H08-N-10 | 1 |
| Fagron | Triclosan | 13H08-N100450/1231 | 1 |
| Fagron | Triclosan | 13h09-n01 | 1 |
| Fagron | Triclosan | 13H09N01 | 2 |
| Fagron | Triclosan | 13H09-N01 | 60 |
| Fagron | Triclosan | 13H09-N011296/2856 | 1 |
| Fagron | Triclosan | 13H09-No1 | 1 |
| Fagron | Triclosan | 13L18-35-289995 | 1 |
| Fagron | Triclosan | 13L18-B35 | 12 |
| Fagron | Triclosan | 13L18-B35_289995 | 1 |
| Fagron | Triclosan | 13L18-B35-289 | 1 |
| Fagron | Triclosan | 13L18-B35-289983 | 10 |
| Fagron | Triclosan | 13l18-b35-289984 | 1 |
| Fagron | Triclosan | 13L18B35289984 | 1 |
| Fagron | Triclosan | 13L18-B35-289984 | 5 |
| Fagron | Triclosan | 13L18-B35-289985 | 12 |
| Fagron | Triclosan | 13L18-B35-289985 | 1 |
| Fagron | Triclosan | 13L-18-B35-289985 | 1 |
| Fagron | Triclosan | 13L18-B35-289986 | 7 |
| Fagron | Triclosan | 13L18B35289987 | 1 |
| Fagron | Triclosan | 13L18-B35-289987 | 6 |
| Fagron | Triclosan | 13L18-B35-289988 | 1 |
| Fagron | Triclosan | 13L18-B35-289992 | 2 |
| Fagron | Triclosan | 13L18-B35-289993 | 4 |
| Fagron | Triclosan | 13l18-b35-289994 | 1 |
| Fagron | Triclosan | 13L18-B35-289994 | 7 |
| Fagron | Triclosan | 13L18-B35-289995 | 8 |
| Fagron | Triclosan | 14022014C | 1 |
| Fagron | Triclosan | 14F23-B02 | 5 |
| Fagron | Triclosan | 14F23-B02_295756 | 1 |
| Fagron | Triclosan | 14F23-B02-293852 | 2 |
| Fagron | Triclosan | 14F23-B02-295756 | 2 |
| Fagron | Triclosan | 14f23-b02-295757 | 1 |
| Fagron | Triclosan | 14F23-B02295757 | 1 |
| Fagron | Triclosan | 14F23-B02-295757 | 6 |
| Fagron | Triclosan | 14f23-b02-295758 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triclosan | 14F23B02295758 | 1 |
| Fagron | Triclosan | 14F23-B02-295758 | 12 |
| Fagron | Triclosan | 14F23-B02-295759 | 9 |
| Fagron | Triclosan | 14F23-B02-295760 | 8 |
| Fagron | Triclosan | 14F23-B02-295761 | 11 |
| Fagron | Triclosan | 14F23-B02-295762 | 3 |
| Fagron | Triclosan | 14F23B02295763 | 1 |
| Fagron | Triclosan | 14F23-B02-295763 | 3 |
| Fagron | Triclosan | 14F23-B02-295764 | 2 |
| Fagron | Triclosan | 14F23-B02-295765 | 6 |
| Fagron | Triclosan | 14F23-B02-295947 | 6 |
| Fagron | Triclosan | 14F23-B02-295948 | 4 |
| Fagron | Triclosan | 14F23-B02-2959947 | 1 |
| Fagron | Triclosan | 14F23B02300219 | 1 |
| Fagron | Triclosan | 14F23-B02-300219 | 7 |
| Fagron | Triclosan | 14F23-Bo2-295947 | 1 |
| Fagron | Triclosan | 14F-B02-293859 | 1 |
| Fagron | Triclosan | 151010-B06-312984 | 1 |
| Fagron | Triclosan | 15203604 | 1 |
| Fagron | Triclosan | 15301510 | 1 |
| Fagron | Triclosan | 15607-B03-310035 | 1 |
| Fagron | Triclosan | 15C10-806-312981 | 1 |
| Fagron | Triclosan | 15C10-B03-312982 | 1 |
| Fagron | Triclosan | 15C10-B06 | 5 |
| Fagron | Triclosan | 15C10-B06_312980 | 1 |
| Fagron | Triclosan | 15C10B06310031 | 2 |
| Fagron | Triclosan | 15C10-B06-310031 | 7 |
| Fagron | Triclosan | 15C10-B06-310032 | 4 |
| Fagron | Triclosan | 15c10-B06-311161 | 1 |
| Fagron | Triclosan | 15C10B06311161 | 2 |
| Fagron | Triclosan | 15C10-B06-311161 | 13 |
| Fagron | Triclosan | 15c10-b06-312980 | 1 |
| Fagron | Triclosan | 15c10-B06-312980 | 1 |
| Fagron | Triclosan | 15C10-B06-312980 | 6 |
| Fagron | Triclosan | 15c10-b06-312981 | 1 |
| Fagron | Triclosan | 15c10-B06-312981 | 1 |
| Fagron | Triclosan | 15C10B06312981 | 2 |
| Fagron | Triclosan | 15C10-B06-312981 | 24 |
| Fagron | Triclosan | 15C10B06312982 | 1 |
| Fagron | Triclosan | 15C10-B06-312982 | 14 |
| Fagron | Triclosan | 15C10B06312983 | 1 |
| Fagron | Triclosan | 15C10-B06-312983 | 7 |
| Fagron | Triclosan | 15C10-B06-3161 | 1 |
| Fagron | Triclosan | 15C-B06-312982 | 1 |
| Fagron | Triclosan | 15G01-B03-310038 | 1 |
| Fagron | Triclosan | 15G047-B03-0001 | 1 |
| Fagron | Triclosan | 15G07 | 1 |
| Fagron | Triclosan | 15G07-B03 | 3 |
| Fagron | Triclosan | 15G07-B03_310037 | 1 |
| Fagron | Triclosan | 15G07-B03-30037 | 1 |
| Fagron | Triclosan | 15g07-b03-310035 | 1 |
| Fagron | Triclosan | 15G07-B03-310035 | 9 |
| Fagron | Triclosan | 15G07-B03-310036 | 4 |
| Fagron | Triclosan | 15G07B03310037 | 1 |
| Fagron | Triclosan | 15G07-B03-310037 | 15 |
| Fagron | Triclosan | 15G07-B03-310038 | 7 |
| Fagron | Triclosan | 15G07-B03-310039 | 3 |
| Fagron | Triclosan | 15G07B03310040 | 1 |
| Fagron | Triclosan | 15G07-B03-310040 | 6 |
| Fagron | Triclosan | 15G07-B03-310041 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Triclosan | 160614 | 1 |
| Fagron | Triclosan | 16084603 | 1 |
| Fagron | Triclosan | 16084614 | 1 |
| Fagron | Triclosan | 1609005-02 | 2 |
| Fagron | Triclosan | 1708025-01 | 3 |
| Fagron | Triclosan | 17081702 | 1 |
| Fagron | Triclosan | 1710025 | 4 |
| Fagron | Triclosan | 17148812 | 1 |
| Fagron | Triclosan | 17149808 | 1 |
| Fagron | Triclosan | 17149815 | 1 |
| Fagron | Triclosan | 17149817 | 2 |
| Fagron | Triclosan | 17149819 | 1 |
| Fagron | Triclosan | 17G07-B03-310038 | 1 |
| Fagron | Triclosan | 17K02 | 1 |
| Fagron | Triclosan | 17K02-B06 | 8 |
| Fagron | Triclosan | 17K02-B06-343543 | 2 |
| Fagron | Triclosan | 17K02-B06-343544 | 10 |
| Fagron | Triclosan | 17K02-B06-343545 | 2 |
| Fagron | Triclosan | 17K02-B06343546 | 1 |
| Fagron | Triclosan | 17K02-B06-343546 | 15 |
| Fagron | Triclosan | 17K02-B06-343547 | 7 |
| Fagron | Triclosan | 17K02-B06-343548 | 11 |
| Fagron | Triclosan | 17K02-B06-34547 | 1 |
| Fagron | Triclosan | 18081414 | 1 |
| Fagron | Triclosan | 18082014B | 1 |
| Fagron | Triclosan | 1901006-01 | 1 |
| Fagron | Triclosan | 190282002 | 1 |
| Fagron | Triclosan | 190615A | 1 |
| Fagron | Triclosan | 1912002-01 | 1 |
| Fagron | Triclosan | 1912002-02 | 2 |
| Fagron | Triclosan | 200315B | 1 |
| Fagron | Triclosan | 20J30-B03 | 1 |
| Fagron | Triclosan | 20J30-B03-2046408 | 1 |
| Fagron | Triclosan | 20J30-B03-204647 | 1 |
| Fagron | Triclosan | 20J30-B03-204648 | 1 |
| Fagron | Triclosan | 20J30-B03-204649 | 1 |
| Fagron | Triclosan | 20J30-B03-2046-49 | 1 |
| Fagron | Triclosan | 21B25-B02 | 1 |
| Fagron | Triclosan | 21B25-B02-203362 | 1 |
| Fagron | Triclosan | 21b25-b02-203393 | 1 |
| Fagron | Triclosan | 21B25-B02-203393 | 3 |
| Fagron | Triclosan | 21B25-BO2-203393 | 2 |
| Fagron | Triclosan | 220601601 | 1 |
| Fagron | Triclosan | 22B15-B05-218336 | 1 |
| Fagron | Triclosan | 2513Q-03402 | 1 |
| Fagron | Triclosan | 2901313402 | 1 |
| Fagron | Triclosan | 2914E-03402 | 1 |
| Fagron | Triclosan | 434083 | 1 |
| Fagron | Triclosan | 4394083 | 1 |
| Fagron | Triclosan | 4516I-03402 | 1 |
| Fagron | Triclosan | 5846205 | 2 |
| Fagron | Triclosan | 6012014E | 1 |
| Fagron | Triclosan | 700228-0005 | 1 |
| Fagron | Triclosan | 90000383 | 1 |
| Fagron | Triclosan | 9000383 | 2 |
| Fagron | Triclosan | B03-2046409 | 1 |
| Fagron | Triclosan | C12H7Cl302 | 1 |
| Fagron | Triclosan | KOO1-1/14/12/823 | 1 |
| Fagron | Triclosan | TCS0214037 | 2 |
| Fargon / Gehe | Triclosan | 14F23-B02-295760 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fargon/Fönix | Triclosan | 17081725 | 2 |
| Fargon/Fönix | Triclosan | 170817285 | 1 |
| Fargon/Noweda | Triclosan | 18081414 | 1 |
| Fargon | Triclosan | 12C21-N05 | 1 |
| fargon | Triclosan | 12G17-N04 | 1 |
| Fargon | Triclosan | 13D02-N02 | 2 |
| Fargon | Triclosan | 14F23-B02-295948 | 1 |
| Fargon | Triclosan | 4394403 | 1 |
| Faron | Triclosan | 14F23-B02-300219 | 2 |
| Fiebig | Triclosan | 15C10-B06-312923 | 1 |
| Fiebig | Triclosan | 1607002-01 | 1 |
| Fiebig | Triclosan | 16280811 | 1 |
| Fiebig | Triclosan | 17149813 | 1 |
| Fiebig | Triclosan | 17149814 | 1 |
| Fiebig | Triclosan | 17149819 | 1 |
| Fiebig | Triclosan | 17149821 | 1 |
| Fiebig | Triclosan | 18081413 | 2 |
| Fiebig | Triclosan | 21000427015 | 1 |
| Fischar/Gehe | Triclosan | 13D02-N02 | 1 |
| Fragon/Sanacorp | Triclosan | 1710025 | 3 |
| Fragron | Triclosan | 13D02-N02 | 1 |
| Fragron | Triclosan | 15G07-B03-310040 | 1 |
| Gatt-Koller | Triclosan | 21J01875 | 1 |
| GEHE 17.06.2014 | Triclosan | 14052102 | 1 |
| GEHE 22.04.2014 | Triclosan | 13391804 | 1 |
| Gehe amax | Triclosan | 15301503 | 1 |
| Gehe/Fragon | Triclosan | 15G07B03310036 | 2 |
| Gehe | Triclosan | | 1 |
| Gehe | Triclosan | 11J28-N02 | 1 |
| Gehe | Triclosan | 12145910 | 1 |
| Gehe | Triclosan | 12359104 | 1 |
| Gehe | Triclosan | 12359105 | 1 |
| Gehe | Triclosan | 12359112 | 1 |
| Gehe | Triclosan | 12359114 | 1 |
| Gehe | Triclosan | 12106-n01 | 1 |
| Gehe | Triclosan | 13391804 | 2 |
| Gehe | Triclosan | 13391811 | 1 |
| Gehe | Triclosan | 13A11-N03 | 1 |
| Gehe | Triclosan | 13D02-N02 | 1 |
| Gehe | Triclosan | 13L18-B35-289992 | 1 |
| Gehe | Triclosan | 14052105 | 1 |
| Gehe | Triclosan | 1408024-01 | 2 |
| Gehe | Triclosan | 14121210 | 1 |
| Gehe | Triclosan | 14121211 | 1 |
| Gehe | Triclosan | 14205904 | 1 |
| Gehe | Triclosan | 14F23B02295947 | 1 |
| Gehe | Triclosan | 14F23-B02-295947 | 1 |
| Gehe | Triclosan | 1505009-01 | 1 |
| Gehe | Triclosan | 16084614 | 1 |
| Gehe | Triclosan | 16280808 | 1 |
| Gehe | Triclosan | 16280811 | 1 |
| Gehe | Triclosan | 1701032-01 | 1 |
| GEHE | Triclosan | 1701032-01 | 1 |
| Gehe | Triclosan | 1701032-02 | 1 |
| GEHE | Triclosan | 1701032-02 | 1 |
| Gehe | Triclosan | 1705011-01 | 1 |
| Gehe | Triclosan | 17081710 | 1 |
| GEHE | Triclosan | 17081710 | 1 |
| Gehe | Triclosan | 17149806 | 1 |
| Gehe | Triclosan | 17149809 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Triclosan | 17149816 | 1 |
| Gehe | Triclosan | 17149820 | 2 |
| GEHE | Triclosan | 17149824 | 1 |
| Gehe | Triclosan | 18081408 | 1 |
| Gehe | Triclosan | 18253706 | 1 |
| Gehe | Triclosan | 18253709 | 1 |
| Gehe | Triclosan | 18253716 | 1 |
| GEHE | Triclosan | 18253724 | 1 |
| Gehe | Triclosan | 1901006-01 | 4 |
| Gehe | Triclosan | 190100602 | 1 |
| Gehe | Triclosan | 1912002-02 | 3 |
| gehe | Triclosan | 1912002-03 | 1 |
| Gehe | Triclosan | 1912002-03 | 1 |
| Gehe | Triclosan | 2001027-01 | 1 |
| Gehe | Triclosan | 21000427003 | 1 |
| Gehe | Triclosan | 21000427007 | 1 |
| Gehe | Triclosan | 21000427011 | 1 |
| Gehe | Triclosan | 21000427014 | 1 |
| GEHE | Triclosan | 21000427014 | 2 |
| Gehe | Triclosan | 21000427015 | 3 |
| Gehe | Triclosan | 21000427016 | 1 |
| Gehe | Triclosan | 21000427017 | 2 |
| Gehe | Triclosan | 21000428009 | 1 |
| gehe | Triclosan | 210102901 | 1 |
| Gehe | Triclosan | 2101029-01 | 4 |
| Gehe | Triclosan | 2101029-02 | 4 |
| Gehe | Triclosan | 22060016-01 | 1 |
| Gehe | Triclosan | 2206016-02 | 1 |
| gehe | Triclosan | 23002009001 | 4 |
| Gehe | Triclosan | 23002009001 | 1 |
| Gehe | Triclosan | 23002009003 | 1 |
| Gehe | Triclosan | 23002009005 | 4 |
| Gehe | Triclosan | 23002009014 | 1 |
| Gehe | Triclosan | Caelo | 2 |
| Gehe-Fragon | Triclosan | 14F23B02300219 | 2 |
| Geilenkirchen | Triclosan | 18253707 | 1 |
| Geilenkirchen | Triclosan | 18253711 | 1 |
| Geilenkirchen | Triclosan | 192709012 | 1 |
| Gutenberg-Apotheke | Triclosan | 13H09-N01 | 2 |
| Gutenberg-Apotheke | Triclosan | 13L18-B35 | 1 |
| Henry Lamotte/ Noweda | Triclosan | 15203606 | 1 |
| Holdermann | Triclosan | 21000427015 | 1 |
| Ichtyhol Gesellschaf... | Triclosan | 1701032-02 | 1 |
| Jenne | Triclosan | 18081417 | 3 |
| Jenne | Triclosan | 1912002-03 | 1 |
| Jenne | Triclosan | 20J30-B03 | 2 |
| Jenne | Triclosan | 21000427014 | 3 |
| Jenne | Triclosan | 21000427015 | 1 |
| Jenne | Triclosan | 21000428003 | 2 |
| Jenne | Triclosan | 21000428010 | 2 |
| Jenne | Triclosan | 23002009005 | 1 |
| Jenne | Triclosan | 23002009010 | 1 |
| Jenne | Triclosan | 230919(21000428022) | 1 |
| Jiangsu EqualChem Co... | Triclosan | 1710025 | 1 |
| Kehr Holdermann | Triclosan | 2101029-04 | 1 |
| Kehr.09.07.2020 | Triclosan | 2001027-01 | 1 |
| Kehr | Triclosan | 21000427005 | 1 |
| Kehr | Triclosan | 21000427011 | 3 |
| Kehr | Triclosan | 21000427017 | 3 |
| Kehr | Triclosan | 2206016-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Kehr-Holdermann | Triclosan | 2206016-02 | 1 |
| Klenk | Triclosan | 192709023 | 1 |
| Klenk | Triclosan | 21000428010 | 1 |
| Klosterring | Triclosan | 16280801 | 2 |
| Klosterring | Triclosan | 18081405 | 1 |
| Kremer/Phönix | Triclosan | 15/157/T | 1 |
| Krieger/Euro | Triclosan | 2101029-01 | 1 |
| Krieger | Triclosan | 12g17-N04 | 1 |
| Krieger | Triclosan | 2206016-01 | 1 |
| Krieger | Triclosan | 2206016-02 | 1 |
| Kumar Organic Produc... | Triclosan | 182537001 | 1 |
| Kumar Organic Products | Triclosan | 192709023 | 1 |
| Kumar Organic/Noweda | Triclosan | 15C10-B06 | 1 |
| Kumar/Noweda | Triclosan | | 3 |
| Kumar/Noweda | Triclosan | K0011/19/07/337 | 1 |
| L12 | Triclosan | 16280819 | 1 |
| L12 | Triclosan | 1628081917181722 | 1 |
| L12 | Triclosan | 18081408 | 1 |
| L30/Alliance | Triclosan | 1607002-01 | 1 |
| Midas | Triclosan | 17081714 | 2 |
| Midas | Triclosan | 17081721 | 1 |
| Midas | Triclosan | 17149815 | 1 |
| Midas | Triclosan | 17149819 | 1 |
| Mvda_23.01.2019 | Triclosan | 18081416 | 1 |
| Nachprüfung | Triclosan | AP200710-04 | 1 |
| Noewed | Triclosan | 21000427006 | 1 |
| Nov | Triclosan | 192709011 | 1 |
| Noveda | Triclosan | 18253707 | 1 |
| now | Triclosan | 18257001 | 1 |
| Noweda 06.12.2019 | Triclosan | 18253721 | 1 |
| Noweda 15.7.17 | Triclosan | 16280817 | 1 |
| Noweda/EuRo | Triclosan | 1801049-01 | 1 |
| Noweda | Triclosan | 12359107 | 1 |
| Noweda | Triclosan | 12G17-N04 | 2 |
| Noweda | Triclosan | 13247903 | 1 |
| noweda | Triclosan | 13L18-B35-289985 | 1 |
| Noweda | Triclosan | 1408024-01 | 1 |
| Noweda | Triclosan | 14F23-B02-295765 | 1 |
| Noweda | Triclosan | 15203604 | 1 |
| Noweda | Triclosan | 16084614 | 1 |
| Noweda | Triclosan | 16280818 | 1 |
| Noweda | Triclosan | 1705011-01 | 1 |
| Noweda | Triclosan | 17081703 | 1 |
| Noweda | Triclosan | 17081710 | 1 |
| Noweda | Triclosan | 17081711 | 1 |
| Noweda | Triclosan | 17081714 | 1 |
| Noweda | Triclosan | 17081721 | 1 |
| Noweda | Triclosan | 17081724 | 1 |
| Noweda | Triclosan | 17149801 | 1 |
| Noweda | Triclosan | 17149805 | 1 |
| Noweda | Triclosan | 17149815 | 1 |
| Noweda | Triclosan | 17K02-B06 | 1 |
| Noweda | Triclosan | 17K02-B06-343547 | 2 |
| Noweda | Triclosan | 18081413 | 1 |
| Noweda | Triclosan | 18081417 | 1 |
| Noweda | Triclosan | 182537002 | 1 |
| Noweda | Triclosan | 18253705 | 1 |
| Noweda | Triclosan | 18253708 | 2 |
| Noweda | Triclosan | 18253716 | 2 |
| Noweda | Triclosan | 18253717 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Triclosan | 1912002-01 | 2 |
| Noweda | Triclosan | 192709007 | 1 |
| Noweda | Triclosan | 192709011 | 3 |
| Noweda | Triclosan | 192709012 | 1 |
| Noweda | Triclosan | 192709022 | 2 |
| Noweda | Triclosan | 20J30-B03-204648 | 1 |
| Noweda | Triclosan | 210000428009 | 1 |
| Noweda | Triclosan | 21000427007 | 1 |
| Noweda | Triclosan | 21000427008 | 2 |
| Noweda | Triclosan | 21000427009 | 1 |
| Noweda | Triclosan | 21000427011 | 2 |
| Noweda | Triclosan | 21000427014 | 2 |
| Noweda | Triclosan | 21000427017 | 1 |
| Noweda | Triclosan | 21000428004 | 1 |
| Noweda | Triclosan | 21000428009 | 1 |
| Noweda | Triclosan | 21000428015 | 1 |
| Noweda | Triclosan | 21000428020 | 3 |
| Noweda | Triclosan | 2101029-02 | 1 |
| Noweda | Triclosan | 21B25-B02-203359 | 1 |
| Noweda | Triclosan | 21B25-B02-203393 | 1 |
| Noweda | Triclosan | 2206016-01 | 1 |
| Noweda | Triclosan | 23002009001 | 2 |
| Noweda | Triclosan | 23002009010 | 1 |
| Ph.Eur 8.0 | Triclosan | 17081705 | 1 |
| Phoenix 19.11.14 | Triclosan | 14121207 | 1 |
| Phoenix | Triclosan | 12003202 | 1 |
| Phoenix | Triclosan | 14205903 | 1 |
| Phoenix | Triclosan | 15301506 | 2 |
| Phoenix | Triclosan | 15C10-B06 | 1 |
| Phoenix | Triclosan | 16084614 | 1 |
| Phoenix | Triclosan | 1609005-02 | 1 |
| Phoenix | Triclosan | 16280809 | 2 |
| Phoenix | Triclosan | 1701032-01 | 1 |
| Phoenix | Triclosan | 1701032-02 | 1 |
| Phoenix | Triclosan | 17081709 | 1 |
| Phoenix | Triclosan | 17081721 | 1 |
| Phoenix | Triclosan | 17081723 | 2 |
| Phoenix | Triclosan | 17081726 | 1 |
| Phoenix | Triclosan | 17149809 | 1 |
| Phoenix | Triclosan | 17149820 | 1 |
| Phoenix | Triclosan | 17K02-B06-343547 | 1 |
| Phoenix | Triclosan | 18081407 | 1 |
| Phoenix | Triclosan | 18081408 | 1 |
| Phoenix | Triclosan | 18081414 | 1 |
| Phoenix | Triclosan | 18253705 | 1 |
| Phoenix | Triclosan | 18253706 | 1 |
| Phoenix | Triclosan | 18253708 | 1 |
| Phoenix | Triclosan | 18253716 | 2 |
| Phoenix | Triclosan | 18253717 | 1 |
| Phoenix | Triclosan | 18253718 | 1 |
| Phoenix | Triclosan | 18253721 | 3 |
| Phoenix | Triclosan | 1901006-01 | 1 |
| Phoenix | Triclosan | 1912002-02 | 1 |
| Phoenix | Triclosan | 21000427003 | 1 |
| Phoenix | Triclosan | 21000427005 | 1 |
| Phoenix | Triclosan | 21000427009 | 2 |
| Phoenix | Triclosan | 21000427014 | 2 |
| Phoenix | Triclosan | 21000427015 | 1 |
| Phoenix | Triclosan | 21000428011 | 2 |
| Phoenix | Triclosan | 21000428022 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phoenix | Triclosan | 23002009005 | 1 |
| Phoenix | Triclosan | 2300200901007/25P | 1 |
| Phoenix | Triclosan | 3417 | 1 |
| Phönix 27.6.2019 | Triclosan | 18253705 | 1 |
| Phönix 5.4.19 | Triclosan | 18253706 | 2 |
| Phönix Berlin / Lamotte | Triclosan | 17081711 | 1 |
| Phönix Gotha | Triclosan | 13391807 | 1 |
| Phönix Gotha | Triclosan | 1408024-01 | 2 |
| Phönix Mvda 3.7.2019 | Triclosan | 18253714 | 1 |
| Phönix/Caesar&Lorenz… | Triclosan | 21000428008 | 2 |
| Phönix/Caesar&Lorenz10,0 | Triclosan | 21000428016 | 2 |
| Phönix/Caesar&Lorenz… | Triclosan | 21000427005 | 1 |
| Phönix/EuRho | Triclosan | 1701032-02 | 2 |
| Phönix/Eurho | Triclosan | 2101029-01 | 1 |
| Phönix/Fagon | Triclosan | 15C10-B06-312981 | 1 |
| Phönix/Noweda | Triclosan | 21000428008 | 1 |
| Phönix | Triclosan | | 1 |
| Phönix | Triclosan | 12145908 | 1 |
| Phönix | Triclosan | 12359109 | 1 |
| Phönix | Triclosan | 12359111 | 1 |
| Phönix | Triclosan | 12L06-N01 | 1 |
| Phönix | Triclosan | 13A11-N03 | 1 |
| Phönix | Triclosan | 13H09-N01 | 1 |
| Phonix | Triclosan | 13L18-B35 | 1 |
| Phönix | Triclosan | 13L18-B35-289985 | 1 |
| Phönix | Triclosan | 13L18-B35-289995 | 2 |
| Phönix | Triclosan | 13L8-B35 | 1 |
| Phönix | Triclosan | 1516A-03402 | 1 |
| Phönix | Triclosan | 16280801 | 1 |
| PHÖNIX | Triclosan | 16280801 | 2 |
| Phönix | Triclosan | 16280811 | 2 |
| Phönix | Triclosan | 17081710 | 1 |
| phönix | Triclosan | 17081712 | 1 |
| Phönix | Triclosan | 17081725 | 1 |
| Phönix | Triclosan | 17149808 | 1 |
| Phönix | Triclosan | 17149815 | 1 |
| Phönix | Triclosan | 17149821 | 1 |
| Phönix | Triclosan | 17k02-b06-343544 | 1 |
| Phönix | Triclosan | 18081415 | 1 |
| Phönix | Triclosan | 182537001 | 1 |
| Phönix | Triclosan | 18253706 | 1 |
| Phönix | Triclosan | 18253718 | 1 |
| Phönix | Triclosan | 18253721 | 2 |
| Phönix | Triclosan | 1912002-01 | 1 |
| Phönix | Triclosan | 1912002-02 | 1 |
| Phönix | Triclosan | 192709012 | 1 |
| Phönix | Triclosan | 192709018 | 1 |
| Phönix | Triclosan | 192709020 | 3 |
| Phönix | Triclosan | 192709023 | 3 |
| phönix | Triclosan | 21000427002 | 1 |
| Phönix | Triclosan | 21000427006 | 2 |
| Phönix | Triclosan | 21000427007 | 1 |
| Phönix | Triclosan | 21000427008 | 1 |
| Phönix | Triclosan | 21000427014 | 5 |
| Phönix | Triclosan | 21000427017 | 1 |
| phönix | Triclosan | 21000428010 | 1 |
| Phönix | Triclosan | 2100042802041/23P | 1 |
| Phönix | Triclosan | 21000428021 | 1 |
| Phönix | Triclosan | 2100427014 | 1 |
| phönix | Triclosan | 2101029 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Triclosan | 2206016-02 | 1 |
| Phönix | Triclosan | 23002009001 | 3 |
| Phönix | Triclosan | 23002009003 | 3 |
| phönix | Triclosan | 23002009014 | 1 |
| Phönix | Triclosan | 23002009014 | 1 |
| Phönix | Triclosan | 3180 | 1 |
| Raben-Apotheke Mildenau | Triclosan | 13L18-B35-289984 | 2 |
| Rondell Apotheke | Triclosan | 11965460 | 1 |
| Röntgen | Triclosan | 17K02-B06-343546 | 1 |
| Röntgen | Triclosan | 1801049-01 | 1 |
| Röntgen | Triclosan | 1912002-03 | 2 |
| Röntgen | Triclosan | 2101029-01 | 2 |
| Sana 05.12,14 3,38 | Triclosan | 14121210 | 2 |
| Sana 06.11.14 EK 3,38 | Triclosan | 14121209 | 1 |
| sana corp | Triclosan | 12359106 | 1 |
| Sana | Triclosan | 2206016-02 | 1 |
| sanacorb | Triclosan | 18253711 | 1 |
| Sanacorp 28.05.2019 5,55EUR | Triclosan | 1901006-01 | 1 |
| Sanacorp WE: 30.04.1… | Triclosan | 1708025-01 | 1 |
| Sanacorp WE:05.09.16… | Triclosan | 1602003-01 | 2 |
| Sanacorp | Triclosan | | 1 |
| Sanacorp | Triclosan | 10666066 | 1 |
| Sanacorp | Triclosan | 12359105 | 2 |
| Sanacorp | Triclosan | 12359106 | 1 |
| Sanacorp | Triclosan | 13247904 | 2 |
| Sanacorp | Triclosan | 13391807 | 2 |
| Sanacorp | Triclosan | 13D02-N02 | 1 |
| Sanacorp | Triclosan | 13H09-N01 | 1 |
| sanacorp | Triclosan | 13L18-B35-289987 | 1 |
| Sanacorp | Triclosan | 14052103 | 1 |
| Sanacorp | Triclosan | 14121211 | 1 |
| Sanacorp | Triclosan | 14121215 | 1 |
| Sanacorp | Triclosan | 1505009-01 | 1 |
| Sanacorp | Triclosan | 151004501 | 1 |
| Sanacorp | Triclosan | 17071717 | 1 |
| Sanacorp | Triclosan | 17081717 | 1 |
| Sanacorp | Triclosan | 17081725 | 1 |
| Sanacorp | Triclosan | 17149806 | 1 |
| Sanacorp | Triclosan | 17149807 | 1 |
| Sanacorp | Triclosan | 17149808 | 3 |
| Sanacorp | Triclosan | 17149812 | 1 |
| Sanacorp | Triclosan | 17149814 | 1 |
| Sanacorp | Triclosan | 17149821 | 1 |
| Sanacorp | Triclosan | 18081405 | 2 |
| Sanacorp | Triclosan | 18081415 | 1 |
| Sanacorp | Triclosan | 18081416 | 1 |
| Sanacorp | Triclosan | 182537001 | 1 |
| Sanacorp | Triclosan | 182537002 | 1 |
| Sanacorp | Triclosan | 18253702 | 1 |
| Sanacorp | Triclosan | 18253707 | 1 |
| Sanacorp | Triclosan | 18253710 | 1 |
| Sanacorp | Triclosan | 18253711 | 1 |
| Sanacorp | Triclosan | 18253712 | 1 |
| Sanacorp | Triclosan | 18253714 | 1 |
| sanacorp | Triclosan | 18253726 | 1 |
| sanacorp | Triclosan | 1901006-02 | 1 |
| Sanacorp | Triclosan | 1912002-04 | 1 |
| Sanacorp | Triclosan | 192709003 | 1 |
| Sanacorp | Triclosan | 192709022 | 1 |
| Sanacorp | Triclosan | 21000427002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Triclosan | 21000427005 | 1 |
| sanacorp | Triclosan | 21000427016 | 1 |
| Sanacorp | Triclosan | 21000428005 | 1 |
| Sanacorp | Triclosan | 2101029-03 | 1 |
| Sanacorp | Triclosan | 2206016-01 | 2 |
| Sanacorp | Triclosan | 2206016-02 | 1 |
| Sanacorp | Triclosan | 23002009014 | 1 |
| Sanacorp | Triclosan | 26/AKD1 | 1 |
| Sanacorp | Triclosan | 28/AKD4 | 1 |
| Schulzendorfer-Apotheke | Triclosan | 21000427011 | 1 |
| Sonnenberg-Apotheke | Triclosan | 13L18-B35-289995 | 1 |
| Spangropharm | Triclosan | 13D02-V02 | 1 |
| triclosan | Triclosan | 15C10-B06-310032 | 1 |
| WE:02.04.2016 Sanaco… | Triclosan | 15C10-B06-312982 | 3 |

- 249 944 spectra from 1665 *Apo-Ident* customers from a total of 51 401 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Triclosan* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Triclosan* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 410 | 0 | 157 916 |
| **Type B** | 0 | 800 | 0 | 212 140 |
| **Type C** | 0 | 6934 | 8 | 249 944 |

The substance/substance group *Triclosan* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5366 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2500 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8848 % (> 99.8415 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21509 | 22373 | 3.89 | 265.94 |
| 21591 | 22373 | 4.97 | 265.27 |
| 21615 | 22373 | 6.54 | 264.64 |
| 21856 | 21856 | 0.00 | 264.60 |
| 22227 | 22227 | 0.00 | 264.87 |
| 22373 | 22373 | 0.00 | 265.55 |
| 22987 | 22987 | 0.00 | 264.35 |
| 23915 | 22227 | 12.90 | 264.12 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Trometamol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20004-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Trometamol; Trometamolum

### Special notes

When selecting the *Trometamol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Trometamol | 9 | 8 | 234 |

### Second-stage model

For differentiation of the substance/substance group *Trometamol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Trometamol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Arginine | 120.30 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Trometamol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Trometamol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Trometamol | 14050002 | 21358 | 40 | 20140220 |
| Caelo | Trometamol | 161688 | 22629 | 40 | 20160615* |
| Caelo | Trometamol | 16168810 | 23498 | 40 | 20160615 |
| Caelo | Trometamol | 22000894 | 26112 | 40 | 20220331* |
| Caelo | Trometamol | 22000894 | 26112SI | 20 | 20220331* |
| Caelo | Trometamol | 22002697 | 26360 | 40 | 20220921* |
| Caelo | Trometamol | 22002697 | 26360SI | 20 | 20220921* |
| Caelo | Trometamol | 23002408 | 26972 | 40 | 20231012* |
| Euro OTC | Trometamol | 1803016 | 24063 | 40 | 20180320* |
| Fagron | Trometamol | 13E22-N05 | 20856 | 40 | AR-17-FG-016395-01 |
| Fagron | Trometamol | 18A23-B10-351258 | 24816 | 40 | 20180306 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 400 spectra of 11 reference samples from the substance/substance group *Trometamol*. These samples are listed above in the *calibration samples* section. The reference samples come from 9 different batches.

- 157 926 spectra from a total of 2948 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 380 spectra of 10 reference samples from the substance/substance group *Trometamol*.

- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Trometamol | 173208 | 23787 | 40 |
| Caelo | Trometamol | 190887 | 25206 | 40 |
| Caelo | Trometamol | 20002276 | 25640 | 40 |
| Caelo | Trometamol | 23000494 | 26709 | 40 |
| Caelo | Trometamol | 24000307 | 27260 | 40 |
| Euro OTC | Trometamol | 2303016 | 26650 | 40 |
| Fagron | Trometamol | 17A16-B04-334121 | 23516 | 40 |
| Fagron | Trometamol | 22I20-B05-225357 | 26465 | 40 |
| Fagron | Trometamol | 17A16-B04-334121 | 23517 | 40 |
| Fagron | Trometamol | 22I20-B05-225357 | 26465SI | 20 |

- 212 560 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1604 spectra from 816 *Apo-Ident* customers from 242 batches from the substance/substance group *Trometamol*.

- Among them are spectra of independent samples from 232 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Trometamol | | 1 |
| | Trometamol | 2100283014 | 1 |
| | Trometamol | 21002838011 | 3 |
| | Trometamol | 21002838014 | 5 |
| | Trometamol | 22000894006 | 1 |
| | Trometamol | 22002697006 | 10 |
| | Trometamol | 22002697016 | 9 |
| | Trometamol | 23000494005 | 27 |
| | Trometamol | 23000494007 | 4 |
| | Trometamol | 23001254008 | 6 |
| | Trometamol | 23001254010 | 3 |
| | Trometamol | 23003309002 | 8 |
| | Trometamol | 23003309005 | 5 |
| | Trometamol | 24000307003 | 7 |
| | Trometamol | 24002319006 | 3 |
| AHC | Trometamol | 2300154008 | 1 |
| AHD | Trometamol | 13095910 | 1 |
| AHD | Trometamol | 17320801 | 1 |
| AHD | Trometamol | 18197103 | 1 |
| Alliance Healthcare | Trometamol | 16168820 | 1 |
| Alliance Healthcare | Trometamol | 23003309005 | 1 |
| Alliance | Trometamol | 21002838005 | 1 |
| Alliance | Trometamol | 23003309022 | 1 |
| Anzag | Trometamol | 12113512 | 1 |
| ANZAG | Trometamol | 12113512 | 1 |
| Anzag | Trometamol | 13095911 | 1 |
| Bartschat | Trometamol | 190887007 | 1 |
| Bombastus | Trometamol | 17320811 | 1 |
| Bombastus | Trometamol | 18197103 | 1 |
| Caelo | Trometamol | | 6 |
| Caelo | Trometamol | 1001312519 | 1 |
| Caelo | Trometamol | 1018U-02519 | 1 |
| Caelo | Trometamol | 11160706 | 1 |
| Caelo | Trometamol | 11160707 | 1 |
| Caelo | Trometamol | 11160711 | 1 |
| Caelo | Trometamol | 11160714 | 2 |
| Caelo | Trometamol | 1119I-02519 | 1 |
| Caelo | Trometamol | 11376005 | 5 |
| Caelo | Trometamol | 11376006 | 8 |
| Caelo | Trometamol | 1180116 | 1 |
| Caelo | Trometamol | 12113502 | 3 |
| Caelo | Trometamol | 12113505 | 1 |
| Caelo | Trometamol | 12113506 | 9 |
| Caelo | Trometamol | 12113507 | 3 |
| Caelo | Trometamol | 12113510 | 2 |
| Caelo | Trometamol | 12113511 | 1 |
| Caelo | Trometamol | 12113512 | 10 |
| Caelo | Trometamol | 12113515 | 4 |
| Caelo | Trometamol | 13051401 | 1 |
| Caelo | Trometamol | 13095901 | 8 |
| Caelo | Trometamol | 13095902 | 12 |
| Caelo | Trometamol | 13095905 | 1 |
| Caelo | Trometamol | 13095910 | 5 |
| Caelo | Trometamol | 13095911 | 12 |
| Caelo | Trometamol | 13095912 | 14 |
| Caelo | Trometamol | 13095913 | 3 |
| Caelo | Trometamol | 13095915 | 4 |
| Caelo | Trometamol | 13339103 | 9 |
| Caelo | Trometamol | 13339107 | 8 |
| Caelo | Trometamol | 13339108 | 11 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Trometamol | 1339103 | 1 |
| Caelo | Trometamol | 13C-08-N07 | 1 |
| Caelo | Trometamol | 14050002 | 7 |
| Caelo | Trometamol | 14050003 | 2 |
| Caelo | Trometamol | 14050004 | 4 |
| Caelo | Trometamol | 14050006 | 1 |
| Caelo | Trometamol | 14332402 | 23 |
| Caelo | Trometamol | 14332403 | 1 |
| Caelo | Trometamol | 14332404 | 1 |
| Caelo | Trometamol | 14F19B03304293 | 1 |
| Caelo | Trometamol | 14F19-B03-304293 | 1 |
| Caelo | Trometamol | 150703 | 1 |
| Caelo | Trometamol | 15070304 | 10 |
| Caelo | Trometamol | 15070307 | 4 |
| Caelo | Trometamol | 15070308 | 29 |
| Caelo | Trometamol | 15070309 | 1 |
| Caelo | Trometamol | 15070311 | 27 |
| Caelo | Trometamol | 15094401 | 15 |
| Caelo | Trometamol | 15094404 | 1 |
| Caelo | Trometamol | 15277602 | 1 |
| Caelo | Trometamol | 15377602 | 25 |
| Caelo | Trometamol | 15377604 | 2 |
| Caelo | Trometamol | 15377605 | 1 |
| Caelo | Trometamol | 15377607 | 31 |
| Caelo | Trometamol | 15377611 | 29 |
| Caelo | Trometamol | 15377661 | 1 |
| Caelo | Trometamol | 161013T/15377607 | 1 |
| Caelo | Trometamol | 161668810 | 1 |
| Caelo | Trometamol | 16168801 | 1 |
| Caelo | Trometamol | 16168807 | 1 |
| Caelo | Trometamol | 16168810 | 40 |
| Caelo | Trometamol | 16168810-11417/3 | 1 |
| Caelo | Trometamol | 16168810-6417/1 | 1 |
| Caelo | Trometamol | 16168812 | 2 |
| Caelo | Trometamol | 16168816 | 2 |
| Caelo | Trometamol | 16168819 | 18 |
| Caelo | Trometamol | 16168820 | 27 |
| Caelo | Trometamol | 16168825 | 2 |
| Caelo | Trometamol | 1618810 | 2 |
| Caelo | Trometamol | 16D14-b-09-328729 | 1 |
| Caelo | Trometamol | 17020304 | 16 |
| Caelo | Trometamol | 17053184 | 1 |
| Caelo | Trometamol | 171978 | 1 |
| Caelo | Trometamol | 17197804 | 30 |
| Caelo | Trometamol | 17197806 | 3 |
| Caelo | Trometamol | 17197809 | 9 |
| Caelo | Trometamol | 1719804 | 1 |
| Caelo | Trometamol | 1730804 | 1 |
| Caelo | Trometamol | 173200816 | 1 |
| Caelo | Trometamol | 17320611 | 1 |
| Caelo | Trometamol | 17320801 | 41 |
| Caelo | Trometamol | 17320801/1160518 | 1 |
| Caelo | Trometamol | 17320802 | 2 |
| Caelo | Trometamol | 17320804 | 44 |
| Caelo | Trometamol | 17320810 | 2 |
| Caelo | Trometamol | 17320811 | 56 |
| Caelo | Trometamol | 17320816 | 33 |
| Caelo | Trometamol | 1732816 | 1 |
| Caelo | Trometamol | 17A16-B14 | 1 |
| Caelo | Trometamol | 18041815 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Trometamol | 18081503 | 1 |
| Caelo | Trometamol | 181016182 | 1 |
| Caelo | Trometamol | 18197101 | 14 |
| Caelo | Trometamol | 18197103 | 23 |
| Caelo | Trometamol | 18197109 | 27 |
| Caelo | Trometamol | 18197414 | 1 |
| Caelo | Trometamol | 1897103 | 1 |
| Caelo | Trometamol | 18A23-B10-347884 | 1 |
| Caelo | Trometamol | 18A23-B10-349673 | 1 |
| Caelo | Trometamol | 18H13-B04 | 1 |
| Caelo | Trometamol | 190502205 | 1 |
| Caelo | Trometamol | 190887006 | 2 |
| Caelo | Trometamol | 190887007 | 39 |
| Caelo | Trometamol | 190887009 | 1 |
| Caelo | Trometamol | 19088702 | 3 |
| Caelo | Trometamol | 19088705 | 40 |
| Caelo | Trometamol | 19088706 | 1 |
| Caelo | Trometamol | 19197103 | 1 |
| Caelo | Trometamol | 200002276005 | 1 |
| Caelo | Trometamol | 200004247003 | 1 |
| Caelo | Trometamol | 20002276003 | 1 |
| Caelo | Trometamol | 20002276004 | 1 |
| Caelo | Trometamol | 20002276005 | 34 |
| Caelo | Trometamol | 20002276006 | 28 |
| Caelo | Trometamol | 20002276009 | 1 |
| Caelo | Trometamol | 2000424016 | 1 |
| Caelo | Trometamol | 20004247002 | 1 |
| Caelo | Trometamol | 20004247003 | 18 |
| Caelo | Trometamol | 20004247004 | 1 |
| Caelo | Trometamol | 20004247010 | 3 |
| Caelo | Trometamol | 20004247012 | 1 |
| Caelo | Trometamol | 20004247016 | 20 |
| Caelo | Trometamol | 2002276005 | 1 |
| Caelo | Trometamol | 2002276006 | 1 |
| Caelo | Trometamol | 2004247016 | 1 |
| Caelo | Trometamol | 2100048001 | 1 |
| Caelo | Trometamol | 21000487001 | 49 |
| Caelo | Trometamol | 2100048701 | 1 |
| Caelo | Trometamol | 21002838005 | 20 |
| Caelo | Trometamol | 21002838009 | 1 |
| Caelo | Trometamol | 21002838011 | 10 |
| Caelo | Trometamol | 21002838013 | 1 |
| Caelo | Trometamol | 21002838014 | 3 |
| Caelo | Trometamol | 21082013A | 1 |
| Caelo | Trometamol | 213E-02519 | 1 |
| Caelo | Trometamol | 215I-02519 | 1 |
| Caelo | Trometamol | 22002697006 | 2 |
| Caelo | Trometamol | 22002697016 | 2 |
| Caelo | Trometamol | 23000494005 | 1 |
| Caelo | Trometamol | 23000494007 | 1 |
| Caelo | Trometamol | 23062015B | 1 |
| Caelo | Trometamol | 26111201 | 1 |
| Caelo | Trometamol | 27111304 | 1 |
| Caelo | Trometamol | 314Q2519 | 1 |
| Caelo | Trometamol | 318A-02519 | 1 |
| Caelo | Trometamol | 3308 | 1 |
| Caelo | Trometamol | 3439 | 1 |
| Caelo | Trometamol | 3713E-02519 | 1 |
| Caelo | Trometamol | 4616M-02519 | 1 |
| Caelo | Trometamol | 5012M-02519 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Trometamol | 5315I-02519 | 1 |
| Caelo | Trometamol | 8031301 | 1 |
| Caelo | Trometamol | 8721 | 1 |
| Caelo | Trometamol | 914I-02519 | 1 |
| Caeolo/Sanacorp | Trometamol | 18197101 | 1 |
| Caesar & Loretz / Sa... | Trometamol | 20002276005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 18197101 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 19088705 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838011 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 19088705 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 20002276005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21000487001 | 2 |
| Caesar & Loretz GmbH... | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 22002697016 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 19088705 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | E300003986 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 11160714 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 13095902 | 1 |
| Caesar & Loretz GmbH/ AHD | Trometamol | 18197108 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 20002276005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH/AHD | Trometamol | 20002276006 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 190887007 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 20002276005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21000487001 | 1 |
| Caesar & Loretz GmbH/Gehe | Trometamol | 190887007 | 1 |
| Caesar & Loretz GmbH/Gehe | Trometamol | 19088705 | 2 |
| Caesar & Loretz GmbH/Gehe | Trometamol | 20002276006 | 1 |
| Caesar & Loretz GmbH/Gehe | Trometamol | 20004247016 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21000487001 | 2 |
| Caesar & Loretz GmbH/Kehr | Trometamol | 18197103 | 1 |
| Caesar & Loretz GmbH/L50 | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 19088705 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21000487001 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838011 | 1 |
| Caesar & Loretz GmbH/Phoe | Trometamol | 190887006 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 190887007 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 20002276006 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21000487001 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21002838005 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 17320816 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 190887 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 20004247003 | 2 |
| Caesar & Loretz GmbH... | Trometamol | 21000487001 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 22002697006 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 18197103 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 18197103 | 1 |
| Caesar & Loretz GmbH... | Trometamol | 21000487001 | 1 |
| Caesar & Loretz GmbH | Trometamol | 14050003 | 1 |
| Caesar & Loretz GmbH | Trometamol | 17320811 | 1 |
| Caesar & Loretz GmbH | Trometamol | 18197101 | 2 |
| Caesar & Loretz GmbH | Trometamol | 18197103 | 3 |
| Caesar & Loretz GmbH | Trometamol | 18197109 | 6 |
| Caesar & Loretz GmbH | Trometamol | 190887006 | 3 |
| Caesar & Loretz GmbH | Trometamol | 190887007 | 17 |
| Caesar & Loretz GmbH | Trometamol | 19088702 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Trometamol | 19088705 | 11 |
| Caesar & Loretz GmbH | Trometamol | 20002276005 | 10 |
| Caesar & Loretz GmbH | Trometamol | 20002276006 | 4 |
| Caesar & Loretz GmbH | Trometamol | 20004247003 | 7 |
| Caesar & Loretz GmbH | Trometamol | 20004247010 | 2 |
| Caesar & Loretz GmbH | Trometamol | 20004247016 | 7 |
| Caesar & Loretz GmbH | Trometamol | 20005576005 | 1 |
| Caesar & Loretz GmbH | Trometamol | 21000487001 | 23 |
| Caesar & Loretz GmbH | Trometamol | 21002838005 | 10 |
| Caesar & Loretz GmbH | Trometamol | 21002838011 | 5 |
| Caesar & Loretz GmbH | Trometamol | 22002697016 | 1 |
| Caesar & Loretz/Geil... | Trometamol | 20004247003 | 1 |
| Caesar & Loretz/Phoenix | Trometamol | 21000487001 | 1 |
| Caesar & Loretz | Trometamol | 16168819 | 1 |
| Caesar & Loretz | Trometamol | 20002276005 | 1 |
| Caesar / Gehe | Trometamol | 15377607 | 1 |
| Caesar Loretz | Trometamol | 190887007 | 1 |
| Caesar&Loretz | Trometamol | 16168820 | 1 |
| Calo, Hilden/ Phönix | Trometamol | 18197109 | 1 |
| Caolo | Trometamol | 13095901 | 2 |
| Cealo/Anzag | Trometamol | 18197103 | 1 |
| Cealo | Trometamol | 2002276005 | 1 |
| Celo/Phönix | Trometamol | 16168810 | 1 |
| E300025088 | Trometamol | 21B15-F03-377086 | 2 |
| Euro OTC | Trometamol | 1203005-02 | 3 |
| Euro OTC | Trometamol | 15070308 | 1 |
| Euro OTC | Trometamol | 15377602 | 1 |
| Euro OTC | Trometamol | 15377611 | 2 |
| Euro OTC | Trometamol | 16168810 | 1 |
| Euro OTC | Trometamol | 17197809 | 2 |
| Euro OTC | Trometamol | 17320804 | 1 |
| Euro OTC | Trometamol | 17320816 | 1 |
| Euro OTC | Trometamol | 18197101 | 1 |
| Fa.Phönix | Trometamol | 21002838011 | 1 |
| Fagron | Trometamol | 10B26-N05 | 1 |
| Fagron | Trometamol | 12E25-B40 | 1 |
| Fagron | Trometamol | 12I27-N03 | 1 |
| Fagron | Trometamol | 12I27-No3 | 1 |
| Fagron | Trometamol | 12K14-N05 | 2 |
| Fagron | Trometamol | 12k14no5 | 1 |
| Fagron | Trometamol | 13/19-B02 | 1 |
| Fagron | Trometamol | 13/19-B02-286158 | 3 |
| Fagron | Trometamol | 13/19-B02-293595 | 3 |
| Fagron | Trometamol | 13119-B02 | 1 |
| Fagron | Trometamol | 13C08-N07 | 3 |
| Fagron | Trometamol | 13E22-N05 | 5 |
| Fagron | Trometamol | 13I19-B02 | 1 |
| Fagron | Trometamol | 13I19-B02-286158 | 1 |
| Fagron | Trometamol | 13I19-B02-293595 | 2 |
| Fagron | Trometamol | 13l19-B02-286158 | 1 |
| Fagron | Trometamol | 14F19-B03 | 1 |
| Fagron | Trometamol | 14F19-B03-304293 | 4 |
| Fagron | Trometamol | 16(18A23-B10-347884 | 1 |
| Fagron | Trometamol | 16D14-B09 | 1 |
| Fagron | Trometamol | 16d14-b09-328729 | 1 |
| Fagron | Trometamol | 16D14-B09-328729 | 2 |
| Fagron | Trometamol | 17320816 | 1 |
| Fagron | Trometamol | 17A16-B04 | 2 |
| Fagron | Trometamol | 17A16-B04-334121 | 4 |
| Fagron | Trometamol | 17A16-B04-337589 | 1 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Trometamol | 17A16-B04-340796 | 4 |
| Fagron | Trometamol | 17A16-B04-345550 | 1 |
| Fagron | Trometamol | 18A23-B10-347884 | 3 |
| Fagron | Trometamol | 18A23-B10-349673 | 5 |
| Fagron | Trometamol | 18A23-B10-351258 | 5 |
| Fagron | Trometamol | 18A-23-B10-351258 | 1 |
| Fagron | Trometamol | 18H13-B04-363961 | 3 |
| Fagron | Trometamol | 18H13-B04-363962 | 1 |
| Fagron | Trometamol | 18H13-B04-370289 | 4 |
| Fagron | Trometamol | 20H05-F06-373066 | 2 |
| Fagron | Trometamol | 20H05-F06-373351 | 2 |
| Fagron | Trometamol | 21E18-B03-215278 | 6 |
| Fagron | Trometamol | 21I30-B05 | 1 |
| Fagron | Trometamol | 21130-B05-213590 | 1 |
| Fagron | Trometamol | 220728(E300025088) | 1 |
| Fagron | Trometamol | 294101 | 1 |
| Fagron | Trometamol | 3377086 | 1 |
| Fagron | Trometamol | 610I-02519 | 1 |
| Fagron | Trometamol | 8386E050 | 1 |
| Fagron | Trometamol | 8386H037 | 1 |
| Fagron | Trometamol | 8386J009 | 2 |
| Fagron | Trometamol | 8386K059 | 1 |
| Fagron | Trometamol | E300003986 | 2 |
| Fagron | Trometamol | E300021548 | 3 |
| Fagron | Trometamol | E30021548 | 1 |
| Fagron | Trometamol | F06-3730607 | 1 |
| Fagron | Trometamol | TM284375698 | 1 |
| fargon/gehe | Trometamol | 17K23-B04-355709 | 1 |
| Fargon/Kehr | Trometamol | 17A16-B04-337589 | 1 |
| Fiebig | Trometamol | 16168825 | 1 |
| Fiebig | Trometamol | 17320804 | 1 |
| Gatt-Koller | Trometamol | 1801776 | 1 |
| Gatt-Koller | Trometamol | 1804167 | 1 |
| Gehe 04.11.21 EK:6,97EUR | Trometamol | 211105TR | 1 |
| Gehe/Fragron | Trometamol | 18A23-B10 | 1 |
| Gehe | Trometamol | 11025103 | 1 |
| Gehe | Trometamol | 11160708 | 1 |
| Gehe | Trometamol | 13E22-N05 | 1 |
| Gehe | Trometamol | 15070311 | 1 |
| Gehe | Trometamol | 15377611 | 1 |
| GEHE | Trometamol | 16168810 | 1 |
| Gehe | Trometamol | 17020304 | 1 |
| Gehe | Trometamol | 17A16-B04-345550 | 1 |
| Gehe | Trometamol | 1819701 | 1 |
| Gehe | Trometamol | 18197101 | 1 |
| GEHE | Trometamol | 18A23-B10 | 1 |
| Gehe | Trometamol | 190887007 | 1 |
| Gehe | Trometamol | 19088705 | 1 |
| Gehe | Trometamol | 21000487001 | 3 |
| Gehe | Trometamol | 21002838005 | 1 |
| Gehe | Trometamol | 22002697016 | 1 |
| Gehe | Trometamol | 23000494005 | 1 |
| Holdermann | Trometamol | 23000494005 | 1 |
| Jenne | Trometamol | 17320811 | 1 |
| Jenne | Trometamol | 23003309002 | 1 |
| Kehr | Trometamol | 23000494005 | 1 |
| Klenk | Trometamol | 13095902 | 2 |
| Krieger am 17.08.2018 | Trometamol | 17320801 | 1 |
| Merck | Trometamol | 8386F017 | 1 |
| Merck | Trometamol | E300000206913 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Midas | Trometamol | 17197804 | 1 |
| Nachprüfung | Trometamol | 3082019-2 | 1 |
| Noweda | Trometamol | 11376005 | 1 |
| Noweda | Trometamol | 18197101 | 1 |
| Noweda | Trometamol | 19088705 | 1 |
| Noweda | Trometamol | 21002838011 | 1 |
| Noweda | Trometamol | 22002697006 | 1 |
| Noweda | Trometamol | 22002697016 | 2 |
| Noweda | Trometamol | 23000494005 | 1 |
| Noweda | Trometamol | 23001254008 | 1 |
| Noweda | Trometamol | 23001254010 | 2 |
| Phoenix Hannover | Trometamol | 20002276006 | 1 |
| Phoenix/Cealo | Trometamol | 16168825 | 1 |
| Phoenix | Trometamol | 16168819 | 1 |
| Phoenix | Trometamol | 17197804 | 1 |
| Phoenix | Trometamol | 17320804 | 1 |
| Phoenix | Trometamol | 18197109 | 1 |
| Phoenix | Trometamol | 23000494005 | 1 |
| Phoenix | Trometamol | 3039 | 1 |
| Phoenix | Trometamol | 3114 | 1 |
| Phoenix | Trometamol | 3218 | 1 |
| Phoenix | Trometamol | 3409 | 1 |
| Phönix Gotha | Trometamol | 13/19-B02-286158 | 1 |
| Phönix Gotha | Trometamol | 1319-B02-286158 | 1 |
| Phönix | Trometamol | 12113512 | 1 |
| Phönix | Trometamol | 13095912 | 2 |
| Phönix | Trometamol | 14332402 | 1 |
| Phönix | Trometamol | 16168819 | 1 |
| phönix | Trometamol | 17197804 | 1 |
| Phönix | Trometamol | 17197804 | 1 |
| Phönix | Trometamol | 17320804 | 2 |
| Phönix | Trometamol | 17320816 | 1 |
| Phönix | Trometamol | 20002276005 | 1 |
| PHÖNIX | Trometamol | 20004247003 | 1 |
| phönix | Trometamol | 21002838005 | 1 |
| Phönix | Trometamol | 23000494005 | 1 |
| Phönix | Trometamol | 23000494007 | 1 |
| Post Apotheke | Trometamol | 18197101 | 1 |
| Röntgen | Trometamol | 17320801 | 1 |
| Sanacorp | Trometamol | 12113506 | 1 |
| Sanacorp | Trometamol | 13095912 | 1 |
| Sanacorp | Trometamol | 15377602 | 1 |
| Sanacorp | Trometamol | 16168820 | 1 |
| Sanacorp | Trometamol | 17197809 | 1 |
| Sanacorp | Trometamol | 17320804 | 1 |
| Sanacorp | Trometamol | 18197103 | 1 |
| Sanacorp | Trometamol | 21000487001 | 3 |
| Sanacorp | Trometamol | 22002697006 | 2 |
| Sanacorp | Trometamol | 22002697010 | 1 |
| Sanacorp | Trometamol | 23000494005 | 1 |
| Sanacorp | Trometamol | 3686G018 | 1 |
| Sanacorp | Trometamol | 8386H037 | 1 |
| SanacorpWE: 21.05.16... | Trometamol | 15070311 | 2 |
| Spangro 25.02.2019 | Trometamol | 18197101 | 1 |
| vwr chemicals | Trometamol | E300027934 | 1 |

- 255 282 spectra from 1666 *Apo-Ident* customers from a total of 51 914 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,


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the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Trometamol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Trometamol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 400 | 0 | 157 926 |
| **Type B** | 0 | 380 | 0 | 212 560 |
| **Type C** | 0 | 1604 | 0 | 255 282 |

The substance/substance group *Trometamol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.5000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.4211 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 99.6259 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20856 | 20856 | 0.00 | 232.29 |
| 21358 | 26112 | 6.01 | 211.45 |
| 22629 | 22629 | 0.00 | 216.20 |
| 23498 | 22629 | 10.77 | 236.66 |
| 24063 | 24063 | 0.00 | 224.41 |
| 24816 | 22629 | 9.85 | 222.24 |
| 26112 | 26112 | 0.00 | 213.40 |
| 26360 | 26360 | 0.00 | 206.13 |
| 26972 | 26972 | 0.00 | 244.46 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by

laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tropicamide** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20598-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tropicamide; Tropicamidum

### Special notes

When selecting the *Tropicamide* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tropicamide | 6 | 8 | 49 |

### Second-stage model

For differentiation of the substance/substance group *Tropicamide* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tropicamide* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 130.66 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tropicamide* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tropicamide*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Tropicamide | 2001016 | 25299 | 40 | 20200807* |
| Euro OTC | Tropicamide | 2106001 | 25709 | 50 | 20210720* |
| Fagron | Tropicamide | 14D23-B04-293294 | 21685 | 60 | AR-15-FG-001641-01 |
| Fagron | Tropicamide | 16G19-B05-324829 | 22885 | 40 | 20160905 |
| Fagron | Tropicamide | 17J06-B04-341322 | 23982 | 40 | 1807428 |
| Fagron | Tropicamide | 21A11-F03-376917 | 25665 | 50 | 20210120 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 280 spectra of 6 reference samples from the substance/substance group *Tropicamide*. These

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 046 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 420 spectra of 12 reference samples from the substance/substance group *Tropicamide*.
- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Audor Pharma | Tropicamide | APFP/TD003/09/17/TR | 23983 | 40 |
| Euro OTC | Tropicamide | 2203001 | 26043 | 40 |
| Euro OTC | Tropicamide | 2204015 | 26223 | 40 |
| Euro OTC | Tropicamide | 2402034 | 27209 | 40 |
| Euro OTC | Tropicamide | 2309014 | 27213 | 40 |
| Fagron | Tropicamide | 17D25-B07-336833 | 23506 | 40 |
| Fagron | Tropicamide | 18H14-B06-362792 | 25367 | 40 |
| Fagron | Tropicamide | 24J17-B03-008553 | 27636 | 40 |
| Euro OTC | Tropicamide | 2106001 | 25709SI† | 10 |
| Euro OTC | Tropicamide | 2203001 | 26043SI | 40 |
| Euro OTC | Tropicamide | 2204015 | 26223SI | 40 |
| Fagron | Tropicamide | 21A11-F03-376917 | 25665SI† | 10 |

- 212 520 spectra from a total of 4277 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 119 spectra from 30 *Apo-Ident* customers from 51 batches from the substance/substance group *Tropicamide*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 49 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Tropicamide | 22D14-B02-220415 | 1 |
| | Tropicamide | 22L08-B03-222105 | 1 |
| ALH | Tropicamide | 15F18-B04-310971 | 1 |
| Caelo | Tropicamide | 17J06-B04-348766 | 1 |
| Euro OTC | Tropicamide | 2001016-01 | 1 |
| Euro OTC | Tropicamide | 2106001-01 | 2 |
| Fagron | Tropicamide | 1/06/2000 | 1 |
| Fagron | Tropicamide | 12F18-N06 | 4 |
| Fagron | Tropicamide | 12l04-n03 | 1 |
| Fagron | Tropicamide | 14D23B04293294 | 1 |
| Fagron | Tropicamide | 14l04-b02-315694 | 1 |
| Fagron | Tropicamide | 14L04B02315694 | 1 |
| Fagron | Tropicamide | 14L04-B02-315694 | 2 |
| Fagron | Tropicamide | 15F18-B04 | 1 |
| Fagron | Tropicamide | 15F18-B04-308977 | 1 |
| Fagron | Tropicamide | 15F18B04312001 | 1 |
| Fagron | Tropicamide | 15F18-B04-312001 | 1 |
| Fagron | Tropicamide | 17D25-B07-336833 | 6 |
| Fagron | Tropicamide | 17J06-B04 | 2 |
| Fagron | Tropicamide | 17J06-B04-341323 | 5 |
| Fagron | Tropicamide | 17J06-B04-343279 | 2 |
| Fagron | Tropicamide | 17J06-B04-348766 | 4 |
| Fagron | Tropicamide | 17J06-B04-352344 | 2 |
| Fagron | Tropicamide | 17J06-B04-354804 | 3 |
| Fagron | Tropicamide | 18H014-B06-357220 | 1 |
| Fagron | Tropicamide | 18H14-B06 | 1 |
| Fagron | Tropicamide | 18H14-B06-357220 | 5 |
| Fagron | Tropicamide | 18H14-B06-359927 | 6 |
| Fagron | Tropicamide | 18H14-B06-362475 | 3 |
| Fagron | Tropicamide | 18H14-B06-362476 | 8 |
| Fagron | Tropicamide | 18H14-B06-362792 | 1 |
| Fagron | Tropicamide | 18H14-B06-362794 | 7 |
| Fagron | Tropicamide | 18H14-B06-362796 | 1 |
| Fagron | Tropicamide | 18H14-B06-363716 | 1 |
| Fagron | Tropicamide | 18H14-B06-369986 | 1 |
| Fagron | Tropicamide | 2/05/1008 | 1 |
| Fagron | Tropicamide | 20021302 | 1 |
| Fagron | Tropicamide | 20C06F03-3699807 | 1 |
| Fagron | Tropicamide | 20C06-F03-369987 | 3 |
| Fagron | Tropicamide | 20C06-F03-371990 | 2 |
| Fagron | Tropicamide | 21H13-B17-213648 | 2 |
| Fagron | Tropicamide | 21H13-B17-216490 | 6 |
| Fagron | Tropicamide | 21J15-B04-216491 | 2 |
| Fagron | Tropicamide | 23071508 | 1 |
| Fagron | Tropicamide | B06-3627902 | 2 |
| Fagron | Tropicamide | B06-3627904 | 1 |
| Fagron | Tropicamide | B06-362794 | 1 |
| Fagron | Tropicamide | F03-3699807 | 2 |
| Fagron | Tropicamide | FP/TD/003/09/17 | 1 |
| Gehe | Tropicamide | 15F18-B04 | 1 |
| Gehe | Tropicamide | 15F-18B-04 | 1 |
| GEHE | Tropicamide | 17J06-B04 | 5 |
| GEHE | Tropicamide | 18H14-B06 | 2 |
| Phoenix | Tropicamide | 14L04-B02 | 2 |
| PHÖNIX | Tropicamide | 16G19-B05-324829 | 1 |


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- 256 767 spectra from 1666 *Apo-Ident* customers from a total of 52 102 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tropicamide* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tropicamide* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 280 | 0 | 158 046 |
| **Type B** | 0 | 420 | 0 | 212 520 |
| **Type C** | 0 | 118 | 1 | 256 767 |

The substance/substance group *Tropicamide* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.8571 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.5714 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.1597 % (> 96.6387 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21685 | 21685 | 0.00 | 144.41 |
| 22885 | 23982 | 11.32 | 147.58 |
| 23982 | 23982 | 0.00 | 145.79 |
| 25299 | 25299 | 0.00 | 143.43 |
| 25665 | 25709 | 5.20 | 140.24 |
| 25709 | 25709 | 0.00 | 141.71 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all

substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tryptophan** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20336-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tryptophan; Tryptophanum

### Special notes

When selecting the *Tryptophan* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tryptophan | 7 | 7 | 11 |

### Second-stage model

For differentiation of the substance/substance group *Tryptophan* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tryptophan* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Polymyxin B sulfate | 194.92 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tryptophan* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tryptophan*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Tryptophan | 1506003 | 21866 | 60 | 20150630* |
| Euro OTC | Tryptophan | 1506003 | 21871 | 60 | 20150630* |
| Euro OTC | Tryptophan | 1712006 | 23876 | 40 | 20180105* |
| Euro OTC | Tryptophan | 1910016 | 24972 | 40 | 20191106* |
| Euro OTC | Tryptophan | 2004025 | 25259 | 40 | 20200720* |
| Euro OTC | Tryptophan | 2203027 | 26051 | 40 | 20220413* |
| Fagron | Tryptophan | 14B05-B32-293485 | 21784 | 60 | AR-15-FG-009473-01 |
| Fagron | Tryptophan | 17G19-B01-343931 | 23998 | 40 | 20170919 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 380 spectra of 8 reference samples from the substance/substance group *Tryptophan*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 946 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 320 spectra of 10 reference samples from the substance/substance group *Tryptophan*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Tryptophan | 1806006 | 24144 | 40 |
| Euro OTC | Tryptophan | 1812002 | 24426 | 40 |
| Euro OTC | Tryptophan | 1906018 | 24795 | 40 |
| Euro OTC | Tryptophan | 2009041 | 25421 | 40 |
| Euro OTC | Tryptophan | 2302015 | 26638 | 40 |
| Euro OTC | Tryptophan | 2401010 | 27148 | 30 |
| Fagron | Tryptophan | 16E11-B03-322919 | 23195 | 40 |
| Euro OTC | Tryptophan | 2203027 | 26051SI† | 10 |
| Euro OTC | Tryptophan | 2302015 | 26638SI | 20 |
| Euro OTC | Tryptophan | 2401010 | 27148SI | 20 |

- 212 620 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 17 spectra from 5 *Apo-Ident* customers from 11 batches from the substance/substance group *Tryptophan*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- Among them are spectra of independent samples from 11 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tryptophan | 131046 | 1 |
| Euro OTC | Tryptophan | 1307004-01 | 2 |
| Euro OTC | Tryptophan | 150600302 | 1 |
| Euro OTC | Tryptophan | 1506003-03 | 2 |
| Euro OTC | Tryptophan | 1712006-01 | 1 |
| Euro OTC | Tryptophan | 180600601 | 1 |
| Euro OTC | Tryptophan | 190601801 | 1 |
| Euro OTC | Tryptophan | 2000402501 | 1 |
| Euro OTC | Tryptophan | 2004025-01 | 1 |
| Euro OTC | Tryptophan | 2203027-01 | 1 |
| euroct/gehe | Tryptophan | 1212010-01 | 5 |

- 256 869 spectra from 1666 *Apo-Ident* customers from a total of 52 142 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tryptophan* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tryptophan* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 380 | 0 | 157 946 |
| **Type B** | 0 | 320 | 0 | 212 620 |
| **Type C** | 0 | 17 | 0 | 256 869 |

The substance/substance group *Tryptophan* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.4211 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.1250 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21784 | 21784 | 0.00 | 335.27 |
| 21866 | 21866 | 0.00 | 335.17 |
| 21871 | 21871 | 0.00 | 333.97 |
| 23876 | 23876 | 0.00 | 335.60 |
| 23998 | 24972 | 4.65 | 337.47 |
| 24972 | 24972 | 0.00 | 335.71 |
| 25259 | 25259 | 0.00 | 332.27 |
| 26051 | 26051 | 0.00 | 330.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tyrosine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21574-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tyrosine; Tyrosinum

### Special notes

When selecting the *Tyrosine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tyrosine | 6 | 3 | 5 |

### Second-stage model

For differentiation of the substance/substance group *Tyrosine* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tyrosine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 108.18 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tyrosine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tyrosine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Tyrosine | 2204019 | 26095 | 40 | 20220519* |
| Euro OTC | Tyrosine | 2204019 | 26095SI | 20 | 20220519* |
| Fagron | Tyrosine | 13G24-N22 | 21574 | 60 | 1411030 |
| Fagron | Tyrosine | 16B26-B01-322911 | 23533 | 40 | 20160324 |
| Fagron | Tyrosine | 18E15-B02-359934 | 24692 | 40 | 20181001 |
| Fagron | Tyrosine | 22B07-B15-221081 | 26166 | 40 | 20220602 |
| Fagron | Tyrosine | 22B07-B15-221081 | 26166SI | 20 | 20220602 |
| Fagron | Tyrosine | 22H12-B03-222150 | 26388 | 40 | 20220927 |
| Fagron | Tyrosine | 22H12-B03-222150 | 26388SI | 20 | 20220927 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 320 spectra of 9 reference samples from the substance/substance group *Tyrosine*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 130 spectra of 3 reference samples from the substance/substance group *Tyrosine*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Tyrosine | 17B06-B03-338139 | 24008 | 40 |
| Fagron | Tyrosine | 19I20-F02-365384 | 25749 | 50 |
| Fagron | Tyrosine | 23B21-B03-227898 | 27024 | 40 |

- 212 810 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 5 spectra from 4 *Apo-Ident* customers from 5 batches from the substance/substance group *Tyrosine*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Tyrosine | 2204019-01 | 1 |
| Euro OTC | Tyrosine | L1210050-01 | 1 |
| Euro OTC | Tyrosine | L1401037 | 1 |
| Euro OTC | Tyrosine | L1506022-02 | 1 |
| Euro OTC | Tyrosine | L1506022-05 | 1 |

- 256 881 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tyrosine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tyrosine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 130 | 0 | 212 810 |
| **Type C** | 0 | 5 | 0 | 256 881 |

The substance/substance group *Tyrosine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.3846 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21574 | 21574 | 0.00 | 198.88 |
| 23533 | 26095 | 8.08 | 205.41 |
| 24692 | 26095 | 13.61 | 208.78 |
| 26095 | 26095 | 0.00 | 206.58 |
| 26166 | 26095 | 14.99 | 210.24 |
| 26388 | 26095 | 15.00 | 209.63 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at


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least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Tyrothricin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20732-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Tyrothricin; Tyrothricinum

### Special notes

When selecting the *Tyrothricin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Tyrothricin | 3 | 2 | 16 |

### Second-stage model

For differentiation of the substance/substance group *Tyrothricin* the following second-stage model is used:

- Submodel 02

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Tyrothricin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Gramicidin | 56.46 | 49.09 |
| ⋮ | ⋮ | ⋮ |
| Methylprednisolone | >50 | 71.34 |
| Fluocinolone acetonide | >50 | 85.25 |
| Betamethasone | >50 | 98.74 |
| Triamcinolone acetonide | >50 | 105.21 |
| Prednisolone | >50 | 111.50 |
| Dexamethasone | >50 | 131.65 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Tyrothricin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Tyrothricin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Tyrothricin | 12K14-N01 | 20732 | 40 | 1509178 |
| Fagron | Tyrothricin | 12K14-N01 | 21683 | 60 | AR-15-FG-001172-01 |
| Fagron | Tyrothricin | 14A23-B05-294146 | 21876 | 60 | AR-15-FG-015005-01 |
| Fagron | Tyrothricin | 19C05-B01-370262 | 25183 | 40 | 20200511 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.


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- 200 spectra of 4 reference samples from the substance/substance group *Tyrothricin*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

- 158 126 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 90 spectra of 3 reference samples from the substance/substance group *Tyrothricin*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Tyrothricin | 17E09-B03-341231 | 23742 | 40 |
| Fagron | Tyrothricin | 20L15-F03-376267 | 26066 | 40 |
| Fagron | Tyrothricin | 20L15-F03-376267 | 26066SI | 10 |

- 212 850 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 30 spectra from 21 *Apo-Ident* customers from 18 batches from the substance/substance group *Tyrothricin*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tyrothricin | 13A14-N04 | 1 |
| Fagron | Tyrothricin | 15A06-B02-3005 | 1 |
| Fagron | Tyrothricin | 15A06-B02-303893 | 1 |
| Fagron | Tyrothricin | 15a06-B02-323005 | 1 |
| Fagron | Tyrothricin | 15A06-B02-323005 | 5 |
| Fagron | Tyrothricin | 17E09-B03 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Tyrothricin | 17E09-B03-341231 | 2 |
| Fagron | Tyrothricin | 17E09-B03-350209 | 1 |
| Fagron | Tyrothricin | 17E09-B03-351982 | 1 |
| Fagron | Tyrothricin | 17E09B03352743 | 1 |
| Fagron | Tyrothricin | 17E09-B03-352743 | 5 |
| Fagron | Tyrothricin | 17E09-B03-355400 | 1 |
| Fagron | Tyrothricin | 19C05-B01370262 | 1 |
| Fagron | Tyrothricin | 19C05-B01-370262 | 1 |
| Fagron | Tyrothricin | 19C05-B01-370998 | 3 |
| Fagron | Tyrothricin | B2500226 | 2 |
| Parthe Apotheke | Tyrothricin | 171/19 | 1 |
| Sanacorp | Tyrothricin | 20L15-F03-376267 | 1 |

- 256 856 spectra from 1666 *Apo-Ident* customers from a total of 52 135 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Tyrothricin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Tyrothricin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 90 | 0 | 212 850 |
| **Type C** | 0 | 30 | 0 | 256 856 |

The substance/substance group *Tyrothricin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 93.3333 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 80.0000 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20732 | 20732 | 0.00 | 96.07 |
| 21683 | 21683 | 0.00 | 97.26 |
| 21876 | 21876 | 0.00 | 91.11 |
| 25183 | 21876 | 13.21 | 92.30 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ubidecarenone** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20392-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ubidecarenone; Ubidecarenonum

### Special notes

When selecting the *Ubidecarenone* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ubidecarenone | 11 | 16 | 35 |

### Second-stage model

For differentiation of the substance/substance group *Ubidecarenone* the following second-stage model is used:

- Submodel 05

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ubidecarenone* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 85.35 | – |
| ⋮ | ⋮ | ⋮ |
| Progesterone | >50 | 101.27 |
| Fusidic acid | >50 | 102.09 |
| Spironolactone | >50 | 118.18 |
| Povidone iodine | >50 | 134.09 |
| Testosterone propionate | >50 | 140.43 |
| Povidone | >50 | 191.63 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ubidecarenone* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ubidecarenone*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Ubidecarenone | 14004504 | 21388 | 60 | AR-15-FG-009220-01 |
| Caelo | Ubidecarenone | 17209402 | 23580 | 40 | 20170823 |
| Caelo | Ubidecarenone | 17209402 | 23581 | 40 | 20170823 |
| Caelo | Ubidecarenone | 172094 | 23647 | 35 | 20170823* |
| Euro OTC | Ubidecarenone | 1205029-01 | 21247 | 40 | 20121009 |
| Euro OTC | Ubidecarenone | 1605030 | 22696 | 40 | 20160623* |
| Euro OTC | Ubidecarenone | 1703026 | 23127 | 40 | 20170406* |
| Euro OTC | Ubidecarenone | 1801019 | 23881 | 40 | 20180126* |
| Euro OTC | Ubidecarenone | 2004036 | 25282 | 40 | 20200618* |
| Euro OTC | Ubidecarenone | 2010017 | 25544 | 40 | 20210108* |
| Fagron | Ubidecarenone | 16G26-B01-331742 | 23161 | 40 | 20170110 |
| Fagron | Ubidecarenone | 18J24-B01-357225 | 24688 | 40 | 20181121 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 495 spectra of 12 reference samples from the substance/substance group *Ubidecarenone*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 831 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 720 spectra of 21 reference samples from the substance/substance group *Ubidecarenone*.

- Among them are spectra of independent samples from 16 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Ubidecarenone | 182298 | 24281 | 40 |
| Caelo | Ubidecarenone | 21002685002 | 25975 | 40 |
| Caelo | Ubidecarenone | 22002474 | 26351 | 40 |
| Euro OTC | Ubidecarenone | 1802025 | 24074 | 40 |
| Euro OTC | Ubidecarenone | 1804020 | 24116 | 40 |
| Euro OTC | Ubidecarenone | 1810012 | 24305 | 40 |
| Euro OTC | Ubidecarenone | 1902030 | 24630 | 40 |
| Euro OTC | Ubidecarenone | 2003002 | 25142 | 40 |
| Euro OTC | Ubidecarenone | 2101025 | 25541 | 40 |
| Euro OTC | Ubidecarenone | 2110011 | 25894 | 50 |
| Euro OTC | Ubidecarenone | 2205006 | 26191 | 40 |
| Euro OTC | Ubidecarenone | 2303015 | 26642 | 40 |
| Euro OTC | Ubidecarenone | 2402030 | 27215 | 40 |
| Euro OTC | Ubidecarenone | 2410012 | 27460 | 40 |
| Fagron | Ubidecarenone | 21K09-B08-215716 | 26075 | 40 |
| Fagron | Ubidecarenone | 23H07-B02-223783 | 27035 | 40 |
| Caelo | Ubidecarenone | 21002685002 | 25975SI | 10 |
| Caelo | Ubidecarenone | 22002474 | 26351SI | 20 |
| Euro OTC | Ubidecarenone | 2110011 | 25894SI | 10 |
| Euro OTC | Ubidecarenone | 2205006 | 26191SI | 20 |
| Fagron | Ubidecarenone | 21K09-B08-215716 | 26075SI | 10 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 220 spectra from a total of 4271 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 53 spectra from 19 *Apo-Ident* customers from 36 batches from the substance/substance group *Ubidecarenone*.

- Among them are spectra of independent samples from 35 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Ubidecarenone | 2101025-03 | 1 |
| Audor Pharma | Ubidecarenone | APSCFQ150614C | 1 |
| Audor Pharma | Ubidecarenone | APSZFQ150614C | 1 |
| Audor Pharma | Ubidecarenone | APSZFQ170617C | 1 |
| Caelo | Ubidecarenone | 18048401 | 1 |
| Caelo | Ubidecarenone | 22002474001 | 1 |
| Caelo | Ubidecarenone | 22002474002 | 1 |
| Caesar & Loretz GmbH | Ubidecarenone | 20003319001 | 1 |
| Dr. Behr | Ubidecarenone | WE18020018 | 1 |
| Euro OTC | Ubidecarenone | 1014E-07029 | 1 |
| Euro OTC | Ubidecarenone | 1403020-02 | 1 |
| Euro OTC | Ubidecarenone | 1515M-07029 | 1 |
| Euro OTC | Ubidecarenone | 1605030-01 | 3 |
| Euro OTC | Ubidecarenone | 1801019-01 | 1 |
| Euro OTC | Ubidecarenone | 1802025-01 | 4 |
| Euro OTC | Ubidecarenone | 1804020-01 | 1 |
| Euro OTC | Ubidecarenone | 1810012-01 | 2 |
| Euro OTC | Ubidecarenone | 1902030-01 | 3 |
| Euro OTC | Ubidecarenone | 1902030-02 | 3 |
| Euro OTC | Ubidecarenone | 2101025-03 | 1 |
| Euro OTC | Ubidecarenone | 2110011-01 | 1 |
| Euro OTC | Ubidecarenone | 2205006-01 | 2 |
| Euro OTC | Ubidecarenone | L1403020-01 | 1 |
| Fagron | Ubidecarenone | 14E12-B06-293861 | 1 |
| Fagron | Ubidecarenone | 14H26-B04-298244 | 1 |
| Fagron | Ubidecarenone | 16B10-B05-327606 | 1 |
| Fagron | Ubidecarenone | 16G26-B01 | 3 |
| Fagron | Ubidecarenone | 16G26-B01-344334 | 2 |
| Fagron | Ubidecarenone | 18A16-B03 | 2 |
| Fagron | Ubidecarenone | 18a16-b03-351350 | 1 |
| Fagron | Ubidecarenone | 18A16-B03-351350 | 1 |
| Fagron | Ubidecarenone | 18J24-B01 | 1 |
| Fagron | Ubidecarenone | 21K09-B08-215716 | 2 |
| Fragon | Ubidecarenone | 18J24-B01-362124 | 1 |
| Sanacorp | Ubidecarenone | 2004036-02 | 1 |
| Sanacorp | Ubidecarenone | 2101025-01 | 1 |
| Sanacorp | Ubidecarenone | 51-1911123 | 1 |

- 256 833 spectra from 1666 *Apo-Ident* customers from a total of 52 118 batches from a further


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724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ubidecarenone* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ubidecarenone* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 495 | 0 | 157 831 |
| **Type B** | 0 | 720 | 0 | 212 220 |
| **Type C** | 0 | 51 | 2 | 256 833 |

The substance/substance group *Ubidecarenone* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7879 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.1667 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 96.2264 % (> 90.5660 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21247 | 21388 | 6.25 | 133.69 |
| 21388 | 21388 | 0.00 | 134.17 |
| 22696 | 22696 | 0.00 | 137.81 |
| 23127 | 23127 | 0.00 | 135.41 |
| 23161 | 23127 | 2.26 | 134.13 |
| 23580 | 22696 | 4.73 | 131.39 |
| 23581 | 21388 | 4.90 | 131.81 |
| 23647 | 23647 | 0.00 | 134.62 |
| 23881 | 23881 | 0.00 | 136.67 |
| 24688 | 23881 | 5.66 | 134.69 |
| 25282 | 25282 | 0.00 | 136.62 |
| 25544 | 25544 | 0.00 | 136.51 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Urea** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20017-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Urea; Ureum

### Special notes

When selecting the *Urea* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Urea | 11 | 18 | 645 |

### Second-stage model

For differentiation of the substance/substance group *Urea* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Urea* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 117.49 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Urea* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Urea*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Urea | 15154103 | 22315 | 60 | 20150722 |
| Caelo | Urea | 15154103 | 22315SI | 60 | 20150722 |
| Caelo | Urea | 161074 | 22466 | 60 | 20160509* |
| Caelo | Urea | 170216 | 23033 | 40 | 20170202* |
| Caelo | Urea | 18023003 | 24294 | 40 | 20180216 |
| Euro OTC | Urea | 1404024-01 | 21537 | 60 | 20140519 |
| Euro OTC | Urea | 1601044 | 22376 | 40 | 20160208* |
| Euro OTC | Urea | 1604044 | 22552 | 40 | 20160512* |
| Euro OTC | Urea | 2102002 | 25549 | 40 | 20210205* |
| Euro OTC | Urea | 2301020 | 26518 | 40 | 20230125* |
| Euro OTC | Urea | 2301020 | 26518SI | 40 | 20230125* |
| Fagron | Urea | 12F25-N05 | 20712 | 40 | 20120724 |
| Fagron | Urea | 14I18-B03-303581 | 22317 | 60 | 20141003 |
| Fagron | Urea | 14I18-B03-303581 | 22317SI | 60 | 20141003 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 680 spectra of 14 reference samples from the substance/substance group *Urea*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 646 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 1340 spectra of 33 reference samples from the substance/substance group *Urea*.

- Among them are spectra of independent samples from 18 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Urea | 180242 | 24042 | 40 |
| Caelo | Urea | 180230 | 24043 | 40 |
| Caelo | Urea | 190316 | 24550 | 40 |
| Caelo | Urea | 21002313009 | 25930 | 40 |
| Caelo | Urea | 22002605 | 26355 | 40 |
| Caelo | Urea | 23001146 | 26892 | 40 |
| Caelo | Urea | 24001776 | 27330 | 40 |
| Euro OTC | Urea | 1702023 | 23156 | 40 |
| Euro OTC | Urea | 1707015 | 23535 | 40 |
| Euro OTC | Urea | 1804007 | 24078 | 40 |
| Euro OTC | Urea | 1811012 | 24340 | 40 |
| Euro OTC | Urea | 1908016 | 24865 | 40 |
| Euro OTC | Urea | 2004010 | 25143 | 40 |
| Euro OTC | Urea | 2109001 | 25829 | 50 |
| Euro OTC | Urea | 2205037 | 26198 | 40 |
| Euro OTC | Urea | 2309011 | 26923 | 40 |
| Fagron | Urea | 21L08-B04-219541 | 26165 | 40 |
| Fagron | Urea | 23C21-B01-228852 | 27173 | 40 |
| Caelo | Urea | 170216 | 23033SI† | 40 |
| Caelo | Urea | 18023003 | 24294SI† | 40 |
| Caelo | Urea | 21002313009 | 25930SI | 40 |
| Caelo | Urea | 22002605 | 26355SI | 40 |
| Caelo | Urea | 23001146 | 26892SI | 40 |
| Caelo | Urea | 24001776 | 27330SI | 40 |
| Euro OTC | Urea | 1604044 | 22552SI† | 40 |
| Euro OTC | Urea | 1702023 | 23156SI | 40 |
| Euro OTC | Urea | 1804007 | 24078SI | 40 |
| Euro OTC | Urea | 1811012 | 24340SI | 40 |
| Euro OTC | Urea | 2109001 | 25829SI | 50 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Urea | 2205037 | 26198SI | 40 |
| Euro OTC | Urea | 2309011 | 26923SI | 40 |
| Fagron | Urea | 21L08-B04-219541 | 26165SI | 40 |
| Fagron | Urea | 23C21-B01-228852 | 27173SI | 40 |

- 211 600 spectra from a total of 4266 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 7238 spectra from 1473 *Apo-Ident* customers from 663 batches from the substance/substance group *Urea*.
- Among them are spectra of independent samples from 642 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Urea | | 3 |
| | Urea | 12111808 | 1 |
| | Urea | 1234 | 2 |
| | Urea | 12345 | 2 |
| | Urea | 181023/2 | 1 |
| | Urea | 20003817006 | 1 |
| | Urea | 20003817013 | 2 |
| | Urea | 20309011-01 | 1 |
| | Urea | 210002313015 | 1 |
| | Urea | 21002313006 | 1 |
| | Urea | 21002313009 | 1 |
| | Urea | 21002313014 | 2 |
| | Urea | 21002313015 | 3 |
| | Urea | 21002313016 | 1 |
| | Urea | 21002313017 | 5 |
| | Urea | 2109001-01 | 2 |
| | Urea | 213456 | 1 |
| | Urea | 21L08-B04-219541 | 1 |
| | Urea | 22002605001 | 18 |
| | Urea | 22002605003 | 17 |
| | Urea | 22002605005 | 6 |
| | Urea | 22002605008 | 3 |
| | Urea | 22002605009 | 34 |
| | Urea | 22002605010 | 36 |
| | Urea | 22002605011 | 1 |
| | Urea | 2200265001 | 1 |
| | Urea | 2200265009 | 1 |
| | Urea | 2200605009 | 1 |
| | Urea | 2205037 | 1 |
| | Urea | 2205037-01 | 17 |
| | Urea | 2205037-02 | 4 |

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[†]These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.


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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Urea | 22H29-B03-223929 | 1 |
| | Urea | 22L02-B12-226179 | 4 |
| | Urea | 22L02-B12-226180 | 1 |
| | Urea | 23001146001 | 52 |
| | Urea | 23001146002 | 49 |
| | Urea | 2300114600226/24P | 1 |
| | Urea | 23001146003 | 10 |
| | Urea | 2300146003 | 1 |
| | Urea | 23003219003 | 2 |
| | Urea | 23003219004 | 19 |
| | Urea | 23003219005 | 14 |
| | Urea | 23003219007 | 9 |
| | Urea | 23003219009 | 6 |
| | Urea | 23003219010 | 26 |
| | Urea | 23003219011 | 6 |
| | Urea | 23003219012 | 10 |
| | Urea | 23003219013 | 2 |
| | Urea | 2301020-01 | 8 |
| | Urea | 2301020-02 | 3 |
| | Urea | 2309011-01 | 22 |
| | Urea | 2309011-02 | 8 |
| | Urea | 2309011-03 | 3 |
| | Urea | 2309011-04 | 1 |
| | Urea | 23C21-B01-228852 | 1 |
| | Urea | 23C21-B01-228853 | 2 |
| | Urea | 23J00550 | 1 |
| | Urea | 24001776001 | 14 |
| | Urea | 24001776003 | 4 |
| | Urea | 24001776004 | 13 |
| | Urea | 24001776005 | 1 |
| | Urea | 24001776009 | 2 |
| | Urea | 24001776010 | 2 |
| | Urea | 24B20-B08-238069 | 2 |
| | Urea | 24B20-B08-239659 | 1 |
| | Urea | 34567 | 1 |
| | Urea | B12-2261709 | 2 |
| | Urea | TCPharm00a | 1 |
| | Urea | V034-2022 | 4 |
| | Urea | V034-22022 | 1 |
| | Urea | V101-2022 | 2 |
| 10,68 | Urea | 23001146003 | 1 |
| ACM | Urea | KNC0236J16 | 2 |
| ACM | Urea | KNC0557J15 | 3 |
| ACM | Urea | KNC1795J14 | 1 |
| AEP | Urea | 22002605001 | 2 |
| Aep | Urea | 23003219011 | 1 |
| AHC | Urea | 15154110 | 1 |
| AHD | Urea | 14E07-B05-293469 | 1 |
| AHD | Urea | 16107428 | 1 |
| AHD | Urea | 18023003 | 1 |
| AHD | Urea | 21002313017 | 1 |
| AHD | Urea | 2109001-01 | 1 |
| AHD | Urea | 22002605010 | 1 |
| AHD | Urea | 2205037-01 | 1 |
| AHD | Urea | 22H29-B03-223930 | 1 |
| AHD | Urea | 23001146001 | 1 |
| AHD | Urea | 23003219005 | 1 |
| AHD | Urea | 23003219012 | 3 |
| ahd | Urea | 2301020-01 | 1 |
| ahd | Urea | 230-1020-01 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AHD | Urea | 2301020-01 | 2 |
| ahd | Urea | 2309011-01 | 2 |
| AHD | Urea | 2309011-01 | 1 |
| AHD | Urea | 2309011-02 | 1 |
| AHD | Urea | 3514E-02544 | 1 |
| Ahde 27.11.17 | Urea | 16107422 | 1 |
| Alliance healfcare | Urea | 18023015 | 1 |
| Alliance healfcare | Urea | 19031604 | 2 |
| Alliance Health care | Urea | 23001146002 | 1 |
| Alliance health | Urea | 14E07-B05-297167 | 1 |
| Alliance Healthcare | Urea | 12003219010 | 1 |
| Alliance Healthcare | Urea | 12111823 | 1 |
| Alliance Healthcare | Urea | 190316003 | 1 |
| Alliance Healthcare | Urea | 19031609 | 1 |
| Alliance Healthcare | Urea | 20003817002 | 1 |
| Alliance Healthcare | Urea | 2102002-01 | 1 |
| Alliance Healthcare | Urea | 22002605002 | 1 |
| Alliance Healthcare | Urea | 22002605010 | 1 |
| Alliance | Urea | 102002-012 | 1 |
| Alliance | Urea | 21002313006 | 1 |
| Alliance | Urea | 21002313015 | 1 |
| Alliance | Urea | 23001146001 | 1 |
| Anzag / Noweda | Urea | 13064206 | 1 |
| Anzag 17.04.13 ek:6,84EUR | Urea | 12111823 | 1 |
| Anzag/Henry Lamotte | Urea | 13-18-B03-303581 | 1 |
| Anzag | Urea | 12111801 | 1 |
| anzag | Urea | 14E07-B05-293469 | 1 |
| Anzag | Urea | 16107411 | 1 |
| Anzag | Urea | 19031614 | 1 |
| Anzag | Urea | 22002605009 | 1 |
| Anzag | Urea | 22002605010 | 1 |
| Anzag | Urea | 2309011-02 | 1 |
| apo-ident | Urea | 2205037-01 | 1 |
| Apotheke | Urea | 920A-07062 | 1 |
| Audor Pharma | Urea | | 1 |
| Audor Pharma | Urea | 2102002-01 | 2 |
| Audor Pharma | Urea | PU145 | 1 |
| Beiersdorf AG | Urea | 14/18-B03-303576 | 1 |
| Beiersdorf | Urea | 15154112 | 1 |
| Beyvers/AHD | Urea | 15087104 | 1 |
| Bombastus | Urea | 11150721 | 1 |
| Bombastus | Urea | 14107108 | 1 |
| Bombastus | Urea | 14107117 | 2 |
| Bombastus | Urea | 15087107 | 1 |
| Bombastus | Urea | 15154104 | 1 |
| Bombastus | Urea | 1601044-01 | 1 |
| Bombastus | Urea | 1707015-01 | 1 |
| Bombastus | Urea | 18023004 | 1 |
| Bombastus | Urea | 18023010 | 1 |
| Bombastus | Urea | 18023012 | 1 |
| Bombastus | Urea | 1804007-01 | 1 |
| cae | Urea | 15154111 | 1 |
| cae | Urea | 16107428 | 1 |
| Caelo | Urea | | 10 |
| Caelo | Urea | 10038587 | 4 |
| Caelo | Urea | 10038593 | 1 |
| Caelo | Urea | 100385993 | 1 |
| Caelo | Urea | 10081208 | 1 |
| Caelo | Urea | 10116 | 1 |
| Caelo | Urea | 10169722 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Urea | 10169726 | 3 |
| Caelo | Urea | 1019E-02544 | 1 |
| Caelo | Urea | 1061801 | 1 |
| Caelo | Urea | 107063 | 1 |
| Caelo | Urea | 10823004 | 1 |
| Caelo | Urea | 109316003 | 1 |
| Caelo | Urea | 110087-3 | 1 |
| Caelo | Urea | 1113A-025 | 1 |
| Caelo | Urea | 11150702 | 2 |
| Caelo | Urea | 11150703 | 1 |
| Caelo | Urea | 11150713 | 1 |
| Caelo | Urea | 11150714 | 1 |
| Caelo | Urea | 11150721 | 1 |
| Caelo | Urea | 11150722 | 3 |
| Caelo | Urea | 11150725 | 3 |
| Caelo | Urea | 11150736 | 4 |
| Caelo | Urea | 11150738 | 1 |
| Caelo | Urea | 1171003 | 1 |
| Caelo | Urea | 118023004 | 1 |
| Caelo | Urea | 12111801 | 4 |
| Caelo | Urea | 12111802 | 8 |
| Caelo | Urea | 12111803 | 1 |
| Caelo | Urea | 12111804 | 4 |
| Caelo | Urea | 12111806 | 5 |
| Caelo | Urea | 12111807 | 5 |
| Caelo | Urea | 12111808 | 9 |
| Caelo | Urea | 12111809 | 12 |
| Caelo | Urea | 12111810 | 14 |
| Caelo | Urea | 12111820 | 12 |
| Caelo | Urea | 12111822 | 15 |
| Caelo | Urea | 12111823 | 9 |
| Caelo | Urea | 12111826 | 6 |
| Caelo | Urea | 12111828 | 20 |
| Caelo | Urea | 12111834 | 3 |
| Caelo | Urea | 1211804 | 1 |
| Caelo | Urea | 1211806 | 1 |
| Caelo | Urea | 1211808 | 1 |
| Caelo | Urea | 1211809 | 1 |
| Caelo | Urea | 1211820 | 1 |
| Caelo | Urea | 1222 | 1 |
| Caelo | Urea | 12312478 | 1 |
| Caelo | Urea | 1234 | 1 |
| Caelo | Urea | 12345 | 1 |
| Caelo | Urea | 123456 | 4 |
| Caelo | Urea | 123566 | 1 |
| Caelo | Urea | 1236 | 1 |
| Caelo | Urea | 1241017 | 1 |
| Caelo | Urea | 12L10-N08 | 1 |
| Caelo | Urea | 13042015B | 1 |
| Caelo | Urea | 13062415 | 1 |
| Caelo | Urea | 1306412 | 1 |
| Caelo | Urea | 13064201 | 6 |
| Caelo | Urea | 13064202 | 12 |
| Caelo | Urea | 13064203 | 12 |
| Caelo | Urea | 13064206 | 18 |
| Caelo | Urea | 13064207 | 18 |
| Caelo | Urea | 13064212 | 23 |
| Caelo | Urea | 13064213 | 5 |
| Caelo | Urea | 13064214 | 13 |
| Caelo | Urea | 13064215 | 25 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Urea | 13064217 | 1 |
| Caelo | Urea | 1306422 | 1 |
| Caelo | Urea | 13064221 | 6 |
| Caelo | Urea | 13064223 | 33 |
| Caelo | Urea | 13064224 | 2 |
| Caelo | Urea | 13064226 | 13 |
| Caelo | Urea | 13064227 | 5 |
| Caelo | Urea | 13064228 | 24 |
| Caelo | Urea | 13064230 | 15 |
| Caelo | Urea | 13064231 | 9 |
| Caelo | Urea | 13064232 | 17 |
| Caelo | Urea | 13064233 | 17 |
| Caelo | Urea | 13064236 | 9 |
| Caelo | Urea | 13064239 | 2 |
| Caelo | Urea | 13072015B | 1 |
| Caelo | Urea | 1317B02-287602 | 1 |
| Caelo | Urea | 1364212 | 1 |
| Caelo | Urea | 13E21-N05 | 1 |
| Caelo | Urea | 14011513 | 1 |
| Caelo | Urea | 14064233 | 1 |
| Caelo | Urea | 1407109 | 1 |
| Caelo | Urea | 14107101 | 15 |
| Caelo | Urea | 14107102 | 27 |
| Caelo | Urea | 14107103 | 8 |
| Caelo | Urea | 14107108 | 10 |
| Caelo | Urea | 14107109 | 21 |
| Caelo | Urea | 14107112 | 20 |
| Caelo | Urea | 14107113 | 17 |
| Caelo | Urea | 14107117 | 8 |
| Caelo | Urea | 14107118 | 8 |
| Caelo | Urea | 14107119 | 25 |
| Caelo | Urea | 14107120 | 10 |
| Caelo | Urea | 14107122 | 17 |
| Caelo | Urea | 14107424 | 1 |
| Caelo | Urea | 14107428 | 1 |
| Caelo | Urea | 14197118 | 1 |
| Caelo | Urea | 14E07-B05-289706 | 1 |
| Caelo | Urea | 14E07-B05-293469 | 1 |
| Caelo | Urea | 14I18-B03 | 1 |
| Caelo | Urea | 14I18-B03-303581 | 1 |
| Caelo | Urea | 1501232 | 1 |
| Caelo | Urea | 1508/104 | 1 |
| Caelo | Urea | 15087102 | 8 |
| Caelo | Urea | 15087103 | 23 |
| Caelo | Urea | 15087104 | 20 |
| Caelo | Urea | 15087105 | 12 |
| Caelo | Urea | 15087107 | 20 |
| Caelo | Urea | 15087110 | 26 |
| Caelo | Urea | 151154112 | 1 |
| Caelo | Urea | 1514107 | 1 |
| Caelo | Urea | 1514109 | 1 |
| Caelo | Urea | 1514110 | 2 |
| Caelo | Urea | 1514112 | 1 |
| Caelo | Urea | 15145112 | 1 |
| Caelo | Urea | 1515404 | 1 |
| Caelo | Urea | 151541 | 2 |
| Caelo | Urea | 15154101 | 1 |
| Caelo | Urea | 15154103 | 54 |
| Caelo | Urea | 15154104 | 96 |
| Caelo | Urea | 15154107 | 25 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Urea | 15154109 | 10 |
| Caelo | Urea | 15154110 | 44 |
| Caelo | Urea | 15154111 | 44 |
| Caelo | Urea | 151541111 | 1 |
| Caelo | Urea | 15154112 | 50 |
| Caelo | Urea | 15154113 | 27 |
| Caelo | Urea | 15154116 | 16 |
| Caelo | Urea | 15154116I-020117/1 | 1 |
| Caelo | Urea | 1517E-02544 | 1 |
| Caelo | Urea | 15299506 | 1 |
| Caelo | Urea | 16/13-B02-332593 | 1 |
| Caelo | Urea | 1601044-01 | 2 |
| Caelo | Urea | 160125/2 | 1 |
| Caelo | Urea | 1604044-01 | 1 |
| Caelo | Urea | 160612/3 | 1 |
| Caelo | Urea | 160620UP | 1 |
| Caelo | Urea | 1607406 | 1 |
| Caelo | Urea | 1607407 | 1 |
| Caelo | Urea | 1607417 | 1 |
| Caelo | Urea | 1607422 | 1 |
| Caelo | Urea | 161017411 | 1 |
| Caelo | Urea | 1610407 | 1 |
| Caelo | Urea | 1610426 | 1 |
| Caelo | Urea | 161072422 | 1 |
| Caelo | Urea | 16107248 | 1 |
| Caelo | Urea | 161074 | 2 |
| Caelo | Urea | 16107404 | 1 |
| Caelo | Urea | 16107405 | 13 |
| Caelo | Urea | 16107406 | 24 |
| Caelo | Urea | 16107407 | 43 |
| Caelo | Urea | 16107408 | 2 |
| Caelo | Urea | 16107411 | 40 |
| Caelo | Urea | 16107412 | 104 |
| Caelo | Urea | 16107413 | 11 |
| Caelo | Urea | 16107416 | 19 |
| Caelo | Urea | 161074165325 | 1 |
| Caelo | Urea | 16107417 | 37 |
| Caelo | Urea | 16107417-60717/1 | 1 |
| Caelo | Urea | 16107418 | 35 |
| Caelo | Urea | 16107419 | 26 |
| Caelo | Urea | 16107420 | 61 |
| Caelo | Urea | 16107422 | 53 |
| Caelo | Urea | 16107423 | 12 |
| Caelo | Urea | 16107424 | 91 |
| Caelo | Urea | 16107425 | 7 |
| Caelo | Urea | 16107426 | 27 |
| Caelo | Urea | 16107427 | 1 |
| Caelo | Urea | 16107428 | 31 |
| Caelo | Urea | 16107429 | 10 |
| Caelo | Urea | 1610743 | 1 |
| Caelo | Urea | 161107417 | 1 |
| Caelo | Urea | 161122-1315 | 1 |
| Caelo | Urea | 16D22-B02-322526 | 1 |
| Caelo | Urea | 16I13-B02-330166 | 1 |
| Caelo | Urea | 16I13-B02-332953 | 1 |
| Caelo | Urea | 17011405 | 1 |
| Caelo | Urea | 1702023-01 | 3 |
| Caelo | Urea | 17021601 | 5 |
| Caelo | Urea | 170509UP/16107407 | 1 |
| Caelo | Urea | 1707015-01 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Urea | 17101310 | 1 |
| Caelo | Urea | 17107429 | 1 |
| Caelo | Urea | 17321206 | 1 |
| Caelo | Urea | 18012012 | 1 |
| Caelo | Urea | 1802003 | 1 |
| Caelo | Urea | 180223003 | 1 |
| Caelo | Urea | 18023001 | 18 |
| Caelo | Urea | 18023003 | 62 |
| Caelo | Urea | 18023003-20180830Ma2 | 1 |
| Caelo | Urea | 18023004 | 165 |
| Caelo | Urea | 18023006 | 74 |
| Caelo | Urea | 18023007 | 44 |
| Caelo | Urea | 18023007P-190225-12 | 1 |
| Caelo | Urea | 18023008 | 1 |
| Caelo | Urea | 18023010 | 75 |
| Caelo | Urea | 18023011 | 106 |
| Caelo | Urea | 18023012 | 116 |
| Caelo | Urea | 18023015 | 111 |
| Caelo | Urea | 18023016 | 8 |
| Caelo | Urea | 18023018 | 60 |
| Caelo | Urea | 18023019 | 6 |
| Caelo | Urea | 18023022 | 6 |
| Caelo | Urea | 1802304 | 1 |
| Caelo | Urea | 1802310 | 1 |
| Caelo | Urea | 1802401 | 1 |
| Caelo | Urea | 1802402 | 1 |
| Caelo | Urea | 18024201 | 58 |
| Caelo | Urea | 18024202 | 58 |
| Caelo | Urea | 18024210 | 1 |
| Caelo | Urea | 1803003 | 1 |
| Caelo | Urea | 180322H/18024202 | 1 |
| Caelo | Urea | 1804007-01 | 1 |
| Caelo | Urea | 18109801 | 1 |
| Caelo | Urea | 18203012 | 1 |
| Caelo | Urea | 18214703 | 1 |
| Caelo | Urea | 1823004 | 1 |
| Caelo | Urea | 1824202 | 1 |
| Caelo | Urea | 18G04-B03-353339 | 1 |
| Caelo | Urea | 19016003 | 1 |
| Caelo | Urea | 19031 | 1 |
| Caelo | Urea | 19031314 | 1 |
| Caelo | Urea | 190316001 | 1 |
| Caelo | Urea | 190316002 | 9 |
| Caelo | Urea | 190316003 | 112 |
| Caelo | Urea | 190316003/4520 | 1 |
| Caelo | Urea | 190316003-1 | 1 |
| Caelo | Urea | 190316004 | 107 |
| Caelo | Urea | 190316005 | 3 |
| Caelo | Urea | 190316006 | 51 |
| Caelo | Urea | 19031602 | 1 |
| Caelo | Urea | 19031603 | 8 |
| Caelo | Urea | 19031604 | 89 |
| Caelo | Urea | 19031605 | 64 |
| Caelo | Urea | 19031606 | 51 |
| Caelo | Urea | 19031607 | 4 |
| Caelo | Urea | 19031609 | 54 |
| Caelo | Urea | 19031610 | 47 |
| Caelo | Urea | 19031611 | 7 |
| Caelo | Urea | 19031612 | 1 |
| Caelo | Urea | 19031614 | 48 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Urea | 19031615 | 58 |
| Caelo | Urea | 19031616 | 8 |
| Caelo | Urea | 19031616P-200402-3 | 1 |
| Caelo | Urea | 190318003 | 1 |
| Caelo | Urea | 190319614 | 1 |
| Caelo | Urea | 190321604 | 1 |
| Caelo | Urea | 1903604 | 1 |
| Caelo | Urea | 19041703 | 1 |
| Caelo | Urea | 19061615 | 1 |
| Caelo | Urea | 1908019-01 | 1 |
| Caelo | Urea | 2/20141507 | 1 |
| Caelo | Urea | 200001171004 | 1 |
| Caelo | Urea | 2000011710054 | 1 |
| Caelo | Urea | 200003817011 | 1 |
| Caelo | Urea | 200003817013 | 1 |
| Caelo | Urea | 200003817016 | 2 |
| Caelo | Urea | 2000117002 | 1 |
| Caelo | Urea | 20001171002 | 10 |
| Caelo | Urea | 20001171003 | 11 |
| Caelo | Urea | 20001171004 | 73 |
| Caelo | Urea | 200011711002 | 1 |
| Caelo | Urea | 200011711004 | 1 |
| Caelo | Urea | 2000171004 | 1 |
| Caelo | Urea | 2000381 | 1 |
| Caelo | Urea | 20003817001 | 1 |
| Caelo | Urea | 20003817002 | 29 |
| Caelo | Urea | 20003817004 | 15 |
| Caelo | Urea | 20003817005 | 5 |
| Caelo | Urea | 20003817006 | 7 |
| Caelo | Urea | 20003817008 | 3 |
| Caelo | Urea | 20003817010 | 4 |
| Caelo | Urea | 20003817011 | 16 |
| Caelo | Urea | 20003817012 | 24 |
| Caelo | Urea | 20003817013 | 46 |
| Caelo | Urea | 20003817014 | 7 |
| Caelo | Urea | 20003817015 | 69 |
| Caelo | Urea | 20003817016 | 35 |
| Caelo | Urea | 20003817017 | 1 |
| Caelo | Urea | 2000381705 | 1 |
| Caelo | Urea | 20003817061 | 1 |
| Caelo | Urea | 20003817105 | 1 |
| Caelo | Urea | 2000387004 | 1 |
| Caelo | Urea | 2001171004 | 1 |
| Caelo | Urea | 20013100721 | 1 |
| Caelo | Urea | 20031514 | 1 |
| Caelo | Urea | 2003817006 | 1 |
| Caelo | Urea | 200401001 | 1 |
| Caelo | Urea | 2004010-01 | 1 |
| Caelo | Urea | 20130912-4 | 1 |
| Caelo | Urea | 2016142709 | 1 |
| Caelo | Urea | 20A30-B16-196837 | 1 |
| Caelo | Urea | 210002313009 | 2 |
| Caelo | Urea | 2100231008 | 1 |
| Caelo | Urea | 2100231009 | 3 |
| Caelo | Urea | 2100231017 | 1 |
| Caelo | Urea | 2100231300 | 1 |
| Caelo | Urea | 21002313002 | 5 |
| Caelo | Urea | 21002313004 | 46 |
| Caelo | Urea | 21002313005 | 4 |
| Caelo | Urea | 21002313006 | 58 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Urea | 21002313007 | 38 |
| Caelo | Urea | 21002313008 | 6 |
| Caelo | Urea | 21002313009 | 23 |
| Caelo | Urea | 21002313013 | 2 |
| Caelo | Urea | 21002313014 | 32 |
| Caelo | Urea | 21002313015 | 56 |
| Caelo | Urea | 21002313016 | 5 |
| Caelo | Urea | 21002313017 | 24 |
| Caelo | Urea | 21003006231 | 1 |
| Caelo | Urea | 2100313007 | 1 |
| Caelo | Urea | 210231304 | 1 |
| Caelo | Urea | 21041802 | 1 |
| Caelo | Urea | 21051304 | 1 |
| Caelo | Urea | 2109212544 | 1 |
| Caelo | Urea | 211100231006 | 1 |
| Caelo | Urea | 21111806 | 1 |
| Caelo | Urea | 2116A-02544 | 1 |
| Caelo | Urea | 22002605001 | 20 |
| Caelo | Urea | 22002605002 | 7 |
| Caelo | Urea | 22002605003 | 14 |
| Caelo | Urea | 22002605005 | 3 |
| Caelo | Urea | 22002605009 | 3 |
| Caelo | Urea | 22002605010 | 3 |
| Caelo | Urea | 2200605001 | 1 |
| Caelo | Urea | 2202605010 | 1 |
| Caelo | Urea | 22111305 | 1 |
| Caelo | Urea | 23001146001 | 2 |
| Caelo | Urea | 23003219003 | 1 |
| Caelo | Urea | 23003219005 | 3 |
| Caelo | Urea | 230320/2 | 1 |
| Caelo | Urea | 2324534 | 1 |
| Caelo | Urea | 2416I-02544 | 1 |
| Caelo | Urea | 24882000381715 | 1 |
| Caelo | Urea | 25082015A | 1 |
| Caelo | Urea | 26071304 | 1 |
| Caelo | Urea | 2738 | 1 |
| Caelo | Urea | 30031304 | 1 |
| Caelo | Urea | 3012A-02544 | 1 |
| Caelo | Urea | 3017E-02544 | 1 |
| Caelo | Urea | 314Q2544 | 1 |
| Caelo | Urea | 3270 | 1 |
| Caelo | Urea | 3357 | 1 |
| Caelo | Urea | 34567890 | 1 |
| Caelo | Urea | 4013Q2544 | 1 |
| Caelo | Urea | 4111M-02544 | 1 |
| Caelo | Urea | 4116M-02544 | 1 |
| Caelo | Urea | 4517M-02544 | 1 |
| Caelo | Urea | 4914I-02544 | 1 |
| Caelo | Urea | 502172207 | 1 |
| Caelo | Urea | 5061410 | 1 |
| Caelo | Urea | 5100 | 1 |
| Caelo | Urea | 5208 | 1 |
| Caelo | Urea | 54215 | 1 |
| Caelo | Urea | 568900 | 1 |
| Caelo | Urea | 6101703 | 1 |
| Caelo | Urea | 62/AKD49 | 1 |
| Caelo | Urea | 63/AKD4 | 1 |
| Caelo | Urea | 813051Up | 1 |
| Caelo | Urea | 84(18023010) | 1 |
| Caelo | Urea | 85(18023012) | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Urea | 86(19031605) | 1 |
| Caelo | Urea | 87(190316003) | 1 |
| Caelo | Urea | 88(20003817002) | 1 |
| Caelo | Urea | 9031606 | 1 |
| Caelo | Urea | 9031615 | 1 |
| Caelo | Urea | 9240908 | 1 |
| Caelo | Urea | AKD6 | 1 |
| Caelo | Urea | Caelo13064233 | 1 |
| Caelo | Urea | P171218UP08/18 | 1 |
| Caelo | Urea | Validierungsmessung | 1 |
| Caeolo/Gehe | Urea | 16107424 | 1 |
| Caeolo/Noweda | Urea | 14107112 | 1 |
| Caeolo/Noweda | Urea | 18023004 | 1 |
| Caerlo | Urea | 18023018 | 1 |
| Caesar & Lorenz GmbH | Urea | 15087107 | 1 |
| Caesar & Lorenz GmbH | Urea | 190316004 | 1 |
| Caesar & Lorenz GmbH | Urea | 19031604 | 1 |
| Caesar & Loretz / Gehe | Urea | 16107428 | 1 |
| Caesar & Loretz /Phönix | Urea | 21002313006 | 1 |
| Caesar & Loretz GmbH… | Urea | 20003817012 | 1 |
| Caesar & Loretz GmbH… | Urea | 16107422 | 2 |
| Caesar & Loretz GmbH… | Urea | 15154111 | 1 |
| Caesar & Loretz GmbH… | Urea | 18023010 | 1 |
| Caesar & Loretz GmbH… | Urea | 19031603 | 1 |
| Caesar & Loretz GmbH… | Urea | 20003817012 | 1 |
| Caesar & Loretz GmbH… | Urea | 16107417 | 1 |
| Caesar & Loretz GmbH… | Urea | 17347901 | 1 |
| Caesar & Loretz GmbH… | Urea | 18023003 | 1 |
| Caesar & Loretz GmbH… | Urea | 20003817011 | 3 |
| Caesar & Loretz GmbH… | Urea | 21002313005 | 1 |
| Caesar & Loretz GmbH… | Urea | 21002313015 | 1 |
| Caesar & Loretz GmbH… | Urea | 22002605010 | 1 |
| Caesar & Loretz GmbH… | Urea | 19031605 | 1 |
| Caesar & Loretz GmbH… | Urea | 21002313002 | 1 |
| Caesar & Loretz GmbH… | Urea | 21002313006 | 1 |
| Caesar & Loretz GmbH… | Urea | 190316003 | 1 |
| Caesar & Loretz GmbH… | Urea | 19031616 | 1 |
| Caesar & Loretz GmbH… | Urea | 21002313004 | 1 |
| Caesar & Loretz GmbH… | Urea | 21002313007 | 2 |
| Caesar & Loretz GmbH… | Urea | 19031610 | 1 |
| Caesar & Loretz GmbH… | Urea | 190316003 | 2 |
| Caesar & Loretz GmbH… | Urea | 21002313007 | 1 |
| Caesar & Loretz GmbH… | Urea | 20003817015 | 1 |
| Caesar & Loretz GmbH… | Urea | 190316004 | 2 |
| Caesar & Loretz GmbH… | Urea | 11150736 | 1 |
| Caesar & Loretz GmbH… | Urea | 12111804 | 1 |
| Caesar & Loretz GmbH… | Urea | 12111810 | 2 |
| Caesar & Loretz GmbH… | Urea | 12111822 | 1 |
| Caesar & Loretz GmbH… | Urea | 12111828 | 2 |
| Caesar & Loretz GmbH… | Urea | 13064206 | 2 |
| Caesar & Loretz GmbH… | Urea | 13064212 | 3 |
| Caesar & Loretz GmbH/ AEP | Urea | 20001171004 | 1 |
| Caesar & Loretz GmbH… | Urea | 19031604 | 1 |
| Caesar & Loretz GmbH… | Urea | 19031615 | 1 |
| Caesar & Loretz GmbH… | Urea | 20001171003 | 1 |
| Caesar & Loretz GmbH… | Urea | 20001171004 | 1 |
| Caesar & Loretz GmbH… | Urea | 190316006 | 2 |
| Caesar & Loretz GmbH… | Urea | 19031605 | 1 |
| Caesar & Loretz GmbH… | Urea | 19031606 | 1 |
| Caesar & Loretz GmbH… | Urea | 20003817002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Urea | 20003817013 | 1 |
| Caesar & Loretz GmbH... | Urea | 20001171003 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313014 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031606 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316004 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313020 | 1 |
| Caesar & Loretz GmbH... | Urea | 18023015 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031609 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031610 | 1 |
| Caesar & Loretz GmbH/A | Urea | 21002313007 | 1 |
| Caesar & Loretz GmbH/AHD | Urea | 20001171004 | 2 |
| Caesar & Loretz GmbH/AHD | Urea | 20003817015 | 1 |
| Caesar & Loretz GmbH/All | Urea | 190316005 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817016 | 1 |
| Caesar & Loretz GmbH... | Urea | 18023018 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316004 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031611 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817015 | 1 |
| Caesar & Loretz GmbH/E | Urea | 19031614 | 1 |
| Caesar & Loretz GmbH/E | Urea | 20003817015 | 1 |
| Caesar & Loretz GmbH... | Urea | 18023011 | 1 |
| Caesar & Loretz GmbH... | Urea | 18023015 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316004 | 3 |
| Caesar & Loretz GmbH... | Urea | 20003817011 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313006 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313015 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 18023011 | 1 |
| Caesar & Loretz GmbH/GEHE | Urea | 18023011 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 190316003 | 3 |
| Caesar & Loretz GmbH/Gehe | Urea | 190316004 | 1 |
| Caesar & Loretz GmbH/GEHE | Urea | 190316004 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 190316006 | 3 |
| Caesar & Loretz GmbH/Gehe | Urea | 19031604 | 1 |
| Caesar & Loretz GmbH/GEHE | Urea | 19031604 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 19031609 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 19031614 | 4 |
| Caesar & Loretz GmbH/gehe | Urea | 19031615 | 1 |
| Caesar & Loretz GmbH/GEHE | Urea | 19031615 | 1 |
| Caesar & Loretz GmbH/GEHE | Urea | 20001171003 | 2 |
| Caesar & Loretz GmbH/Gehe | Urea | 20001171004 | 2 |
| Caesar & Loretz GmbH/GEHE | Urea | 20001171004 | 2 |
| Caesar & Loretz GmbH/Gehe | Urea | 20003817006 | 2 |
| Caesar & Loretz GmbH/GEHE | Urea | 20003817015 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 20003817016 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 21002313004 | 2 |
| Caesar & Loretz GmbH/Gehe | Urea | 21002313006 | 1 |
| Caesar & Loretz GmbH/Gehe | Urea | 22002605001 | 1 |
| Caesar & Loretz GmbH... | Urea | 20001171003 | 2 |
| Caesar & Loretz GmbH... | Urea | 20003817008 | 1 |
| Caesar & Loretz GmbH... | Urea | 18023019 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316003 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313014 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817016 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316002 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031603 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031610 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031616 | 1 |
| Caesar & Loretz GmbH/kehr | Urea | 18023007 | 2 |
| Caesar & Loretz GmbH/Kehr | Urea | 18023015 | 1 |
| Caesar & Loretz GmbH/Kehr | Urea | 18023019 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH/Kehr | Urea | 190316002 | 1 |
| Caesar & Loretz GmbH/Kehr | Urea | 190316003 | 2 |
| Caesar & Loretz GmbH/Kehr | Urea | 19031616 | 1 |
| Caesar & Loretz GmbH/Kehr | Urea | 21002313015 | 2 |
| Caesar & Loretz GmbH... | Urea | 190316004 | 2 |
| Caesar & Loretz GmbH... | Urea | 19031615 | 1 |
| Caesar & Loretz GmbH... | Urea | 20001171004 | 2 |
| Caesar & Loretz GmbH... | Urea | 19031614 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817016 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316004 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316006 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031615 | 1 |
| Caesar & Loretz GmbH... | Urea | 20001171004 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313006 | 1 |
| Caesar & Loretz GmbH/Phoe | Urea | 20003817012 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316006 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031606 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817005 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817015 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313007 | 2 |
| Caesar & Loretz GmbH... | Urea | 18023006 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316003 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316004 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316006 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031611 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031615 | 1 |
| Caesar & Loretz GmbH... | Urea | 20001171003 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817004 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817015 | 4 |
| Caesar & Loretz GmbH... | Urea | 21002313004 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313007 | 2 |
| Caesar & Loretz GmbH... | Urea | 21002313009 | 1 |
| Caesar & Loretz GmbH... | Urea | 21002313015 | 1 |
| Caesar & Loretz GmbH... | Urea | 22002605010 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316003 | 1 |
| Caesar & Loretz GmbH... | Urea | 190316006 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031604 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031606 | 1 |
| Caesar & Loretz GmbH... | Urea | 19031615 | 1 |
| Caesar & Loretz GmbH... | Urea | 20001171004 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817006 | 1 |
| Caesar & Loretz GmbH... | Urea | 20003817015 | 2 |
| Caesar & Loretz GmbH... | Urea | 21002313007 | 3 |
| Caesar & Loretz GmbH... | Urea | 22002605001 | 1 |
| Caesar & Loretz GmbH... | Urea | AP210316-01 | 1 |
| Caesar & Loretz GmbH | Urea | 12111822 | 1 |
| Caesar & Loretz GmbH | Urea | 13064206 | 1 |
| Caesar & Loretz GmbH | Urea | 1306421 | 1 |
| Caesar & Loretz GmbH | Urea | 13064223 | 1 |
| Caesar & Loretz GmbH | Urea | 15087103 | 1 |
| Caesar & Loretz GmbH | Urea | 15087105 | 1 |
| Caesar & Loretz GmbH | Urea | 15154104 | 1 |
| Caesar & Loretz GmbH | Urea | 16107411 | 1 |
| Caesar & Loretz GmbH | Urea | 16107417 | 1 |
| Caesar & Loretz GmbH | Urea | 16107419 | 1 |
| Caesar & Loretz GmbH | Urea | 18023003 | 3 |
| Caesar & Loretz GmbH | Urea | 18023004 | 2 |
| Caesar & Loretz GmbH | Urea | 18023006 | 1 |
| Caesar & Loretz GmbH | Urea | 18023007 | 3 |
| Caesar & Loretz GmbH | Urea | 18023008 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Urea | 18023010 | 2 |
| Caesar & Loretz GmbH | Urea | 18023011 | 6 |
| Caesar & Loretz GmbH | Urea | 18023012 | 9 |
| Caesar & Loretz GmbH | Urea | 18023013 | 1 |
| Caesar & Loretz GmbH | Urea | 18023015 | 23 |
| Caesar & Loretz GmbH | Urea | 18023016 | 1 |
| Caesar & Loretz GmbH | Urea | 18023018 | 6 |
| Caesar & Loretz GmbH | Urea | 18023019 | 2 |
| Caesar & Loretz GmbH | Urea | 18023022 | 1 |
| Caesar & Loretz GmbH | Urea | 18024201 | 1 |
| Caesar & Loretz GmbH | Urea | 190316002 | 6 |
| Caesar & Loretz GmbH | Urea | 190316003 | 29 |
| Caesar & Loretz GmbH | Urea | 190316004 | 43 |
| Caesar & Loretz GmbH | Urea | 190316005 | 9 |
| Caesar & Loretz GmbH | Urea | 190316006 | 14 |
| Caesar & Loretz GmbH | Urea | 19031602 | 1 |
| Caesar & Loretz GmbH | Urea | 19031603 | 8 |
| Caesar & Loretz GmbH | Urea | 19031604 | 18 |
| Caesar & Loretz GmbH | Urea | 19031605 | 14 |
| Caesar & Loretz GmbH | Urea | 19031606 | 13 |
| Caesar & Loretz GmbH | Urea | 19031607 | 1 |
| Caesar & Loretz GmbH | Urea | 19031608 | 1 |
| Caesar & Loretz GmbH | Urea | 19031609 | 9 |
| Caesar & Loretz GmbH | Urea | 19031610 | 13 |
| Caesar & Loretz GmbH | Urea | 19031611 | 4 |
| Caesar & Loretz GmbH | Urea | 19031612 | 3 |
| Caesar & Loretz GmbH | Urea | 19031614 | 16 |
| Caesar & Loretz GmbH | Urea | 19031615 | 20 |
| Caesar & Loretz GmbH | Urea | 19031616 | 8 |
| Caesar & Loretz GmbH | Urea | 19032609 | 1 |
| Caesar & Loretz GmbH | Urea | 20000092002 | 1 |
| Caesar & Loretz GmbH | Urea | 20001171002 | 2 |
| Caesar & Loretz GmbH | Urea | 20001171003 | 7 |
| Caesar & Loretz GmbH | Urea | 20001171004 | 28 |
| Caesar & Loretz GmbH | Urea | 2000171004 | 1 |
| Caesar & Loretz GmbH | Urea | 20003817002 | 14 |
| Caesar & Loretz GmbH | Urea | 20003817004 | 3 |
| Caesar & Loretz GmbH | Urea | 20003817005 | 1 |
| Caesar & Loretz GmbH | Urea | 20003817006 | 4 |
| Caesar & Loretz GmbH | Urea | 20003817008 | 2 |
| Caesar & Loretz GmbH | Urea | 20003817010 | 4 |
| Caesar & Loretz GmbH | Urea | 20003817011 | 3 |
| Caesar & Loretz GmbH | Urea | 20003817012 | 6 |
| Caesar & Loretz GmbH | Urea | 20003817013 | 13 |
| Caesar & Loretz GmbH | Urea | 20003817014 | 2 |
| Caesar & Loretz GmbH | Urea | 20003817015 | 28 |
| Caesar & Loretz GmbH | Urea | 20003817016 | 12 |
| Caesar & Loretz GmbH | Urea | 21002313001 | 2 |
| Caesar & Loretz GmbH | Urea | 21002313002 | 2 |
| Caesar & Loretz GmbH | Urea | 21002313004 | 14 |
| Caesar & Loretz GmbH | Urea | 21002313005 | 2 |
| Caesar & Loretz GmbH | Urea | 21002313006 | 21 |
| Caesar & Loretz GmbH | Urea | 21002313007 | 25 |
| Caesar & Loretz GmbH | Urea | 21002313008 | 7 |
| Caesar & Loretz GmbH | Urea | 21002313009 | 12 |
| Caesar & Loretz GmbH | Urea | 21002313013 | 1 |
| Caesar & Loretz GmbH | Urea | 21002313014 | 17 |
| Caesar & Loretz GmbH | Urea | 21002313015 | 22 |
| Caesar & Loretz GmbH | Urea | 21002313016 | 2 |
| Caesar & Loretz GmbH | Urea | 21002313017 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Urea | 220002605001 | 1 |
| Caesar & Loretz GmbH | Urea | 22002605001 | 11 |
| Caesar & Loretz GmbH | Urea | 22002605003 | 3 |
| Caesar & Loretz GmbH | Urea | 22002605009 | 1 |
| Caesar & Loretz GmbH | Urea | 22002605010 | 3 |
| Caesar & Loretz GmbH | Urea | 23001146001 | 1 |
| Caesar & Loretz GmbH7Gehe | Urea | 20003817015 | 1 |
| Caesar & Loretz Hild... | Urea | 19031614 | 1 |
| Caesar & Loretz Hilden | Urea | 18023012 | 1 |
| Caesar & Loretz Hilden | Urea | 190316004 | 1 |
| Caesar & Loretz Hilden | Urea | 19031609 | 1 |
| Caesar & Loretz/AHD | Urea | 18023007 | 2 |
| Caesar & Loretz/Gehe | Urea | 19031606 | 1 |
| Caesar & Loretz/Geil... | Urea | 190316003 | 1 |
| Caesar & Loretz | Urea | 16107426 | 1 |
| Caesar & Loretz | Urea | 18023004 | 2 |
| Caesar & Loretz | Urea | 18024201 | 1 |
| Caesar & Loretz | Urea | 20003817002 | 1 |
| Caesar & Loretz | Urea | 20003817015 | 1 |
| Caesar & Loretz | Urea | 21002313006 | 1 |
| Caesar &Loretz GmbH | Urea | 13064203 | 1 |
| Caesar u Loretz | Urea | 12111828 | 1 |
| Caesar und Loretz Gm... | Urea | 18023015 | 1 |
| Caesar und Loretz GmbH | Urea | 20001171004 | 1 |
| Caesar und Loretz | Urea | 16107420 | 1 |
| Caesar&Loretz GmbH /Anzag | Urea | 14107113 | 1 |
| Caesar&Loretz GmbH /Anzag | Urea | 15087110 | 1 |
| Caesar&Loretz GmbH D... | Urea | 12111808 | 2 |
| Caesar&Loretz GmbH,P... | Urea | 16107411 | 1 |
| Caesar&Loretz GmbH/ ... | Urea | 18023001 | 2 |
| Caesar&Loretz GmbH/Anzag | Urea | 13064217 | 1 |
| Caesar&Loretz GmbH/Anzag | Urea | 13064231 | 1 |
| Caesar&Loretz GmbH | Urea | 14107101 | 1 |
| Caesar&Loretz GmbH | Urea | 15154111 | 1 |
| Caesar&Loretz GmbH | Urea | 16107417 | 1 |
| Caesar&Loretz GmbH | Urea | 20003817013 | 1 |
| Caesar&Loretz GmbH | Urea | 21002313004 | 1 |
| Caesar&loretz,Anzag | Urea | 11150738 | 1 |
| Caesar&loretz,Phoenix | Urea | 11150713 | 1 |
| Caesar&loretz,Phoenix | Urea | 12111806 | 3 |
| Caesar&Loretz/Caesar... | Urea | 15154104 | 1 |
| Caesar&Loretz | Urea | 16107428 | 1 |
| Caesar/Lorenz | Urea | 12111822 | 1 |
| Caesar/Noweda | Urea | 12111823 | 1 |
| Caesar/Noweda | Urea | 13064208 | 1 |
| CaesarLoretz/Gehe | Urea | 16107407 | 1 |
| CaesarLoretz/Gehe | Urea | 16107418 | 1 |
| CaesarLoretz/Gehe | Urea | 18023004 | 1 |
| Caeser & Loretz GmbH/AEP | Urea | 21002313006 | 1 |
| Caeser / Gehe | Urea | 15154109 | 1 |
| Caeser und Loretz GmbH | Urea | 18023018 | 1 |
| Caleo/Noveda | Urea | 20003817011 | 1 |
| Caleo | Urea | 18023018 | 1 |
| Calo/AHD | Urea | 15154104 | 1 |
| Castor/Phönix | Urea | 15154104 | 1 |
| Cealo/AHD | Urea | 16107417 | 1 |
| Cealo/Gehe | Urea | 20003817015 | 1 |
| Cealo/Jenne | Urea | 220321(21002313004) | 1 |
| Cealo/Jenne | Urea | 221026(21002313014) | 2 |
| Cealo/Phoenix | Urea | 18023018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Cealo/Phönix | Urea | 13064231 | 1 |
| Cealo/Sanacorp | Urea | 1804007-01 | 1 |
| Cealo | Urea | 16107416 | 1 |
| Cordes/Noweda | Urea | 17021601 | 1 |
| Dan Pharma | Urea | D08118 | 1 |
| Delta | Urea | 18023004 | 1 |
| Dr. August Wolff | Urea | 13E17N02 | 1 |
| Dr.Wolff | Urea | 1234567 | 1 |
| Ebert & Jacobi | Urea | 15154111 | 1 |
| Eur | Urea | 1707015-01 | 1 |
| EuRho / AHD | Urea | 2205037-01 | 3 |
| EurHo/ Noweda 11.10.18 | Urea | 1804007-01 | 1 |
| EuRho/Noveda | Urea | 2004010-02 | 2 |
| EuRho/Noweda | Urea | 1707015-01 | 1 |
| EuRho/Phönix | Urea | 2102002-01 | 1 |
| EuRho | Urea | 1212007-01 | 1 |
| Eurho | Urea | 1404024-01 | 1 |
| EuRho | Urea | 1404024-01 | 5 |
| EuRho | Urea | 150304201 | 1 |
| EuRho | Urea | 1702023-01 | 1 |
| EuRho | Urea | 1707015-01 | 1 |
| EuRho | Urea | 2004010-01 | 1 |
| euRho | Urea | 2102002-01 | 1 |
| Euro / AHD | Urea | 1804007-01 | 1 |
| Euro OTC | Urea | | 13 |
| Euro OTC | Urea | 1008016-01 | 1 |
| Euro OTC | Urea | 1110023-01 | 1 |
| Euro OTC | Urea | 1212007-01 | 6 |
| Euro OTC | Urea | 1212007-02 | 3 |
| Euro OTC | Urea | 13064239 | 1 |
| Euro OTC | Urea | 1404024-01 | 8 |
| Euro OTC | Urea | 14107108 | 1 |
| Euro OTC | Urea | 150304201 | 1 |
| Euro OTC | Urea | 1503042-01 | 24 |
| Euro OTC | Urea | 1515404 | 1 |
| Euro OTC | Urea | 15154103 | 2 |
| Euro OTC | Urea | 15154104 | 3 |
| Euro OTC | Urea | 160104401 | 1 |
| Euro OTC | Urea | 1601044-01 | 28 |
| Euro OTC | Urea | 160404401 | 2 |
| Euro OTC | Urea | 1604044-01 | 30 |
| Euro OTC | Urea | 16107411 | 1 |
| Euro OTC | Urea | 16107412 | 1 |
| Euro OTC | Urea | 16107428 | 1 |
| Euro OTC | Urea | 16I13-B02-332953 | 1 |
| Euro OTC | Urea | 1702023 | 1 |
| Euro OTC | Urea | 170202301 | 4 |
| Euro OTC | Urea | 1702023-01 | 30 |
| Euro OTC | Urea | 170701501 | 4 |
| Euro OTC | Urea | 1707015-01 | 43 |
| Euro OTC | Urea | 18023006 | 1 |
| Euro OTC | Urea | 18023010 | 1 |
| Euro OTC | Urea | 18023012 | 1 |
| Euro OTC | Urea | 18023015 | 1 |
| Euro OTC | Urea | 18024201 | 1 |
| Euro OTC | Urea | 180400701 | 1 |
| Euro OTC | Urea | 1804007-01 | 57 |
| Euro OTC | Urea | 1804007-02 | 9 |
| Euro OTC | Urea | 1804007-1 | 1 |
| Euro OTC | Urea | 18040701 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Urea | 1811012_01 | 1 |
| Euro OTC | Urea | 181101201 | 1 |
| Euro OTC | Urea | 1811012-01 | 69 |
| Euro OTC | Urea | 18110-12-01 | 1 |
| Euro OTC | Urea | 18A24-B07-349015 | 1 |
| Euro OTC | Urea | 19031611 | 1 |
| Euro OTC | Urea | 190801601 | 2 |
| Euro OTC | Urea | 1908016-01 | 43 |
| Euro OTC | Urea | 1908016-16 | 1 |
| Euro OTC | Urea | 1908016-61 | 1 |
| Euro OTC | Urea | 1915M-02544 | 1 |
| Euro OTC | Urea | 20003817010 | 1 |
| Euro OTC | Urea | 200401001 | 2 |
| Euro OTC | Urea | 2004010-01 | 36 |
| Euro OTC | Urea | 2004010-02 | 7 |
| Euro OTC | Urea | 2004010-10 | 1 |
| Euro OTC | Urea | 21002313009 | 1 |
| Euro OTC | Urea | 2101002-02 | 1 |
| Euro OTC | Urea | 210200-01 | 1 |
| Euro OTC | Urea | 2102002 | 1 |
| Euro OTC | Urea | 2102002-01 | 33 |
| Euro OTC | Urea | 2102002-02 | 6 |
| Euro OTC | Urea | 2102002-2 | 1 |
| Euro OTC | Urea | 21090001-01 | 1 |
| Euro OTC | Urea | 2109001-01 | 23 |
| Euro OTC | Urea | 2205037 | 1 |
| Euro OTC | Urea | 2205037-01 | 23 |
| Euro OTC | Urea | 2205037-02 | 1 |
| Euro OTC | Urea | 220537-01 | 1 |
| Euro OTC | Urea | 72/14 | 1 |
| Euro OTC | Urea | hcvovo | 1 |
| Euro OTC | Urea | UP250171017 | 1 |
| Euro OTC | Urea | V038-2017 | 1 |
| Euro OTC | Urea | V076-2016 | 1 |
| Euro OTC | Urea | V081-2018 | 3 |
| Euro/Sanacorp | Urea | 1707015-01 | 1 |
| Euro/Sanacorp | Urea | 1804007-01 | 1 |
| Euro/Sanacorp | Urea | 1908016-01 | 2 |
| Fa.Alliance Healtc. | Urea | 16107412 | 1 |
| Fa.Phönix | Urea | 20003817015 | 2 |
| Fa.Phönix | Urea | 21002313015 | 1 |
| Fagon/Noweda | Urea | 18A24-B07-351975 | 1 |
| Fagon/Noweda | Urea | 19G11-B01 | 1 |
| Fagon/Noweda | Urea | B01-2014803 | 1 |
| Fagon/Noweda | Urea | B16-1928504 | 1 |
| Fagon/Noweda | Urea | V016-2019 | 1 |
| Fagron | Urea | 118900-0001 | 1 |
| Fagron | Urea | 11C25-N01 | 1 |
| Fagron | Urea | 11F24-N16 | 1 |
| Fagron | Urea | 11H01-N08 | 2 |
| Fagron | Urea | 1211822 | 1 |
| Fagron | Urea | 1232255144 | 1 |
| Fagron | Urea | 123456 | 1 |
| Fagron | Urea | 12C20-N05 | 1 |
| Fagron | Urea | 12F25-N05 | 5 |
| Fagron | Urea | 12I04-N06 | 1 |
| Fagron | Urea | 12l04-N06 | 1 |
| Fagron | Urea | 12l10-n08 | 1 |
| Fagron | Urea | 12L10-N08 | 7 |
| Fagron | Urea | 13/17-1302-287602 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Urea | 13D03-N01 | 9 |
| Fagron | Urea | 13D03-NO01 | 1 |
| Fagron | Urea | 13E17-N02 | 1 |
| Fagron | Urea | 13E21-N05 | 2 |
| Fagron | Urea | 13J17-B02 | 2 |
| Fagron | Urea | 13J17-B02-287602 | 2 |
| Fagron | Urea | 13J17B02-287604 | 1 |
| Fagron | Urea | 13J17-B02-287604 | 5 |
| Fagron | Urea | 13L20B03 | 1 |
| Fagron | Urea | 13L20-B03_289708 | 1 |
| Fagron | Urea | 13L20-B03-289708 | 6 |
| Fagron | Urea | 14/18-B03-303576 | 2 |
| Fagron | Urea | 14/18B03303581 | 1 |
| Fagron | Urea | 14/18-B03-303581 | 9 |
| Fagron | Urea | 14107117 | 1 |
| Fagron | Urea | 1418b03303581 | 1 |
| Fagron | Urea | 1418B03303581 | 1 |
| Fagron | Urea | 1418-B03-303581 | 1 |
| Fagron | Urea | 14E07B05 | 3 |
| Fagron | Urea | 14E07-B05 | 8 |
| Fagron | Urea | 14E07-B05-289706 | 1 |
| Fagron | Urea | 14E07B05293469 | 1 |
| Fagron | Urea | 14E07-B05-293469 | 9 |
| Fagron | Urea | 14E-07-B05-293469 | 1 |
| Fagron | Urea | 14E07-B05-297165 | 4 |
| Fagron | Urea | 14E07-B05-297167 | 6 |
| Fagron | Urea | 14E07-B07-293469 | 1 |
| Fagron | Urea | 14E8900-0001 | 1 |
| Fagron | Urea | 14I18-B03 | 4 |
| Fagron | Urea | 14I18-B03-303576 | 7 |
| Fagron | Urea | 14I18-B03-303581 | 3 |
| Fagron | Urea | 14l18-B03 | 1 |
| Fagron | Urea | 14l18-B03-0303581 | 1 |
| Fagron | Urea | 15087104 | 1 |
| Fagron | Urea | 15154104 | 2 |
| Fagron | Urea | 15154112 | 1 |
| Fagron | Urea | 16/13-B02 | 1 |
| Fagron | Urea | 16/13-B02-330166 | 2 |
| Fagron | Urea | 16/13-B02-332953 | 2 |
| Fagron | Urea | 1607417 | 1 |
| Fagron | Urea | 16107407 | 1 |
| Fagron | Urea | 16107418 | 1 |
| Fagron | Urea | 16107422 | 1 |
| Fagron | Urea | 1613-B02-328152 | 2 |
| Fagron | Urea | 1613b02332953 | 1 |
| Fagron | Urea | 16D22-B02-326481 | 1 |
| Fagron | Urea | 16D22-B02 | 3 |
| Fagron | Urea | 16D22-B02-3221532 | 1 |
| Fagron | Urea | 16D22-B02-322426 | 1 |
| Fagron | Urea | 16D22-B02-322526 | 6 |
| Fagron | Urea | 16D22-B02-322532 | 5 |
| Fagron | Urea | 16D22B02326481 | 1 |
| Fagron | Urea | 16D22-B02-326481 | 9 |
| Fagron | Urea | 16D22-B02-36481 | 1 |
| Fagron | Urea | 16I13-B02 | 1 |
| Fagron | Urea | 16I13-B02-328152 | 3 |
| Fagron | Urea | 16I13-B02-330166 | 4 |
| Fagron | Urea | 16l13-B02-332953 | 2 |
| Fagron | Urea | 1707015-01 | 1 |
| Fagron | Urea | 17D20-B01-335312 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Urea | 17H16-B01 | 3 |
| Fagron | Urea | 17H16-B01-340516 | 1 |
| Fagron | Urea | 17H16-B01-342080 | 4 |
| Fagron | Urea | 18023006 | 1 |
| Fagron | Urea | 18023010 | 2 |
| Fagron | Urea | 18023012 | 1 |
| Fagron | Urea | 18023015 | 2 |
| Fagron | Urea | 18024202 | 1 |
| Fagron | Urea | 18A24-B07 | 3 |
| Fagron | Urea | 18A24-B07-346692 | 5 |
| Fagron | Urea | 18A24-B07-347410 | 1 |
| Fagron | Urea | 18A24-B07-3490 | 1 |
| Fagron | Urea | 18A24-B07-349015 | 4 |
| Fagron | Urea | 18A24-B07-351975 | 8 |
| Fagron | Urea | 18A24-B07-352707 | 3 |
| Fagron | Urea | 18-B03-303581 | 1 |
| Fagron | Urea | 18G04-B03 | 1 |
| Fagron | Urea | 18G04-B03-353339 | 4 |
| Fagron | Urea | 18G04-B03-35339 | 1 |
| Fagron | Urea | 18G04-B03-355378 | 1 |
| Fagron | Urea | 18G04-B03-355387 | 3 |
| Fagron | Urea | 19011-B01-194615 | 1 |
| Fagron | Urea | 19E07-B16-190548 | 3 |
| Fagron | Urea | 19e07-b16-192854 | 1 |
| Fagron | Urea | 19E07B16192854 | 1 |
| Fagron | Urea | 19E07-B16-192854 | 13 |
| Fagron | Urea | 19G11_B01_192855 | 1 |
| Fagron | Urea | 19G11-B01_194615 | 1 |
| Fagron | Urea | 19G11-B01-194615 | 13 |
| Fagron | Urea | 20003817015 | 1 |
| Fagron | Urea | 2014162937 | 3 |
| Fagron | Urea | 2016142709 | 4 |
| Fagron | Urea | 2018163455 | 1 |
| Fagron | Urea | 20A30-B16 | 2 |
| Fagron | Urea | 20A30-B16-1968307 | 1 |
| Fagron | Urea | 20A30-b16-196837 | 1 |
| Fagron | Urea | 20A30-B16-196837 | 7 |
| Fagron | Urea | 20A30-B16-196838 | 2 |
| Fagron | Urea | 20E07-801-201907 | 1 |
| Fagron | Urea | 20E07-B01 | 4 |
| Fagron | Urea | 20E07-B01-201455 | 4 |
| Fagron | Urea | 20E07-B01-201483 | 7 |
| Fagron | Urea | 20E07B01201907 | 2 |
| Fagron | Urea | 20E07-B01-201907 | 9 |
| Fagron | Urea | 211120-B02 | 1 |
| Fagron | Urea | 21C16-802 | 1 |
| Fagron | Urea | 21C16-B02 | 3 |
| Fagron | Urea | 21C16-B02_210554 | 1 |
| Fagron | Urea | 21C16-B02-210554 | 3 |
| Fagron | Urea | 21C16-B02-210584 | 3 |
| Fagron | Urea | 21C16B02214451 | 1 |
| Fagron | Urea | 21C16-B02-214451 | 6 |
| Fagron | Urea | 21C16-B02-215566 | 17 |
| Fagron | Urea | 21C16-B02-215659 | 2 |
| Fagron | Urea | 21C16-BO2-214451 | 1 |
| Fagron | Urea | 21L08-B04-219541 | 3 |
| Fagron | Urea | 2205037 | 1 |
| Fagron | Urea | 22H29-B03-223930 | 1 |
| Fagron | Urea | 235/12I04-N06 | 1 |
| Fagron | Urea | 2OE07B01201483 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Urea | 3613M-02544 | 1 |
| Fagron | Urea | 7L17-N01 | 1 |
| Fagron | Urea | 9K27-M01 | 1 |
| Fagron | Urea | B01-2019007 | 2 |
| Fagron | Urea | B02-2105504 | 3 |
| Fagron | Urea | B03-303581 | 1 |
| Fagron | Urea | V018-2021 | 1 |
| Fagron | Urea | V041-2020 | 2 |
| Fagron | Urea | V073-2019 | 1 |
| Fargon/Alliance HC | Urea | 14E07-B05-293469 | 1 |
| Fargon | Urea | 14e07-b05-297165 | 1 |
| Fiebig | Urea | 15087103 | 1 |
| Fiebig | Urea | 15154112 | 1 |
| Fiebig | Urea | 16107411 | 1 |
| Fiebig | Urea | 16107417 | 1 |
| Fiebig | Urea | 16107425 | 1 |
| Fiebig | Urea | 16107428 | 1 |
| Fiebig | Urea | 18023004 | 1 |
| Fiebig | Urea | 18023010 | 1 |
| Fiebig | Urea | 18023011 | 2 |
| Fiebig | Urea | 18023018 | 2 |
| Fiebig | Urea | 18024201 | 1 |
| Fiebig | Urea | 2309011-01 | 1 |
| Finteler Apotheke | Urea | 16107417 | 1 |
| Finze | Urea | 1264 | 1 |
| Gatt-Koller | Urea | 1800697 | 1 |
| Gatt-Koller | Urea | 1803268 | 3 |
| Gehe am 11.10.2017 | Urea | 16107419 | 1 |
| Gehe amax | Urea | 16107417 | 1 |
| Gehe amax | Urea | 16107422 | 1 |
| Gehe amax | Urea | 18023006 | 1 |
| Gehe amax | Urea | 190316003 | 1 |
| Gehe amax | Urea | 19031614 | 1 |
| Gehe,05.04.17, 5,30EUR | Urea | 16107412 | 1 |
| Gehe/Fragon | Urea | 16D22-B02-326481 | 1 |
| Gehe | Urea | 10038593 | 1 |
| Gehe | Urea | 12111808 | 1 |
| Gehe | Urea | 12111810 | 1 |
| Gehe | Urea | 12111822 | 1 |
| Gehe | Urea | 12111826 | 1 |
| Gehe | Urea | 13064232 | 1 |
| Gehe | Urea | 14107112 | 1 |
| Gehe | Urea | 14107122 | 1 |
| Gehe | Urea | 15087103 | 1 |
| Gehe | Urea | 15087107 | 2 |
| Gehe | Urea | 15154103 | 1 |
| Gehe | Urea | 15154112 | 1 |
| Gehe | Urea | 16107411 | 2 |
| Gehe | Urea | 16107412 | 3 |
| GEHE | Urea | 16107412 | 1 |
| GEHE | Urea | 16107416 | 1 |
| Gehe | Urea | 16107417 | 1 |
| Gehe | Urea | 16107419 | 1 |
| Gehe | Urea | 16107422 | 3 |
| GEHE | Urea | 16107422 | 1 |
| Gehe | Urea | 16107424 | 1 |
| gehe | Urea | 16107425 | 1 |
| Gehe | Urea | 16107425 | 1 |
| Gehe | Urea | 16107428 | 1 |
| Gehe | Urea | 1707015 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Urea | 18023004 | 3 |
| GEHE | Urea | 18023006 | 1 |
| GEHE | Urea | 18023007 | 1 |
| Gehe | Urea | 18023011 | 3 |
| gehe | Urea | 18023012 | 1 |
| Gehe | Urea | 18023012 | 2 |
| Gehe | Urea | 18023015 | 2 |
| Gehe | Urea | 18023018 | 1 |
| gehe | Urea | 18024201 | 1 |
| Gehe | Urea | 18024202 | 1 |
| Gehe | Urea | 1804007-01 | 1 |
| Gehe | Urea | 190316002 | 2 |
| Gehe | Urea | 190316004 | 1 |
| Gehe | Urea | 19031604 | 2 |
| Gehe | Urea | 19031606 | 1 |
| Gehe | Urea | 20001171004 | 2 |
| Gehe | Urea | 21002313006 | 1 |
| Gehe | Urea | 21002313014 | 1 |
| Gehe | Urea | 210200201 | 1 |
| GEHE | Urea | 2102313014 | 1 |
| Gehe | Urea | 21C16-B02 | 1 |
| Gehe | Urea | 22002605003 | 2 |
| Gehe | Urea | 22002605010 | 2 |
| GEHE | Urea | 2205037-02 | 1 |
| Gehe | Urea | 23001146001 | 4 |
| GEHE | Urea | 23001146001 | 1 |
| Gehe | Urea | 23003219005 | 2 |
| gehe | Urea | 23003219010 | 1 |
| Gehe | Urea | 23003219011 | 2 |
| Gehe | Urea | 2301020-01 | 2 |
| Gehe | Urea | 2309011-01 | 1 |
| gehe | Urea | 2309011-02 | 1 |
| Gehe | Urea | fgjhghk | 1 |
| Geilenkirchen | Urea | 18023011 | 1 |
| Geilenkirchen | Urea | 18023015 | 1 |
| Gutenberg-Apotheke | Urea | | 1 |
| Gutenberg-Apotheke | Urea | 13064227 | 1 |
| Hänseler | Urea | | 3 |
| Harnstoff | Urea | 20003817016 | 1 |
| Hedinger | Urea | 1503042-01 | 2 |
| Hirsch | Urea | 810811 | 1 |
| Holdermann | Urea | 23003219007 | 1 |
| Ichthyol/Noweda | Urea | | 1 |
| Ichthyol/Phoenix | Urea | 15154104 | 1 |
| ichtxol-Gesellschaft... | Urea | 18023010 | 2 |
| Infectopharm/Phönix | Urea | 18023011 | 1 |
| Jenne 15.11.21, 4,79EUR | Urea | 211125 | 1 |
| Jenne | Urea | 18023018 | 1 |
| Jenne | Urea | 23001146001 | 2 |
| Jenne | Urea | 2309011-02 | 1 |
| Jenne | Urea | 240222(23001146001) | 1 |
| Jenne | Urea | 250120(24001776001) | 1 |
| Kehhr Holderman | Urea | 22002605009 | 1 |
| Kehr | Urea | 16107418 | 1 |
| Kehr | Urea | 1802007 | 1 |
| Kehr | Urea | 18023004 | 1 |
| Kehr | Urea | 21C16-B02-215566 | 1 |
| Kehr | Urea | 22002605001 | 1 |
| Kehr | Urea | 22002605011 | 1 |
| Kehr | Urea | 2205037-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Kehr | Urea | 23001146001 | 1 |
| Kehr | Urea | 23003219010 | 1 |
| Kehr | Urea | 2300321902 | 1 |
| Kirsch Pharma GmbH/Noweda | Urea | 14E07-B05-293469 | 1 |
| Kirsch Pharma | Urea | 18A24B07346692 | 1 |
| Klenk | Urea | 19E07-B16-162854 | 2 |
| Krieger | Urea | 15154110 | 1 |
| krieger | Urea | 19031604 | 1 |
| Krieger | Urea | 19031610 | 2 |
| L10 | Urea | 21C16-B02 | 1 |
| L12 | Urea | 16107418 | 1 |
| L30 | Urea | 16107407 | 1 |
| L30 | Urea | 16107424 | 1 |
| L30 | Urea | 18023011 | 1 |
| Laborchemie Apolda/J... | Urea | 12345 | 1 |
| Lamotte | Urea | 19031611 | 1 |
| Löns Apotheke | Urea | 20349 | 1 |
| Löns Apotheke | Urea | 40003 | 1 |
| Max Jenne | Urea | 2309011-01 | 2 |
| Nachprüfung | Urea | 2082019-12 | 1 |
| Nachprüfung | Urea | iu98769879 | 1 |
| Noveda | Urea | 19031610 | 1 |
| Noveda | Urea | 20001171004 | 1 |
| Noweda 02.08.2019 | Urea | 18023018 | 1 |
| Noweda 02.09.2019 | Urea | 18023019 | 1 |
| Noweda/KremerGmbH | Urea | 13064201 | 1 |
| Noweda | Urea | 11150714 | 1 |
| Noweda | Urea | 12111822 | 2 |
| Noweda | Urea | 13064223 | 1 |
| Noweda | Urea | 14107101 | 1 |
| Noweda | Urea | 15154110 | 1 |
| Noweda | Urea | 15154112 | 1 |
| Noweda | Urea | 16107416 | 1 |
| Noweda | Urea | 16107419 | 3 |
| Noweda | Urea | 16107422 | 1 |
| Noweda | Urea | 18023001 | 2 |
| Noweda | Urea | 18023004 | 1 |
| Noweda | Urea | 18023012 | 1 |
| Noweda | Urea | 18023015 | 3 |
| Noweda | Urea | 18024201 | 1 |
| Noweda | Urea | 18024202 | 2 |
| Noweda | Urea | 19031604 | 1 |
| Noweda | Urea | 19031609 | 1 |
| Noweda | Urea | 19031611 | 1 |
| Noweda | Urea | 20003817004 | 1 |
| Noweda | Urea | 2003817015 | 1 |
| Noweda | Urea | 20E07-B01-201907 | 2 |
| Noweda | Urea | 21002313015 | 2 |
| Noweda | Urea | 21002313017 | 2 |
| Noweda | Urea | 210200-01 | 1 |
| noweda | Urea | 2109001-01 | 1 |
| Noweda | Urea | 22002605005 | 2 |
| Noweda | Urea | 22002605008 | 1 |
| Noweda | Urea | 22002605009 | 8 |
| NOWEDA | Urea | 22002605009 | 1 |
| Noweda | Urea | 22002605010 | 6 |
| Noweda | Urea | 22002605011 | 2 |
| Noweda | Urea | 2205037-01 | 1 |
| Noweda | Urea | 2205037-02 | 1 |
| Noweda | Urea | 22H29-B03 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Urea | 23001146002 | 1 |
| Noweda | Urea | 23003219004 | 1 |
| noweda | Urea | 23003219012 | 2 |
| Noweda | Urea | 2301020-01 | 1 |
| Noweda | Urea | 2309011-02 | 1 |
| Noweda | Urea | 23C21-B01-228853 | 2 |
| Noweda | Urea | 24001776001 | 1 |
| Noweda | Urea | 4109M-02544 | 1 |
| Pala | Urea | 18G04-B03-353339 | 1 |
| Ph.Eur.7.0 | Urea | 14107109 | 1 |
| PHOENIX 02.05.2014 | Urea | 13J17-B02-287602 | 2 |
| Phoenix 11.09.2017 | Urea | 16107419 | 1 |
| Phoenix 17.2.2014 | Urea | 13064227 | 1 |
| Phoenix 20.07.2019 4,30EUR | Urea | 18023018 | 1 |
| PHOENIX 29.08.2014 | Urea | | 1 |
| Phoenix 31.07.19 | Urea | 18023001 | 1 |
| Phoenix | Urea | 13064231 | 1 |
| Phoenix | Urea | 15154113 | 1 |
| Phoenix | Urea | 16107411 | 1 |
| Phoenix | Urea | 16107420 | 1 |
| Phoenix | Urea | 16107424 | 1 |
| Phoenix | Urea | 16107428 | 1 |
| Phoenix | Urea | 18023004 | 2 |
| Phoenix | Urea | 18023006 | 2 |
| Phoenix | Urea | 18023012 | 1 |
| Phoenix | Urea | 18024201 | 2 |
| Phoenix | Urea | 190316004 | 1 |
| Phoenix | Urea | 19031605 | 1 |
| Phoenix | Urea | 19031615 | 2 |
| Phoenix | Urea | 20001171004 | 1 |
| Phoenix | Urea | 20002817013 | 1 |
| Phoenix | Urea | 20003817002 | 1 |
| Phoenix | Urea | 20003817006 | 1 |
| Phoenix | Urea | 20003817012 | 2 |
| Phoenix | Urea | 21002313014 | 1 |
| Phoenix | Urea | 22002605001 | 1 |
| Phoenix | Urea | 23001146001 | 2 |
| Phoenix | Urea | 23001146002 | 3 |
| Phoenix | Urea | 23003219004 | 1 |
| Phoenix | Urea | 23003219005 | 2 |
| Phoenix | Urea | 23003219010 | 2 |
| Phoenix | Urea | 23003219012 | 1 |
| Phoenix | Urea | 24001776001 | 1 |
| Phoenix | Urea | 2401776004 | 1 |
| Phoenix | Urea | 3201 | 1 |
| Phönix Gotha | Urea | 1212007-01 | 1 |
| Phönix Gotha | Urea | 13064202 | 1 |
| Phönix Gotha | Urea | 1404024-01 | 1 |
| Phönix Gotha | Urea | 16107417 | 2 |
| Phönix Gotha | Urea | V096/2012 | 1 |
| Phönix, Caesar&Loret… | Urea | 19031615 | 2 |
| Phönix, Caesar&Loret… | Urea | 190316004 | 3 |
| Phönix/Fagon | Urea | 18024201 | 2 |
| Phönix/Gehe | Urea | 18024201 | 2 |
| Phönix | Urea | 1190316004 | 1 |
| Phönix | Urea | 12111822 | 1 |
| Phönix | Urea | 123456 | 1 |
| Phönix | Urea | 13064207 | 1 |
| Phönix | Urea | 13064215 | 1 |
| Phönix | Urea | 13064223 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Urea | 13064236 | 1 |
| Phönix | Urea | 14107109 | 1 |
| Phönix | Urea | 15087110 | 1 |
| phönix | Urea | 15154103 | 2 |
| Phönix | Urea | 15154104 | 2 |
| phönix | Urea | 15154111 | 1 |
| phönix | Urea | 15154112 | 2 |
| Phönix | Urea | 15154113 | 1 |
| phönix | Urea | 16107412 | 2 |
| Phönix | Urea | 16107419 | 1 |
| phönix | Urea | 16107420 | 1 |
| Phönix | Urea | 16107424 | 1 |
| Phönix | Urea | 17H16-B01-342080 | 1 |
| PHÖNIX | Urea | 18023001 | 1 |
| Phönix | Urea | 18023003 | 2 |
| Phönix | Urea | 18023004 | 4 |
| Phönix | Urea | 18023006 | 1 |
| Phönix | Urea | 18023007 | 2 |
| Phönix | Urea | 18023010 | 1 |
| Phönix | Urea | 18023011 | 1 |
| Phönix | Urea | 18023015 | 1 |
| Phönix | Urea | 18024201 | 1 |
| Phönix | Urea | 190316006 | 1 |
| Phönix | Urea | 19031604 | 2 |
| Phönix | Urea | 19031614 | 2 |
| Phönix | Urea | 19031615 | 1 |
| PHÖNIX | Urea | 19031615 | 1 |
| Phönix | Urea | 1908016-01 | 1 |
| Phönix | Urea | 20003817002 | 1 |
| Phönix | Urea | 20003817012 | 1 |
| PHÖNIX | Urea | 20003817015 | 1 |
| Phönix | Urea | 2004010-01 | 1 |
| Phönix | Urea | 2100231015 | 1 |
| Phönix | Urea | 21002313017 | 2 |
| Phönix | Urea | 2102002-01 | 1 |
| PHönix | Urea | 2102002-01 | 1 |
| Phönix | Urea | 22002605001 | 2 |
| phönix | Urea | 22002605003 | 1 |
| Phönix | Urea | 22002605003 | 1 |
| Phönix | Urea | 22002605010 | 1 |
| Phönix | Urea | 23001146001 | 1 |
| Phönix | Urea | 23001146002 | 4 |
| Phönix | Urea | 2300114601 | 1 |
| Phönix | Urea | 23003219005 | 2 |
| Phönix | Urea | 23003219007 | 1 |
| Phönix | Urea | 23003219009 | 2 |
| Phönix | Urea | 23003219010 | 2 |
| Phönix | Urea | 24001776005 | 1 |
| Phönix | Urea | UP11 | 1 |
| Phöpnix | Urea | 20003817015 | 1 |
| Px/Phoenix | Urea | 18023004 | 1 |
| Raben-Apotheke Mildenau | Urea | 13J17-B02-287604 | 2 |
| Raben-Apotheke Mildenau | Urea | 13J17-Bo2-287604 | 1 |
| Röntgen | Urea | 1811012-01 | 1 |
| Röntgen | Urea | 190316003 | 1 |
| Röntgen | Urea | 20003817103 | 1 |
| sanacorb | Urea | 16107424 | 1 |
| Sanacorp | Urea | 1110023-01 | 1 |
| Sanacorp | Urea | 12111808 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Urea | 12111810 | 1 |
| Sanacorp | Urea | 12111820 | 1 |
| Sanacorp | Urea | 1212007 | 1 |
| Sanacorp | Urea | 13064203 | 1 |
| Sanacorp | Urea | 13064212 | 1 |
| Sanacorp | Urea | 13064223 | 1 |
| Sanacorp | Urea | 1405028-01 | 1 |
| Sanacorp | Urea | 14107102 | 1 |
| Sanacorp | Urea | 14107112 | 1 |
| Sanacorp | Urea | 14107113 | 1 |
| Sanacorp | Urea | 16107417 | 1 |
| Sanacorp | Urea | 16107418 | 2 |
| Sanacorp | Urea | 16107423 | 1 |
| Sanacorp | Urea | 16D22-B02 | 1 |
| Sanacorp | Urea | 18023004 | 2 |
| Sanacorp | Urea | 18023007 | 1 |
| Sanacorp | Urea | 18023011 | 1 |
| Sanacorp | Urea | 18024202 | 1 |
| Sanacorp | Urea | 1804007-01 | 2 |
| Sanacorp | Urea | 1811012-01 | 1 |
| Sanacorp | Urea | 190316002 | 1 |
| Sanacorp | Urea | 19031604 | 1 |
| Sanacorp | Urea | 19031609 | 2 |
| Sanacorp | Urea | 19031610 | 1 |
| Sanacorp | Urea | 19031615 | 1 |
| Sanacorp | Urea | 1908016-01 | 1 |
| Sanacorp | Urea | 19E07-B16-192854 | 3 |
| Sanacorp | Urea | 2004010-01 | 2 |
| Sanacorp | Urea | 20A30-B16-196837 | 1 |
| Sanacorp | Urea | 21002312001 | 1 |
| Sanacorp | Urea | 21002313007 | 1 |
| Sanacorp | Urea | 21002313016 | 1 |
| Sanacorp | Urea | 210200201 | 1 |
| Sanacorp | Urea | 2102002-01 | 2 |
| Sanacorp | Urea | 21C16-B02-210554 | 1 |
| Sanacorp | Urea | 21C16-B02-214451 | 3 |
| Sanacorp | Urea | 22002605003 | 1 |
| sanacorp | Urea | 22002605009 | 1 |
| Sanacorp | Urea | 22002605009 | 4 |
| Sanacorp | Urea | 220026050100 | 1 |
| Sanacorp | Urea | 23001146001 | 1 |
| Sanacorp | Urea | 23003219005 | 1 |
| Sanacorp | Urea | 23003219007 | 1 |
| Sanacorp | Urea | 23003219012 | 1 |
| sanacorp | Urea | 2301020-01 | 1 |
| Sanacorp | Urea | 2301020-01 | 1 |
| Sanacorp | Urea | 2301020-02 | 1 |
| Sanacorp | Urea | 2309011-01 | 2 |
| Sanacorp | Urea | 24001776001 | 1 |
| Sanacorp | Urea | 24001776003 | 1 |
| Sanacorp | Urea | 62/AKD50s | 1 |
| Sanacorp | Urea | 63/AKD1 | 1 |
| Sanacorp | Urea | Caelo | 1 |
| Sanacorp | Urea | V016-2019 | 1 |
| SKW Stickstoffwerke | Urea | 1804007-01 | 1 |
| SKW | Urea | 1404024-01 | 1 |
| Spangro 07.02.2014 | Urea | 13064226 | 1 |
| Spangro 17.01.2019 | Urea | 18023007 | 1 |
| Spangro 22.05.2014 | Urea | 13064230 | 1 |
| Spangro_07.11.2018 | Urea | 18023010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| test | Urea | `test` | 1 |
| THC/Phönix | Urea | `18023006` | 1 |
| Träger | Urea | `14107112` | 1 |
| VDL;05.02.15;10.15EUR | Urea | `14107113` | 1 |
| WE:Phoenix 11.08.16 … | Urea | `15154111` | 1 |

- 249 648 spectra from 1665 *Apo-Ident* customers from a total of 51 509 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Urea* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Urea* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 680 | 0 | 157 646 |
| **Type B** | 0 | 1340 | 0 | 211 600 |
| **Type C** | 0 | 7234 | 4 | 249 648 |

The substance/substance group *Urea* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.1176 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.5522 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.9447 % (> 99.9033 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20712 | 22552 | 4.60 | 212.33 |
| 21537 | 22466 | 4.03 | 214.90 |
| 22315 | 22466 | 8.16 | 209.90 |
| 22317 | 22466 | 4.96 | 211.05 |
| 22376 | 22376 | 0.00 | 212.67 |
| 22466 | 22466 | 0.00 | 214.01 |
| 22552 | 22552 | 0.00 | 212.83 |
| 23033 | 23033 | 0.00 | 210.87 |
| 24294 | 22466 | 8.34 | 209.71 |
| 25549 | 25549 | 0.00 | 211.91 |
| 26518 | 26518 | 0.00 | 211.13 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Ursodeoxycholic acid** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006311-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Ursodeoxycholic acid; Acidum ursodeoxycholicum

### Special notes

When selecting the *Ursodeoxycholic acid* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Ursodeoxycholic acid | 4 | 3 | 0 |

### Second-stage model

For differentiation of the substance/substance group *Ursodeoxycholic acid* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Ursodeoxycholic acid* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Menthol | 81.75 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Ursodeoxycholic acid* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Ursodeoxycholic acid*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Fagron | Ursodeoxycholic acid | 20F18-F22-372321 | 26471 | 40 | 240603341 |
| Fagron | Ursodeoxycholic acid | 22C09-B03-223073 | 26472 | 40 | 20220526 |
| Fagron | Ursodeoxycholic acid | 23E29-B08-228646 | 26902 | 40 | 20230704 |
| Fagron | Ursodeoxycholic acid | 23E29-B08-228646 | 26902SI | 20 | 20230704 |
| Fagron | Ursodeoxycholic acid | UDCA-II-20240633 | BR20032 | 40 | 20240709* |
| Fagron | Ursodeoxycholic acid | UDCA-II-20240633 | BR20032SI | 20 | 20240709* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 200 spectra of 6 reference samples from the substance/substance group *Ursodeoxycholic acid*.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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These samples are listed above in the *calibration samples* section. The reference samples come from 4 different batches.

- 158 126 spectra from a total of 2953 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 7 reference samples from the substance/substance group *Ursodeoxycholic acid*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Fagron | Ursodeoxycholic acid | 24C07-B17-236823 | 27265 | 40 |
| Fagron | Ursodeoxycholic acid | UDCA-II-20240807 | BR20033 | 40 |
| Fagron | Ursodeoxycholic acid | UDCA-II-20240312 | BR20034 | 40 |
| Fagron | Ursodeoxycholic acid | 20F18-F22-372321 | 26471SI† | 20 |
| Fagron | Ursodeoxycholic acid | 22C09-B03-223073 | 26472SI† | 20 |
| Fagron | Ursodeoxycholic acid | UDCA-II-20240807 | BR20033SI | 20 |
| Fagron | Ursodeoxycholic acid | UDCA-II-20240312 | BR20034SI | 20 |

- 212 740 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Ursodeoxycholic acid*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 256 886 spectra from 1666 *Apo-Ident* customers from a total of 52 153 batches from a further 725 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model,

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Ursodeoxycholic acid* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Ursodeoxycholic acid* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 200 | 0 | 158 126 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 0 | 0 | 256 886 |

The substance/substance group *Ursodeoxycholic acid* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9029 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26471 | 26471 | 0.00 | 149.35 |
| 26472 | 26471 | 49.89 | 145.67 |
| 26902 | 26471 | 50.07 | 145.22 |
| BR20032 | BR20032 | 0.00 | 142.09 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Valine** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20405-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Valine; Valinum

### Special notes

When selecting the *Valine* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Valine | 7 | 14 | 14 |

### Second-stage model

For differentiation of the substance/substance group *Valine* the following second-stage model is used:

- Submodel 13

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Valine* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Isoleucine | 65.90 | – |
| ⋮ | ⋮ | ⋮ |
| Levocarnitine | >50 | 35.75 |
| Oxybutynin hydrochloride | >50 | 118.99 |
| Cyproterone acetate | >50 | 155.21 |
| Prednicarbate | >50 | 164.30 |
| Capsaicin | >50 | 189.95 |
| Sodium citrate | >50 | 226.51 |
| Amitriptyline hydrochloride | >50 | 315.44 |
| Norethisterone acetate | >50 | 352.66 |
| Methoxsalen | >50 | 363.31 |
| Tetracaine | >50 | 367.09 |
| Pyridoxal-5-phosphate hydrate | >50 | 435.43 |
| Alfatradiol | >50 | 469.46 |
| Quinine hydrochloride dihydrate | >50 | 548.61 |
| Ciprofloxacin hydrochloride | >50 | 635.49 |
| Heparin sodium | >50 | 830.87 |
| Triclosan | >50 | 1716.56 |
| Amifampridine | >50 | 2492.80 |
| Sucrose | >50 | 2562.82 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Valine* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Valine*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Valine | 1604055 | 22571 | 40 | 20160601* |
| Euro OTC | Valine | 1701026 | 23131 | 40 | 20170222* |
| Euro OTC | Valine | 1904006 | 24611 | 40 | 20190423* |
| Euro OTC | Valine | 1909028 | 24971 | 40 | 20191015* |
| Euro OTC | Valine | 2004021 | 25169 | 40 | 20200505* |
| Euro OTC | Valine | 2006020 | 25335 | 40 | 20200814* |
| Fagron | Valine | 15A14-B07-307756 | 21953 | 60 | 9198 |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 300 spectra of 7 reference samples from the substance/substance group *Valine*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.
- 158 026 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 610 spectra of 17 reference samples from the substance/substance group *Valine*.
- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Valine | 1609009 | 22799 | 40 |
| Euro OTC | Valine | 1705017 | 23426 | 40 |
| Euro OTC | Valine | 1710003 | 23770 | 40 |
| Euro OTC | Valine | 1712005 | 23867 | 40 |
| Euro OTC | Valine | 1803017 | 24091 | 40 |
| Euro OTC | Valine | 1805014 | 24119 | 40 |
| Euro OTC | Valine | 1809027 | 24304 | 40 |
| Euro OTC | Valine | 2009046 | 25422 | 40 |
| Euro OTC | Valine | 2201022 | 25962 | 40 |
| Euro OTC | Valine | 2205007 | 26190 | 40 |
| Euro OTC | Valine | 2301008 | 26574 | 40 |
| Euro OTC | Valine | 2308006 | 26880 | 40 |
| Euro OTC | Valine | 2403016 | 27282 | 40 |
| Fagron | Valine | 24F26-B07-003667 | 27484 | 40 |
| Euro OTC | Valine | 2201022 | 25962SI | 10 |
| Euro OTC | Valine | 2205007 | 26190SI | 20 |
| Euro OTC | Valine | 2301008 | 26574SI | 20 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 212 330 spectra from a total of 4273 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 19 spectra from 10 *Apo-Ident* customers from 14 batches from the substance/substance group *Valine*.
- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Valine | 1604055-01 | 2 |
| Euro OTC | Valine | 1710003-01 | 1 |
| Euro OTC | Valine | 1805014-01 | 1 |
| Euro OTC | Valine | 1805014-02 | 2 |
| Euro OTC | Valine | 2006020-01 | 3 |
| Euro OTC | Valine | 2009045-03 | 1 |
| Euro OTC | Valine | 2009046-01 | 2 |
| Euro OTC | Valine | 2009046-03 | 1 |
| Euro OTC | Valine | L1309029-02 | 1 |
| Fagron | Valine | 121259 | 1 |
| Fagron | Valine | 13B13-N05 | 1 |
| Fagron | Valine | 17B27-B03-336205 | 1 |
| Fagron | Valine | 17H14-B04 | 1 |
| Fagron | Valine | 20B12-B02-196844 | 1 |

- 256 867 spectra from 1666 *Apo-Ident* customers from a total of 52 139 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Valine* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Valine* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 300 | 0 | 158 026 |
| **Type B** | 0 | 610 | 0 | 212 330 |
| **Type C** | 0 | 18 | 1 | 256 867 |

The substance/substance group *Valine* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:


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| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0164 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21953 | 21953 | 0.00 | 100.32 |
| 22571 | 22571 | 0.00 | 100.61 |
| 23131 | 23131 | 0.00 | 101.49 |
| 24611 | 24611 | 0.00 | 98.04 |
| 24971 | 24971 | 0.00 | 99.39 |
| 25169 | 25169 | 0.00 | 104.44 |
| 25335 | 25335 | 0.00 | 102.64 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Vancomycin hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 21748-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Vancomycin hydrochloride; Vancomycini hydrochloridum

### Special notes

When selecting the *Vancomycin hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Vancomycin hydrochloride | 11 | 7 | 5 |

### Second-stage model

For differentiation of the substance/substance group *Vancomycin hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Vancomycin hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, CBD-dominant type | 48.25 | – |
| Sodium cromoglicate | 49.32 | – |
| Cannabis flower, THC-dominant type | 52.16 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Vancomycin hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Vancomycin hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Audor Pharma | Vancomycin hydrochloride | APHAP1609006EV | 23532 | 40 | AR-18-FG-000670-01 |
| Euro OTC | Vancomycin hydrochloride | 1407047-01 | 21748 | 60 | AR-15-FG-008950-01 |
| Euro OTC | Vancomycin hydrochloride | 1506029 | 21826 | 60 | AR-15-FG-009077-01 |
| Euro OTC | Vancomycin hydrochloride | 1610038 | 22878 | 40 | 20161208* |
| Euro OTC | Vancomycin hydrochloride | 1810013 | 24325 | 40 | 20181029* |
| Euro OTC | Vancomycin hydrochloride | 1908025 | 24854 | 40 | 20190923* |
| Euro OTC | Vancomycin hydrochloride | 2002019 | 25269 | 40 | 20200629* |
| Euro OTC | Vancomycin hydrochloride | 2203002 | 26048 | 40 | 20220419* |
| Euro OTC | Vancomycin hydrochloride | 2402018 | 27294 | 40 | 20240710* |
| Fagron | Vancomycin hydrochloride | 17I18-B08-340944 | 24010 | 40 | 20171109 |
| Fagron | Vancomycin hydrochloride | 18L18-B02-359948 | 24696 | 40 | 20190207 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 480 spectra of 11 reference samples from the substance/substance group *Vancomycin hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 11 different batches.

- 157 846 spectra from a total of 2946 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 330 spectra of 10 reference samples from the substance/substance group *Vancomycin hydrochloride*.

- Among them are spectra of independent samples from 7 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Vancomycin hydrochloride | 1604037 | 22891 | 40 |
| Euro OTC | Vancomycin hydrochloride | 1812005 | 24421 | 40 |
| Euro OTC | Vancomycin hydrochloride | 1902014 | 24492 | 40 |
| Euro OTC | Vancomycin hydrochloride | 2211001 | 26525 | 40 |
| Euro OTC | Vancomycin hydrochloride | 2501013 | 27492 | 40 |
| Fagron | Vancomycin hydrochloride | 22G01-B07-221838 | 26383 | 40 |
| Fagron | Vancomycin hydrochloride | 23G06-B01-230986 | 26988 | 40 |
| Euro OTC | Vancomycin hydrochloride | 2203002 | 26048SI† | 10 |
| Euro OTC | Vancomycin hydrochloride | 2211001 | 26525SI | 20 |
| Fagron | Vancomycin hydrochloride | 22G01-B07-221838 | 26383SI | 20 |

- 212 610 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 7 spectra from 2 *Apo-Ident* customers from 5 batches from the substance/substance group *Vancomycin hydrochloride*.
- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Vancomycin hydrochloride | 1902014-01 | 2 |
| Euro OTC | Vancomycin hydrochloride | 2101015-01 | 1 |
| Fagron | Vancomycin hydrochloride | 20G16-F07 | 1 |
| Fagron | Vancomycin hydrochloride | 21G16-B01-217709 | 2 |
| Fagron | Vancomycin hydrochloride | 21G16-B01 | 1 |

- 256 879 spectra from 1666 *Apo-Ident* customers from a total of 52 148 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Vancomycin hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Vancomycin hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 480 | 0 | 157 846 |
| **Type B** | 0 | 330 | 0 | 212 610 |
| **Type C** | 0 | 6 | 1 | 256 879 |

The substance/substance group *Vancomycin hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.7500 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.1818 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.


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### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21748 | 21748 | 0.00 | 111.01 |
| 21826 | 21826 | 0.00 | 89.69 |
| 22878 | 22878 | 0.00 | 102.96 |
| 23532 | 23532 | 0.00 | 89.00 |
| 24010 | 23532 | 27.11 | 94.56 |
| 24325 | 24325 | 0.00 | 89.16 |
| 24696 | 26048 | 11.80 | 102.49 |
| 24854 | 24854 | 0.00 | 114.54 |
| 25269 | 25269 | 0.00 | 102.79 |
| 26048 | 26048 | 0.00 | 108.81 |
| 27294 | 27294 | 0.00 | 96.71 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Vanillin** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20204-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Vanillin; Vanillinum

### Special notes

When selecting the *Vanillin* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Vanillin | 6 | 4 | 61 |

### Second-stage model

For differentiation of the substance/substance group *Vanillin* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Vanillin* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Sodium cromoglicate | 99.47 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Vanillin* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Vanillin*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Vanillin | 14044413 | 21737 | 60 | 20140227 |
| Caelo | Vanillin | 15135302 | 21924 | 60 | AR-17-FG-022168-03 |
| Caelo | Vanillin | 160895 | 22484 | 60 | 20160421* |
| Caelo | Vanillin | 191201 | 24719 | 40 | 20190515* |
| Caelo | Vanillin | 22001135 | 26109 | 40 | 20220408* |
| Fagron | Vanillin | 13J01-N07 | 21738 | 60 | 20130926 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 320 spectra of 6 reference samples from the substance/substance group *Vanillin*. These samples

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 006 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 200 spectra of 6 reference samples from the substance/substance group *Vanillin*.
- Among them are spectra of independent samples from 4 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Vanillin | 171172 | 23308 | 40 |
| Caelo | Vanillin | 17117201 | 23561 | 40 |
| Caelo | Vanillin | 173088 | 23805 | 40 |
| Caelo | Vanillin | 23003197 | 27118 | 40 |
| Caelo | Vanillin | 22001135 | 26109SI† | 20 |
| Caelo | Vanillin | 23003197 | 27118SI | 20 |

- 212 740 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 257 spectra from 197 *Apo-Ident* customers from 65 batches from the substance/substance group *Vanillin*.
- Among them are spectra of independent samples from 61 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Vanillin | 21001092003 | 1 |
| | Vanillin | 22001135004 | 8 |
| | Vanillin | 22001135012 | 9 |
| | Vanillin | 23003197003 | 3 |
| AHD | Vanillin | 22001135004 | 1 |
| Alliance healfcare | Vanillin | 17117207 | 1 |
| Anzag | Vanillin | 12H09-N06 | 1 |
| Anzag | Vanillin | 16089508 | 1 |
| Caelo | Vanillin | | 1 |
| Caelo | Vanillin | 10066811 | 1 |
| Caelo | Vanillin | 10066830 | 1 |
| Caelo | Vanillin | 1089501 | 1 |
| Caelo | Vanillin | 112901 | 1 |
| Caelo | Vanillin | 12071401 | 1 |
| Caelo | Vanillin | 12079407 | 2 |
| Caelo | Vanillin | 12079410 | 2 |
| Caelo | Vanillin | 12079412 | 2 |
| Caelo | Vanillin | 12079417 | 1 |
| Caelo | Vanillin | 12079424 | 2 |
| Caelo | Vanillin | 12079428 | 1 |
| Caelo | Vanillin | 14044419 | 3 |
| Caelo | Vanillin | 15135302 | 2 |
| Caelo | Vanillin | 1514006 | 1 |
| Caelo | Vanillin | 15154006 | 1 |
| Caelo | Vanillin | 15154014 | 4 |
| Caelo | Vanillin | 15154017 | 2 |
| Caelo | Vanillin | 15154020 | 6 |
| Caelo | Vanillin | 15227317 | 1 |
| Caelo | Vanillin | 16089501 | 3 |
| Caelo | Vanillin | 16089506 | 12 |
| Caelo | Vanillin | 16089508 | 3 |
| Caelo | Vanillin | 17117201 | 2 |
| Caelo | Vanillin | 17117207 | 19 |
| Caelo | Vanillin | 17117208 | 3 |
| Caelo | Vanillin | 18073501 | 9 |
| Caelo | Vanillin | 18073506 | 3 |
| Caelo | Vanillin | 18073507 | 7 |
| Caelo | Vanillin | 18073509 | 4 |
| Caelo | Vanillin | 18073511 | 5 |
| Caelo | Vanillin | 18073515 | 5 |
| Caelo | Vanillin | 191201005 | 10 |
| Caelo | Vanillin | 19120102 | 9 |
| Caelo | Vanillin | 20000477003 | 5 |
| Caelo | Vanillin | 20003608002 | 4 |
| Caelo | Vanillin | 20003608006 | 4 |
| Caelo | Vanillin | 2000477003 | 1 |
| Caelo | Vanillin | 21001092003 | 5 |
| Caelo | Vanillin | 21001092009 | 6 |
| Caelo | Vanillin | 211029 | 1 |
| Caelo | Vanillin | 2200135004 | 2 |
| Caelo | Vanillin | 250220004773 | 1 |
| Caelo | Vanillin | 4216I-02548 | 1 |
| Caelo | Vanillin | 90961269 | 1 |
| Caesar & Loretz GmbH... | Vanillin | 21001092003 | 1 |
| Caesar & Loretz GmbH... | Vanillin | 18073515 | 1 |
| Caesar & Loretz GmbH... | Vanillin | 18073507 | 1 |
| Caesar & Loretz GmbH... | Vanillin | 10066830 | 1 |
| Caesar & Loretz GmbH... | Vanillin | 12079401 | 1 |
| Caesar & Loretz GmbH... | Vanillin | 12079412 | 1 |
| Caesar & Loretz GmbH | Vanillin | 16089508 | 2 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Vanillin | 18073511 | 1 |
| Caesar & Loretz GmbH | Vanillin | 18073515 | 1 |
| Caesar & Loretz GmbH | Vanillin | 191201005 | 7 |
| Caesar & Loretz GmbH | Vanillin | 20000477003 | 1 |
| Caesar & Loretz GmbH | Vanillin | 20003608002 | 3 |
| Caesar & Loretz GmbH | Vanillin | 20003608006 | 1 |
| Caesar & Loretz GmbH | Vanillin | 21001092003 | 2 |
| Caesar & Loretz GmbH | Vanillin | 21001092009 | 4 |
| Caesar & Loretz GmbH | Vanillin | 22001135011 | 1 |
| Caesar & Loretz/Geil... | Vanillin | 191201005 | 1 |
| Caleo / Phoenix | Vanillin | 20000477003 | 1 |
| Dr.Hollborn | Vanillin | 6082015 | 1 |
| Fagron | Vanillin | 11G28-N09 | 1 |
| Fagron | Vanillin | 12D02-N03 | 1 |
| Fagron | Vanillin | 12H09-N06 | 2 |
| Fagron | Vanillin | 13J01-N07 | 6 |
| Fagron | Vanillin | 14G02-B99-296988 | 1 |
| Fagron | Vanillin | 18073501 | 1 |
| Fagron | Vanillin | 232050-0004 | 1 |
| Fagron | Vanillin | 314Q2548 | 1 |
| Fagron | Vanillin | 8L05-N07 | 1 |
| fargron | Vanillin | 13/01-N07 | 1 |
| Finteler Apotheke | Vanillin | 17117201 | 1 |
| Gatt-Koller | Vanillin | 201770800 | 1 |
| Gehe/Noweda | Vanillin | 15154006 | 1 |
| Gehe | Vanillin | 12079412 | 1 |
| Gehe | Vanillin | 16089506 | 1 |
| Gehe | Vanillin | 20000477003 | 1 |
| Gehe | Vanillin | 22001135004 | 1 |
| Hedinger/Ebert | Vanillin | 13A30-N10 | 1 |
| Jenne | Vanillin | 18073501 | 1 |
| Jenne | Vanillin | 241101(22001135012) | 1 |
| Klosterring | Vanillin | 17117207 | 1 |
| L10 | Vanillin | 18073506 | 1 |
| L12 | Vanillin | 16089508 | 1 |
| L12 | Vanillin | 17117201 | 1 |
| L12 | Vanillin | 18073501 | 1 |
| labor | Vanillin | 101010101 | 1 |
| Noweda | Vanillin | 18073501 | 1 |
| Phoenix | Vanillin | 21001092003 | 1 |
| Reagenz Ph.Eur. | Vanillin | | 1 |
| Rhodia GmbH/Noweda | Vanillin | 12D02-N03 | 1 |
| Sanacorp | Vanillin | 12H09-N06 | 1 |
| Sanacorp | Vanillin | 18073511 | 1 |
| Sanacorp | Vanillin | 20000477003 | 1 |

- 256 629 spectra from 1666 *Apo-Ident* customers from a total of 52 091 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Vanillin* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Vanillin* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table

breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 320 | 0 | 158 006 |
| **Type B** | 0 | 200 | 0 | 212 740 |
| **Type C** | 0 | 256 | 1 | 256 629 |

The substance/substance group *Vanillin* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.1250 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.0000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6109 % (> 98.4436 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21737 | 21924 | 2.92 | 198.07 |
| 21738 | 21924 | 4.00 | 202.32 |
| 21924 | 21924 | 0.00 | 190.68 |
| 22484 | 22484 | 0.00 | 206.15 |
| 24719 | 24719 | 0.00 | 208.16 |
| 26109 | 26109 | 0.00 | 220.45 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Waxes / Fats** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20865-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Waxes / Fats; Adeps solidus; Adeps solidus W35; Beeswax, white; Beeswax, yellow; Cera alba; Cera flava; Cetyl palmitate; Cetylis palmitas; Cocoa butter; Hard fat; Hard fat W35; Microcrystalline wax; Natrii laurilsulfas; Paraffin, hard; Paraffin, microcrystalline; Paraffina microcristallina; Paraffinum solidum; Sodium dodecyl sulfate; Sodium dodecyl sulphate; Theobromatis oleum

### Special notes

When selecting the *Waxes / Fats* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Waxes / Fats | 59 | 57 | 1207 |

### Second-stage model

For differentiation of the substance/substance group *Waxes / Fats* the following second-stage model is used:

- Submodel 01

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Waxes / Fats* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Magnesium stearate | 66.78 | 21.80 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Waxes / Fats* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Waxes / Fats*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Beeswax, white | 13378619 | 21483 | 20 | 1509364 |
| Caelo | Beeswax, white | 14336620 | 22244 | 60 | 20141125 |
| Caelo | Beeswax, white | 15292022 | 22956 | 40 | 20150827 |
| Caelo | Beeswax, white | 20003825001 | 25739 | 50 | 20201123 |
| Caelo | Beeswax, white | 22000795006 | 26622 | 40 | 20220329 |
| Fagron | Beeswax, white | 21C26-B07-204255 | 25723 | 50 | 2110141 |
| Fagron | Beeswax, white | 23I12-B02-233063 | 27268 | 40 | 20230927 |
| Fagron | Beeswax, white | 23I12-B02-233063 | 27268SI | 20 | 20230927 |
| Bombastus | Beeswax, yellow | 23002495 | 26910 | 40 | 20230530 |
| Caelo | Beeswax, yellow | 13335507 | 21433 | 60 | 20131011 |
| Caelo | Beeswax, yellow | 15317602 | 22245 | 60 | 20151007 |
| Caelo | Beeswax, yellow | 21004132003 | 26734 | 40 | 20220128 |
| Caelo | Beeswax, yellow | 21004132003 | 26734SI | 20 | 20220128 |
| Klenk | Beeswax, yellow | 0290A170314 | 23511 | 40 | 1908177 |
| Klenk | Beeswax, yellow | 0290A170915 | 24870 | 40 | 20190507 |
| Caelo | Cetyl palmitate | 12331916 | 20865 | 40 | 1402429 |
| Caelo | Cetyl palmitate | 14351606 | 21875 | 60 | 20141219 |
| Caelo | Cetyl palmitate | 15301703 | 21984 | 60 | AR-16-FG-007435-01 |
| Caelo | Cetyl palmitate | 15301703 | 22325 | 60 | 20151013 |
| Caelo | Cetyl palmitate | 160538 | 22486 | 60 | 20160323* |
| Caelo | Cetyl palmitate | 17043503 | 23560 | 40 | 20170306 |
| Caelo | Cetyl palmitate | 171640 | 23639 | 40 | 20170719* |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Cetyl palmitate | 172715 | 23817 | 40 | 20171124* |
| Caelo | Cetyl palmitate | 191390 | 24720 | 40 | 20190702* |
| Caelo | Cetyl palmitate | 23001428 | 26959 | 40 | 20231108* |
| Caelo | Cocoa butter | 13292013 | 21482 | 40 | 20130924 |
| Caelo | Cocoa butter | 14348906 | 22348 | 60 | 20150122 |
| Caelo | Cocoa butter | 163165 | 23067 | 40 | 20161116* |
| Caelo | Cocoa butter | 17055907 | 23707 | 33 | 20170310 |
| Caelo | Cocoa butter | 190360 | 24813 | 40 | 20190227* |
| Caelo | Cocoa butter | 19000676008 | 25384 | 40 | 20200318 |
| Bombastus | Hard fat | 306363 | 23565 | 34 | 20161213 |
| Bombastus | Hard fat | 308558 | 23705 | 40 | 20170321 |
| Bombastus | Hard fat | 20002467 | 25381 | 40 | 20200518 |
| Caelo | Hard fat | 12158122 | 21067 | 40 | 20120627 |
| Caelo | Hard fat | 160278 | 22479 | 60 | 20160407* |
| Caelo | Hard fat | 20003131 | 25639 | 40 | 20201210* |
| Caelo | Hard fat | 22002076 | 26362 | 40 | 20220805* |
| Fagron | Hard fat W35 | 15A07-B12-302751 | 21880 | 60 | 1604639 |
| Fagron | Hard fat W35 | 15A07-B12-309245 | 22338 | 60 | 20150115 |
| Fagron | Hard fat W35 | 16K08-B10-334910 | 23601 | 40 | 20161229 |
| Fagron | Hard fat W35 | 19C04-B09-191420 | 25047 | 40 | 20190330 |
| Fagron | Hard fat W35 | 20H17-B09-202675 | 25445 | 40 | 20200904 |
| Fagron | Hard fat W35 | 23G27-B04-231463 | 27034 | 40 | 20230830 |
| Caelo | Paraffin, hard | 13390413 | 21731 | 60 | 20131213 |
| Caelo | Paraffin, hard | 15232004 | 22349 | 60 | 1702507 |
| Caelo | Paraffin, hard | 192463001 | 25387 | 40 | 20191024 |
| Caelo | Paraffin, hard | 21001748 | 26745 | 40 | 20210701 |
| Caelo | Paraffin, hard | 21001748 | 26745SI | 20 | 20210701 |
| Caelo | Paraffin, microcrystalline | 14307104 | 21682 | 60 | AR-15-FG-005277-01 |
| Caelo | Paraffin, microcrystalline | 14307106 | 21766 | 60 | 20141014 |
| Caelo | Paraffin, microcrystalline | 154128 | 22330 | 60 | 20160112* |
| Caelo | Paraffin, microcrystalline | 19234501 | 25434 | 40 | 20191015 |
| Caelo | Paraffin, microcrystalline | 23003019 | 27418 | 40 | 20240126* |
| Caelo | Paraffin, microcrystalline | 23003019 | 27418SI | 20 | 20240126* |
| Caelo | Sodium dodecyl sulfate | 13099011 | 20986 | 40 | 1403108 |
| Caelo | Sodium dodecyl sulfate | 15344503 | 22352 | 60 | 20151022 |
| Caelo | Sodium dodecyl sulfate | 16229217 | 23242 | 40 | 20160809 |
| Caelo | Sodium dodecyl sulfate | 170955 | 23278 | 40 | 20170503* |
| Caelo | Sodium dodecyl sulfate | 191243 | 24715 | 40 | 20190521* |
| Caelo | Sodium dodecyl sulfate | 190923 | 24716 | 40 | 20190521* |
| Caelo | Sodium dodecyl sulfate | 20001260 | 25216 | 40 | 20200512* |
| Caelo | Sodium dodecyl sulfate | 22000409 | 26108 | 40 | 20220427* |
| Caelo | Sodium dodecyl sulfate | 22000409 | 26108SI | 20 | 20220427* |
| Caelo | Sodium dodecyl sulfate | 23000156 | 26696 | 40 | 20230209* |
| Caelo | Sodium dodecyl sulfate | 23000156 | 26696SI | 20 | 20230209* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 2847 spectra of 66 reference samples from the substance/substance group *Waxes / Fats*. These samples are listed above in the *calibration samples* section. The reference samples come from 59 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

- 155 479 spectra from a total of 2898 batches from further 488 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 2523 spectra of 71 reference samples from the substance/substance group *Waxes / Fats*.
- Among them are spectra of independent samples from 57 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Beeswax, white | 161631 | 22587 | 40 |
| Caelo | Beeswax, white | 16163109 | 23513 | 40 |
| Caelo | Beeswax, white | 182391 | 24351 | 40 |
| Caelo | Beeswax, white | 23002638008 | 27587 | 40 |
| Fagron | Beeswax, white | 21G17-B03-215725 | 26057 | 40 |
| Bombastus | Beeswax, yellow | 22000930 | 26027 | 40 |
| Bombastus | Beeswax, yellow | 24003398 | 27489 | 40 |
| Caelo | Beeswax, yellow | 162750 | 22767 | 40 |
| Caelo | Beeswax, yellow | 17011602 | 23512 | 40 |
| Caelo | Beeswax, yellow | 20003602005 | 25738 | 50 |
| Caelo | Beeswax, yellow | 23003594 | 27338 | 40 |
| Caelo | Cetyl palmitate | 13295919 | 21316 | 20 |
| Caelo | Cetyl palmitate | 181499 | 24221 | 40 |
| Caelo | Cetyl palmitate | 182737 | 24356 | 40 |
| Caelo | Cetyl palmitate | 192859 | 25224 | 40 |
| Caelo | Cetyl palmitate | 21000860001 | 25933 | 40 |
| Caelo | Cetyl palmitate | 22000395002 | 26411 | 40 |
| Caelo | Cetyl palmitate | 24001934 | 27451 | 40 |
| Caelo | Cetyl palmitate | 25000646 | 27660 | 40 |
| Caelo | Cocoa butter | 173149 | 23795 | 40 |
| Caelo | Cocoa butter | 181351 | 24226 | 40 |
| Caelo | Cocoa butter | 182544 | 24363 | 40 |
| Caelo | Cocoa butter | 21002516002 | 25934 | 40 |
| Caelo | Cocoa butter | 23001467 | 27106 | 40 |
| Caelo | Cocoa butter | 24002448 | 27536 | 40 |
| Euro OTC | Cocoa butter | 2502011 | 27630 | 40 |
| Bombastus | Hard fat | 18006248 | 24663 | 40 |
| Bombastus | Hard fat | 21004219 | 26026 | 40 |
| Bombastus | Hard fat | 23001364 | 26623 | 40 |
| Bombastus | Hard fat | 23004847 | 27488 | 40 |
| Bombastus | Hard fat | 25001337 | 27655 | 40 |
| Caelo | Hard fat | 173076 | 23814 | 40 |
| Caelo | Hard fat | 181479 | 24228 | 40 |
| Caelo | Hard fat | 183339 | 24529 | 40 |
| Caelo | Hard fat | 191940 | 24887 | 40 |

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| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Hard fat | 21003046 | 25846 | 50 |
| Caelo | Hard fat | 23000561 | 26700 | 35 |
| Caelo | Hard fat | 23001036 | 27120 | 40 |
| Caelo | Hard fat | 24001755 | 27450 | 40 |
| Euro OTC | Hard fat | 2303007 | 26674 | 40 |
| Euro OTC | Hard fat | 2307014 | 26920 | 40 |
| Euro OTC | Hard fat | 2501014 | 27628 | 40 |
| Fagron | Hard fat W35 | 15J08-B04-324959 | 22806 | 40 |
| Fagron | Hard fat W35 | 17K09-B03-343779 | 24114 | 40 |
| Fagron | Hard fat W35 | 20J07-B02-202717 | 25748 | 50 |
| Fagron | Hard fat W35 | 21B23-B98-211232 | 25908 | 40 |
| Caelo | Paraffin, hard | 16277704 | 23190 | 40 |
| Caelo | Paraffin, hard | 23003232 | 27416 | 40 |
| Caelo | Paraffin, microcrystalline | 15412801 | 23724 | 40 |
| Caelo | Paraffin, microcrystalline | 21003773006 | 26237 | 35 |
| Caelo | Sodium dodecyl sulfate | 13411305 | 21465 | 60 |
| Caelo | Sodium dodecyl sulfate | 16229205 | 23243 | 40 |
| Caelo | Sodium dodecyl sulfate | 172363 | 23664 | 40 |
| Caelo | Sodium dodecyl sulfate | 181822 | 24292 | 40 |
| Caelo | Sodium dodecyl sulfate | 190187 | 24549 | 40 |
| Caelo | Sodium dodecyl sulfate | 20001952 | 25222 | 40 |
| Caelo | Sodium dodecyl sulfate | 24001699 | 27333 | 40 |
| Caelo | Beeswax, white | 22000795006 | 26622SI† | 20 |
| Fagron | Beeswax, white | 21G17-B03-215725 | 26057SI | 10 |
| Bombastus | Beeswax, yellow | 22000930 | 26027SI | 10 |
| Bombastus | Beeswax, yellow | 23002495 | 26910SI† | 20 |
| Caelo | Cetyl palmitate | 13295919 | 21522 | 40 |
| Caelo | Cetyl palmitate | 21000860001 | 25933SI | 10 |
| Caelo | Cetyl palmitate | 23001428 | 26959SI† | 20 |
| Caelo | Cetyl palmitate | 24001934 | 27451SI | 20 |
| Caelo | Cocoa butter | 17055907 | 23707† | 7 |
| Bombastus | Hard fat | 306363 | 23565† | 6 |
| Bombastus | Hard fat | 21004219 | 26026SI | 10 |
| Caelo | Paraffin, hard | 23003232 | 27416SI | 20 |
| Caelo | Paraffin, microcrystalline | 21003773006 | 26237SI | 10 |
| Caelo | Sodium dodecyl sulfate | 24001699 | 27333SI | 20 |

- 210 417 spectra from a total of 4225 batches from further 864 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 6158 spectra from 1088 *Apo-Ident* customers from 1177 batches from the substance/substance group *Waxes / Fats*.

- Among them are spectra of independent samples from 1129 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Cocoa butter | 1222300201 | 1 |
| | Cocoa butter | 18254412 | 1 |
| | Beeswax, yellow | 20000280008 | 1 |
| | Beeswax, white | 20000885007 | 1 |
| | Hard fat | 20003131003 | 1 |
| | Beeswax, yellow | 20003602009 | 1 |
| | Cetyl palmitate | 20003842013 | 1 |
| | Hard fat | 201023/1 | 1 |
| | Beeswax, yellow | 2090A230413-01 | 1 |
| | Beeswax, white | 21001267002 | 1 |
| | Beeswax, white | 21001267008 | 1 |
| | Beeswax, white | 21001267012 | 5 |
| | Beeswax, yellow | 21001423003 | 6 |
| | Beeswax, yellow | 21001423010 | 3 |
| | Paraffin, hard | 2100174018 | 1 |
| | Paraffin, hard | 21001748004 | 1 |
| | Paraffin, hard | 21001748011 | 1 |
| | Paraffin, hard | 21001748012 | 3 |
| | Paraffin, hard | 21001748014 | 3 |
| | Paraffin, hard | 21001748017 | 1 |
| | Paraffin, hard | 21001748018 | 10 |
| | Cocoa butter | 21002516020 | 2 |
| | Hard fat | 21003046006 | 1 |
| | Hard fat | 21003046011 | 1 |
| | Paraffin, microcrystalline | 21003773008 | 1 |
| | Beeswax, yellow | 21004132003 | 23 |
| | Beeswax, white | 21004132004 | 6 |
| | Beeswax, yellow | 21004132010 | 8 |
| | Beeswax, white | 21115-01 | 1 |
| | Beeswax, white | 22000795001 | 12 |
| | Beeswax, white | 22000795006 | 5 |
| | Beeswax, white | 22000795007 | 8 |
| | Beeswax, white | 2200079501 | 1 |
| | Cetyl palmitate | 220017004 | 1 |
| | Cetyl palmitate | 22001717001 | 5 |
| | Cetyl palmitate | 22001717004 | 6 |
| | Cetyl palmitate | 22001785003 | 8 |
| | Hard fat | 22002076002 | 3 |
| | Hard fat | 22002076008 | 1 |
| | Hard fat | 22002076009 | 1 |
| | Hard fat | 22002076010 | 3 |
| | Hard fat W35 | 22002377 | 1 |
| | Cocoa butter | 22003120004 | 5 |
| | Cocoa butter | 22003120014 | 1 |
| | Sodium dodecyl sulfate | 22003127001 | 2 |
| | Beeswax, white | 22003630003 | 18 |
| | Beeswax, yellow | 22003888002 | 23 |
| | Beeswax, yellow | 22003888003 | 9 |
| | Hard fat | 22004876 | 2 |
| | Cetyl palmitate | 2201717001 | 1 |
| | Beeswax, white | 221115-001 | 2 |
| | Hard fat W35 | 22J26-B12-224506 | 1 |
| | Sodium dodecyl sulfate | 23000156006 | 1 |
| | Sodium dodecyl sulfate | 23000156007 | 1 |
| | Sodium dodecyl sulfate | 23000156014 | 1 |
| | Hard fat | 23000446 | 1 |
| | Hard fat | 23000447 | 6 |
| | Hard fat | 23000561002 | 22 |
| | Hard fat | 23000561003 | 6 |
| | Hard fat | 23000561004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Hard fat | 23000561006 | 2 |
| | Hard fat | 23000561008 | 4 |
| | Hard fat | 23001036002 | 4 |
| | Hard fat | 23001036003 | 1 |
| | Hard fat | 23001036004 | 8 |
| | Paraffin, hard | 23001089003 | 1 |
| | Hard fat W35 | 23001364 | 4 |
| | Cetyl palmitate | 23001428003 | 1 |
| | Cetyl palmitate | 23001428006 | 14 |
| | Cocoa butter | 23001467004 | 2 |
| | Cocoa butter | 23001467005 | 7 |
| | Paraffin, hard | 23002594001 | 1 |
| | Beeswax, white | 23002638001 | 11 |
| | Beeswax, white | 23002638005 | 1 |
| | Beeswax, white | 23002638006 | 1 |
| | Beeswax, white | 23002638007 | 1 |
| | Beeswax, white | 23002638008 | 5 |
| | Beeswax, white | 23002638013 | 2 |
| | Cocoa butter | 23003224001 | 1 |
| | Paraffin, hard | 2300323005 | 3 |
| | Paraffin, hard | 23003232003 | 2 |
| | Paraffin, hard | 23003232004 | 2 |
| | Paraffin, hard | 23003232005 | 6 |
| | Paraffin, hard | 23003232007 | 7 |
| | Beeswax, yellow | 23003298002 | 10 |
| | Beeswax, yellow | 23003298003 | 8 |
| | Beeswax, yellow | 23003298007 | 1 |
| | Beeswax, yellow | 23003298008 | 2 |
| | Beeswax, yellow | 23003298009 | 2 |
| | Hard fat | 2300561002 | 1 |
| | Beeswax, yellow | 230120-001 | 1 |
| | Beeswax, yellow | 230413-001 | 5 |
| | Beeswax, white | 230413-003 | 2 |
| | Hard fat | 24000084001 | 1 |
| | Cetyl palmitate | 24000124003 | 8 |
| | Sodium dodecyl sulfate | 24001699002 | 1 |
| | Hard fat | 24001755003 | 2 |
| | Cetyl palmitate | 24001934001 | 3 |
| | Cetyl palmitate | 24001934007 | 3 |
| | Cocoa butter | 24002448006 | 3 |
| | Cocoa butter | 24300201 | 1 |
| | Beeswax, white | 280A22111501 | 1 |
| | Beeswax, white | 280A221115-01 | 5 |
| | Beeswax, white | 280A230413-01 | 2 |
| | Beeswax, white | 280A230413-02 | 3 |
| | Beeswax, yellow | 290A230120-01 | 6 |
| | Beeswax, yellow | 290A230413-001 | 1 |
| | Beeswax, yellow | 290A230413-01 | 6 |
| | Beeswax, yellow | 30413-01 | 2 |
| | Cocoa butter | 423300201 | 1 |
| | Beeswax, white | 42374 | 2 |
| | Beeswax, yellow | 44064 | 1 |
| | Paraffin, hard | 45338 | 1 |
| | Beeswax, yellow | 45524 | 1 |
| | Paraffin, hard | 46422 | 1 |
| | Paraffin, hard | 47249 | 1 |
| / AHD | Cocoa butter | 20004174002 | 1 |
| 04748126 | Cocoa butter | 21002516017 | 2 |
| ACM | Cocoa butter | KNC1605J15 | 1 |
| aep | Beeswax, yellow | 21001423010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AEP | Cocoa butter | 24002448006 | 1 |
| AHC | Beeswax, yellow | 21001423003 | 1 |
| AHC | Paraffin, hard | 23003232005 | 1 |
| AHD | Cocoa butter | 14348906 | 1 |
| AHD | Beeswax, yellow | 15022908 | 1 |
| AHD | Beeswax, yellow | 18299202 | 1 |
| AHD | Beeswax, white | 22000795001 | 1 |
| AHD | Beeswax, white | 22000795006 | 1 |
| AHD | Cetyl palmitate | 22001785003 | 1 |
| AHD | Cocoa butter | 22003120004 | 1 |
| AHD | Beeswax, yellow | 22003888002 | 1 |
| AHD | Hard fat | 23000561002 | 1 |
| AHD | Cetyl palmitate | 23001428006 | 2 |
| AHD | Beeswax, yellow | 23003298002 | 1 |
| AHD | Cetyl palmitate | 24001934005 | 1 |
| Alliance H. | Cetyl palmitate | 15301709 | 1 |
| Alliance Halth Care | Hard fat | 240017 | 1 |
| Alliance Health 14.0… | Beeswax, yellow | 280A130115 | 1 |
| Alliance Healthcare | Cetyl palmitate | 13131905 | 1 |
| Alliance Healthcare | Beeswax, yellow | 290A120627 | 1 |
| Alliance Healthcare | Beeswax, white | 5443200038243 | 1 |
| Alliance | Paraffin, hard | 21001748007 | 1 |
| Alliance | Paraffin, hard | 21001748018 | 1 |
| Alliance | Beeswax, yellow | 21004132003 | 1 |
| Alliance | Cetyl palmitate | 22001785003 | 1 |
| alliance | Beeswax, white | 23002638001 | 1 |
| Alliance | Beeswax, yellow | 280A130115 | 1 |
| Anzag | Cocoa butter | 11117816 | 1 |
| Anzag | Cetyl palmitate | 12018208 | 1 |
| Anzag | Cocoa butter | 12342004 | 1 |
| Anzag | Beeswax, yellow | 1462 | 1 |
| Anzag | Paraffin, hard | 21000732001 | 1 |
| Anzag | Beeswax, yellow | 23003298002 | 2 |
| Anzag | Beeswax, yellow | 230606 | 1 |
| Anzag | Paraffin, hard | 240513(23003232004) | 1 |
| Anzag | Paraffin, hard | 42241 | 1 |
| apomix | Cocoa butter | 1017300203 | 1 |
| apomix | Hard fat | 18147901 | 1 |
| Apotheker Bauer & Ci… | Beeswax, white | 17091802 | 1 |
| Bambastus/Gehe | Hard fat W35 | 18006248 | 1 |
| Beiersdorf | Beeswax, white | 15292014 | 1 |
| BOM | Hard fat W35 | 22004876 | 1 |
| Bombastus | Beeswax, white | 16163109 | 1 |
| Bombastus | Beeswax, yellow | 17011604 | 1 |
| Bombastus | Hard fat | 17107304 | 2 |
| Bombastus | Beeswax, yellow | 17207405 | 1 |
| Bombastus | Cocoa butter | 17314901 | 1 |
| Bombastus | Hard fat | 18000345 | 1 |
| Bombastus | Hard fat | 18000346 | 6 |
| Bombastus | Hard fat | 18004024 | 6 |
| Bombastus | Hard fat | 18006248 | 3 |
| Bombastus | Hard fat | 19001444 | 1 |
| Bombastus | Hard fat | 19001445 | 3 |
| Bombastus | Hard fat | 19002628 | 1 |
| Bombastus | Hard fat | 19002629 | 2 |
| Bombastus | Hard fat | 20000603 | 7 |
| Bombastus | Hard fat | 20002467 | 7 |
| Bombastus | Hard fat W35 | 20005051 | 2 |
| Bombastus | Hard fat | 21004217 | 1 |
| Bombastus | Hard fat | 21004219 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Hard fat W35 | 22002377 | 8 |
| Bombastus | Hard fat | 22004876 | 3 |
| Bombastus | Hard fat | 23000446 | 1 |
| Bombastus | Hard fat | 23000447 | 2 |
| Bombastus | Beeswax, yellow | 267702 | 1 |
| Bombastus | Beeswax, yellow | 270682 | 3 |
| Bombastus | Hard fat | 273759 | 1 |
| Bombastus | Hard fat | 277212 | 2 |
| Bombastus | Beeswax, yellow | 279999 | 1 |
| Bombastus | Beeswax, white | 280A171019 | 1 |
| Bombastus | Beeswax, yellow | 285109 | 1 |
| Bombastus | Hard fat | 287287 | 1 |
| Bombastus | Beeswax, yellow | 290A170915 | 1 |
| Bombastus | Beeswax, yellow | 292025 | 1 |
| Bombastus | Paraffin, hard | 293848 | 7 |
| Bombastus | Beeswax, yellow | 296261 | 1 |
| Bombastus | Hard fat W35 | 302709 | 3 |
| Bombastus | Hard fat | 306363 | 5 |
| Bombastus | Hard fat | 308559 | 3 |
| Bombastus | Beeswax, yellow | caelo | 1 |
| Bombstus/Geilenkirchen | Hard fat W35 | 18004024 | 1 |
| cae | Beeswax, yellow | 15317608 | 1 |
| Cae4lo | Hard fat | 15185002 | 1 |
| Caele | Beeswax, yellow | 17011607 | 1 |
| Caelo | Beeswax, white | | 9 |
| Caelo | Beeswax, white | 10023025 | 1 |
| Caelo | Cetyl palmitate | 10068410 | 1 |
| Caelo | Beeswax, yellow | 10121302 | 1 |
| Caelo | Hard fat | 10158813 | 1 |
| Caelo | Cocoa butter | 1018302053 | 1 |
| Caelo | Paraffin, hard | 10194101 | 2 |
| Caelo | Cocoa butter | 103276705 | 1 |
| Caelo | Beeswax, yellow | 10364810 | 1 |
| Caelo | Beeswax, yellow | 10364837 | 1 |
| Caelo | Beeswax, white | 10651388 | 1 |
| Caelo | Beeswax, yellow | 11017308 | 1 |
| Caelo | Beeswax, yellow | 11017314 | 1 |
| Caelo | Beeswax, yellow | 11017315 | 1 |
| Caelo | Beeswax, yellow | 11017318 | 3 |
| Caelo | Paraffin, hard | 11021202 | 1 |
| Caelo | Cetyl palmitate | 11021502 | 1 |
| Caelo | Cocoa butter | 11034718 | 1 |
| Caelo | Cocoa butter | 11034719 | 1 |
| Caelo | Cetyl palmitate | 11042019 | 1 |
| Caelo | Hard fat | 11109617 | 1 |
| Caelo | Hard fat | 11109623 | 2 |
| Caelo | Cocoa butter | 11117816 | 1 |
| Caelo | Sodium dodecyl sulfate | 11220208 | 1 |
| Caelo | Beeswax, yellow | 11285001 | 2 |
| Caelo | Beeswax, yellow | 11285014 | 2 |
| Caelo | Beeswax, yellow | 11285015 | 1 |
| Caelo | Beeswax, yellow | 11308305 | 1 |
| Caelo | Beeswax, yellow | 11308311 | 2 |
| Caelo | Hard fat | 11345904 | 1 |
| Caelo | Hard fat | 11345905 | 3 |
| Caelo | Hard fat | 11345917 | 3 |
| Caelo | Hard fat | 11345918 | 8 |
| Caelo | Hard fat | 1135917 | 1 |
| Caelo | Paraffin, hard | 1136206 | 1 |
| Caelo | Paraffin, hard | 11363205 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Paraffin, hard | 11363206 | 2 |
| Caelo | Paraffin, hard | 11363220 | 3 |
| Caelo | Cetyl palmitate | 12018204 | 3 |
| Caelo | Cetyl palmitate | 12018204/Int212191 | 1 |
| Caelo | Cetyl palmitate | 12018208 | 6 |
| Caelo | Cetyl palmitate | 12018215 | 1 |
| Caelo | Cocoa butter | 12040802 | 1 |
| Caelo | Cocoa butter | 12040803 | 1 |
| Caelo | Cocoa butter | 12040807 | 2 |
| Caelo | Beeswax, yellow | 12041303 | 1 |
| Caelo | Cetyl palmitate | 12082901 | 1 |
| Caelo | Beeswax, yellow | 12091404 | 1 |
| Caelo | Paraffin, microcrystalline | 12095101 | 1 |
| Caelo | Hard fat | 12111204 | 1 |
| Caelo | Beeswax, yellow | 12124801 | 4 |
| Caelo | Beeswax, yellow | 12124802 | 2 |
| Caelo | Beeswax, yellow | 121248024-2015 | 1 |
| Caelo | Beeswax, yellow | 12124805 | 4 |
| Caelo | Beeswax, yellow | 12124806 | 2 |
| Caelo | Beeswax, yellow | 12124807 | 3 |
| Caelo | Beeswax, yellow | 12124810 | 4 |
| Caelo | Beeswax, yellow | 12124811 | 1 |
| Caelo | Beeswax, yellow | 12124812 | 8 |
| Caelo | Beeswax, yellow | 12124814 | 2 |
| Caelo | Beeswax, yellow | 12124816 | 1 |
| Caelo | Beeswax, yellow | 12124817 | 2 |
| Caelo | Beeswax, yellow | 1214816 | 1 |
| Caelo | Sodium dodecyl sulfate | 12153003 | 1 |
| Caelo | Sodium dodecyl sulfate | 12153004 | 1 |
| Caelo | Sodium dodecyl sulfate | 12153010 | 3 |
| Caelo | Sodium dodecyl sulfate | 12153019 | 1 |
| Caelo | Hard fat | 12158104 | 5 |
| Caelo | Hard fat | 12158109 | 3 |
| Caelo | Hard fat | 12158114 | 3 |
| Caelo | Hard fat | 12158115 | 8 |
| Caelo | Hard fat | 12158119 | 1 |
| Caelo | Hard fat | 12158122 | 1 |
| Caelo | Cetyl palmitate | 122228801/Int212191 | 1 |
| Caelo | Cetyl palmitate | 12228805 | 1 |
| Caelo | Cetyl palmitate | 12228808 | 3 |
| Caelo | Cetyl palmitate | 12228818 | 5 |
| Caelo | Paraffin, hard | 12252205 | 2 |
| Caelo | Paraffin, hard | 12252206 | 1 |
| Caelo | Paraffin, hard | 12252211 | 3 |
| Caelo | Paraffin, hard | 12252221 | 3 |
| Caelo | Beeswax, white | 122570 | 1 |
| Caelo | Beeswax, yellow | 12257002 | 3 |
| Caelo | Beeswax, yellow | 12257004 | 2 |
| Caelo | Beeswax, yellow | 12257009 | 7 |
| Caelo | Beeswax, yellow | 12257012 | 3 |
| Caelo | Beeswax, yellow | 12257022 | 3 |
| Caelo | Cocoa butter | 12270201 | 2 |
| Caelo | Cocoa butter | 12270202 | 4 |
| Caelo | Cocoa butter | 12270203 | 6 |
| Caelo | Cocoa butter | 12270209 | 3 |
| Caelo | Cocoa butter | 12270210 | 4 |
| Caelo | Cetyl palmitate | 1228808 | 1 |
| Caelo | Beeswax, yellow | 12330116 | 1 |
| Caelo | Cetyl palmitate | 12331916 | 8 |
| Caelo | Cetyl palmitate | 12331919 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Cocoa butter | 12342003 | 7 |
| Caelo | Cocoa butter | 12342004 | 2 |
| Caelo | Paraffin, microcrystalline | 12355001 | 1 |
| Caelo | Paraffin, hard | 123654 | 1 |
| Caelo | Beeswax, yellow | 12367020 | 1 |
| Caelo | Beeswax, yellow | 12367901 | 12 |
| Caelo | Beeswax, yellow | 12367904 | 5 |
| Caelo | Beeswax, yellow | 12367910 | 11 |
| Caelo | Beeswax, yellow | 12367911 | 2 |
| Caelo | Beeswax, yellow | 12367912 | 3 |
| Caelo | Beeswax, yellow | 12367915 | 8 |
| Caelo | Beeswax, yellow | 12367916 | 6 |
| Caelo | Beeswax, yellow | 12367916-3429311150 | 1 |
| Caelo | Beeswax, yellow | 12367921 | 1 |
| Caelo | Beeswax, yellow | 12K20B05287421 | 1 |
| Caelo | Sodium dodecyl sulfate | 13014604 | 2 |
| Caelo | Cocoa butter | 13027202 | 4 |
| Caelo | Cocoa butter | 13027203 | 1 |
| Caelo | Cocoa butter | 13027204 | 4 |
| Caelo | Cocoa butter | 13027207 | 1 |
| Caelo | Cocoa butter | 13027221 | 4 |
| Caelo | Cocoa butter | 13027224 | 5 |
| Caelo | Cocoa butter | 13027226 | 4 |
| Caelo | Cocoa butter | 13027227 | 3 |
| Caelo | Beeswax, yellow | 13031201 | 4 |
| Caelo | Beeswax, yellow | 13031206 | 8 |
| Caelo | Beeswax, yellow | 13031220 | 3 |
| Caelo | Beeswax, yellow | 13031221 | 1 |
| Caelo | Beeswax, yellow | 13031222 | 3 |
| Caelo | Beeswax, yellow | 13031231 | 6 |
| Caelo | Beeswax, yellow | 13031239 | 11 |
| Caelo | Beeswax, yellow | 13051401 | 1 |
| Caelo | Beeswax, yellow | 13061503 | 1 |
| Caelo | Sodium dodecyl sulfate | 13099006 | 3 |
| Caelo | Sodium dodecyl sulfate | 13099011 | 3 |
| Caelo | Paraffin, hard | 13109203 | 4 |
| Caelo | Paraffin, hard | 13109213 | 6 |
| Caelo | Paraffin, hard | 13109214 | 4 |
| Caelo | Paraffin, hard | 13109218 | 1 |
| Caelo | Paraffin, hard | 13109221 | 1 |
| Caelo | Paraffin, hard | 13109224 | 4 |
| Caelo | Cetyl palmitate | 1313190 | 1 |
| Caelo | Cetyl palmitate | 13131905 | 3 |
| Caelo | Cetyl palmitate | 13131905NP | 1 |
| Caelo | Cetyl palmitate | 13131906 | 8 |
| Caelo | Cetyl palmitate | 13131911 | 2 |
| Caelo | Cetyl palmitate | 13131914 | 4 |
| Caelo | Cocoa butter | 13140401 | 1 |
| Caelo | Cocoa butter | 13140402 | 1 |
| Caelo | Cocoa butter | 13140404 | 2 |
| Caelo | Cocoa butter | 13140405 | 4 |
| Caelo | Cocoa butter | 13140406 | 3 |
| Caelo | Cocoa butter | 13140407 | 3 |
| Caelo | Cocoa butter | 13140409 | 2 |
| Caelo | Hard fat | 13243301 | 5 |
| Caelo | Hard fat | 13243403 | 8 |
| Caelo | Hard fat | 13243409 | 5 |
| Caelo | Hard fat | 13243411 | 3 |
| Caelo | Hard fat | 13243412 | 2 |
| Caelo | Hard fat | 13243414 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hard fat | 13243416 | 1 |
| Caelo | Hard fat | 13243418 | 3 |
| Caelo | Hard fat | 13243419 | 3 |
| Caelo | Hard fat | 13243420 | 1 |
| Caelo | Paraffin, microcrystalline | 13274301 | 1 |
| Caelo | Paraffin, microcrystalline | 13274303 | 5 |
| Caelo | Cocoa butter | 13292001 | 2 |
| Caelo | Cocoa butter | 13292006 | 4 |
| Caelo | Cocoa butter | 13292007 | 9 |
| Caelo | Cocoa butter | 13292011 | 2 |
| Caelo | Cocoa butter | 13292012 | 3 |
| Caelo | Cocoa butter | 13292013 | 9 |
| Caelo | Cocoa butter | 13292015 | 1 |
| Caelo | Cocoa butter | 13292019 | 3 |
| Caelo | Cetyl palmitate | 13295910 | 8 |
| Caelo | Cetyl palmitate | 13295919 | 10 |
| Caelo | Cetyl palmitate | 13295921 | 1 |
| Caelo | Beeswax, yellow | 133335507 | 1 |
| Caelo | Beeswax, yellow | 13335502 | 9 |
| Caelo | Beeswax, yellow | 13335503 | 6 |
| Caelo | Beeswax, yellow | 13335505 | 1 |
| Caelo | Beeswax, yellow | 13335507 | 6 |
| Caelo | Beeswax, yellow | 13335508 | 1 |
| Caelo | Beeswax, yellow | 13335509 | 2 |
| Caelo | Beeswax, yellow | 13335513 | 3 |
| Caelo | Beeswax, yellow | 13335516 | 1 |
| Caelo | Beeswax, yellow | 13335517 | 4 |
| Caelo | Beeswax, yellow | 13335518 | 2 |
| Caelo | Beeswax, yellow | 1335503 | 1 |
| Caelo | Beeswax, yellow | 13378602 | 1 |
| Caelo | Beeswax, yellow | 13378603 | 1 |
| Caelo | Beeswax, yellow | 13378619 | 13 |
| Caelo | Beeswax, yellow | 13378630 | 2 |
| Caelo | Beeswax, yellow | 13378634 | 6 |
| Caelo | Beeswax, yellow | 13378636 | 1 |
| Caelo | Beeswax, yellow | 13378639 | 3 |
| Caelo | Beeswax, white | 13378640 | 3 |
| Caelo | Paraffin, hard | 13390403 | 1 |
| Caelo | Paraffin, hard | 13390406 | 4 |
| Caelo | Paraffin, hard | 13390408 | 1 |
| Caelo | Paraffin, hard | 13390413 | 1 |
| Caelo | Paraffin, hard | 13390415 | 3 |
| Caelo | Sodium dodecyl sulfate | 13411302 | 2 |
| Caelo | Sodium dodecyl sulfate | 13411304 | 1 |
| Caelo | Sodium dodecyl sulfate | 13411305 | 3 |
| Caelo | Cocoa butter | 1392013 | 1 |
| Caelo | Cetyl palmitate | 14041505 | 1 |
| Caelo | Cocoa butter | 14045104 | 1 |
| Caelo | Cetyl palmitate | 14060705 | 6 |
| Caelo | Cetyl palmitate | 14060706 | 6 |
| Caelo | Cetyl palmitate | 14060709 | 6 |
| Caelo | Cocoa butter | 14123609 | 2 |
| Caelo | Cocoa butter | 14123611 | 6 |
| Caelo | Cocoa butter | 14123617 | 4 |
| Caelo | Cocoa butter | 14123620 | 6 |
| Caelo | Cocoa butter | 14123621 | 1 |
| Caelo | Hard fat | 1412602 | 1 |
| Caelo | Paraffin, hard | 14126202 | 5 |
| Caelo | Hard fat | 14126203 | 7 |
| Caelo | Hard fat | 14126204 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hard fat | 14126205 | 1 |
| Caelo | Hard fat | 14126210 | 3 |
| Caelo | Hard fat | 14126216 | 2 |
| Caelo | Hard fat | 14126217 | 4 |
| Caelo | Hard fat | 14126218 | 2 |
| Caelo | Sodium dodecyl sulfate | 14127406 | 3 |
| Caelo | Sodium dodecyl sulfate | 14127411 | 1 |
| Caelo | Beeswax, yellow | 1418915 | 1 |
| Caelo | Beeswax, yellow | 14189901 | 1 |
| Caelo | Beeswax, yellow | 14189902 | 2 |
| Caelo | Beeswax, yellow | 14189905 | 3 |
| Caelo | Beeswax, yellow | 14189906 | 1 |
| Caelo | Beeswax, yellow | 14189907 | 2 |
| Caelo | Beeswax, yellow | 14189908 | 1 |
| Caelo | Beeswax, yellow | 14189909 | 5 |
| Caelo | Beeswax, yellow | 14189912 | 6 |
| Caelo | Beeswax, yellow | 14189913 | 2 |
| Caelo | Beeswax, yellow | 14189914 | 4 |
| Caelo | Beeswax, yellow | 14189915 | 2 |
| Caelo | Beeswax, yellow | 14189917 | 3 |
| Caelo | Beeswax, yellow | 14189919 | 2 |
| Caelo | Beeswax, yellow | 14189920 | 1 |
| Caelo | Cetyl palmitate | 14213705 | 3 |
| Caelo | Cetyl palmitate | 14213706 | 1 |
| Caelo | Cetyl palmitate | 14213709 | 4 |
| Caelo | Cetyl palmitate | 14213710 | 2 |
| Caelo | Cetyl palmitate | 142137710 | 1 |
| Caelo | Sodium dodecyl sulfate | 14224206 | 1 |
| Caelo | Sodium dodecyl sulfate | 14283904 | 3 |
| Caelo | Paraffin, hard | 14286502 | 1 |
| Caelo | Paraffin, hard | 14286503 | 1 |
| Caelo | Paraffin, hard | 14286504 | 1 |
| Caelo | Paraffin, hard | 14286511 | 2 |
| Caelo | Paraffin, hard | 14286517 | 4 |
| Caelo | Cocoa butter | 14304703 | 1 |
| Caelo | Paraffin, microcrystalline | 14307108 | 2 |
| Caelo | Paraffin, microcrystalline | 14307110 | 1 |
| Caelo | Beeswax, yellow | 14336605 | 3 |
| Caelo | Beeswax, yellow | 14336607 | 11 |
| Caelo | Beeswax, yellow | 14336608 | 3 |
| Caelo | Beeswax, yellow | 14336609 | 2 |
| Caelo | Beeswax, yellow | 14336616 | 11 |
| Caelo | Beeswax, yellow | 14336617 | 1 |
| Caelo | Beeswax, yellow | 14336618 | 1 |
| Caelo | Beeswax, yellow | 14336620 | 8 |
| Caelo | Beeswax, white | 14336621 | 1 |
| Caelo | Hard fat | 14338703 | 3 |
| Caelo | Hard fat | 14338704 | 4 |
| Caelo | Hard fat | 14338705 | 1 |
| Caelo | Hard fat | 14338706 | 1 |
| Caelo | Hard fat | 14338707 | 3 |
| Caelo | Hard fat | 14338708 | 1 |
| Caelo | Hard fat | 14338711 | 2 |
| Caelo | Cocoa butter | 14348906 | 9 |
| Caelo | Cocoa butter | 14348908 | 2 |
| Caelo | Cocoa butter | 14348909 | 2 |
| Caelo | Cetyl palmitate | 14351601 | 2 |
| Caelo | Cetyl palmitate | 14351602 | 5 |
| Caelo | Cetyl palmitate | 14351606 | 4 |
| Caelo | Cetyl palmitate | 14351607 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Cetyl palmitate | 14351609 | 3 |
| Caelo | Cetyl palmitate | 14351612 | 15 |
| Caelo | Cetyl palmitate | 14351614 | 1 |
| Caelo | Beeswax, yellow | 1436607 | 1 |
| Caelo | Beeswax, yellow | 1436616 | 1 |
| Caelo | Beeswax, yellow | 1436620 | 1 |
| Caelo | Beeswax, yellow | 14G07-B04-300495 | 1 |
| Caelo | Beeswax, yellow | 15022902 | 7 |
| Caelo | Beeswax, yellow | 15022904 | 4 |
| Caelo | Beeswax, yellow | 15022907 | 1 |
| Caelo | Beeswax, yellow | 15022908 | 9 |
| Caelo | Beeswax, yellow | 15023003 | 5 |
| Caelo | Beeswax, yellow | 15023004 | 9 |
| Caelo | Beeswax, yellow | 15023006 | 3 |
| Caelo | Beeswax, yellow | 15041301 | 1 |
| Caelo | Beeswax, yellow | 150622CF | 1 |
| Caelo | Cocoa butter | 15088903 | 1 |
| Caelo | Cocoa butter | 15088904 | 1 |
| Caelo | Cocoa butter | 15088905 | 1 |
| Caelo | Sodium dodecyl sulfate | 15095404 | 1 |
| Caelo | Beeswax, yellow | 15098901 | 1 |
| Caelo | Beeswax, yellow | 15098902 | 1 |
| Caelo | Hard fat | 15111402 | 1 |
| Caelo | Sodium dodecyl sulfate | 15119907 | 4 |
| Caelo | Beeswax, white | 151210CA | 1 |
| Caelo | Hard fat | 15185002 | 17 |
| Caelo | Hard fat | 15185003 | 11 |
| Caelo | Hard fat | 15185005 | 15 |
| Caelo | Hard fat | 15185007 | 2 |
| Caelo | Hard fat | 15185009 | 10 |
| Caelo | Hard fat | 1518505 | 1 |
| Caelo | Paraffin, hard | 1523002 | 1 |
| Caelo | Paraffin, hard | 152320004 | 1 |
| Caelo | Paraffin, hard | 15232001 | 1 |
| Caelo | Paraffin, hard | 15232004 | 8 |
| Caelo | Cocoa butter | 15246102 | 6 |
| Caelo | Beeswax, white | 1529003 | 1 |
| Caelo | Beeswax, yellow | 152920004 | 1 |
| Caelo | Beeswax, white | 15292002 | 1 |
| Caelo | Beeswax, white | 15292003 | 9 |
| Caelo | Beeswax, yellow | 15292004 | 14 |
| Caelo | Beeswax, yellow | 15292005 | 7 |
| Caelo | Beeswax, yellow | 15292007 | 1 |
| Caelo | Beeswax, white | 15292009 | 4 |
| Caelo | Beeswax, white | 15292010 | 1 |
| Caelo | Beeswax, white | 15292011 | 1 |
| Caelo | Beeswax, white | 15292014 | 27 |
| Caelo | Beeswax, white | 15292015 | 1 |
| Caelo | Beeswax, white | 15292022 | 10 |
| Caelo | Beeswax, white | 15292023 | 1 |
| Caelo | Paraffin, hard | 15295405 | 5 |
| Caelo | Paraffin, hard | 15295406 | 3 |
| Caelo | Paraffin, hard | 15295407 | 2 |
| Caelo | Paraffin, hard | 15295410 | 4 |
| Caelo | Paraffin, hard | 15295411 | 2 |
| Caelo | Paraffin, hard | 15295414 | 3 |
| Caelo | Cetyl palmitate | 15301701 | 7 |
| Caelo | Cetyl palmitate | 15301703 | 11 |
| Caelo | Cetyl palmitate | 15301704 | 6 |
| Caelo | Cetyl palmitate | 15301705 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Cetyl palmitate | 15301708 | 1 |
| Caelo | Cetyl palmitate | 15301709 | 5 |
| Caelo | Cetyl palmitate | 15301711 | 7 |
| Caelo | Beeswax, yellow | 15317601 | 8 |
| Caelo | Beeswax, yellow | 15317602 | 4 |
| Caelo | Beeswax, yellow | 15317603 | 3 |
| Caelo | Beeswax, yellow | 15317607 | 10 |
| Caelo | Beeswax, yellow | 15317608 | 8 |
| Caelo | Beeswax, yellow | 15317609 | 12 |
| Caelo | Beeswax, yellow | 15317610 | 6 |
| Caelo | Beeswax, yellow | 15317611 | 1 |
| Caelo | Beeswax, yellow | 15317613 | 8 |
| Caelo | Sodium dodecyl sulfate | 15344503 | 5 |
| Caelo | Sodium dodecyl sulfate | 15344505 | 2 |
| Caelo | Sodium dodecyl sulfate | 15344510 | 7 |
| Caelo | Sodium dodecyl sulfate | 15344511 | 1 |
| Caelo | Sodium dodecyl sulfate | 15344515 | 2 |
| Caelo | Paraffin, microcrystalline | 15412801 | 2 |
| Caelo | Paraffin, microcrystalline | 15412808 | 1 |
| Caelo | Cetyl palmitate | 15632 | 1 |
| Caelo | Beeswax, yellow | 1595 | 1 |
| Caelo | Paraffin, hard | 16(18070131) | 1 |
| Caelo | Paraffin, hard | 16000903 | 3 |
| Caelo | Paraffin, hard | 16000910 | 2 |
| Caelo | Paraffin, microcrystalline | 16000911 | 5 |
| Caelo | Paraffin, hard | 16000912 | 5 |
| Caelo | Paraffin, hard | 16000921 | 2 |
| Caelo | Paraffin, hard | 16000922 | 3 |
| Caelo | Hard fat | 16021503 | 1 |
| Caelo | Hard fat | 16027801 | 6 |
| Caelo | Hard fat | 16027802 | 7 |
| Caelo | Hard fat W35 | 16027805 | 4 |
| Caelo | Hard fat | 16027806 | 1 |
| Caelo | Beeswax, yellow | 16034206 | 1 |
| Caelo | Beeswax, yellow | 16038201 | 21 |
| Caelo | Beeswax, yellow | 16038202 | 19 |
| Caelo | Beeswax, yellow | 16038203 | 10 |
| Caelo | Beeswax, yellow | 16038205 | 2 |
| Caelo | Beeswax, yellow | 16038206 | 23 |
| Caelo | Beeswax, yellow | 16038207 | 10 |
| Caelo | Beeswax, yellow | 16038210 | 5 |
| Caelo | Cocoa butter | 16049201 | 5 |
| Caelo | Cocoa butter | 16049209 | 2 |
| Caelo | Beeswax, yellow | 16051702 | 1 |
| Caelo | Cetyl palmitate | 16053803 | 9 |
| Caelo | Cetyl palmitate | 16053804 | 1 |
| Caelo | Cetyl palmitate | 16053805 | 2 |
| Caelo | Cetyl palmitate | 16053811 | 8 |
| Caelo | Cocoa butter | 16062602 | 1 |
| Caelo | Cocoa butter | 16062604 | 1 |
| Caelo | Beeswax, yellow | 161202CF/15317611 | 1 |
| Caelo | Beeswax, white | 16163101 | 1 |
| Caelo | Beeswax, white | 16163105 | 36 |
| Caelo | Beeswax, white | 16163106 | 1 |
| Caelo | Beeswax, white | 16163109 | 22 |
| Caelo | Beeswax, yellow | 16163112 | 2 |
| Caelo | Beeswax, white | 16163114 | 26 |
| Caelo | Beeswax, white | 16163115 | 6 |
| Caelo | Cetyl palmitate | 16186805 | 17 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Cetyl palmitate | 16186806 | 1 |
| Caelo | Cetyl palmitate | 16186809 | 19 |
| Caelo | Sodium dodecyl sulfate | 16229205 | 6 |
| Caelo | Sodium dodecyl sulfate | 16229206 | 4 |
| Caelo | Sodium dodecyl sulfate | 16229209 | 1 |
| Caelo | Sodium dodecyl sulfate | 16229213 | 2 |
| Caelo | Sodium dodecyl sulfate | 16229217 | 7 |
| Caelo | Sodium dodecyl sulfate | 16229218 | 1 |
| Caelo | Sodium dodecyl sulfate | 16229220 | 3 |
| Caelo | Hard fat W35 | 16271201 | 1 |
| Caelo | Hard fat | 16274201 | 15 |
| Caelo | Hard fat | 16274202 | 1 |
| Caelo | Hard fat | 16274203 | 16 |
| Caelo | Hard fat | 16274205 | 3 |
| Caelo | Hard fat | 16274207 | 1 |
| Caelo | Hard fat | 16274208 | 18 |
| Caelo | Paraffin, hard | 16277704 | 6 |
| Caelo | Paraffin, hard | 16277705 | 3 |
| Caelo | Paraffin, hard | 16277706 | 6 |
| Caelo | Paraffin, hard | 16277710 | 3 |
| Caelo | Paraffin, hard | 16277714 | 1 |
| Caelo | Paraffin, hard | 16277716 | 1 |
| Caelo | Cocoa butter | 163116508 | 1 |
| Caelo | Cocoa butter | 16315602 | 1 |
| Caelo | Cocoa butter | 16316501 | 4 |
| Caelo | Cocoa butter | 16316503 | 6 |
| Caelo | Cocoa butter | 16316508 | 25 |
| Caelo | Cocoa butter | 16316509 | 5 |
| Caelo | Cocoa butter | 163316508 | 1 |
| Caelo | Hard fat W35 | 16K08-B10 | 1 |
| Caelo | Paraffin, hard | 17(21000732001) | 1 |
| Caelo | Beeswax, yellow | 170011602 | 1 |
| Caelo | Beeswax, yellow | 170011607 | 2 |
| Caelo | Beeswax, yellow | 17011403 | 1 |
| Caelo | Beeswax, yellow | 17011602 | 14 |
| Caelo | Beeswax, yellow | 17011604 | 10 |
| Caelo | Beeswax, yellow | 17011605 | 1 |
| Caelo | Beeswax, yellow | 17011607 | 14 |
| Caelo | Beeswax, yellow | 17011609 | 9 |
| Caelo | Beeswax, yellow | 17011610 | 2 |
| Caelo | Beeswax, yellow | 17011611 | 11 |
| Caelo | Beeswax, yellow | 17011612 | 30 |
| Caelo | Beeswax, yellow | 17011619 | 1 |
| Caelo | Beeswax, yellow | 1701607 | 1 |
| Caelo | Beeswax, yellow | 1701611 | 1 |
| Caelo | Hard fat | 17041401 | 1 |
| Caelo | Beeswax, yellow | 17041402 | 1 |
| Caelo | Cetyl palmitate | 17043503 | 11 |
| Caelo | Cetyl palmitate | 17043504 | 9 |
| Caelo | Cetyl palmitate | 17043509 | 1 |
| Caelo | Cocoa butter | 170555901 | 1 |
| Caelo | Cocoa butter | 17055902 | 12 |
| Caelo | Cocoa butter | 17055905 | 1 |
| Caelo | Cocoa butter | 17055907 | 17 |
| Caelo | Cocoa butter | 17055908 | 11 |
| Caelo | Cocoa butter | 17055913 | 1 |
| Caelo | Paraffin, hard | 1706989 | 1 |
| Caelo | Beeswax, white | 17091802 | 37 |
| Caelo | Beeswax, white | 17091803 | 7 |
| Caelo | Hard fat | 170921AS/16274208 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium dodecyl sulfate | 17095504 | 8 |
| Caelo | Sodium dodecyl sulfate | 17095505 | 1 |
| Caelo | Sodium dodecyl sulfate | 17095511 | 13 |
| Caelo | Hard fat | 17107301 | 8 |
| Caelo | Paraffin, hard | 17107304 | 12 |
| Caelo | Hard fat | 17107305 | 1 |
| Caelo | Hard fat | 17107306 | 2 |
| Caelo | Beeswax, yellow | 17121201 | 1 |
| Caelo | Beeswax, yellow | 17121202 | 1 |
| Caelo | Paraffin, microcrystalline | 17137502 | 1 |
| Caelo | Cetyl palmitate | 17164004 | 19 |
| Caelo | Cetyl palmitate | 17164005 | 20 |
| Caelo | Cetyl palmitate | 17164007 | 1 |
| Caelo | Beeswax, yellow | 172007402 | 1 |
| Caelo | Beeswax, yellow | 17207402 | 24 |
| Caelo | Beeswax, yellow | 17207403 | 13 |
| Caelo | Beeswax, yellow | 17207404 | 2 |
| Caelo | Beeswax, yellow | 17207405 | 1 |
| Caelo | Sodium dodecyl sulfate | 17236302 | 1 |
| Caelo | Paraffin, hard | 17245602 | 14 |
| Caelo | Paraffin, hard | 17245604 | 1 |
| Caelo | Cetyl palmitate | 17271502 | 8 |
| Caelo | Cetyl palmitate | 17271502P-180920-3 | 1 |
| Caelo | Cetyl palmitate | 17271502P-181227-7 | 1 |
| Caelo | Cetyl palmitate | 17271504 | 14 |
| Caelo | Cetyl palmitate | 17271505 | 16 |
| Caelo | Cetyl palmitate | 17271506 | 1 |
| Caelo | Hard fat | 17307601 | 32 |
| Caelo | Hard fat | 17307602 | 9 |
| Caelo | Hard fat | 17307603 | 1 |
| Caelo | Hard fat | 17307604 | 1 |
| Caelo | Hard fat | 17307607 | 2 |
| Caelo | Hard fat | 1730765 | 1 |
| Caelo | Cocoa butter | 17314901 | 4 |
| Caelo | Cocoa butter | 17314902 | 31 |
| Caelo | Paraffin, hard | 1734701 | 1 |
| Caelo | Paraffin, hard | 17347701 | 22 |
| Caelo | Hard fat | 18040401 | 17 |
| Caelo | Hard fat | 18040401P-181227-5 | 1 |
| Caelo | Sodium dodecyl sulfate | 18045202 | 2 |
| Caelo | Sodium dodecyl sulfate | 18045203 | 1 |
| Caelo | Beeswax, white | 18048901 | 45 |
| Caelo | Beeswax, white | 18048903 | 6 |
| Caelo | Beeswax, white | 18048904 | 1 |
| Caelo | Beeswax, white | 18048904P-181227-1 | 1 |
| Caelo | Beeswax, white | 18048906 | 40 |
| Caelo | Beeswax, white | 18048907 | 6 |
| Caelo | Beeswax, yellow | 18049001 | 29 |
| Caelo | Beeswax, yellow | 18049002 | 3 |
| Caelo | Beeswax, yellow | 18049003 | 8 |
| Caelo | Paraffin, hard | 18070103P-181227-2 | 1 |
| Caelo | Paraffin, hard | 18070107 | 30 |
| Caelo | Paraffin, hard | 18070110P-190624-3 | 1 |
| Caelo | Paraffin, hard | 18070112 | 15 |
| Caelo | Paraffin, hard | 18070118 | 17 |
| Caelo | Paraffin, hard | 18070130P-200217-5 | 1 |
| Caelo | Paraffin, hard | 18070131 | 31 |
| Caelo | Beeswax, white | 180748901 | 1 |
| Caelo | Beeswax, yellow | 18113501 | 42 |
| Caelo | Beeswax, yellow | 18113502 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Beeswax, yellow | 18113503 | 1 |
| Caelo | Beeswax, yellow | 18113505 | 48 |
| Caelo | Beeswax, yellow | 18113506 | 13 |
| Caelo | Beeswax, yellow | 18113507 | 1 |
| Caelo | Beeswax, yellow | 18113507P-191022-6 | 1 |
| Caelo | Beeswax, yellow | 18113507P-200102-2 | 1 |
| Caelo | Beeswax, yellow | 18113509 | 7 |
| Caelo | Beeswax, yellow | 18121201 | 1 |
| Caelo | Sodium dodecyl sulfate | 1812207 | 1 |
| Caelo | Cocoa butter | 18135101 | 1 |
| Caelo | Cocoa butter | 18135102 | 3 |
| Caelo | Cocoa butter | 18135106 | 4 |
| Caelo | Cocoa butter | 18135107 | 1 |
| Caelo | Cocoa butter | 18135112 | 7 |
| Caelo | Hard fat | 18147901 | 5 |
| Caelo | Hard fat | 18147902 | 32 |
| Caelo | Hard fat | 18147905 | 2 |
| Caelo | Hard fat | 18147907 | 3 |
| Caelo | Hard fat | 18147908 | 10 |
| Caelo | Cetyl palmitate | 181499004 | 1 |
| Caelo | Cetyl palmitate | 18149902 | 4 |
| Caelo | Cetyl palmitate | 18149904 | 24 |
| Caelo | Cetyl palmitate | 18149911 | 5 |
| Caelo | Cetyl palmitate | 18149911P-190405-3 | 1 |
| Caelo | Cetyl palmitate | 18149911P-190718-9 | 1 |
| Caelo | Cetyl palmitate | 18149912 | 18 |
| Caelo | Sodium dodecyl sulfate | 18182206 | 6 |
| Caelo | Sodium dodecyl sulfate | 18182207 | 1 |
| Caelo | Sodium dodecyl sulfate | 18182216 | 1 |
| Caelo | Beeswax, white | 18239102 | 34 |
| Caelo | Beeswax, white | 18239104 | 7 |
| Caelo | Beeswax, white | 18239106 | 28 |
| Caelo | Beeswax, white | 18239107 | 4 |
| Caelo | Beeswax, white | 18239108 | 1 |
| Caelo | Beeswax, white | 18239108P-191206-5 | 1 |
| Caelo | Beeswax, white | 18239108P-200217-4 | 1 |
| Caelo | Beeswax, white | 18239108P-200609-6 | 1 |
| Caelo | Cocoa butter | 18254402 | 2 |
| Caelo | Cocoa butter | 18254412 | 7 |
| Caelo | Cetyl palmitate | 18273704 | 23 |
| Caelo | Cetyl palmitate | 18273705 | 3 |
| Caelo | Cetyl palmitate | 18273709P-191022-5 | 1 |
| Caelo | Cetyl palmitate | 18273709P-200102-3 | 1 |
| Caelo | Cetyl palmitate | 182737704 | 1 |
| Caelo | Beeswax, yellow | 18299201 | 13 |
| Caelo | Beeswax, yellow | 18299202 | 7 |
| Caelo | Beeswax, yellow | 18299206 | 1 |
| Caelo | Beeswax, yellow | 18299208 | 13 |
| Caelo | Beeswax, yellow | 18299210 | 3 |
| Caelo | Hard fat | 18333903 | 1 |
| Caelo | Hard fat | 18333904 | 17 |
| Caelo | Hard fat | 18333905 | 28 |
| Caelo | Hard fat W35 | 18333906 | 1 |
| Caelo | Hard fat | 18333908 | 1 |
| Caelo | Hard fat | 1833905 | 1 |
| Caelo | Hard fat W35 | 18G13-B02-356977 | 1 |
| Caelo | Cocoa butter | 19000676001 | 1 |
| Caelo | Cocoa butter | 19000676007 | 2 |
| Caelo | Cocoa butter | 19000676008 | 4 |
| Caelo | Cocoa butter | 19000676010 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Cocoa butter | 19000676011 | 5 |
| Caelo | Sodium dodecyl sulfate | 19018702 | 1 |
| Caelo | Sodium dodecyl sulfate | 19018704 | 3 |
| Caelo | Cetyl palmitate | 1902859003 | 1 |
| Caelo | Beeswax, yellow | 19031810 | 1 |
| Caelo | Cocoa butter | 190360009 | 5 |
| Caelo | Cocoa butter | 190360010 | 1 |
| Caelo | Cocoa butter | 19036003 | 5 |
| Caelo | Cocoa butter | 19036006 | 1 |
| Caelo | Cocoa butter | 19036007 | 3 |
| Caelo | Cocoa butter | 19036008 | 6 |
| Caelo | Beeswax, yellow | 19041704 | 1 |
| Caelo | Sodium dodecyl sulfate | 19075403 | 1 |
| Caelo | Cetyl palmitate | 190902a | 1 |
| Caelo | Sodium dodecyl sulfate | 190923001 | 2 |
| Caelo | Cetyl palmitate | 19121803 | 1 |
| Caelo | Beeswax, white | 191242001 | 7 |
| Caelo | Beeswax, white | 191242004 | 22 |
| Caelo | Beeswax, white | 19124202 | 30 |
| Caelo | Beeswax, white | 19124203 | 2 |
| Caelo | Beeswax, white | 19124206 | 31 |
| Caelo | Beeswax, white | 19124207 | 3 |
| Caelo | Beeswax, white | 19124208 | 1 |
| Caelo | Beeswax, white | 19124210 | 23 |
| Caelo | Beeswax, white | 19124211 | 4 |
| Caelo | Beeswax, yellow | 191372001 | 30 |
| Caelo | Beeswax, yellow | 191372002 | 1 |
| Caelo | Beeswax, yellow | 191372003 | 1 |
| Caelo | Beeswax, yellow | 19137201 | 5 |
| Caelo | Beeswax, yellow | 19137202 | 34 |
| Caelo | Beeswax, yellow | 19137206 | 20 |
| Caelo | Cetyl palmitate | 19139004 | 33 |
| Caelo | Cetyl palmitate | 19139005 | 4 |
| Caelo | Cetyl palmitate | 19139005P-200206-4 | 1 |
| Caelo | Cetyl palmitate | 1913905 | 1 |
| Caelo | Beeswax, yellow | 1917202 | 1 |
| Caelo | Hard fat | 191940001 | 10 |
| Caelo | Hard fat | 191940002 | 30 |
| Caelo | Hard fat | 191940004 | 1 |
| Caelo | Hard fat | 191940005 | 8 |
| Caelo | Hard fat | 19194001 | 1 |
| Caelo | Beeswax, yellow | 19237202 | 1 |
| Caelo | Paraffin, hard | 1924603010 | 1 |
| Caelo | Paraffin, hard | 192463001 | 24 |
| Caelo | Paraffin, hard | 192463002 | 1 |
| Caelo | Paraffin, hard | 192463002P-200507-7 | 1 |
| Caelo | Paraffin, hard | 192463009 | 1 |
| Caelo | Paraffin, hard | 192463010 | 19 |
| Caelo | Cetyl palmitate | 192859002 | 7 |
| Caelo | Cetyl palmitate | 192859002P-200511-2 | 1 |
| Caelo | Cetyl palmitate | 192859002P-200602-2 | 1 |
| Caelo | Cetyl palmitate | 192859003 | 41 |
| Caelo | Beeswax, white | 2000 | 1 |
| Caelo | Beeswax, white | 200000885007 | 1 |
| Caelo | Hard fat | 200000906007 | 1 |
| Caelo | Cetyl palmitate | 200000975002 | 1 |
| Caelo | Beeswax, yellow | 20000280002 | 10 |
| Caelo | Beeswax, yellow | 20000280003 | 17 |
| Caelo | Beeswax, yellow | 20000280005 | 1 |
| Caelo | Beeswax, yellow | 20000280007 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Beeswax, yellow | 20000280008 | 29 |
| Caelo | Beeswax, yellow | 2000028003 | 1 |
| Caelo | Beeswax, yellow | 2000028007 | 1 |
| Caelo | Beeswax, yellow | 2000028008 | 1 |
| Caelo | Hard fat W35 | 200003131008 | 1 |
| Caelo | Beeswax, white | 200003825001 | 1 |
| Caelo | Cocoa butter | 200004174002 | 1 |
| Caelo | Beeswax, white | 20000885003 | 28 |
| Caelo | Beeswax, white | 20000885004 | 1 |
| Caelo | Beeswax, white | 20000885007 | 32 |
| Caelo | Beeswax, white | 20000885008 | 6 |
| Caelo | Hard fat | 20000906003 | 14 |
| Caelo | Hard fat | 20000906004 | 7 |
| Caelo | Hard fat W35 | 20000906005 | 2 |
| Caelo | Hard fat | 20000906007 | 14 |
| Caelo | Cetyl palmitate | 20000974002 | 6 |
| Caelo | Cetyl palmitate | 20000975002 | 17 |
| Caelo | Sodium dodecyl sulfate | 20001260003 | 2 |
| Caelo | Cocoa butter | 20001695003 | 16 |
| Caelo | Cocoa butter | 20001695004 | 2 |
| Caelo | Beeswax, yellow | 200028008 | 1 |
| Caelo | Hard fat | 20003131003 | 12 |
| Caelo | Hard fat | 20003131004 | 3 |
| Caelo | Hard fat | 20003131006 | 2 |
| Caelo | Hard fat | 20003131007 | 14 |
| Caelo | Hard fat | 20003131008 | 1 |
| Caelo | Paraffin, hard | 2000359911 | 1 |
| Caelo | Beeswax, yellow | 20003601001 | 1 |
| Caelo | Beeswax, yellow | 20003602001 | 18 |
| Caelo | Beeswax, yellow | 20003602002 | 4 |
| Caelo | Beeswax, yellow | 20003602003 | 6 |
| Caelo | Beeswax, yellow | 20003602005 | 19 |
| Caelo | Beeswax, yellow | 20003602009 | 7 |
| Caelo | Beeswax, yellow | 2000362001 | 1 |
| Caelo | Beeswax, white | 20003824003 | 5 |
| Caelo | Beeswax, white | 20003825001 | 24 |
| Caelo | Beeswax, white | 20003825005 | 1 |
| Caelo | Beeswax, white | 2000382501 | 1 |
| Caelo | Cetyl palmitate | 20003842006 | 5 |
| Caelo | Cetyl palmitate | 20003842013 | 7 |
| Caelo | Beeswax, white | 2000385001 | 2 |
| Caelo | Cocoa butter | 20004174002 | 6 |
| Caelo | Cocoa butter | 20004174003 | 1 |
| Caelo | Cocoa butter | 20004174006 | 3 |
| Caelo | Cocoa butter | 20004174009 | 3 |
| Caelo | Cocoa butter | 20004174010 | 5 |
| Caelo | Beeswax, white | 2000885008 | 2 |
| Caelo | Hard fat | 2000906007 | 1 |
| Caelo | Cetyl palmitate | 2000975002 | 1 |
| Caelo | Beeswax, yellow | 20031516 | 1 |
| Caelo | Beeswax, yellow | 20031517 | 1 |
| Caelo | Hard fat | 20071501 | 1 |
| Caelo | Beeswax, yellow | 20071503 | 1 |
| Caelo | Cetyl palmitate | 21000359001 | 17 |
| Caelo | Cetyl palmitate | 2100066001 | 1 |
| Caelo | Paraffin, hard | 21000732001 | 21 |
| Caelo | Paraffin, hard | 21000732004 | 1 |
| Caelo | Paraffin, hard | 21000732007 | 5 |
| Caelo | Cetyl palmitate | 21000860001 | 21 |
| Caelo | Cetyl palmitate | 21000860010 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Beeswax, white | 21001267002 | 21 |
| Caelo | Beeswax, white | 21001267003 | 5 |
| Caelo | Beeswax, white | 21001267005 | 1 |
| Caelo | Beeswax, white | 21001267008 | 4 |
| Caelo | Beeswax, white | 21001267012 | 2 |
| Caelo | Beeswax, white | 21001267022 | 1 |
| Caelo | Beeswax, white | 2100127008 | 1 |
| Caelo | Beeswax, yellow | 21001423001 | 9 |
| Caelo | Beeswax, yellow | 21001423003 | 27 |
| Caelo | Beeswax, yellow | 21001423004 | 1 |
| Caelo | Beeswax, yellow | 21001423005 | 12 |
| Caelo | Beeswax, yellow | 21001423010 | 12 |
| Caelo | Beeswax, yellow | 2100143003 | 1 |
| Caelo | Paraffin, hard | 210017480 | 1 |
| Caelo | Paraffin, hard | 21001748003 | 1 |
| Caelo | Paraffin, hard | 21001748004 | 8 |
| Caelo | Paraffin, hard | 21001748007 | 23 |
| Caelo | Paraffin, hard | 21001748012 | 7 |
| Caelo | Paraffin, hard | 21001748014 | 4 |
| Caelo | Paraffin, hard | 21001748018 | 1 |
| Caelo | Sodium dodecyl sulfate | 21001909003 | 2 |
| Caelo | Sodium dodecyl sulfate | 21001909004 | 1 |
| Caelo | Hard fat W35 | 21002076006 | 2 |
| Caelo | Cocoa butter | 21002516002 | 13 |
| Caelo | Cocoa butter | 21002516003 | 3 |
| Caelo | Cocoa butter | 21002516004 | 6 |
| Caelo | Cocoa butter | 21002516017 | 1 |
| Caelo | Cocoa butter | 21002516018 | 1 |
| Caelo | Cocoa butter | 21002516020 | 7 |
| Caelo | Cocoa butter | 21002516036 | 1 |
| Caelo | Hard fat | 21003046008 | 12 |
| Caelo | Hard fat | 21003046010 | 3 |
| Caelo | Hard fat | 21003046011 | 7 |
| Caelo | Sodium dodecyl sulfate | 21003606002 | 1 |
| Caelo | Sodium dodecyl sulfate | 21003606003 | 1 |
| Caelo | Paraffin, microcrystalline | 21003773004 | 2 |
| Caelo | Beeswax, yellow | 21004132003 | 5 |
| Caelo | Beeswax, yellow | 21004132004 | 3 |
| Caelo | Beeswax, yellow | 2100423003 | 1 |
| Caelo | Paraffin, hard | 2100732001 | 1 |
| Caelo | Cetyl palmitate | 2100860001 | 1 |
| Caelo | Cetyl palmitate | 2100860010 | 1 |
| Caelo | Cetyl palmitate | 22000395002 | 8 |
| Caelo | Cetyl palmitate | 220003955002 | 1 |
| Caelo | Beeswax, white | 22000795001 | 5 |
| Caelo | Beeswax, white | 22000795006 | 11 |
| Caelo | Cetyl palmitate | 22001150003 | 1 |
| Caelo | Cetyl palmitate | 22001717001 | 3 |
| Caelo | Cetyl palmitate | 22001717004 | 2 |
| Caelo | Cetyl palmitate | 22001785005 | 1 |
| Caelo | Hard fat | 22002076002 | 6 |
| Caelo | Hard fat | 22002076007 | 2 |
| Caelo | Hard fat | 22002076008 | 1 |
| Caelo | Hard fat | 22002076011 | 1 |
| Caelo | Cocoa butter | 22003120014 | 1 |
| Caelo | Sodium dodecyl sulfate | 22003127001 | 1 |
| Caelo | Beeswax, yellow | 22003888002 | 1 |
| Caelo | Beeswax, yellow | 220425E | 1 |
| Caelo | Beeswax, yellow | 220510/2 | 1 |
| Caelo | Beeswax, yellow | 22071301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Beeswax, yellow | 220829C | 1 |
| Caelo | Beeswax, white | 2271200 | 1 |
| Caelo | Hard fat | 23000561002 | 2 |
| Caelo | Cetyl palmitate | 24000124003 | 1 |
| Caelo | Sodium dodecyl sulfate | 24001699002 | 1 |
| Caelo | Hard fat | 24011302 | 1 |
| Caelo | Sodium dodecyl sulfate | 26031508 | 1 |
| Caelo | Cetyl palmitate | 26071201 | 1 |
| Caelo | Beeswax, yellow | 26091302 | 1 |
| Caelo | Hard fat | 27101703 | 1 |
| Caelo | Beeswax, yellow | 280003 | 1 |
| Caelo | Beeswax, yellow | 28011501 | 1 |
| Caelo | Cetyl palmitate | 28041731 | 1 |
| Caelo | Beeswax, white | 280A150528 | 1 |
| Caelo | Beeswax, white | 280A171019 | 1 |
| Caelo | Beeswax, white | 280A210503-01 | 1 |
| Caelo | Beeswax, white | 280A220609-02 | 1 |
| Caelo | Hard fat | 29061803 | 1 |
| Caelo | Beeswax, white | 29091805 | 1 |
| Caelo | Beeswax, yellow | 290A0151214 | 1 |
| Caelo | Beeswax, yellow | 290A170915 | 1 |
| Caelo | Hard fat | 293848 | 1 |
| Caelo | Beeswax, yellow | 30011407 | 1 |
| Caelo | Paraffin, microcrystalline | 30101202 | 1 |
| Caelo | Cetyl palmitate | 30101301 | 1 |
| Caelo | Beeswax, yellow | 30101308 | 1 |
| Caelo | Paraffin, hard | 302709 | 1 |
| Caelo | Paraffin, microcrystalline | 3042012M1 | 1 |
| Caelo | Beeswax, white | 3051808 | 1 |
| Caelo | Beeswax, yellow | 3253 | 1 |
| Caelo | Cetyl palmitate | 3785734 | 1 |
| Caelo | Beeswax, yellow | 4031403 | 1 |
| Caelo | Cetyl palmitate | 43204210008601 | 1 |
| Caelo | Beeswax, yellow | 4910A-01239 | 1 |
| Caelo | Beeswax, yellow | 5022904 | 1 |
| Caelo | Beeswax, yellow | 5121707 | 1 |
| Caelo | Cocoa butter | 515A-03176 | 1 |
| Caelo | Paraffin, microcrystalline | 52622395 | 1 |
| Caelo | Beeswax, yellow | 60(191372001) | 1 |
| Caelo | Beeswax, yellow | 61(20003602001) | 1 |
| Caelo | Beeswax, yellow | 6111407 | 1 |
| Caelo | Beeswax, yellow | 7091704 | 1 |
| Caelo | Hard fat | 7101304 | 1 |
| Caelo | Paraffin, microcrystalline | 7111201 | 1 |
| Caelo | Paraffin, microcrystalline | 7111202 | 1 |
| Caelo | Sodium dodecyl sulfate | 720E-01907 | 1 |
| Caelo | Hard fat | 8041710 | 1 |
| Caelo | Hard fat | 8051810 | 1 |
| Caelo | Hard fat | 90915429 | 1 |
| Caelo | Hard fat W35 | W0000906005 | 2 |
| Caesa / Alliance Hea… | Beeswax, white | 20003825001 | 1 |
| Caesa / Alliance Hea… | Cetyl palmitate | 20003842013 | 1 |
| Caesar & Lorenz GmbH | Cetyl palmitate | 17043504 | 1 |
| Caesar & Lorenz GmbH | Cetyl palmitate | 18149912 | 1 |
| Caesar & Lorenz GmbH | Sodium dodecyl sulfate | 18182206 | 1 |
| Caesar & Lorenz GmbH | Sodium dodecyl sulfate | 19018704 | 1 |
| Caesar & Lorenz GmbH | Cetyl palmitate | 19139004 | 2 |
| Caesar & Lorenz GmbH | Cetyl palmitate | 192859003 | 1 |
| Caesar & Lorenz | Cocoa butter | 13140404 | 1 |
| Caesar & Lorenz | Beeswax, white | 20003824003 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Paraffin, hard | 21001748007 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 15023004 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 15292010 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 16316503 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 17055908 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 20000885007 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 191940002 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 191940005 | 3 |
| Caesar & Loretz GmbH... | Beeswax, white | 19124210 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 192859003 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 23000561002 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 15317613 | 1 |
| Caesar & Loretz GmbH... | Sodium dodecyl sulfate | 16229205 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 16316508 | 2 |
| Caesar & Loretz GmbH... | Cocoa butter | 16316509 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 17271505 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 17307601 | 2 |
| Caesar & Loretz GmbH... | Beeswax, white | 18048907 | 2 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18049001 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18113505 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18333905 | 2 |
| Caesar & Loretz GmbH... | Cocoa butter | 190360009 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 20000906003 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 20003131003 | 2 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 21001423001 | 1 |
| Caesar & Loretz GmbH... | Sodium dodecyl sulfate | 21001909003 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 21004132003 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 22000395002 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 22001785003 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 18149912 | 1 |
| Caesar & Loretz GmbH... | Paraffin, hard | 18070118 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18113509 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 19139004 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 192859003 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 17307607 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 12158104 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 11285008 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 11345918 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 12367901 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 12367910 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 13243403 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18113505 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18049001 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18333905 | 2 |
| Caesar & Loretz GmbH... | Hard fat | 18147908 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18333904 | 1 |
| Caesar & Loretz GmbH... | Paraffin, hard | 192463010 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 21002516002 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20000280003 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 18254412 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 191372001 | 1 |
| Caesar & Loretz GmbH... | Paraffin, hard | 21000732001 | 1 |
| Caesar & Loretz GmbH/ Ph | Beeswax, yellow | 18299201 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 20000280008 | 2 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 21001423001 | 2 |
| Caesar & Loretz GmbH/AHD | Beeswax, yellow | 19137206 | 1 |
| Caesar & Loretz GmbH/AHD | Beeswax, yellow | 21001423010 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20003602005 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 20004174002 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18147908 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Beeswax, white | 20000885003 | 1 |
| Caesar & Loretz GmbH/E | Hard fat | 18333904 | 1 |
| Caesar & Loretz GmbH/E | Beeswax, white | 20000885003 | 1 |
| Caesar & Loretz GmbH/E | Beeswax, yellow | 20003602001 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 18254402 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18333904 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18333905 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 191940002 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 20000906003 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 20000975002 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 21000359001 | 1 |
| Caesar & Loretz GmbH/Gehe | Cocoa butter | 19036003 | 1 |
| Caesar & Loretz GmbH/Gehe | Beeswax, white | 19124206 | 1 |
| Caesar & Loretz GmbH/Gehe | Beeswax, yellow | 191372001 | 2 |
| Caesar & Loretz GmbH/GEHE | Beeswax, yellow | 19137202 | 1 |
| Caesar & Loretz GmbH/Gehe | Cetyl palmitate | 192859003 | 3 |
| Caesar & Loretz GmbH/Gehe | Hard fat | 20003131007 | 2 |
| Caesar & Loretz GmbH/Gehe | Beeswax, white | 20003825001 | 2 |
| Caesar & Loretz GmbH/Gehe | Cetyl palmitate | 20003842013 | 1 |
| Caesar & Loretz GmbH/Gehe | Cocoa butter | 20004174009 | 2 |
| Caesar & Loretz GmbH/GEHE | Cetyl palmitate | 22001717004 | 1 |
| Caesar & Loretz GmbH/GEHE | Sodium dodecyl sulfate | 23000156007 | 1 |
| Caesar & Loretz GmbH... | Sodium dodecyl sulfate | 21001910005 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18147908 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 19124206 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 20000885008 | 2 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 21000359001 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 21000860010 | 1 |
| Caesar & Loretz GmbH... | Cocoa butter | 22003120004 | 1 |
| Caesar & Loretz GmbH/K | Beeswax, yellow | 18113505 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 19137202 | 3 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 19137202 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 19137206 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20000280003 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20000280007 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 20003131003 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20003602005 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 21001423003 | 1 |
| Caesar & Loretz GmbH/PH | Cetyl palmitate | 18273704 | 1 |
| Caesar & Loretz GmbH/Ph | Beeswax, yellow | 191372001 | 1 |
| Caesar & Loretz GmbH/Ph | Cetyl palmitate | 192859003 | 1 |
| Caesar & Loretz GmbH/Ph | Beeswax, yellow | 2000080008 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20003602009 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 21001267003 | 2 |
| Caesar & Loretz GmbH... | Beeswax, white | 21001267008 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 21001267012 | 2 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 21001423010 | 1 |
| Caesar & Loretz GmbH... | Paraffin, hard | 21001748007 | 1 |
| Caesar & Loretz GmbH... | Paraffin, hard | 21001748012 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 191372001 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18333904 | 2 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 19137202 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 192859003 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 20000974002 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20003602001 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 21003046011 | 2 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 220001717001 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 22000395002 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 22001717001 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 22002076002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH... | Hard fat | 22002076008 | 1 |
| Caesar & Loretz GmbH/Sa | Beeswax, white | 19124206 | 2 |
| Caesar & Loretz GmbH/Sa | Cetyl palmitate | 20000974002 | 1 |
| Caesar & Loretz GmbH/Sa | Cetyl palmitate | 20000975002 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18113507 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 18273704 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18299210 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 183339 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 18333906 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 191242001 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 19137203 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 19194001 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 192859003 | 3 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 20000280007 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 2000028005 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 20000885008 | 2 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 20000974002 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 20003825001 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 21000860009 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 21001423005 | 1 |
| Caesar & Loretz GmbH... | Sodium dodecyl sulfate | 21001909003 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 21003046008 | 1 |
| Caesar & Loretz GmbH... | Cetyl palmitate | 22000395002 | 1 |
| Caesar & Loretz GmbH... | Beeswax, white | 22000795001 | 1 |
| Caesar & Loretz GmbH... | Hard fat | 22002076001 | 1 |
| Caesar & Loretz GmbH... | Beeswax, yellow | 18113502 | 1 |
| Caesar & Loretz GmbH | Cetyl palmitate | 10068402 | 2 |
| Caesar & Loretz GmbH | Beeswax, yellow | 12367910 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 13031221 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 16163105 | 1 |
| Caesar & Loretz GmbH | Cetyl palmitate | 16186805 | 1 |
| Caesar & Loretz GmbH | Sodium dodecyl sulfate | 17095504 | 1 |
| Caesar & Loretz GmbH | Cetyl palmitate | 17164005 | 1 |
| Caesar & Loretz GmbH | Hard fat W35 | 17307601 | 1 |
| Caesar & Loretz GmbH | Paraffin, hard | 17347701 | 1 |
| Caesar & Loretz GmbH | Hard fat | 18040401 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 18048901 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 18048906 | 2 |
| Caesar & Loretz GmbH | Paraffin, hard | 18070107 | 4 |
| Caesar & Loretz GmbH | Paraffin, hard | 18070110 | 1 |
| Caesar & Loretz GmbH | Paraffin, hard | 18070112 | 1 |
| Caesar & Loretz GmbH | Paraffin, hard | 18070118 | 3 |
| Caesar & Loretz GmbH | Paraffin, hard | 18070130 | 1 |
| Caesar & Loretz GmbH | Paraffin, hard | 18070131 | 4 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18113502 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18113505 | 3 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18113506 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18113509 | 1 |
| Caesar & Loretz GmbH | Cocoa butter | 18135106 | 2 |
| Caesar & Loretz GmbH | Hard fat | 18147901 | 2 |
| Caesar & Loretz GmbH | Hard fat | 18147902 | 2 |
| Caesar & Loretz GmbH | Hard fat | 18147908 | 1 |
| Caesar & Loretz GmbH | Cetyl palmitate | 18149904 | 2 |
| Caesar & Loretz GmbH | Cetyl palmitate | 18149911 | 1 |
| Caesar & Loretz GmbH | Cetyl palmitate | 18149912 | 1 |
| Caesar & Loretz GmbH | Sodium dodecyl sulfate | 18182206 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 18239102 | 7 |
| Caesar & Loretz GmbH | Beeswax, white | 18239104 | 5 |
| Caesar & Loretz GmbH | Beeswax, white | 18239106 | 4 |
| Caesar & Loretz GmbH | Beeswax, white | 18239107 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Cocoa butter | 18254402 | 2 |
| Caesar & Loretz GmbH | Cetyl palmitate | 18273704 | 10 |
| Caesar & Loretz GmbH | Cetyl palmitate | 18273705 | 1 |
| Caesar & Loretz GmbH | Cetyl palmitate | 18273709 | 2 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18299201 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18299202 | 2 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18299203 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18299206 | 2 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18299208 | 3 |
| Caesar & Loretz GmbH | Beeswax, yellow | 18299210 | 1 |
| Caesar & Loretz GmbH | Hard fat | 18333903 | 2 |
| Caesar & Loretz GmbH | Hard fat | 18333904 | 3 |
| Caesar & Loretz GmbH | Hard fat | 18333905 | 9 |
| Caesar & Loretz GmbH | Cocoa butter | 19000676011 | 1 |
| CAESAR & LORETZ GMBH | Cocoa butter | 190360009 | 1 |
| Caesar & Loretz GmbH | Cocoa butter | 19036007 | 2 |
| Caesar & Loretz GmbH | Cocoa butter | 19036008 | 3 |
| Caesar & Loretz GmbH | Cocoa butter | 19036011 | 3 |
| Caesar & Loretz GmbH | Sodium dodecyl sulfate | 19075403 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 191242004 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 19124202 | 6 |
| Caesar & Loretz GmbH | Beeswax, white | 19124203 | 5 |
| Caesar & Loretz GmbH | Beeswax, white | 19124206 | 5 |
| Caesar & Loretz GmbH | Beeswax, white | 19124210 | 4 |
| Caesar & Loretz GmbH | Beeswax, white | 19124211 | 4 |
| Caesar & Loretz GmbH | Beeswax, yellow | 19137202 | 11 |
| Caesar & Loretz GmbH | Beeswax, yellow | 19137203 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 19137206 | 5 |
| Caesar & Loretz GmbH | Cetyl palmitate | 19139004 | 8 |
| Caesar & Loretz GmbH | Cetyl palmitate | 19139005 | 3 |
| Caesar & Loretz GmbH | Beeswax, yellow | 19172001 | 1 |
| Caesar & Loretz GmbH | Hard fat | 191940001 | 3 |
| Caesar & Loretz GmbH | Hard fat | 191940002 | 9 |
| Caesar & Loretz GmbH | Hard fat | 19194001 | 1 |
| Caesar & Loretz GmbH | Paraffin, hard | 192463001 | 8 |
| Caesar & Loretz GmbH | Paraffin, hard | 192463010 | 2 |
| Caesar & Loretz GmbH | Cetyl palmitate | 192859002 | 4 |
| Caesar & Loretz GmbH | Cetyl palmitate | 192859003 | 18 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20000280002 | 5 |
| CAESAR & LORETZ GMBH | Beeswax, yellow | 20000280003 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20000280007 | 3 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20000280008 | 5 |
| Caesar & Loretz GmbH | Beeswax, white | 20000885003 | 8 |
| Caesar & Loretz GmbH | Beeswax, white | 20000885004 | 2 |
| Caesar & Loretz GmbH | Beeswax, white | 20000885007 | 13 |
| Caesar & Loretz GmbH | Beeswax, white | 20000885008 | 3 |
| Caesar & Loretz GmbH | Hard fat | 20000906003 | 7 |
| Caesar & Loretz GmbH | Hard fat | 20000906004 | 4 |
| Caesar & Loretz GmbH | Hard fat | 20000906005 | 2 |
| Caesar & Loretz GmbH | Hard fat | 20000906007 | 4 |
| Caesar & Loretz GmbH | Hard fat | 20000906008 | 2 |
| Caesar & Loretz GmbH | Cetyl palmitate | 20000974002 | 2 |
| Caesar & Loretz GmbH | Cetyl palmitate | 20000975002 | 5 |
| Caesar & Loretz GmbH | Sodium dodecyl sulfate | 20001260003 | 1 |
| Caesar & Loretz GmbH | Cocoa butter | 20001695002 | 2 |
| Caesar & Loretz GmbH | Cocoa butter | 20001695003 | 5 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20001776002 | 2 |
| Caesar & Loretz GmbH | Hard fat | 20003131003 | 4 |
| Caesar & Loretz GmbH | Hard fat | 20003131004 | 2 |
| Caesar & Loretz GmbH | Hard fat | 20003131007 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Hard fat | 20003131008 | 5 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20003602001 | 8 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20003602002 | 4 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20003602003 | 2 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20003602005 | 6 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20003602009 | 3 |
| CAESAR & LORETZ GMBH | Beeswax, yellow | 20003602009 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 20003824003 | 2 |
| Caesar & Loretz GmbH | Beeswax, yellow | 20003825001 | 10 |
| Caesar & Loretz GmbH | Cetyl palmitate | 20003842006 | 5 |
| Caesar & Loretz GmbH | Cetyl palmitate | 20003842013 | 4 |
| Caesar & Loretz GmbH | Cocoa butter | 20004174002 | 2 |
| Caesar & Loretz GmbH | Cocoa butter | 20004174006 | 1 |
| Caesar & Loretz GmbH | Cocoa butter | 20004174010 | 2 |
| Caesar & Loretz GmbH | Cetyl palmitate | 21000359001 | 11 |
| Caesar & Loretz GmbH | Paraffin, hard | 21000732001 | 10 |
| Caesar & Loretz GmbH | Cetyl palmitate | 21000860001 | 5 |
| Caesar & Loretz GmbH | Cetyl palmitate | 21000860009 | 3 |
| Caesar & Loretz GmbH | Cetyl palmitate | 21000860010 | 14 |
| Caesar & Loretz GmbH | Beeswax, white | 21001267002 | 3 |
| CAESAR & LORETZ GMBH | Beeswax, white | 21001267002 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 21001267003 | 3 |
| Caesar & Loretz GmbH | Beeswax, white | 21001267008 | 5 |
| Caesar & Loretz GmbH | Beeswax, white | 21001267012 | 3 |
| Caesar & Loretz GmbH | Beeswax, yellow | 2100142 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 21001423001 | 2 |
| Caesar & Loretz GmbH | Beeswax, yellow | 21001423003 | 4 |
| Caesar & Loretz GmbH | Beeswax, yellow | 21001423004 | 5 |
| Caesar & Loretz GmbH | Beeswax, yellow | 21001423010 | 2 |
| Caesar & Loretz GmbH | Paraffin, hard | 21001748004 | 5 |
| Caesar & Loretz GmbH | Paraffin, hard | 21001748007 | 3 |
| Caesar & Loretz GmbH | Paraffin, hard | 21001748014 | 1 |
| Caesar & Loretz GmbH | Cocoa butter | 21002516002 | 3 |
| Caesar & Loretz GmbH | Cocoa butter | 21002516004 | 2 |
| Caesar & Loretz GmbH | Cocoa butter | 21002516017 | 1 |
| Caesar & Loretz GmbH | Cocoa butter | 21002516018 | 1 |
| Caesar & Loretz GmbH | Cocoa butter | 21002516020 | 3 |
| Caesar & Loretz GmbH | Hard fat | 21003046001 | 2 |
| Caesar & Loretz GmbH | Hard fat | 21003046008 | 15 |
| Caesar & Loretz GmbH | Hard fat | 21003046009 | 2 |
| Caesar & Loretz GmbH | Hard fat | 21003046010 | 1 |
| Caesar & Loretz GmbH | Hard fat | 21003046011 | 7 |
| Caesar & Loretz GmbH | Paraffin, microcrystalline | 21003773003 | 1 |
| Caesar & Loretz GmbH | Beeswax, yellow | 21004132003 | 5 |
| Caesar & Loretz GmbH | Cetyl palmitate | 22000395002 | 4 |
| Caesar & Loretz GmbH | Beeswax, yellow | 22000795006 | 3 |
| Caesar & Loretz GmbH | Cetyl palmitate | 22001717001 | 1 |
| Caesar & Loretz GmbH | Cetyl palmitate | 22001717004 | 1 |
| Caesar & Loretz GmbH | Hard fat | 22002076002 | 1 |
| Caesar & Loretz GmbH | Hard fat | 22002076007 | 1 |
| Caesar & Loretz GmbH | Hard fat | 22002076010 | 1 |
| Caesar & Loretz GmbH | Sodium dodecyl sulfate | 22003127001 | 1 |
| Caesar & Loretz GmbH | Beeswax, white | 2200795006 | 1 |
| Caesar & Loretz GmbH | Sodium dodecyl sulfate | 23000156006 | 1 |
| Caesar & Loretz GmbH | Hard fat | 23000561002 | 1 |
| Caesar & Loretz GmbH… | Cetyl palmitate | 20000975002 | 1 |
| Caesar & Loretz Hild… | Hard fat | 20000906003 | 1 |
| Caesar & Loretz Hild… | Beeswax, yellow | 19137202 | 1 |
| Caesar & Loretz/AHD | Beeswax, yellow | 16038206 | 1 |
| Caesar & Loretz/Gehe | Beeswax, yellow | 191372001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz/Gehe | Beeswax, yellow | 19137202 | 1 |
| Caesar & Loretz/Geil... | Beeswax, yellow | 19137202 | 2 |
| Caesar & Loretz/Noweda | Beeswax, white | 191242001 | 1 |
| Caesar & Loretz/Noweda | Beeswax, white | 19124210 | 1 |
| Caesar & Loretz/Noweda | Paraffin, hard | 192463001 | 1 |
| Caesar & Loretz/Noweda | Beeswax, white | 20000885004 | 1 |
| Caesar & Loretz | Beeswax, yellow | 15317613 | 1 |
| Caesar & Loretz | Beeswax, yellow | 16038201 | 1 |
| Caesar & Loretz | Paraffin, hard | 18070107 | 1 |
| Caesar / Ebert | Paraffin, hard | 15295405 | 1 |
| Caesar / Gehe | Beeswax, yellow | 15023004 | 1 |
| Caesar / Gehe | Beeswax, yellow | 15292009 | 1 |
| Caesar Loretz Gmbh | Hard fat | 17307602 | 1 |
| Caesar u Loretz | Cetyl palmitate | 14213710 | 1 |
| Caesar und Loretz GmbH | Hard fat | 17307601 | 3 |
| Caesar und Loretz GmbH | Hard fat | 18040401 | 1 |
| Caesar&Lorenz | Beeswax, yellow | 21001423001 | 1 |
| Caesar&Loretz GmbH D... | Hard fat | 11109617 | 1 |
| Caesar&Loretz GmbH | Beeswax, yellow | 16038210 | 1 |
| Caesar&Loretz | Cetyl palmitate | 17271504 | 2 |
| Caesar/Gehe | Beeswax, white | 18048906 | 1 |
| Caesar/Noweda | Beeswax, yellow | 12124811 | 3 |
| Caesar/Noweda | Cetyl palmitate | 12228801 | 1 |
| Caesar/Noweda | Beeswax, yellow | 13031220 | 1 |
| Caesar/Noweda | Cetyl palmitate | 13295909 | 1 |
| Caesar/Noweda | Hard fat | 14126203 | 1 |
| Caesar/Noweda | Cetyl palmitate | 15301701 | 1 |
| Caeser und Loretz GmbH | Hard fat | 18333905 | 1 |
| Caleo/ Noweda | Beeswax, yellow | 18049003 | 1 |
| Caleo/Sanacorp | Beeswax, yellow | 18299201 | 1 |
| calo | Beeswax, yellow | 17011612 | 1 |
| Carlo/Gehe/10,80 | Cetyl palmitate | 18273705 | 1 |
| Carlo/Gehe/8,52 | Beeswax, yellow | 18299206 | 1 |
| Cealo / Noweda | Cocoa butter | 13292011 | 1 |
| Cealo / Anzag | Paraffin, hard | 220826(21001748007) | 1 |
| Cealo/Gehe | Beeswax, yellow | 13335502 | 1 |
| Cealo/GEHE | Cetyl palmitate | 192859003 | 1 |
| Cealo/Kehr | Beeswax, yellow | 20000280002 | 1 |
| Cealo/Noweda | Cetyl palmitate | 22000395002 | 1 |
| Cealo/Sanacorp | Hard fat | 20003131007 | 1 |
| Cealo | Beeswax, yellow | 18113509 | 1 |
| Cealo | Beeswax, yellow | 20000280003 | 1 |
| Cealo | Paraffin, hard | 21000732007 | 1 |
| Cealo | Cetyl palmitate | 21000860001 | 1 |
| Ceasar & Loretz GmbH... | Cetyl palmitate | 18149904 | 1 |
| Cesar&Loretz GmbH Noweda | Cetyl palmitate | 20000974002 | 1 |
| China Medica | Hard fat | 3244303 | 1 |
| coelo/Sana | Cetyl palmitate | 14351612 | 1 |
| Cordes/Gehe | Beeswax, white | 18048907 | 1 |
| E Plus | Beeswax, yellow | 17011612 | 3 |
| E-Plus | Beeswax, yellow | 16038202 | 1 |
| Euro OTC | Beeswax, yellow | 1201012-01 | 1 |
| Euro OTC | Cetyl palmitate | 12228808 | 1 |
| Euro OTC | Paraffin, hard | 13109224 | 1 |
| Euro OTC | Beeswax, yellow | 1407013-01 | 1 |
| Euro OTC | Cocoa butter | 14123621 | 1 |
| Euro OTC | Beeswax, yellow | 1503013-01 | 1 |
| Euro OTC | Hard fat | 15185005 | 1 |
| Euro OTC | Paraffin, hard | 15232004 | 1 |
| Euro OTC | Cetyl palmitate | 15301705 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Beeswax, yellow | 16038201 | 1 |
| Euro OTC | Cetyl palmitate | 160419C | 1 |
| Euro OTC | Beeswax, white | 16163104 | 1 |
| Euro OTC | Cetyl palmitate | 16186809 | 1 |
| Euro OTC | Cocoa butter | 16316508 | 1 |
| Euro OTC | Beeswax, yellow | 17011607 | 1 |
| Euro OTC | Cetyl palmitate | 17043504 | 2 |
| Euro OTC | Beeswax, white | 17091802 | 1 |
| Euro OTC | Hard fat | 17107304 | 1 |
| Euro OTC | Hard fat W35 | 17K09B03343780 | 1 |
| Euro OTC | Hard fat | 18004023 | 1 |
| Euro OTC | Beeswax, white | 18048901 | 2 |
| Euro OTC | Paraffin, hard | 18070107 | 1 |
| Euro OTC | Beeswax, yellow | 18113501 | 1 |
| Euro OTC | Beeswax, yellow | 18113505 | 3 |
| Euro OTC | Cetyl palmitate | 18149904 | 1 |
| Euro OTC | Cetyl palmitate | 20000975002 | 1 |
| Euro OTC | Cetyl palmitate | 20003842013 | 1 |
| Euro/Sanacorp | Beeswax, yellow | 1708506 | 1 |
| Euroo | Beeswax, yellow | 1407013-01 | 1 |
| Fagron | Hard fat | | 1 |
| Fagron | Cetyl palmitate | 12C27-N07 | 2 |
| Fagron | Cetyl palmitate | 12D19-N02 | 1 |
| Fagron | Beeswax, yellow | 12D23-N05 | 2 |
| Fagron | Hard fat | 12G04-N18 | 1 |
| Fagron | Hard fat | 12I04-N11 | 1 |
| Fagron | Hard fat | 12K01-N12 | 3 |
| Fagron | Hard fat | 13243301 | 1 |
| Fagron | Beeswax, yellow | 13B04-N04 | 2 |
| Fagron | Hard fat | 13D10-N06 | 1 |
| Fagron | Beeswax, yellow | 13I02-B01 | 1 |
| Fagron | Beeswax, yellow | 13L02-B01-291452 | 1 |
| Fagron | Beeswax, yellow | 13L02-B01-294113 | 2 |
| Fagron | Beeswax, yellow | 13L02-B01-294114 | 1 |
| Fagron | Beeswax, yellow | 14336616 | 1 |
| Fagron | Hard fat | 14G03-B03-296731 | 1 |
| Fagron | Beeswax, yellow | 14G07-B04-300495 | 3 |
| Fagron | Hard fat | 14L01-B06 | 2 |
| Fagron | Hard fat | 14L01-B06-303380 | 3 |
| Fagron | Beeswax, white | 15292009 | 1 |
| Fagron | Beeswax, white | 15292022 | 1 |
| Fagron | Beeswax, yellow | 15317603 | 1 |
| Fagron | Hard fat W35 | 15A07-B12-309245 | 1 |
| Fagron | Hard fat | 15F03-B06 | 4 |
| Fagron | Hard fat | 15F03-B06-308708 | 3 |
| Fagron | Hard fat W35 | 15J08-B04-322726 | 1 |
| Fagron | Hard fat W35 | 15J08-B04-322727 | 1 |
| Fagron | Hard fat W35 | 15J08-B04-324217 | 1 |
| Fagron | Hard fat W35 | 15J08-B04-324959 | 2 |
| Fagron | Sodium dodecyl sulfate | 16229205 | 1 |
| Fagron | Beeswax, white | 16a28_b10_322948 | 1 |
| Fagron | Beeswax, white | 16A28-B10-322948 | 1 |
| Fagron | Hard fat | 16H01-B03-334976 | 2 |
| Fagron | Beeswax, white | 16J28-B06 | 1 |
| Fagron | Hard fat W35 | 16K08-B10-328956 | 1 |
| Fagron | Hard fat W35 | 16K08-B10-332763 | 3 |
| Fagron | Hard fat W35 | 16k08-b10-334910 | 1 |
| Fagron | Hard fat W35 | 16K08-B10-339077 | 6 |
| Fagron | Hard fat W35 | 16K09-B03-346709 | 1 |
| Fagron | Hard fat W35 | 16K-B10-334910 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Beeswax, yellow | 17011607 | 1 |
| Fagron | Beeswax, white | 1701947 | 1 |
| Fagron | Beeswax, white | 17091802 | 1 |
| Fagron | Cetyl palmitate | 17164005 | 1 |
| Fagron | Paraffin, hard | 17245604 | 1 |
| Fagron | Paraffin, hard | 17347701 | 2 |
| Fagron | Beeswax, white | 17C15-B01-342088 | 1 |
| Fagron | Beeswax, white | 17C15-B01-354806 | 1 |
| Fagron | Hard fat W35 | 17K09-B03 | 2 |
| Fagron | Hard fat W35 | 17k09-b03-346709 | 1 |
| Fagron | Hard fat W35 | 17K09-B03-346709 | 5 |
| Fagron | Hard fat W35 | 17K09-B03-348770 | 4 |
| Fagron | Hard fat W35 | 17k09-b03-351980 | 1 |
| Fagron | Hard fat W35 | 17K09-B03-351980 | 5 |
| Fagron | Hard fat W35 | 17K09-B03-355397 | 1 |
| Fagron | Beeswax, white | 17L04-B05-348865 | 3 |
| Fagron | Cetyl palmitate | 18149904 | 1 |
| Fagron | Sodium dodecyl sulfate | 18182206 | 1 |
| Fagron | Hard fat W35 | 18G13-B02 | 1 |
| Fagron | Hard fat W35 | 18G13-B02-355398 | 1 |
| Fagron | Hard fat W35 | 18G13-B02-356977 | 4 |
| Fagron | Hard fat W35 | 18G13B02356978 | 1 |
| Fagron | Hard fat | 18I12-B04-354348 | 1 |
| Fagron | Hard fat W35 | 19C04-B04 | 1 |
| Fagron | Hard fat W35 | 19C04-B09 | 2 |
| Fagron | Hard fat W35 | 19C04-B09-191420 | 2 |
| Fagron | Hard fat W35 | 19C04B09191422 | 1 |
| Fagron | Hard fat W35 | 19CO4-B04 | 1 |
| Fagron | Hard fat | 19I09-F04 | 2 |
| Fagron | Hard fat | 19I09-F04-365037 | 3 |
| Fagron | Beeswax, white | 19J17-B01-196942 | 2 |
| Fagron | Hard fat W35 | 20A08-B03 | 1 |
| Fagron | Hard fat W35 | 20A08-B03-197663 | 2 |
| Fagron | Hard fat W35 | 20A08-B03-197664 | 3 |
| Fagron | Hard fat W35 | 20A08-B03-197665 | 1 |
| Fagron | Cetyl palmitate | 20B04-F08 | 1 |
| Fagron | Hard fat | 20B04-F08-368439 | 1 |
| Fagron | Hard fat W35 | 20F10-B05 | 1 |
| Fagron | Hard fat | 20F10-B05-201350 | 2 |
| Fagron | Hard fat W35 | 20G01-F02 | 1 |
| Fagron | Hard fat | 20G01-F02-372412 | 2 |
| Fagron | Hard fat | 20G01-F02-372412210030 | 1 |
| Fagron | Hard fat | 20G01-F02-376138 | 3 |
| Fagron | Hard fat W35 | 20H17-B09-202675 | 3 |
| Fagron | Hard fat W35 | 20J07-B02-202717 | 1 |
| Fagron | Beeswax, white | 2155 | 1 |
| Fagron | Hard fat W35 | 21D14-B12 | 1 |
| Fagron | Hard fat W35 | 21D14-B12-216502 | 1 |
| Fagron | Hard fat W35 | 21D14-B12-219382 | 1 |
| Fagron | Hard fat W35 | 21D14-B12-219988 | 1 |
| Fagron | Hard fat W35 | 22D12-B01 | 2 |
| Fagron | Hard fat W35 | 22D12-B01-220445 | 1 |
| Fagron | Hard fat W35 | 22D12-B01-224504 | 1 |
| Fagron | Hard fat | 22H04-B02-222151 | 3 |
| Fagron | Hard fat W35 | 22J26-B12-229479 | 1 |
| Fagron | Beeswax, yellow | 280A140306 | 1 |
| Fagron | Hard fat | 2OG01-F02-373358 | 1 |
| Fagron | Hard fat W35 | 2OJ07-B02 | 1 |
| Fagron | Hard fat W35 | 3518A-03934 | 1 |
| Fagron | Hard fat W35 | 3914E-02328 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Hard fat W35 | 3917M-02328 | 1 |
| Fagron | Hard fat | 5628 | 1 |
| Fagron | Hard fat | 606469 | 1 |
| Fagron | Hard fat W35 | 904381 | 1 |
| Fagron | Hard fat | 909394 | 2 |
| Fagron | Hard fat W35 | B02-2027107 | 1 |
| Fagron | Hard fat W35 | B0520134008 | 1 |
| Fagron | Hard fat W35 | B05-2013408 | 2 |
| Fargon/Alliance HC | Cetyl palmitate | 14351612 | 1 |
| Fargon | Hard fat | 20G01-F02-372412 | 2 |
| Fargon | Hard fat | 41319264 | 1 |
| Fiebig | Hard fat | 20000906003 | 1 |
| Finze | Beeswax, yellow | 10145002 | 1 |
| Fischer/Phönix | Cetyl palmitate | 15301711 | 1 |
| Gatt-Koller | Cocoa butter | 1803838 | 1 |
| Gehe | Hard fat | 11345918 | 1 |
| Gehe | Beeswax, yellow | 12079412 | 1 |
| Gehe | Beeswax, yellow | 12367910 | 1 |
| Gehe | Hard fat | 13243403 | 1 |
| GEHE | Beeswax, yellow | 13335502 | 1 |
| Gehe | Sodium dodecyl sulfate | 14127404 | 1 |
| Gehe | Paraffin, hard | 14286511 | 1 |
| Gehe | Beeswax, yellow | 14336607 | 1 |
| GEHE | Paraffin, hard | 15295409 | 1 |
| Gehe | Paraffin, hard | 15295410 | 1 |
| Gehe | Beeswax, yellow | 16038207 | 2 |
| GEHE | Beeswax, white | 16163109 | 1 |
| GEHE | Sodium dodecyl sulfate | 16229205 | 1 |
| GEHE | Hard fat | 16274203 | 1 |
| Gehe | Paraffin, microcrystalline | 17137508 | 1 |
| Gehe | Beeswax, yellow | 18049001 | 1 |
| GEHE | Beeswax, yellow | 18113501 | 1 |
| GEHE | Hard fat | 18147901 | 2 |
| Gehe | Cocoa butter | 19036008 | 1 |
| Gehe | Beeswax, white | 191242004 | 1 |
| Gehe | Beeswax, white | 19124206 | 1 |
| Gehe | Beeswax, yellow | 19137202 | 1 |
| Gehe | Hard fat | 20003131008 | 1 |
| Gehe | Paraffin, hard | 21001748007 | 1 |
| Gehe | Beeswax, yellow | 210041320003 | 1 |
| Gehe | Cetyl palmitate | 22001785003 | 2 |
| Gehe | Beeswax, yellow | 22003888003 | 1 |
| Gehe | Hard fat W35 | 22004876 | 1 |
| Gehe | Sodium dodecyl sulfate | 23000156007 | 2 |
| gehe | Hard fat | 23000561002 | 1 |
| Gehe | Hard fat | 23000561002 | 2 |
| Gehe | Hard fat | 23000561003 | 1 |
| Gehe | Cetyl palmitate | 23001428006 | 1 |
| Gehe | Beeswax, yellow | 23003298002 | 1 |
| Gehe | Beeswax, yellow | 290A230413-01 | 2 |
| Gehe | Cetyl palmitate | 8209646 | 1 |
| Gehe-Berlin | Cetyl palmitate | 23001428006 | 7 |
| Geibo | Beeswax, yellow | 290A170915 | 1 |
| Gutenberg-Apotheke | Cocoa butter | 13292007 | 1 |
| Hänseler | Beeswax, yellow | | 6 |
| HCK | Paraffin, hard | 16277705 | 1 |
| Hedinger GmbH/Noweda | Paraffin, hard | 17347701 | 1 |
| Henry Lamotte/ Allia… | Cocoa butter | 19036003 | 1 |
| Hirsch | Beeswax, yellow | 12257012 | 1 |
| Holdermann | Cetyl palmitate | 23001428006 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Ichthyol/Phönix | Sodium dodecyl sulfate | 15344510 | 1 |
| Ichthyol | Beeswax, yellow | 13031239 | 1 |
| Intern Drogen | Sodium dodecyl sulfate | 216991080 | 1 |
| INTERN-DROGEN | Hard fat | 20003131003 | 1 |
| INTERN-DROGEN | Beeswax, white | 20003825001 | 2 |
| INTERN-DROGEN | Beeswax, yellow | 21001423005 | 1 |
| INTERN-DROGEN | Paraffin, hard | 21001748004 | 4 |
| Jenne | Paraffin, hard | 17347701 | 1 |
| Jenne | Beeswax, white | 22003630003 | 2 |
| Jenne | Cetyl palmitate | 23001428006 | 1 |
| Jenne | Beeswax, white | 23002638001 | 1 |
| Jenne | Beeswax, yellow | 241011(23003298002) | 1 |
| Kehr | Paraffin, hard | 17347701 | 1 |
| Kehr | Hard fat W35 | 17K09-B03-351980 | 1 |
| Kehr | Beeswax, white | 18048906 | 1 |
| Kehr | Beeswax, yellow | 18113501 | 1 |
| Kehr | Beeswax, white | 21001267012 | 1 |
| kehr | Paraffin, hard | 21001748004 | 1 |
| Kehr | Beeswax, yellow | 21004132003 | 2 |
| Kehr | Beeswax, white | 22003630003 | 2 |
| Kehr | Hard fat | 2202076002 | 1 |
| Klenk | Beeswax, white | 10503-01 | 1 |
| Klenk | Beeswax, yellow | 13335513 | 1 |
| Klenk | Beeswax, yellow | 160311 | 1 |
| Klenk | Beeswax, white | 19071005 | 1 |
| Klenk | Beeswax, yellow | 190A170314 | 1 |
| Klenk | Beeswax, yellow | 20110-01 | 1 |
| Klenk | Beeswax, yellow | 20110-03 | 1 |
| Klenk | Beeswax, white | 206090002 | 1 |
| Klenk | Beeswax, white | 20609-01 | 2 |
| Klenk | Beeswax, yellow | 220110-001 | 1 |
| Klenk | Beeswax, yellow | 220110-002 | 1 |
| Klenk | Beeswax, yellow | 220110-003 | 1 |
| Klenk | Beeswax, white | 221115-001 | 1 |
| Klenk | Beeswax, white | 230413-001 | 1 |
| Klenk | Beeswax, yellow | 280A110110 | 1 |
| Klenk | Beeswax, yellow | 280A120627 | 5 |
| Klenk | Beeswax, yellow | 280-A120627 | 1 |
| Klenk | Beeswax, yellow | 280A130115 | 26 |
| Klenk | Beeswax, yellow | 280A13011A | 1 |
| Klenk | Beeswax, yellow | 280A140306 | 7 |
| Klenk | Beeswax, yellow | 280A150528 | 13 |
| Klenk | Beeswax, white | 280A160311 | 17 |
| Klenk | Beeswax, white | 280A171019 | 31 |
| Klenk | Beeswax, white | 280A190715 | 18 |
| Klenk | Beeswax, white | 280A190715-01 | 1 |
| Klenk | Beeswax, white | 280A2008005-01 | 1 |
| Klenk | Beeswax, white | 280A200804 | 1 |
| Klenk | Beeswax, white | 280A200804-01 | 6 |
| Klenk | Beeswax, white | 280A200805-01 | 3 |
| Klenk | Beeswax, white | 280A210503-01 | 9 |
| Klenk | Beeswax, white | 280A220609-01 | 1 |
| Klenk | Beeswax, white | 280A220609-02 | 2 |
| Klenk | Beeswax, white | 280A221115-01 | 3 |
| Klenk | Beeswax, white | 280A230413-01 | 1 |
| Klenk | Beeswax, yellow | 282A120627 | 1 |
| Klenk | Beeswax, yellow | 282A140306 | 1 |
| Klenk | Beeswax, yellow | 290A081210 | 1 |
| Klenk | Beeswax, yellow | 290A110803 | 1 |
| Klenk | Beeswax, yellow | 290A120627 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Beeswax, yellow | 290A140903 | 5 |
| Klenk | Beeswax, white | 290A150716 | 5 |
| Klenk | Beeswax, yellow | 290A151214 | 5 |
| Klenk | Beeswax, yellow | 290A170314 | 5 |
| Klenk | Beeswax, yellow | 290A170915 | 18 |
| Klenk | Beeswax, yellow | 290A200108-01 | 1 |
| Klenk | Beeswax, yellow | 290A200108-02 | 2 |
| Klenk | Beeswax, yellow | 290A220110-002 | 1 |
| Klenk | Beeswax, yellow | 290A220110-01 | 6 |
| Klenk | Beeswax, yellow | 290A220110-02 | 2 |
| Klenk | Beeswax, yellow | 290A230120-01 | 3 |
| Klenk | Beeswax, yellow | 290A230413-01 | 2 |
| Klenk | Beeswax, yellow | 416E01240 | 1 |
| Klenk | Beeswax, white | 804-01 | 1 |
| Klenk | Beeswax, white | 805-01 | 1 |
| Krieger | Hard fat | 23000447 | 1 |
| L10 | Cetyl palmitate | 16053811 | 1 |
| L10 | Cetyl palmitate | 16186805 | 1 |
| L10 | Beeswax, yellow | 17207403 | 1 |
| L12 | Cocoa butter | 16316508 | 1 |
| L12 | Paraffin, microcrystalline | 17137502 | 1 |
| L12 | Beeswax, yellow | 18113502 | 1 |
| L12 | Beeswax, yellow | 18113506 | 1 |
| L12 | Cetyl palmitate | 18149904 | 2 |
| L30 | Cetyl palmitate | 17271505 | 1 |
| L30 | Paraffin, hard | 17347701 | 1 |
| Lamotte/Allia | Hard fat | 18004024 | 1 |
| Mittelwand bio 2017 | Beeswax, yellow | 5022017 | 1 |
| Nachprüfung vom 31.0… | Hard fat | 15185002 | 1 |
| Nachprüfung | Cetyl palmitate | 123456 | 1 |
| Nachprüfung | Paraffin, hard | 16000921 | 2 |
| Nachprüfung | Paraffin, hard | 18070131 | 1 |
| Nachprüfung | Beeswax, yellow | 18113509 | 2 |
| Nachprüfung | Cetyl palmitate | 3012U01241 | 1 |
| Nachprüfung | Cetyl palmitate | 4917I-01242 | 1 |
| Noweda | Cocoa butter | 11117813 | 2 |
| Noweda | Hard fat | 11345909 | 1 |
| Noweda | Paraffin, hard | 11363206 | 1 |
| Noweda | Beeswax, yellow | 12124810 | 1 |
| Noweda | Paraffin, microcrystalline | 12266304 | 1 |
| Noweda | Paraffin, hard | 14286517 | 1 |
| Noweda | Beeswax, yellow | 150230004 | 1 |
| Noweda | Beeswax, yellow | 15023002 | 1 |
| Noweda | Hard fat W35 | 16027801 | 1 |
| Noweda | Beeswax, white | 16163114 | 1 |
| Noweda | Paraffin, hard | 16277710 | 1 |
| Noweda | Paraffin, hard | 163277710 | 1 |
| Noweda | Cetyl palmitate | 17271505 | 1 |
| Noweda | Paraffin, hard | 17347701 | 1 |
| Noweda | Hard fat W35 | 18006248 | 1 |
| Noweda | Beeswax, white | 18048901 | 1 |
| noweda | Beeswax, yellow | 18049001 | 1 |
| Noweda | Hard fat | 18147901 | 1 |
| Noweda | Beeswax, white | 18239106 | 1 |
| Noweda | Hard fat | 18333904 | 1 |
| Noweda | Cetyl palmitate | 19139004 | 1 |
| Noweda | Beeswax, yellow | 20000280008 | 2 |
| Noweda | Beeswax, white | 20000885007 | 1 |
| Noweda | Beeswax, yellow | 21001423001 | 2 |
| Noweda | Beeswax, yellow | 21001423003 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Beeswax, yellow | 21001423005 | 1 |
| Noweda | Paraffin, hard | 21001748004 | 2 |
| Noweda | Paraffin, hard | 2100174801 | 1 |
| Noweda | Paraffin, hard | 21001748012 | 2 |
| Noweda | Beeswax, white | 22000795001 | 4 |
| Noweda | Cetyl palmitate | 22001717001 | 2 |
| Noweda | Sodium dodecyl sulfate | 23000156006 | 1 |
| Noweda | Sodium dodecyl sulfate | 23000156007 | 1 |
| Noweda | Hard fat | 23000561002 | 1 |
| Noweda | Beeswax, white | 23002638001 | 1 |
| Noweda | Beeswax, yellow | 280A120627 | 2 |
| Noweda | Beeswax, white | 280A230413-01 | 1 |
| Noweda | Beeswax, white | 280A230413-02 | 1 |
| Noweda | Beeswax, yellow | 290A220110-02 | 1 |
| Noweda | Beeswax, yellow | 290A23012001 | 1 |
| Noweda | Beeswax, yellow | 290A230120-01 | 1 |
| Noweda | Beeswax, yellow | 290A230413-01 | 2 |
| Otto | Beeswax, yellow | WG10052021 | 1 |
| Ph.Eur. | Beeswax, yellow | 17207402 | 1 |
| Pharmachem | Beeswax, white | 15292014 | 1 |
| Pharmachem | Beeswax, yellow | 16038202 | 1 |
| PHOENIX 24.07.2014 | Beeswax, yellow | 13001206 | 1 |
| Phoenix 3.3.14 | Hard fat | 13243414 | 1 |
| Phoenix goettingen 08.05 | Beeswax, yellow | 15098901 | 1 |
| Phoenix goettingen 09.05 | Paraffin, hard | 13390415 | 1 |
| Phoenix | Cetyl palmitate | 14060705 | 1 |
| Phoenix | Beeswax, white | 15292003 | 1 |
| Phoenix | Paraffin, hard | 15295410 | 1 |
| Phoenix | Beeswax, white | 16163109 | 1 |
| Phoenix | Hard fat W35 | 16k08-b10-332763 | 1 |
| Phoenix | Cetyl palmitate | 17164005 | 1 |
| Phoenix | Paraffin, hard | 18070131 | 1 |
| Phoenix | Hard fat | 18147902 | 2 |
| Phoenix | Cetyl palmitate | 18149912 | 1 |
| Phoenix | Hard fat | 18333904 | 1 |
| Phoenix | Beeswax, white | 19124206 | 1 |
| Phoenix | Beeswax, yellow | 20000280008 | 1 |
| Phoenix | Paraffin, hard | 21000732007 | 1 |
| Phoenix | Beeswax, white | 21001267002 | 1 |
| Phoenix | Hard fat | 21003046011 | 2 |
| Phoenix | Cetyl palmitate | 22001717001 | 1 |
| Phoenix | Beeswax, yellow | 22003888002 | 1 |
| Phoenix | Sodium dodecyl sulfate | 23000156006 | 1 |
| Phoenix | Cetyl palmitate | 23001428006 | 1 |
| Phoenix | Beeswax, white | 280A221115-01 | 1 |
| Phoenix | Hard fat W35 | 3076 | 1 |
| Phönix / 2 | Beeswax, yellow | 20000280002 | 1 |
| Phönix, Caesar&Loret… | Beeswax, yellow | 191372001 | 1 |
| Phönix | Beeswax, yellow | 10849001 | 1 |
| Phönix | Paraffin, hard | 11166911 | 3 |
| Phönix | Beeswax, yellow | 12367901 | 1 |
| Phönix | Beeswax, yellow | 12367904 | 1 |
| Phönix | Beeswax, yellow | 12367915 | 1 |
| Phönix | Beeswax, yellow | 13031206 | 1 |
| Phönix | Cetyl palmitate | 13131906 | 1 |
| Phönix | Paraffin, microcrystalline | 13274301 | 1 |
| Phönix | Cetyl palmitate | 13295919 | 1 |
| phönix | Beeswax, white | 15292022 | 1 |
| Phönix | Cetyl palmitate | 15301711 | 1 |
| Phönix | Beeswax, yellow | 15317609 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Beeswax, yellow | 16038206 | 2 |
| phönix | Beeswax, yellow | 16038207 | 1 |
| phönix | Beeswax, white | 16163109 | 1 |
| Phönix | Hard fat | 16274203 | 1 |
| PHÖNIX | Beeswax, yellow | 17011611 | 1 |
| Phönix | Cetyl palmitate | 17043504 | 1 |
| Phönix | Cocoa butter | 17314902 | 1 |
| Phönix | Hard fat | 18000346 | 1 |
| Phönix | Beeswax, yellow | 18049001 | 1 |
| Phönix | Beeswax, yellow | 18113501 | 1 |
| Phönix | Cocoa butter | 18135106 | 1 |
| Phönix | Cetyl palmitate | 18149912 | 1 |
| Phönix | Cocoa butter | 19000676003 | 4 |
| Phönix | Cocoa butter | 19036011 | 3 |
| Phönix | Cetyl palmitate | 19139004 | 1 |
| Phönix | Paraffin, hard | 192463010 | 1 |
| Phönix | Cetyl palmitate | 192869002 | 1 |
| Phönix | Beeswax, yellow | 20000280008 | 2 |
| Phönix | Cocoa butter | 2000169002 | 1 |
| Phönix | Beeswax, yellow | 20003602005 | 1 |
| Phönix | Beeswax, white | 20003825001 | 1 |
| Phönix | Paraffin, hard | 21000732007 | 1 |
| Phönix | Beeswax, white | 21001267002 | 1 |
| Phönix | Cetyl palmitate | 22001717004 | 1 |
| Phönix | Cetyl palmitate | 22001785003 | 2 |
| Phönix | Cocoa butter | 22003120004 | 1 |
| Phönix | Beeswax, yellow | 220038888002 | 1 |
| Phönix | Hard fat | 23000561002 | 1 |
| Phönix | Cetyl palmitate | 23001428006 | 1 |
| Phönix | Beeswax, yellow | 23003298002 | 1 |
| Phönix | Cocoa butter | 27121 | 1 |
| Phönix | Hard fat | 277212 | 1 |
| Phönix | Beeswax, white | 280A171019 | 1 |
| Phönix | Hard fat W35 | B05-2013409 | 1 |
| Phytocomm | Hard fat | 209314 | 1 |
| Purren Apotheke | Hard fat | 10I03-N08 | 1 |
| Rondell Apotheke | Hard fat | 15185002 | 1 |
| Sanacorp 03.01.22 | Cetyl palmitate | 220103CP | 1 |
| Sanacorp WE:18.04.16… | Beeswax, yellow | 15023004 | 1 |
| Sanacorp | Beeswax, yellow | | 1 |
| Sanacorp | Cocoa butter | 1121300203 | 1 |
| Sanacorp | Beeswax, yellow | 12257009 | 1 |
| Sanacorp | Beeswax, yellow | 12367910 | 1 |
| Sanacorp | Cocoa butter | 13027207 | 1 |
| sanacorp | Cocoa butter | 13140407 | 1 |
| Sanacorp | Beeswax, yellow | 13335502 | 1 |
| Sanacorp | Beeswax, yellow | 13378619 | 1 |
| Sanacorp | Hard fat | 14126203 | 1 |
| sanacorp | Hard fat | 14338703 | 1 |
| Sanacorp | Beeswax, yellow | 16038203 | 1 |
| Sanacorp | Beeswax, white | 16163105 | 1 |
| Sanacorp | Beeswax, white | 16163114 | 1 |
| Sanacorp | Cetyl palmitate | 16186805 | 1 |
| Sanacorp | Hard fat | 16274202 | 1 |
| Sanacorp | Beeswax, yellow | 17011604 | 2 |
| Sanacorp | Beeswax, yellow | 17011609 | 1 |
| Sanacorp | Beeswax, yellow | 17011612 | 1 |
| Sanacorp | Cetyl palmitate | 17043504 | 1 |
| Sanacorp | Cocoa butter | 170559908 | 1 |
| Sanacorp | Cetyl palmitate | 17164004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Sanacorp | Cocoa butter | 17314902 | 1 |
| Sanacorp | Hard fat W35 | 17k09-b03-346709 | 1 |
| Sanacorp | Paraffin, hard | 18070131 | 1 |
| Sanacorp | Beeswax, yellow | 18113501 | 1 |
| Sanacorp | Beeswax, yellow | 18113502 | 1 |
| Sanacorp | Cocoa butter | 18135106 | 3 |
| Sanacorp | Hard fat | 18147907 | 1 |
| Sanacorp | Beeswax, white | 18239106 | 1 |
| Sanacorp | Beeswax, yellow | 18299201 | 1 |
| Sanacorp | Beeswax, white | 191242002 | 1 |
| Sanacorp | Beeswax, yellow | 191372001 | 1 |
| Sanacorp | Beeswax, yellow | 19137202 | 1 |
| Sanacorp | Paraffin, hard | 19246300 | 1 |
| Sanacorp | Cetyl palmitate | 192859003 | 1 |
| Sanacorp | Cetyl palmitate | 192859005 | 1 |
| Sanacorp | Beeswax, yellow | 20000280008 | 1 |
| Sanacorp | Hard fat W35 | 20000603 | 3 |
| Sanacorp | Cetyl palmitate | 20000975002 | 1 |
| Sanacorp | Beeswax, white | 20003825001 | 1 |
| Sanacorp | Beeswax, yellow | 21001423001 | 1 |
| Sanacorp | Cocoa butter | 21002516002 | 2 |
| Sanacorp | Beeswax, yellow | 21004132003 | 2 |
| Sanacorp | Cetyl palmitate | 22000395002 | 1 |
| Sanacorp | Beeswax, white | 22000795001 | 2 |
| Sanacorp | Beeswax, white | 22000795009 | 1 |
| Sanacorp | Cocoa butter | 22003120004 | 1 |
| Sanacorp | Beeswax, yellow | 22003888003 | 4 |
| Sanacorp | Hard fat | 23000561002 | 3 |
| Sanacorp | Hard fat | 23000561008 | 1 |
| Sanacorp | Cocoa butter | 23001467005 | 2 |
| Sanacorp | Beeswax, white | 23002638002 | 1 |
| Sanacorp | Paraffin, hard | 23003232004 | 1 |
| Sanacorp | Beeswax, white | 280A171019 | 1 |
| Sanacorp | Sodium dodecyl sulfate | 5/AKD1 | 1 |
| Sanacorp | Sodium dodecyl sulfate | 5/AKD6 | 1 |
| Sanacorp | Cetyl palmitate | 8/AKD12 | 1 |
| Sanacorp | Cetyl palmitate | 8/AKD13 | 1 |
| Sanacorp | Cocoa butter | AKD27 | 1 |
| Sanacorp | Cocoa butter | AKD28 | 1 |
| Spinnrad / Phönix | Cocoa butter | 719300202 | 1 |
| Spinnrad/ Noweda/ 08… | Cocoa butter | 920300201 | 1 |
| Spinnrad/ Sanacorp 2… | Cocoa butter | 719300202 | 1 |
| Spinnrad/GEHE | Cocoa butter | 920300201 | 1 |
| Spinnrad/Noweda | Beeswax, white | 118048061 | 2 |
| Spinnrad/Noweda | Cocoa butter | 317300201 | 1 |
| Spinnrad/Noweda | Cocoa butter | 717300202 | 1 |
| Spinnrad | Cocoa butter | 1017300203 | 1 |
| Spinnrad | Cocoa butter | 1017300212 | 1 |
| Spinnrad | Beeswax, white | 1018048062 | 1 |
| Spinnrad | Beeswax, white | 1121402003 | 1 |
| Spinnrad | Beeswax, white | 118048061 | 1 |
| spinnrad | Cocoa butter | 1218300203 | 1 |
| Spinnrad | Cocoa butter | 221302051 | 1 |
| Spinnrad | Beeswax, white | 317048061 | 1 |
| Spinnrad | Cocoa butter | 319300201 | 1 |
| spinnrad | Cocoa butter | 3252 | 1 |
| Spinnrad | Cocoa butter | 512300202 | 1 |
| spinnrad | Beeswax, white | 718402002 | 1 |
| Symbiotica | Cetyl palmitate | 2208030-01 | 1 |
| Wachs alt | Beeswax, yellow | | 2 |



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- 250 728 spectra from 1666 *Apo-Ident* customers from a total of 50 986 batches from a further 716 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Waxes / Fats* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Waxes / Fats* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 2847 | 0 | 155 479 |
| **Type B** | 0 | 2518 | 5 | 210 417 |
| **Type C** | 0 | 6151 | 7 | 250 728 |

The substance/substance group *Waxes / Fats* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 99.7893 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 99.8018 % (> 99.6829 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.8863 % (> 99.8376 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 20865 | 20865 | 0.00 | 149.88 |
| 20986 | 20986 | 0.00 | 109.17 |
| 21067 | 22479 | 14.94 | 146.40 |
| 21433 | 23511 | 5.33 | 134.07 |
| 21482 | 24813 | 17.13 | 148.80 |
| 21483 | 21483 | 0.00 | 87.96 |
| 21682 | 21682 | 0.00 | 66.78 |
| 21731 | 22349 | 2.96 | 124.46 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21766 | 22330 | 6.74 | 69.65 |
| 21875 | 23639 | 5.38 | 126.78 |
| 21880 | 21880 | 0.00 | 137.70 |
| 21984 | 21984 | 0.00 | 140.78 |
| 22244 | 23511 | 8.70 | 138.34 |
| 22245 | 23511 | 5.72 | 125.40 |
| 22325 | 21984 | 4.20 | 123.11 |
| 22330 | 22330 | 0.00 | 67.65 |
| 22338 | 21880 | 6.07 | 137.24 |
| 22348 | 23067 | 8.03 | 141.68 |
| 22349 | 22349 | 0.00 | 127.96 |
| 22352 | 23278 | 13.83 | 102.34 |
| 22479 | 22479 | 0.00 | 140.99 |
| 22486 | 22486 | 0.00 | 111.91 |
| 22956 | 23511 | 20.62 | 136.48 |
| 23067 | 23067 | 0.00 | 145.05 |
| 23242 | 24715 | 12.47 | 102.07 |
| 23278 | 23278 | 0.00 | 97.68 |
| 23511 | 23511 | 0.00 | 129.66 |
| 23560 | 23817 | 7.40 | 126.15 |
| 23565 | 23067 | 45.13 | 144.65 |
| 23601 | 21880 | 5.64 | 137.85 |
| 23639 | 23639 | 0.00 | 120.94 |
| 23705 | 23067 | 45.68 | 145.60 |
| 23707 | 23067 | 6.51 | 145.12 |
| 23817 | 23817 | 0.00 | 110.42 |
| 24715 | 24715 | 0.00 | 94.84 |
| 24716 | 24716 | 0.00 | 96.32 |
| 24720 | 24720 | 0.00 | 136.29 |
| 24813 | 24813 | 0.00 | 147.67 |
| 24870 | 23511 | 4.41 | 134.30 |
| 25047 | 21880 | 13.52 | 138.98 |
| 25216 | 25216 | 0.00 | 93.16 |
| 25381 | 22479 | 23.96 | 144.94 |
| 25384 | 23067 | 6.15 | 152.38 |
| 25387 | 22349 | 7.51 | 142.68 |
| 25434 | 27418 | 14.22 | 136.87 |
| 25445 | 21880 | 9.02 | 139.13 |
| 25639 | 25639 | 0.00 | 141.21 |
| 25723 | 25723 | 0.00 | 77.46 |
| 25739 | 23511 | 18.33 | 105.27 |
| 26108 | 26108 | 0.00 | 94.02 |
| 26362 | 26362 | 0.00 | 139.28 |
| 26622 | 23511 | 39.96 | 158.16 |
| 26696 | 26696 | 0.00 | 95.30 |
| 26734 | 21483 | 18.03 | 100.43 |
| 26745 | 22349 | 6.31 | 127.28 |
| 26910 | 23511 | 8.26 | 113.73 |
| 26959 | 26959 | 0.00 | 111.33 |
| 27034 | 21880 | 17.18 | 140.04 |
| 27268 | 23511 | 19.88 | 105.87 |

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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 27418 | 27418 | 0.00 | 143.19 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Wool alcohols** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20495-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Wool alcohols; Alcoholes lanae

### Special notes

When selecting the *Wool alcohols* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Wool alcohols | 6 | 2 | 22 |

### Second-stage model

For differentiation of the substance/substance group *Wool alcohols* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Wool alcohols* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Glycerol monostearate, emulsifying | 74.96 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Wool alcohols* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Wool alcohols*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Wool alcohols | 13380601 | 21520 | 40 | 1412037 |
| Caelo | Wool alcohols | 153703 | 22328 | 60 | 20151111* |
| Caelo | Wool alcohols | 153703 | 22329 | 60 | 20151111* |
| Caelo | Wool alcohols | 163530 | 23098 | 40 | 20161223* |
| Caelo | Wool alcohols | 191275 | 24722 | 40 | 20190606* |
| Caelo | Wool alcohols | 22002307001 | 26302 | 40 | 20220805 |
| Caelo | Wool alcohols | 22002307001 | 26302SI | 20 | 20220805 |
| Caelo | Wool alcohols | 24002633 | 27419 | 40 | 20241125* |
| Caelo | Wool alcohols | 24002633 | 27419SI | 20 | 20241125* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 360 spectra of 9 reference samples from the substance/substance group *Wool alcohols*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 157 966 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 2 reference samples from the substance/substance group *Wool alcohols*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Wool alcohols | 173160 | 23972 | 40 |
| Caelo | Wool alcohols | 181619 | 24165 | 40 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 38 spectra from 24 *Apo-Ident* customers from 23 batches from the substance/substance group *Wool alcohols*.

- Among them are spectra of independent samples from 22 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Wool alcohols | 11011401 | 1 |
| Caelo | Wool alcohols | 12340505 | 1 |
| Caelo | Wool alcohols | 13071502 | 1 |
| Caelo | Wool alcohols | 13083906 | 2 |
| Caelo | Wool alcohols | 13083912 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Wool alcohols | 13226408 | 1 |
| Caelo | Wool alcohols | 13380601 | 1 |
| Caelo | Wool alcohols | 14262501 | 1 |
| Caelo | Wool alcohols | 15304502 | 1 |
| Caelo | Wool alcohols | 15304505 | 3 |
| Caelo | Wool alcohols | 17169701 | 3 |
| Caelo | Wool alcohols | 18092502 | 3 |
| Caelo | Wool alcohols | 18161904 | 1 |
| Caelo | Wool alcohols | 18161912 | 1 |
| Caelo | Wool alcohols | 19127504 | 2 |
| Caelo | Wool alcohols | 20002460003 | 1 |
| Caelo | Wool alcohols | 21002143004 | 1 |
| Caelo | Wool alcohols | 23101408 | 1 |
| Caelo | Wool alcohols | 4/2015 | 1 |
| Caelo | Wool alcohols | 6111801 | 1 |
| Caesar & Loretz GmbH... | Wool alcohols | 22002784002 | 1 |
| Caesar & Loretz GmbH... | Wool alcohols | 20002460003 | 1 |
| Caesar & Loretz GmbH... | Wool alcohols | 19127504 | 1 |
| Caesar & Loretz GmbH... | Wool alcohols | 20002460003 | 1 |
| Caesar & Loretz GmbH | Wool alcohols | 18161904 | 1 |
| Caesar & Loretz GmbH | Wool alcohols | 19127504 | 1 |
| Caesar & Loretz GmbH | Wool alcohols | 20002460003 | 1 |
| Cealo/ Noweda | Wool alcohols | 13380601 | 1 |
| Fagron | Wool alcohols | 16235702 | 1 |
| Noweda | Wool alcohols | 22002784004 | 1 |

- 256 848 spectra from 1666 *Apo-Ident* customers from a total of 52 130 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Wool alcohols* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Wool alcohols* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 37 | 1 | 256 848 |

The substance/substance group *Wool alcohols* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 97.3684 % (> 89.4737 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several


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new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21520 | 21520 | 0.00 | 115.65 |
| 22328 | 22328 | 0.00 | 128.71 |
| 22329 | 22329 | 0.00 | 125.18 |
| 23098 | 23098 | 0.00 | 121.75 |
| 24722 | 24722 | 0.00 | 125.78 |
| 26302 | 24722 | 18.88 | 126.46 |
| 27419 | 27419 | 0.00 | 126.18 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Xylitol** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20994-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Xylitol; Xylitolum

### Special notes

When selecting the *Xylitol* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Xylitol | 7 | 5 | 29 |

### Second-stage model

For differentiation of the substance/substance group *Xylitol* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Xylitol* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 70.05 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Xylitol* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Xylitol*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Xylitol | 14068206 | 21755 | 60 | 20140317 |
| Caelo | Xylitol | 15135405 | 22248 | 60 | 20150417 |
| Caelo | Xylitol | 15135405 | 22579 | 40 | 20150417 |
| Caelo | Xylitol | 20002926 | 25619 | 40 | 20201027* |
| Caelo | Xylitol | 23000539 | 26692 | 40 | 20230331* |
| Caelo | Xylitol | 23000539 | 26692SI | 20 | 20230331* |
| Caelo | Xylitol | 24000699 | 27256 | 40 | 20240411* |
| Caelo | Xylitol | 24000699 | 27256SI | 20 | 20240411* |
| Fagron | Xylitol | 14G04-B04-298356 | 21754 | 60 | AR-15-FG-008046-01 |
| Fagron | Xylitol | 14G04-B04-303524 | 22254 | 60 | 20140919 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 440 spectra of 10 reference samples from the substance/substance group *Xylitol*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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batches.

- 157 886 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 210 spectra of 6 reference samples from the substance/substance group *Xylitol*.
- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Xylitol | 15388101 | 22578 | 40 |
| Caelo | Xylitol | 163174 | 23061 | 40 |
| Caelo | Xylitol | 181133 | 24041 | 40 |
| Caelo | Xylitol | 21004147 | 26002 | 40 |
| Caelo | Xylitol | 24002073 | 27306 | 40 |
| Caelo | Xylitol | 21004147 | 26002SI | 10 |

- 212 730 spectra from a total of 4282 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 49 spectra from 22 *Apo-Ident* customers from 32 batches from the substance/substance group *Xylitol*.
- Among them are spectra of independent samples from 29 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Xylitol | 21004147010 | 1 |
| | Xylitol | 23000539005 | 1 |
| | Xylitol | 23000699002 | 1 |
| Caelo | Xylitol | 1219Q-02787 | 1 |
| Caelo | Xylitol | 12240612 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Xylitol | 12J25-N06 | 2 |
| Caelo | Xylitol | 13230302 | 1 |
| Caelo | Xylitol | 13230305 | 1 |
| Caelo | Xylitol | 13230309 | 1 |
| Caelo | Xylitol | 13230315 | 1 |
| Caelo | Xylitol | 14061401 | 1 |
| Caelo | Xylitol | 14068206 | 1 |
| Caelo | Xylitol | 15388104 | 3 |
| Caelo | Xylitol | 16317401 | 1 |
| Caelo | Xylitol | 18045302 | 4 |
| Caelo | Xylitol | 18113304 | 2 |
| Caelo | Xylitol | 18113308 | 2 |
| Caelo | Xylitol | 18235907 | 2 |
| Caelo | Xylitol | 18235908 | 2 |
| Caelo | Xylitol | 19120404 | 2 |
| Caelo | Xylitol | 20003607001 | 2 |
| Caelo | Xylitol | 3314M-02787 | 1 |
| Caelo | Xylitol | 5112I-02787 | 1 |
| Caelo | Xylitol | 718I-02787 | 1 |
| Caesar & Loretz GmbH | Xylitol | 20003607001 | 2 |
| Caesar & Loretz GmbH | Xylitol | 20003607013 | 1 |
| Fagron | Xylitol | 13/23-N06 | 1 |
| Fagron | Xylitol | 13H28N10 | 1 |
| Fagron | Xylitol | 13H28-N10 | 2 |
| Fagron | Xylitol | 14G04-B04-298356 | 2 |
| Fagron | Xylitol | 14G04-B04-303524 | 2 |
| Fagron | Xylitol | 16c14-B02-320887 | 1 |
| Gehe | Xylitol | 1234567 | 1 |

- 256 837 spectra from 1666 *Apo-Ident* customers from a total of 52 122 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Xylitol* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Xylitol* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 440 | 0 | 157 886 |
| **Type B** | 0 | 210 | 0 | 212 730 |
| **Type C** | 0 | 49 | 0 | 256 837 |

The substance/substance group *Xylitol* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.6364 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 97.1429 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 87.7551 %) |


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In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21754 | 21754 | 0.00 | 192.23 |
| 21755 | 26692 | 6.82 | 187.51 |
| 22248 | 26692 | 6.33 | 187.32 |
| 22254 | 21754 | 5.52 | 189.40 |
| 22579 | 27256 | 6.94 | 190.00 |
| 25619 | 25619 | 0.00 | 187.92 |
| 26692 | 26692 | 0.00 | 186.73 |
| 27256 | 27256 | 0.00 | 190.17 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Xylometazoline hydrochloride** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20025-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Xylometazoline hydrochloride; Xylometazolini hydrochloridum

### Special notes

When selecting the *Xylometazoline hydrochloride* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Xylometazoline hydrochloride | 7 | 5 | 85 |

### Second-stage model

For differentiation of the substance/substance group *Xylometazoline hydrochloride* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Xylometazoline hydrochloride* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Ornithine aspartate | 64.89 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Xylometazoline hydrochloride* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Xylometazoline hydrochloride*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Xylometazoline hydrochloride | 13344901 | 21516 | 60 | 1501655 |
| Caelo | Xylometazoline hydrochloride | 13344901 | 21517 | 60 | 20131119 |
| Caelo | Xylometazoline hydrochloride | 16074211 | 23246 | 40 | 20160318 |
| Fagron | Xylometazoline hydrochloride | 13I18-B03-295481 | 21722 | 60 | AR-15-FG-007785-01 |
| Fagron | Xylometazoline hydrochloride | 14K19-B05-305006 | 21927 | 60 | 20141128 |
| Fagron | Xylometazoline hydrochloride | 14K19-B05-305006 | 21927SI | 60 | 20141128 |
| Fagron | Xylometazoline hydrochloride | 19B07-B02-373357 | 25735 | 40 | 20190408 |
| Fagron | Xylometazoline hydrochloride | 19B07-B02-373357 | 25735SI | 40 | 20190408 |
| Fagron | Xylometazoline hydrochloride | 21K10-B04-215749 | 26060 | 40 | 20211207 |
| Fagron | Xylometazoline hydrochloride | 21K10-B04-215749 | 26060SI | 40 | 20211207 |
| Fagron | Xylometazoline hydrochloride | 23L07-B05-227259 | 27047 | 40 | 20231213 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.


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- 540 spectra of 11 reference samples from the substance/substance group *Xylometazoline - hydrochloride*. These samples are listed above in the *calibration samples* section. The reference samples come from 7 different batches.

- 157 786 spectra from a total of 2950 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 620 spectra of 15 reference samples from the substance/substance group *Xylometazoline hydrochloride*.

- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Xylometazoline hydrochloride | 170739 | 23314 | 40 |
| Caelo | Xylometazoline hydrochloride | 173457 | 23832 | 40 |
| Caelo | Xylometazoline hydrochloride | 21000078002 | 25734 | 40 |
| Caelo | Xylometazoline hydrochloride | 22000302 | 26023 | 40 |
| Caelo | Xylometazoline hydrochloride | 24001236 | 27315 | 40 |
| Caelo | Xylometazoline hydrochloride | 13344901 | 21517SI† | 60 |
| Caelo | Xylometazoline hydrochloride | 16074211 | 23246SI† | 40 |
| Caelo | Xylometazoline hydrochloride | 170739 | 23314SI | 40 |
| Caelo | Xylometazoline hydrochloride | 170739 | 23320 | 40 |
| Caelo | Xylometazoline hydrochloride | 170739 | 23320SI | 40 |
| Caelo | Xylometazoline hydrochloride | 173457 | 23832SI | 40 |
| Caelo | Xylometazoline hydrochloride | 21000078002 | 25734SI | 40 |
| Caelo | Xylometazoline hydrochloride | 22000302 | 26023SI | 40 |
| Caelo | Xylometazoline hydrochloride | 24001236 | 27315SI | 40 |
| Fagron | Xylometazoline hydrochloride | 23L07-B05-227259 | 27047SI† | 40 |

- 212 320 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

provided by the customer regarding manufacturer and batch number.

- 269 spectra from 179 *Apo-Ident* customers from 87 batches from the substance/substance group *Xylometazoline hydrochloride*.
- Among them are spectra of independent samples from 85 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Xylometazoline hydrochloride | 22000302001 | 2 |
| | Xylometazoline hydrochloride | 22000302006 | 1 |
| | Xylometazoline hydrochloride | 22000302010 | 2 |
| | Xylometazoline hydrochloride | 22000302011 | 1 |
| | Xylometazoline hydrochloride | 22000302013 | 1 |
| | Xylometazoline hydrochloride | 2200302004 | 1 |
| | Xylometazoline hydrochloride | 2300249001 | 1 |
| | Xylometazoline hydrochloride | 23002949001 | 2 |
| | Xylometazoline hydrochloride | 23002949004 | 4 |
| Alliance | Xylometazoline hydrochloride | 22000302004 | 1 |
| Anzag | Xylometazoline hydrochloride | 12027911 | 1 |
| Caelo | Xylometazoline hydrochloride | 10118821 | 2 |
| Caelo | Xylometazoline hydrochloride | 12027906 | 2 |
| Caelo | Xylometazoline hydrochloride | 12287201 | 2 |
| Caelo | Xylometazoline hydrochloride | 12287203 | 8 |
| Caelo | Xylometazoline hydrochloride | 12287204 | 2 |
| Caelo | Xylometazoline hydrochloride | 12287210 | 7 |
| Caelo | Xylometazoline hydrochloride | 12287212 | 2 |
| Caelo | Xylometazoline hydrochloride | 12287213 | 1 |
| Caelo | Xylometazoline hydrochloride | 13171202 | 10 |
| Caelo | Xylometazoline hydrochloride | 13171203 | 2 |
| Caelo | Xylometazoline hydrochloride | 13171205 | 1 |
| Caelo | Xylometazoline hydrochloride | 13344901 | 1 |
| Caelo | Xylometazoline hydrochloride | 13344908 | 1 |
| Caelo | Xylometazoline hydrochloride | 15037906 | 1 |
| Caelo | Xylometazoline hydrochloride | 15037907 | 6 |
| Caelo | Xylometazoline hydrochloride | 15037910 | 2 |
| Caelo | Xylometazoline hydrochloride | 15037912 | 1 |
| Caelo | Xylometazoline hydrochloride | 15292803 | 3 |
| Caelo | Xylometazoline hydrochloride | 15292804 | 5 |
| Caelo | Xylometazoline hydrochloride | 15292811 | 1 |
| Caelo | Xylometazoline hydrochloride | 15292812 | 2 |
| Caelo | Xylometazoline hydrochloride | 153037907 | 1 |
| Caelo | Xylometazoline hydrochloride | 160740209 | 1 |
| Caelo | Xylometazoline hydrochloride | 16074201 | 4 |
| Caelo | Xylometazoline hydrochloride | 16074202 | 2 |
| Caelo | Xylometazoline hydrochloride | 16074205 | 6 |
| Caelo | Xylometazoline hydrochloride | 16074209 | 9 |
| Caelo | Xylometazoline hydrochloride | 160742095416 | 1 |
| Caelo | Xylometazoline hydrochloride | 16074216 | 3 |
| Caelo | Xylometazoline hydrochloride | 16074217 | 3 |
| Caelo | Xylometazoline hydrochloride | 16322082 | 1 |
| Caelo | Xylometazoline hydrochloride | 1703902 | 1 |
| Caelo | Xylometazoline hydrochloride | 1703909 | 1 |
| Caelo | Xylometazoline hydrochloride | 17073902 | 3 |
| Caelo | Xylometazoline hydrochloride | 17073905 | 8 |
| Caelo | Xylometazoline hydrochloride | 17073908 | 1 |
| Caelo | Xylometazoline hydrochloride | 17073909 | 4 |
| Caelo | Xylometazoline hydrochloride | 17344512 | 1 |
| Caelo | Xylometazoline hydrochloride | 17345703 | 12 |
| Caelo | Xylometazoline hydrochloride | 17345706 | 2 |
| Caelo | Xylometazoline hydrochloride | 17345707 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Xylometazoline hydrochloride | 17345708 | 4 |
| Caelo | Xylometazoline hydrochloride | 17345712 | 4 |
| Caelo | Xylometazoline hydrochloride | 181102181 | 1 |
| Caelo | Xylometazoline hydrochloride | 192751007 | 1 |
| Caelo | Xylometazoline hydrochloride | 192761005 | 15 |
| Caelo | Xylometazoline hydrochloride | 192761007 | 7 |
| Caelo | Xylometazoline hydrochloride | 2031502 | 1 |
| Caelo | Xylometazoline hydrochloride | 21000078001 | 1 |
| Caelo | Xylometazoline hydrochloride | 21000078002 | 2 |
| Caelo | Xylometazoline hydrochloride | 21000078003 | 2 |
| Caelo | Xylometazoline hydrochloride | 21000078004 | 3 |
| Caelo | Xylometazoline hydrochloride | 2100078001 | 1 |
| Caelo | Xylometazoline hydrochloride | 2100078004 | 1 |
| Caelo | Xylometazoline hydrochloride | 21003217001 | 3 |
| Caelo | Xylometazoline hydrochloride | 21003217002 | 4 |
| Caelo | Xylometazoline hydrochloride | 2200030004 | 1 |
| Caelo | Xylometazoline hydrochloride | 22000302003 | 1 |
| Caelo | Xylometazoline hydrochloride | 22000302004 | 3 |
| Caelo | Xylometazoline hydrochloride | 22000302008 | 1 |
| Caelo | Xylometazoline hydrochloride | 220003302003 | 1 |
| Caelo | Xylometazoline hydrochloride | 23051820 | 1 |
| Caelo | Xylometazoline hydrochloride | 24111202 | 1 |
| Caelo | Xylometazoline hydrochloride | 9276404 | 1 |
| Caelo | Xylometazoline hydrochloride | 9278404 | 1 |
| Caesar & Loretz GmbH... | Xylometazoline hydrochloride | 21000078002 | 1 |
| Caesar & Loretz GmbH... | Xylometazoline hydrochloride | 21000078004 | 1 |
| Caesar & Loretz GmbH... | Xylometazoline hydrochloride | 17345712 | 1 |
| Caesar & Loretz GmbH... | Xylometazoline hydrochloride | 192761005 | 1 |
| Caesar & Loretz GmbH... | Xylometazoline hydrochloride | 17345710 | 1 |
| Caesar & Loretz GmbH... | Xylometazoline hydrochloride | 192761005 | 1 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 17073902 | 1 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 17345706 | 1 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 17345707 | 1 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 17345708 | 3 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 17345710 | 3 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 17345712 | 1 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 192761007 | 4 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 21000078001 | 2 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 21000078004 | 7 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 21003217002 | 4 |
| Caesar & Loretz GmbH | Xylometazoline hydrochloride | 22000302001 | 1 |
| Celoa vdL | Xylometazoline hydrochloride | 13171202 | 1 |
| Fagron | Xylometazoline hydrochloride | 10416XMHC | 1 |
| Fagron | Xylometazoline hydrochloride | 12287210 | 1 |
| Fagron | Xylometazoline hydrochloride | 12G31-N01 | 1 |
| Fagron | Xylometazoline hydrochloride | 13171203 | 1 |
| Fagron | Xylometazoline hydrochloride | 1318-B03-295479 | 1 |
| Fagron | Xylometazoline hydrochloride | 13E06-N11 | 1 |
| Fagron | Xylometazoline hydrochloride | 13I09-N02 | 1 |
| Fagron | Xylometazoline hydrochloride | 15Jo6-B99-313751 | 1 |
| Fagron | Xylometazoline hydrochloride | 15K25-B07-318956 | 1 |
| Fagron | Xylometazoline hydrochloride | 21K10-B04-215749 | 1 |
| Gehe | Xylometazoline hydrochloride | 10118802 | 1 |
| Gehe | Xylometazoline hydrochloride | 16074201 | 1 |
| GEHE | Xylometazoline hydrochloride | 16074209 | 1 |
| Gehe | Xylometazoline hydrochloride | 17345703 | 1 |
| Geilenkirchen | Xylometazoline hydrochloride | 16074209 | 1 |
| Geilenkirchen | Xylometazoline hydrochloride | 17345708 | 1 |
| InfectoPharm/Gehe | Xylometazoline hydrochloride | 17345707 | 1 |
| Nachprüfung | Xylometazoline hydrochloride | 4317E-03337 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Xylometazoline hydrochloride | 12027902 | 1 |
| Noweda | Xylometazoline hydrochloride | 12287203 | 1 |
| Noweda | Xylometazoline hydrochloride | 17345708 | 1 |
| Phönix | Xylometazoline hydrochloride | 22000302003 | 1 |
| Sanacorp | Xylometazoline hydrochloride | 12027902 | 1 |
| Sanacorp | Xylometazoline hydrochloride | 15037906 | 1 |
| Sanacorp | Xylometazoline hydrochloride | 17345703 | 1 |
| sanacorp | Xylometazoline hydrochloride | 22000302003 | 1 |
| Siegrfried Pharma Ch… | Xylometazoline hydrochloride | 22000302008 | 1 |

- 256 617 spectra from 1666 *Apo-Ident* customers from a total of 52 067 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Xylometazoline hydrochloride* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Xylometazoline hydrochloride* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 540 | 0 | 157 786 |
| **Type B** | 0 | 620 | 0 | 212 320 |
| **Type C** | 0 | 268 | 1 | 256 617 |

The substance/substance group *Xylometazoline hydrochloride* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.8889 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.0323 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.6283 % (> 98.5130 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21516 | 21516 | 0.00 | 84.88 |
| 21517 | 21516 | 5.35 | 85.90 |
| 21722 | 21722 | 0.00 | 88.82 |
| 21927 | 21722 | 7.75 | 89.92 |
| 23246 | 21722 | 6.41 | 87.12 |
| 25735 | 21722 | 10.97 | 88.50 |
| 26060 | 21722 | 8.82 | 88.29 |
| 27047 | 21722 | 19.59 | 89.96 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Xylose** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20517-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Xylose; Xylosum

### Special notes

When selecting the *Xylose* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Xylose | 6 | 8 | 27 |

### Second-stage model

For differentiation of the substance/substance group *Xylose* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Xylose* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 71.36 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Xylose* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Xylose*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Xylose | 14218902 | 21606 | 60 | AR-14-FG-013086-01 |
| Caelo | Xylose | 17160902 | 23413 | 40 | 20170704 |
| Caelo | Xylose | 191802002 | 25437 | 40 | 20190819 |
| Caelo | Xylose | 21000133001 | 25732 | 50 | 20210219 |
| Fagron | Xylose | 13A31-B40-292395 | 21763 | 60 | 20140407 |
| Fagron | Xylose | 16A25-B05-328261 | 23524 | 40 | 20160215 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 290 spectra of 6 reference samples from the substance/substance group *Xylose*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 036 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for


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model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 370 spectra of 11 reference samples from the substance/substance group *Xylose*.
- Among them are spectra of independent samples from 8 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Xylose | 13133402 | 20868 | 40 |
| Caelo | Xylose | 162064 | 22758 | 40 |
| Caelo | Xylose | 171609 | 23656 | 40 |
| Caelo | Xylose | 173188 | 23849 | 40 |
| Caelo | Xylose | 190499 | 24527 | 40 |
| Caelo | Xylose | 22000045004 | 26310 | 30 |
| Caelo | Xylose | 23000619 | 27123 | 40 |
| Caelo | Xylose | 24001729005 | 27585 | 40 |
| Caelo | Xylose | 22000045004 | 26310SI | 20 |
| Caelo | Xylose | 23000619 | 27123SI | 20 |
| Caelo | Xylose | 24001729005 | 27585SI | 20 |

- 212 570 spectra from a total of 4279 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 45 spectra from 15 *Apo-Ident* customers from 29 batches from the substance/substance group *Xylose*.
- Among them are spectra of independent samples from 27 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Xylose | 23000619001 | 2 |
| Caelo | Xylose | 11031501 | 1 |
| Caelo | Xylose | 12120101 | 1 |
| Caelo | Xylose | 13133404 | 2 |
| Caelo | Xylose | 13133410 | 1 |
| Caelo | Xylose | 13133414 | 3 |
| Caelo | Xylose | 16002301 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Xylose | 16002302 | 2 |
| Caelo | Xylose | 16002309 | 3 |
| Caelo | Xylose | 16206405 | 1 |
| Caelo | Xylose | 17160902 | 2 |
| Caelo | Xylose | 17160905 | 2 |
| Caelo | Xylose | 17318803 | 4 |
| Caelo | Xylose | 17318809 | 1 |
| Caelo | Xylose | 19049902 | 1 |
| Caelo | Xylose | 19180205 | 2 |
| Caelo | Xylose | 21000133002 | 1 |
| Caelo | Xylose | 5031501 | 1 |
| Caesar & Loretz GmbH | Xylose | 20000783003 | 2 |
| Eigenherstellung | Xylose | 80414HJK01 | 1 |
| Euro OTC | Xylose | | 1 |
| Fagron | Xylose | 10121401 | 1 |
| Fagron | Xylose | 13133415 | 1 |
| Fagron | Xylose | 14E-B03_300658 | 1 |
| Fagron | Xylose | 28111405 | 1 |
| Fagron | Xylose | 80414PJK01 | 1 |
| Falcento | Xylose | 2013051801 | 1 |
| Phoenix 20.06.2014 | Xylose | 13A31-B04-292396 | 1 |
| Phoenix Goettin | Xylose | 13133422 | 1 |

- 256 841 spectra from 1666 *Apo-Ident* customers from a total of 52 124 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Xylose* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Xylose* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 290 | 0 | 158 036 |
| **Type B** | 0 | 370 | 0 | 212 570 |
| **Type C** | 0 | 45 | 0 | 256 841 |

The substance/substance group *Xylose* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.9310 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 98.3784 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 100.0000 % (> 86.6667 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to


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exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21606 | 21606 | 0.00 | 157.67 |
| 21763 | 21606 | 20.77 | 158.97 |
| 23413 | 21606 | 17.15 | 160.08 |
| 23524 | 21606 | 18.68 | 156.65 |
| 25437 | 21606 | 27.06 | 179.00 |
| 25732 | 21606 | 18.48 | 170.61 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Zinc acetate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20398-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Zinc acetate dihydrate; Zinci acetas dihydricus

### Special notes

When selecting the *Zinc acetate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Zinc acetate dihydrate | 6 | 3 | 29 |

### Second-stage model

For differentiation of the substance/substance group *Zinc acetate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Zinc acetate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Carbomers | 93.93 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Zinc acetate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Zinc acetate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Zinc acetate dihydrate | 15383301 | 22728 | 40 | 20151127 |
| Caelo | Zinc acetate dihydrate | 153833 | 23030 | 40 | 20151127* |
| Caelo | Zinc acetate dihydrate | 170204 | 23031 | 40 | 20170126* |
| Caelo | Zinc acetate dihydrate | 170204 | 23637 | 40 | 20172601* |
| Caelo | Zinc acetate dihydrate | 19000422 | 25208 | 40 | 20191230* |
| Caelo | Zinc acetate dihydrate | 21000302 | 25652 | 40 | 20210303* |
| Caelo | Zinc acetate dihydrate | 22002583 | 26479 | 30 | 20221109* |
| Caelo | Zinc acetate dihydrate | 22002583 | 26479SI | 20 | 20221109* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 290 spectra of 8 reference samples from the substance/substance group *Zinc acetate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 6 different batches.

- 158 036 spectra from a total of 2951 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 140 spectra of 4 reference samples from the substance/substance group *Zinc acetate dihydrate*.

- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Zinc acetate dihydrate | 17020404 | 23514 | 40 |
| Caelo | Zinc acetate dihydrate | 182046 | 24213 | 40 |
| Caelo | Zinc acetate dihydrate | 23001173 | 26895 | 40 |
| Caelo | Zinc acetate dihydrate | 23001173 | 26895SI | 20 |

- 212 800 spectra from a total of 4284 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 105 spectra from 87 *Apo-Ident* customers from 30 batches from the substance/substance group *Zinc acetate dihydrate*.

- Among them are spectra of independent samples from 29 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Zinc acetate dihydrate | 21000302011 | 1 |
| | Zinc acetate dihydrate | 22002583004 | 1 |
| | Zinc acetate dihydrate | 22002583006 | 2 |
| | Zinc acetate dihydrate | 22002583010 | 3 |
| Caelo | Zinc acetate dihydrate | 12134801 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Zinc acetate dihydrate | 12134803 | 1 |
| Caelo | Zinc acetate dihydrate | 12316401 | 2 |
| Caelo | Zinc acetate dihydrate | 12316403 | 2 |
| Caelo | Zinc acetate dihydrate | 12316404 | 2 |
| Caelo | Zinc acetate dihydrate | 12316405 | 1 |
| Caelo | Zinc acetate dihydrate | 14133201 | 1 |
| Caelo | Zinc acetate dihydrate | 15160801 | 1 |
| Caelo | Zinc acetate dihydrate | 15160804 | 1 |
| Caelo | Zinc acetate dihydrate | 15383304 | 1 |
| Caelo | Zinc acetate dihydrate | 15383306 | 4 |
| Caelo | Zinc acetate dihydrate | 15383308 | 2 |
| Caelo | Zinc acetate dihydrate | 17020403 | 3 |
| Caelo | Zinc acetate dihydrate | 17020404 | 3 |
| Caelo | Zinc acetate dihydrate | 17197601 | 10 |
| Caelo | Zinc acetate dihydrate | 17365807 | 1 |
| Caelo | Zinc acetate dihydrate | 18204604 | 7 |
| Caelo | Zinc acetate dihydrate | 18204610 | 1 |
| Caelo | Zinc acetate dihydrate | 19000422007 | 4 |
| Caelo | Zinc acetate dihydrate | 19000422011 | 1 |
| Caelo | Zinc acetate dihydrate | 20004443001 | 2 |
| Caelo | Zinc acetate dihydrate | 21000302002 | 2 |
| Caelo | Zinc acetate dihydrate | 21000302006 | 5 |
| Caelo | Zinc acetate dihydrate | 21000302011 | 1 |
| Caelo | Zinc acetate dihydrate | 22002583004 | 3 |
| Caesar & Loretz GmbH… | Zinc acetate dihydrate | 19000422011 | 1 |
| Caesar & Loretz GmbH… | Zinc acetate dihydrate | 18204610 | 1 |
| Caesar & Loretz GmbH… | Zinc acetate dihydrate | 22002583004 | 1 |
| Caesar & Loretz GmbH/Kehr | Zinc acetate dihydrate | 20004443001 | 1 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 18204604 | 2 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 19000422007 | 1 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 19000422011 | 4 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 21000302002 | 2 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 21000302006 | 4 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 21000302014 | 1 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 22002583004 | 2 |
| Caesar & Loretz GmbH | Zinc acetate dihydrate | 22002583006 | 1 |
| Caesar/Sanacorp | Zinc acetate dihydrate | 18204604 | 1 |
| Cealo | Zinc acetate dihydrate | 17197601 | 1 |
| Cealo | Zinc acetate dihydrate | 19000422007 | 1 |
| Euro OTC | Zinc acetate dihydrate | 15383301 | 1 |
| Gehe | Zinc acetate dihydrate | 17020404 | 1 |
| Noweda | Zinc acetate dihydrate | 18204604 | 1 |
| phönix | Zinc acetate dihydrate | 15383301 | 1 |
| Phönix | Zinc acetate dihydrate | 17197601 | 1 |
| PHÖNIX | Zinc acetate dihydrate | 19000422011 | 1 |
| Phönix | Zinc acetate dihydrate | 2200253006 | 1 |
| phönix | Zinc acetate dihydrate | 22002583004 | 1 |
| Sanacorp | Zinc acetate dihydrate | 19000422011 | 1 |
| sanacorp | Zinc acetate dihydrate | 22002583004 | 2 |

- 256 781 spectra from 1666 *Apo-Ident* customers from a total of 52 124 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.


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### Validation results

The validation runs checked whether the substance/substance group *Zinc acetate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Zinc acetate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 290 | 0 | 158 036 |
| **Type B** | 0 | 140 | 0 | 212 800 |
| **Type C** | 0 | 104 | 1 | 256 781 |

The substance/substance group *Zinc acetate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 97.9310 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 95.7143 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.0476 % (> 96.1905 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 22728 | 23030 | 4.38 | 157.58 |
| 23030 | 23030 | 0.00 | 157.45 |
| 23031 | 23031 | 0.00 | 154.82 |
| 23637 | 23637 | 0.00 | 154.93 |
| 25208 | 25208 | 0.00 | 157.01 |
| 25652 | 25652 | 0.00 | 152.60 |
| 26479 | 26479 | 0.00 | 153.10 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Zinc gluconate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20379-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Zinc gluconate; Zinci gluconas

### Special notes

When selecting the *Zinc gluconate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Zinc gluconate | 8 | 17 | 58 |

### Second-stage model

For differentiation of the substance/substance group *Zinc gluconate* the following second-stage model is used:

- Submodel 04

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Zinc gluconate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 30.98 | – |
| Cannabis flower, CBD-dominant type | 43.94 | – |
| Cannabis flower, THC/CBD-intermedia… | 50.19 | – |
| ⋮ | ⋮ | ⋮ |
| Tobramycin sulfate | >50 | 28.47 |
| Neomycin sulfate | >50 | 54.95 |
| Riboflavin sodium phosphate hydrate | >50 | 55.70 |
| Gentamicin sulfate | >50 | 76.19 |
| Magnesium citrate | >50 | 86.46 |
| Carbomers | >50 | 117.95 |
| Mg-Ca-K colamine phosphate | >50 | 118.13 |
| Sodium tetraborate | >50 | 306.42 |
| Finasteride | >50 | 1495.46 |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Zinc gluconate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Zinc gluconate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Zinc gluconate | 170165 | 23034 | 40 | 20170125* |
| Caelo | Zinc gluconate | 170951 | 23292 | 40 | 20170518* |
| Euro OTC | Zinc gluconate | 1407033-02 | 21709 | 60 | 20140902 |
| Euro OTC | Zinc gluconate | 1508007 | 21882 | 60 | 20150827* |
| Euro OTC | Zinc gluconate | 1603035 | 22513 | 40 | 20160427* |
| Euro OTC | Zinc gluconate | 1807019 | 24150 | 40 | 20180725* |
| Euro OTC | Zinc gluconate | 2007007 | 25318 | 40 | 20200826* |
| Euro OTC | Zinc gluconate | 2103006 | 25603 | 40 | 20210323* |


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### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 360 spectra of 8 reference samples from the substance/substance group *Zinc gluconate*. These samples are listed above in the *calibration samples* section. The reference samples come from 8 different batches.
- 157 966 spectra from a total of 2949 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 760 spectra of 21 reference samples from the substance/substance group *Zinc gluconate*.
- Among them are spectra of independent samples from 17 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Zinc gluconate | 161788 | 22619 | 40 |
| Caelo | Zinc gluconate | 20002679 | 25611 | 40 |
| Caelo | Zinc gluconate | 23001539 | 26893 | 40 |
| Euro OTC | Zinc gluconate | 1606018 | 22700 | 40 |
| Euro OTC | Zinc gluconate | 1701017 | 22994 | 40 |
| Euro OTC | Zinc gluconate | 1706009 | 23544 | 40 |
| Euro OTC | Zinc gluconate | 1711004 | 23730 | 40 |
| Euro OTC | Zinc gluconate | 1810014 | 24347 | 40 |
| Euro OTC | Zinc gluconate | 1902017 | 24635 | 40 |
| Euro OTC | Zinc gluconate | 1910010 | 24942 | 40 |
| Euro OTC | Zinc gluconate | 2007027 | 25316 | 40 |
| Euro OTC | Zinc gluconate | 2110001 | 25887 | 50 |
| Euro OTC | Zinc gluconate | 2208029 | 26338 | 40 |
| Euro OTC | Zinc gluconate | 2302019 | 26641 | 40 |
| Euro OTC | Zinc gluconate | 2312003 | 27074 | 40 |
| Euro OTC | Zinc gluconate | 2405017 | 27293 | 40 |
| Fagron | Zinc gluconate | 22L30-B04-225958 | 26919 | 40 |

*continued on the next page*

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.

*continued from previous page*

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Zinc gluconate | 23001539 | 26893SI | 20 |
| Euro OTC | Zinc gluconate | 2110001 | 25887SI | 10 |
| Euro OTC | Zinc gluconate | 2208029 | 26338SI | 20 |
| Euro OTC | Zinc gluconate | 2302019 | 26641SI | 20 |

- 212 180 spectra from a total of 4270 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 449 spectra from 23 *Apo-Ident* customers from 60 batches from the substance/substance group *Zinc gluconate*.

- Among them are spectra of independent samples from 58 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Zinc gluconate | 23003413005 | 1 |
| | Zinc gluconate | 2312003-01 | 1 |
| | Zinc gluconate | 23C22-B09 | 2 |
| | Zinc gluconate | 7500200698 | 1 |
| Alliance Healthcare | Zinc gluconate | 23003413003 | 1 |
| Caelo | Zinc gluconate | 16001601 | 1 |
| Caelo | Zinc gluconate | 16178801 | 1 |
| Caelo | Zinc gluconate | 17016502 | 3 |
| Caelo | Zinc gluconate | 17095103 | 1 |
| Caelo | Zinc gluconate | 18069506 | 1 |
| Caelo | Zinc gluconate | 18069511 | 1 |
| Caelo | Zinc gluconate | 19044602 | 3 |
| Caelo | Zinc gluconate | 19044603 | 2 |
| Caelo | Zinc gluconate | 19044607 | 1 |
| Caelo | Zinc gluconate | 191451002 | 1 |
| Caelo | Zinc gluconate | 19145103 | 1 |
| Caelo | Zinc gluconate | 20000647001 | 1 |
| Caelo | Zinc gluconate | 20000647002 | 1 |
| Caelo | Zinc gluconate | 20002679003 | 1 |
| Caelo | Zinc gluconate | 20002679004 | 1 |
| Caelo | Zinc gluconate | 20003987 | 1 |
| Caelo | Zinc gluconate | 20003987001 | 3 |
| Caelo | Zinc gluconate | 20003987002 | 1 |
| Caelo | Zinc gluconate | 20003987005 | 1 |
| Caelo | Zinc gluconate | 21003511001 | 3 |
| Caelo | Zinc gluconate | 21003511003 | 2 |
| Caelo | Zinc gluconate | 22003957003 | 3 |
| Caelo | Zinc gluconate | 23001539001 | 1 |
| Caelo | Zinc gluconate | 23003413002 | 1 |
| Caesar & Loretz GmbH | Zinc gluconate | 19044607 | 1 |
| Caesar & Loretz GmbH | Zinc gluconate | 20003987004 | 1 |
| Euro OTC | Zinc gluconate | 1312010-01 | 1 |
| Euro OTC | Zinc gluconate | 1405011-01 | 1 |
| Euro OTC | Zinc gluconate | 1508007-01 | 16 |

*continued on the next page*


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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Zinc gluconate | 1508007-02 | 40 |
| Euro OTC | Zinc gluconate | 1603035-01 | 40 |
| Euro OTC | Zinc gluconate | 1606018-01 | 34 |
| Euro OTC | Zinc gluconate | 1606018-02 | 36 |
| Euro OTC | Zinc gluconate | 1701017-01 | 31 |
| Euro OTC | Zinc gluconate | 1706009-01 | 66 |
| Euro OTC | Zinc gluconate | 170901201 | 9 |
| Euro OTC | Zinc gluconate | 1709012-0103707875 | 1 |
| Euro OTC | Zinc gluconate | 1711004-01 | 28 |
| Euro OTC | Zinc gluconate | 1807019 | 1 |
| Euro OTC | Zinc gluconate | 1807019-01 | 14 |
| Euro OTC | Zinc gluconate | 1810014-01 | 29 |
| Euro OTC | Zinc gluconate | 1902017-01 | 1 |
| Euro OTC | Zinc gluconate | 1902018-01 | 5 |
| Euro OTC | Zinc gluconate | 191001001 | 1 |
| Euro OTC | Zinc gluconate | 1910010-01 | 2 |
| Euro OTC | Zinc gluconate | 2007007 | 1 |
| Euro OTC | Zinc gluconate | 2007007-01 | 6 |
| Euro OTC | Zinc gluconate | 2007027-01 | 19 |
| Euro OTC | Zinc gluconate | 2103006-01 | 9 |
| Euro OTC | Zinc gluconate | 211000101 | 1 |
| Euro OTC | Zinc gluconate | 2110001-01 | 8 |
| Euro OTC | Zinc gluconate | 27061711 | 1 |
| Euro OTC | Zinc gluconate | ZGE-USP2004028 | 1 |
| Fagron | Zinc gluconate | 14J30-B06-300520 | 1 |
| Fagron | Zinc gluconate | 20G06-F01-372826 | 1 |
| Fagron | Zinc gluconate | 22A21-B08-216993 | 1 |

- 256 437 spectra from 1666 *Apo-Ident* customers from a total of 52 094 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Zinc gluconate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Zinc gluconate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 360 | 0 | 157 966 |
| **Type B** | 0 | 760 | 0 | 212 180 |
| **Type C** | 0 | 448 | 1 | 256 437 |

The substance/substance group *Zinc gluconate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 98.3333 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 99.2105 %) |
| **Type C** | 100.0000 % (> 99.9026 %) | 99.7773 % (> 99.1091 %) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21709 | 25603 | 5.78 | 63.21 |
| 21882 | 21882 | 0.00 | 63.63 |
| 22513 | 22513 | 0.00 | 72.35 |
| 23034 | 23034 | 0.00 | 61.04 |
| 23292 | 23292 | 0.00 | 61.59 |
| 24150 | 24150 | 0.00 | 69.75 |
| 25318 | 25318 | 0.00 | 61.52 |
| 25603 | 25603 | 0.00 | 65.88 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.


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# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Zinc orotate dihydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 20424-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Zinc orotate dihydrate; Zincum oroticum dihydricum

### Special notes

When selecting the *Zinc orotate dihydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Zinc orotate dihydrate | 3 | 1 | 5 |

### Second-stage model

For differentiation of the substance/substance group *Zinc orotate dihydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Zinc orotate dihydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cannabis flower, THC-dominant type | 68.08 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Zinc orotate dihydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Zinc orotate dihydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Zinc orotate dihydrate | 1203014-01 | 21038 | 40 | 1407431 |
| Euro OTC | Zinc orotate dihydrate | 13050005-02 | 21326 | 40 | 20130628* |
| Euro OTC | Zinc orotate dihydrate | 2312002 | 26993 | 40 | 20231214* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

- 120 spectra of 3 reference samples from the substance/substance group *Zinc orotate dihydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 158 206 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 80 spectra of 3 reference samples from the substance/substance group *Zinc orotate dihydrate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Euro OTC | Zinc orotate dihydrate | 2302021 | 26631 | 40 |
| Euro OTC | Zinc orotate dihydrate | 2302021 | 26631SI | 20 |
| Euro OTC | Zinc orotate dihydrate | 2312002 | 26993SI† | 20 |

- 212 860 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 5 spectra from 3 *Apo-Ident* customers from 5 batches from the substance/substance group *Zinc orotate dihydrate*.
- Among them are spectra of independent samples from 5 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Zinc orotate dihydrate | 2302021-01 | 1 |
| | Zinc orotate dihydrate | 2302021-02 | 1 |
| | Zinc orotate dihydrate | 2312001-01 | 1 |
| | Zinc orotate dihydrate | 2312002-01 | 1 |
| Ichtyol/Phönix | Zinc orotate dihydrate | 12B02-N02 | 1 |

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 256 881 spectra from 1666 *Apo-Ident* customers from a total of 52 149 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Zinc orotate dihydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Zinc orotate dihydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 120 | 0 | 158 206 |
| **Type B** | 0 | 80 | 0 | 212 860 |
| **Type C** | 0 | 4 | 1 | 256 881 |

The substance/substance group *Zinc orotate dihydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.0000 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 92.5000 %) |
| **Type C** | 100.0000 % (> 99.9028 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 21038 | 21038 | 0.00 | 234.68 |
| 21326 | 21326 | 0.00 | 242.04 |
| 26993 | 26993 | 0.00 | 152.61 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Zinc stearate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 24018-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Zinc stearate; Zinci stearas

### Special notes

When selecting the *Zinc stearate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Zinc stearate | 3 | 1 | 1 |

### Second-stage model

For differentiation of the substance/substance group *Zinc stearate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Zinc stearate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Cetyl palmitate | 33.74 | – |
| Beeswax, white | 35.69 | – |
| Beeswax, yellow | 38.30 | – |
| Paraffin, hard | 38.66 | – |
| Magnesium stearate | 49.88 | – |
| Hard fat | 51.07 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Zinc stearate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Zinc stearate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Caelo | Zinc stearate | 180628 | 24018 | 40 | 20180322* |
| Caelo | Zinc stearate | 22000651 | 26123 | 40 | 20220426* |
| Caelo | Zinc stearate | 22000651 | 26123SI | 20 | 20220426* |
| Caelo | Zinc stearate | 23003244004 | 27574 | 40 | 20240110 |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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**Type A** All calibration spectra.

- 140 spectra of 4 reference samples from the substance/substance group *Zinc stearate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

- 158 186 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 60 spectra of 2 reference samples from the substance/substance group *Zinc stearate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Zinc stearate | 182279 | 24500 | 40 |
| Caelo | Zinc stearate | 23003244004 | 27574SI† | 20 |

- 212 880 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Zinc stearate*.

- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Zinc stearate | 22002130001 | 1 |

†These spectra were recorded from material of the same package as the corresponding calibration spectra (*Type A*). Hence, these spectra are not independent and are not of *Type B*.

- 256 885 spectra from 1666 *Apo-Ident* customers from a total of 52 152 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Zinc stearate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Zinc stearate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type (*A*/*B*/*C*).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 140 | 0 | 158 186 |
| **Type B** | 0 | 60 | 0 | 212 880 |
| **Type C** | 0 | 1 | 0 | 256 885 |

The substance/substance group *Zinc stearate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 95.7143 %) |
| **Type B** | 100.0000 % (> 99.9918 %) | 100.0000 % (> 90.0000 %) |
| **Type C** | 100.0000 % (> 99.9038 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:

| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 24018 | 24018 | 0.00 | 46.49 |
| 26123 | 26123 | 0.00 | 44.11 |
| 27574 | 24018 | 32.49 | 49.88 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances,


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thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# VALIDATION REPORT

## IdentModule 2.10-2025-04

| | |
|---|---|
| Validated substance/substance group | **Zinc sulfate heptahydrate** |
| Substance class | APIs & excipients, solid |
| Report date | 30/09/2025 |
| Report number | 10006391-2025-09-30 |
| Executing company | HiperScan GmbH<br>Weißeritzstraße 3<br>01067 Dresden<br>Germany |

### Relevant substance names

Zinc sulfate heptahydrate; Zinc sulphate heptahydrate; Zinci sulfas heptahydricus

### Special notes

When selecting the *Zinc sulfate heptahydrate* substance/substance group, the following information is displayed to the user:

*no information*

### Applicable documents

| | |
|---|---|
| 978-3-7692-8026-5 | *European Pharmacopoeia 11th Edition, Basic Version 2022* [3] |
| Komm2.2.40 | *Erfüllung von* Ph. Eur. 2.2.40 *durch* Apo-Ident [4] |
| AA010 | *Creation of IdentModule Updates* |

### Validation method

Validation is performed after every change to the chemometric model (also "database") in three steps:

1. The chemometric model is calculated from the calibration spectra using a *PCA algorithm*. The calibration spectra originate from the calibration samples of all substances in this class.
2. In the *chemometric model* generated, the distances between all separable substances are checked for compliance with the specified safety distances.
3. All spectra are presented to the generated chemometric model for evaluation. In three runs, the reference spectra (*Type A*), spectra from independent samples (*Type B*), and spectra from the field (*Type C*) are presented successively. Here, no single *false positive* result is permitted.

Finally, a report is generated from the validation run results and is archived together with the parameters of the model generation in audit-compliant manner.

### Number of independent samples (batches) in calibration and validation

A sample is considered independent if no sample from the same batch has been included in the calibration of the chemometric model.

| Substance/substance group | Type A | Type B | Type C |
|---|---|---|---|
| Zinc sulfate heptahydrate | 3 | 2 | 14 |

### Second-stage model

For differentiation of the substance/substance group *Zinc sulfate heptahydrate* the following second-stage model is used:

*no second-stage model*

### Nearest chemometric neighbors (distance to the nearest foreign sample)

The following table lists the nearest chemometric neighbors of the substance/substance group *Zinc sulfate heptahydrate* in the substance class *APIs & excipients, solid*. For *Mahalanobis distances* M that do not meet the criterion $M \geq 9$, the differentiation is questioned. However, it is often possible that substances that the main model could not reliably separate from each other can be differentiated in a second-stage model.
A necessary condition for the output of a clear result is therefore: All substances in the second-stage model must have a distance $M \geq 9$ from each other. All remaining substances must reach $M \geq 9$ in the main model.
Where this is not achieved, an ambiguous result is shown as result which includes at least the two substances that are too close to each other as possible identities (substance group). Alternatively these substances can be excluded from the list of substances identifiable with Apo-Ident.

| Substance | Distance in main model | Distance in second-stage model |
|---|---|---|
| Magnesium sulfate heptahydrate | 24.82 | – |
| Sodium cromoglicate | 60.97 | – |

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Zinc sulfate heptahydrate* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

### Calibration samples

Only spectra which have been recorded under the control of *HiperScan GmbH* from traceable samples are used for the generation of the chemometric models. The following samples have been obtained from the substance/substance group *Zinc sulfate heptahydrate*:

| Supplier | Substance | Batch | Sample ID | Spectra | Certificate |
|---|---|---|---|---|---|
| Euro OTC | Zinc sulfate heptahydrate | 2206010 | 26554 | 40 | 20220624* |
| Euro OTC | Zinc sulfate heptahydrate | 2206010 | 26554SI | 20 | 20220624* |
| Euro OTC | Zinc sulfate heptahydrate | 2210021 | 26555 | 40 | 20221122* |
| Euro OTC | Zinc sulfate heptahydrate | 2210021 | 26555SI | 20 | 20221122* |
| Euro OTC | Zinc sulfate heptahydrate | 2410005 | 27619 | 40 | 20250407* |
| Euro OTC | Zinc sulfate heptahydrate | 2410005 | 27619SI | 20 | 20250407* |

### Validation samples

A total of 628 152 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

**Type A** All calibration spectra.

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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- 180 spectra of 6 reference samples from the substance/substance group *Zinc sulfate heptahydrate*. These samples are listed above in the *calibration samples* section. The reference samples come from 3 different batches.

- 158 146 spectra from a total of 2954 batches from further 496 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix A*. The samples in *Appendix A* were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

**Type B** Spectra from independent samples not included in the database structure. Measurement is carried out under the control of *HiperScan GmbH*.

Samples from batches of which no spectra have been included in the database structure are considered as independent samples. The number of batches from which independent samples supplied *Type B* spectra for validation is shown below, representing the number of independent *Type B* samples. Samples, of which some of the spectra have been included in the database structure and other spectra in the validation, are marked with a †. The following applies to the remaining unmarked samples: In the same batch, there was at least one additional sample (other sales container, other sample ID) from which reference spectra (*Type A*) were included in the database structure.

- 90 spectra of 2 reference samples from the substance/substance group *Zinc sulfate heptahydrate*.

- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

| Supplier | Substance | Batch | Sample ID | Spectra |
|---|---|---|---|---|
| Caelo | Zinc sulfate heptahydrate | 23002587 | 27077 | 40 |
| Euro OTC | Zinc sulfate heptahydrate | 2107023 | 25788 | 50 |

- 212 850 spectra from a total of 4285 batches from further 872 substances. These spectra were recorded under the control of *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix B*.

**Type C** Spectra of independent samples not included in the database structure. *Apo-Ident* customers carry out the measurements. *HiperScan GmbH* generally does not verify the information provided by the customer regarding manufacturer and batch number.

- 15 spectra from 11 *Apo-Ident* customers from 14 batches from the substance/substance group *Zinc sulfate heptahydrate*.

- Among them are spectra of independent samples from 14 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Zinc sulfate heptahydrate | 23002587001 | 1 |
| Caelo | Zinc sulfate heptahydrate | 11095601 | 1 |
| Caelo | Zinc sulfate heptahydrate | 11095621 | 1 |
| Caelo | Zinc sulfate heptahydrate | 12257802 | 1 |
| Caelo | Zinc sulfate heptahydrate | 12257809 | 2 |
| Caelo | Zinc sulfate heptahydrate | 12257816 | 1 |
| Caelo | Zinc sulfate heptahydrate | 12257818 | 1 |

*continued on the next page*

*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Zinc sulfate heptahydrate | 4012Q-02798 | 1 |
| Caelo | Zinc sulfate heptahydrate | 81554199 | 1 |
| Euro OTC | Zinc sulfate heptahydrate | 1105002-01 | 1 |
| Euro OTC | Zinc sulfate heptahydrate | 1201031-01 | 1 |
| Euro OTC | Zinc sulfate heptahydrate | 1201031-02 | 1 |
| Euro OTC | Zinc sulfate heptahydrate | 1201031-2 | 1 |
| Euro OTC | Zinc sulfate heptahydrate | 1309011_0 | 1 |

- 256 871 spectra from 1666 *Apo-Ident* customers from a total of 52 139 batches from a further 724 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this chemometric model, the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in *Appendix C*.

### Validation results

The validation runs checked whether the substance/substance group *Zinc sulfate heptahydrate* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Zinc sulfate heptahydrate* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive*/*negative*) and the validation spectrum type ($A/B/C$).

| | False positive | True positive | False negative | True negative |
|---|---|---|---|---|
| **Type A** | 0 | 180 | 0 | 158 146 |
| **Type B** | 0 | 90 | 0 | 212 850 |
| **Type C** | 0 | 15 | 0 | 256 871 |

The substance/substance group *Zinc sulfate heptahydrate* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

| | Specificity | Recognition rate |
|---|---|---|
| **Type A** | 100.0000 % (> 99.9915 %) | 100.0000 % (> 96.6667 %) |
| **Type B** | 100.0000 % (> 99.9917 %) | 100.0000 % (> 93.3333 %) |
| **Type C** | 100.0000 % (> 99.9027 %) | n/a (n/a) |

In order to ensure that each substance is entered with the same weight irrespective of the number of spectra available, each spectrum is weighted with the reciprocal value of its number. (If several new spectra of a substance with a very distinctive spectrum are added, the values for *specificity* and *recognition rate* are safer, but are by no means idealised.)

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.
Where the number of spectra does not exceed 20, no *recognition rate* is provided.

### Identity according to identity test using NIR spectroscopy

For each substance, a certificate of the correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the following table the *Mahalanobis distance* to the reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance:


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| Sample ID | Reference sample ID | Distance to reference sample | Distance to next foreign sample |
|---|---|---|---|
| 26554 | 26554 | 0.00 | 74.79 |
| 26555 | 26555 | 0.00 | 43.83 |
| 27619 | 27619 | 0.00 | 91.82 |

The identity of a sample will be confirmed by NIR if the distance to the next foreign sample is at least 50 % greater than the distance to a reference sample whose identity has been established by laboratory testing. This criterion is always considered in the chemometric model, which contains all substances of the substance class, even if a second-stage dissolves a subgroup of similar substances, thereby increasing the distances between them. The samples confirmed by NIR support the statistical variance of the original reference substance, but cannot add new aspects or forms of the substance.

# *Appendix A:* Additional calibration samples (*Type A*)

Substance spectra also enter the generation of the chemometric model which cannot be identified with this model. This serves the purpose that substances which the model is not supposed to recognise are safely rejected. The spectra of these samples are entered into the validation as *Type A*. They were recorded under the control of *HiperScan GmbH*.

The samples originate from 378 batches. From these, 15 938 spectra were recorded. The calibration spectra of substances which can be identified with the model are listed respectively in the section *calibration samples* for the individual substances and do not appear again elsewhere in this list.

0 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Aloes, cape, powdered | 12183008 | 40 | 20120802 |
| Caelo | Aluminium potassium sulfate dodecahydrate | 12144605 | 40 | from supplier |
| Caelo | Amphetamine sulfate | 13344603 | 40 | 0814J-03361 |
| Caelo | Amphetamine sulfate | 16153902 | 40 | 2017A-03361 |
| Caelo | Amphetamine sulfate | 13344603 | 60 | 0814J-03361 |
| Fagron | Amphetamine sulfate | 13G08-N11 | 40 | 0814K-03361 |
| Fagron | Amphetamine sulfate | 15L01-B05-315291 | 60 | 1316Q-03361 |
| Fagron | Amphetamine sulfate | 13G08-N11 | 60 | 0814K-03361 |
| Fagron | Amphetamine sulfate | 15L01-B05-315291 | 60 | 1316Q-03361 |
| Th. Geyer | Amphetamine sulfate | 67002 | 40 | 0814I-03361 |
| Th. Geyer | Amphetamine sulfate | 067043 | 40 | 2017C-03361 |
| Th. Geyer | Amphetamine sulfate | 67002 | 60 | 0814I-03361 |
| Flora Apot… | Amygdalin | 13121802 | 40 | 1405619 |
| Auropure L… | Amygdalin, bitter almond extract 98% | PA02099-17102131 | 40 | from supplier |
| Safic-Alcan | Amygdalin, bitter almond extract 98% | BAE150902 | 60 | from supplier |
| Safic-Alcan | Amygdalin, bitter almond extract 98% | BAE150902 | 60 | from supplier |
| Caelo | Aniseed | 13333903 | 40 | 20131018 |
| Caelo | Aniseed, pounded | 13357101 | 40 | 20131202 |
| Klenk | Asparagus root, cut | 6151B110304 | 40 | 1403480 |

**B**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Barbital sodium | 12F27-N02 | 40 | 0814I-07775 |
| Fagron | Barbital sodium | 14K14-B04-303353 | 60 | 1516I-07775 |
| Fagron | Barbital sodium | 12F27-N02 | 60 | 0814I-07775 |
| Fagron | Barbital sodium | 14K14-B04-303353 | 60 | 1516I-07775 |
| Euro OTC | Benfotiamine | 2207006 | 40 | 20220729* |
| Euro OTC | Benfotiamine | 2207006 | 20 | 20220729* |
| Caelo | Benzalkonium chloride | 16171603 | 40 | 20160715 |
| Merck KGaA | Benzoyl peroxide, hydrous | S7012241509 | 60 | 20130317 |
| Sigma-Aldrich | Betamethasone acetate | LRAA8500 | 40 | CRS |
| Sigma-Aldrich | Betamethasone sodium phosphate | MKBS9676V | 40 | CRS |
| Caelo | Bilberry fruit, dried | 10265602 | 40 | 20101206 |
| Klenk | Birch bark, cut | 0561A121121 | 40 | 20121127 |
| Caelo | Black cumin seed | 161157 | 60 | 20160708 |
| Caelo | Blackcurrants | 12272801 | 40 | 1403468 |
| Caelo | Buprenorphine hydrochloride | 12172908 | 40 | 0814I-07774 |
| Caelo | Buprenorphine hydrochloride | 16143001 | 40 | 2017A-07774 |

## C

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Euro OTC | Calcium carbonate | 1611008-01 | 40 | 20161201 |
| Flora Apot… | Calcium colamine phosphate | 14384 | 40 | from supplier |
| Pharmorgana | Calcium colamine phosphate | 1000200822 | 40 | from supplier |
| Pharmorgana | Calcium colamine phosphate | 1000210678 | 50 | from supplier |
| Pharmorgana | Calcium colamine phosphate | 1000230793 | 40 | from supplier |
| Th. Geyer | Calcium colamine phosphate | 33299 | 60 | from supplier |
| Th. Geyer | Calcium colamine phosphate | 66606 | 40 | from supplier |
| Pharmorgana | Calcium L-aspartate trihydrate | 1000230427 | 40 | from supplier |
| Euro OTC | Calcium orotate dihydrate | 1401006-01 | 40 | 1412540 |
| Euro OTC | Calcium orotate dihydrate | 1603003 | 40 | 20160329* |
| Euro OTC | Calcium orotate dihydrate | 1603003 | 40 | 20180615* |
| Fagron | Calcium orotate dihydrate | 12L04-N07 | 40 | from supplier |
| Fagron | Calcium orotate dihydrate | 13J23-N05 | 40 | from supplier |
| Flora Apot… | Calcium orotate dihydrate | ORC00119 | 40 | from supplier |
| bubatzbros.de | Cannabis flower, CBD-dominant type | BBCD11-092023 | 30 | 20231010 |
| Cansativa | Cannabis flower, CBD-dominant type | C038 | 30 | 20231010 |
| Cansativa | Cannabis flower, CBD-dominant type | 22H08FR22I28 | 30 | 20231010 |
| Cansativa | Cannabis flower, CBD-dominant type | P22058FT | 30 | 20231010 |
| Cansativa | Cannabis flower, CBD-dominant type | C038 | 29 | 20231010 |
| Cansativa | Cannabis flower, CBD-dominant type | P22058FT | 30 | 20231010 |
| Cansativa | Cannabis flower, CBD-dominant type | C038 | 31 | 20231010 |
| Cansativa | Cannabis flower, CBD-dominant type | P22058FT | 30 | 20231010 |
| CBD NOL | Cannabis flower, CBD-dominant type | CNRK8-092023 | 30 | 20231010 |
| CBD NOL | Cannabis flower, CBD-dominant type | CNPK6-092023 | 30 | 20231010 |
| CBDblueten.de | Cannabis flower, CBD-dominant type | CÄ2225631yCGPP | 30 | 20250319 |
| CBDblueten.de | Cannabis flower, CBD-dominant type | LJ2220703yCGPP3 | 30 | 20250319 |
| CBDblueten.de | Cannabis flower, CBD-dominant type | CÄ2225631yCGPP | 30 | 20250319 |
| Hanfgarten.at | Cannabis flower, CBD-dominant type | HCB000019 | 37 | 20231010 |
| Hanfgarten.at | Cannabis flower, CBD-dominant type | HCB000021 | 30 | 20231010 |
| Hanfgarten.at | Cannabis flower, CBD-dominant type | HCB000015 | 40 | 20231010 |
| justbob | Cannabis flower, CBD-dominant type | ES239230223 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | 22K28FB23C15 | 30 | 20231010 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Cansativa | Cannabis flower, THC/CBD-intermediate type | S87B2056CA-2R3-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | P22050FT-A | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | 22GS12WLC010105 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | D043 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | S87B2056CA-2R3-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | P22050FT-A | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | 22GS12WLC010105 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | D043 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | HSK2145CA-3R2-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | P22050FT-A | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | 22GS12WLC010105 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | D043 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | CMMA24FSBL061488 | 30 | 20250319 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | E215 | 30 | 20250319 |
| Cansativa | Cannabis flower, THC-dominant type | 06051825121-2-P2 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | ICC230503 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | WES230301 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | GG4230303Y | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | ZRP230101 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 28202 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 02209916122-1-P3 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | C086 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22I05EY22K30 | 30 | 20231010 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Cansativa | Cannabis flower, THC-dominant type | 91K2137CA-1R2-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | LSK2216001-1R2-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS02SI010202 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | C091 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | D016 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | D013 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | D032 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 030122LS-T22/10 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | P22057FT | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | P22055FT | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 02209951121-2-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 02209910122-3-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | CMNG23FSRE032877 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 02209912122-1-P3 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS12MG010102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 2203GG010402 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 21GS11HB040104 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 2203PD010105 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22TC08HB010103 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 21GS06ISS040102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 21GS06ISS040102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 21GS06MG030106 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22TC05SI010102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 2GS02BB010105 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS02GWO010103 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22TC07PK010103 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | C060 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 02209920122-1-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS12WLC010105 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | TRP230603 | 30 | 20231010 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Cansativa | Cannabis flower, THC-dominant type | GG4230506 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 2306605 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | VA0163-2301 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | ICC230503 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | WES230301 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | ZRP230101 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 28202 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | LSK2216001-1R2-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | D013 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | D032 | 31 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | P22057FT | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS12WLC010105 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | TRP230603 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 2306605 | 20 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | LSK2216001-1R2-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | D032 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | P22057FT | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 2306605 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 06051825121-2-P2 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS12MG010102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | D013 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS12WLC010105 | 40 | 20231010 |
| Caelo | Carnauba wax | 170903 | 40 | 20170512* |
| Caelo | Carnauba wax | 183330 | 40 | 20190114* |
| Caelo | Castoreum, powdered | 12137409 | 40 | 1402590 |
| Klenk | Celery root, cut | 6091A110110 | 40 | 1410177 |
| Caelo | Chicory root | 11374504 | 40 | 20120112 |
| Euro OTC | Cholecalciferol dry concentrate | 1508032 | 60 | 20150901* |
| Euro OTC | Cholecalciferol dry concentrate | 1608002 | 40 | 20160824* |
| Euro OTC | Cholecalciferol dry concentrate | 2001007 | 40 | 20200316* |
| Pharmorgana | Chromium(III) orotate hexahydrate | 760020 | 40 | from supplier |
| Klenk | Clove, powdered (spice) | 1264B141007 | 60 | AR-15-FG-014858-01 |
| Caelo | Cocaine hydrochloride | 13259305 | 40 | 0814J-01278 |
| Caelo | Cocaine hydrochloride | 15224802 | 60 | 1316Q-01278 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Cocaine hydrochloride | 15224802 | 60 | 1316Q-01278 |
| Caelo | Cocaine hydrochloride | 17003902 | 40 | 1917S-01278 |
| Caelo | Cocaine hydrochloride | 13259305 | 60 | 0814J-01278 |
| Caelo | Cocaine hydrochloride | 15224802 | 60 | 1316Q-01278 |
| Caelo | Cocaine hydrochloride | 15224802 | 60 | 1316Q-01278 |
| Fagron | Cocaine hydrochloride | 13I17-N02 | 40 | 0814I-01278 |
| Fagron | Cocaine hydrochloride | 16B11-B05-323386 | 40 | 1917Q-1278 |
| Fagron | Cocaine hydrochloride | 13I17-N02 | 60 | 0814I-01278 |
| Th. Geyer | Cocaine hydrochloride | 60145 | 40 | 0814K-01278 |
| Th. Geyer | Cocaine hydrochloride | 60145 | 60 | 0814K-01278 |
| Caelo | Codeine phosphate hemihydrate | 13071504 | 40 | 0814J-01279 |
| Caelo | Codeine phosphate hemihydrate | 15350703 | 60 | 1316R-01279 |
| Caelo | Codeine phosphate hemihydrate | 13071504 | 60 | 0814J-01279 |
| Caelo | Codeine phosphate hemihydrate | 15350703 | 60 | 1316R-01279 |
| Fagron | Codeine phosphate hemihydrate | 13C11-N10 | 40 | 0814I-01279 |
| Fagron | Codeine phosphate hemihydrate | 15F09-B02-310520 | 60 | 1316Q-01279 |
| Fagron | Codeine phosphate hemihydrate | 16E17-B05-324109 | 40 | 2017A-01279 |
| Fagron | Codeine phosphate hemihydrate | 13C11-N10 | 60 | 0814I-01279 |
| Fagron | Codeine phosphate hemihydrate | 15F09-B02-310520 | 60 | 1316Q-01279 |
| Th. Geyer | Codeine phosphate hemihydrate | 67038 | 40 | 0814K-01279 |
| Th. Geyer | Codeine phosphate hemihydrate | 067054 | 40 | 2017D-01279 |
| Th. Geyer | Codeine phosphate hemihydrate | 67038 | 60 | 0814K-01279 |
| Caelo | Colophony | 12301410 | 60 | AR-15-FG-016314-01 |
| Caelo | Colophony | 173014 | 40 | 20180102* |
| Caelo | Colophony | 191664 | 40 | 20190701* |
| Klenk | Comfrey root | 6244B130624 | 40 | 20130625 |
| Klenk | Cumin, powdered | 2824B121001 | 40 | 20121009 |
| Fagron | Curcumin | CP2404071 | 40 | 20240410* |
| Fagron | Curcumin | CP2403046 | 40 | 20240320* |

## D

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Euro OTC | Deoxycholic acid | 1305051-01 | 40 | from supplier |
| New Zealan... | Deoxycholic acid | 0416720 | 40 | from supplier |
| Sigma-Aldrich | Dexamethasone sodium phosphate | LRAC1690 | 40 | CRS |
| Fagron | Dexamphetamine sulfate | 13I23-N01 | 40 | 0814M-03582 |
| Fagron | Dexamphetamine sulfate | 15H06-B04-313862 | 60 | 1316Q-03582 |
| Fagron | Dexamphetamine sulfate | 16D20-B01-321049 | 40 | 2017B-03582 |
| Fagron | Dexamphetamine sulfate | 13I23-N01 | 60 | 0814M-03582 |
| Sigma-Aldrich | Diclofenac potassium | D1039990 | 40 | CRS |
| Caelo | Dihydrocodeine hydrogen tartrate | 13267601 | 40 | 0914A-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 12142506 | 40 | 0914B-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15295901 | 60 | 1316Q-03065 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Dihydrocodeine hydrogen tartrate | 13267601 | 60 | 0914A-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 12142506 | 60 | 0914B-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15295901 | 60 | 1316Q-03065 |
| Fagron | Dihydrocodeine hydrogen tartrate | 13H19-N03 | 40 | 0914C-03065 |
| Fagron | Dihydrocodeine hydrogen tartrate | 14K26-B04-306298 | 60 | 1516I-03065 |
| Fagron | Dihydrocodeine hydrogen tartrate | 15F18-B07-323388 | 40 | 2017A-03065 |
| Fagron | Dihydrocodeine hydrogen tartrate | 13H19-N03 | 60 | 0914C-03065 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 67035 | 40 | 0914D-03065 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 067052 | 40 | 2017D-03065 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 67035 | 60 | 0914D-03065 |
| Caelo | Dill herb, cut | 11295103 | 40 | 20111103 |
| Safic-Alcan | Dimercaptosuccinic acid | 20170210 | 40 | from supplier |
| Fagron | Diosmin | DSM240602 | 40 | 20241031* |
| Fagron | Diosmin | DSM240401 | 40 | 20241031* |

**E**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Econazole nitrate | 12H08-N02 | 40 | 1312442 |
| Fagron | Econazole nitrate | 11F09-N16 | 40 | 20110606 |
| Fagron | Econazole nitrate | 12I06-B40-306925 | 40 | AR-16-FG-011359-01 |
| Fagron | Econazole nitrate | 14G22-B07-327805 | 40 | 20140804 |
| Yino Pharma | Enoxaparin sodium | YN010232209001 | 40 | 20230524* |
| Yino Pharma | Enoxaparin sodium | YN010232210002 | 40 | 20230524* |
| Yino Pharma | Enoxaparin sodium | YN010232209001 | 20 | 20230524* |
| Yino Pharma | Enoxaparin sodium | YN010232210002 | 20 | 20230524* |
| Fagron | Ergotamine tartrate | 13H02-N01 | 100 | 20120412 |
| EDQM | Erythromycin lactobionate | 1.0 | 40 | CRS |
| Caelo | Eucalyptus leaf | 11307706 | 40 | 20111111 |

**F**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Fentanyl citrate | 13G30-N06 | 40 | 0814M-07678 |
| Fagron | Fentanyl citrate | 15F18-B01-525098 | 60 | 1316R-03686 |
| Fagron | Fentanyl citrate | 15F18-B01-525166 | 60 | 1316Q-03686 |
| Fagron | Fentanyl citrate | 13G30-N06 | 60 | 0814M-07678 |
| Fagron | Fentanyl citrate | 15F18-B01-525098 | 60 | 1316R-03686 |
| Fagron | Fentanyl citrate | 15F18-B01-525166 | 60 | 1316Q-03686 |
| EDQM | Fenticonazole nitrate | 1.3 | 40 | CRS |
| Euro OTC | Fexofenadine hydrochloride | 2310018 | 30 | 20240222* |
| Flora Apot… | Frankincense | JR-RX20230716CG | 40 | not required |

**G**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Ginger | 12180601 | 40 | 20120730 |
| Caelo | Ginger | 11325715 | 40 | 20111205 |
| Klenk | Ginger, peeled, powdered | 6954B160429 | 60 | 1704440 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Glucosamine sulfate potassium chloride | TSM-K-2404002 | 40 | 20240928* |
| Fagron | Glucosamine sulfate potassium chloride | TSM-K-2404001 | 40 | 20240928* |
| Flora Apot… | Glycyrrhizic acid | 10588 | 40 | from supplier |
| Caelo | Green bean pod | 11030601 | 50 | 20110221 |
| Fagron | Green tea dry extract 50% | 24I05-B029 | 40 | 20241009* |
| Fagron | Green tea dry extract 50% | 24I25-B006 | 40 | 20241028* |
| Euro OTC | Griffonia seed extract | 1205027 | 40 | from supplier |
| Euro OTC | Griffonia seed extract | 1705007 | 40 | 20170601* |
| Euro OTC | Griffonia seed extract | 1905017 | 40 | 20190709* |
| Pharmorgana | Griffonia seed extract | 1000200297 | 40 | from supplier |

**H**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Hay flowers | 12317104 | 40 | 20121122 |
| Klenk | Hay flowers | 1400A130304 | 40 | 20130403 |
| Fagron | Hydrocortisone butyrate | 15J12-B03-322394 | 40 | 20151028 |
| Caelo | Hydromorphone hydrochloride | 13267702 | 40 | 0914A-01334 |
| Caelo | Hydromorphone hydrochloride | 15393602 | 60 | 1516J-01334 |
| Caelo | Hydromorphone hydrochloride | 13267702 | 60 | 0914A-01334 |
| Caelo | Hydromorphone hydrochloride | 15393602 | 60 | 1516J-01334 |
| Fagron | Hydromorphone hydrochloride | 13E16-N02 | 40 | 0914B-01334 |
| Fagron | Hydromorphone hydrochloride | 13I25-N05 | 60 | 1516I-01334 |
| Fagron | Hydromorphone hydrochloride | 15L08-B08-316877 | 40 | 1917Q-01334 |
| Fagron | Hydromorphone hydrochloride | 13E16-N02 | 60 | 0914B-01334 |
| Fagron | Hydromorphone hydrochloride | 13I25-N05 | 60 | 1516I-01334 |
| Fagron | Hydroxychloroquine sulfate | 25B20-B021 | 40 | 20250319* |
| Fagron | Hydroxychloroquine sulfate | 24I05-B040 | 40 | 20240926* |

**I**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Iceland moss | 12187106 | 40 | 1403493 |
| Caelo | Iceland moss | 13350803 | 40 | 20131114 |
| Caelo | Ispaghula husks | 13238005 | 40 | 20130816 |

**J**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Juniper berry, pounded | 13367302 | 40 | 20131122 |

**K**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Kap-Aloe | 11048808 | 40 | 20110315 |
| Caelo | Kelp, cut | 13230805 | 40 | AR-15-FG-007678-01 |
| Caelo | Kelp, cut | 15418801 | 60 | AR-17-FG-007505-01 |


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## L

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Dr. Behr | L-Carnitine hydrochloride | WE11030091 | 60 | from supplier |
| Dr. Behr | L-Carnitine tartrate | WE11060069 | 40 | from supplier |
| Dr. Behr | L-Carnitine tartrate | WE15080050 | 60 | from supplier |
| Euro OTC | L-Carnitine tartrate | 1302017-01 | 40 | from supplier |
| Fagron | L-Carnitine tartrate | 10100220240309 | 40 | 20260228* |
| Flora Apot... | Levamisole hydrochloride | LV17203 | 40 | from supplier |
| Caelo | Linseed | 12186902 | 60 | 20120705 |
| Caelo | Linseed | 13412801 | 40 | 20140113 |
| Fagron | Lipoic acid | 24I03-B070 | 40 | 20241210* |
| Fagron | Lipoic acid | 24C12-B023-205920 | 40 | 20240322* |
| Galke | Liqourice root, peeled | 22728 | 40 | from supplier |
| Fagron | Losartan potassium | D5440-24-006 | 40 | 20240410* |
| Fagron | Lutein 10% | 24I26-B053 | 40 | pending |

## M

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Magnesium carbonate, heavy | 182282 | 40 | 20180906* |
| Caelo | Marshmallow root | 11101905 | 40 | 20110406 |
| Caelo | Marshmallow root | 13214804 | 40 | 20130806 |
| Caelo | Methadone hydrochloride | 12344818 | 40 | 0914E-02949 |
| Caelo | Methadone hydrochloride | 15244715 | 60 | 1516A-02949 |
| Caelo | Methadone hydrochloride | 12344818 | 60 | 0914E-02949 |
| Caelo | Methadone hydrochloride | 15244715 | 60 | 1516A-02949 |
| Fagron | Methadone hydrochloride | 13J24-B06 | 40 | 0914F-02949 |
| Fagron | Methadone hydrochloride | 15E29-B02-313098 | 60 | 1516B-02949 |
| Fagron | Methadone hydrochloride | 16F24-B02-323183 | 40 | 1917Q-02949 |
| Fagron | Methadone hydrochloride | 13J24-B06 | 60 | 0914F-02949 |
| Fagron | Methadone hydrochloride | 15E29-B02-313098 | 60 | 1516B-02949 |
| Th. Geyer | Methadone hydrochloride | 67033 | 40 | 0914G-02949 |
| Th. Geyer | Methadone hydrochloride | 67047 | 40 | 0914H-02949 |
| Th. Geyer | Methadone hydrochloride | 67033 | 60 | 0914G-02949 |
| Th. Geyer | Methadone hydrochloride | 67047 | 60 | 0914H-02949 |
| Flora Apot... | Mg-Ca-K colamine phosphate | 1000190952 | 40 | from supplier |
| Th. Geyer | Mg-Ca-K colamine phosphate | 36985 | 60 | from supplier |
| Th. Geyer | Mg-Ca-K colamine phosphate | 46816 | 40 | from supplier |
| Th. Geyer | Mg-Ca-K colamine phosphate | 54610 | 40 | from supplier |
| Th. Geyer | Mg-Ca-K colamine phosphate | 80919 | 40 | from supplier |
| Caelo | Midazolam hydrochloride | 12215811 | 40 | 0914E-03538 |
| Caelo | Midazolam hydrochloride | 15224602 | 60 | 1516B-03538 |
| Caelo | Midazolam hydrochloride | 12215811 | 60 | 0914E-03538 |
| Caelo | Midazolam hydrochloride | 15224602 | 60 | 1516B-03538 |
| Fagron | Midazolam hydrochloride | 13E22-N09 | 40 | 0914F-03538 |
| Fagron | Midazolam hydrochloride | 14L23-B04-300245 | 60 | 1516A-03538 |
| Fagron | Midazolam hydrochloride | 15H04-B03-314396 | 40 | 1917R-03538 |
| Fagron | Midazolam hydrochloride | 16C14-B12-332469 | 40 | 0718E-03538 |
| Fagron | Midazolam hydrochloride | 13E22-N09 | 60 | 0914F-03538 |
| Fagron | Midazolam hydrochloride | 14L23-B04-300245 | 60 | 1516A-03538 |
| Fagron | Midazolam hydrochloride | 16C14-B12-332469 | 40 | 0718E-03538 |
| Fagron | Minoxidil sulfate | 01801022407017 | 40 | 20241230* |
| Fagron | Minoxidil sulfate | 01801022405015 | 40 | 20240930* |
| Caelo | Mistletoe | 11294003 | 30 | 20111027 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Morphine hydrochloride trihydrate | 13125207 | 40 | 0914E-01879 |
| Caelo | Morphine hydrochloride trihydrate | 13349505 | 40 | 0914F-01879 |
| Caelo | Morphine hydrochloride trihydrate | 15439404 | 60 | 1416R-01879 |
| Caelo | Morphine hydrochloride trihydrate | 16184605 | 40 | 1917S-01879 |
| Caelo | Morphine hydrochloride trihydrate | 13125207 | 60 | 0914E-01879 |
| Caelo | Morphine hydrochloride trihydrate | 13349505 | 60 | 0914F-01879 |
| Caelo | Morphine hydrochloride trihydrate | 15439404 | 60 | 1416R-01879 |
| Fagron | Morphine hydrochloride trihydrate | 13G08-N04 | 40 | 0914G-01879 |
| Fagron | Morphine hydrochloride trihydrate | 15I09-B08-312694 | 60 | 1416Q-01879 |
| Fagron | Morphine hydrochloride trihydrate | 13G08-N04 | 60 | 0914G-01879 |
| Fagron | Morphine hydrochloride trihydrate | 15I09-B08-312694 | 60 | 1416Q-01879 |
| Th. Geyer | Morphine hydrochloride trihydrate | 67036 | 40 | 0914H-01879 |
| Th. Geyer | Morphine hydrochloride trihydrate | 67036 | 60 | 0914H-01879 |
| Caelo | Myrrh | 11277111 | 60 | 1403081 |
| Caelo | Myrrh | 13108701 | 40 | AR-15-FG-000946-01 |

## N

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Klenk | Nutmeg, powdered (spice) | 7325A160405 | 60 | 9888 |

## O

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Orlistat | 6012307004-01 | 40 | 20240523* |
| Fagron | Orlistat | 6012307003-02 | 40 | 20240526* |
| Caelo | Orris root | 11026705 | 40 | 20110221 |

## P

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Klenk | Parsley seed | 7370A130909 | 40 | 1407600 |
| Fagron | Phenibut | 24H26-B009 | 40 | 20240917* |
| Fagron | Phenibut | 24I12-B037 | 40 | 20241016* |
| Caelo | Phenobarbital | 12173202 | 40 | 0914E-01040 |
| Caelo | Phenobarbital | 12173202 | 60 | 0914E-01040 |
| Fagron | Phenobarbital | 15G07-B06-311718 | 60 | 1416Q-01040 |
| Fagron | Phenobarbital | 15G07-B06-311718 | 60 | 1416Q-01040 |
| Th. Geyer | Phenobarbital | 67045 | 40 | 0914F-01040 |
| Th. Geyer | Phenobarbital | 067056 | 40 | 2017A-01040 |
| Th. Geyer | Phenobarbital | 67045 | 60 | 0914F-01040 |
| Fagron | Pinus pinaster dry extract 95% | 24I05-B046 | 40 | 20240417* |
| Fagron | Pinus pinaster dry extract 95% | 25C26-B010 | 40 | 20240805* |
| Fagron | Piperine (NLT 98%) | 25D05-B008 | 40 | 20250306* |
| Fagron | Piperine (NLT 98%) | 25E06-B006 | 40 | 20250312* |

*continued on the next page*



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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Piracetam | 25B15-B041 | 40 | 20250312* |
| Fagron | Piracetam | 24I10-B067 | 40 | 20241127* |
| Fagron | Piroctone Olamine | 24J03-B068 | 40 | 20241101* |
| Fagron | Piroctone Olamine | 24I03-B001 | 40 | 20241011* |
| Fagron | Piroxicam | VLSPRM0022425 | 40 | 20240512* |
| Fagron | Piroxicam | 23K01-B060-201815 | 40 | 20231202* |
| Euro OTC | Potassium orotate | 1203038V-02 | 60 | from supplier |
| Euro OTC | Potassium orotate | 1203038V-02 | 40 | 9757 |
| Flora Apot… | Potassium orotate | ORK00117 | 40 | from supplier |
| Fagron | Pullulan | 24H27-B078 | 40 | 20240916* |

## Q

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Quercetin dihydrate | 25E09-B033 | 40 | 20250218* |
| Fagron | Quercetin dihydrate | 25F10-B044 | 40 | 20250523* |

## R

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Rhubarb | 11057818 | 40 | 20110314 |
| Fagron | Rutin 70% | 24J14-B044 | 40 | 20241030* |
| Fagron | Rutin 70% | 24I16-B041 | 40 | 20240925* |

## S

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Siam benzoin | 12321312 | 40 | 20121031 |
| Caelo | Siam benzoin | 12321314 | 40 | 20121031 |
| Fagron | Silymarin | 25D28-B010 | 40 | 20241012* |
| Fagron | Silymarin | 25D28-B009 | 40 | 20241012* |
| Pharmorgana | Sodium dichloroacetate | 1000150016 | 40 | from supplier |
| Caelo | Star anise | 11314104 | 30 | 20111121 |
| Fagron | Sulbutiamine | 25C05-B030 | 40 | 20250324* |
| Fagron | Sulbutiamine | 24I10-B011 | 40 | 20241109* |
| Fagron | Sunset yellow | 13I05_N04 | 40 | 20130903 |

## T

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Tadalafil | 24I12-B048 | 40 | 20240417* |
| Fagron | Tadalafil | 24I12-B049 | 40 | 20240417* |
| Fagron | Theacrine | 24I18-B028 | 40 | 20241011* |
| Fagron | Theacrine | 24I03-B049 | 40 | 20241010* |
| Klenk | Tormentil | 6911B141114 | 60 | AR-15-FG-014020-01 |
| EDQM | Triamcinolone hexacetonide | 3.0 | 40 | CRS |
| Fagron | Tribulus terrestris 40% | 20240402 | 40 | 20240926* |
| Fagron | Tribulus terrestris 40% | 24H29-B005 | 40 | 20240918* |

## W

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | White mustard seed | 12361002 | 40 | 1403473 |
| Caelo | White mustard seed, powdered | 12349601 | 60 | 1403281 |
| Caelo | White mustard seed, powdered | 12375705 | 40 | 20130110 |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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# *Appendix B:* Additional validation samples (*Type B*)

It is necessary that spectra also enter the validation which cannot be identified with this model. In this manner, it is verified that the model also rejects unknown substances. The spectra for these samples were recorded under the control of *HiperScan GmbH*. They are allocated to the *Type B*. They also include the calibration spectra for other models.

The samples originate from 1289 batches. From these 51 281 spectra were recorded. The spectra recorded on independent samples of substances which can be identified with the model are listed respectively in the section *Type B* for the individual substances and do not appear again elsewhere in this list.

0 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | (R,S)-epinephrine hydrochloride | 12H08-N03 | 40 | no certificate available |
| Fagron | (R,S)-epinephrine hydrochloride | 14A22-B05-291560 | 60 | no certificate available |
| Fagron | (R,S)-epinephrine hydrochloride | 16H23-B98-325052 | 40 | 20160913 |
| Fagron | 5-fluorouracil | 13F19-N03 | 40 | 1402308 |
| Fagron | 5-fluorouracil | 13F19-N03 | 60 | 1608169 |
| Fagron | 5-fluorouracil | 16D01-U05/3-327376 | 40 | 20161117 |
| Fagron | 8-quinolinol sulfate monohydrate | 12H21-N08 | 40 | 20120831 |
| Fagron | gamma-Aminobutyric acid | 1524040601 | 40 | 20240406* |
| Fagron | gamma-Aminobutyric acid | 1524040601 | 20 | 20240406* |

**A**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Acetyl-L-carnitine hydrochloride | 24H27-B070 | 40 | 20240923* |
| Fagron | Acetyl-L-carnitine hydrochloride | 24I10-B001 | 40 | not required |
| Fagron | Acetyl-L-carnitine hydrochloride | 24H27-B070 | 20 | 20240923* |
| Fagron | Acetyl-L-carnitine hydrochloride | 24I10-B001 | 20 | not required |
| Caelo | Acorus root | 12076404 | 40 | 20120328 |
| Caelo | Acorus root, peeled | 12239001 | 40 | 20120905 |
| Caelo | Acorus root, peeled | 12295902 | 40 | 20121025 |
| Caelo | Agarikon | 11024502 | 40 | 20110125 |
| Caelo | Agarikon | 13130602 | 48 | 1405003 |
| Caelo | Agarikon | 14190702 | 60 | 20140730 |
| Caelo | Agarikon | 14190706 | 60 | 20140730 |
| Klenk | Agarikon | 1061A120312 | 40 | 20120322 |
| Caelo | Agnus castus fruit | 12274003 | 40 | 1501649 |
| Caelo | Agnus castus fruit | 13193401 | 40 | AR-15-FG-006453-01 |
| Caelo | Agnus castus fruit | 15318705 | 60 | 20150916 |
| Caelo | Agrimony | 10325505 | 45 | 20101221 |
| Caelo | Agrimony | 11374004 | 40 | 20120125 |
| Caelo | Alchemilla | 12153306 | 40 | 20120618 |
| Caelo | Alchemilla alpina herb, cut | 12147201 | 40 | 20120608 |
| Caelo | Allspice, powdered (spice) | 12042703 | 40 | from supplier |
| Caelo | Almonds, bitter, whole | 13220401 | 40 | 1406296 |
| Caelo | Aloes, cape, powdered | 11132115 | 40 | 1404400 |
| Caelo | Aloes, cape, powdered | 11132115 | 40 | 20110520 |
| Caelo | Aluminium oxide, hydrated | 12163019 | 40 | 20120621 |
| Caelo | Aluminium oxide, hydrated | 13119121 | 40 | 20130503 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Sigma-Aldrich | Aluminum hydroxide hydrate | 102465140 | 40 | not required |
| Sigma-Aldrich | Aluminum sodium silicate | 102527683 | 40 | not required |
| Fagron | Amiodarone hydrochloride | 18J26-B01-368910 | 40 | 20200429 |
| Fagron | Amiodarone hydrochloride | 18J26-B01-368910 | 20 | 20200429 |
| Sigma-Aldrich | Ammonium bromide | 0000097635 | 40 | not required |
| Caelo | Ammonium chloride | 12356101 | 40 | 20121206 |
| Euro OTC | Ammonium chloride | 1209013-01 | 40 | 20120928 |
| Caelo | Amphetamine sulfate | 18186907 | 40 | 1919M-03361 |
| Caelo | Amphetamine sulfate | 16153902 | 40 | 2017A-03361 |
| Caelo | Amphetamine sulfate | 18186907 | 40 | 1919M-03361 |
| Fagron | Amphetamine sulfate | 16A29-B03-324577 | 40 | 2017B-03361 |
| Fagron | Amphetamine sulfate | 16A29-B03-324577 | 40 | 2017B-03361 |
| Th. Geyer | Amphetamine sulfate | 067043 | 40 | 2017C-03361 |
| abcr GmbH | Amygdalin | 1310927 | 40 | from supplier |
| abcr GmbH | Amygdalin | 1310579 | 40 | from supplier |
| Auropure L... | Amygdalin, bitter almond extract 98% | PA02099-160822 | 30 | from supplier |
| Caelo | Angelica root | 12168701 | 40 | 20120703 |
| Caelo | Angelica root | 12080404 | 40 | 1403053 |
| Caelo | Angelica root | 12080409 | 40 | 20120322 |
| Klenk | Angelica root | 6085B120614 | 40 | 20120621 |
| Klenk | Angelica root | 6085B120614 | 60 | 1509356 |
| Caelo | Aniseed | 11370301 | 40 | 20120117 |
| Klenk | Aniseed | 2700A140129 | 60 | 20140926 |
| Klenk | Aniseed | 2700A160511 | 60 | 1708049 |
| Caelo | Aniseed, pounded | 12111301 | 40 | 20120420 |
| Caelo | Aniseed, powdered | 11306203 | 40 | 20111110 |
| Caelo | Apple, cut | 11229807 | 60 | from supplier |
| Fagron | Arbutin | 24I04-B053 | 40 | not required |
| Fagron | Arbutin | 24I25-B029 | 40 | not required |
| Fagron | Arbutin | 24I04-B053 | 20 | not required |
| Fagron | Arbutin | 24I25-B029 | 20 | not required |
| Caelo | Arnica flower | 11285702 | 40 | 20111118 |
| Caelo | Arnica flower | 11259801 | 40 | 20110923 |
| Caelo | Artichoke leaf | 12173302 | 40 | 20120706 |
| Caelo | Artichoke leaf | 13310707 | 40 | 20130930 |
| Caelo | Artificial thermal salt a | 181633 | 40 | 20180621* |
| Klenk | Ash bark, cut | 0871B110127 | 60 | 20110128 |
| Caelo | Ash leaf, cut | 11031303 | 40 | 20110224 |
| Caelo | Asparagus root, cut | 10299010 | 40 | 20101119 |
| Fagron | Aspartame | 21I21-B07-213840 | 40 | 20211216 |
| Fagron | Aspartame | 23L11-B02-004164 | 40 | 20240212 |
| Fagron | Aspartame | 21I21-B07-213840 | 20 | 20211216 |
| Fagron | Aspartame | 23L11-B02-004164 | 20 | 20240212 |
| Fagron | Atenolol | 24E11-B04-005022 | 40 | 20241004 |
| Fagron | Atenolol | 24E11-B04-005022 | 20 | 20241004 |
| Fagron | Azithromycin | 20F22-F01-372739 | 50 | 20200813 |
| Fagron | Azithromycin | 24C14-B02-231046 | 40 | 20240507 |
| Fagron | Azithromycin | 24C14-B02-231046 | 20 | 20240507 |

**B**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Barberries | 11058309 | 40 | 20110315 |
| Caelo | Barberries | 12217109 | 60 | 20120802 |
| Caelo | Barberries | 14057312 | 60 | 1508391 |
| Caelo | Barberry root bark, cut | 12112601 | 40 | 20120430 |
| Fagron | Barbital sodium | 15L07-B02-324539 | 40 | 2017A-07775 |
| Fagron | Barbital sodium | 15L07-B02-324539 | 40 | 2017A-07775 |
| Caelo | Barium sulfate | 171113 | 40 | 20170509* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Basil, rubbed | 12066404 | 50 | 20120321 |
| Caelo | Bearberry leaf | 12186502 | 40 | 20120705 |
| Fagron | Benfotiamine | NL/BA/0152324 | 40 | 20240801* |
| Fagron | Benfotiamine | NL/BA/0152324 | 20 | 20240801* |
| Caelo | Bentonite | 12237603 | 40 | 20120810 |
| Caelo | Betony herb, cut | 12007205 | 40 | 20120118 |
| Caelo | Betony herb, cut | 12007205 | 60 | 20120118 |
| Caelo | Bilberry leaf | 12140206 | 40 | 20120605 |
| Caelo | Birch leaf | 12193105 | 40 | 20120710 |
| Caelo | Bismuth subnitrate, heavy | 181942 | 40 | 20181010* |
| Fagron | Bisoprolol fumarate | 24I18-B04-003143 | 40 | 20241003 |
| Fagron | Bisoprolol fumarate | 24I18-B04-003143 | 20 | 20241003 |
| Caelo | Bitter-Orange flower (petals) | 12266605 | 40 | 20120907 |
| Caelo | Bitter-Orange flower (petals) | 12266703 | 40 | 20120907 |
| Caelo | Bitter-Orange peel | 12067405 | 40 | 20120327 |
| Caelo | Black cohosh | 10281112 | 40 | 20101118 |
| Caelo | Black cohosh | 13237901 | 40 | 20130812 |
| Caelo | Black cohosh | 13237903 | 40 | 20130812 |
| Caelo | Black cumin seed | 11233503 | 40 | 1403495 |
| Caelo | Black mustard seed | 12189303 | 40 | 1403472 |
| Caelo | Black mustard seed | 15120405 | 60 | AR-17-FG-007964-01 |
| Caelo | Black mustard seed | 23000940006 | 30 | 20230523 |
| Klenk | Black mustard seed | 7430A120813 | 40 | AR-15-FG-001050-01 |
| Caelo | Black mustard seed, powdered | 12350204 | 80 | 1403711 |
| Caelo | Black mustard seed, powdered | 13358304 | 40 | 20131113 |
| Caelo | Black mustard seed, powdered | 16051807 | 60 | 9887 |
| Klenk | Black mustard seed, powdered | 7434A120712 | 40 | AR-15-FG-006711-01 |
| Caelo | Blackberry leaf | 11030707 | 40 | 20110303 |
| Galke | Blackberry leaf | 18060 | 40 | 20111021 |
| Caelo | Blackcurrant leaf, cut | 12168804 | 40 | 20120711 |
| Caelo | Blackcurrants | 14212502 | 60 | 20140829 |
| Caelo | Blackcurrants | 14212509 | 60 | 20140829 |
| Caelo | Blackthorn flower | 12178101 | 40 | 20120718 |
| Caelo | Blessed thistle, cut | 12038203 | 40 | 20120306 |
| Caelo | Blue bottle flower | 10291105 | 40 | 20101108 |
| Caelo | Blue bottle flower | 13241902 | 60 | AR-15-FG-005838-01 |
| Caelo | Bogbean leaf, cut | 12226101 | 40 | 20120809 |
| Caelo | Boldo leaf | 13367904 | 40 | 20131122 |
| Galke | Boldo leaf | 19855 | 40 | 20120727 |
| Klenk | Boldo leaf | 1911A100714 | 40 | 20111214 |
| Caelo | Borage herb, cut | 11206712 | 40 | 20110822 |
| Roth | Brilliant blue R 250 (C.I.42660) | 314217301 | 60 | from supplier |
| Fagron | Bromelain | 14F20-B03295501 | 40 | pending |
| Fagron | Bromelain | 14F20-B03295501 | 60 | 20140701 |
| Sigma-Aldrich | Bromelain | BCBM1589V | 40 | from supplier |
| EDQM | Bromhexine hydrochloride | 5.0 | 40 | CRS |
| Caelo | Bucho leaf | 12034903 | 40 | 20120221 |
| Klenk | Buckwheat seed | 7510A111011 | 40 | from supplier |
| Klenk | Buckwheat seed | 7510A111011 | 60 | 20130730 |
| Caelo | Buprenorphine hydrochloride | 16143001 | 40 | 0718E-07774 |
| Caelo | Buprenorphine hydrochloride | 16143001 | 40 | 1919M-07774 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Buprenorphine hydrochloride | 12172908 | 60 | 0814I-07774 |
| Caelo | Buprenorphine hydrochloride | 16143001 | 40 | 2017A-07774 |
| Caelo | Buprenorphine hydrochloride | 16143001 | 40 | 0718E-07774 |
| Caelo | Buprenorphine hydrochloride | 16143001 | 40 | 1919M-07774 |
| Caelo | Burdock root | 11100801 | 40 | 20110523 |
| Caelo | Burnet root | 12027410 | 40 | 20120206 |
| Caelo | Burnet root | 12027407 | 40 | 20120206 |
| Caelo | Burnet root | 12024406 | 40 | 20120206 |

## C

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Gatt-Koller | Caffeine-sodium benzoate | 22J00803 | 40 | 20220530 |
| Gatt-Koller | Caffeine-sodium benzoate | 23J01215 | 40 | 20230803 |
| Gatt-Koller | Caffeine-sodium benzoate | 22J00803 | 20 | 20220530 |
| Gatt-Koller | Caffeine-sodium benzoate | 23J01215 | 20 | 20230803 |
| Caelo | Calcium chloride dihydrate | 182411 | 35 | 20181022* |
| Caelo | Calcium chloride dihydrate | 23001613 | 40 | 20230717* |
| VWR Intern... | Calcium chloride hexahydrate | 22K294102 | 40 | not required |
| Th. Geyer | Calcium colamine phosphate | 36986 | 40 | from supplier |
| Euro OTC | Calcium orotate dihydrate | 1009035-01 | 40 | 20101019 |
| Euro OTC | Calcium orotate dihydrate | 1411003 | 40 | 20160331* |
| Fagron | Calcium orotate dihydrate | 16F13-B04-324144 | 40 | 20161108 |
| Caelo | Calcium oxide | 182244 | 39 | 20181106* |
| Caelo | Calcium sulfate dihydrate | 163363 | 40 | 20161214* |
| Caelo | Calcium sulfate hemihydrate | 153451 | 30 | 20151103* |
| Bombastus | Calendula flower | 24002342 | 30 | 20240528 |
| Caelo | Calendula flower | 11221404 | 40 | 20110930 |
| Caelo | Calendula flower | 22003249004 | 30 | 20221214 |
| Klenk | Calendula flower | 1241B130321 | 40 | 20130408 |
| Caelo | Calendula flower, cut | 11187605 | 40 | 20110930 |
| Caelo | Campeche wood | 11074105 | 40 | from supplier |
| PhytoLab G... | Cannabidiolic acid | 19802 | 30 | 20240730 |
| bubatzbros.de | Cannabis flower, CBD-dominant type | BBMK11-092023 | 30 | 20231010 |
| CBDblueten.de | Cannabis flower, CBD-dominant type | JUHQ2428923yGPP4 | 30 | 20250319 |
| Hanfgarten.at | Cannabis flower, CBD-dominant type | HCB000014 | 31 | 20231010 |
| Hanfgarten.at | Cannabis flower, CBD-dominant type | HCB000040 | 31 | 20231010 |
| Hanfgarten.at | Cannabis flower, CBD-dominant type | HCB000046 | 30 | 20231010 |
| Luckyhemp.de | Cannabis flower, CBD-dominant type | BN-0009-03 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | 24D29FB24E29 | 30 | 20250319 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | 23GS11WLC010102 | 30 | 20250319 |
| Cansativa | Cannabis flower, THC/CBD-intermediate type | E256 | 30 | 20250319 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Cansativa | Cannabis flower, THC/CBD-intermediate type | N094-250101 | 30 | 20250319 |
| Cansativa | Cannabis flower, THC/CBD-lean | 1374362001 | 30 | 20250319 |
| CBD NOL | Cannabis flower, THC/CBD-lean | CNSLH5-092023 | 30 | 20231010 |
| CBD NOL | Cannabis flower, THC/CBD-lean | CNC5-092023 | 30 | 20231010 |
| CBD NOL | Cannabis flower, THC/CBD-lean | CNAH6-092023 | 30 | 20231010 |
| CBD NOL | Cannabis flower, THC/CBD-lean | CNPE6-092023 | 30 | 20231010 |
| CBD NOL | Cannabis flower, THC/CBD-lean | CNBB0-092023 | 30 | 20231010 |
| CBD NOL | Cannabis flower, THC/CBD-lean | CNBA10-092023 | 30 | 20231010 |
| CBDblueten.de | Cannabis flower, THC/CBD-lean | LJ2121915yGPP4 | 30 | 20250319 |
| Hanfgarten.at | Cannabis flower, THC/CBD-lean | HCB000020 | 30 | 20231010 |
| happy420.de | Cannabis flower, THC/CBD-lean | 100000318 | 30 | 20231010 |
| happy420.de | Cannabis flower, THC/CBD-lean | 100000019 | 30 | 20231010 |
| happy420.de | Cannabis flower, THC/CBD-lean | 100000814 | 30 | 20231010 |
| happy420.de | Cannabis flower, THC/CBD-lean | 100000017 | 30 | 20231010 |
| happy420.de | Cannabis flower, THC/CBD-lean | 100000024 | 30 | 20231010 |
| happy420.de | Cannabis flower, THC/CBD-lean | 100000365 | 30 | 20231010 |
| happy420.de | Cannabis flower, THC/CBD-lean | 100000167 | 30 | 20231010 |
| justbob | Cannabis flower, THC/CBD-lean | ES259061222 | 30 | 20231010 |
| justbob | Cannabis flower, THC/CBD-lean | ES326090523 | 30 | 20231010 |
| Luckyhemp.de | Cannabis flower, THC/CBD-lean | BN-0033-03 | 30 | 20231010 |
| Luckyhemp.de | Cannabis flower, THC/CBD-lean | BN-0003-03 | 30 | 20231010 |
| Luckyhemp.de | Cannabis flower, THC/CBD-lean | BN-0041-03 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | ICC230402 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 13302 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 06051822121-3-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | C082 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | BKS2290001-1R1-6 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22K07FP23A18 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | AKH2311001-1R1-6 | 30 | 20231010 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Cansativa | Cannabis flower, THC-dominant type | 22TC06HB010102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS15BB010202 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS02MK020102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS10PPS010102 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 02209913122-1-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 28302 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 28303 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 06051821121-1-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 02209913122-1-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 28302 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 28303 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 28302 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 06051822121-3-P1 | 30 | 20231010 |
| Cansativa | Cannabis flower, THC-dominant type | 22GS15BB010202 | 30 | 20231010 |
| Bombastus | Caraway fruit | 23004707 | 30 | 20231023 |
| Caelo | Caraway fruit | 11003217 | 40 | 20110209 |
| Caelo | Caraway fruit | 13397104 | 40 | AR-15-FG-001526-01 |
| Caelo | Caraway fruit | 13397104 | 60 | AR-15-FG-001527-01 |
| Caelo | Caraway fruit | 13306006 | 60 | AR-16-FG-000540-03 |
| Caelo | Caraway fruit | 15097115 | 60 | AR-17-FG-006649-01 |
| Caelo | Caraway fruit | 22003284004 | 30 | 20230228 |
| Caelo | Caraway fruit, pounded | 12116904 | 40 | 20120503 |
| Caelo | Caraway fruit, pounded | 13367101 | 40 | 20130503 |
| Caelo | Caraway fruit, pounded | 14358801 | 60 | AR-15-FG-014914-01 |
| Caelo | Caraway fruit, pounded | 16073201 | 60 | AR-17-FG-006648-01 |
| Caelo | Carbachol | 11150302 | 31 | 1401147 |
| Fagron | Carbidopa monohydrate | 23A26-B05-226465 | 40 | 20230330 |
| Fagron | Carbidopa monohydrate | 23I12-B04-236349 | 40 | 20231108 |
| Fagron | Carbidopa monohydrate | 23A26-B05-226465 | 20 | 20230330 |
| Fagron | Carbidopa monohydrate | 23I12-B04-236349 | 20 | 20231108 |
| Caelo | Cardamom fruit | 11309107 | 40 | 20111111 |
| Caelo | Cardamom fruit | 13260504 | 40 | 20130906 |
| Klenk | Cardamom, excorticated, powdered (spice) | 2765A130524 | 60 | AR-15-FG-015285-01 |
| Lycored corp. | Caromix | CMX-LLCV-011401 | 40 | 20140131 |
| Fagron | Carvedilol | 22B21-F02-383500 | 40 | 20221111 |
| Fagron | Carvedilol | 24K04-B18-007137 | 40 | 20250115 |
| Fagron | Carvedilol | 22B21-F02-383500 | 20 | 20221111 |
| Fagron | Carvedilol | 24K04-B18-007137 | 20 | 20250115 |
| Caelo | Castoreum, powdered | 13410403 | 40 | 20131231 |
| Caelo | Castoreum, powdered | 13410403 | 40 | 20131231 |
| Euro OTC | Cefaclor monohydrate | 2311015 | 40 | 20240110* |
| Euro OTC | Cefaclor monohydrate | 2310002 | 40 | 20240110* |
| Euro OTC | Cefaclor monohydrate | 2311015 | 20 | 20240110* |
| Euro OTC | Cefaclor monohydrate | 2310002 | 20 | 20240110* |
| Klenk | Celery fruit | 7140A130625 | 40 | 1405177 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Klenk | Celery fruit | 7140A131122 | 60 | 20131204 |
| Klenk | Celery fruit | 7140A230110-01 | 30 | 20230214 |
| Caelo | Celery root, cut | 10270002 | 40 | 20101006 |
| Caelo | Centaury | 11097602 | 40 | 20110428 |
| Caelo | Charcoal, activated | 181885 | 40 | 20180813* |
| Klenk | Chervil, rubbed | 3721A100329 | 40 | 20111128 |
| Caelo | Chickweed, cut | 13040502 | 40 | 1403482 |
| Caelo | Chickweed, cut | 13254411 | 40 | 1412550 |
| Caelo | Chicory herb | 12034303 | 60 | 20120228 |
| Caelo | Chicory herb | 12354302 | 100 | 20121211 |
| Fagron | Chlorhexidine dihydrochloride | 14A09-B03-290724 | 40 | AR-15-FG-012308-01 |
| Fagron | Chlorhexidine dihydrochloride | 16C11-B02-324203 | 40 | 20160412 |
| Fagron | Chlorhexidine dihydrochloride | 16C11-B02-322510 | 40 | 20160412 |
| Fagron | Chlorhexidine dihydrochloride | 16C11-B02-329881 | 40 | 20160412 |
| Fagron | Chlorobutanol hemihydrate | 14A06-B31-290310 | 60 | 1412458 |
| Fagron | Chloroquine phosphate | 24002C3RJ | 40 | 20240124* |
| Fagron | Chloroquine phosphate | 24002C3RJ | 20 | 20240124* |
| Euro OTC | Cholecalciferol dry concentrate | 1210051-01 | 40 | 1403341 |
| Euro OTC | Cholecalciferol dry concentrate | 1304016-02 | 40 | 20130425 |
| Euro OTC | Cholecalciferol dry concentrate | 1502021-01 | 60 | 20150309 |
| Euro OTC | Cholecalciferol dry concentrate | 1602019 | 40 | 20160307* |
| Euro OTC | Cholecalciferol dry concentrate | 1701053 | 40 | 20170208* |
| Euro OTC | Cholecalciferol dry concentrate | 1707027 | 40 | 20171020* |
| Euro OTC | Cholecalciferol dry concentrate | 1802014 | 40 | 20180223* |
| Euro OTC | Cholecalciferol dry concentrate | 1801038 | 40 | 20180206* |
| Euro OTC | Cholecalciferol dry concentrate | 1806003 | 40 | 20180618* |
| Euro OTC | Cholecalciferol dry concentrate | 1812010 | 40 | 20190114* |
| Euro OTC | Cholecalciferol dry concentrate | 1901050 | 40 | 20190221* |
| Euro OTC | Cholecalciferol dry concentrate | 1906009 | 40 | 20190619* |
| Fagron | Chromium picolinate | 24H27-B003 | 40 | not required |
| Fagron | Chromium picolinate | 24H27-B004 | 40 | not required |
| Fagron | Chromium picolinate | 24H27-B003 | 20 | not required |
| Fagron | Chromium picolinate | 24H27-B004 | 20 | not required |
| Fagron | Cimetidine | 2403109C03 | 40 | 20240321* |
| Fagron | Cimetidine | 2403109C03 | 20 | 20240321* |
| Fagron | Cinchocaine hydrochloride | 12F25-N10 | 40 | 1401148 |
| Fagron | Cinchocaine hydrochloride | 13G24-N05 | 40 | 20130826 |
| Caelo | Cinchona bark, cut | 11238512 | 40 | 1403463 |
| Caelo | Cinchona bark, cut | 13031007 | 40 | 20130207 |
| Caelo | Cinchona bark, cut | 14009304 | 40 | AR-15-FG-007677-01 |
| Caelo | Cinchona bark, cut | 15301903 | 60 | AR-17-FG-007831-01 |
| Caelo | Cinnamon | 12309902 | 40 | 20121022 |
| Caelo | Cinnamon | 13304414 | 40 | 20130912 |
| Caelo | Cinnamon | 14175010 | 60 | 1505349 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Cinnamon | 16114401 | 60 | 1704441 |
| Caelo | Cinnamon rods (Ceylonese Cinnamon) | 13241807 | 40 | 20130905 |
| Fagron | Cinnarizine | 11L22-N13 | 40 | 20120104 |
| Fagron | Cinnarizine | 13H01-N07 | 40 | 1402306 |
| Fagron | Cinnarizine | 14D09-B01-294702 | 60 | AR-16-FG-008930-01 |
| Klenk | Cleavers goosegrass, cut | 4731B110809 | 40 | 20110930 |
| Caelo | Clove | 12095805 | 40 | 20120417 |
| Caelo | Clove | 16207804 | 60 | 1708676 |
| Caelo | Clove | 25100028001 | 30 | 20240411 |
| Klenk | Clove | 1260A150916 | 40 | 1708050 |
| Caelo | Cocaine hydrochloride | 16142710 | 40 | 1917T-01278 |
| Caelo | Cocaine hydrochloride | 18266104 | 40 | 1919M-01278 |
| Caelo | Cocaine hydrochloride | 17003902 | 40 | 1917S-01278 |
| Caelo | Cocaine hydrochloride | 16142710 | 40 | 1917T-01278 |
| Caelo | Cocaine hydrochloride | 18266104 | 40 | 1919M-01278 |
| Fagron | Cocaine hydrochloride | 14H27-B03-304551 | 40 | 1917R-01278 |
| Fagron | Cocaine hydrochloride | 18J01-B07-353630 | 40 | 1919I-01278 |
| Fagron | Cocaine hydrochloride | 16B11-B05-323386 | 40 | 1917Q-1278 |
| Fagron | Cocaine hydrochloride | 14H27-B03-304551 | 40 | 1917R-01278 |
| Fagron | Cocaine hydrochloride | 18J01-B07-353630 | 40 | 1919I-01278 |
| Fagron | Codeine monohydrate | 12C05-N05 | 40 | 0814I-01280 |
| Fagron | Codeine monohydrate | 12C05-N05 | 60 | 0814I-01280 |
| Caelo | Codeine phosphate hemihydrate | 16349702 | 40 | 2017C-01279 |
| Caelo | Codeine phosphate hemihydrate | 16169807 | 40 | 2017B-01279 |
| Caelo | Codeine phosphate hemihydrate | 18187906 | 40 | 1919M-01279 |
| Caelo | Codeine phosphate hemihydrate | 16349702 | 40 | 2017C-01279 |
| Caelo | Codeine phosphate hemihydrate | 16169807 | 40 | 2017B-01279 |
| Caelo | Codeine phosphate hemihydrate | 18187906 | 40 | 1919M-01279 |
| Fagron | Codeine phosphate hemihydrate | 16E17-B05-324109 | 40 | 2017A-01279 |
| Th. Geyer | Codeine phosphate hemihydrate | 067054 | 40 | 2017D-01279 |
| Caelo | Colophony | 15186804 | 60 | AR-16-FG-005931-01 |
| Caelo | Colophony | 161332 | 40 | 20160510* |
| Caelo | Colophony | 173014 | 40 | 20180102* |
| Caelo | Colophony | 192081 | 40 | 20190731* |
| Caelo | Common wormwood herb | 12016705 | 40 | 20120131 |
| Euro OTC | Copper orotate dihydrate | 1901040-01 | 50 | 20190319 |
| Euro OTC | Copper orotate dihydrate | 2203016 | 40 | 20220520* |
| Euro OTC | Copper orotate dihydrate | 2203016 | 20 | 20220520* |
| Euro OTC | Copper(II) gluconate | 2202011 | 40 | 20220301* |
| Euro OTC | Copper(II) gluconate | 2202011 | 40 | 20220301* |
| Caelo | Copper(II) sulfate pentahydrate | 162409 | 40 | 20160825* |
| Caelo | Coriander | 12080904 | 40 | 20120322 |
| Caelo | Coriander | 13299403 | 40 | 1412548 |
| Caelo | Coriander | 16010212 | 60 | AR-17-FG-015965-01 |
| EDQM | Cortisone acetate | 6.0 | 20 | CRS |
| Caelo | Cottonwood bud | 12027505 | 40 | 20120131 |
| Klenk | Cottonwood bud, pounded | 3266B130826 | 40 | 1410178 |
| Klenk | Cottonwood bud, pounded | 3266B150624 | 60 | 20150701 |
| Caelo | Couch grass rhizome, cut | 12186702 | 40 | 20120629 |
| Caelo | Cowberry leaf, cut | 11334302 | 40 | 20111129 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Cumin | 11378308 | 30 | 20120124 |
| Euro OTC | Curcuma extract 95% | L1408013 | 60 | 20140815 |
| Fagron | Curcumin | CP2403043 | 40 | 20240319* |
| Fagron | Curcumin | CP2404071 | 20 | 20240410* |
| Fagron | Curcumin | CP2403043 | 20 | 20240319* |
| Fagron | Curcumin | CP2403046 | 20 | 20240320* |
| Euro OTC | Cyclopentolate hydrochloride | 2311002 | 40 | 20240322* |
| Euro OTC | Cyclopentolate hydrochloride | 2409009 | 40 | 20241106* |
| Euro OTC | Cyclopentolate hydrochloride | 2311002 | 20 | 20240322* |
| Euro OTC | Cyclopentolate hydrochloride | 2409009 | 20 | 20241106* |

## D

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Daisy flower | 11068306 | 40 | 20110323 |
| Caelo | Damiana leaf, cut | 11026608 | 40 | 20110221 |
| Caelo | Dandelion herb without root | 11217109 | 40 | 20110824 |
| Caelo | Dandelion root | 12363102 | 40 | 1403708 |
| Caelo | Dandelion root | 13329701 | 40 | 20131017 |
| Caelo | Dandelion root | 13329708 | 40 | 1411089 |
| Klenk | Dandelion root | 6621B151029 | 60 | AR-17-FG-007535-01 |
| Caelo | Dapsone | 160735 | 60 | 20160405* |
| Caelo | Dapsone | 16073502 | 40 | 20160405 |
| Caelo | Dapsone | 16073502 | 40 | 20160405 |
| Caelo | Dapsone | 170311 | 39 | 20170221* |
| Caelo | Dapsone | 182792 | 40 | 20181214* |
| Caelo | Dapsone | 191135 | 40 | 20190726* |
| Fagron | Deflazacort | 24I05B022 | 40 | not required |
| Fagron | Deflazacort | 6017-240501 | 40 | 20240518* |
| Fagron | Deflazacort | 24I05B022 | 20 | not required |
| Fagron | Deflazacort | 6017-240501 | 20 | 20240518* |
| Fagron | Deoxycholic acid | 14A02-B32-303429 | 60 | AR-16-FG-004648-01 |
| Fagron | Deoxycholic acid | 14A02-B32-303429 | 40 | from supplier |
| Euro OTC | Devil's claw dry extract | 2101020 | 40 | 20210203* |
| Euro OTC | Devil's claw dry extract | 1210003-02 | 40 | 1707472 |
| Euro OTC | Devil's claw dry extract | 1210003-02 | 40 | 20151102 |
| Euro OTC | Devil's claw dry extract | 1210003-02 | 40 | 20151102 |
| Caelo | Devil's claw root | 12031806 | 40 | 20120222 |
| Caelo | Devil's claw root | 13298202 | 40 | 20130926 |
| Sigma-Aldrich | Dexamethasone isonicotinate | Y0000538 | 40 | CRS |
| Fagron | Dexamphetamine sulfate | 16F09-B02-328352 | 40 | 2017A-03582 |
| Fagron | Dexamphetamine sulfate | 15H06-B04-313862 | 60 | 1316Q-03582 |
| Fagron | Dexamphetamine sulfate | 16D20-B01-321049 | 40 | 2017B-03582 |
| Fagron | Dexamphetamine sulfate | 16F09-B02-328352 | 40 | 2017A-03582 |
| Caelo | Dihydrocodeine hydrogen tartrate | 16106209 | 40 | 2017C-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15295910 | 40 | 2017B-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 18115205 | 40 | 1919M-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 16106209 | 40 | 2017C-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15295910 | 40 | 2017B-03065 |
| Caelo | Dihydrocodeine hydrogen tartrate | 18115205 | 40 | 1919M-03065 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Dihydrocodeine hydrogen tartrate | 14K26-B04-306298 | 60 | 1516I-03065 |
| Fagron | Dihydrocodeine hydrogen tartrate | 15F18-B07-323388 | 40 | 2017A-03065 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 067052 | 40 | 2017D-03065 |
| Fagron | Dihydroergotamine mesilate | 22A11-F01-384535 | 40 | 20220328 |
| Fagron | Dihydroergotamine mesilate | 22A11-F01-384535 | 20 | 20220328 |
| Gatt-Koller | Dihydroergotamine mesilate | 22J02560 | 40 | 20230109 |
| Gatt-Koller | Dihydroergotamine mesilate | 22J02560 | 20 | 20230109 |
| Caelo | Dill fruit | 23001474001 | 30 | 20231010 |
| Caelo | Dill herb, cut | 11295107 | 40 | 20111103 |
| Caelo | Dill herb, cut | 13007602 | 40 | 1402204 |
| Caelo | Dill herb, cut | 13007610 | 40 | 20130208 |
| Fagron | Dimenhydrinate | 21J13-B12-223576 | 40 | 20220117* |
| Fagron | Dimenhydrinate | 21J13-B12-223576 | 20 | 20220117* |
| abcr GmbH | Dimercaptosuccinic acid | 1005874 | 39 | from supplier |
| Safic-Alcan | Dimercaptosuccinic acid | 20180130 | 40 | from supplier |
| Caelo | Dimethyl fumarate | 13269801 | 60 | 1506634 |
| Euro OTC | Dimethyl fumarate | 1410013-01 | 60 | 20141125 |
| Euro OTC | Dimethyl fumarate | 1601013-01 | 40 | 20160204 |
| Fagron | Diosmin | DSM240603 | 40 | 20241031* |
| Fagron | Diosmin | DSM240602 | 20 | 20241031* |
| Fagron | Diosmin | DSM240401 | 20 | 20241031* |
| Fagron | Diosmin | DSM240603 | 20 | 20241031* |
| Sigma-Aldrich | Disodium hydrogen phosphate | 102544017 | 40 | not required |
| Fagron | Doxazosin mesylate | DM0060624 | 40 | 20240705* |
| Fagron | Doxazosin mesylate | DM0060624 | 20 | 20240705* |
| Fagron | Drofenine hydrochloride | 13I09-N05 | 40 | 20130524 |
| Fagron | Drofenine hydrochloride | 15G01-B04-323028 | 40 | 20150709 |
| Fagron | Drofenine hydrochloride | 15G01-B04-330979 | 40 | AR-17-FG-015434-02 |
| Fagron | Drofenine hydrochloride | 15G01-B04-330979 | 40 | 20150709 |
| Fagron | Drofenine hydrochloride | 18A18-B99-345993 | 40 | 20180308 |
| THC-Pharma GmbH | Dronabinol | S21-035A01 | 42 | 20220209 |

**E**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| EDQM | Econazole | 1.0 | 10 | CRS |
| Caelo | Elder berries | 12267807 | 40 | 1403466 |
| Caelo | Elder berries | 13367704 | 40 | 1410179 |
| Klenk | Elder berries | 3010A120202 | 40 | 20120531 |
| Caelo | Elder flower | 12221902 | 40 | 20120821 |
| Klenk | Elder leaf, cut | 2321B130221 | 60 | 20130226 |
| Caelo | Elecampane rhizome, cut | 12113303 | 40 | 20120427 |
| Klenk | Elecampane rhizome, cut | 6341B120611 | 40 | 20120620 |
| Caelo | Eleutherococcus, cut | 10381814 | 30 | 20110113 |
| Caelo | Elm bark, cut | 10347205 | 60 | 20101223 |
| Yino Pharma | Enoxaparin sodium | YN010232210003 | 40 | 20230524* |
| Yino Pharma | Enoxaparin sodium | YN010232210003 | 20 | 20230524* |
| Caelo | Equisetum stem | 10375515 | 40 | 20110114 |
| Fagron | Ergotamine tartrate | 13I24-B10-288648 | 50 | 20131024 |
| Fagron | Ergotamine tartrate | 13I24-B10-288650 | 60 | 20131024 |
| Fagron | Ergotamine tartrate | 15B16-B05-308418 | 45 | 9384 |
| Fagron | Ergotamine tartrate | 15B16-B05-308417 | 40 | 20150302 |
| Fagron | Ergotamine tartrate | 15B16-B05-308418 | 45 | 9384 |
| Fagron | Ergotamine tartrate | 15B16-B05-308417 | 40 | 20150302 |
| EDQM | Erythromycin estolate | 1.4 | 40 | CRS |
| Fagron | Erythromycin estolate | EV/EE-085/24 | 40 | 20240803* |
| Fagron | Erythromycin estolate | EV/EE-085/24 | 20 | 20240803* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| EDQM | Erythromycin stearate | 1.2 | 40 | CRS |
| Euro OTC | Escin, water-soluble | 1310020-01 | 40 | AR-15-FG-005777-01 |
| Euro OTC | Escin, water-soluble | 1506038 | 60 | 20150708* |
| Euro OTC | Escin, water-soluble | 1605021 | 40 | 20160609* |
| Euro OTC | Escin, water-soluble | 1612012 | 40 | 20170213* |
| Euro OTC | Escin, water-soluble | 1807015-01 | 40 | 20180801 |
| Euro OTC | Escin, water-soluble | 1911023 | 40 | 20191211* |
| Euro OTC | Escin, water-soluble | 2009019 | 40 | 20201009* |
| Euro OTC | Escin, water-soluble | 2106010 | 50 | 20210715* |
| Fagron | Escin, water-soluble | 12K22-N13 | 40 | 20121127 |
| Fagron | Escin, water-soluble | 12I07-B40-306607 | 40 | 1610369 |
| Fagron | Ethyl hydrogen fumarate | 14C12-B07-292760 | 60 | 1410436 |
| Fagron | Ethyl hydrogen fumarate | 14C12-B07-292760 | 60 | 20140417 |
| Euro OTC | Ethyl hydrogen fumarate calcium | 1310029-01 | 60 | 20131126 |
| Euro OTC | Ethyl hydrogen fumarate calcium | 1306012-01 | 60 | 1505456 |
| Euro OTC | Ethyl hydrogen fumarate calcium | 1510005 | 60 | 20151030* |
| Euro OTC | Ethyl hydrogen fumarate calcium | 1601011 | 60 | 20160114* |
| Euro OTC | Ethyl hydrogen fumarate calcium | 2001042 | 40 | 20200331* |
| Fagron | Ethyl hydrogen fumarate calcium | 13B25-N08 | 60 | 1411090 |
| Euro OTC | Ethyl hydrogen fumarate magnesium | 1306014-01 | 60 | 20130805 |
| Euro OTC | Ethyl hydrogen fumarate magnesium | 1510006 | 60 | 20151030* |
| Euro OTC | Ethyl hydrogen fumarate magnesium | 1601010 | 60 | 20160114* |
| Euro OTC | Ethyl hydrogen fumarate magnesium | 1510006-01 | 40 | AR-18-FG-000547-01 |
| Fagron | Ethyl hydrogen fumarate magnesium | 13G10-N01 | 60 | 1411091 |
| Klenk | Euphrasy herb | 3871B100713 | 40 | 20100721 |

## F

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Famotidine | 24I05-B011 | 40 | not required |
| Fagron | Famotidine | 24I05-B008 | 40 | not required |
| Fagron | Famotidine | 24I05-B011 | 20 | not required |
| Fagron | Famotidine | 24I05-B008 | 20 | not required |
| Bombastus | Fennel, bitter | 289870 | 60 | AR-15-FG-008161-01 |
| Bombastus | Fennel, bitter | 24000576 | 30 | 20240129 |
| Caelo | Fennel, bitter | 12094708 | 40 | 20120411 |
| Caelo | Fennel, bitter | 12167102 | 40 | 20120705 |
| Caelo | Fennel, bitter | 13413702 | 40 | 1412549 |
| Caelo | Fennel, bitter | 14376403 | 60 | 20150108 |
| Caelo | Fennel, bitter | 161603 | 60 | 20160718* |
| Caelo | Fennel, bitter | 17020610 | 40 | 1708048 |
| Caelo | Fennel, bitter | 23002233002 | 30 | 20231212 |
| Klenk | Fennel, bitter | 2880N120418 | 40 | 1412547 |
| Klenk | Fennel, bitter | 2880N120418 | 40 | AR-15-FG-002805-02 |
| Klenk | Fennel, bitter | 2860A140613 | 60 | AR-15-FG-008160-01 |
| Klenk | Fennel, sweet | 2870A110412 | 40 | 20110421 |
| Klenk | Fennel, sweet | 2870A130304 | 40 | 1405154 |
| Fagron | Fenofibrate | 25C24-B004 | 40 | 20241130* |
| Fagron | Fenofibrate | 25B04-B007 | 40 | 20240830* |
| Fagron | Fenofibrate | 25C24-B004 | 20 | 20241130* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Fenofibrate | 25B04-B007 | 20 | 20240830* |
| Fagron | Fentanyl citrate | 16E26-B01-525360 | 40 | 2017A-03686 |
| Fagron | Fentanyl citrate | 16E26-B01-525360 | 40 | 2017A-03686 |
| Caelo | Fenugreek | 11313204 | 40 | 20111122 |
| Caelo | Fenugreek, powdered | 12149605 | 40 | 20120629 |
| Caelo | Fenugreek, powdered | 15308704 | 60 | AR-17-FG-006625-01 |
| Klenk | Fenugreek, powdered | 7264B130205 | 40 | 1408080 |
| Klenk | Fenugreek, powdered | 7264A151001 | 60 | AR-16-FG-014493-01 |
| Euro OTC | Fexofenadine hydrochloride | 2310018 | 20 | 20240222* |
| Caelo | Flax weed herb | 13007505 | 40 | 1403462 |
| Caelo | Flax weed herb | 14005309 | 60 | 20140203 |
| Caelo | Flax weed herb | 20003289005 | 30 | 20201130 |
| Audor | Fluconazole | AP061502911F | 60 | AR-16-FG-008733-01 |
| Audor | Fluconazole | AP061502911F | 40 | AR-16-FG-014225-01 |
| Audor | Fluconazole | AP061502911F | 40 | 20150821 |
| Audor | Fluconazole | APAFLNC0217023F | 40 | 20170421 |
| Audor | Fluconazole | AP061502911F | 60 | 20150821 |
| Audor | Fluconazole | AP061502911F | 40 | 20150821 |
| Audor | Fluconazole | AP061502911F | 40 | 20150821 |
| Caelo | Frangula bark | 12185901 | 40 | 20120710 |
| Caelo | Frankincense | 12120005 | 40 | 1402495 |
| Caelo | Frankincense | 13112801 | 40 | 20130503 |
| Euro OTC | Frankincense extract 80% | 1308020-01 | 60 | 8958 |
| Euro OTC | Frankincense extract 80% | 1602008 | 60 | 20160215* |
| Euro OTC | Frankincense extract 80% | 1602008 | 60 | 20160215* |
| Euro OTC | Frankincense extract 80% | 1611023-01 | 60 | 9889 |
| Caelo | Fraxinella root, cut | 10189103 | 40 | 20100804 |
| Caelo | Fraxinella root, cut | 11314705 | 40 | 20111115 |
| Caelo | Fraxinella root, cut | 11314705 | 80 | 20111115 |
| Caelo | Fraxinella root, cut | 14110802 | 60 | 20140428 |
| Caelo | Fumitory | 12103402 | 40 | 20120425 |

## G

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Galangal root | 12125001 | 40 | 20120516 |
| Caelo | Galangal root | 11375904 | 40 | 20120109 |
| Caelo | Galangal root | 12330305 | 40 | 1403491 |
| Caelo | Galangal root | 11375909 | 40 | 1403324 |
| Caelo | Galangal root | 12330308 | 40 | 20121203 |
| Caelo | Galangal root | 14159504 | 60 | 1511617 |
| Klenk | Galeopsis herb, cut | 3911A090219 | 40 | 20120426 |
| Caelo | Garden violet, cut | 10292002 | 40 | 20101014 |
| Caelo | Garden violet, cut | 13038703 | 40 | 1403481 |
| Caelo | Garden violet, cut | 13232103 | 40 | 20130821 |
| Caelo | Gentian root | 12244603 | 40 | 20120914 |
| Caelo | Gentian root, powdered | 12007103 | 50 | 1403630 |
| Caelo | Gentian root, powdered | 12007106 | 40 | 20120117 |
| Caelo | Gentian root, powdered | 13410503 | 40 | 1508394 |
| Caelo | Ginger | 14120701 | 40 | 20140516 |
| Caelo | Ginger | 13321904 | 40 | 20131016 |
| Klenk | Ginger, peeled, powdered | 6954B140724 | 60 | AR-15-FG-014915-01 |
| Klenk | Ginger, peeled, powdered | 6954B150325 | 60 | 1606616 |
| Klenk | Ginger, peeled, powdered | 6954B170127 | 60 | 1708675 |
| Fagron | Ginkgo biloba dry extract (NLT 24% of total flavonoids) | 24H27-B082 | 40 | 20240925* |
| Fagron | Ginkgo biloba dry extract (NLT 24% of total flavonoids) | 24H27-B082 | 20 | 20240925* |
| Caelo | Ginkgo extract | 12192505 | 40 | 1403672 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Ginkgo leaf | 12151703 | 40 | 20120613 |
| Caelo | Ginkgo leaf | 13340904 | 40 | 1411088 |
| Caelo | Ginkgo leaf | 13340907 | 60 | 20131028 |
| Caelo | Ginkgo leaf | 16281501 | 60 | 1708047 |
| Caelo | Ginkgo leaf | 24100105001 | 30 | 20241011 |
| Klenk | Ginkgo leaf | 2461B220718-01 | 30 | 20220802 |
| Caelo | Ginseng root | 12080208 | 40 | 20120329 |
| Caelo | Ginseng root | 11349206 | 40 | 20111227 |
| Caelo | Ginseng root | 13341008 | 40 | 20131029 |
| Caelo | Ginseng root | 13237805 | 40 | 20130816 |
| Fagron | Glucosamine sulfate potassium chloride | TSM-K-2404003 | 40 | 20240928* |
| Fagron | Glucosamine sulfate potassium chloride | TSM-K-2404002 | 20 | 20240928* |
| Fagron | Glucosamine sulfate potassium chloride | TSM-K-2404003 | 20 | 20240928* |
| Fagron | Glucosamine sulfate potassium chloride | TSM-K-2404001 | 20 | 20240928* |
| abcr GmbH | Glycyrrhizic acid | 1222024 | 40 | from supplier |
| Klenk | Goat's rue, cut | 3901C110905 | 40 | 20111005 |
| Klenk | Greater celandine herb | 3731K120904 | 40 | 20120920 |
| Klenk | Greek mountain herb, cut | 4511K130314 | 40 | 20130402 |
| Klenk | Green tea | 5100A100611 | 40 | 20120126 |
| Fagron | Green tea dry extract 50% | 24I12-B077 | 40 | 20241026* |
| Fagron | Green tea dry extract 50% | 24I05-B029 | 20 | 20241009* |
| Fagron | Green tea dry extract 50% | 24I25-B006 | 20 | 20241028* |
| Fagron | Green tea dry extract 50% | 24I12-B077 | 20 | 20241026* |
| Euro OTC | Griffonia seed extract | 1810009 | 40 | 20181025* |
| Fagron | Griffonia seed extract (L-5 Hydroxytryptophan) | 20240412 | 40 | not required |
| Fagron | Griffonia seed extract (L-5 Hydroxytryptophan) | 2024020 | 40 | not required |
| Fagron | Griffonia seed extract (L-5 Hydroxytryptophan) | 20240414 | 40 | not required |
| Fagron | Griffonia seed extract (L-5 Hydroxytryptophan) | 20240412 | 20 | not required |
| Fagron | Griffonia seed extract (L-5 Hydroxytryptophan) | 2024020 | 40 | not required |
| Fagron | Griffonia seed extract (L-5 Hydroxytryptophan) | 20240414 | 20 | not required |
| Caelo | Guaiacum wood | 11352001 | 40 | 1406340 |
| Caelo | Guaiacum wood | 11352012 | 40 | 20111222 |
| Caelo | Guaiacum wood | 13343802 | 40 | 20131113 |

## H

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Hamamelis bark, cut | 12361301 | 40 | 20121213 |
| Caelo | Hamamelis bark, cut | 12361303 | 40 | 20121213 |
| Caelo | Hamamelis leaf | 10102915 | 40 | 20100517 |
| Caelo | Hamamelis leaf | 13269902 | 40 | 1405176 |
| Caelo | Hamamelis leaf | 13269904 | 40 | 20130924 |
| Caelo | Hawthorn flower | 10157201 | 40 | 20100701 |
| Caelo | Hawthorn flower | 13010403 | 40 | 20130130 |
| Caelo | Hawthorn fruit | 11183010 | 40 | 20110701 |
| Caelo | Hawthorn fruit | 11278205 | 30 | 20111025 |
| Caelo | Hawthorn leaf with flower | 10273515 | 40 | 20101028 |
| Caelo | Hawthorn leaf with flower | 10273513 | 40 | 20101028 |
| Caelo | Hawthorn leaf with flower | 13276706 | 40 | 20130927 |
| Galke | Hawthorn leaf with flower | 21126 | 40 | 20121109 |
| Caelo | Heather flower, rubbed | 10270508 | 40 | 20101018 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Heather, cut | 11011209 | 40 | 20110218 |
| Caelo | Henna powder | 12122302 | 40 | from supplier |
| Caelo | Henna powder | 12267304 | 40 | from supplier |
| Bombastus | Hop strobile | 23003461 | 30 | 20230809 |
| Caelo | Hop strobile | 12008305 | 40 | 20120213 |
| Caelo | Hop strobile | 12221802 | 40 | 20120817 |
| Caelo | Hop strobile | 23001009005 | 30 | 20230823 |
| Caelo | Horse chestnut leaf | 11063503 | 40 | 20110315 |
| Fagron | Hydrocortisone butyrate | 13I26-N01 | 60 | AR-15-FG-000944-01 |
| Fagron | Hydrocortisone butyrate | 14D23-B01-296716 | 60 | 20140509 |
| Fagron | Hydrocortisone butyrate | 13I26-N01 | 60 | 20130920 |
| Fagron | Hydrocortisone butyrate | 16F20-B05-323903 | 40 | 20160805 |
| Fagron | Hydrocortisone butyrate | 15J12-B03-322394 | 40 | 20151028 |
| Fagron | Hydrocortisone butyrate | 16J21-B01-333229 | 40 | 20161206 |
| Fagron | Hydrocortisone butyrate | 16J21-B01-333229 | 40 | 20161206 |
| Fagron | Hydrocortisone butyrate | 14D23-B01-296716 | 48 | 20140509 |
| Fagron | Hydrocortisone butyrate | 13I26-N01 | 45 | 20130920 |
| Fagron | Hydrocortisone butyrate | 16F20-B05-323903 | 20 | 20160805 |
| Fagron | Hydrocortisone butyrate | 15J12-B03-322394 | 25 | 20151028 |
| Fagron | Hydrocortisone butyrate | 15J12-B03-322394 | 22 | 20151028 |
| Fagron | Hydrocortisone butyrate | 16J21-B01-333229 | 37 | 20161206 |
| Fagron | Hydrocortisone butyrate | 16J21-B01-333229 | 36 | 20161206 |
| EDQM | Hydrocortisone hydrogen succinate | 3.0 | 40 | CRS |
| Caelo | Hydromorphone hydrochloride | 16123804 | 40 | 1917R-01334 |
| Caelo | Hydromorphone hydrochloride | 18316002 | 40 | 1919M-01334 |
| Caelo | Hydromorphone hydrochloride | 16123804 | 40 | 1917R-01334 |
| Caelo | Hydromorphone hydrochloride | 18316002 | 40 | 1919M-01334 |
| Fagron | Hydromorphone hydrochloride | 17F01-B01-337510 | 40 | 1919I-01334 |
| Fagron | Hydromorphone hydrochloride | 15L08-B08-316877 | 40 | 1917Q-01334 |
| Fagron | Hydromorphone hydrochloride | 17F01-B01-337510 | 40 | 1919I-01334 |
| Caelo | Hydroxychloroquine sulfate | 20001292 | 40 | 20200427* |
| Fagron | Hydroxychloroquine sulfate | 24I05-B042 | 40 | 20240926* |
| Fagron | Hydroxychloroquine sulfate | 25B20-B021 | 20 | 20250319* |
| Fagron | Hydroxychloroquine sulfate | 24I05-B042 | 20 | 20240926* |
| Fagron | Hydroxychloroquine sulfate | 24I05-B040 | 20 | 20240926* |

## I

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Indigo carmine | 13K12-N01 | 40 | 1601099 |
| Spinnrad | Inulin | 1112300433 | 40 | from supplier |
| Caelo | Iodine | 181635 | 40 | 20180704* |
| Caelo | Iron(II) sulfate heptahydrate | 11340509 | 40 | 1401568 |
| Caelo | Iron(III) chlorid hexahydrate | 12354703 | 40 | 1401391 |
| Caelo | Iron(III) chlorid hexahydrate | 22000819 | 40 | 20220323* |
| Caelo | Iron(III) chlorid hexahydrate | 24002426 | 40 | 20241021* |
| Caelo | Iron(III) chlorid hexahydrate | 22000819 | 10 | 20220323* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Iron(III) chlorid hexahydrate | 24002426 | 20 | 20241021* |
| Caelo | Iron(III) sulfate hydrate | 170991 | 40 | 20170523* |
| EDQM | Isoconazole | 1.1 | 40 | CRS |
| EDQM | Isoconazole nitrate | 1.1 | 40 | CRS |
| Caelo | Isomalt | 170812 | 40 | 20170421* |
| Caelo | Ispaghula husks | 12148103 | 40 | 20120628 |
| Caelo | Ispaghula seed | 11185807 | 40 | 20110727 |
| Caelo | Ivy leaf, cut | 11229505 | 40 | 20110829 |
| Caelo | Ivy leaf, cut | 13276304 | 40 | 20130913 |

**J**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Jasmine flower | 12143201 | 40 | 20120606 |
| Caelo | Java tea | 12225702 | 40 | 20120809 |
| Caelo | Java tea | 13258805 | 40 | 20130826 |
| Klenk | Java tea | 2221B110718 | 40 | 20120605 |
| Caelo | Juniper berry | 12028609 | 40 | 20120207 |
| Caelo | Juniper berry | 13267210 | 40 | 20130828 |
| Caelo | Juniper berry, pounded | 12278903 | 40 | 1405296 |
| Klenk | Juniper berry, powdered | 2894B130320 | 40 | 1411362 |
| Klenk | Juniper berry, powdered | 2894B150922 | 60 | 1704439 |

**K**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Euro OTC | Kaolin, heavy | 2303011 | 40 | 20230412* |
| Euro OTC | Kaolin, heavy | 2303011 | 20 | 20230412* |
| Caelo | Kaolin, red | 12093503 | 40 | from supplier |
| Caelo | Kap-Aloe | 14087106 | 60 | 20140404 |
| Euro OTC | Ketotifen hydrogen fumarate | 2109027 | 50 | 20211026* |
| Euro OTC | Ketotifen hydrogen fumarate | 2304008 | 40 | 20230420* |
| Euro OTC | Ketotifen hydrogen fumarate | 2109027 | 10 | 20211026* |
| Euro OTC | Ketotifen hydrogen fumarate | 2304008 | 20 | 20230420* |
| Caelo | Kidney vetch, coarsely rubbed | 10249206 | 40 | 20100928 |
| Caelo | Knotgrass | 14079304 | 40 | 20140402 |
| Klenk | Knotgrass | 4301A120912 | 40 | 20120924 |

**L**

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Lady's bedstraw herb | 11265103 | 40 | 20111006 |
| Klenk | Lady's bedstraw herb | 3921B101012 | 40 | 20111216 |
| Caelo | Lapacho wood, cut | 12239305 | 40 | 20120831 |
| Caelo | Lapis Pumicis | 180533 | 40 | 20180222* |
| Caelo | Laurel leaf | 12299103 | 40 | 20121108 |
| Klenk | Laurel leaf, powdered | 2124A110329 | 40 | 1411032 |
| Klenk | Laurel leaf, powdered | 2124A110329 | 60 | 20140310 |
| Bombastus | Lavender flower | 24000229 | 30 | 20240111 |
| Caelo | Lavender flower | 12088003 | 60 | 20120411 |
| Caelo | Lavender flower | 13336005 | 40 | from supplier |
| Caelo | Lavender flower | 23001761001 | 30 | 20231129 |
| Euro OTC | L-Carnitine tartrate | 1708023 | 40 | 20170907* |
| Euro OTC | L-Carnitine tartrate | 2007043 | 40 | 20200810* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Euro OTC | L-Carnitine tartrate | 2105018 | 50 | 20210625* |
| Euro OTC | L-Carnitine tartrate | 2207004 | 40 | 20221213* |
| Euro OTC | L-Carnitine tartrate | 2305008 | 40 | 20230718* |
| Fagron | L-Carnitine tartrate | 10100220240309 | 20 | 20260228* |
| Pharmorgana | L-Carnitine tartrate | 1000160672 | 40 | from supplier |
| Pharmorgana | L-Carnitine tartrate | 1000170113 | 40 | from supplier |
| Caelo | Lemon peel, cut | 12217402 | 40 | 20120823 |
| Caelo | Lemon verbena leaf, cut | 12137505 | 40 | 20120605 |
| Caelo | Lemon verbena leaf, cut | 12137503 | 40 | 20120605 |
| Flora Apot… | Levamisole hydrochloride | LV19305 | 40 | from supplier |
| Caelo | Lime flower | 11086305 | 55 | 20110420 |
| Caelo | Linseed | 12092102 | 60 | 20120402 |
| Caelo | Linseed | 13296703 | 40 | 20131008 |
| Fagron | Lipoic acid | 24I11-B022 | 40 | 20241108* |
| Fagron | Lipoic acid | 24I03-B070 | 20 | 20241210* |
| Fagron | Lipoic acid | 24I11-B022 | 20 | 20241108* |
| Fagron | Lipoic acid | 24C12-B023-205920 | 20 | 20240322* |
| Caelo | Liqourice root | 12267103 | 40 | 20120917 |
| Caelo | Liqourice root, peeled | 12227101 | 40 | 20120813 |
| Caelo | Liqourice root, peeled | 12227106 | 40 | 20120813 |
| Caelo | Liquorice | 13068904 | 40 | 20130315 |
| Caelo | Liquorice | 14050601 | 60 | from supplier |
| Caelo | Liquorice | 13180904 | 60 | 20130613 |
| Fagron | L-Malic acid | 15J09-B03-313987 | 60 | 9346 |
| Fagron | L-Malic acid | 15J09-B03-313987 | 40 | 20151106 |
| Fagron | L-Malic acid | 15J09-B03-313987 | 40 | 20151106 |
| Fagron | L-Malic acid | 16J06-B98-327269 | 40 | 20161117 |
| Fagron | L-Malic acid | 16J06-B98-327269 | 40 | 20161117 |
| Fagron | L-Malic acid | 17E23-B03-335458 | 40 | 20170621 |
| Caelo | Locust bean gum, powdered | 10376516 | 40 | 20110106 |
| Caelo | Locust bean gum, powdered | 13379403 | 40 | from supplier |
| Fagron | Losartan potassium | 23F22-B037-106397 | 40 | not required |
| Fagron | Losartan potassium | D5440-24-006 | 20 | 20240410* |
| Fagron | Losartan potassium | 23F22-B037-106397 | 20 | not required |
| Caelo | Lovage root | 11181609 | 40 | 20110629 |
| Fagron | Lutein 10% | 24I10-B006 | 40 | not required |
| Fagron | Lutein 10% | 24I10-B006 | 20 | not required |
| Fagron | Lutein 10% | 24I26-B053 | 20 | not required |

## M

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Macrogols 6000 powder | 14C11-B01-296014 | 60 | 20140324 |
| Fagron | Macrogols 6000 powder | 14J17-B01-309247 | 60 | 20141027 |
| Fagron | Macrogols 6000 powder | 14J17-B01-309247 | 60 | AR-16-FG-011486-01 |
| Caelo | Magensium hydrogen phosphate trihydrate | 12181911 | 40 | 20120716 |
| Fagron | Magnesium aspartate dihydrate | 15I24-B89-313231 | 60 | AR-16-FG-008660-03 |
| Fagron | Magnesium aspartate dihydrate | 15I24-B89-313231 | 60 | 20151016 |
| Fagron | Magnesium aspartate dihydrate | 17C21-B05-333111 | 40 | 20170412 |
| Fagron | Magnesium aspartate dihydrate | 18D23-B01-350069 | 40 | 20180625 |
| Euro OTC | Magnesium carbonate, light, basic | 1711011-01 | 40 | 20171116 |
| Euro OTC | Magnesium carbonate, light, basic | 2201023 | 40 | 20220317* |
| Euro OTC | Magnesium carbonate, light, basic | 2201023 | 20 | 20220317* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| VWR Intern... | Magnesium chloride 4,5-hydrate | 22E054108 | 40 | not required |
| Caelo | Magnesium hydroxide | 16253301 | 30 | 20160921 |
| Euro OTC | Magnesium oxide, heavy | 1709011-02 | 40 | 20170915 |
| Caelo | Magnesium oxide, light | 180818 | 40 | 20180322* |
| Caelo | Magnesium sulfate, dried | 172990 | 40 | 20171129* |
| Euro OTC | Magnesium trisilicate hydrate | 1608024-01 | 40 | 20160908 |
| Bombastus | Maize style | 274920 | 40 | 66662 |
| Caelo | Maize style | 10325906 | 40 | 20101217 |
| Caelo | Maize style | 13381501 | 40 | 20140103 |
| Klenk | Maize style | 5581A111206 | 40 | 20111214 |
| Caelo | Male speedwell wort | 12162503 | 40 | 20120703 |
| Caelo | Mallow flower | 12187405 | 40 | 20120719 |
| Caelo | Mallow leaf | 12153403 | 40 | 20120614 |
| Caelo | Manna | 11308907 | 60 | 20111117 |
| Caelo | Manna | 13127007 | 40 | 20130424 |
| Caelo | Manna, powdered | 11308807 | 40 | 1403534 |
| Caelo | Manna, powdered | 14001401 | 40 | 20140115 |
| Caelo | Marian thistle fruit | 11126703 | 40 | 20110608 |
| Caelo | Marian thistle fruit | 13342002 | 40 | from supplier |
| Caelo | Marian thistle herb | 10365601 | 40 | 20110111 |
| Caelo | Marshmallow leaf | 12328206 | 40 | 20121114 |
| Caelo | Masterwort root, cut | 12101804 | 60 | 20120405 |
| Caelo | Masterwort root, cut | 13341204 | 40 | 20131030 |
| Caelo | Maté leaf | 11091707 | 40 | 20110428 |
| Caelo | Maté leaf | 13118004 | 40 | 20130506 |
| Caelo | Maté leaf | 24100015001 | 30 | 20240610 |
| Galke | Maté leaf | 21684 | 40 | from supplier |
| Bombastus | Matricaria flower | 24004030 | 30 | 20240926 |
| Caelo | Matricaria flower | 12294804 | 40 | 20121113 |
| Caelo | Matricaria flower | 12337605 | 40 | 20121122 |
| Caelo | Matricaria flower | 24100110001 | 30 | 20241031 |
| Caelo | Matricaria flower for bathing | 12115805 | 40 | from supplier |
| Klenk | Meadowsweet | 4541A120313 | 60 | 20120327 |
| Caelo | Meadowsweet flower, rubbed | 12275701 | 40 | 20121023 |
| EDQM | Medroxyprogesterone - acetate | 3.0 | 40 | CRS |
| Bombastus | Mellisa leaf | 24001976 | 30 | 20240423 |
| Caelo | Mellisa leaf | 12032318 | 40 | 20120302 |
| Caelo | Mellisa leaf | 13214713 | 40 | 20130806 |
| Caelo | Mellisa leaf | 24100001001 | 30 | 20240502 |
| Galke | Mellisa leaf | 22218 | 40 | from supplier |
| Klenk | Mellisa leaf | 2161A090630 | 130 | 20120328 |
| Klenk | Mellisa leaf | 2161A121029 | 55 | 20121113 |
| Caelo | Methadone hydrochloride | 16135309 | 40 | 1917R-02949 |
| Caelo | Methadone hydrochloride | 18132413 | 40 | 1919Q-02949 |
| Caelo | Methadone hydrochloride | 16135309 | 40 | 1917R-02949 |
| Caelo | Methadone hydrochloride | 18132413 | 40 | 1919Q-02949 |
| Fagron | Methadone hydrochloride | 18G02-B02-355990 | 40 | 1919I-02949 |
| Fagron | Methadone hydrochloride | 16F24-B02-323183 | 40 | 1917Q-02949 |
| Fagron | Methadone hydrochloride | 18G02-B02-355990 | 40 | 1919I-02949 |
| Th. Geyer | Methadone hydrochloride | 067055 | 40 | 1917S-02949 |
| Th. Geyer | Methadone hydrochloride | 067055 | 40 | 1917S-02949 |
| EDQM | Methylprednisolone acetate | 2.0 | 20 | CRS |
| EDQM | Methylprednisolone hydrogen succinate | 3.0 | 40 | CRS |
| Caelo | Methylrosanilinium chloride | 12276308 | 40 | 1509299 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Methylrosanilinium chloride | 13H28-N03 | 60 | 20130625 |
| Fagron | Methylrosanilinium chloride | 13H28-N03 | 60 | AR-15-FG-004742-01 |
| USP | Metoprolol succinate | R11100 | 40 | CRS |
| Fagron | Metronidazole benzoate | 22A17-B10-216356 | 40 | 20220607 |
| Fagron | Metronidazole benzoate | 24D16-B04-003377 | 40 | 20240808 |
| Fagron | Metronidazole benzoate | 22A17-B10-216356 | 20 | 20220607 |
| Fagron | Metronidazole benzoate | 24D16-B04-003377 | 20 | 20240808 |
| Th. Geyer | Mg-Ca-K colamine phosphate | 54610 | 40 | from supplier |
| Dr. K. Hol... | Miconazole | 029C064 | 40 | 20190415 |
| Fagron | Midazolam | 13K05-N01 | 40 | 0914E-07393 |
| Fagron | Midazolam | 14C12-B31-313222 | 60 | 1516A-07393 |
| Fagron | Midazolam | 16J03-B09-326963 | 40 | 1917Q-07393 |
| Fagron | Midazolam | 17J16-B01-342518 | 40 | 1919I-07393 |
| Fagron | Midazolam | 13K05-N01 | 60 | 0914E-07393 |
| Fagron | Midazolam | 14C12-B31-313222 | 60 | 1516A-07393 |
| Fagron | Midazolam | 16J03-B09-326963 | 30 | 1917Q-07393 |
| Fagron | Midazolam | 17J16-B01-342518 | 40 | 1919I-07393 |
| Caelo | Midazolam hydrochloride | 15224611 | 40 | 1917S-03538 |
| Caelo | Midazolam hydrochloride | 15224611 | 30 | 1917S-03538 |
| Fagron | Midazolam hydrochloride | 15J07-B01-320717 | 40 | 1917Q-03538 |
| Fagron | Midazolam hydrochloride | 18B28-B05-354856 | 40 | 1919J-03538 |
| Fagron | Midazolam hydrochloride | 15J07-B01-320717 | 30 | 1917Q-03538 |
| Fagron | Midazolam hydrochloride | 15H04-B03-314396 | 30 | 1917R-03538 |
| Fagron | Midazolam hydrochloride | 18B28-B05-354856 | 40 | 1919J-03538 |
| Fagron | Minoxidil sulfate | 01801022406016 | 40 | 20241230* |
| Fagron | Minoxidil sulfate | 01801022407017 | 20 | 20241230* |
| Fagron | Minoxidil sulfate | 01801022406016 | 20 | 20241230* |
| Fagron | Minoxidil sulfate | 01801022405015 | 20 | 20240930* |
| MEDICHEM S.A. | Mirtazapine | A-180132 | 50 | 20180312 |
| MEDICHEM S.A. | Mirtazapine | A-210100 | 50 | 20210211 |
| MEDICHEM S.A. | Mirtazapine | 2024A152 | 40 | 20241023 |
| MEDICHEM S.A. | Mirtazapine | A-180132 | 50 | 20180312 |
| MEDICHEM S.A. | Mirtazapine | A-210100 | 50 | 20210211 |
| MEDICHEM S.A. | Mirtazapine | 2024A152 | 40 | 20241023 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 12153212 | 40 | 0914F-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 11333103 | 40 | 0914E-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 15255703 | 60 | 1416Q-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 15295802 | 40 | 1917R-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 17331510 | 40 | 2319I-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 12153212 | 60 | 0914F-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 11333103 | 60 | 0914E-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 15255703 | 60 | 1416Q-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 15295802 | 40 | 1917R-07776 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 17331510 | 40 | 2319I-07776 |
| Fagron | Morphine hemisulfate 2.5-hydrate | 13J07-N04 | 40 | 0914G-07776 |
| Fagron | Morphine hemisulfate 2.5-hydrate | 14F02-B06-315405 | 40 | 1917Q-07776 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Morphine hemisulfate 2.5-hydrate | 13J07-N04 | 60 | 0914G-07776 |
| Fagron | Morphine hemisulfate 2.5-hydrate | 14F02-B06-315405 | 40 | 1917Q-07776 |
| Caelo | Morphine hydrochloride trihydrate | 15439411 | 40 | 1917R-01879 |
| Caelo | Morphine hydrochloride trihydrate | 18188607 | 40 | 1919Q-01879 |
| Caelo | Morphine hydrochloride trihydrate | 16184605 | 40 | 1917S-01879 |
| Caelo | Morphine hydrochloride trihydrate | 15439411 | 40 | 1917R-01879 |
| Caelo | Morphine hydrochloride trihydrate | 18188607 | 40 | 1919Q-01879 |
| Fagron | Morphine hydrochloride trihydrate | 16D21-B02-322088 | 40 | 1917Q-01879 |
| Fagron | Morphine hydrochloride trihydrate | 17F22-B01-338170 | 40 | 1919I-01879 |
| Fagron | Morphine hydrochloride trihydrate | 16D21-B02-322088 | 40 | 1917Q-01879 |
| Fagron | Morphine hydrochloride trihydrate | 17F22-B01-338170 | 40 | 1919I-01879 |
| Klenk | Motherwort | 4071A121211 | 40 | 20130104 |
| Caelo | Mullein flower | 11366403 | 40 | 20120105 |
| Caelo | Mullein flower, cut | 11233402 | 60 | 20110914 |
| Caelo | Myrrh | 12269901 | 40 | 1403470 |
| Klenk | Myrrh | 3355B120628 | 40 | AR-15-FG-000945-01 |

## N

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Euro OTC | N-Acetyltyrosine | 2307037 | 40 | 20230915* |
| Euro OTC | N-Acetyltyrosine | 2501041 | 40 | 20250305* |
| Euro OTC | N-Acetyltyrosine | 2307037 | 20 | 20230915* |
| Euro OTC | N-Acetyltyrosine | 2501041 | 20 | 20250305* |
| Caelo | Nettle leaf | 12184702 | 40 | 20120628 |
| Galke | Nettle leaf | 21238 | 40 | from supplier |
| Caelo | Nettle root | 11254903 | 40 | 20111121 |
| Caelo | Nettle seed | 12131507 | 40 | 1402203 |
| Caelo | Nettle seed | 11126211 | 40 | 20110504 |
| Caelo | Nettle seed | 13387110 | 40 | 1410300 |
| Klenk | Nettle seed | 7470A111117 | 40 | 20111130 |
| Klenk | Nettle seed | 7470A221024-02 | 30 | 20221122 |
| Caelo | Nutmeg | 22002543003 | 30 | 20221004 |

## O

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Oak bark | 10348617 | 40 | 20101221 |
| Caelo | Oak bark | 11351207 | 40 | 1403492 |
| Caelo | Oak bark | 13360306 | 40 | 20131203 |
| Caelo | Oak bark, powdered | 11235004 | 40 | 20110909 |
| Caelo | Oat straw | 11280008 | 40 | 20111020 |
| Caelo | Olive leaf | 11270106 | 40 | 20111013 |
| Caelo | Olive leaf | 12316808 | 60 | AR-15-FG-001051-01 |
| Fagron | Ondansetron hydrochloride dihydrate | 24H07-H03-00987 | 40 | 20240808 |
| Fagron | Ondansetron hydrochloride dihydrate | 24H07-H03-00987 | 20 | 20240808 |
| Fagron | Orlistat | 2406002 | 40 | 20240906* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Orlistat | 6012307007-01 | 40 | 20230524* |
| Fagron | Orlistat | 6012307004-01 | 20 | 20240523* |
| Fagron | Orlistat | 6012307003-02 | 20 | 20240526* |
| Fagron | Orlistat | 2406002 | 20 | 20240906* |
| Fagron | Orlistat | 6012307007-01 | 20 | 20230524* |
| Fagron | Orphenadrine citrate | 24J01-B007 | 40 | not required |
| Fagron | Orphenadrine citrate | 24I03-B081 | 40 | not required |
| Fagron | Orphenadrine citrate | 24J01-B007 | 20 | not required |
| Fagron | Orphenadrine citrate | 24I03-B081 | 20 | not required |
| Caelo | Orris root | 12206802 | 40 | 20120813 |
| Caelo | Oxycodone hydrochloride | 12268908 | 40 | 0914E-07734 |
| Caelo | Oxycodone hydrochloride | 12034515 | 40 | 0914F-07734 |
| Caelo | Oxycodone hydrochloride | 12268914 | 60 | 1416Q-07734 |
| Caelo | Oxycodone hydrochloride | 12268913 | 60 | 1416R-07734 |
| Caelo | Oxycodone hydrochloride | 15220205 | 40 | 2017A-07734 |
| Caelo | Oxycodone hydrochloride | 17270202 | 40 | 1919Q-07734 |
| Caelo | Oxycodone hydrochloride | 12268908 | 60 | 0914E-07734 |
| Caelo | Oxycodone hydrochloride | 12034515 | 60 | 0914F-07734 |
| Caelo | Oxycodone hydrochloride | 12268914 | 60 | 1416Q-07734 |
| Caelo | Oxycodone hydrochloride | 12268913 | 60 | 1416R-07734 |
| Caelo | Oxycodone hydrochloride | 15220205 | 40 | 2017A-07734 |
| Caelo | Oxycodone hydrochloride | 17270202 | 40 | 1919Q-07734 |
| EDQM | Oxytetracycline | 8.0 | 40 | CRS |

## P

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Pale coneflower root | 12244501 | 40 | 20120817 |
| Caelo | Pale coneflower root | 14120602 | 40 | 20140417 |
| Caelo | Pancreas powder | 13118902 | 40 | 1402190 |
| Caelo | Pancreas powder | 13395203 | 60 | 20131218 |
| Caelo | Pancreas powder | 161397 | 60 | 20160527* |
| Caelo | Pancreas powder | 16139708 | 40 | 20160527 |
| Caelo | Pancreas powder | 16139708 | 40 | 20160527 |
| Caelo | Pancreas powder | 173226 | 40 | 20180125* |
| Caelo | Pancreas powder | 20002501001 | 40 | 20200929 |
| Klenk | Parsley herb, rubbed | 4262A091116 | 60 | 20110719 |
| Caelo | Parsley root | 12080301 | 40 | 20120329 |
| Klenk | Passionflower herb | 4231A120329 | 40 | 20120419 |
| Klenk | Peony root, cut | 6421B120327 | 60 | 20120403 |
| Caelo | Pepper | 11193905 | 40 | 20110727 |
| Caelo | Pepper | 12192311 | 40 | 1403490 |
| Caelo | Pepper | 13221114 | 40 | 20130805 |
| Caelo | Pepper | 23001971003 | 30 | - |
| Caelo | Pepper | 24100075001 | 30 | 20240924 |
| Bombastus | Peppermint leaf | 24003080 | 30 | 20240716 |
| Caelo | Peppermint leaf | 11347607 | 40 | 20111220 |
| Caelo | Peppermint leaf | 11294401 | 40 | 20111104 |
| Caelo | Peppermint leaf | 12321503 | 130 | 20121026 |
| Caelo | Peppermint leaf | 13288303 | 40 | 20131002 |
| Caelo | Peppermint leaf | 24100035002 | 30 | 20240717 |
| Galke | Peppermint leaf | 20244 | 40 | 20120518 |
| Galke | Peppermint leaf | 19537 | 40 | from supplier |
| Fagron | Phenibut | 24I24-B021 | 40 | 20241127* |
| Fagron | Phenibut | 24H26-B009 | 20 | 20240917* |
| Fagron | Phenibut | 24I24-B021 | 20 | 20241127* |
| Fagron | Phenibut | 24I12-B037 | 20 | 20241016* |
| Fagron | Phenobarbital | 16G20-B04-328344 | 40 | 2017B-01040 |
| Fagron | Phenobarbital | 16G20-B04-328344 | 40 | 2017B-01040 |
| Th. Geyer | Phenobarbital | 067056 | 40 | 2017A-01040 |
| Caelo | Phenol | 23002846 | 40 | 20231108* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Phenol | 24001307 | 40 | 20240701* |
| Caelo | Phenol | 24001307 | 20 | 20240701* |
| Fagron | Phenolphthalein | 20G24-F01-375331 | 40 | 20201202 |
| Fagron | Phenolphthalein | 22J07-B02-227243 | 40 | 20221102 |
| Fagron | Phenolphthalein | 20G24-F01-375331 | 20 | 20201202 |
| Fagron | Phenolphthalein | 22J07-B02-227243 | 20 | 20221102 |
| Caelo | Pine sprouts, cut | 11164708 | 60 | 20110610 |
| Caelo | Pine sprouts, cut | 13256105 | 40 | 20130828 |
| Fagron | Pinus pinaster dry extract 95% | 24I05-B058 | 40 | 20240326* |
| Fagron | Pinus pinaster dry extract 95% | 24I05-B046 | 20 | 20240417* |
| Fagron | Pinus pinaster dry extract 95% | 25C26-B010 | 20 | 20240805* |
| Fagron | Pinus pinaster dry extract 95% | 24I05-B058 | 20 | 20240326* |
| Caelo | Piper cubeba | 11081903 | 37 | 20110404 |
| Fagron | Piperine (NLT 98%) | 25C22-B034 | 40 | 20241029* |
| Fagron | Piperine (NLT 98%) | 25D05-B008 | 20 | 20250306* |
| Fagron | Piperine (NLT 98%) | 25E06-B006 | 20 | 20250312* |
| Fagron | Piperine (NLT 98%) | 25C22-B034 | 20 | 20241029* |
| Fagron | Piracetam | 25A23-B041 | 40 | 20250315* |
| Fagron | Piracetam | 25A23-B041 | 20 | 20250315* |
| Fagron | Piracetam | 25B15-B041 | 20 | 20250312* |
| Fagron | Piracetam | 24I10-B067 | 20 | 20241127* |
| Fagron | Piroctone Olamine | 24I05-B063 | 40 | 20240926* |
| Fagron | Piroctone Olamine | 24I05-B063 | 20 | 20240926* |
| Fagron | Piroctone Olamine | 24J03-B068 | 20 | 20241101* |
| Fagron | Piroctone Olamine | 24I03-B001 | 20 | 20241011* |
| Fagron | Piroxicam | 24H20-B004 | 40 | 20241028* |
| Fagron | Piroxicam | VLSPRM0022425 | 20 | 20240512* |
| Fagron | Piroxicam | 24H20-B004 | 20 | 20241028* |
| Fagron | Piroxicam | 23K01-B060-201815 | 20 | 20231202* |
| Caelo | Podophyllum resin (from podophyllum peltatum) | 12287810 | 40 | 1405242 |
| Caelo | Potassium bromide | 11208211 | 40 | 20110803 |
| Caelo | Potassium carbonate | 180995 | 40 | 20180412* |
| Caelo | Potassium hydrogen tartrate | 11345805 | 40 | 20120103 |
| Caelo | Potassium hydrogen tartrate | 15354609 | 40 | 20151030 |
| Caelo | Potassium hydrogen tartrate | 170656 | 40 | 20170511* |
| Caelo | Potassium hydrogen tartrate | 17065604 | 40 | 20170511 |
| Caelo | Potassium hydrogen tartrate | 17065603 | 40 | 20170511 |
| Caelo | Potassium hydrogen tartrate | 182051 | 40 | 20180903* |
| Caelo | Potassium hydrogen tartrate | 20001056 | 40 | 20200513* |
| Caelo | Potassium hydrogen tartrate | 22001645 | 40 | 20220701* |
| Caelo | Potassium hydrogen tartrate | 22001645 | 20 | 20220701* |
| Caelo | Potassium hydroxide | 180083 | 40 | 20180118* |
| Caelo | Potassium iodide | 11090222 | 40 | 20110415 |
| Caelo | Potassium metabisulfite | 12325906 | 40 | 20121106 |
| Caelo | Potassium monohydrogen phosphate | 12366501 | 40 | 10401307 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Potassium monohydrogen phosphate | 21001529 | 50 | 20210712* |
| Caelo | Potassium nitrate | 12236703 | 40 | 20120807 |
| Euro OTC | Potassium orotate | 1203038V-02 | 40 | from supplier |
| Flora Apot… | Potassium orotate | ORK00119 | 40 | from supplier |
| Euro OTC | Potassium permanganate | 1708016-02 | 40 | 20170824 |
| Caelo | Potassium sodium tartrate tetrahydrate | 12030207 | 40 | 20120213 |
| Caelo | Potassium sodium tartrate tetrahydrate | 13216605 | 40 | 1404530 |
| Caelo | Potassium sodium tartrate tetrahydrate | 14376001 | 60 | 20150204 |
| Caelo | Potassium sodium tartrate tetrahydrate | 15375607 | 40 | 20151030 |
| Caelo | Potassium sodium tartrate tetrahydrate | 172577 | 40 | 20171128* |
| Caelo | Potassium sodium tartrate tetrahydrate | 20000750003 | 40 | 20200506 |
| Caelo | Potassium tartrate hemihydrate | 13331101 | 40 | 1403536 |
| Caelo | Potassium tartrate hemihydrate | 13331104 | 60 | 20131002 |
| Caelo | Potassium tartrate hemihydrate | 15167701 | 60 | 20150608 |
| Caelo | Potassium tartrate hemihydrate | 160289 | 60 | 20160405* |
| Caelo | Potassium tartrate hemihydrate | 182203 | 40 | 20180907* |
| Caelo | Potassium tartrate hemihydrate | 192911 | 40 | 20191125* |
| Caelo | Potassium tartrate hemihydrate | 193079 | 40 | 20191125* |
| Sigma-Aldrich | Prednisolone pivalate | P2805000 | 40 | CRS |
| Caelo | Primrose flower | 11206806 | 100 | 20110809 |
| Caelo | Primrose flower | 11268002 | 40 | 20111007 |
| Caelo | Primrose root, cut | 12064506 | 40 | 20120319 |
| Caelo | Promethazine hydrochloride | 13119214 | 60 | 20130506 |
| Caelo | Promethazine hydrochloride | 161466 | 40 | 20160621* |
| Caelo | Promethazine hydrochloride | 17058601 | 40 | 20170310 |
| Caelo | Promethazine hydrochloride | 170586 | 40 | 20170310* |
| Caelo | Propolis extract (96%) 2:1 | 11124120 | 40 | 1403460 |
| Caelo | Propolis extract (96%) 2:1 | 13396103 | 40 | 20131212 |
| Caelo | Propolis extract (96%) 2:1 | 13396103 | 40 | 20131212 |
| Caelo | Psyllium seed | 10291206 | 40 | 20101119 |
| Caelo | Psyllium seed | 10291205 | 80 | 20101119 |
| Caelo | Psyllium seed | 13305903 | 40 | 20131011 |
| Fagron | Pullulan | 24H27-B078 | 20 | 20240916* |
| Caelo | Pumpkin seed | 12249002 | 40 | 1404542 |
| Caelo | Pumpkin seed | 12249006 | 40 | 20120917 |

## Q

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Quercetin dihydrate | 24J14-B043 | 40 | 20240430* |
| Fagron | Quercetin dihydrate | 25E09-B033 | 20 | 20250218* |
| Fagron | Quercetin dihydrate | 24J14-B043 | 20 | 20240430* |
| Fagron | Quercetin dihydrate | 25F10-B044 | 20 | 20250523* |
| Caelo | Quinine dihydrochloride | 16269603 | 40 | 1709386 |
| Caelo | Quinine dihydrochloride | 16269603 | 40 | 20161021 |
| Caelo | Quinine dihydrochloride | 162696 | 40 | 20161021* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Quinine dihydrochloride | 172129 | 40 | 20173008* |
| Caelo | Quinine dihydrochloride | 172072 | 40 | 20170830* |
| Caelo | Quinolinol sulfate potassium sulfate | 13071104 | 40 | 1403095 |
| Caelo | Quinolinol sulfate potassium sulfate | 13403501 | 60 | 20131218 |
| Caelo | Quinolinol sulfate potassium sulfate | 15147704 | 40 | 20150618 |
| Caelo | Quinolinol sulfate potassium sulfate | 15147704 | 40 | 20150618 |
| Caelo | Quinolinol sulfate potassium sulfate | 162218 | 40 | 20160808* |
| Caelo | Quinolinol sulfate potassium sulfate | 16221809 | 40 | 20160808 |

## R

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Ramsons herb | 12380801 | 40 | 1404538 |
| Caelo | Ramsons herb | 13072801 | 40 | 20130326 |
| Caelo | Raspberry leaf | 12362701 | 40 | 20121219 |
| Caelo | Red poppy petals, cut | 12008104 | 40 | 20120131 |
| Caelo | Red-rose Flower | 11299204 | 40 | from supplier |
| Caelo | Red-rose petal | 11304912 | 40 | 20111107 |
| Caelo | Redwood, cut | 12049604 | 40 | 20120229 |
| Caelo | Restharrow root | 12330001 | 40 | 20121127 |
| Klenk | Restharrow root | 6411B130404 | 40 | 20130507 |
| Fagron | Resveratrol | 24I18-B028 | 40 | 20241008* |
| Fagron | Resveratrol | 24I18-B025 | 40 | 20241008* |
| Fagron | Resveratrol | 24I18-B028 | 20 | 20241008* |
| Fagron | Resveratrol | 24I18-B025 | 20 | 20241008* |
| Caelo | Rhubarb | 12211906 | 40 | 20120827 |
| Caelo | Rhubarb | 13235213 | 40 | 20130822 |
| Caelo | Rhubarb, powdered | 11043818 | 60 | 1403280 |
| Caelo | Rhubarb, powdered | 16009901 | 60 | 9886 |
| Euro OTC | Ribavirin | 1304027-01 | 45 | AR-16-FG-007485-01 |
| Euro OTC | Ribavirin | 1308001 | 45 | 20130902* |
| Euro OTC | Ribavirin | 1604012 | 40 | 20160428* |
| Euro OTC | Ribavirin | 1304027-02 | 40 | 20160429 |
| Caelo | Ribwort plantain | 12362902 | 40 | 20121220 |
| Caelo | Rifampicin | 152446 | 40 | 20150831* |
| Caelo | Rifaximin | 161053 | 60 | 20160607* |
| Caelo | Rose hips peel | 11301407 | 60 | 20111110 |
| Klenk | Rose hips seed | 7240A120402 | 60 | 20120404 |
| Caelo | Rose hips with peel, cut | 12064202 | 40 | 20120328 |
| Caelo | Rose hips with peel, cut | 11232204 | 40 | 20110919 |
| Caelo | Rose mallow flower, cut | 10244508 | 60 | 20100917 |
| Caelo | Roselle | 12007311 | 60 | 20120124 |
| Caelo | Roselle | 11036509 | 60 | 20110303 |
| Bombastus | Rosemary leaf | 23004436 | 30 | 20231017 |
| Caelo | Rosemary leaf | 11193408 | 40 | 20110728 |
| Caelo | Rosemary leaf | 14159601 | 60 | 20140617 |
| Caelo | Rosemary leaf | 23001738001 | 30 | 20231124 |
| Klenk | Rosemary leaf | 2261A131118 | 60 | AR-15-FG-008499-01 |
| Klenk | Ruscus rhizome, cut | 7081B110301 | 60 | 20130131 |
| Fagron | Rutin 70% | 24I16-B039 | 40 | 20240925* |
| Fagron | Rutin 70% | 24J14-B044 | 20 | 20241030* |
| Fagron | Rutin 70% | 24I16-B039 | 20 | 20240925* |
| Fagron | Rutin 70% | 24I16-B041 | 20 | 20240925* |
| Fagron | Rutoside trihydrate | 13K12-B06-295483 | 60 | 20131204 |

## S

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | s-Acetylglutathione | 22G01-B02-225858 | 40 | 20220706 |
| Fagron | s-Acetylglutathione | 23D21-B10-229486 | 40 | 20230809 |
| Fagron | s-Acetylglutathione | 22G01-B02-225858 | 20 | 20220706 |
| Fagron | s-Acetylglutathione | 23D21-B10-229486 | 20 | 20230809 |
| Klenk | Saffron | 0384A121022 | 40 | 20121114 |
| Caelo | Sage leaf | 11347503 | 40 | 20120102 |
| Caelo | Sarsaparilla root, cut | 10230402 | 60 | 20100909 |
| Euro OTC | Selenium disulfide | 1411011-02 | 40 | 20141211 |
| Caelo | Selenium yeast | 13347911 | 40 | 1509355 |
| Caelo | Selenium yeast | 17002202 | 40 | 1707512 |
| Caelo | Selenium yeast | 17002208 | 40 | 20170126 |
| Caelo | Selenium yeast | 173332 | 40 | 20180207* |
| Caelo | Selenium yeast | 192450005 | 40 | 2106135 |
| Caelo | Selenium yeast | 20003859005 | 40 | 20201221 |
| Caelo | Selenium yeast | 20003859005 | 10 | 20201221 |
| Euro OTC | Selenium yeast | L1401013-01 | 40 | 20140207 |
| Bombastus | Senna leaflet | 24000491 | 30 | 20240130 |
| Caelo | Senna leaflet | 12273106 | 40 | 20120927 |
| Caelo | Senna leaflet | 23001268010 | 30 | 20230714 |
| Caelo | Senna leaflet, powdered | 11193307 | 120 | 20110804 |
| Caelo | Senna leaflet, powdered | 12369908 | 40 | 1408079 |
| Klenk | Senna leaflet, powdered | 2334B130606 | 60 | AR-15-FG-015212-01 |
| Caelo | Senna pods, tinnevelly | 12267605 | 40 | 20120921 |
| Caelo | Senna pods, tinnevelly | 11154404 | 40 | 20110607 |
| Caelo | Senna pods, tinnevelly | 13395106 | 40 | 20140106 |
| EDQM | Sertaconazole nitrate | 2.0 | 26 | CRS |
| Caelo | Shepherd's purse | 11328208 | 40 | 20111205 |
| Caelo | Silica, colloidal anhydrous | 181124 | 40 | 20180424* |
| Caelo | Silver nitrate | 181276 | 40 | 20180716* |
| Caelo | Silver, colloidal | 173615 | 40 | 20180312* |
| Caelo | Silverweed | 11328105 | 40 | 20111130 |
| Galke | Silverweed | 22840 | 40 | from supplier |
| Fagron | Silymarin | 25D28-B008 | 40 | 20241011* |
| Fagron | Silymarin | 25D28-B010 | 20 | 20241012* |
| Fagron | Silymarin | 25D28-B009 | 20 | 20241012* |
| Fagron | Silymarin | 25D28-B008 | 20 | 20241011* |
| Fagron | Simvastatin | 24D29-B07-002224 | 40 | 20240730 |
| Fagron | Simvastatin | 24H01-B12-002225 | 40 | 20240927 |
| Fagron | Simvastatin | 24D29-B07-002224 | 20 | 20240730 |
| Fagron | Simvastatin | 24H01-B12-002225 | 20 | 20240927 |
| Euro OTC | Sodium alginate | 2305007 | 40 | 20230720* |
| Euro OTC | Sodium alginate | 2305007 | 20 | 20230720* |
| Fagron | Sodium alginate | 14G22-B99-297091 | 60 | 20140813 |
| Gatt-Koller | Sodium alginate | 22J01179 | 40 | 20220714 |
| Gatt-Koller | Sodium alginate | 22J01179 | 20 | 20220714 |
| Caelo | Sodium bromide | 171191 | 40 | 20170510* |
| Caelo | Sodium carbonate decahydrate | 173613 | 40 | 20180115* |
| Gatt-Koller | Sodium carbonate decahydrate | 23J00898 | 37 | 20230516 |
| Gatt-Koller | Sodium carbonate decahydrate | 23J00898 | 28 | 20230516 |
| Caelo | Sodium carbonate monohydrate | 16310205 | 40 | 20161221 |
| Merck KGaA | Sodium diphosphate decahydrate | K55034491332 | 40 | not required |
| Fagron | Sodium fusidate | 23A04-B10-219743 | 40 | 20230209 |
| Fagron | Sodium fusidate | 23F12-B05-22913 | 40 | 20230705 |
| Fagron | Sodium fusidate | 23A04-B10-219743 | 20 | 20230209 |

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*continued from previous page*

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Sodium fusidate | 23F12-B05-22913 | 20 | 20230705 |
| Audor | Sodium hyaluronate | AP30101404H | 60 | 20141203 |
| Audor | Sodium hyaluronate | AP30101702H | 40 | 1802037 |
| Caelo | Sodium hyaluronate | 172347 | 40 | 20171004* |
| Euro OTC | Sodium hyaluronate | L1302028-01 | 40 | 1403532 |
| Euro OTC | Sodium hyaluronate | L1302028-01 | 60 | 20130314 |
| Kraeber & ... | Sodium hyaluronate | 3462 | 40 | 20180723 |
| Kraeber & ... | Sodium hyaluronate | 3829 | 40 | 2104160 |
| Kraeber & ... | Sodium hyaluronate | 3897 | 40 | 20200408 |
| Caelo | Sodium hydrocarbonate | 23002402 | 40 | 20230919* |
| Caelo | Sodium hydrocarbonate | 23002402 | 20 | 20230919* |
| Euro OTC | Sodium hydrocarbonate | 1807021-01 | 40 | 20180725 |
| Euro OTC | Sodium hydrocarbonate | 2202008 | 40 | 20220317* |
| Euro OTC | Sodium hydrocarbonate | 2302009 | 40 | 20230309* |
| Euro OTC | Sodium hydrocarbonate | 2306010 | 40 | 20230718* |
| Euro OTC | Sodium hydrocarbonate | 2505001 | 40 | 20250617* |
| Euro OTC | Sodium hydrocarbonate | 2202008 | 20 | 20220317* |
| Euro OTC | Sodium hydrocarbonate | 2302009 | 20 | 20230309* |
| Caelo | Sodium iodide | 161701 | 40 | 20160706* |
| Caelo | Sodium methyl-4-hydroxybenzoate | 15358708 | 40 | AR-16-FG-015095-01 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 15358708 | 40 | 20151127 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 15358709 | 40 | 20151127 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 15358713 | 40 | 20151127 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 170519 | 40 | 20170308* |
| Caelo | Sodium methyl-4-hydroxybenzoate | 191439 | 40 | 20190628* |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 22000404 | 40 | 20220211* |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 22001508 | 40 | 20220531 |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 22002975 | 40 | 20220930* |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 23002592 | 40 | 20231024* |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 24000747 | 40 | 20240507* |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 24002861 | 40 | 20241218* |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 22000404 | 20 | 20220211* |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 22001508 | 20 | 20220531 |
| Caelo | Sodium monohydrogenphosphate dodecahydrate | 22002975 | 20 | 20220930* |
| Caelo | Sodium monohydrogenphosphate heptahydrate | 12109002 | 40 | 20120424 |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Sodium monohydrogenphosphate heptahydrate | 21003087 | 40 | 20210927* |
| Caelo | Sodium monohydrogenphosphate heptahydrate | 21003087 | 20 | 20210927* |
| Caelo | Sodium nitrate | 11045910 | 40 | 20110225 |
| Caelo | Sodium nitrite | 171360 | 30 | 20170522* |
| Euro OTC | Sodium sulfate, anhydrous | 1801046-01 | 40 | 20180202 |
| Caelo | Sodium thiosulfate | 181648 | 40 | 20180712* |
| Caelo | Softisan® 601 | 13296104 | 40 | 1403144 |
| Caelo | Softisan® 601 | 14099604 | 40 | 1504720 |
| Caelo | Softisan® 601 | 15184905 | 60 | 20150611 |
| Caelo | Softisan® 601 | 162364 | 40 | 20160823* |
| Caelo | Softisan® 601 | 162364 | 40 | 20160823* |
| Caelo | Softisan® 601 | 172178 | 40 | 20170817* |
| Caelo | Softisan® 601 | 20003054001 | 40 | 20201001 |
| Caelo | Solanum dulcamara stems, cut | 10375602 | 40 | 20110113 |
| Caelo | Solanum dulcamara stems, cut | 13254305 | 40 | 20130806 |
| Caelo | Sour cherry stems, cut | 12042302 | 40 | 1503570 |
| Caelo | Spearmint leaf | 12133906 | 40 | 20120516 |
| Sigma-Aldrich | Stannous chloride dihydrate | K54805315247 | 40 | not required |
| Caelo | Star anise | 11314104 | 10 | 20111121 |
| Caelo | Star anise, cut | 12226301 | 60 | 20120731 |
| Caelo | Star anise, cut | 13041401 | 40 | 1403709 |
| Caelo | Star anise, cut | 15329302 | 60 | AR-16-FG-004770-01 |
| Caelo | Stemless carline root | 12163702 | 40 | 20120628 |
| Caelo | Stemless carline root | 12232802 | 40 | 20120822 |
| Caelo | Strawberry leaf | 11117903 | 40 | 20110428 |
| Klenk | Strawberry leaf | 2031B110224 | 40 | 20110304 |
| Klenk | Strawberry leaf | 2031B120925 | 40 | 20121005 |
| Fagron | Sulbutiamine | 24I05-B021 | 40 | 20241109* |
| Fagron | Sulbutiamine | 25C05-B030 | 20 | 20250324* |
| Fagron | Sulbutiamine | 24I10-B011 | 20 | 20241109* |
| Fagron | Sulbutiamine | 24I05-B021 | 20 | 20241109* |
| Caelo | Sulfamerazine | 10218403 | 30 | 20100914 |
| Fagron | Sulfamethoxazole | 22H23-B16-225919 | 40 | 20220909 |
| Fagron | Sulfamethoxazole | 22H23-B16-225919 | 20 | 20220909 |
| Caelo | Sweet woodruff herb | 10375812 | 30 | 20110114 |

## T

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Tadalafil | 25D15-B015 | 40 | 20250228* |
| Fagron | Tadalafil | 25D15-B015 | 20 | 20250228* |
| Fagron | Tadalafil | 24I12-B048 | 20 | 20240417* |
| Fagron | Tadalafil | 24I12-B049 | 20 | 20240417* |
| Caelo | Talcum | 22002768 | 40 | 20220928* |
| Euro OTC | Talcum | 2204002 | 40 | 20220511* |
| Otto Fischar | Talcum | 90841/1 | 40 | from supplier |
| Caelo | Thalidomide | 13395704 | 60 | 20140207 |
| Caelo | Thalidomide | 162703 | 40 | 20160929* |
| Caelo | Thalidomide | 15276711 | 40 | 1704508 |
| Caelo | Thalidomide | 172100 | 40 | 20170821* |
| Caelo | Thalidomide | 182496 | 40 | 20181022* |
| Fagron | Thalidomide | 14E27B04295348 | 60 | 1503608 |
| Fagron | Thalidomide | 15A13-B01-312230 | 40 | 1704509 |
| LGC Standa... | THCA-A | 1457348 | 30 | 20240417 |
| Fagron | Theacrine | 24I02-B026 | 40 | 20240918* |
| Fagron | Theacrine | 24I14-B018 | 40 | 20241011* |

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| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Fagron | Theacrine | 24I02-B026 | 20 | 20240918* |
| Fagron | Theacrine | 24I03-B049 | 20 | 20241010* |
| Fagron | Theophylline-ethylenediamine | 19C04-B04-363517 | 40 | 20190823 |
| Fagron | Theophylline-ethylenediamine | 20J13-F05-375387 | 40 | 20201207 |
| Caelo | Theriac | 12289307 | 40 | 1405122 |
| Caelo | Theriac | 13407301 | 40 | 1410336 |
| Klenk | Theriac | 13816 | 60 | 1705088 |
| Fagron | Thiamine nitrate | 15A30-B06-309069 | 60 | AR-16-FG-005855-01 |
| Euro OTC | Thioctic acid | 2503005 | 40 | 20250613* |
| Euro OTC | Thioctic acid | 2503005 | 20 | 20250613* |
| Bombastus | Thyme | 23005529 | 30 | 20231213 |
| Caelo | Thyme | 11345004 | 60 | 20111213 |
| Caelo | Thyme | 22003890005 | 30 | 20230622 |
| Galke | Thyme | 21932 | 40 | from supplier |
| Euro OTC | Titanium dioxide | 1708015-01 | 40 | 20170822 |
| USP | Tobramycin | M0M058 | 40 | CRS |
| Caelo | Tonka beans | 12145101 | 40 | 20120604 |
| Caelo | Tormentil | 12040708 | 40 | 1403487 |
| Caelo | Tormentil | 12013103 | 40 | 1403048 |
| Caelo | Tormentil | 12040715 | 40 | 1403710 |
| Caelo | Tormentil | 13220502 | 40 | 1403049 |
| Caelo | Tormentil | 14360103 | 60 | 1606520 |
| Klenk | Tormentil | 6914B120112 | 40 | 20120118 |
| Caelo | Tragacanth | 13277804 | 60 | 1507149 |
| Caelo | Tragacanth | 15085602 | 60 | 20150410 |
| Caelo | Tragacanth | 15379906 | 60 | 20151124 |
| Caelo | Tragacanth | 16110802 | 60 | AR-17-FG-007533-01 |
| Caelo | Tribromophenol bismuth | 18144202 | 40 | 20180706 |
| Fagron | Tribulus terrestris 40% | 24I03-B002 | 40 | 20241015* |
| Fagron | Tribulus terrestris 40% | 24I05-B047 | 20 | 20240926* |
| Fagron | Tribulus terrestris 40% | 24H29-B005 | 20 | 20240918* |
| Fagron | Tribulus terrestris 40% | 24I03-B002 | 20 | 20241015* |
| Euro OTC | Tricalcium phosphate | 1206002-01 | 40 | 1402298 |
| Fagron | Trimethoprim | 21J11-B07-219183 | 40 | 20220125 |
| Fagron | Trimethoprim | 23B17-B03-232012 | 40 | 20230322 |
| Fagron | Trimethoprim | 24I10-B11-008711 | 40 | 200250313 |
| Fagron | Trimethoprim | 21J11-B07-219183 | 20 | 20220125 |
| Fagron | Trimethoprim | 23B17-B03-232012 | 20 | 20230322 |
| Fagron | Trimethoprim | 24I10-B11-008711 | 20 | 20250313 |
| Caelo | Turmeric rhizome | 11160403 | 60 | 20110628 |
| Caelo | Turmeric rhizome | 12136503 | 40 | 1405295 |
| Caelo | Turmeric rhizome | 13360202 | 40 | 1411363 |
| Caelo | Turmeric, javanese | 12185605 | 40 | 1403465 |
| Caelo | Turmeric, javanese | 12319206 | 40 | 20121130 |
| Caelo | Turmeric, javanese | 13262904 | 40 | 20130926 |
| Kräuter Schulte | Twotoothed achyranthes root, cut | 45053 | 40 | from supplier |

## U

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Audor | Uridine | APIB1600169AU | 40 | 20170711 |
| Audor | Uridine | APIB160018211AU | 40 | 20161118 |
| Fagron | Uridine | 11G07-N04 | 60 | 1402481 |
| Fagron | Uridine | 13K18-B31-288497 | 60 | 20131129 |

## V

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Valerian root, cut | 12033809 | 40 | 20120228 |
| Caelo | Valerian root, powdered | 12138005 | 40 | 1403809 |
| Caelo | Valerian root, powdered | 12138008 | 40 | 1508496 |
| Caelo | Valerian root, powdered | 13113204 | 60 | 20130419 |
| Caelo | Verbena herb | 12187602 | 40 | 20120719 |
| Klenk | Verbena herb | 4651B120611 | 40 | 20121123 |
| Fagron | Vinpocetine | 20240501 | 40 | 20240512* |
| Fagron | Vinpocetine | 20240501 | 20 | 20240512* |
| Euro OTC | Vitamin A acetate | 2303019 | 40 | 20230414* |
| Euro OTC | Vitamin A acetate | 2303019 | 20 | 20230414* |

## W

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Walnut bark | 11325603 | 40 | 20111124 |
| Caelo | Walnut leaf | 11103007 | 40 | 1403091 |
| Fagron | Warfarin sodium | 24K22-B03-008546 | 40 | 20250410 |
| Fagron | Warfarin sodium | 24K22-B03-008546 | 20 | 20250410 |
| Caelo | White deadnettle flower | 11371604 | 40 | 20120103 |
| Caelo | White mustard seed | 13064301 | 40 | 20130326 |
| Caelo | White mustard seed | 13380501 | 40 | 20140103 |
| Caelo | White pepper | 12294902 | 40 | 1403488 |
| Caelo | White pepper | 12294905 | 40 | 20121130 |
| Caelo | White pepper | 14010703 | 40 | 20140122 |
| Caelo | Wild pansy | 10291007 | 60 | 20101103 |
| Caelo | Willow bark | 12185204 | 40 | 20120730 |
| Caelo | Willow herb | 11347311 | 40 | 20111216 |
| Caelo | Willowherb, small flowered | 10326106 | 40 | 20101216 |
| Caelo | Willowherb, small flowered | 13355904 | 60 | 20140113 |
| Klenk | Willowherb, small flowered | 4721A140203 | 60 | 20140219 |
| Caelo | Wormwood | 12355801 | 40 | 20121211 |

## Y

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Dr. Behr | Yam root extract | WE14020005-05 | 40 | 20130204 |
| Caelo | Yarrow flower | 12267703 | 40 | 20120921 |
| Caelo | Yellow chaste weed | 11293101 | 40 | 20111028 |
| Fagron | Yohimbine hydrochloride | 24I09-B014 | 40 | not required |
| Fagron | Yohimbine hydrochloride | 25C18-B001 | 40 | not required |
| Fagron | Yohimbine hydrochloride | 24I09-B014 | 20 | not required |
| Fagron | Yohimbine hydrochloride | 25C18-B001 | 20 | not required |

## Z

| Supplier | Substance | Batch | Spectra | Certificate |
|---|---|---|---|---|
| Caelo | Zedoary root | 12125301 | 40 | 20120522 |
| Caelo | Zedoary root, powdered | 12344601 | 40 | 1403489 |
| Caelo | Zedoary root, powdered | 13165501 | 40 | 20130613 |
| Caelo | Zedoary root, powdered | 14249001 | 60 | 20141008 |
| Caelo | Zinc oxide | 14038101 | 40 | 20140205 |
| Caelo | Zinc oxide-talcum powder mixture 1:1 | 181487 | 40 | 20180702* |

*The spectra were taken from a part of the same sample which the supplier used for its analysis (identity, purity, content). In this case the manufacturer certificates proof the identity and quality of the sample from those the spectra descend.


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# *Appendix C:* Additional validation samples (*Type C*)

Spectra for substances from the field which cannot be identified with this model also enter the validation. In this manner, it is verified that the model also rejects unknown substances. The spectra for these samples were recorded by *Apo-Ident* customers. They belong to *Type C*. The information provided by the customer regarding the manufacturer and batch number is taken over by *HiperScan GmbH* to a large extent unchecked.

The samples originate from 8064 batches. From these, 19 268 spectra were recorded. The spectra recorded on independent samples of substances from the field which can be identified with the model are listed respectively in the section *Type C* for the individual substances and do not appear again elsewhere in this list.

0 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | (R,S)-epinephrine hydrochloride | 2021503 | 1 |
| Fagron | (R,S)-epinephrine hydrochloride | 10022015E | 1 |
| Fagron | (R,S)-epinephrine hydrochloride | 14a22-B05 | 1 |
| Fagron | (R,S)-epinephrine hydrochloride | 14A22-B05 | 1 |
| Fagron | (R,S)-epinephrine hydrochloride | 16H23-B98-325052 | 1 |
| Dermapharm | 8-quinolinol sulfate monohydrate | 140804 | 1 |
| Dermapharm | 8-quinolinol sulfate monohydrate | 100804 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 13D24-N11 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 10F01-N15 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 11/09-N09 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 11L08-N07 | 2 |
| Fagron | 8-quinolinol sulfate monohydrate | 11L19-N14 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 13G10-N06 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 13/21-N23 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 12A04-N05 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 11I09-N09 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 13A04-N05 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 12H21-N08 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 12D26-N04 | 1 |
| Fagron | 8-quinolinol sulfate monohydrate | 13032014C | 1 |
| Dermapharm | 8-quinolinol sulfate monohydrate | 120905 | 1 |
| siehe WE-Prüfprotokoll | 8-quinolinol sulfate monohydrate | 96/09 | 1 |

**A**

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Abrotani herb, cut | 2091305 | 1 |
| Klenk | Abrotani herb, cut | 3451A120312 | 19 |
| Klenk | Abrotani herb, cut | 26011403 | 1 |
| Klenk | Abrotani herb, cut | 21081301 | 1 |
| Nachprüfung | Abrotani herb, cut | 3451A070919 | 1 |
| Bombastus | Acorus root | 276260 | 2 |
| Bombastus | Acorus root | 224114 | 1 |
| Bombastus | Acorus root | 281692 | 2 |
| Bombastus | Acorus root | 277958 | 1 |
| Bombastus | Acorus root | 274159 | 1 |
| Caelo | Acorus root | 13127801 | 1 |
| Gehe | Acorus root | 284875 | 2 |
| Klenk | Acorus root | B130807 | 1 |
| Caelo | Acorus root | 12066501 | 1 |
| Aurica/Phönix | Acorus root, peeled | 150649 | 1 |
| Bahnhof-Apotheke | Acorus root, peeled | 17-121107 | 1 |
| Bombastus | Acorus root, peeled | 267365 | 1 |
| Bombastus | Acorus root, peeled | 274159 | 3 |
| Caelo | Acorus root, peeled | 12295903 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Acorus root, peeled | 15061202 | 1 |
| Caelo | Acorus root, peeled | 241013010 | 1 |
| Caelo | Acorus root, peeled | 8031306 | 1 |
| Caelo | Acorus root, peeled | 24081203 | 1 |
| Caelo | Acorus root, peeled | 28121205 | 1 |
| Caelo | Acorus root, peeled | 7061302 | 1 |
| Caelo | Acorus root, peeled | 12295901 | 1 |
| Caelo | Acorus root, peeled | 12066502 | 1 |
| Caelo | Acorus root, peeled | 12275604 | 2 |
| Caelo | Acorus root, peeled | 12295904 | 4 |
| Caelo | Acorus root, peeled | 12056703 | 1 |
| Caelo | Acorus root, peeled | 313060 | 1 |
| Caelo | Acorus root, peeled | 12275602 | 7 |
| Caelo | Acorus root, peeled | 12239008 | 1 |
| Caelo | Acorus root, peeled | 13101306 | 1 |
| Caelo | Acorus root, peeled | 12066501 | 7 |
| Caelo | Acorus root, peeled | 12056701 | 1 |
| Caelo | Acorus root, peeled | 12295902 | 4 |
| Caelo | Acorus root, peeled | 12275604-3544411013 | 1 |
| Galke | Acorus root, peeled | 18944 | 1 |
| Gehe | Acorus root, peeled | 6701B130807 | 9 |
| Klenk | Acorus root, peeled | 6701B150407 | 1 |
| Klenk | Acorus root, peeled | 106212173 | 1 |
| Klenk | Acorus root, peeled | 6701B130103 | 21 |
| Klenk | Acorus root, peeled | 6701B120817 | 6 |
| Klenk | Acorus root, peeled | 6701B130870 | 1 |
| Klenk | Acorus root, peeled | 6711B110606 | 1 |
| Klenk | Acorus root, peeled | 4797362 | 1 |
| Klenk | Acorus root, peeled | 6701b130103 | 1 |
| Klenk | Acorus root, peeled | 6701b120301 | 1 |
| Klenk | Acorus root, peeled | 6701B120301 | 3 |
| Klenk | Acorus root, peeled | 6701B120427 | 7 |
| Caelo | Agarikon | 11024502 | 1 |
| Caelo | Agnus castus fruit | 12274009 | 3 |
| Caelo | Agnus castus fruit | 12016908 | 1 |
| Caelo | Agnus castus fruit | 15318718 | 1 |
| Caelo | Agnus castus fruit | 15318702 | 1 |
| Caelo | Agnus castus fruit | 1513546 | 1 |
| Caelo | Agnus castus fruit | 12274008 | 1 |
| Caelo | Agnus castus fruit | 14194401 | 4 |
| Caelo | Agnus castus fruit | 13193407 | 1 |
| Caelo | Agnus castus fruit | 15318705 | 1 |
| Caelo | Agnus castus fruit | 11026309 | 1 |
| Caelo | Agnus castus fruit | 13193410 | 2 |
| Caelo | Agnus castus fruit | 12274003 | 4 |
| Caelo | Agnus castus fruit | 12016909 | 4 |
| Caelo | Agnus castus fruit | 12274014 | 1 |
| Caelo | Agnus castus fruit | 13193403 | 1 |
| Caelo | Agnus castus fruit | 14194408 | 1 |
| Caelo | Agnus castus fruit | 9245308 | 1 |
| Caelo | Agnus castus fruit | 12016902 | 1 |
| Caelo | Agnus castus fruit | 12274006 | 3 |
| Caelo | Agnus castus fruit | 12274002 | 1 |
| Caelo | Agnus castus fruit | 13193406 | 1 |
| Caelo | Agnus castus fruit | 12274010 | 10 |
| Caelo | Agnus castus fruit | 15065105 | 1 |
| Caelo | Agnus castus fruit | 13193401 | 2 |
| Caelo | Agnus castus fruit | 11026318 | 1 |
| Caelo | Agnus castus fruit | 12274013 | 2 |
| Caelo | Agnus castus fruit | 3413A-03015 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Agnus castus fruit | 80175158 | 2 |
| Caelo | Agnus castus fruit | 13193404 | 1 |
| Caesar & Loretz Gm… | Agnus castus fruit | 12274007 | 3 |
| Gutenberg-Apotheke | Agnus castus fruit | 61765 | 1 |
| Caelo | Agnus castus fruit | 12016905 | 2 |
| Klenk | Agnus castus fruit | 7110N090701 | 1 |
| Klenk | Agnus castus fruit | 7110A120803 | 1 |
| Klenk | Agnus castus fruit | A130613 | 1 |
| Klenk | Agnus castus fruit | A120803 | 1 |
| Klenk | Agnus castus fruit | A110614 | 3 |
| Klenk | Agnus castus fruit | 7110A110614 | 2 |
| Klenk | Agnus castus fruit | 7110N150121 | 1 |
| Klenk | Agnus castus fruit | 7110A130613 | 1 |
| Caelo | Agnus castus fruit | 12274012 | 1 |
| Alliance | Agrimony | 11374004 | 5 |
| Caelo | Agrimony | 11374006 | 6 |
| Caelo | Agrimony | 12382901 | 3 |
| Caelo | Agrimony | 10325502 | 2 |
| Caelo | Agrimony | 10325505 | 1 |
| Caelo | Agrimony | 12382903 | 1 |
| Caelo | Agrimony | 1137407 | 1 |
| Caelo | Agrimony | 11374005 | 2 |
| Caelo | Agrimony | 3481-A-110324 | 1 |
| Celo | Agrimony | 11374003 | 1 |
| Finze | Agrimony | 11374002 | 3 |
| Galke | Agrimony | 2002 | 1 |
| Herbasinica | Agrimony | 11374007 | 1 |
| Caelo | Agrimony | 12382905 | 5 |
| Klenk | Agrimony | 3481C120508 | 1 |
| Noweda | Agrimony | 10325503 | 2 |
| Noweda | Agrimony | 9300106 | 1 |
| Alfred Galke | Alchemilla | 20921 | 1 |
| Bahnhof-Apotheke | Alchemilla | 17-121107 | 1 |
| Bombastus | Alchemilla | 282032 | 2 |
| Bombastus | Alchemilla | 276173 | 3 |
| Bombastus | Alchemilla | 272021 | 5 |
| Bombastus | Alchemilla | 278889 | 1 |
| Bombastus | Alchemilla | 14066007 | 1 |
| Bombastus | Alchemilla | 521203995 | 1 |
| Bombastus | Alchemilla | 279070 | 5 |
| Bombastus | Alchemilla | 231013B | 1 |
| Bombastus | Alchemilla | 266404 | 1 |
| Caelo | Alchemilla | 1406211616 | 1 |
| Caelo | Alchemilla | 3613M01616 | 1 |
| Caelo | Alchemilla | 13141102 | 6 |
| Caelo | Alchemilla | 12153306 | 5 |
| Caelo | Alchemilla | 13141101 | 7 |
| Caelo | Alchemilla | 12153307 | 3 |
| Caelo | Alchemilla | H-040513-2 | 1 |
| Caelo | Alchemilla | 13141106 | 8 |
| Caelo | Alchemilla | 11063605 | 1 |
| Caelo | Alchemilla | 12153303 | 7 |
| Caelo | Alchemilla | 8121201 | 1 |
| Caelo | Alchemilla | 21081203 | 1 |
| Caelo | Alchemilla | 27011401 | 1 |
| Caelo | Alchemilla | 9011405 | 1 |
| Caelo | Alchemilla | 5041301 | 1 |
| Caelo | Alchemilla | 13091304 | 1 |
| Caelo | Alchemilla | 2081304 | 1 |
| Caelo | Alchemilla | 15147002 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Alchemilla | 14066008 | 1 |
| Caelo | Alchemilla | 11182808 | 1 |
| Caelo | Alchemilla | 14066002 | 2 |
| Caelo | Alchemilla | 12153301 | 3 |
| Caelo | Alchemilla | 11182805 | 1 |
| Caelo | Alchemilla | 11182807 | 2 |
| Caelo | Alchemilla | 1100912 | 1 |
| Caelo | Alchemilla | 11182804 | 3 |
| Caelo | Alchemilla | 12342901 | 1 |
| Caelo | Alchemilla | intch:318080 | 1 |
| Caelo | Alchemilla | 125306 | 1 |
| Caelo | Alchemilla | 1118206 | 1 |
| Caelo | Alchemilla | 11182801 | 3 |
| Caelo | Alchemilla | 1213309 | 1 |
| Caelo | Alchemilla | 11182806 | 6 |
| Caelo | Alchemilla | 13141103 | 36 |
| Caelo | Alchemilla | 12153305 | 25 |
| Caelo | Alchemilla | 1215305 | 2 |
| Caelo | Alchemilla | 131411002 | 1 |
| Caelo | Alchemilla | 5013I1616 | 1 |
| Caelo | Alchemilla | 13141105 | 3 |
| Caelo | Alchemilla | 11002906 | 5 |
| Caelo | Alchemilla | 1215309 | 1 |
| Caelo | Alchemilla | 13141107 | 3 |
| Caelo | Alchemilla | 13141103-3400310161 | 1 |
| Caelo | Alchemilla | 13141103-3456311103 | 1 |
| Caelo | Alchemilla | 13141106-3545412081 | 1 |
| Caelo | Alchemilla | 13141103-3382319003 | 1 |
| Galke | Alchemilla | 21963 | 3 |
| Galke | Alchemilla | 19835 | 1 |
| Galke | Alchemilla | 22291 | 1 |
| Galke | Alchemilla | 21141 | 1 |
| Gehe | Alchemilla | 1341102 | 1 |
| Hepart AG | Alchemilla | B-698kbA | 1 |
| Klenk | Alchemilla | 3501A110301 | 3 |
| Klenk | Alchemilla | 3501B100428 | 1 |
| Klenk | Alchemilla | 12153309 | 14 |
| Klenk | Alchemilla | 3501B090417 | 1 |
| Klenk | Alchemilla | 3501C121105 | 4 |
| Noweda | Alchemilla | 12153302 | 13 |
| Caelo | Alchemilla | 14066003 | 1 |
| Fagron | Alchemilla | 11182802 | 1 |
| Wolf | Alchemilla | B-698 | 2 |
| Wolf | Alchemilla | 23187 | 4 |
| Wolf | Alchemilla | p931 | 1 |
| Wolf | Alchemilla | E-822 | 1 |
| Caelo | Alchemilla alpina herb, cut | 12147205 | 2 |
| Caelo | Alchemilla alpina herb, cut | 12147202 | 3 |
| Caelo | Alchemilla alpina herb, cut | 12147203 | 1 |
| Caelo | Alchemilla alpina herb, cut | 1214204 | 1 |
| Caelo | Alchemilla alpina herb, cut | 12147203-3470312131 | 1 |
| Caelo | Alchemilla alpina herb, cut | 12147206 | 3 |
| Caelo | Alchemilla alpina herb, cut | 11063608 | 1 |
| Klenk | Almonds, bitter, whole | 40A-150904 | 2 |
| apomix | Almonds, bitter, whole | 40A161206 | 8 |
| Apotheke Bühlau | Almonds, bitter, whole | 267467 | 2 |
| Bombastus | Almonds, bitter, whole | 275001 | 3 |
| Bombastus | Almonds, bitter, whole | 275600 | 1 |
| Bombastus | Almonds, bitter, whole | 284978 | 1 |
| Bombastus | Almonds, bitter, whole | 17000353 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Almonds, bitter, whole | 283369 | 1 |
| Bombastus | Almonds, bitter, whole | 297921 | 1 |
| Bombastus | Almonds, bitter, whole | 1700352 | 2 |
| Bombastus | Almonds, bitter, whole | 304961 | 1 |
| Bombastus | Almonds, bitter, whole | 306048 | 1 |
| Bombastus | Almonds, bitter, whole | 303218 | 2 |
| Bombastus | Almonds, bitter, whole | 305322 | 2 |
| Bombastus | Almonds, bitter, whole | 275601 | 1 |
| Bombastus | Almonds, bitter, whole | 267529 | 1 |
| Caelo | Almonds, bitter, whole | 5121301 | 1 |
| Caelo | Almonds, bitter, whole | 12239604 | 1 |
| Caelo | Almonds, bitter, whole | 13242001 | 1 |
| Caelo | Almonds, bitter, whole | 15193103 | 1 |
| Euro OTC | Almonds, bitter, whole | 290973 | 2 |
| Fagron | Almonds, bitter, whole | 40A121010 | 11 |
| Caelo | Almonds, bitter, whole | 16221202 | 1 |
| Klenk | Almonds, bitter, whole | 40A161005 | 5 |
| Klenk | Almonds, bitter, whole | 40A150904 | 18 |
| Klenk | Almonds, bitter, whole | 40A0130909 | 1 |
| Klenk | Almonds, bitter, whole | 40A111117 | 7 |
| Klenk | Almonds, bitter, whole | 40A111004 | 1 |
| Klenk | Almonds, bitter, whole | 40A140908 | 19 |
| Klenk | Almonds, bitter, whole | 40A120924 | 4 |
| Klenk | Almonds, bitter, whole | 40A161028 | 13 |
| Klenk | Almonds, bitter, whole | 40A150905 | 1 |
| Klenk | Almonds, bitter, whole | 40A0161005 | 1 |
| Klenk | Almonds, bitter, whole | 40A130909 | 9 |
| Anzag 22.03.13 ek:… | Aloes, cape, powdered | 12232102 | 1 |
| Caelo | Aloes, cape, powdered | 11132115 | 1 |
| Caelo | Aloes, cape, powdered | 12183007 | 1 |
| Caelo | Aloes, cape, powdered | 15206501 | 1 |
| Caelo | Aloes, cape, powdered | 14065905 | 1 |
| Caelo | Aloes, cape, powdered | 12183008 | 1 |
| Caelo | Aloes, cape, powdered | 12183001 | 1 |
| Caelo | Aloes, cape, powdered | 14065906 | 1 |
| Caelo | Aloes, cape, powdered | 11132116 | 2 |
| Caelo | Aloes, cape, powdered | 15206514 | 1 |
| Caelo | Aloes, cape, powdered | 15206516 | 1 |
| Caelo | Aloes, cape, powdered | 15206507 | 2 |
| Caelo | Aloes, cape, powdered | 12183009 | 3 |
| Caelo | Aloes, cape, powdered | 11132116 | 1 |
| Caelo | Aloes, cape, powdered | 12183013 | 3 |
| Klenk | Aloes, cape, powdered | 24A160620 | 1 |
| Caelo | Aloes, cape, powdered | 16202410 | 1 |
| Caelo | Aluminium potassium sulfate… | 14263804 | 1 |
| Alliance | Aluminium potassium sulfate… | 13025401 | 3 |
| Alliance Healthcare | Aluminium potassium sulfate… | 13025404 | 1 |
| Anzag | Aluminium potassium sulfate… | 1218441 | 1 |
| Caelo | Aluminium potassium sulfate… | 1218411 | 1 |
| Caelo | Aluminium potassium sulfate… | 12022444 | 1 |
| Caelo | Aluminium potassium sulfate… | 11017211 | 1 |
| Caelo | Aluminium potassium sulfate… | 13025404 | 3 |
| Caelo | Aluminium potassium sulfate… | 504311092 | 1 |
| Caelo | Aluminium potassium sulfate… | 2713Q1092 | 1 |
| Caelo | Aluminium potassium sulfate… | 510211092 | 1 |
| Caelo | Aluminium potassium sulfate… | 13025401 | 3 |
| Caelo | Aluminium potassium sulfate… | 12184407 | 5 |
| Caelo | Aluminium potassium sulfate… | 15172501 | 1 |
| Caelo | Aluminium potassium sulfate… | 12184407 | 3 |
| Caelo | Aluminium potassium sulfate… | 90033229 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Aluminium potassium sulfate… | 12239102 | 2 |
| Caelo | Aluminium potassium sulfate… | 12022404 | 1 |
| Caelo | Aluminium potassium sulfate… | 12184411 | 2 |
| Caelo | Aluminium potassium sulfate… | 12184411 | 1 |
| Caelo | Aluminium potassium sulfate… | 12184401 | 1 |
| Caelo | Aluminium potassium sulfate… | 12144605 | 4 |
| Caelo | Aluminium potassium sulfate… | 12144602 | 1 |
| Caelo | Aluminium potassium sulfate… | 12184406 | 2 |
| Caelo | Aluminium potassium sulfate… | 11254805 | 1 |
| Caelo | Aluminium potassium sulfate… | 12184408 | 3 |
| Caelo | Aluminium potassium sulfate… | 11218611 | 2 |
| Caelo | Aluminium potassium sulfate… | 12184402 | 3 |
| Caelo | Aluminium potassium sulfate… | 13098702 | 1 |
| Caelo | Aluminium potassium sulfate… | 12022409 | 1 |
| Caelo | Aluminium potassium sulfate… | 12022401 | 1 |
| Caelo | Aluminium potassium sulfate… | 12022406 | 1 |
| Caelo | Aluminium potassium sulfate… | 12022406 | 2 |
| Euro OTC | Aluminium potassium sulfate… | 1004046-02 | 1 |
| Fagron | Aluminium potassium sulfate… | 103638 | 1 |
| Fagron | Aluminium potassium sulfate… | A1-063-Al | 1 |
| Fagron | Aluminium potassium sulfate… | 12/24-M02 | 1 |
| Fagron | Aluminium potassium sulfate… | A1-063-AL | 1 |
| Fagron | Aluminium potassium sulfate… | 13D08-N01 | 1 |
| Caelo | Aluminium potassium sulfate… | 12\|24-M03 | 1 |
| Caelo | Aluminium potassium sulfate… | 12184401 | 2 |
| Krömpke | Aluminium potassium sulfate… | 12144607 | 2 |
| Fagron | Aluminium potassium sulfate… | 13D29-N04 | 1 |
| Sanacorp | Aluminium potassium sulfate… | 12184402 | 2 |
| Caelo | Aluminium potassium sulfate… | 12144603 | 1 |
| Fagron | Aluminium potassium sulfate… | 12I24-M03 | 1 |
| Caesar/Noweda | American liverwort, cut | 11254608 | 1 |
| Caelo | Ammonium chloride | 12240302 | 4 |
| Caelo | Ammonium chloride | 10176319 | 2 |
| Caelo | Ammonium chloride | 12356101 | 3 |
| Caelo | Ammonium chloride | 10176309 | 1 |
| Euro OTC | Ammonium chloride | 1303029-01 | 1 |
| Euro OTC | Ammonium chloride | 1212017-01 | 2 |
| Euro OTC | Ammonium chloride | 1203029-01 | 1 |
| Euro OTC | Ammonium chloride | 512A-01104 | 1 |
| | Amphetamine sulfate | 24E23-F02-386349 | 2 |
| | Amphetamine sulfate | 22I08-F02-383423 | 1 |
| | Amphetamine sulfate | 22003072003 | 4 |
| Bombastus | Amphetamine sulfate | C18H28N2O4S | 1 |
| Caelo | Amphetamine sulfate | 18186903 | 1 |
| Caelo | Amphetamine sulfate | 16143001 | 1 |
| Caelo | Amphetamine sulfate | 16153909 | 1 |
| Caelo | Amphetamine sulfate | 20004272001 | 5 |
| Caelo | Amphetamine sulfate | 20004272011 | 2 |
| Caelo | Amphetamine sulfate | 12I24-N03 | 1 |
| Caelo | Amphetamine sulfate | 16153903 | 4 |
| Caelo | Amphetamine sulfate | 17K03-B01 | 1 |
| Caelo | Amphetamine sulfate | 1807171 | 1 |
| Caelo | Amphetamine sulfate | 13344609 | 1 |
| Caelo | Amphetamine sulfate | 18186906 | 1 |
| Caelo | Amphetamine sulfate | 15193204 | 3 |
| Caelo | Amphetamine sulfate | 16153902 | 1 |
| Caelo | Amphetamine sulfate | lot067002 | 1 |
| Caelo | Amphetamine sulfate | 15L01-B05 | 3 |
| Caelo | Amphetamine sulfate | 200004272009 | 1 |
| Caelo | Amphetamine sulfate | 22003072004 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Amphetamine sulfate | 2004272001 | 1 |
| Caelo | Amphetamine sulfate | 200004272001 | 1 |
| Caelo | Amphetamine sulfate | 16153905 | 4 |
| Caelo | Amphetamine sulfate | 12B06-N013 | 1 |
| Caelo | Amphetamine sulfate | 13G08-N11 | 3 |
| Caesar & Loretz GmbH | Amphetamine sulfate | 20004272002 | 2 |
| Caesar & Loretz GmbH | Amphetamine sulfate | 16153901 | 1 |
| Caesar & Loretz GmbH | Amphetamine sulfate | 22003072002 | 1 |
| Euro OTC | Amphetamine sulfate | 16A29-B03-324578 | 4 |
| Fa.Phönix | Amphetamine sulfate | 20004272006 | 1 |
| Fa.Phönix | Amphetamine sulfate | 19H05-B01-365582 | 4 |
| Fagron | Amphetamine sulfate | F001287 | 1 |
| Fagron | Amphetamine sulfate | 12B06-N13 | 2 |
| Fagron | Amphetamine sulfate | 15L01-B05-315291 | 6 |
| Fagron | Amphetamine sulfate | 16A29-B03-328317 | 7 |
| Fagron | Amphetamine sulfate | 16A29-B03 | 11 |
| Fagron | Amphetamine sulfate | 13B11-N04 | 2 |
| Fagron | Amphetamine sulfate | 96200 | 2 |
| Fagron | Amphetamine sulfate | 16A29B03318744 | 1 |
| Fagron | Amphetamine sulfate | 88689 | 2 |
| Fagron | Amphetamine sulfate | 16a29-B03-319156 | 1 |
| Fagron | Amphetamine sulfate | 13D09-N03 | 1 |
| Fagron | Amphetamine sulfate | 15l01-b05-315292 | 1 |
| Fagron | Amphetamine sulfate | 324577 | 2 |
| Fagron | Amphetamine sulfate | 315291 | 1 |
| Fagron | Amphetamine sulfate | B01_3655801 | 1 |
| Fagron | Amphetamine sulfate | 16A29-B03-324577 | 1 |
| Fagron | Amphetamine sulfate | 78012 | 1 |
| Fagron | Amphetamine sulfate | 1117I-03361 | 1 |
| Fagron | Amphetamine sulfate | 16K08-B04-336362 | 1 |
| Fagron | Amphetamine sulfate | 16A29-B03-318743 | 6 |
| Fagron | Amphetamine sulfate | 22I08-F02-383424 | 1 |
| Fagron | Amphetamine sulfate | 16A29_B03_318744 | 1 |
| Fagron | Amphetamine sulfate | 11/01-N01 | 1 |
| Fagron | Amphetamine sulfate | 12E11-N06 | 2 |
| Fagron | Amphetamine sulfate | 2213Q-03361 | 1 |
| Fagron | Amphetamine sulfate | 16A29-B03-328318 | 1 |
| Fagron | Amphetamine sulfate | 11D04-N13 | 1 |
| Fagron | Amphetamine sulfate | 19H05-B01-365581 | 2 |
| Fagron | Amphetamine sulfate | 13J18B40 | 1 |
| Fagron | Amphetamine sulfate | 16a29-b03-318744 | 2 |
| Fagron | Amphetamine sulfate | 19H05-B01-364791 | 1 |
| Fagron | Amphetamine sulfate | 13J18-B40 | 1 |
| Fagron | Amphetamine sulfate | 14E19-B09 | 2 |
| Fagron | Amphetamine sulfate | 19H05-B01-363346 | 4 |
| Fagron | Amphetamine sulfate | 12/24N-03 | 1 |
| Fagron | Amphetamine sulfate | 20I18-F06 | 2 |
| Fagron | Amphetamine sulfate | 15L01-B05-315290 | 1 |
| Fagron | Amphetamine sulfate | 17K03-B01-344122 | 3 |
| Fagron | Amphetamine sulfate | 16K08-B04-336361 | 3 |
| Fagron | Amphetamine sulfate | 15L01-B05-315292 | 7 |
| Fagron | Amphetamine sulfate | 19H05-B01-3633407 | 1 |
| Fagron | Amphetamine sulfate | 16K08B04336362 | 1 |
| Fagron | Amphetamine sulfate | 19H05-B01-363347 | 1 |
| Fagron | Amphetamine sulfate | 14E19-B09-304502 | 2 |
| Fagron | Amphetamine sulfate | 13J18-B40-290538 | 1 |
| Fagron | Amphetamine sulfate | 19H05-B01 | 1 |
| Fagron | Amphetamine sulfate | 16K08-B04 | 1 |
| Gatt Koller/Herba | Amphetamine sulfate | 942/03130814 | 1 |
| Gatt-Koller | Amphetamine sulfate | 18.03969 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gatt-Koller | Amphetamine sulfate | 22J01850 | 1 |
| Th. Geyer | Amphetamine sulfate | 67043P-180924-1 | 1 |
| Th. Geyer | Amphetamine sulfate | 70325P-190404-1 | 1 |
| Th. Geyer | Amphetamine sulfate | LOT070325 | 2 |
| Th. Geyer | Amphetamine sulfate | 57043 | 1 |
| Noweda | Amphetamine sulfate | 16A29-B03-318744 | 3 |
| Noweda 7.8.19 | Amphetamine sulfate | 70325P-190808-1 | 1 |
| Fagron | Amphetamine sulfate | 14E19-B09-294572 | 1 |
| Phoenix | Amphetamine sulfate | 16A29-B03-328317 | 1 |
| Phönix | Amphetamine sulfate | 22108-F02-383423 | 1 |
| Phönix | Amphetamine sulfate | 16a29-b03-328317 | 1 |
| Phönix | Amphetamine sulfate | 19H05-B01-363345 | 7 |
| Phönix | Amphetamine sulfate | 13B11N04 | 1 |
| Fagron | Amphetamine sulfate | 19h05b01365581 | 1 |
| Sanacorp | Amphetamine sulfate | 12/24-N03 | 1 |
| Th. Geyer | Amphetamine sulfate | 20170808-03361 | 1 |
| Th. Geyer | Amphetamine sulfate | LOT067043 | 1 |
| Th. Geyer | Amphetamine sulfate | LOT:070325 | 1 |
| Th. Geyer | Amphetamine sulfate | 6703 | 1 |
| Th. Geyer | Amphetamine sulfate | PH10051 | 3 |
| Th. Geyer | Amphetamine sulfate | 21082013B | 1 |
| Th. Geyer | Amphetamine sulfate | 70525 | 1 |
| Th. Geyer | Amphetamine sulfate | 67002 | 51 |
| Th. Geyer | Amphetamine sulfate | 67043 | 96 |
| Th. Geyer | Amphetamine sulfate | | 1 |
| Th. Geyer | Amphetamine sulfate | 618E-03361 | 1 |
| Th.Greyer/Krieger | Amphetamine sulfate | 70325 | 124 |
| - | Angelica root | 130924 | 1 |
| Bombastus | Angelica root | 275879 | 1 |
| Aurica/Phönix | Angelica root | 520800638 | 1 |
| Bombastus | Angelica root | 285732 | 2 |
| Bombastus | Angelica root | 269775 | 2 |
| Bombastus | Angelica root | 272954 | 1 |
| Bombastus | Angelica root | 270117 | 1 |
| Bombastus | Angelica root | 272895 | 1 |
| Bombastus | Angelica root | 301768 | 1 |
| Bombastus | Angelica root | 290309 | 1 |
| Bombastus | Angelica root | 281280 | 7 |
| Bombastus | Angelica root | 307041 | 4 |
| Bombastus | Angelica root | 291848 | 1 |
| Bombastus | Angelica root | 295085 | 2 |
| Bombastus | Angelica root | 305460 | 1 |
| Bombastus | Angelica root | 301767 | 3 |
| Bombastus | Angelica root | 275878 | 1 |
| Caelo | Angelica root | 12350703 | 9 |
| Caelo | Angelica root | 12350705 | 1 |
| Caelo | Angelica root | 17053302 | 1 |
| Caelo | Angelica root | 15101304 | 1 |
| Caelo | Angelica root | 30011302 | 1 |
| Caelo | Angelica root | 10071306 | 1 |
| Caelo | Angelica root | 13041711 | 1 |
| Caelo | Angelica root | 5091303 | 1 |
| Caelo | Angelica root | 28101402 | 1 |
| Caelo | Angelica root | 21011402 | 1 |
| Caelo | Angelica root | 12080403 | 1 |
| Caelo | Angelica root | 12080412 | 1 |
| Caelo | Angelica root | 11093304 | 1 |
| Caelo | Angelica root | 269740 | 1 |
| Caelo | Angelica root | 12168703 | 2 |
| Caelo | Angelica root | Int.Ch:318090 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Angelica root | 274128 | 2 |
| Caelo | Angelica root | 15162604 | 2 |
| Caelo | Angelica root | 12350704 | 2 |
| Caelo | Angelica root | 12168701 | 3 |
| Caelo | Angelica root | 14179506 | 2 |
| Caelo | Angelica root | 16128006 | 1 |
| Caelo | Angelica root | 16128002 | 3 |
| Caelo | Angelica root | 303299 | 1 |
| Caelo | Angelica root | 12168705 | 2 |
| Caelo | Angelica root | 9030301 | 1 |
| Caelo | Angelica root | 17053301 | 1 |
| Caelo | Angelica root | 5162606 | 1 |
| gasser | Angelica root | 950049 | 1 |
| Gehe | Angelica root | 285732 | 1 |
| Bombastus | Angelica root | 296334/1121115 | 1 |
| Klenk | Angelica root | 6081B130410 | 4 |
| Klenk | Angelica root | 17053308 | 1 |
| Klenk | Angelica root | 6081B140918 | 2 |
| Klenk | Angelica root | | 1 |
| Klenk | Angelica root | 6081N120110 | 14 |
| Klenk | Angelica root | 6081B150701 | 7 |
| Klenk | Angelica root | B130109 | 2 |
| Klenk | Angelica root | 6081B130109 | 7 |
| Klenk | Angelica root | 6091B130109 | 1 |
| Klenk | Angelica root | 6081n120110 | 1 |
| Klenk | Angelica root | 6081B130109 | 1 |
| Klenk | Angelica root | 6081B130726 | 1 |
| Klenk | Angelica root | 6081B170601 | 4 |
| Klenk | Angelica root | 6085B120614 | 1 |
| Klenk | Angelica root | 6082b130410 | 1 |
| Klenk | Angelica root | 6081b130109 | 2 |
| Caelo | Angelica root | 17053304 | 2 |
| Noweda | Angelica root | 272720 | 2 |
| Bombastus | Angelica root | 278294 | 1 |
| Caelo | Angelica root | 14178506 | 1 |
| Phönix Gotha | Angelica root | 278757 | 4 |
| Sanacorp | Angelica root | 277310 | 1 |
| Klenk | Angelica root | 6081B160908 | 1 |
| Weltecke | Angelica root | 38011111 | 1 |
| Anzag 06.04.2016 | Aniseed | 15398601 | 1 |
| Caelo | Aniseed | 1137033 | 1 |
| Aurica | Aniseed | 521302895 | 1 |
| Bahnhof-Apotheke | Aniseed | 7-120913 | 1 |
| Berkel AHK | Aniseed | 14194401 | 1 |
| Berkel AHK | Aniseed | 11374103 | 1 |
| Bombastus | Aniseed | 309836 | 1 |
| Bombastus | Aniseed | 285778 | 2 |
| Bombastus | Aniseed | 289846 | 2 |
| Bombastus | Aniseed | 282917 | 2 |
| Bombastus | Aniseed | 285777 | 1 |
| Bombastus | Aniseed | 305177 | 1 |
| Caelo | Aniseed | 13333913 | 1 |
| Caelo | Aniseed | PrüfNr4913E-01530 | 1 |
| Caelo | Aniseed | 13333901 | 6 |
| Caelo | Aniseed | 13333910 | 4 |
| Caelo | Aniseed | 16165305 | 6 |
| Caelo | Aniseed | 15046109 | 5 |
| Caelo | Aniseed | 16165303 | 1 |
| Caelo | Aniseed | 13333914 | 1 |
| Caelo | Aniseed | 15398602 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Aniseed | 13037901 | 1 |
| Caelo | Aniseed | 16200801 | 5 |
| Caelo | Aniseed | 16165304 | 4 |
| Caelo | Aniseed | 13333908 | 7 |
| Caelo | Aniseed | 13333903 | 4 |
| Caelo | Aniseed | 13037807 | 2 |
| Caelo | Aniseed | 2700A150601 | 11 |
| Caelo | Aniseed | 5061301 | 1 |
| Caelo | Aniseed | 11121705 | 1 |
| Caelo | Aniseed | 5121401 | 1 |
| Caelo | Aniseed | 10081207 | 1 |
| Caelo | Aniseed | 4061301 | 1 |
| Caelo | Aniseed | 5091304 | 1 |
| Caelo | Aniseed | 17045603 | 3 |
| Caelo | Aniseed | 17045609 | 4 |
| Caelo | Aniseed | 11101202 | 3 |
| Caelo | Aniseed | 15046103 | 3 |
| Caelo | Aniseed | 13037801 | 1 |
| Caelo | Aniseed | 15398607 | 1 |
| Caelo | Aniseed | 11101214 | 6 |
| Caelo | Aniseed | 10247202 | 1 |
| Caelo | Aniseed | 161635305 | 1 |
| Caelo | Aniseed | 17045601 | 1 |
| Caelo | Aniseed | 11101201 | 1 |
| Caelo | Aniseed | 15049103 | 1 |
| Caelo | Aniseed | 13333916 | 1 |
| Caelo | Aniseed | 16165308 | 1 |
| Caelo | Aniseed | 15046106 | 1 |
| Caelo | Aniseed | 16165302 | 1 |
| Caelo | Aniseed | 13333909 | 2 |
| Caelo | Aniseed | 12360801 | 1 |
| Caelo | Aniseed | 11101215 | 3 |
| Caelo | Aniseed | 13037809 | 12 |
| Caelo | Aniseed | 17045602 | 3 |
| Caelo | Aniseed | 15283201 | 6 |
| Caelo | Aniseed | 15046102 | 12 |
| Caelo | Aniseed | 11370301 | 10 |
| Caelo | Aniseed | 111101213 | 1 |
| Caelo | Aniseed | 11101213 | 2 |
| Caelo | Aniseed | 3314E-01530 | 1 |
| Caelo | Aniseed | 2215M-01530 | 1 |
| Caelo | Aniseed | 2916E-01530 | 1 |
| Caelo | Aniseed | 13333902 | 9 |
| Caelo | Aniseed | 15398603 | 5 |
| Caelo | Aniseed | | 1 |
| Caelo | Aniseed | 11101203 | 6 |
| Caelo | Aniseed | 13333907 | 4 |
| Caelo | Aniseed | 140913a | 1 |
| Caelo | Aniseed | 13333906 | 3 |
| Caelo | Aniseed | 17045608 | 1 |
| Caelo | Aniseed | 1539805 | 1 |
| Caelo | Aniseed | 13037802 | 9 |
| Caelo | Aniseed | 13333912 | 3 |
| Caelo | Aniseed | 13037804 | 7 |
| Caelo | Aniseed | 15046110 | 1 |
| Caelo | Aniseed | 12226402 | 5 |
| Caelo | Aniseed | 15046101 | 5 |
| Caelo | Aniseed | 13037808-3560412014 | 1 |
| Caelo | Aniseed | 15398601I-301216/5 | 1 |
| Caeol/Phönix | Aniseed | 15398605 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz/Noweda | Aniseed | 153986002 | 1 |
| Fagron | Aniseed | 11370304 | 7 |
| galke | Aniseed | 19654 | 1 |
| Galke | Aniseed | 23464 | 1 |
| Galke | Aniseed | 22274 | 1 |
| Galke | Aniseed | 21278 | 1 |
| GALKE | Aniseed | 29047 | 1 |
| Gehe | Aniseed | 11370303 | 14 |
| Gehe | Aniseed | 10247203 | 1 |
| Gutenberg-Apotheke | Aniseed | 1333902 | 1 |
| Hepart AG | Aniseed | B216346,kbA | 1 |
| Caelo | Aniseed | 13037808 | 9 |
| Klenk | Aniseed | 13037805 | 11 |
| Klenk | Aniseed | 2700A120320 | 8 |
| Klenk | Aniseed | 2901311530 | 1 |
| Klenk | Aniseed | 2103311530 | 1 |
| Klenk | Aniseed | 3113Q01530 | 1 |
| Klenk | Aniseed | 2700A130527 | 15 |
| Klenk | Aniseed | 212M-01530 | 1 |
| Klenk | Aniseed | 2700A110701 | 7 |
| Klenk | Aniseed | 2700A150810 | 2 |
| Klenk | Aniseed | 2700A170803 | 1 |
| Klenk | Aniseed | 2700A190107 | 1 |
| Klenk | Aniseed | 2700A-110701 | 1 |
| Klenk | Aniseed | 2700a120320 | 1 |
| Klenk | Aniseed | 2700A150901 | 3 |
| Klenk | Aniseed | 2700A12107 | 1 |
| Klenk | Aniseed | 2700A160511 | 8 |
| Klenk | Aniseed | 814Q01530 | 1 |
| Klenk | Aniseed | 2700A140129 | 9 |
| Klenk | Aniseed | Klenk2700A131015 | 1 |
| Klenk | Aniseed | 2700A121107 | 1 |
| Caelo | Aniseed | 16165306 | 5 |
| Caelo | Aniseed | 17045611 | 3 |
| nachprüfung | Aniseed | C1246 | 1 |
| Nachprüfung | Aniseed | 5010U-01530 | 1 |
| Noweda | Aniseed | 11370308 | 3 |
| Phönix | Aniseed | 13037803 | 2 |
| Phönix | Aniseed | 11370302 | 4 |
| Sanacorp | Aniseed | 2700A131015 | 2 |
| siehe Protokoll | Aniseed | sieheProtokoll | 1 |
| Wolf | Aniseed | B216346 | 14 |
| Wolf | Aniseed | 216346 | 1 |
| Wolf | Aniseed | B-671 | 2 |
| Wolf | Aniseed | B671 | 1 |
| Wolf | Aniseed | L401F292b | 4 |
| Wolf | Aniseed | L401F1413 | 1 |
| Wolf | Aniseed | 215346 | 1 |
| Caelo | Aniseed, pounded | 23041303 | 1 |
| Caelo | Aniseed, pounded | 4041302 | 1 |
| Caelo | Aniseed, pounded | 15149702 | 1 |
| Caelo | Aniseed, pounded | 12111304 | 1 |
| Caelo | Aniseed, pounded | 11242003 | 1 |
| Caelo | Aniseed, pounded | 1314990 | 1 |
| Caelo | Aniseed, pounded | 12111303 | 3 |
| Gahlke | Aniseed, pounded | 21401 | 1 |
| Gehe | Aniseed, pounded | 13149903 | 1 |
| Caelo | Aniseed, pounded | 13149902 | 1 |
| Caelo | Aniseed, pounded | 12360803 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Aniseed, pounded | 2706B100120 | 1 |
| Aurica Naturheilmi… | Aniseed, powdered | 521405796 | 1 |
| Klenk | Aniseed, powdered | 2704B110824 | 1 |
| vedono | Aniseed, powdered | 11306208 | 1 |
| Caelo | Apple, cut | 12227301 | 1 |
| Klenk | Apple, cut | A120302 | 3 |
| Caelo | Arnica flower | 11259803 | 1 |
| Caelo | Arnica flower | 10081204 | 1 |
| Caelo | Arnica flower | 28071201 | 1 |
| Caelo | Arnica flower | 12227203 | 1 |
| Caelo | Arnica flower | 11285705 | 1 |
| Caelo | Arnica flower | 11259804 | 1 |
| Caelo | Arnica flower | 6112013A | 1 |
| Caelo | Arnica flower | 11374102 | 2 |
| Caelo | Arnica flower | 11374101 | 2 |
| Caelo | Arnica flower | 122227202 | 1 |
| Caelo | Arnica flower | 11374105 | 1 |
| Caelo | Arnica flower | 10207405 | 1 |
| Caelo | Arnica flower | 11285703 | 1 |
| Caelo | Arnica flower | 1222702 | 1 |
| Caelo | Arnica flower | IntCh:212032 | 1 |
| Caelo | Arnica flower | 12227202 | 1 |
| Caelo | Arnica flower | 11374103 | 1 |
| Gehe | Arnica flower | 11259801 | 2 |
| Klenk | Arnica flower | 1181B130605 | 1 |
| Bombastus | Artichoke leaf | 8202213593 | 1 |
| Caelo | Artichoke leaf | 12173302 | 3 |
| Caelo | Artichoke leaf | 12173306 | 2 |
| Caelo | Artichoke leaf | 12173304 | 3 |
| Caelo | Artichoke leaf | 2312I-03593 | 1 |
| Caelo | Artichoke leaf | 13037608 | 1 |
| Caelo | Artichoke leaf | 12173307 | 6 |
| Caelo | Artichoke leaf | 1981B121025 | 2 |
| Caelo | Artichoke leaf | 13037603 | 1 |
| Caelo | Artichoke leaf | 13037607 | 4 |
| Caelo | Artichoke leaf | 81232298 | 1 |
| Caelo | Artichoke leaf | 12173307-3260315072 | 1 |
| Caelo | Artichoke leaf | 13310706 | 1 |
| Kenk / Phoenix | Artichoke leaf | 1981B130111 | 3 |
| Klenk | Artichoke leaf | B121025 | 2 |
| Klenk | Artichoke leaf | 1981B120413 | 1 |
| Caelo | Ash leaf, cut | 12225504 | 1 |
| Caelo | Ash leaf, cut | 12225502 | 1 |
| Caelo | Ash leaf, cut | 12225505 | 2 |
| Klenk | Ash leaf, cut | 5111A-01491 | 1 |
| Caelo | Asparagus root, cut | 13193308 | 1 |
| Caelo | Asparagus root, cut | 13193302 | 1 |
| Caelo | Asparagus root, cut | 15010802 | 1 |
| Galke | Asparagus root, cut | 20178 | 1 |
| Caelo | Asparagus root, cut | 13071002 | 1 |
| Klenk | Asparagus root, cut | 6151B100332 | 1 |
| Klenk | Asplenium scolopendrium, cut | 4451B120605 | 1 |
| Klenk | Asplenium scolopendrium, cut | 4451B091116 | 1 |

**B**

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Barberries | 12217111 | 1 |
| Caelo | Barberries | 12217103 | 3 |
| Caelo | Barberries | 11058320 | 1 |
| Caelo | Barberries | 12217113 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Barberries | 12217106 | 1 |
| Caelo | Barberries | 12217116 | 1 |
| Caelo | Barberries | 16224202 | 1 |
| Caelo | Barberries | 1221707 | 1 |
| Caelo | Barberries | 12217109 | 4 |
| Caelo | Barberries | 12217107 | 1 |
| Caaelo | Barberry root bark, cut | 551B110128 | 4 |
| Caelo | Barberry root bark, cut | 11083509 | 1 |
| Caelo | Barberry root bark, cut | 12112606 | 5 |
| Caelo | Barberry root bark, cut | 12112603 | 2 |
| Caelo | Barberry root bark, cut | 55B110128 | 1 |
| Caelo | Barberry root bark, cut | 12112605 | 1 |
| Klenk | Barberry root bark, cut | 551B120320 | 1 |
| Caelo | Barberry root bark, cut | 12112608 | 1 |
| Fagron | Barbital sodium | 15L07-B02 | 1 |
| Caelo | Basil, rubbed | 12007010 | 4 |
| Caelo | Basil, rubbed | 12066404 | 1 |
| Caelo | Basil, rubbed | 13048601 | 2 |
| Caelo | Basil, rubbed | 13048605 | 1 |
| Caelo | Basil, rubbed | 12007008 | 2 |
| Caelo | Basil, rubbed | 13048605-3519411022 | 1 |
| Klenk | Basil, rubbed | A110201 | 1 |
| Klenk | Basil, rubbed | A120502 | 1 |
| Klenk | Basil, rubbed | 3632A120502 | 4 |
| Klenk | Basil, rubbed | 3632a120502 | 1 |
| Klenk | Basil, rubbed | 3632A110201 | 3 |
| VDL | Basil, rubbed | 12007004 | 1 |
| Caelo | Bearberry leaf | 12186506 | 3 |
| Bombastus | Bearberry leaf | 275491 | 3 |
| Bombastus | Bearberry leaf | 267926 | 1 |
| Bombastus | Bearberry leaf | 272297 | 8 |
| Caelo | Bearberry leaf | 13067802 | 3 |
| Caelo | Bearberry leaf | 4021407 | 1 |
| Caelo | Bearberry leaf | 4091301 | 1 |
| Caelo | Bearberry leaf | 20111210 | 1 |
| Caelo | Bearberry leaf | 17121306 | 1 |
| Caelo | Bearberry leaf | 5111301 | 1 |
| Caelo | Bearberry leaf | 15051303 | 1 |
| Caelo | Bearberry leaf | 15116201 | 1 |
| Caelo | Bearberry leaf | 11213010 | 1 |
| Caelo | Bearberry leaf | 12186503 | 1 |
| Caelo | Bearberry leaf | 12186504 | 1 |
| Caelo | Bearberry leaf | 17311305 | 1 |
| Caelo | Bearberry leaf | 18304202 | 2 |
| Caelo | Bearberry leaf | 17311308 | 1 |
| Caelo | Bearberry leaf | 1218602 | 1 |
| Caelo | Bearberry leaf | 280889 | 3 |
| Caelo | Bearberry leaf | 11213005 | 4 |
| Caelo | Bearberry leaf | 412A-01518 | 1 |
| Caelo | Bearberry leaf | 13067805-3390311080 | 1 |
| Caesar & Loretz GmbH | Bearberry leaf | 11213011 | 3 |
| Galke | Bearberry leaf | 19936 | 3 |
| Caelo | Bearberry leaf | 13067805 | 6 |
| Klenk | Bearberry leaf | 2391B120314 | 6 |
| Klenk | Bearberry leaf | 2391B110209 | 3 |
| Klenk | Bearberry leaf | 2391B120719 | 13 |
| Klenk | Bearberry leaf | 2391B130328 | 9 |
| Klenk | Bearberry leaf | 2391B07030901 | 1 |
| Klenk | Bearberry leaf | 2391b120314 | 2 |
| Caelo | Bearberry leaf | 12186502 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Bentonite | fürHerrSalloch | 1 |
| Caelo | Bentonite | 1307016-01 | 1 |
| Caelo | Bentonite | 1311014-01 | 1 |
| Clariant - Mindel-Food | Bentonite | 1301 | 1 |
| Noweda | Bentonite | 11304415 | 1 |
| Caelo | Betony herb, cut | 12007205 | 2 |
| Caelo | Betony herb, cut | 12007208 | 1 |
| Caelo | Betony herb, cut | 13048906 | 1 |
| Caelo | Betony herb, cut | 134048903 | 1 |
| Caelo | Betony herb, cut | 13367802 | 1 |
| Sanacorp | Betony herb, cut | 13048903 | 3 |
| Caelo | Betony herb, cut | 12007201 | 1 |
| Cae | Bilberry fruit, dried | 212172 | 1 |
| Caelo | Bilberry fruit, dried | 13130504 | 1 |
| Caelo | Bilberry fruit, dried | 10265601 | 1 |
| Caelo | Bilberry fruit, dried | 18101307 | 1 |
| Caelo | Bilberry fruit, dried | 26061301 | 1 |
| Caelo | Bilberry fruit, dried | 12183701 | 2 |
| Caelo | Bilberry fruit, dried | 13130501 | 1 |
| Caelo | Bilberry fruit, dried | 10273708 | 1 |
| Caelo | Bilberry fruit, dried | 10273709 | 1 |
| Caelo | Bilberry fruit, dried | 10265603 | 1 |
| Caelo | Bilberry fruit, dried | 2910N110304 | 5 |
| Caelo | Bilberry fruit, dried | 10273711 | 1 |
| Caelo | Bilberry fruit, dried | 12183704 | 4 |
| Fagron | Bilberry fruit, dried | 2910N121022 | 7 |
| Fiebig 05.11.12 ek… | Bilberry fruit, dried | 2910A120410 | 1 |
| Klenk | Bilberry fruit, dried | 2910N130131 | 11 |
| Klenk | Bilberry fruit, dried | 2010N110304 | 1 |
| Klenk | Bilberry fruit, dried | N121022 | 1 |
| Klenk | Bilberry fruit, dried | N130131 | 2 |
| Klenk | Bilberry fruit, dried | 2910A090717 | 1 |
| Klenk | Bilberry fruit, dried | 2910N120921 | 2 |
| Klenk | Bilberry fruit, dried | 2910n130131 | 1 |
| Klenk | Bilberry fruit, dried | 910N130131 | 1 |
| Klenk | Bilberry fruit, dried | 2910n110304 | 1 |
| Bombastus | Bilberry leaf | 272176 | 2 |
| Caelo | Bilberry leaf | 23111201 | 1 |
| Caelo | Bilberry leaf | 3091302 | 1 |
| Caelo | Bilberry leaf | 12140204 | 4 |
| Caelo | Bilberry leaf | 12140206 | 2 |
| Caelo | Bilberry leaf | 13009907 | 2 |
| Caelo | Bilberry leaf | 12140201 | 2 |
| Caelo | Bilberry leaf | 13009901 | 3 |
| Caelo | Bilberry leaf | 9367603 | 2 |
| Caelo | Bilberry leaf | 13009903 | 4 |
| Caelo | Bilberry leaf | 13009904 | 3 |
| Caelo | Bilberry leaf | 1300907 | 1 |
| Hedinger/Sanacorp | Bilberry leaf | 2191A130410 | 2 |
| Klenk | Bilberry leaf | 2191N110516 | 5 |
| Klenk | Bilberry leaf | N110516 | 1 |
| Klenk | Bilberry leaf | 4042013 | 1 |
| Aurica | Birch leaf | 521205644 | 1 |
| Bahnhof-Apotheke | Birch leaf | 18-120702 | 1 |
| Bombastus | Birch leaf | 287280 | 1 |
| Bombastus | Birch leaf | 280677 | 1 |
| Bombastus | Birch leaf | 272385 | 1 |
| Bombastus | Birch leaf | 267077 | 1 |
| Bombastus | Birch leaf | 270743 | 1 |
| Caelo | Birch leaf | 12193108 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Birch leaf | 14360702 | 1 |
| Caelo | Birch leaf | 13337302 | 1 |
| Caelo | Birch leaf | 11189507 | 1 |
| Caelo | Birch leaf | 13108917 | 1 |
| Caelo | Birch leaf | 11189510 | 3 |
| Caelo | Birch leaf | 13108906 | 1 |
| Caelo | Birch leaf | 13337303 | 1 |
| Caelo | Birch leaf | 11189508 | 1 |
| Caelo | Birch leaf | IntCh:311092 | 1 |
| Caelo | Birch leaf | 12193109 | 15 |
| Caelo | Birch leaf | 13108916 | 1 |
| Caelo | Birch leaf | 1901C120508 | 18 |
| Caelo | Birch leaf | 12193104 | 1 |
| Caelo | Birch leaf | 107063 | 1 |
| Caelo | Birch leaf | 11189502 | 1 |
| Caelo | Birch leaf | 11050102 | 3 |
| Caelo | Birch leaf | 12193004 | 5 |
| Caelo | Birch leaf | 12193105 | 3 |
| Caelo | Birch leaf | 13108905 | 8 |
| Caelo | Birch leaf | 13337303-3561412013 | 1 |
| Fagron | Birch leaf | 7061301 | 1 |
| Galke | Birch leaf | 20904 | 1 |
| Galke | Birch leaf | 21226 | 1 |
| Klenk | Birch leaf | 1901A110726 | 24 |
| Klenk | Birch leaf | F-040413-1 | 1 |
| Klenk | Birch leaf | 4021409 | 1 |
| Klenk | Birch leaf | 21061303 | 1 |
| Klenk | Birch leaf | 20111201 | 1 |
| Klenk | Birch leaf | 27121301 | 1 |
| Klenk | Birch leaf | 28101306 | 1 |
| Klenk | Birch leaf | A121130 | 2 |
| Klenk | Birch leaf | C120802 | 1 |
| Klenk | Birch leaf | 1901A130318 | 2 |
| Klenk | Birch leaf | 1901A140214 | 1 |
| Klenk | Birch leaf | 1901c120508 | 1 |
| Klenk | Birch leaf | 1901c120802 | 1 |
| Klenk | Birch leaf | 1901A-110726 | 3 |
| Klenk | Birch leaf | 1901A130218 | 5 |
| Klenk | Birch leaf | 1901A121130 | 24 |
| Klenk | Birch leaf | 1901C120802 | 19 |
| Klenk | Birch leaf | 4213I01481 | 1 |
| Klenk | Birch leaf | 1901A05051801 | 1 |
| Klenk | Birch leaf | 4113A-01481 | 1 |
| Spangropharm | Birch leaf | 264603 | 1 |
| 5N Plus Lübeck Gmb… | Bismuth subnitrate, heavy | 12146908 | 1 |
| Caelo | Bismuth subnitrate, heavy | 12146913 | 2 |
| Caelo | Bismuth subnitrate, heavy | 4513M-01186 | 1 |
| Caelo | Bismuth subnitrate, heavy | M468105 | 1 |
| Caelo | Bismuth subnitrate, heavy | 12146902 | 1 |
| Caelo | Bismuth subnitrate, heavy | 12146911 | 3 |
| Caelo | Bismuth subnitrate, heavy | 10013208 | 1 |
| Caelo | Bismuth subnitrate, heavy | 10F09-N13 | 1 |
| Caelo | Bismuth subnitrate, heavy | 11052809 | 1 |
| Caelo | Bismuth subnitrate, heavy | 10013213 | 1 |
| Caelo | Bismuth subnitrate, heavy | 11052805 | 1 |
| Caesar & Loretz GmbH | Bismuth subnitrate, heavy | 12146903 | 4 |
| Caesar & Loretz/ Noweda | Bismuth subnitrate, heavy | 12145701 | 1 |
| Fagron | Bismuth subnitrate, heavy | 13C15-N05 | 3 |
| Fagron | Bismuth subnitrate, heavy | 1309211186 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Bismuth subnitrate, heavy | 1001311186 | 1 |
| Fagron | Bismuth subnitrate, heavy | 12D26-N03 | 1 |
| Fagron | Bismuth subnitrate, heavy | 12C08-N06 | 3 |
| Fagron | Bismuth subnitrate, heavy | 13H28-B04-291385 | 1 |
| Fagron | Bismuth subnitrate, heavy | 11D28-N16 | 1 |
| Fagron | Bismuth subnitrate, heavy | 13B25-N02 | 3 |
| Fagron | Bismuth subnitrate, heavy | 11/13-N01 | 1 |
| Merck | Bismuth subnitrate, heavy | 75419201 | 1 |
| Noweda | Bismuth subnitrate, heavy | 13/01-N02 | 1 |
| Purren Apotheke | Bismuth subnitrate, heavy | 11H31-N06 | 1 |
| Sanacorp | Bismuth subnitrate, heavy | 12146909 | 2 |
| - | Bitter-Orange flower (petals) | 2011A-01445 | 1 |
| Caelo | Bitter-Orange flower (petals) | 6051301 | 1 |
| Caelo | Bitter-Orange flower (petals) | 2712E-01445 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266609 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266608 | 6 |
| Caelo | Bitter-Orange flower (petals) | 12266608 | 2 |
| Caelo | Bitter-Orange flower (petals) | 13352701 | 1 |
| Caelo | Bitter-Orange flower (petals) | 11049212 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266708 | 1 |
| Caelo | Bitter-Orange flower (petals) | 13067903 | 2 |
| Caelo | Bitter-Orange flower (petals) | 11049202 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266614 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266703 | 2 |
| Caelo | Bitter-Orange flower (petals) | 12266705 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266707 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266605 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266611 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266605 | 1 |
| Caelo | Bitter-Orange flower (petals) | 12266611 | 1 |
| Caelo | Bitter-Orange flower (petals) | 13352701-3518411022 | 1 |
| Hepart AG | Bitter-Orange flower (petals) | B120822 | 1 |
| Klenk | Bitter-Orange flower (petals) | 1201B110809 | 1 |
| Klenk | Bitter-Orange flower (petals) | 1201B120822 | 1 |
| Klenk | Bitter-Orange flower (petals) | 3613m-01445 | 1 |
| Bombastus | Bitter-Orange peel | 274240 | 3 |
| Bombastus | Bitter-Orange peel | 278233 | 4 |
| Caelo | Bitter-Orange peel | 17111201 | 1 |
| Caelo | Bitter-Orange peel | 27011403 | 1 |
| Caelo | Bitter-Orange peel | 21101302 | 1 |
| Caelo | Bitter-Orange peel | 4312M-01531 | 1 |
| Caelo | Bitter-Orange peel | 12067402 | 1 |
| Caelo | Bitter-Orange peel | 13049001 | 1 |
| Caelo | Bitter-Orange peel | 12067405 | 1 |
| Caelo | Bitter-Orange peel | 12239203 | 3 |
| Klenk | Bitter-Orange peel | 511A110411 | 1 |
| Klenk | Bitter-Orange peel | C130226 | 3 |
| Klenk | Bitter-Orange peel | B120830 | 1 |
| Klenk | Bitter-Orange peel | 511B120830 | 4 |
| Klenk | Bitter-Orange peel | 511B110321 | 2 |
| Klenk | Bitter-Orange peel | 511C130226 | 1 |
| Klenk | Bitter-Orange peel | 2711B111207 | 1 |
| Klenk | Bitter-Orange peel | 3613M-01531 | 1 |
| kräuter schulte | Bitter-Orange peel | 51265 | 1 |
| Caelo | Black cohosh | 13142101 | 1 |
| Caelo | Black cohosh | 10281112 | 1 |
| Caelo | Black cohosh | 13237907 | 1 |
| Caelo | Black cohosh | 10281104 | 1 |
| Caelo | Black cohosh | 10281118 | 2 |
| Caelo | Black cohosh | 51981386 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Black cohosh | 13237903 | 1 |
| Klenk | Black cohosh | 6721B141202 | 1 |
| Caelo | Black cohosh | 13237901 | 2 |
| Klenk | Black cohosh | B130528 | 2 |
| Klenk | Black cohosh | 6721B1130528 | 1 |
| Klenk | Black cohosh | 3794377 | 1 |
| Klenk | Black cohosh | 6721B081208 | 1 |
| Klenk | Black cohosh | 6721B130528 | 3 |
| Klenk | Black cohosh | 6721b130528 | 1 |
| Kräuter Schulte | Black cohosh | 3308M-02176 | 1 |
| Nachprüfung | Black cohosh | 10281113 | 1 |
| Klenk | Black cohosh | 6721B130214 | 10 |
| Akazie | Black cumin seed | 20.09.2015 | 1 |
| Caelo | Black cumin seed | 10121916 | 1 |
| Caelo | Black cumin seed | 11233502 | 2 |
| Caelo | Black cumin seed | 14359905 | 1 |
| Caelo | Black cumin seed | 10121915 | 1 |
| Caelo | Black cumin seed | 16115710 | 1 |
| Caelo | Black cumin seed | 12358901 | 2 |
| Caelo | Black cumin seed | 13326406 | 1 |
| Caelo | Black cumin seed | 12358906 | 2 |
| Caelo | Black cumin seed | 13326405 | 2 |
| Caelo | Black cumin seed | 16115706 | 1 |
| Caelo | Black cumin seed | 11233507 | 1 |
| Caelo | Black cumin seed | 13122013b | 1 |
| Caelo | Black cumin seed | 16115703 | 2 |
| Caelo | Black cumin seed | 14359903 | 3 |
| Caelo | Black cumin seed | 15300401 | 3 |
| Caelo | Black cumin seed | 16115708 | 3 |
| Caelo | Black cumin seed | 14359906 | 2 |
| Hepart AG | Black cumin seed | 20720,kbA | 1 |
| Caelo | Black cumin seed | 12358902 | 1 |
| Caelo | Black cumin seed | 12358904 | 1 |
| Klenk | Black cumin seed | A120703 | 1 |
| Klenk | Black cumin seed | 7330A120703 | 1 |
| Caelo | Black cumin seed | 11233503 | 1 |
| Spinnrad | Black cumin seed | 11931059 | 1 |
| Spinnrad/Phoenix | Black cumin seed | 613310592 | 1 |
| Caelo | Black cumin seed | 12358903 | 2 |
| Wolf | Black cumin seed | L310F141b | 6 |
| Wolf | Black cumin seed | 20720 | 8 |
| Wolf | Black cumin seed | L402F1713 | 1 |
| Wolf | Black cumin seed | B-471 | 1 |
| Wolf | Black cumin seed | L402F171b | 3 |
| Wolf | Black cumin seed | | 1 |
| Wolf | Black cumin seed | 207204 | 1 |
| Caelo | Black mustard seed | 14057702 | 1 |
| Caelo | Black mustard seed | 12189307 | 1 |
| Caelo | Black mustard seed | 16139102 | 1 |
| Caelo | Black mustard seed | 13038904 | 1 |
| Klenk | Black mustard seed | 7430A120813 | 2 |
| Klenk | Black mustard seed, powdered | 7434A120712 | 1 |
| Caelo | Black mustard seed, powdered | 13097701 | 11 |
| Caelo | Black mustard seed, powdered | 12350208 | 7 |
| Caelo | Black mustard seed, powdered | 12350202 | 16 |
| Caelo | Black mustard seed, powdered | 12208602 | 5 |
| Caelo | Black mustard seed, powdered | 14162810 | 3 |
| Caelo | Black mustard seed, powdered | 25011401 | 1 |
| Caelo | Black mustard seed, powdered | 23061401 | 1 |
| Caelo | Black mustard seed, powdered | 15214713 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Black mustard seed, powdered | 15214707 | 1 |
| Caelo | Black mustard seed, powdered | 15214703 | 1 |
| Caelo | Black mustard seed, powdered | 12350209 | 1 |
| Caelo | Black mustard seed, powdered | 12208601 | 3 |
| Caelo | Black mustard seed, powdered | 12350204 | 2 |
| Caelo | Black mustard seed, powdered | 12350205 | 2 |
| Caelo | Black mustard seed, powdered | 12350210 | 1 |
| Caelo | Black mustard seed, powdered | 14162802 | 1 |
| Caelo | Black mustard seed, powdered | 12009706 | 1 |
| Caelo | Black mustard seed, powdered | 14162810 | 2 |
| Caelo | Black mustard seed, powdered | 16051807 | 1 |
| Caelo | Black mustard seed, powdered | 15214706 | 3 |
| Caelo | Black mustard seed, powdered | 17196303 | 4 |
| Caelo | Black mustard seed, powdered | 12208604 | 3 |
| Caelo | Black mustard seed, powdered | 15214714 | 1 |
| Caelo | Black mustard seed, powdered | 11276701 | 1 |
| Caelo | Black mustard seed, powdered | 12009703 | 1 |
| Caelo | Black mustard seed, powdered | 16051807 | 1 |
| Caelo | Black mustard seed, powdered | 15131101 | 1 |
| Caelo | Black mustard seed, powdered | 14293706 | 1 |
| Caelo | Black mustard seed, powdered | 15214707 | 2 |
| Caelo | Black mustard seed, powdered | 2015Q-02244 | 1 |
| Caelo | Black mustard seed, powdered | 12009702 | 4 |
| Caelo | Black mustard seed, powdered | 17196306 | 1 |
| Caelo | Black mustard seed, powdered | 16272707 | 4 |
| Caelo | Black mustard seed, powdered | 14293701 | 2 |
| Caelo | Black mustard seed, powdered | 15214703 | 7 |
| Caelo | Black mustard seed, powdered | 14293710 | 2 |
| Caelo | Black mustard seed, powdered | 14162807 | 3 |
| Caelo | Black mustard seed, powdered | 15131102 | 3 |
| Caelo | Black mustard seed, powdered | 16051802 | 3 |
| Caelo | Black mustard seed, powdered | 16333501 | 2 |
| Caelo | Black mustard seed, powdered | 15131104 | 1 |
| Caelo | Black mustard seed, powdered | 13358304 | 4 |
| Caelo | Black mustard seed, powdered | 17196301 | 1 |
| Caelo | Black mustard seed, powdered | 14245601 | 1 |
| Caelo | Black mustard seed, powdered | 1633503 | 1 |
| Caelo | Black mustard seed, powdered | 13097704 | 4 |
| Caelo | Black mustard seed, powdered | 16051810 | 4 |
| Caelo | Black mustard seed, powdered | 15131105 | 1 |
| Caelo | Black mustard seed, powdered | 14162808 | 1 |
| Caelo | Black mustard seed, powdered | 13097706 | 2 |
| Caelo | Black mustard seed, powdered | 16272704 | 2 |
| Caelo | Black mustard seed, powdered | 14293713 | 1 |
| Caelo | Black mustard seed, powdered | 14293711 | 3 |
| Caelo | Black mustard seed, powdered | 14293702 | 6 |
| Caelo | Black mustard seed, powdered | 16272703 | 6 |
| Caelo | Black mustard seed, powdered | 15214708 | 4 |
| Caelo | Black mustard seed, powdered | 13358302 | 13 |
| Caelo | Black mustard seed, powdered | 13097705 | 6 |
| Caelo | Black mustard seed, powdered | 13097702 | 4 |
| Caelo | Black mustard seed, powdered | 12350202-3369319012 | 1 |
| Caesar / Ebert & Jacobi | Black mustard seed, powdered | 16051809 | 1 |
| Caelo | Black mustard seed, powdered | 17276404 | 1 |
| Caelo | Black mustard seed, powdered | 12350207 | 5 |
| Caelo | Black mustard seed, powdered | 12350211 | 3 |
| Klenk | Black mustard seed, powdered | A130422 | 1 |
| Klenk | Black mustard seed, powdered | 7434A130422 | 3 |
| Klenk | Black mustard seed, powdered | 7434a150608 | 1 |
| Klenk | Black mustard seed, powdered | 7434A140923 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Black mustard seed, powdered | 7434A150608 | 4 |
| Noweda/Henry Lamotte | Black mustard seed, powdered | 1493708 | 1 |
| Phönix/Phönix | Black mustard seed, powdered | 16333503 | 3 |
| Anzag | Blackberry leaf | 10136412 | 1 |
| Anzag 27.12.12 ek:2,79 | Blackberry leaf | 10136048 | 1 |
| Bahnhof-Apotheke | Blackberry leaf | 18-120702 | 1 |
| Bombastus | Blackberry leaf | 267122 | 1 |
| Bombastus | Blackberry leaf | 273668 | 2 |
| Caelo | Blackberry leaf | 2271c120508 | 1 |
| Caelo | Blackberry leaf | 11030704 | 4 |
| Caelo | Blackberry leaf | 14111318 | 1 |
| Caelo | Blackberry leaf | 3091303 | 1 |
| Caelo | Blackberry leaf | 13091206 | 1 |
| Caelo | Blackberry leaf | 28061202 | 1 |
| Caelo | Blackberry leaf | 14019010 | 1 |
| Caelo | Blackberry leaf | 15039301 | 1 |
| Caelo | Blackberry leaf | 3011E-01512 | 1 |
| Caelo | Blackberry leaf | 10136403 | 1 |
| Caelo | Blackberry leaf | 11030706 | 1 |
| Caelo | Blackberry leaf | 13101610 | 1 |
| Caelo | Blackberry leaf | 13127901 | 1 |
| Caelo | Blackberry leaf | 11030701 | 2 |
| Caelo | Blackberry leaf | 10136408 | 6 |
| Caelo | Blackberry leaf | 11030707 | 5 |
| Gehe | Blackberry leaf | 10136409 | 1 |
| Klenk | Blackberry leaf | 2271B111216 | 1 |
| Caelo | Blackcurrant leaf, cut | 9373913 | 1 |
| Caelo | Blackcurrant leaf, cut | 12115902 | 1 |
| Caelo | Blackcurrant leaf, cut | 12168804 | 1 |
| Caelo | Blackcurrant leaf, cut | 12168810 | 3 |
| Caelo | Blackcurrant leaf, cut | 80558228 | 1 |
| Klenk | Blackcurrant leaf, cut | 2251A110204 | 4 |
| Klenk | Blackcurrant leaf, cut | 2251a110204 | 1 |
| Nachprüfung | Blackcurrant leaf, cut | 1003 | 1 |
| Caelo | Blackcurrants | 12272804 | 3 |
| Caelo | Blackcurrants | 14212507 | 1 |
| Galke | Blackcurrants | 21348 | 1 |
| Klenk | Blackcurrants | A121106 | 1 |
| Klenk | Blackcurrants | 2990A110620 | 1 |
| Caelo | Blackthorn flower | 12178102 | 9 |
| Caelo | Blackthorn flower | 11206906 | 1 |
| Caelo | Blackthorn flower | 12178105 | 1 |
| Caelo | Blackthorn flower | 12178101 | 2 |
| Caelo | Blackthorn flower | 12178103 | 2 |
| Klenk | Blackthorn flower | 2612E-01468 | 1 |
| Phönix 28.12.2013 | Blackthorn flower | 12178104 | 4 |
| Caelo | Blackthorn flower, rubbed | 1150N101109 | 2 |
| Klenk | Blackthorn flower, rubbed | N101109 | 2 |
| Klenk | Blackthorn flower, rubbed | 1150n101109 | 1 |
| Kräuter Schulte | Blackthorn flower, rubbed | 53233 | 2 |
| an | Blessed thistle, cut | 13389704 | 1 |
| Anzag | Blessed thistle, cut | 282281 | 1 |
| Bombastus | Blessed thistle, cut | 271946 | 1 |
| Caelo | Blessed thistle, cut | 13025902 | 1 |
| Caelo | Blessed thistle, cut | 3091301 | 1 |
| Caelo | Blessed thistle, cut | 27111205 | 1 |
| Caelo | Blessed thistle, cut | 12038203 | 2 |
| Caelo | Blessed thistle, cut | 13025901 | 5 |
| Caelo | Blessed thistle, cut | 4743554 | 1 |
| Caelo | Blessed thistle, cut | 12038202 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Blessed thistle, cut | 13025903 | 3 |
| Caelo | Blessed thistle, cut | 9355208 | 1 |
| Caelo | Blessed thistle, cut | 10325404 | 1 |
| Caelo | Blessed thistle, cut | 13389701 | 1 |
| Gehe | Blessed thistle, cut | 10325402 | 5 |
| Gehe / 08.03.13 Redwood | Blessed thistle, cut | 205007 | 1 |
| Klenk | Blessed thistle, cut | A110517 | 1 |
| Apofit | Blue bottle flower | 278776 | 1 |
| Bombastus | Blue bottle flower | 275759 | 2 |
| Bombastus | Blue bottle flower | 284030 | 1 |
| Caelo | Blue bottle flower | 11059209 | 2 |
| Caelo | Blue bottle flower | 14323302 | 1 |
| Caelo | Blue bottle flower | 12232501 | 2 |
| Caelo | Blue bottle flower | 15206601 | 1 |
| Caelo | Blue bottle flower | 72767368 | 1 |
| Caelo | Blue bottle flower | 12060205 | 4 |
| Caelo | Blue bottle flower | 11059206 | 2 |
| Caelo | Blue bottle flower | 11059211 | 2 |
| Caelo | Blue bottle flower | 12060202 | 2 |
| Caelo | Blue bottle flower | 12060203 | 4 |
| Galke | Blue bottle flower | 23131 | 2 |
| Klenk | Blue bottle flower | | 1 |
| Caelo | Bogbean leaf, cut | 13123901 | 2 |
| Caelo | Bogbean leaf, cut | 1226101 | 1 |
| Caelo | Bogbean leaf, cut | 12226101 | 1 |
| Caelo | Bogbean leaf, cut | 13123902 | 2 |
| Caelo | Bogbean leaf, cut | 12226104 | 1 |
| Caesar/Noweda | Bogbean leaf, cut | 1510U-01517 | 1 |
| Caelo | Bogbean leaf, cut | 13149001 | 1 |
| Caelo | Boldo leaf | 11016511 | 1 |
| Caelo | Boldo leaf | 12227005 | 1 |
| Caelo | Boldo leaf | 12064303 | 1 |
| Caelo | Boldo leaf | 11016509 | 1 |
| Caelo | Boldo leaf | 655456 | 1 |
| Caelo | Boldo leaf | 12064305 | 1 |
| Caelo | Boldo leaf | 12064306 | 1 |
| Caelo | Boldo leaf | 12227004 | 1 |
| Galke | Boldo leaf | 19855 | 1 |
| Klenk | Boldo leaf | 1911A100714 | 7 |
| Klenk | Boldo leaf | 1911B090709 | 1 |
| VDL | Boldo leaf | 11016503 | 1 |
| Caelo | Bucho leaf | 13056601 | 2 |
| Caelo | Bucho leaf | 13056602 | 2 |
| Caelo | Bucho leaf | 13056605 | 1 |
| Kräuter Schulte | Bucho leaf | 54519 | 1 |
| Caelo | Buckwheat herb, cut | 11212612 | 1 |
| Caelo | Buckwheat herb, cut | 11212808 | 2 |
| Caelo | Buckwheat herb, cut | 13051303 | 1 |
| Caelo | Buckwheat herb, cut | 30041301 | 1 |
| Caelo | Buckwheat herb, cut | 5111302 | 1 |
| Caelo | Buckwheat herb, cut | 2051303 | 1 |
| Caelo | Buckwheat herb, cut | 11212809 | 1 |
| Caelo | Buckwheat herb, cut | 11212807 | 2 |
| Caelo | Buckwheat herb, cut | 13193203 | 1 |
| Caelo | Buckwheat herb, cut | 11212814 | 2 |
| Caelo | Buckwheat herb, cut | 11212810 | 1 |
| Caelo | Buckwheat herb, cut | 11212817 | 6 |
| Klenk | Buckwheat herb, cut | 4581B120509 | 3 |
| Klenk | Buckwheat herb, cut | B120509 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Buckwheat herb, cut | 11212812 | 1 |
| - | Burdock root | 5110I-02131 | 1 |
| Anzag | Burdock root | 11100801 | 2 |
| Caelo | Burdock root | 12295802 | 4 |
| Caelo | Burdock root | 12295805 | 3 |
| Caelo | Burdock root | 12295801 | 2 |
| Caelo | Burdock root | 10073213 | 1 |
| Caelo | Burdock root | 13122801 | 2 |
| Caelo | Burdock root | 1100801 | 1 |
| Caelo | Burdock root | 13122802 | 1 |
| Caelo | Burdock root | 12295807 | 1 |
| Caelo | Burdock root | 107063 | 1 |
| Euro OTC | Burdock root | 13122803 | 1 |
| Galke | Burdock root | 19802 | 1 |
| Klenk | Burdock root | 6161A120208 | 4 |
| Klenk | Burdock root | A130214 | 1 |
| Klenk | Burdock root | A120206 | 1 |
| Klenk | Burdock root | 6161A101206 | 1 |
| Klenk | Burdock root | 6161A080709 | 1 |
| Klenk | Burdock root | 6161A-120103 | 1 |
| Klenk | Burdock root | 6161A-101206 | 1 |
| Klenk | Burdock root | 6161A120103 | 1 |
| Caelo | Burdock root | 12295808 | 2 |
| Caelo | Burnet root | 12027403 | 1 |
| Caelo | Burnet root | 8111203 | 1 |
| Caelo | Burnet root | 12027411 | 3 |
| Caelo | Burnet root | 12027405 | 2 |
| Caelo | Burnet root | 12027413 | 1 |
| Caelo | Burnet root | 12027409 | 1 |
| Caelo | Burnet root | 12027410 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Calcium chloride dihydrate | 12341409 | 1 |
| Caelo | Calcium chloride dihydrate | 11230921 | 2 |
| Caelo | Calcium chloride dihydrate | 12341404 | 2 |
| Caelo | Calcium chloride dihydrate | 12341406 | 1 |
| Caelo | Calcium chloride dihydrate | 11230915 | 1 |
| Caelo | Calcium chloride dihydrate | 12B09-N11 | 1 |
| Euro OTC | Calcium chloride dihydrate | 1205014-02 | 2 |
| Caelo | Calcium chloride dihydrate | 8237314 | 1 |
| Fagron | Calcium hydroxide | 13D26-N14 | 1 |
| Fagron | Calcium hydroxide | 12J18-N01 | 1 |
| Gehe | Calcium hydroxide | 12F08-N02 | 3 |
| Euro OTC | Calcium orotate dihydrate | 1401006-01 | 1 |
| Euro OTC | Calcium orotate dihydrate | 1203037-01 | 2 |
| Caelo | Calcium sulfate dihydrate | 12316301 | 1 |
| Caelo | Calcium sulfate dihydrate | 10132403 | 1 |
| Caelo | Calcium sulfate hemihydrate | 14101701 | 1 |
| Caelo | Calcium sulfate hemihydrate | 9246320 | 1 |
| Bombastus | Calendula flower | 268626 | 1 |
| Caelo | Calendula flower | 15291501 | 1 |
| Caelo | Calendula flower | 12221706 | 2 |
| Caelo | Calendula flower | 12221705 | 1 |
| Caelo | Calendula flower | 12221710 | 1 |
| Caelo | Calendula flower | 12221708 | 3 |
| Caelo | Calendula flower | 12221511 | 1 |
| Caelo | Calendula flower | 12221508 | 1 |
| Caelo | Calendula flower | 122221707 | 1 |
| Caelo | Calendula flower | 12221510-3356319071 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Calendula flower | 12221510-3435311151 | 1 |
| galke, | Calendula flower | 12028 | 1 |
| Gehe | Calendula flower | 13235502 | 3 |
| Bombastus | Calendula flower | 280306 | 1 |
| Klenk | Calendula flower | C120321 | 1 |
| Klenk | Calendula flower | 1250A110511 | 1 |
| Klenk | Calendula flower | 1241B120312 | 1 |
| Klenk | Calendula flower | 1241B130517 | 1 |
| Phönix | Calendula flower | 13235503 | 3 |
| Wolf | Calendula flower | 23342 | 1 |
| Bahnhof-Apotheke | Calendula flower, cut | 17-121106 | 1 |
| Bombastus | Calendula flower, cut | 253620 | 1 |
| Bombastus | Calendula flower, cut | 279632 | 1 |
| Bombastus | Calendula flower, cut | 270046 | 1 |
| Bombastus | Calendula flower, cut | 275813 | 1 |
| Bombastus | Calendula flower, cut | 275128 | 1 |
| Bombastus | Calendula flower, cut | 234997 | 1 |
| Bombastus | Calendula flower, cut | 207294 | 1 |
| Caelo | Calendula flower, cut | 295556 | 1 |
| Caelo | Calendula flower, cut | 12221706 | 12 |
| Caelo | Calendula flower, cut | 13235505 | 1 |
| Caelo | Calendula flower, cut | 21091301 | 1 |
| Caelo | Calendula flower, cut | 27101201 | 1 |
| Caelo | Calendula flower, cut | 12071201 | 1 |
| Caelo | Calendula flower, cut | 31121202 | 1 |
| Caelo | Calendula flower, cut | 19111206 | 1 |
| Caelo | Calendula flower, cut | 8041302 | 1 |
| Caelo | Calendula flower, cut | 3061301 | 1 |
| Caelo | Calendula flower, cut | 18121301 | 1 |
| Caelo | Calendula flower, cut | 5021305 | 1 |
| Caelo | Calendula flower, cut | 22061203 | 1 |
| Caelo | Calendula flower, cut | 9121303 | 1 |
| Caelo | Calendula flower, cut | 11187610 | 3 |
| Caelo | Calendula flower, cut | 15040301 | 1 |
| Caelo | Calendula flower, cut | 11187611 | 3 |
| Caelo | Calendula flower, cut | 13410202 | 2 |
| Caelo | Calendula flower, cut | 13235501 | 4 |
| Caelo | Calendula flower, cut | 9112013C | 1 |
| Caelo | Calendula flower, cut | 12221710 | 2 |
| Caelo | Calendula flower, cut | 11221407 | 1 |
| Caelo | Calendula flower, cut | 13235502 | 9 |
| Caelo | Calendula flower, cut | 12221708 | 11 |
| Caelo | Calendula flower, cut | 10291904 | 1 |
| Caelo | Calendula flower, cut | 11187612 | 12 |
| Caelo | Calendula flower, cut | 12221705 | 4 |
| Caelo | Calendula flower, cut | 12221701 | 1 |
| Caelo | Calendula flower, cut | 122221704 | 1 |
| Caelo | Calendula flower, cut | 1187612 | 2 |
| Caelo | Calendula flower, cut | 12221709 | 9 |
| Caelo | Calendula flower, cut | 12221704 | 13 |
| Caelo | Calendula flower, cut | AKD1 | 1 |
| Caelo | Calendula flower, cut | 1325502 | 1 |
| Gehe | Calendula flower, cut | 260205 | 1 |
| Caelo | Calendula flower, cut | 13235506 | 2 |
| Klenk | Calendula flower, cut | 1241B160530 | 1 |
| Klenk | Calendula flower, cut | 1241B150902 | 1 |
| Klenk | Calendula flower, cut | 1241N151209 | 1 |
| Klenk | Calendula flower, cut | 1241B130517 | 6 |
| Klenk | Calendula flower, cut | 1240A110418 | 1 |
| Klenk | Calendula flower, cut | 112211448 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Calendula flower, cut | 204311448 | 1 |
| Klenk | Calendula flower, cut | 3013E1448 | 1 |
| Klenk | Calendula flower, cut | 1241B120312 | 4 |
| Klenk | Calendula flower, cut | B130517 | 2 |
| Klenk | Calendula flower, cut | 1241B140211 | 1 |
| Klenk | Calendula flower, cut | 1241B120419 | 2 |
| Klenk | Calendula flower, cut | 1241B130927 | 1 |
| Klenk | Calendula flower, cut | 1241B110118 | 2 |
| Klenk | Calendula flower, cut | 1241C120321 | 4 |
| Klenk | Calendula flower, cut | 1241B130321 | 5 |
| Sanacorp | Calendula flower, cut | 12221707 | 2 |
| Sanacorp | Calendula flower, cut | 12221601 | 4 |
| Caelo | Calendula flower, cut | 12221502 | 2 |
| Euro OTC | Camphor | 1210030-02 | 1 |
| an | Camphor | 12344909 | 1 |
| Caelo | Camphor | 13195316 | 6 |
| Caelo | Camphor | 13108118 | 2 |
| Caelo | Camphor | 13205502 | 1 |
| Caelo | Camphor | | 1 |
| Caelo | Camphor | 14202807 | 3 |
| Caelo | Camphor | 15316807 | 7 |
| Caelo | Camphor | 15320604 | 5 |
| Caelo | Camphor | 13108106 | 2 |
| Caelo | Camphor | 15397704 | 5 |
| Caelo | Camphor | 12054149 | 9 |
| Caelo | Camphor | 12054114 | 2 |
| Caelo | Camphor | 18108904 | 11 |
| Caelo | Camphor | 16209309 | 24 |
| Caelo | Camphor | 12054141 | 3 |
| Caelo | Camphor | 13195314 | 3 |
| Caelo | Camphor | 17324104 | 10 |
| Caelo | Camphor | 16235408 | 5 |
| Caelo | Camphor | 15316815 | 4 |
| Caelo | Camphor | 18019806 | 27 |
| Caelo | Camphor | 17050605 | 30 |
| Caelo | Camphor | 17134703 | 4 |
| Caelo | Camphor | 17288305 | 1 |
| Caelo | Camphor | 15120901 | 2 |
| Caelo | Camphor | 14310713 | 11 |
| Caelo | Camphor | 14310718 | 6 |
| Caelo | Camphor | 15384201 | 1 |
| Caelo | Camphor | 15316819 | 7 |
| Caelo | Camphor | 13111707 | 1 |
| Caelo | Camphor | 7071801 | 1 |
| Caelo | Camphor | 6021901 | 1 |
| Caelo | Camphor | 12091808 | 1 |
| Caelo | Camphor | 12061411 | 1 |
| Caelo | Camphor | 4031503 | 1 |
| Caelo | Camphor | 4101303 | 1 |
| Caelo | Camphor | 25041401 | 1 |
| Caelo | Camphor | 3091203 | 1 |
| Caelo | Camphor | 12091805 | 1 |
| Caelo | Camphor | 7061802 | 1 |
| Caelo | Camphor | 13111708 | 1 |
| Caelo | Camphor | 11286910 | 1 |
| Caelo | Camphor | 11074509 | 1 |
| Caelo | Camphor | 12243701 | 1 |
| Caelo | Camphor | 17325502 | 1 |
| Caelo | Camphor | 18327910 | 2 |
| Caelo | Camphor | 20003828001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Camphor | 192762005 | 2 |
| Caelo | Camphor | 192762009 | 2 |
| Caelo | Camphor | 20004261002 | 1 |
| Caelo | Camphor | 13K28-04-294937 | 1 |
| Caelo | Camphor | 14310705 | 1 |
| Caelo | Camphor | 14310722 | 3 |
| Caelo | Camphor | 13195318 | 1 |
| Caelo | Camphor | 13195327 | 1 |
| Caelo | Camphor | 120564113 | 1 |
| Caelo | Camphor | 13195316 | 1 |
| Caelo | Camphor | 17288360 | 1 |
| Caelo | Camphor | 1728306 | 1 |
| Caelo | Camphor | 13205522 | 3 |
| Caelo | Camphor | 18019807 | 2 |
| Caelo | Camphor | 13195326 | 3 |
| Caelo | Camphor | 15/18.B11-321658 | 1 |
| Caelo | Camphor | 15120902 | 1 |
| Caelo | Camphor | 18196907 | 1 |
| Caelo | Camphor | 17004304 | 1 |
| Caelo | Camphor | 162093029 | 1 |
| Caelo | Camphor | 12344905 | 2 |
| Caelo | Camphor | 11032023 | 1 |
| Caelo | Camphor | 16209306 | 1 |
| Caelo | Camphor | 1531611 | 1 |
| Caelo | Camphor | 13205512 | 2 |
| Caelo | Camphor | 13205522 | 1 |
| Caelo | Camphor | 13195314 | 5 |
| Caelo | Camphor | 13195311 | 1 |
| Caelo | Camphor | 11286905 | 2 |
| Caelo | Camphor | 13205511 | 1 |
| Caelo | Camphor | 1531607 | 1 |
| Caelo | Camphor | 15097803 | 2 |
| Caelo | Camphor | 15397701 | 1 |
| Caelo | Camphor | 150622C | 1 |
| Caelo | Camphor | 140918C | 1 |
| Caelo | Camphor | 1410710 | 1 |
| Caelo | Camphor | 18196902 | 1 |
| Caelo | Camphor | 17325503 | 1 |
| Caelo | Camphor | 18196910 | 1 |
| Caelo | Camphor | 15086806 | 1 |
| Caelo | Camphor | 16209301 | 13 |
| Caelo | Camphor | 1536801 | 1 |
| Caelo | Camphor | 13195301 | 1 |
| Caelo | Camphor | 13195311 | 1 |
| Caelo | Camphor | 13195304 | 1 |
| Caelo | Camphor | 444A170221 | 1 |
| Caelo | Camphor | 17134702 | 5 |
| Caelo | Camphor | 13195318 | 1 |
| Caelo | Camphor | 13195322 | 7 |
| Caelo | Camphor | 18327903P-191111-3 | 1 |
| Caelo | Camphor | 18019803P-190506-3 | 1 |
| Caelo | Camphor | 12228206 | 1 |
| Caelo | Camphor | 15097802 | 2 |
| Caelo | Camphor | 14310710 | 2 |
| Caelo | Camphor | 62(17288306) | 1 |
| Caelo | Camphor | 12054107 | 4 |
| Caelo | Camphor | 3273 | 1 |
| Caelo | Camphor | 14310706 | 1 |
| Caelo | Camphor | 15316823 | 3 |
| Caelo | Camphor | 18019802 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Camphor | 17050606 | 5 |
| Caelo | Camphor | 12054151 | 2 |
| Caelo | Camphor | 13195323 | 1 |
| Caelo | Camphor | 15316805 | 1 |
| Caelo | Camphor | 14224304 | 1 |
| Caelo | Camphor | 2344905 | 1 |
| Caelo | Camphor | 713A-01221 | 1 |
| Caelo | Camphor | 218U-01221 | 1 |
| Caelo | Camphor | 914E-01221 | 1 |
| Caelo | Camphor | 315E-01221 | 1 |
| Caelo | Camphor | 5315I-01221 | 1 |
| Caelo | Camphor | 11286909 | 2 |
| Caelo | Camphor | 14310715 | 1 |
| Caelo | Camphor | 14310709 | 6 |
| Caelo | Camphor | 17004306 | 11 |
| Caelo | Camphor | 17288301 | 11 |
| Caelo | Camphor | 16209305 | 11 |
| Caelo | Camphor | 1412023-01 | 7 |
| Caelo | Camphor | 14224303 | 3 |
| Caelo | Camphor | 18198003 | 1 |
| Caelo | Camphor | 13195301 | 2 |
| Caelo | Camphor | 18019603 | 1 |
| Caelo | Camphor | 18327909 | 2 |
| Caelo | Camphor | 12228205 | 1 |
| Caelo | Camphor | 12054143 | 1 |
| Caelo | Camphor | 17004308 | 2 |
| Caelo | Camphor | 18066404 | 9 |
| Caelo | Camphor | 16209310 | 1 |
| Caelo | Camphor | 15086801 | 1 |
| Caelo | Camphor | 17004307 | 1 |
| Caelo | Camphor | 13205512 | 1 |
| Caelo | Camphor | 15062701 | 1 |
| Caelo | Camphor | 2811Q-01221 | 1 |
| Caelo | Camphor | 17004301 | 21 |
| Caelo | Camphor | 13205501 | 2 |
| Caelo | Camphor | 14310705 | 15 |
| Caelo | Camphor | 14310703 | 1 |
| Caelo | Camphor | 13205517 | 1 |
| Caelo | Camphor | 13205511 | 2 |
| Caelo | Camphor | 15316801 | 4 |
| Caelo | Camphor | 14310109 | 1 |
| Caelo | Camphor | 2803020-01 | 1 |
| Caelo | Camphor | 4444A150721 | 1 |
| Caelo | Camphor | 15316806 | 2 |
| Caelo | Camphor | 16209304 | 3 |
| Caelo | Camphor | 15316812 | 1 |
| Caelo | Camphor | 15062702 | 3 |
| Caelo | Camphor | 18327905 | 3 |
| Caelo | Camphor | 16235402 | 1 |
| Caelo | Camphor | 16235407 | 1 |
| Caelo | Camphor | 12054105 | 1 |
| Caelo | Camphor | 12054142 | 6 |
| Caelo | Camphor | 17004302 | 4 |
| Caelo | Camphor | 2015113782 | 1 |
| Caelo | Camphor | 14310702 | 1 |
| Caelo | Camphor | 17288306 | 18 |
| Caelo | Camphor | 12054124 | 2 |
| Caelo | Camphor | 18019803 | 14 |
| Caesar & Loretz GmbH | Camphor | 18327901 | 2 |
| Caesar & Loretz GmbH | Camphor | 19009704 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz GmbH | Camphor | 17288307 | 2 |
| Caesar & Loretz Gm… | Camphor | 11032035 | 4 |
| Caesar & Loretz Gm… | Camphor | 18019813 | 1 |
| Caesar Loretz | Camphor | 18327903 | 13 |
| Caesar&Loretz | Camphor | 14310719 | 1 |
| Caesar/Noweda | Camphor | 1032 | 1 |
| Caesar/Noweda | Camphor | 13195328 | 1 |
| Calo/AHD | Camphor | 15086803 | 1 |
| Camphor & Allied P… | Camphor | 16209302 | 1 |
| Cealo/ Noweda | Camphor | 13108116 | 1 |
| EuRho | Camphor | 1303013-02 | 11 |
| EuRho | Camphor | 2111E-01219 | 1 |
| Euro OTC | Camphor | 113Q-01221 | 1 |
| Euro OTC | Camphor | 1309019-03 | 1 |
| Euro OTC | Camphor | 121003001 | 1 |
| Euro OTC | Camphor | 1202021 | 1 |
| Euro OTC | Camphor | 130313-02 | 1 |
| Euro OTC | Camphor | 1210030-01 | 1 |
| Euro OTC | Camphor | 1210030-01 | 7 |
| Euro OTC | Camphor | 1406029-02 | 2 |
| Euro OTC | Camphor | 1101029-02/Ch241011 | 1 |
| Euro OTC | Camphor | 121003002 | 1 |
| Euro OTC | Camphor | 1406029-01 | 3 |
| Euro OTC | Camphor | 1101029-02 | 1 |
| euro/ Sanacorp | Camphor | 17050602 | 2 |
| Euro OTC | Camphor | 821509 | 1 |
| Euro OTC | Camphor | 1309019-02 | 1 |
| Euro OTC | Camphor | 2803020-01 | 1 |
| Euro OTC | Camphor | 1210030-02 | 4 |
| Euro OTC | Camphor | 1303013-01 | 5 |
| Fagron | Camphor | 12G02-N09 | 1 |
| Fagron | Camphor | 13H23-B40-294116 | 1 |
| Fagron | Camphor | 13h23-b40-294116 | 1 |
| Fagron | Camphor | 11K23-N04 | 1 |
| Fagron | Camphor | 12D23-N03 | 1 |
| Fagron | Camphor | 8082014A | 1 |
| Fagron | Camphor | 690442 | 1 |
| Fagron | Camphor | 13K28-B04-289340 | 1 |
| Fagron | Camphor | 15/18-B11-321658 | 1 |
| Fagron | Camphor | 17L01-B03 | 1 |
| Fagron | Camphor | 1309019-02 | 1 |
| Fagron | Camphor | 14G23-B04-296868 | 1 |
| Fagron | Camphor | 14G23-B04-301879 | 2 |
| Fagron | Camphor | 13H23-B40-291888 | 1 |
| Fagron | Camphor | 13H23-B04-288376 | 1 |
| Fagron | Camphor | 13K28-B04-294937 | 1 |
| Fagron | Camphor | 14G23-B04-301878 | 3 |
| Fagron | Camphor | 27011 | 1 |
| Fagron | Camphor | 825653 | 1 |
| Fagron | Camphor | 14G23-B04-299202 | 2 |
| Fagron | Camphor | 14G23-B04 | 2 |
| Fagron | Camphor | 13K28-B04 | 1 |
| Fagron | Camphor | 13H23-B40-296252 | 1 |
| Fagron | Camphor | 11H30-N15 | 1 |
| Fagron | Camphor | 13K28_B04_294933 | 1 |
| Fagron | Camphor | 15097801 | 1 |
| Fagron | Camphor | 12B14-N09 | 1 |
| Galke | Camphor | 23624 | 1 |
| Gatt-Koller | Camphor | 1800202 | 3 |
| Gehe | Camphor | 15316811 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Gehe | Camphor | 18019811 | 15 |
| Gehe amax | Camphor | 16235404 | 4 |
| Caelo | Camphor | 17050605/1140418 | 1 |
| Caelo | Camphor | 14224303 | 1 |
| Klenk | Camphor | 444A150721 | 1 |
| Klenk | Camphor | 444A100826 | 1 |
| Klenk | Camphor | 444A180815 | 3 |
| Klenk | Camphor | 444A150721 | 1 |
| Klenk | Camphor | 444A140526 | 5 |
| Klenk | Camphor | 444A170224 | 4 |
| Klenk | Camphor | 444A160817 | 8 |
| L12 | Camphor | 18108901 | 1 |
| Caelo | Camphor | 15397705 | 1 |
| Nachprüfung | Camphor | 1616E-01221 | 1 |
| Nachtestung-Verlän… | Camphor | 242/17 | 1 |
| Noweda | Camphor | 1202021-01 | 3 |
| Phoenix | Camphor | 160209309 | 1 |
| Phoenix | Camphor | 3382 | 1 |
| Phoenix | Camphor | 16235405 | 2 |
| Caelo | Camphor | 12054113 | 1 |
| phönix | Camphor | 444a160817 | 1 |
| phönix | Camphor | 14202801 | 3 |
| Phönix | Camphor | 1202021-02 | 2 |
| Phönix | Camphor | 13K28-B04 | 2 |
| Phönix Gotha | Camphor | 206/06 | 1 |
| Caelo | Camphor | 2018-05-07-AISe | 1 |
| Post-Apotheke 22.0… | Camphor | 11032012 | 1 |
| Sanacorp | Camphor | 444A130115 | 1 |
| Sanacorp | Camphor | 14310720 | 2 |
| Caelo | Camphor | 18108902 | 1 |
| Caelo | Camphor | 18108905 | 2 |
| Vögele | Camphor | 2016114336 | 1 |
| Vögele | Camphor | 2014101206 | 1 |
| xxx | Camphor | 709E-01221 | 1 |
| Alfred Galke | Caraway fruit | 20069 | 1 |
| Bahnhof-Apotheke | Caraway fruit | 18-120709 | 1 |
| Bombastus | Caraway fruit | 275849 | 1 |
| Bombastus | Caraway fruit | 282269 | 1 |
| Bombastus | Caraway fruit | 270124 | 1 |
| Caelo | Caraway fruit | 12226504 | 1 |
| Caelo | Caraway fruit | 12226612 | 8 |
| Caelo | Caraway fruit | 13306006 | 4 |
| Caelo | Caraway fruit | 15409105 | 1 |
| Caelo | Caraway fruit | 15097115 | 6 |
| Caelo | Caraway fruit | 15097101 | 8 |
| Caelo | Caraway fruit | 15409104 | 3 |
| Caelo | Caraway fruit | 13397104 | 2 |
| Caelo | Caraway fruit | 15097108 | 4 |
| Caelo | Caraway fruit | 2103311537 | 1 |
| Caelo | Caraway fruit | 12226606 | 2 |
| Caelo | Caraway fruit | 11003207 | 1 |
| Caelo | Caraway fruit | 12226501 | 5 |
| Caelo | Caraway fruit | 16165308 | 1 |
| Caelo | Caraway fruit | 16308502 | 1 |
| Caelo | Caraway fruit | 12226604 | 5 |
| Caelo | Caraway fruit | 18121717 | 1 |
| Caelo | Caraway fruit | 13091401 | 1 |
| Caelo | Caraway fruit | 11121704 | 1 |
| Caelo | Caraway fruit | 27121202 | 1 |
| Caelo | Caraway fruit | 4061303 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Caraway fruit | 11378309 | 1 |
| Caelo | Caraway fruit | 16308506 | 2 |
| Caelo | Caraway fruit | 13306003 | 1 |
| Caelo | Caraway fruit | 15409102 | 4 |
| Caelo | Caraway fruit | 1226608 | 1 |
| Caelo | Caraway fruit | 413M | 1 |
| Caelo | Caraway fruit | 12343403 | 1 |
| Caelo | Caraway fruit | 13397102 | 2 |
| Caelo | Caraway fruit | 15097110 | 1 |
| Caelo | Caraway fruit | 13306004 | 1 |
| Caelo | Caraway fruit | 12226601 | 1 |
| Caelo | Caraway fruit | 15097109 | 3 |
| Caelo | Caraway fruit | 11003211 | 1 |
| Caelo | Caraway fruit | 16308504 | 1 |
| Caelo | Caraway fruit | 13306005 | 2 |
| Caelo | Caraway fruit | 13306001 | 1 |
| Caelo | Caraway fruit | 24659273 | 1 |
| Caelo | Caraway fruit | 11003216 | 3 |
| Caelo | Caraway fruit | 16308503 | 5 |
| Caelo | Caraway fruit | 11003217 | 5 |
| Caelo | Caraway fruit | 12226605 | 3 |
| Caelo | Caraway fruit | 12226611 | 3 |
| Caelo | Caraway fruit | 15097103 | 5 |
| Caelo | Caraway fruit | 15097111 | 3 |
| Caelo | Caraway fruit | 15097102 | 1 |
| Caelo | Caraway fruit | 12226603 | 7 |
| Caelo | Caraway fruit | 1509101 | 1 |
| Caelo | Caraway fruit | 12226614 | 2 |
| Caelo | Caraway fruit | 13306002 | 5 |
| Caelo | Caraway fruit | 290416 | 1 |
| Caelo | Caraway fruit | 15409101 | 1 |
| Caelo | Caraway fruit | 9267815 | 1 |
| Caelo | Caraway fruit | 13397105 | 8 |
| Caelo | Caraway fruit | 15097002 | 1 |
| Caelo | Caraway fruit | 13306008 | 2 |
| Caelo | Caraway fruit | 17256303 | 2 |
| Caelo | Caraway fruit | 11003213 | 2 |
| Caelo | Caraway fruit | 811E-01537 | 1 |
| Caelo | Caraway fruit | 18303903 | 1 |
| Caelo | Caraway fruit | 15097116 | 1 |
| Caelo | Caraway fruit | 17256304 | 1 |
| Caelo | Caraway fruit | 18009206 | 1 |
| Caelo | Caraway fruit | 15097107 | 2 |
| Caesar & Lorenz | Caraway fruit | 12226609 | 5 |
| Caesar & Loretz Gm… | Caraway fruit | 9267824 | 2 |
| Caesar & Loretz/Noweda | Caraway fruit | 15056601 | 1 |
| Galke | Caraway fruit | 23627 | 1 |
| Galke | Caraway fruit | 21257 | 1 |
| Galke | Caraway fruit | 27450 | 1 |
| GALKE | Caraway fruit | 30030 | 1 |
| Gehe | Caraway fruit | 12226503 | 7 |
| Klenk | Caraway fruit | 2770A130910 | 1 |
| Hepart AG | Caraway fruit | B-224,kbA | 1 |
| Caelo | Caraway fruit | 12226608 | 4 |
| Caelo | Caraway fruit | 1222608 | 1 |
| Klenk | Caraway fruit | 2770A120403 | 14 |
| Klenk | Caraway fruit | 2770A140708 | 6 |
| Klenk | Caraway fruit | A120905 | 3 |
| Klenk | Caraway fruit | 2770A110818 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Caraway fruit | 1810A-01537 | 1 |
| Klenk | Caraway fruit | 2770A120905 | 4 |
| Klenk | Caraway fruit | 2270A130521 | 1 |
| Klenk | Caraway fruit | 2820A150713 | 1 |
| Klenk | Caraway fruit | 412091-1-P | 1 |
| Klenk | Caraway fruit | 2770A130521 | 12 |
| Klenk | Caraway fruit | 2770A160304 | 2 |
| Klenk | Caraway fruit | 2770A131008 | 2 |
| Klenk | Caraway fruit | 2770a120905 | 2 |
| Klenk | Caraway fruit | 2770A110601 | 9 |
| Klenk | Caraway fruit | 5213A1537 | 1 |
| Caelo | Caraway fruit | 15409103 | 3 |
| Noweda | Caraway fruit | 299573 | 2 |
| Caelo | Caraway fruit | 13041903 | 1 |
| Caelo | Caraway fruit | 15097118 | 1 |
| Caelo | Caraway fruit | 2041017/16308501 | 1 |
| sanacorp | Caraway fruit | 2656259 | 1 |
| Sanacorp | Caraway fruit | | 2 |
| Caelo | Caraway fruit | 16308501 | 2 |
| Caelo | Caraway fruit | 15097117 | 1 |
| Caelo | Caraway fruit | 13041901 | 1 |
| VDL;15.06.15;6,83EUR | Caraway fruit | 13306007 | 4 |
| Wolf | Caraway fruit | B-224 | 1 |
| Caelo | Caraway fruit, pounded | 12116904 | 3 |
| Caelo | Caraway fruit, pounded | 13367101 | 1 |
| Galke | Caraway fruit, pounded | 18943 | 1 |
| apomix | Carbachol | 12330703 | 1 |
| Caelo | Cardamom fruit | 11309110 | 1 |
| Caelo | Cardamom fruit | 13260502-3537411072 | 1 |
| Klenk | Cardamom fruit | A110810 | 3 |
| Klenk | Cardamom fruit | A130807 | 1 |
| Klenk | Cardamom fruit | 2750A110810 | 2 |
| Caelo | Cardamom fruit | 13026003 | 1 |
| Caelo | Cayenne pepper, powdered (spice) | 13205106 | 1 |
| Klenk | Celery fruit | 7140A170210 | 1 |
| Caelo | Celery root, cut | 12319107 | 1 |
| Caelo | Celery root, cut | 12319105 | 2 |
| Caelo | Celery root, cut | 10270009 | 1 |
| Caelo | Celery root, cut | 10270012 | 1 |
| Caelo | Celery root, cut | 12319108 | 1 |
| Klenk | Celery root, cut | 6091A110110 | 1 |
| Aurica/Phönix | Centaury | 520702152 | 1 |
| Bombastus | Centaury | 277598 | 3 |
| Caelo | Centaury | 12268601 | 3 |
| Caelo | Centaury | 8021302 | 1 |
| Caelo | Centaury | 15224102 | 1 |
| Caelo | Centaury | 10104012 | 1 |
| Caelo | Centaury | 11097609 | 3 |
| Caelo | Centaury | 11097605 | 2 |
| Caelo | Centaury | 12268602 | 19 |
| Caelo | Centaury | 12268606 | 14 |
| Caelo | Centaury | 12379601 | 1 |
| Caelo | Centaury | 11097602 | 1 |
| Caelo | Centaury | 3711B120628 | 1 |
| Caelo | Centaury | 12268605 | 4 |
| Caelo | Centaury | 16240512 | 1 |
| Caelo | Centaury | 18029609 | 1 |
| Caelo | Centaury | 12268608 | 10 |
| Finze | Centaury | 11097610 | 1 |
| Galke | Centaury | 9721 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Centaury | 3711B111216 | 1 |
| Klenk | Centaury | B120628 | 1 |
| Klenk | Centaury | 3711B-111216 | 1 |
| Phönix | Centaury | 11097612 | 9 |
| Phönix | Centaury | 11093612 | 2 |
| Klenk | Ceylon cinnamon, finely powdered | 614B160818 | 1 |
| Klenk | Ceylon cinnamon, finely powdered | 611B100628 | 1 |
| Klenk | Ceylon cinnamon, finely powdered | 614B121010 | 2 |
| Klenk | Ceylon cinnamon, finely powdered | 614B121024 | 4 |
| Klenk | Ceylon cinnamon, finely powdered | 614B120411 | 2 |
| Klenk | Ceylon cinnamon, finely powdered | 614a120411 | 1 |
| Klenk | Ceylon cinnamon, finely powdered | 614b121024 | 1 |
| Klenk | Ceylon cinnamon, finely powdered | 615B130325 | 3 |
| Caelo | Ceylonese Cinnamon, powdere… | 12242806 | 2 |
| Caelo | Ceylonese Cinnamon, powdere… | 12242815 | 1 |
| Caelo | Ceylonese Cinnamon, powdere… | 12242818 | 1 |
| Klenk | Ceylonese Cinnamon, powdere… | 614B161128 | 1 |
| - | Chickweed, cut | 2011A-01686 | 1 |
| Caelo | Chickweed, cut | 13040501 | 1 |
| Caelo | Chickweed, cut | 13254403 | 2 |
| Caelo | Chickweed, cut | 13040503 | 1 |
| Caelo | Chickweed, cut | 13254401 | 1 |
| Caelo | Chickweed, cut | 4551B130902 | 1 |
| Caelo | Chickweed, cut | 14212411 | 1 |
| Caelo | Chickweed, cut | 16143603 | 1 |
| Caelo | Chickweed, cut | 13040502-3283310662 | 1 |
| Caelo | Chickweed, cut | 16143608 | 2 |
| Caelo | Chickweed, cut | 13040502 | 2 |
| Caelo | Chickweed, cut | 13254404 | 1 |
| Caelo | Chickweed, cut | 13040504 | 1 |
| Klenk | Chickweed, cut | 4551b110222 | 1 |
| Klenk | Chickweed, cut | 4551B090528 | 1 |
| Phoenix | Chickweed, cut | 18100704 | 1 |
| Caelo | Chickweed, cut | 14212405 | 1 |
| - | Chicory herb | 4411I-01634 | 1 |
| Caelo | Chicory herb | 12354302 | 3 |
| Caelo | Chicory herb | 12369101 | 6 |
| Caelo | Chicory herb | 12354304 | 1 |
| Caelo | Chicory herb | 14031315 | 1 |
| Caelo | Chicory herb | 12034303 | 3 |
| Caelo | Chicory herb | 12034302 | 1 |
| Caelo | Chicory herb | 12354306 | 1 |
| Caelo | Chicory herb | 12369102 | 3 |
| Caelo | Chicory herb | 12034301 | 2 |
| Klenk | Chicory herb | 3751A120307 | 7 |
| Klenk | Chicory herb | 3751A120123 | 2 |
| Klenk | Chicory herb | A120123 | 2 |
| Klenk | Chicory herb | 3751A080902 | 1 |
| Klenk | Chicory herb | 3751a120307 | 1 |
| Klenk | Chicory herb | 3751c120614 | 1 |
| Klenk | Chicory herb | 3751A-100118 | 1 |
| Klenk | Chicory herb | 4510I-01634 | 1 |
| Klenk | Chicory root | 66221A101202 | 1 |
| Caelo | Chicory root | 11374506 | 1 |
| Caelo | Chicory root | 11374501 | 1 |
| Caelo | Chicory root | 6221As101202 | 1 |
| Caelo | Chicory root | 11081803 | 1 |
| Caelo | Chicory root | 11374504 | 3 |
| Caelo | Chicory root | 11374510 | 2 |
| Caelo | Chicory root | 91338319 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Chicory root | 6221N130201 | 1 |
| Klenk | Chicory root | A130304 | 1 |
| Klenk | Chicory root | 6221A101202 | 4 |
| Klenk | Chicory root | 6221A090311 | 1 |
| Klenk | Chicory root | 6221A130304 | 1 |
| Kräuter Schulte | China Pai Mu Tan | 52783 | 1 |
| Fagron | Chlorhexidine dihydrochloride | 14A09B03 | 1 |
| Fagron | Chlorhexidine dihydrochloride | 14A09-B03-293425 | 1 |
| Euro OTC | Cholecalciferol dry concentrate | 1801038-01 | 4 |
| Euro OTC | Cholecalciferol dry concentrate | 1012025-01 | 1 |
| Euro OTC | Cholecalciferol dry concentrate | 1707027-01 | 17 |
| Euro OTC | Cholecalciferol dry concentrate | 1608002-01 | 15 |
| Euro OTC | Cholecalciferol dry concentrate | 1701053-01 | 11 |
| Euro OTC | Cholecalciferol dry concentrate | 1802014-01 | 17 |
| Euro OTC | Cholecalciferol dry concentrate | 1602019-02 | 5 |
| Euro OTC | Cholecalciferol dry concentrate | 150803201 | 1 |
| Euro OTC | Cholecalciferol dry concentrate | 1806003-01 | 28 |
| Euro OTC | Cholecalciferol dry concentrate | 170153-01 | 5 |
| Euro OTC | Cholecalciferol dry concentrate | 1508032-01 | 2 |
| Euro OTC | Cholecalciferol dry concentrate | 2001007-01 | 1 |
| Euro OTC | Cholecalciferol dry concentrate | 1906009-02 | 5 |
| Euro OTC | Cholecalciferol dry concentrate | 1906009-01 | 8 |
| Euro OTC | Cholecalciferol dry concentrate | 1901050-01 | 4 |
| Euro OTC | Cholecalciferol dry concentrate | 1502021-01 | 1 |
| Euro OTC | Cholecalciferol dry concentrate | 1210051-01 | 1 |
| Euro OTC | Cholecalciferol dry concentrate | 1602019-01 | 2 |
| Euro OTC | Cholecalciferol dry concentrate | L1403012-01 | 1 |
| Euro OTC | Cholecalciferol dry concentrate | 1806003-02 | 1 |
| Euro OTC | Chromium yeast 0.2% | L1311026-01 | 1 |
| Fagron | Cinchocaine hydrochloride | 12F25-N10 | 1 |
| Phönix | Cinchocaine hydrochloride | 13E13-N07 | 1 |
| Caelo | Cinchona bark, cut | 10381906 | 1 |
| Caelo | Cinchona bark, cut | 15301904 | 2 |
| Caelo | Cinchona bark, cut | 14009305 | 1 |
| Klenk | Cinchona bark, cut | 601B130415 | 1 |
| Klenk | Cinchona bark, cut | 601B130415 | 1 |
| Akazie | Cinnamon | 20.09.2015 | 1 |
| Akazien-Apo | Cinnamon | Test | 1 |
| Caelo | Cinnamon | 13304415 | 1 |
| Caelo | Cinnamon | 12309908 | 1 |
| Caelo | Cinnamon | 11357909 | 1 |
| Caelo | Cinnamon | 12309909 | 1 |
| Caelo | Cinnamon | 25111307 | 1 |
| Caelo | Cinnamon | 13304401 | 2 |
| Caelo | Cinnamon | 12309902 | 3 |
| Caelo | Cinnamon | 13304402 | 2 |
| Caelo | Cinnamon | 11357912 | 2 |
| Caelo | Cinnamon | 13304407 | 1 |
| Caelo | Cinnamon | 13304409 | 1 |
| Caelo | Cinnamon | 15151905 | 1 |
| Caelo | Cinnamon | 16061702 | 1 |
| Fargon / Gehe | Cinnamon | 15104201 | 1 |
| Caelo | Cinnamon | 15151902 | 1 |
| Caelo | Cinnamon | 16245105 | 1 |
| Klenk | Cinnamon | 610A101018 | 1 |
| Klenk | Cinnamon | 610A130927 | 1 |
| siehe Protokoll | Cinnamon | sieheProtokoll | 1 |
| Caelo | Cinnamon rods (Ceylonese Ci… | 12148904 | 1 |
| Klenk | Cinnamon rods (Ceylonese Ci… | B121016 | 1 |
| Klenk | Cinnamon rods (Ceylonese Ci… | A101018 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Cinnamon rods (Ceylonese Ci… | 610A101018 | 1 |
| Phönix | Cinnamon rods (Ceylonese Ci… | 610A130927 | 1 |
| Sanacorp | Cinnamon rods (Ceylonese Ci… | 13231601 | 1 |
| Fagron | Cinnarizine | 14D09-B01-292883 | 1 |
| Fagron | Cinnarizine | 8D11-N04 | 1 |
| Fagron | Cinnarizine | 13I26-N22 | 1 |
| Fagron | Cinnarizine | 13H01-N07 | 4 |
| Fagron | Cinnarizine | 14D09-B01 | 3 |
| Fagron | Cinnarizine | 13I26-N22 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 12l19-N01 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 12I19-N01 | 2 |
| Fagron | Clobetasol-17-propionate 1:… | 12\|19-N01 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 13W16-N01 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 12L19-N06 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 11k04-n17 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 12A03-N03 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 12/19-No1 | 1 |
| Fagron | Clobetasol-17-propionate 1:… | 12K08-N02 | 2 |
| Fagron | Clobetasol-17-propionate 1:… | 12/19-N01003637 | 1 |
| Caelo | Clove | 5398872 | 1 |
| Caelo | Clove | 12095806 | 2 |
| Caelo | Clove | 12095802 | 1 |
| Caelo | Clove | 13371309 | 1 |
| Caelo | Clove | 12266505 | 1 |
| Caelo | Clove | 11233305 | 1 |
| Caelo | Clove | 12095807 | 5 |
| Caelo | Clove | 16207802 | 1 |
| Caelo | Clove | 14057602 | 1 |
| Klenk | Clove | 1260A110608 | 5 |
| Klenk | Clove | 1260A120328 | 6 |
| Klenk | Clove | A120328 | 1 |
| Klenk | Clove | 1260A101223 | 1 |
| Klenk | Clove | 1260A150304 | 2 |
| Klenk | Clove | 1260A100617 | 2 |
| Klenk | Clove | 1260A130903 | 3 |
| Caelo | Clove, powdered (spice) | 12355303 | 1 |
|  | Cocaine hydrochloride | 21004044019 | 1 |
| Caelo | Cocaine hydrochloride | 18J01-B07-353630 | 2 |
| Caelo | Cocaine hydrochloride | 19073003 | 1 |
| Caelo | Cocaine hydrochloride | 18256109 | 1 |
| Caelo | Cocaine hydrochloride | 17003902 | 4 |
| Caelo | Cocaine hydrochloride | 14069209 | 1 |
| Caelo | Cocaine hydrochloride | 12329103 | 1 |
| Caelo | Cocaine hydrochloride | 13259306 | 1 |
| Caelo | Cocaine hydrochloride | 21004044004 | 1 |
| Caelo | Cocaine hydrochloride | 17003909 | 1 |
| Caelo | Cocaine hydrochloride | 18266109 | 3 |
| Caelo | Cocaine hydrochloride | 13112102 | 1 |
| Caesar & Loretz GmbH | Cocaine hydrochloride | 182661001 | 1 |
| Caesar & Loretz GmbH | Cocaine hydrochloride | 21004044009 | 1 |
| Caesar & Loretz Gm… | Cocaine hydrochloride | 20003901001 | 2 |
| Caesar & Loretz Gm… | Cocaine hydrochloride | 182661 | 1 |
| Caesar & Loretz Gm… | Cocaine hydrochloride | 18266104 | 4 |
| Fagron | Cocaine hydrochloride | 13G03-N08 | 2 |
| Fagron | Cocaine hydrochloride | 12G23-N13 | 1 |
| Fagron | Cocaine hydrochloride | 16B11-B05-323385 | 1 |
| Fagron | Cocaine hydrochloride | 15E12-B03 | 1 |
| Fagron | Cocaine hydrochloride | 14H27-B03 | 1 |
| Fagron | Cocaine hydrochloride | 17E17-B07-335110 | 1 |
| Fagron | Cocaine hydrochloride | 15-00638 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Cocaine hydrochloride | 17K28-B05-343075 | 1 |
| Fagron | Cocaine hydrochloride | 21K30-F04 | 1 |
| Fagron | Cocaine hydrochloride | 18J01-B07-353629 | 1 |
| Gatt-Koller | Cocaine hydrochloride | 20172282 | 1 |
| Macfartan | Cocaine hydrochloride | 15224802 | 2 |
| Smith/Noweda | | | |
| Caelo | Cocaine hydrochloride | 16051402 | 1 |
| Synopharm | Cocaine hydrochloride | 16B11-B05 | 1 |
| Caelo | Cocoa bark, cut | 19011303 | 1 |
| Caelo | Cocoa bark, cut | 12126907 | 1 |
| Caelo | Cocoa bark, cut | 12126901 | 1 |
| Caelo | Cocoa bark, cut | 12126905 | 2 |
| Caelo | Cocoa bark, cut | 12126910 | 1 |
| Caelo | Cocoa bark, cut | 1216907 | 1 |
| | Codeine phosphate hemihydrate | 23A31-F01-384419 | 1 |
| Caeleo/ Kehr | Codeine phosphate hemihydrate | 181879001 | 2 |
| Caelo | Codeine phosphate hemihydrate | 17160503 | 3 |
| Caelo | Codeine phosphate hemihydrate | 15350703 | 2 |
| Caelo | Codeine phosphate hemihydrate | 18187960 | 2 |
| Caelo | Codeine phosphate hemihydrate | 181817907 | 1 |
| Caelo | Codeine phosphate hemihydrate | 18187907 | 1 |
| Caelo | Codeine phosphate hemihydrate | 14275910 | 1 |
| Caelo | Codeine phosphate hemihydrate | 15350710 | 3 |
| Caelo | Codeine phosphate hemihydrate | 15219805 | 2 |
| Caelo | Codeine phosphate hemihydrate | 16349708 | 2 |
| Caelo | Codeine phosphate hemihydrate | 18187908 | 1 |
| Caelo | Codeine phosphate hemihydrate | 1427910 | 1 |
| Caelo | Codeine phosphate hemihydrate | 20003804005 | 1 |
| Caelo | Codeine phosphate hemihydrate | 13I27-N06 | 1 |
| Caelo | Codeine phosphate hemihydrate | 16349704 | 2 |
| Caelo | Codeine phosphate hemihydrate | 16169805 | 3 |
| Caelo | Codeine phosphate hemihydrate | 16349707 | 1 |
| Caelo | Codeine phosphate hemihydrate | 20003804007 | 1 |
| Caesar & Loretz GmbH | Codeine phosphate hemihydrate | 18187901 | 1 |
| Caesar & Loretz GmbH | Codeine phosphate hemihydrate | 18187906 | 5 |
| Caesar & Loretz GmbH | Codeine phosphate hemihydrate | 18187902 | 4 |
| Caesar & Loretz Hilden | Codeine phosphate hemihydrate | 18187903 | 5 |
| Euro OTC | Codeine phosphate hemihydrate | CP04236 | 1 |
| Fagron | Codeine phosphate hemihydrate | 16E17-B05-324109 | 4 |
| Fagron | Codeine phosphate hemihydrate | 15F09-B02-310520 | 2 |
| Fagron | Codeine phosphate hemihydrate | 13E21-N04 | 1 |
| Fagron | Codeine phosphate hemihydrate | 12C05-N01 | 1 |
| Fagron | Codeine phosphate hemihydrate | 13C11-N10 | 1 |
| Fagron | Codeine phosphate hemihydrate | 1615I-01279 | 1 |
| Fagron | Codeine phosphate hemihydrate | 11/19-N10 | 1 |
| Fagron | Codeine phosphate hemihydrate | 17L22-B03-343752 | 2 |
| Fagron | Codeine phosphate hemihydrate | 15B17-B99-304623 | 2 |
| Fagron | Codeine phosphate hemihydrate | 13/27-N06 | 2 |
| Fagron | Codeine phosphate hemihydrate | 21D30-F01-380923 | 1 |
| Fagron | Codeine phosphate hemihydrate | B01-3612302 | 2 |
| Fagron | Codeine phosphate hemihydrate | 15F09-B02 | 1 |
| Fagron | Codeine phosphate hemihydrate | 15F09-B02-314033 | 1 |
| Fagron | Codeine phosphate hemihydrate | 15F09-B02-315564 | 2 |
| Fagron | Codeine phosphate hemihydrate | 5040218D | 3 |
| Fagron | Codeine phosphate hemihydrate | 18D03-B01 | 1 |
| Fagron | Codeine phosphate hemihydrate | F04-3825805 | 1 |
| Fagron | Codeine phosphate hemihydrate | 21D30-F01 | 1 |
| Fagron | Codeine phosphate hemihydrate | 913I-01279 | 1 |
| Merck | Codeine phosphate hemihydrate | 120765 | 1 |
| Caelo | Codeine phosphate hemihydrate | 16349706 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Codeine phosphate hemihydrate | 130715 | 1 |
| Th. Geyer | Codeine phosphate hemihydrate | 67038 | 1 |
| Th. Geyer | Codeine phosphate hemihydrate | 70533 | 22 |
| Th. Geyer | Codeine phosphate hemihydrate | 67054 | 31 |
| Caelo | Colophony | 15186807 | 8 |
| Bombastus | Coltsfoot leaf | 278296 | 4 |
| Bombastus | Coltsfoot leaf | 285263 | 3 |
| Bombastus | Coltsfoot leaf | 272019 | 1 |
| Bombastus | Coltsfoot leaf | 265856 | 1 |
| Bombastus | Coltsfoot leaf | 276303 | 5 |
| Bombastus | Coltsfoot leaf | 278758 | 7 |
| Bombastus | Coltsfoot leaf | 277848 | 2 |
| Bombastus | Coltsfoot leaf | 281100 | 4 |
| Bombastus | Coltsfoot leaf | 277131 | 1 |
| Bombastus | Coltsfoot leaf | 232339 | 1 |
| Bombastus | Coltsfoot leaf | 275489 | 3 |
| Bombastus | Coltsfoot leaf | 274289 | 5 |
| Bombastus | Coltsfoot leaf | 269501 | 3 |
| Caelo | Coltsfoot leaf | 23041302 | 1 |
| Caelo | Coltsfoot leaf | Int.Ch:Now16081 | 1 |
| Klenk | Coltsfoot leaf | 2021B121204 | 9 |
| Klenk | Coltsfoot leaf | 2021B120601 | 5 |
| Klenk | Coltsfoot leaf | 2021C130326 | 8 |
| Klenk | Coltsfoot leaf | 2021C140730 | 1 |
| Klenk | Coltsfoot leaf | 2021B150407 | 1 |
| Klenk | Coltsfoot leaf | 2021B130227 | 12 |
| Klenk | Coltsfoot leaf | 2021B130319 | 4 |
| Klenk | Coltsfoot leaf | 20021301 | 1 |
| Klenk | Coltsfoot leaf | 26091301 | 1 |
| Klenk | Coltsfoot leaf | 23121302 | 1 |
| Klenk | Coltsfoot leaf | 5011301 | 1 |
| Klenk | Coltsfoot leaf | 14111302 | 1 |
| Klenk | Coltsfoot leaf | 11101202 | 1 |
| Klenk | Coltsfoot leaf | 8061207 | 1 |
| Klenk | Coltsfoot leaf | B120124 | 1 |
| Klenk | Coltsfoot leaf | B130227 | 1 |
| Klenk | Coltsfoot leaf | 2021B120124 | 4 |
| Klenk | Coltsfoot leaf | 5122013a | 1 |
| Klenk | Coltsfoot leaf | 2021B111111 | 3 |
| Klenk | Coltsfoot leaf | 2021B121203 | 5 |
| Klenk | Coltsfoot leaf | KS100061 | 1 |
| Klenk | Coltsfoot leaf | 2020B120124 | 1 |
| Klenk | Coltsfoot leaf | 2021B111005 | 1 |
| Klenk | Coltsfoot leaf | 2021B140131 | 1 |
| Klenk | Coltsfoot leaf | 2021b121204 | 1 |
| Bombastus | Comfrey herb, cut | 281531 | 1 |
| Klenk | Comfrey herb, cut | 4561B100518 | 2 |
| Caelo | Comfrey root | 2711Q-02135 | 1 |
| Caelo | Comfrey root | 116053 | 1 |
| Hof-Apotheke,St.Afra | Comfrey root | 125041 | 1 |
| Klenk | Comfrey root | 6241B130724 | 7 |
| Klenk | Comfrey root | 6241B120807 | 4 |
| Klenk | Comfrey root | B130619 | 1 |
| Klenk | Comfrey root | 6241B120531 | 3 |
| Klenk | Comfrey root | 6241B100715 | 1 |
| Klenk | Comfrey root | 6241B131009 | 1 |
| Klenk | Comfrey root | 6241B130619 | 8 |
| Klenk | Comfrey root | 6241B121214 | 2 |
| Klenk | Comfrey root | 6244B130624 | 1 |
| Klenk | Comfrey root | 6241B06110202 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Comfrey root | 6241B130312 | 3 |
| Klenk | Comfrey root | 6241b130619 | 1 |
| Klenk | Comfrey root | 6241b130724 | 1 |
| Klenk | Comfrey root | 6241b120807 | 1 |
| Caelo | Common broom herb, cut | 11132209 | 1 |
| Caelo | Common broom herb, cut | 12358804 | 3 |
| Caelo | Common broom herb, cut | 12358802 | 1 |
| Caelo | Common broom herb, cut | 12358803 | 4 |
| Caelo | Common broom herb, cut | 12358805 | 1 |
| Caelo | Common broom herb, cut | 13241601 | 1 |
| Caelo | Common broom herb, cut | 4412Q-01680 | 1 |
| Caelo | Common broom herb, cut | 12358801 | 2 |
| AHD | Common wormwood herb | 16310701 | 1 |
| AHD | Common wormwood herb | 521603580 | 1 |
| Aurica | Common wormwood herb | 521305386 | 1 |
| Caelo | Common wormwood herb | 12382702 | 12 |
| Caelo | Common wormwood herb | 12382701 | 7 |
| Caelo | Common wormwood herb | 18031302 | 1 |
| Caelo | Common wormwood herb | 1081301 | 1 |
| Caelo | Common wormwood herb | 14360605 | 1 |
| Caelo | Common wormwood herb | 12016711 | 3 |
| Caelo | Common wormwood herb | 12016705 | 5 |
| Caelo | Common wormwood herb | 12016707 | 3 |
| Caelo | Common wormwood herb | 12016702 | 1 |
| Caelo | Common wormwood herb | 12382706 | 1 |
| Caelo | Common wormwood herb | 12016709 | 2 |
| Caelo | Common wormwood herb | 9355403 | 1 |
| Galke | Common wormwood herb | 21637 | 1 |
| Gehe | Common wormwood herb | 3591A110119 | 4 |
| Caelo | Common wormwood herb | 10355329 | 1 |
| Caelo | Common wormwood herb | 1238701 | 1 |
| Klenk | Common wormwood herb | 3591A130218 | 10 |
| Klenk | Common wormwood herb | 3591A120123 | 8 |
| Klenk | Common wormwood herb | A120123 | 2 |
| Klenk | Common wormwood herb | 12016708 | 5 |
| Klenk | Common wormwood herb | 3591a130218 | 2 |
| Klenk | Common wormwood herb | 3591a120123 | 1 |
| Klenk | Common wormwood herb | 2591A130218 | 1 |
| Klenk | Common wormwood herb | 3591A11119 | 1 |
| Richter | Common wormwood herb | b200112 | 1 |
| Sanacorp | Common wormwood herb | 12382705 | 2 |
| Caelo | Copper(II) sulfate pentahydrate | 12157107 | 1 |
| Caelo | Copper(II) sulfate pentahydrate | 3411M-01317 | 1 |
| Caelo | Copper(II) sulfate pentahydrate | 10L15-NO6 | 1 |
| Caelo | Copper(II) sulfate pentahydrate | 2913U-01317 | 1 |
| Caelo | Copper(II) sulfate pentahydrate | 3211M-01317 | 1 |
| Fagron | Copper(II) sulfate pentahydrate | 13A25-N06 | 1 |
| Bombastus | Coriander | 263733 | 1 |
| Bombastus | Coriander | 306310 | 1 |
| Caelo | Coriander | 13010304 | 1 |
| Caelo | Coriander | 14031316 | 1 |
| Caelo | Coriander | 4091305 | 1 |
| Caelo | Coriander | 27061305 | 1 |
| Caelo | Coriander | 13010302 | 2 |
| Caelo | Coriander | 13010306 | 2 |
| Caelo | Coriander | 16010209 | 1 |
| Caelo | Coriander | 12080901 | 2 |
| Caelo | Coriander | 9285707 | 1 |
| Caelo | Coriander | 12080906 | 1 |
| Caelo | Coriander | 16010201 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar/Noweda | Coriander | 2010M-01539 | 1 |
| Caelo | Coriander | 12080905 | 1 |
| Klenk | Coriander | 2790A121023 | 7 |
| Klenk | Coriander | 2790A130129 | 2 |
| Klenk | Coriander | A121023 | 3 |
| Klenk | Coriander | 2709A130129 | 1 |
| Klenk | Coriander | 2790A151117 | 1 |
| Klenk | Coriander | 2790a121023 | 1 |
| Klenk | Coriander | 2790A161111 | 5 |
| Caelo | Coriander | 18010209 | 1 |
| sanacorp;3,32;18.06.15 | Coriander | 13299495 | 1 |
| Caelo | Cottonwood bud | 12027506 | 1 |
| Caelo | Cottonwood bud | 70864257 | 1 |
| Klenk | Cottonwood bud | 3260A120828 | 1 |
| Caelo | Cottonwood bud | 12027504 | 1 |
| Bombastus | Couch grass rhizome, cut | 278926 | 1 |
| Bombastus | Couch grass rhizome, cut | 270500 | 2 |
| Bombastus | Couch grass rhizome, cut | 276777 | 3 |
| Bombastus | Couch grass rhizome, cut | 262175 | 1 |
| Bombastus | Couch grass rhizome, cut | 273387 | 3 |
| Caelo | Couch grass rhizome, cut | 3712I-02180 | 1 |
| Caelo | Couch grass rhizome, cut | 10349704 | 1 |
| Caelo | Couch grass rhizome, cut | 10049614 | 1 |
| Caelo | Couch grass rhizome, cut | 10049618 | 2 |
| Caelo | Couch grass rhizome, cut | 10349705 | 1 |
| Caelo | Couch grass rhizome, cut | 12186813 | 4 |
| Caelo | Couch grass rhizome, cut | 12186705 | 1 |
| Caelo | Couch grass rhizome, cut | 12186817 | 3 |
| Galke | Couch grass rhizome, cut | 18781 | 1 |
| Gehe | Couch grass rhizome, cut | 283061 | 1 |
| Gehe | Couch grass rhizome, cut | 12186704 | 1 |
| Kräuter Schulte | Couch grass rhizome, cut | 53016 | 2 |
| Caelo | Cowberry leaf, cut | 12105203 | 1 |
| Caelo | Cowberry leaf, cut | 12105201 | 1 |
| Caelo | Cowberry leaf, cut | 12150205 | 1 |
| Caelo | Cowberry leaf, cut | 11334302 | 1 |
| Klenk | Cowberry leaf, cut | 2431B101006 | 2 |
| Creapure | Creatine | 515941 | 1 |
| Degussa / falcento | Creatine | 422031 | 1 |
| Phönix | Creatine | mysjhskeu | 1 |

## D

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Falcento | D-(+)-mannose | R-4639 | 1 |
| Falcento | D-(+)-mannose | R4640 | 1 |
| Falcento | D-(+)-mannose | R-4641 | 1 |
| Falcento | D-(+)-mannose | R-4638 | 1 |
| Giusto Faravelli | D-(+)-mannose | 161004/1710215001 | 1 |
| Caelo | Daisy flower | 11103201 | 2 |
| Caelo | Daisy flower | 12133703 | 1 |
| Caelo | Daisy flower | 12133704 | 1 |
| Caelo | Daisy flower | 12133705 | 1 |
| Caelo | Daisy flower | 11068308 | 1 |
| Caelo | Daisy flower | 11103203 | 2 |
| Hepart AG | Daisy flower | A130307 | 1 |
| Klenk | Daisy flower | 1210A120215 | 4 |
| Klenk | Daisy flower | A130705 | 1 |
| Klenk | Daisy flower | 1210A110223 | 1 |
| Klenk | Daisy flower | 1210a120215 | 2 |
| Klenk | Daisy flower | 1210A130307 | 4 |

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| Supplier | | Substance | Batch | Spectra |
|---|---|---|---|---|
| Klenk | | Daisy flower | 1210a071301 | 1 |
| Klenk | | Damiana leaf, cut | 12064101 | 1 |
| Caelo | | Damiana leaf, cut | 12330401 | 5 |
| Caelo | | Damiana leaf, cut | 12064103 | 3 |
| Caelo | | Damiana leaf, cut | 12330402 | 7 |
| Caelo | | Damiana leaf, cut | 12330403 | 2 |
| Caelo | | Damiana leaf, cut | 11026607 | 2 |
| Caelo | | Damiana leaf, cut | 12330407 | 2 |
| Klenk | | Damiana leaf, cut | A130206 | 2 |
| Klenk | | Damiana leaf, cut | 1990A130206 | 1 |
| Noweda | | Damiana leaf, cut | 200151 | 1 |
| Redwood | | Damiana leaf, cut | 216451 | 1 |
| Anzag | | Dandelion herb with root | 274030 | 1 |
| Anzag | 10.05.13 | Dandelion herb with root | 6611B130321 | 1 |
| ek:3,16EUR | | | | |
| Anzag | 25.10.12 | Dandelion herb with root | 6611B110131 | 1 |
| ek:3.16EUR | | | | |
| Aurica | | Dandelion herb with root | 521200197 | 1 |
| Bombastus | | Dandelion herb with root | 274030 | 5 |
| Bombastus | | Dandelion herb with root | 271272 | 5 |
| Bombastus | | Dandelion herb with root | 280363 | 5 |
| Bombastus | | Dandelion herb with root | 285264 | 1 |
| Bombastus | | Dandelion herb with root | 290125 | 1 |
| Bombastus | | Dandelion herb with root | 258809 | 1 |
| Bombastus | | Dandelion herb with root | 275126 | 1 |
| Bombastus | | Dandelion herb with root | 280363-3385310110 | 1 |
| Bombastus | | Dandelion herb with root | 282916 | 7 |
| Caelo | | Dandelion herb with root | 20111202 | 1 |
| Caelo | | Dandelion herb with root | 13019802 | 19 |
| Caelo | | Dandelion herb with root | 12236003 | 3 |
| Caelo | | Dandelion herb with root | 2112122165 | 1 |
| Caelo | | Dandelion herb with root | 806212165 | 1 |
| Caelo | | Dandelion herb with root | 13317903 | 1 |
| Caelo | | Dandelion herb with root | 17121305 | 1 |
| Caelo | | Dandelion herb with root | 8111205 | 1 |
| Caelo | | Dandelion herb with root | 11030305 | 1 |
| Caelo | | Dandelion herb with root | 12236002 | 8 |
| Caelo | | Dandelion herb with root | 11030311 | 2 |
| Caelo | | Dandelion herb with root | 13199202 | 2 |
| Caelo | | Dandelion herb with root | 11030309 | 2 |
| Caelo | | Dandelion herb with root | 13018902 | 1 |
| Caelo | | Dandelion herb with root | 11371903 | 1 |
| Caelo | | Dandelion herb with root | Int.Ch:318090 | 1 |
| Caelo | | Dandelion herb with root | Ch.-B.:13019802 | 1 |
| Caelo | | Dandelion herb with root | 12236005 | 5 |
| Caelo | | Dandelion herb with root | 13108802 | 11 |
| Caelo | | Dandelion herb with root | 12236001 | 3 |
| Caelo | | Dandelion herb with root | 11030313 | 2 |
| Caelo | | Dandelion herb with root | 13019801 | 5 |
| Caelo | | Dandelion herb with root | 13108801 | 4 |
| Caelo | | Dandelion herb with root | 6611B100902 | 1 |
| Caelo | | Dandelion herb with root | 19114406 | 1 |
| Caelo | | Dandelion herb with root | 18035117 | 1 |
| Caelo | | Dandelion herb with root | 19114404 | 1 |
| Caelo | | Dandelion herb with root | 13019802-3395310101 | 1 |
| Caelo | | Dandelion herb with root | 13019805 | 1 |
| Caelo | | Dandelion herb with root | 1103011 | 1 |
| Caelo | | Dandelion herb with root | 13108803 | 2 |
| Caelo | | Dandelion herb with root | 11030314 | 4 |
| Caelo | | Dandelion herb with root | 18046901 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dandelion herb with root | 18035108 | 3 |
| Caelo | Dandelion herb with root | 18035113 | 1 |
| Caelo | Dandelion herb with root | 18035103 | 1 |
| Caelo | Dandelion herb with root | 7341703 | 1 |
| Euro OTC | Dandelion herb with root | 11030312 | 4 |
| Galke | Dandelion herb with root | 20531 | 6 |
| Galke | Dandelion herb with root | 22093 | 2 |
| Gehe | Dandelion herb with root | 13019803 | 1 |
| Gehe | Dandelion herb with root | 6611B110104 | 1 |
| Hedinger | Dandelion herb with root | 10121614 | 1 |
| Klenk | Dandelion herb with root | 6611B110131 | 1 |
| Klenk | Dandelion herb with root | 6611B160613 | 1 |
| Klenk | Dandelion herb with root | 5122013b | 1 |
| Klenk | Dandelion herb with root | 6611A110104 | 1 |
| Klenk | Dandelion herb with root | 6611B1104104 | 1 |
| Klenk | Dandelion herb with root | 6611B130314 | 3 |
| Klenk | Dandelion herb with root | 6611B130321 | 29 |
| Klenk | Dandelion herb with root | 6611B090306 | 1 |
| Klenk | Dandelion herb with root | 6611B120620 | 19 |
| Klenk | Dandelion herb with root | 6611B-120620 | 1 |
| Klenk | Dandelion herb with root | 6611B-131206 | 1 |
| Noweda | Dandelion herb with root | 6611B110104 | 5 |
| Klenk | Dandelion herb with root | 6611B110929 | 2 |
| Bombastus | Dandelion herb with root | 277597 | 6 |
| Caelo | Dandelion herb with root | 10121602 | 1 |
| Caelo | Dandelion herb without root | 7031305 | 1 |
| Caelo | Dandelion herb without root | 13091305 | 1 |
| Caelo | Dandelion herb without root | 9011403 | 1 |
| Caelo | Dandelion herb without root | 11217109 | 2 |
| Caelo | Dandelion herb without root | 11371907 | 1 |
| Caelo | Dandelion herb without root | 1127102 | 1 |
| Caelo | Dandelion herb without root | 11371904 | 2 |
| Caelo | Dandelion herb without root | 1137907 | 1 |
| Caelo | Dandelion herb without root | 11217107 | 1 |
| Caelo | Dandelion herb without root | 11371902 | 1 |
| Caelo | Dandelion herb without root | 11030311 | 1 |
| Caelo | Dandelion herb without root | 107063 | 1 |
| Caelo | Dandelion root | 13329702 | 10 |
| Caelo | Dandelion root | 12363103 | 1 |
| Caelo | Dandelion root | 11003311 | 2 |
| Caelo | Dandelion root | 11003307 | 1 |
| Caelo | Dandelion root | 15407703 | 1 |
| Caelo | Dandelion root | 16161308 | 1 |
| Caelo | Dandelion root | 12363107 | 1 |
| Caelo | Dandelion root | 12367916 | 1 |
| Caelo | Dandelion root | 14166502 | 1 |
| Caelo | Dandelion root | 12363109 | 2 |
| Caelo | Dandelion root | 13329705 | 1 |
| Caelo | Dandelion root | 12363110 | 1 |
| Caelo | Dandelion root | 10024710 | 1 |
| Caelo | Dandelion root | 15096601 | 1 |
| Caelo | Dandelion root | 13329708 | 1 |
| Caelo | Dandelion root | 15407703 | 1 |
| Caelo | Dandelion root | 16161303 | 1 |
| Caelo | Dandelion root | 12363102 | 2 |
| Caelo | Dandelion root | 14166504 | 1 |
| Caelo | Dandelion root | 14376602 | 1 |
| Caelo | Dandelion root | 12363106 | 1 |
| Caelo | Dandelion root | 12363108 | 2 |
| Caelo | Dandelion root | 11003313 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dandelion root | 14166501 | 1 |
| Caelo | Dandelion root | 14376603 | 1 |
| Galke | Dandelion root | 126302 | 1 |
| Galke | Dandelion root | 20658 | 1 |
| Caelo | Dandelion root | 1140317 | 1 |
| Caelo | Dandelion root | 12363104 | 3 |
| Klenk | Dandelion root | 6621A120606 | 15 |
| Klenk | Dandelion root | 6101202 | 1 |
| Klenk | Dandelion root | N130813 | 1 |
| Klenk | Dandelion root | A120606 | 1 |
| Klenk | Dandelion root | 6621A120208 | 6 |
| Klenk | Dandelion root | 6621A160111 | 2 |
| Klenk | Dandelion root | 6621A110420 | 1 |
| Klenk | Dandelion root | 6621B170112 | 1 |
| Klenk | Dandelion root | 6621N130813 | 6 |
| Klenk | Dandelion root | 6621A140114 | 3 |
| Klenk | Dandelion root | 6621A140114 | 3 |
| Klenk | Dandelion root | 6621A141027 | 5 |
| noweda | Dandelion root | | 1 |
| Caelo | Dapsone | 18279201 | 4 |
| Cael | Dapsone | 17031101 | 2 |
| Caelo | Dapsone | 19113501 | 3 |
| Caesar & Loretz GmbH | Dapsone | 191135001 | 1 |
| Euro OTC | Deoxycholic acid | 1305051-01 | 1 |
| Fagron | Deoxycholic acid | 13J21-N14 | 1 |
| Gehe | Deoxycholic acid | 2012060253 | 1 |
| GEHE 21.10.2014 | Deoxycholic acid | 13F13-N06 | 1 |
| Caelo | Devil's claw root | 12031809 | 1 |
| Caelo | Devil's claw root | 12031810 | 1 |
| Caelo | Devil's claw root | 12031811 | 1 |
| Caelo | Devil's claw root | 12031806 | 1 |
| Caelo | Devil's claw root | 6331B110426 | 2 |
| Caelo | Devil's claw root | 12031803 | 1 |
| Galke | Devil's claw root | 20282 | 2 |
| Galke | Devil's claw root | 21018 | 2 |
| Gehe | Devil's claw root | 1114005 | 1 |
| Klenk | Devil's claw root | 6331B130129 | 5 |
| Klenk | Devil's claw root | 10111204 | 1 |
| Klenk | Devil's claw root | 6331B120508 | 3 |
| | Dexamphetamine sulfate | 22A18-F01-383287 | 2 |
| | Dexamphetamine sulfate | 23G04-F01-385209 | 1 |
| Caelo | Dexamphetamine sulfate | C9H13N14 | 1 |
| Fagron | Dexamphetamine sulfate | 17B09-B02-339689 | 4 |
| Fagron | Dexamphetamine sulfate | 17B09-B02-339690 | 1 |
| Fagron | Dexamphetamine sulfate | 19D12-B50-363246 | 3 |
| Fagron | Dexamphetamine sulfate | 22A18-F01-383285 | 1 |
| Fagron | Dexamphetamine sulfate | 20D10-F02-370502 | 1 |
| Fagron | Dexamphetamine sulfate | 11F29-N01 | 1 |
| Fagron | Dexamphetamine sulfate | 230918(22A18-F01-383285) | 1 |
| Fagron | Dexamphetamine sulfate | 231208(22A18-F01-383285) | 1 |
| Fagron | Dexamphetamine sulfate | F02-3705003 | 2 |
| Fagron | Dexamphetamine sulfate | B50-3632406 | 2 |
| Fagron | Dexamphetamine sulfate | F01-3764108 | 1 |
| Fagron | Dexamphetamine sulfate | 15H06-B04-313861 | 1 |
| Fagron | Dexamphetamine sulfate | 20D10-F02-370503 | 1 |
| Fagron | Dexamphetamine sulfate | 20D10-F02_370503 | 1 |
| Fagron | Dexamphetamine sulfate | 19D12-B50-363247 | 6 |
| Fagron | Dexamphetamine sulfate | 16F09-B02-328352 | 1 |
| Fagron | Dexamphetamine sulfate | 19D12-B50 | 2 |
| Fagron | Dexamphetamine sulfate | 17B019-B02-339689 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Dexamphetamine sulfate | 20D10-F02 | 3 |
| Fagron | Dexamphetamine sulfate | 17B09-B02 | 2 |
| Fargon/ Phönix | Dexamphetamine sulfate | F000876 | 1 |
| Fargon/Gehe | Dexamphetamine sulfate | 15H06-B04 | 1 |
| | Dihydrocodeine hydrogen tartrate | 21F03-F02-379260 | 3 |
| | Dihydrocodeine hydrogen tartrate | 3020321 | 2 |
| Caelo | Dihydrocodeine hydrogen tartrate | 70162 | 4 |
| Caelo | Dihydrocodeine hydrogen tartrate | 18115205 | 2 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15F18-B07-322054 | 1 |
| Caelo | Dihydrocodeine hydrogen tartrate | 13267604 | 2 |
| Caelo | Dihydrocodeine hydrogen tartrate | 18115202 | 3 |
| Caelo | Dihydrocodeine hydrogen tartrate | 13267603 | 1 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15295903 | 2 |
| Caelo | Dihydrocodeine hydrogen tartrate | 12142503 | 2 |
| Caelo | Dihydrocodeine hydrogen tartrate | 13267608 | 1 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15295907 | 1 |
| Caelo | Dihydrocodeine hydrogen tartrate | 16106203 | 4 |
| Caelo | Dihydrocodeine hydrogen tartrate | 17097502 | 2 |
| Caelo | Dihydrocodeine hydrogen tartrate | 16106202 | 5 |
| Caelo | Dihydrocodeine hydrogen tartrate | 17097508 | 2 |
| Caelo | Dihydrocodeine hydrogen tartrate | 15295905 | 4 |
| Caelo | Dihydrocodeine hydrogen tartrate | 19D15-B02-363307 | 1 |
| Caesar & Loretz GmbH | Dihydrocodeine hydrogen tartrate | 20003430006 | 1 |
| Caesar & Loretz GmbH | Dihydrocodeine hydrogen tartrate | 20003430003 | 1 |
| Caesar & Loretz GmbH | Dihydrocodeine hydrogen tartrate | 192004005 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 17G04-B02-342861 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 16I27-B03-332122 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 13H19-N08 | 3 |
| Fagron | Dihydrocodeine hydrogen tartrate | 15F18-B07-323388 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 12G05-N01 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 15F18-B07 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 16-00326 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 14K26-B04-317257 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 17G04-B02 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 16I27-B03 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 15F18B07 | 2 |
| Fagron | Dihydrocodeine hydrogen tartrate | 14K26-B04 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 14D08-B06 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 10H17-N03 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 3080620 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 21f03-f02-379260 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | 14K26-B04-310974 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | B02-3683109 | 1 |
| Fagron | Dihydrocodeine hydrogen tartrate | F02-3756503 | 4 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 70729 | 6 |
| Caelo | Dihydrocodeine hydrogen tartrate | 12142508 | 2 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 67052 | 10 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 20170808-03065 | 1 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 59819 | 1 |
| Th. Geyer | Dihydrocodeine hydrogen tartrate | 67035 | 2 |
| Akazie | Dill fruit | 20.09.2015 | 1 |
| Caelo | Dill fruit | 12289901 | 1 |
| Caelo | Dill fruit | 12342909 | 5 |
| Caelo | Dill fruit | 12342904 | 7 |
| Caelo | Dill fruit | 12038302 | 2 |
| Caelo | Dill fruit | 12342908 | 2 |
| Caelo | Dill fruit | 12342903 | 1 |
| Caelo | Dill fruit | 12342901 | 2 |
| Caelo | Dill fruit | 12342906 | 2 |
| Caelo | Dill fruit | 12038304 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Dill fruit | 9189003 | 1 |
| Caelo | Dill fruit | 16040406 | 1 |
| Hepart AG | Dill fruit | L30057kbA | 1 |
| Klenk | Dill fruit | 2680A120312 | 8 |
| Klenk | Dill fruit | A120312 | 1 |
| Klenk | Dill fruit | 2680A-120312 | 1 |
| Klenk | Dill fruit | 2680A121211 | 3 |
| Klenk | Dill fruit | 2680a120312 | 1 |
| Kräuter Schulte | Dill fruit | 6363 | 1 |
| Caelo | Dill fruit | 16348702 | 2 |
| Caelo | Dill fruit | 16348707 | 1 |
| Wolf | Dill fruit | L30057 | 5 |
| Wolf | Dill fruit | 23622 | 6 |
| Wolf | Dill fruit | 22422 | 4 |
| Wolf | Dill fruit | E-501 | 1 |
| Bombastus | Dill herb, cut | 50836505 | 1 |
| Caelo | Dill herb, cut | 13007605 | 1 |
| Caelo | Dill herb, cut | 11295109 | 1 |
| Caelo | Dill herb, cut | 13007601 | 1 |
| Caelo | Dill herb, cut | 15178603 | 1 |
| Caelo | Dill herb, cut | 13007602 | 1 |
| Caelo | Dill herb, cut | 13007608 | 1 |
| Klenk | Dill herb, cut | 3531B110726 | 1 |
| Dr. Behr | Dimercaptosuccinic acid | WE14020002 | 1 |
| Lab.Offichem | Dimethyl fumarate | 1805043.0393 | 1 |
| Lab.Offichem | Dimethyl fumarate | 1605052.0393 | 1 |
| Lab.Offichem | Dimethyl fumarate | 1808016.0393 | 1 |
| Lab.Offichem | Dimethyl fumarate | 1809012.0393 | 1 |
| Lab.Offichem | Dimethyl fumarate | 1910037.1814 | 1 |
| Falcento | D-Ribose | 201206712 | 2 |
| Falcento | D-Ribose | JXCZSJ14-D-010 | 1 |
| Falcento | D-Ribose | 201209702 | 1 |
| Unisan | D-Ribose | JXCZSJ13D-013 | 2 |
| Fagron | Drofenine hydrochloride | 11J24-N01 | 1 |
| Fagron | Drofenine hydrochloride | 12D04-N03 | 1 |
| Caelo | Dry beads Caelo orange | 11005811 | 1 |
| Kräuter Schulte | Dryas octopetala herb, cut | 38970 | 1 |

## E

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Econazole nitrate | ECN140301 | 1 |
| Fagron | Econazole nitrate | 11K07-N03 | 1 |
| Fagron | Econazole nitrate | 13D22-N06 | 1 |
| Fagron | Econazole nitrate | 14G22-B07-306926 | 1 |
| Fagron | Econazole nitrate | 12F18-N05 | 1 |
| Fagron | Econazole nitrate | 11F09-N16 | 1 |
| Caelo | Elder berries | 12267801 | 1 |
| Gehe | Elder berries | 12267807 | 1 |
| Klenk | Elder berries | 3010N120921 | 3 |
| Bombastus | Elder flower | 275393 | 4 |
| Bahnhof-Apotheke | Elder flower | 17-121112 | 1 |
| Bombastus | Elder flower | 265631 | 1 |
| Bombastus | Elder flower | 289348 | 1 |
| Bombastus | Elder flower | 279216 | 3 |
| Caelo | Elder flower | 10291312 | 2 |
| Caelo | Elder flower | 12221909 | 1 |
| Caelo | Elder flower | 31051301 | 1 |
| Caelo | Elder flower | 14111317 | 1 |
| Caelo | Elder flower | 13244602 | 2 |
| Caelo | Elder flower | 10291310 | 5 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Elder flower | 5122013d | 1 |
| Caelo | Elder flower | 12221902 | 11 |
| Caelo | Elder flower | 1571a121022 | 1 |
| Caelo | Elder flower | 12221906 | 1 |
| Caelo | Elder flower | 13244601 | 4 |
| Caelo | Elder flower | 10291308 | 2 |
| Caelo | Elder flower | 12221910 | 2 |
| Caelo | Elder flower | 12221907 | 4 |
| Caelo | Elder flower | 12221904 | 10 |
| Caelo | Elder flower | 12221905 | 7 |
| Caelo | Elder flower | 10291309 | 3 |
| Caelo | Elder flower | 12221904-3360319071 | 1 |
| Caesar/Noweda | Elder flower | 4910A-01471 | 1 |
| Finze | Elder flower | 9297415 | 1 |
| Galke | Elder flower | 21934 | 1 |
| Gehe | Elder flower | 1250213 | 1 |
| Gehe | Elder flower | 1090413 | 1 |
| Klenk | Elder flower | 1571A141126 | 1 |
| Klenk | Elder flower | 1571A110223 | 16 |
| Klenk | Elder flower | 1571A121121 | 20 |
| Klenk | Elder flower | 1571A110125 | 2 |
| Klenk | Elder flower | 26061201 | 1 |
| Klenk | Elder flower | 16061201 | 1 |
| Klenk | Elder flower | 13021301 | 1 |
| Klenk | Elder flower | 21091201 | 1 |
| Klenk | Elder flower | A120215 | 1 |
| Klenk | Elder flower | A121121 | 1 |
| Klenk | Elder flower | 1571A130627 | 2 |
| Klenk | Elder flower | 1571A1202015 | 1 |
| Klenk | Elder flower | 1571A-110223 | 1 |
| Klenk | Elder flower | 1571a120215 | 1 |
| Klenk | Elder flower | 1571A130930 | 3 |
| Klenk | Elder flower | 1571A121022 | 14 |
| Klenk | Elder flower | 1571a1211 | 1 |
| Klenk | Elder flower | 1571A120215 | 4 |
| Caelo | Elder flower | 1029310 | 1 |
| Bombastus | Elder flower | 269873 | 2 |
| Wolf | Elder flower | E-738 | 1 |
| Wolf | Elder flower | B-810 | 1 |
| Wolf | Elder flower | 22749 | 1 |
| Wolf | Elder flower | 22765 | 1 |
| Klenk | Elder root, cut | 6281B110427 | 4 |
| Probe | Elder root, cut | 12345 | 1 |
| - | Elecampane rhizome, cut | 712M-02181 | 1 |
| Caelo | Elecampane rhizome, cut | 6341B | 1 |
| Caelo | Elecampane rhizome, cut | 13152402 | 1 |
| Caelo | Elecampane rhizome, cut | 12113304 | 3 |
| Caelo | Elecampane rhizome, cut | 1211334 | 1 |
| Caelo | Elecampane rhizome, cut | 11374702 | 1 |
| Caelo | Elecampane rhizome, cut | 13152403 | 2 |
| Caelo | Elecampane rhizome, cut | 13152401 | 1 |
| Caelo | Elecampane rhizome, cut | 12113303 | 1 |
| Galke | Elecampane rhizome, cut | 21569 | 2 |
| Gehe | Elecampane rhizome, cut | 11196906 | 1 |
| Gehe | Elecampane rhizome, cut | 12113302 | 2 |
| Caelo | Elecampane rhizome, cut | 11374703 | 1 |
| Klenk | Elecampane rhizome, cut | 6341B120611 | 2 |
| Klenk | Elecampane rhizome, cut | 6341B100426 | 2 |
| Klenk | Elecampane rhizome, cut | B130423 | 3 |
| Klenk | Elecampane rhizome, cut | 6311141B130423 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Elecampane rhizome, cut | 6341B130423 | 3 |
| Noweda | Elecampane rhizome, cut | 6341B111118 | 3 |
| Richter | Elecampane rhizome, cut | P158683 | 1 |
| Caelo | Eleutherococcus, cut | 12326703 | 1 |
| Caelo | Eleutherococcus, cut | 10381818 | 2 |
| Caelo | Eleutherococcus, cut | 12326707 | 1 |
| Caelo | Eleutherococcus, cut | 10381817 | 1 |
| Klenk | Eleutherococcus, cut | 7011A121204 | 1 |
| Klenk | Eleutherococcus, cut | 7011A101206 | 1 |
| Klenk | Eleutherococcus, cut | 7011A110714 | 1 |
| Caelo | Eleutherococcus, cut | 12326701 | 1 |
| Caelo | Elm bark, cut | 12287902 | 2 |
| Caelo | Elm bark, cut | 10347204 | 1 |
| Caelo | Elm bark, cut | 10347203 | 1 |
| Klenk | Elm bark, cut | 841a120413 | 1 |
| Klenk | Elm bark, cut | 841A1101120 | 1 |
| Aurica / 11 | Equisetum stem | 521302898 | 1 |
| Bomba/AHD | Equisetum stem | 280449 | 3 |
| Bombastus | Equisetum stem | 273963 | 1 |
| Bombastus | Equisetum stem | 265924 | 1 |
| Bombastus | Equisetum stem | 6011401 | 1 |
| Bombastus | Equisetum stem | 18111304 | 1 |
| Bombastus | Equisetum stem | 278107 | 1 |
| Bombastus | Equisetum stem | 272552 | 2 |
| Bombastus | Equisetum stem | 264100 | 1 |
| Bombastus | Equisetum stem | 280647 | 1 |
| Bombastus | Equisetum stem | 268321 | 1 |
| Bombastus | Equisetum stem | 275891 | 3 |
| Bombastus | Equisetum stem | 264101 | 1 |
| Bombastus | Equisetum stem | 274714 | 1 |
| Caelo | Equisetum stem | 11076305 | 8 |
| Caelo | Equisetum stem | 13159704 | 6 |
| Caelo | Equisetum stem | 12288803 | 14 |
| Caelo | Equisetum stem | 13159706 | 5 |
| Caelo | Equisetum stem | 13344309 | 3 |
| Caelo | Equisetum stem | 13159702 | 10 |
| Caelo | Equisetum stem | 12288809 | 3 |
| Caelo | Equisetum stem | 9101313 | 1 |
| Caelo | Equisetum stem | 13091301 | 1 |
| Caelo | Equisetum stem | 17101203 | 1 |
| Caelo | Equisetum stem | 8051302 | 1 |
| Caelo | Equisetum stem | 6081304 | 1 |
| Caelo | Equisetum stem | 3091201 | 1 |
| Caelo | Equisetum stem | 8041301 | 1 |
| Caelo | Equisetum stem | 2011408 | 1 |
| Caelo | Equisetum stem | 30101305 | 1 |
| Caelo | Equisetum stem | 8101201 | 1 |
| Caelo | Equisetum stem | 20111212 | 1 |
| Caelo | Equisetum stem | 11076301 | 4 |
| Caelo | Equisetum stem | 11076302 | 2 |
| Caelo | Equisetum stem | 13350309 | 1 |
| Caelo | Equisetum stem | 15015404 | 1 |
| Caelo | Equisetum stem | 13344304 | 5 |
| Caelo | Equisetum stem | 13344303 | 6 |
| Caelo | Equisetum stem | 2658181 | 1 |
| Caelo | Equisetum stem | 13350301 | 1 |
| Caelo | Equisetum stem | 13344311 | 1 |
| Caelo | Equisetum stem | 13344305 | 1 |
| Caelo | Equisetum stem | 11021901 | 1 |
| Caelo | Equisetum stem | 12288802 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Equisetum stem | 10328901 | 1 |
| Caelo | Equisetum stem | 1288804 | 1 |
| Caelo | Equisetum stem | 311042 | 1 |
| Caelo | Equisetum stem | 10328915 | 1 |
| Caelo | Equisetum stem | 11021904 | 1 |
| Caelo | Equisetum stem | 11076307 | 1 |
| Caelo | Equisetum stem | 12288808 | 9 |
| Caelo | Equisetum stem | 282573 | 1 |
| Caelo | Equisetum stem | 11076303 | 13 |
| Caelo | Equisetum stem | 12288801 | 16 |
| Caelo | Equisetum stem | 12288804 | 11 |
| Caelo | Equisetum stem | 13159705 | 6 |
| Caelo | Equisetum stem | 13200201 | 1 |
| Caelo | Equisetum stem | 10375520 | 1 |
| Caelo | Equisetum stem | 12231401 | 6 |
| Caelo | Equisetum stem | 13159705-3387310190 | 1 |
| Caelo | Equisetum stem | 13153702 | 1 |
| Caelo | Equisetum stem | 1359702 | 1 |
| Caelo | Equisetum stem | 11076306 | 6 |
| Caelo | Equisetum stem | 13344302 | 3 |
| Caelo | Equisetum stem | 12288807 | 2 |
| Caelo | Equisetum stem | 13159702-3464312101 | 1 |
| Caesar & Loretz Gm… | Equisetum stem | 10375510 | 2 |
| Galke | Equisetum stem | 19663 | 5 |
| Galke | Equisetum stem | 22061 | 1 |
| Gehe | Equisetum stem | 10375515 | 1 |
| Hepart AG | Equisetum stem | B-695,kbA | 1 |
| Klenk | Equisetum stem | 3831A120726 | 18 |
| Klenk | Equisetum stem | 3831A130610 | 5 |
| Klenk | Equisetum stem | 3831A120903 | 8 |
| Hubertus Apotheke | Equisetum stem | 3831C140403 | 1 |
| Klenk | Equisetum stem | 2213U01642 | 1 |
| Klenk | Equisetum stem | 3831A120529 | 8 |
| Klenk | Equisetum stem | 3831c131104 | 1 |
| Klenk | Equisetum stem | 3831A120018 | 1 |
| Klenk | Equisetum stem | 3831A1230726 | 1 |
| Klenk | Equisetum stem | 3831A110922 | 1 |
| Klenk | Equisetum stem | 3831a120611 | 1 |
| Klenk | Equisetum stem | 3831A120611 | 10 |
| Klenk | Equisetum stem | 3831C131104 | 1 |
| Klenk | Equisetum stem | 3831A11124 | 1 |
| Klenk | Equisetum stem | 4713U01642 | 1 |
| Klenk | Equisetum stem | 3831A111124 | 4 |
| Klenk | Equisetum stem | 3831A121018 | 6 |
| Klenk | Equisetum stem | 3831A110601 | 1 |
| Klenk | Equisetum stem | 4413Q1642 | 1 |
| Caelo | Equisetum stem | 13344306 | 1 |
| phönix | Equisetum stem | | 2 |
| Sanacorp | Equisetum stem | 13344307 | 1 |
| Caelo | Equisetum stem | 10375507 | 2 |
| Wolf | Equisetum stem | 21879 | 6 |
| Wolf | Equisetum stem | B233885 | 4 |
| Wolf | Equisetum stem | B-695 | 1 |
| apomix | Ergotamine tartrate | 15L01-B02 | 1 |
| Fagron | Ergotamine tartrate | 15L01-B02-341852 | 1 |
| Fagron | Ergotamine tartrate | 18D05-B01-358419 | 2 |
| Fagron | Ergotamine tartrate | 15B16-B05-308417 | 1 |
| Fagron | Ergotamine tartrate | 18D05-B01-36779 | 1 |
| Euro OTC | Escin, water-soluble | 1612012-01 | 3 |
| Euro OTC | Escin, water-soluble | 1108038 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Euro OTC | Escin, water-soluble | 1310020-01 | 1 |
| Fagron | Escin, water-soluble | 30691/M3 | 1 |
| Euro OTC | Ethyl hydrogen fumarate calcium | 1510005-01 | 12 |
| Lab.Offichem | Ethyl hydrogen fumarate calcium | 1412007.0525 | 1 |
| Lab.Offichem | Ethyl hydrogen fumarate calcium | 1806023.0525 | 1 |
| Lab.Offichem | Ethyl hydrogen fumarate calcium | 1801004.0525 | 1 |
| Fagron | Ethyl hydrogen fumarate mag... | 14H27-B04-299502 | 6 |
| Lab.Offichem | Ethyl hydrogen fumarate mag... | 1604034.0527 | 1 |
| Lab.Offichem | Ethyl hydrogen fumarate mag... | 1805051.0527 | 1 |
| Alliance | Eucalyptus leaf | 2011B120419 | 6 |
| Caelo | Eucalyptus leaf | 9346811 | 1 |
| Caelo | Eucalyptus leaf | 12225202 | 1 |
| Caelo | Eucalyptus leaf | 122250204 | 1 |
| Caelo | Eucalyptus leaf | 12225206 | 1 |
| Caelo | Eucalyptus leaf | 11307708 | 2 |
| Caelo | Eucalyptus leaf | 12225203 | 3 |
| Klenk | Eucalyptus leaf | B120419 | 1 |
| Klenk | Eucalyptus leaf | B130306 | 2 |
| Klenk | Eucalyptus leaf | 2011B110801 | 4 |
| Klenk | Eucalyptus leaf | 2011B130306 | 4 |
| Klenk | Eucalyptus leaf | 2011b130306 | 1 |
| Klenk | Eucalyptus leaf | 2011B130306-35294110 | 1 |
| Bombastus | Euphrasy herb | 270726 | 2 |
| Bombastus | Euphrasy herb | 277846 | 1 |
| Bombastus | Euphrasy herb | 274553 | 1 |
| Bombastus | Euphrasy herb | 278108 | 2 |
| Caelo | Euphrasy herb | 13180001 | 5 |
| Caelo | Euphrasy herb | 11030811 | 3 |
| Caelo | Euphrasy herb | 112211643 | 1 |
| Caelo | Euphrasy herb | 29011302 | 1 |
| Caelo | Euphrasy herb | 7051302 | 1 |
| Caelo | Euphrasy herb | 30101307 | 1 |
| Caelo | Euphrasy herb | 8011419 | 1 |
| Caelo | Euphrasy herb | 11030810 | 1 |
| Caelo | Euphrasy herb | 14019102 | 2 |
| Caelo | Euphrasy herb | 14019107 | 1 |
| Caelo | Euphrasy herb | 13180008 | 1 |
| Caelo | Euphrasy herb | 12103201 | 1 |
| Caelo | Euphrasy herb | 13180005 | 2 |
| Caelo | Euphrasy herb | 312052 | 1 |
| Caelo | Euphrasy herb | 13180004 | 5 |
| Caelo | Euphrasy herb | 12103202 | 9 |
| Caelo | Euphrasy herb | 1213202 | 1 |
| Caelo | Euphrasy herb | 11030812 | 4 |
| Galke | Euphrasy herb | 20262 | 2 |
| Caelo | Euphrasy herb | 12103203 | 10 |
| Caelo | Euphrasy herb | 13180002 | 5 |
| Klenk | Euphrasy herb | 15029806 | 1 |
| Klenk | Euphrasy herb | B101206 | 1 |
| Klenk | Euphrasy herb | B130430 | 1 |
| Klenk | Euphrasy herb | 3871B130430 | 1 |

## F

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| AHD | Fennel, bitter | 15006502 | 1 |
| AHD;11.05.15;3,23 | Fennel, bitter | 14376408 | 3 |
| Alfred Galke | Fennel, bitter | 18270 | 1 |
| Bahnhof-Apotheke | Fennel, bitter | 11-121029 | 1 |
| Bombastus | Fennel, bitter | 299385 | 3 |
| Bombastus | Fennel, bitter | 289870 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Fennel, bitter | 280891 | 2 |
| Bombastus | Fennel, bitter | 285609 | 1 |
| Bombastus | Fennel, bitter | 268130 | 2 |
| Bombastus | Fennel, bitter | 307641 | 1 |
| Bombastus | Fennel, bitter | 299386 | 3 |
| Bombastus | Fennel, bitter | 289870 | 1 |
| Bombastus | Fennel, bitter | 289869 | 2 |
| Bombastus | Fennel, bitter | 293627 | 1 |
| Bombastus | Fennel, bitter | 296877 | 3 |
| Bombastus | Fennel, bitter | 275922 | 4 |
| Cae | Fennel, bitter | Int.Ch.314090 | 1 |
| Caelo | Fennel, bitter | 16061202 | 1 |
| Caelo | Fennel, bitter | 12094725 | 8 |
| Caelo | Fennel, bitter | 12167102 | 4 |
| Caelo | Fennel, bitter | 12094721 | 3 |
| Caelo | Fennel, bitter | 13371605 | 1 |
| Caelo | Fennel, bitter | 15443204 | 8 |
| Caelo | Fennel, bitter | 13371610 | 2 |
| Caelo | Fennel, bitter | 14255802 | 3 |
| Caelo | Fennel, bitter | 15443203 | 2 |
| Caelo | Fennel, bitter | 402311545 | 1 |
| Caelo | Fennel, bitter | 13148305 | 3 |
| Caelo | Fennel, bitter | 15006508 | 3 |
| Caelo | Fennel, bitter | 15443212 | 4 |
| Caelo | Fennel, bitter | 15443213 | 1 |
| Caelo | Fennel, bitter | 6091201 | 1 |
| Caelo | Fennel, bitter | 4061302 | 1 |
| Caelo | Fennel, bitter | 9121305 | 1 |
| Caelo | Fennel, bitter | 5121401 | 1 |
| Caelo | Fennel, bitter | 7031306 | 1 |
| Caelo | Fennel, bitter | 5061302 | 1 |
| Caelo | Fennel, bitter | 14111301 | 1 |
| Caelo | Fennel, bitter | 27121201 | 1 |
| Caelo | Fennel, bitter | 154443204 | 1 |
| Caelo | Fennel, bitter | 12094704 | 4 |
| Caelo | Fennel, bitter | 1209474 | 1 |
| Caelo | Fennel, bitter | 12094710 | 4 |
| Caelo | Fennel, bitter | 15443205 | 2 |
| Caelo | Fennel, bitter | 12094705 | 4 |
| Caelo | Fennel, bitter | 12094716 | 8 |
| Caelo | Fennel, bitter | 13398502 | 1 |
| Caelo | Fennel, bitter | 13371610 | 1 |
| Caelo | Fennel, bitter | 13148306 | 1 |
| Caelo | Fennel, bitter | 12035102 | 2 |
| Caelo | Fennel, bitter | 16298101 | 1 |
| Caelo | Fennel, bitter | 13148303 | 2 |
| Caelo | Fennel, bitter | 12094724 | 4 |
| Caelo | Fennel, bitter | 11185501 | 1 |
| Caelo | Fennel, bitter | 17341502 | 1 |
| Caelo | Fennel, bitter | 11016330 | 1 |
| Caelo | Fennel, bitter | 12362710 | 1 |
| Caelo | Fennel, bitter | 13398502 | 1 |
| Caelo | Fennel, bitter | 15006507 | 1 |
| Caelo | Fennel, bitter | 14376405 | 1 |
| Caelo | Fennel, bitter | 12094703 | 2 |
| Caelo | Fennel, bitter | 12094720 | 7 |
| Caelo | Fennel, bitter | 12167101 | 1 |
| Caelo | Fennel, bitter | 12094712 | 4 |
| Caelo | Fennel, bitter | 12094715 | 4 |
| Caelo | Fennel, bitter | 12345678 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Fennel, bitter | 16005902 | 1 |
| Caelo | Fennel, bitter | 15007601 | 1 |
| Caelo | Fennel, bitter | 14376408;21S08 | 1 |
| Caelo | Fennel, bitter | 13200402 | 2 |
| Caelo | Fennel, bitter | 13148304 | 24 |
| Caelo | Fennel, bitter | 12094717 | 1 |
| Caelo | Fennel, bitter | 12035102 | 1 |
| Caelo | Fennel, bitter | 15443202 | 5 |
| Caelo | Fennel, bitter | 12094726 | 2 |
| Caelo | Fennel, bitter | 15007602 | 2 |
| Caelo | Fennel, bitter | 15443215 | 5 |
| Caelo | Fennel, bitter | 15141004 | 1 |
| Caelo | Fennel, bitter | 15443208 | 2 |
| Caelo | Fennel, bitter | 1302081 | 1 |
| Caelo | Fennel, bitter | 1320041 | 1 |
| Caelo | Fennel, bitter | 1S443206 | 1 |
| Caelo | Fennel, bitter | 15006501 | 2 |
| Caelo | Fennel, bitter | 13148307 | 1 |
| Caelo | Fennel, bitter | 15443209 | 3 |
| Caelo | Fennel, bitter | 19178804 | 2 |
| Caelo | Fennel, bitter | 14376402 | 1 |
| Caelo | Fennel, bitter | 14376406 | 2 |
| Caelo | Fennel, bitter | 17341503 | 1 |
| Caelo | Fennel, bitter | 17341515 | 3 |
| Caelo | Fennel, bitter | 17341510 | 1 |
| Caelo | Fennel, bitter | 13148304-3500411070 | 1 |
| Caelo | Fennel, bitter | 12094716-3408310191 | 1 |
| Caelo | Fennel, bitter | 14376401 | 2 |
| Caelo | Fennel, bitter | 16298102 | 1 |
| Caesar & Loretz Gm… | Fennel, bitter | 11016331 | 1 |
| Caesar & Loretz Gm… | Fennel, bitter | 11016319 | 1 |
| Caesar & Loretz Gm… | Fennel, bitter | 12094711 | 2 |
| Caesar & Loretz Gm… | Fennel, bitter | 12094705 | 2 |
| Caesar & Loretz Gm… | Fennel, bitter | 12094707 | 6 |
| Defektur | Fennel, bitter | 52/13 | 1 |
| Defektur | Fennel, bitter | 7/13 | 1 |
| Defektur | Fennel, bitter | 57/13 | 1 |
| Fagron | Fennel, bitter | 1406211545 | 1 |
| Fagron | Fennel, bitter | | 1 |
| Fagron | Fennel, bitter | 6858913 | 1 |
| Gahlke | Fennel, bitter | 20362 | 1 |
| galke | Fennel, bitter | 19938 | 3 |
| Galke | Fennel, bitter | 22176 | 1 |
| GALKE | Fennel, bitter | 27755 | 1 |
| Gehe | Fennel, bitter | 2860A120412 | 24 |
| Caelo | Fennel, bitter | 1250117/15443216 | 1 |
| Hepart AG | Fennel, bitter | B492,kbA | 1 |
| Caelo | Fennel, bitter | 13200401 | 4 |
| Klenk | Fennel, bitter | 13020801 | 4 |
| K | Fennel, bitter | 2860A160302 | 1 |
| Klenk | Fennel, bitter | 2880N120418 | 4 |
| Klenk | Fennel, bitter | 2860A140612 | 18 |
| Klenk | Fennel, bitter | 3812A-01545 | 1 |
| Klenk | Fennel, bitter | 2860A140224 | 1 |
| Klenk | Fennel, bitter | 2860A140224 | 1 |
| Klenk | Fennel, bitter | 2860A130513 | 2 |
| Klenk | Fennel, bitter | 2860A130226 | 8 |
| Klenk | Fennel, bitter | 2866B100211 | 1 |
| Klenk | Fennel, bitter | 2866B130206 | 1 |
| Klenk | Fennel, bitter | 2866B110318 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Fennel, bitter | 2880A100503 | 2 |
| Klenk | Fennel, bitter | 2860A160606 | 1 |
| Klenk | Fennel, bitter | 2860A110704 | 4 |
| Klenk | Fennel, bitter | 28060A140612 | 1 |
| Klenk | Fennel, bitter | 2860A140613 | 3 |
| Klenk | Fennel, bitter | 2860,A150617 | 1 |
| Klenk | Fennel, bitter | 2860a-140224 | 1 |
| Klenk | Fennel, bitter | 2860A150320 | 21 |
| Klenk | Fennel, bitter | 2860A150617 | 6 |
| Klenk | Fennel, bitter | 2860a120412 | 3 |
| Kottas | Fennel, bitter | P15301479 | 1 |
| Noweda | Fennel, bitter | 2860A180212 | 1 |
| Noweda 06.04.2016 | Fennel, bitter | 15443201 | 1 |
| Phönix | Fennel, bitter | 12094708 | 2 |
| Phönix | Fennel, bitter | 13020802 | 6 |
| Caelo | Fennel, bitter | 2150317 | 1 |
| Sanacorp | Fennel, bitter | 12094719 | 4 |
| Caelo | Fennel, bitter | 17020603 | 1 |
| Caelo | Fennel, bitter | 15443216 | 2 |
| Caelo | Fennel, bitter | 15006506 | 1 |
| Caelo | Fennel, bitter | 11016332 | 1 |
| siehe Protokoll (Galke) | Fennel, bitter | sieheProtokoll | 2 |
| Wolf | Fennel, bitter | B-493 | 1 |
| Wolf | Fennel, bitter | B382 | 1 |
| Wolf | Fennel, bitter | B362 | 2 |
| Wolf | Fennel, bitter | B-492 | 5 |
| Wolf | Fennel, bitter | B-362 | 1 |
| Wolf | Fennel, bitter | B492 | 1 |
| Wolf | Fennel, bitter | B-682 | 1 |
| Caelo | Fennel, sweet | 311903 | 1 |
| Fargron/Noweda | Fennel, sweet | 2870A150810 | 1 |
| Klenk | Fennel, sweet | 2870A140528 | 2 |
| Klenk | Fennel, sweet | 2870130304A | 1 |
| Klenk | Fennel, sweet | 2870A131002 | 1 |
| VDL/30.04.15 7,20 euro | Fennel, sweet | 2870A130304 | 3 |
| Fagron | Fentanyl citrate | 17L14-B04-525660 | 1 |
| Fagron | Fentanyl citrate | 19E27-K04 | 1 |
| Fagron | Fentanyl citrate | 19K21-F02-526085 | 2 |
| Fagron | Fentanyl citrate | 20E20-F12 | 1 |
| Fagron | Fentanyl citrate | 16E26-B01-525231 | 1 |
| Fagron | Fentanyl citrate | 20100911-1 | 1 |
| Fagron | Fentanyl citrate | 19K21-F025 | 1 |
| Fagron | Fentanyl citrate | 14J03-B06-525002 | 1 |
| Fagron | Fentanyl citrate | 14Jo3-B06-525002 | 1 |
| Fagron | Fentanyl citrate | 18L27-B03-525913 | 1 |
| Fagron | Fentanyl citrate | 19D09-B04-525979 | 1 |
| Fagron | Fentanyl citrate | 16J06-B03-525432 | 1 |
| Fagron | Fentanyl citrate | 18B12-B06 | 1 |
| Fagron | Fentanyl citrate | 10H20-N02 | 1 |
| Fagron | Fentanyl citrate | 18L27-B03-525914 | 2 |
| Fagron | Fentanyl citrate | 16E26-B01-525232 | 1 |
| Fagron | Fentanyl citrate | 17L14-B04-525639 | 1 |
| Fagron | Fentanyl citrate | 20E20-F12-526324 | 1 |
| Fagron | Fentanyl citrate | 20E28-K01 | 1 |
| Fagron | Fentanyl citrate | 19-00252 | 1 |
| Fargon/Gehe | Fentanyl citrate | 21A19-K01 | 1 |
| Anzag | Fenugreek | 7260A130603 | 3 |
| Apofit | Fenugreek | 222392 | 1 |
| Caelo | Fenugreek | 11313203 | 1 |
| Caelo | Fenugreek | 12252603 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Fenugreek | 12252601 | 2 |
| Caelo | Fenugreek | 13013801 | 1 |
| Caelo | Fenugreek | 13013803 | 6 |
| Caelo | Fenugreek | 1131206 | 1 |
| Caelo | Fenugreek | 13013805 | 3 |
| Caelo | Fenugreek | 12252602 | 2 |
| Gehe | Fenugreek | 11313204 | 1 |
| Gehe | Fenugreek | 13013811 | 2 |
| Klenk | Fenugreek | 9011301 | 1 |
| Klenk | Fenugreek | 8061301 | 1 |
| Klenk | Fenugreek | A130603 | 1 |
| Klenk | Fenugreek | A120118 | 2 |
| Klenk | Fenugreek | 7260A110530 | 2 |
| Klenk | Fenugreek | 7260A120118 | 2 |
| Caelo | Fenugreek | 11313206 | 7 |
| Caelo | Fenugreek, powdered | 15308703 | 2 |
| Caelo | Fenugreek, powdered | 12149605 | 1 |
| Caelo | Fenugreek, powdered | 12149607 | 1 |
| Caelo | Fenugreek, powdered | 13398302 | 1 |
| Caelo | Fenugreek, powdered | 7264a110201 | 2 |
| Caelo | Fenugreek, powdered | 15120506 | 1 |
| Caelo | Fenugreek, powdered | 14057807 | 1 |
| Caelo | Fenugreek, powdered | 15308704 | 1 |
| Caelo | Fenugreek, powdered | 14377201 | 2 |
| Caelo | Fenugreek, powdered | 14057801 | 1 |
| Fagron | Fenugreek, powdered | 12149603 | 1 |
| Ichthyol/Phoenix | Fenugreek, powdered | 14377205 | 1 |
| Klenk | Fenugreek, powdered | 7264A110201 | 9 |
| Klenk | Fenugreek, powdered | A110201 | 1 |
| Klenk | Fenugreek, powdered | 12082014A | 1 |
| Klenk | Fenugreek, powdered | 7264B150303 | 1 |
| Nachprüfung | Fenugreek, powdered | 2412E02239 | 1 |
| Caelo | Feverfew | 12380201 | 2 |
| Caelo | Feverfew | 12380204 | 1 |
| Caelo | Feverfew | 12380203 | 5 |
| Caelo | Flax weed herb | 14197204 | 1 |
| Caelo | Flax weed herb | 13007507 | 7 |
| Caelo | Flax weed herb | 11104507 | 8 |
| Caelo | Flax weed herb | 14005303 | 1 |
| Caelo | Flax weed herb | 13007505 | 1 |
| Caelo | Flax weed herb | 1711924 | 1 |
| Caelo | Flax weed herb | 16292809 | 1 |
| Caelo | Flax weed herb | 13007502 | 2 |
| Caelo | Flax weed herb | 14005305 | 3 |
| Caelo | Flax weed herb | 16292801 | 1 |
| Caelo | Flax weed herb | 11104505 | 1 |
| Klenk | Flax weed herb | 4011B121207 | 2 |
| Klenk | Flax weed herb | 4011B131115 | 3 |
| Bombastus | Frangula bark | 270733 | 2 |
| Bombastus | Frangula bark | 268407 | 1 |
| Bombastus | Frangula bark | 273926 | 1 |
| Bombastus | Frangula bark | 275998 | 2 |
| Bombastus | Frangula bark | 281284 | 2 |
| Bombastus | Frangula bark | 278599 | 3 |
| Bombastus | Frangula bark | 238812 | 1 |
| Caelo | Frangula bark | 12186006 | 8 |
| Caelo | Frangula bark | 10061301 | 1 |
| Caelo | Frangula bark | 6011402 | 1 |
| Caelo | Frangula bark | 11254006 | 4 |
| Caelo | Frangula bark | 12186002 | 16 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Frangula bark | 14163102 | 1 |
| Caelo | Frangula bark | 11254003 | 2 |
| Caelo | Frangula bark | 13203008 | 1 |
| Caelo | Frangula bark | 11340801 | 1 |
| Caelo | Frangula bark | 11254001 | 2 |
| Caelo | Frangula bark | eztetdt | 1 |
| Caelo | Frangula bark | 12186001 | 1 |
| Caelo | Frangula bark | 12186003 | 1 |
| Caelo | Frangula bark | 12186005 | 1 |
| Caelo | Frangula bark | 1286003 | 1 |
| Caelo | Frangula bark | 12186004 | 11 |
| Caelo | Frangula bark | 12185901 | 10 |
| Caelo | Frangula bark | 121860006 | 1 |
| Caesar&loretz,Phoenix | Frangula bark | 14163104 | 1 |
| Finze | Frangula bark | 249091 | 1 |
| Gehe | Frangula bark | 11254004 | 4 |
| Klenk | Frangula bark | 661B110412 | 4 |
| Klenk | Frangula bark | 6621B110412 | 1 |
| Klenk | Frangula bark | 661B130306 | 1 |
| Klenk | Frangula bark | 661B-090903 | 1 |
| Klenk | Frangula bark | 661B-110412 | 1 |
| Caelo | Frankincense | 10349213 | 1 |
| Caelo | Frankincense | 12120008 | 2 |
| Caelo | Frankincense | 13112809 | 2 |
| Caelo | Frankincense | 4614M-02030 | 1 |
| Caelo | Frankincense | 10349210 | 1 |
| Caelo | Frankincense | 15140810 | 1 |
| Caelo | Frankincense | 802929 | 1 |
| Caelo | Frankincense | 15140805 | 2 |
| Caelo | Frankincense | 15140804 | 1 |
| Caelo | Frankincense | 13112803 | 1 |
| Caelo | Frankincense | 12120006 | 3 |
| Caelo | Frankincense | 14107803 | 2 |
| Caelo | Frankincense | 13112807 | 1 |
| Caelo | Frankincense | 13112803-3494411030 | 1 |
| Caelo | Frankincense | 12120012-3421310191 | 1 |
| Fagron | Frankincense | | 1 |
| Gahlke | Frankincense | 21949 | 1 |
| Caelo | Frankincense | 13112801 | 5 |
| Caelo | Frankincense | 12120005 | 5 |
| Caelo | Frankincense | 15140809 | 2 |
| vedono | Frankincense | 12120009 | 5 |
| vedono | Frankincense | 12120012 | 1 |
| Euro OTC | Frankincense extract 80% | 1104005V-04 | 2 |
| Euro OTC | Frankincense extract 80% | 1705033-01 | 1 |
| Klenk | Fraxinella root, cut | 6271B140708 | 1 |
| Fagron | Fuchsine | 12G18-N01 | 1 |
| Fagron | Fuchsine | 12F28-N02 | 1 |
| Fagron | Fuchsine | 12A03-N06 | 1 |
| Fagron | Fuchsine | 13A30-N05 | 1 |
| Fagron | Fuchsine | 13H23-M04 | 2 |
| Caelo | Fumitory | 12103402 | 2 |
| Caelo | Fumitory | 11101413 | 3 |
| Caelo | Fumitory | 7111201 | 1 |
| Caelo | Fumitory | 31081201 | 1 |
| Caelo | Fumitory | 12103404 | 2 |
| Caelo | Fumitory | 12103405 | 7 |
| Caelo | Fumitory | 12103407 | 6 |
| Caelo | Fumitory | 13202905 | 2 |
| Caelo | Fumitory | 11101410 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Fumitory | 11101406 | 1 |
| Caelo | Fumitory | 12103408 | 5 |
| Caelo | Fumitory | 11101408 | 1 |
| Caelo | Fumitory | 11101411 | 3 |
| Caelo | Fumitory | 1320902 | 1 |
| Caelo | Fumitory | 8312901 | 1 |
| Caelo | Fumitory | 72878477 | 1 |
| Caelo | Fumitory | 13202902 | 11 |
| gehe 20.11.13 | Fumitory | 3881B111013 | 2 |
| Klenk | Fumitory | B120410 | 1 |
| Klenk | Fumitory | 3881B100127 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Galangal root | 12330305 | 1 |
| Caelo | Galangal root | 16196901 | 1 |
| Caelo | Galangal root | 11375904 | 1 |
| Caelo | Galangal root | 16196904 | 1 |
| Caelo | Galangal root | 12330306 | 2 |
| Caelo | Galangal root | 15128008 | 1 |
| Caelo | Galangal root | 4056371 | 1 |
| Caelo | Galangal root | 94614429 | 1 |
| Caelo | Galangal root | 12125004 | 2 |
| Caelo | Galangal root | 1215004 | 1 |
| Caelo | Galangal root | 12330303 | 1 |
| Caelo | Galangal root | 15045701 | 1 |
| Gehe | Galeopsis herb, cut | 3911A130320 | 6 |
| Klenk | Galeopsis herb, cut | 3911A080409 | 1 |
| Klenk | Galeopsis herb, cut | 3911A130110 | 3 |
| Klenk | Galeopsis herb, cut | 3911A090219 | 2 |
| Klenk | Galeopsis herb, cut | 3911a130320 | 1 |
| Caelo | Garden violet, cut | 10011403 | 1 |
| Caelo | Garden violet, cut | 1303872 | 1 |
| Caelo | Garden violet, cut | 13232107 | 1 |
| Caelo | Garden violet, cut | 13038703 | 2 |
| Caelo | Garden violet, cut | 11124008 | 1 |
| Caelo | Garden violet, cut | 11124007 | 1 |
| Caelo | Garden violet, cut | 11124007-3284310662 | 1 |
| Caelo | Garden violet, cut | 13038701 | 4 |
| an | Gentian root | 6311b130305 | 1 |
| Anzag EK7,91 08.08.12 | Gentian root | 10263407 | 1 |
| Caelo | Gentian root | 19071304 | 1 |
| Caelo | Gentian root | 30011301 | 1 |
| Caelo | Gentian root | 10263411 | 1 |
| Caelo | Gentian root | 10263404 | 1 |
| Caelo | Gentian root | 6311B130305 | 2 |
| Caelo | Gentian root | 12244608 | 1 |
| Caelo | Gentian root | 13156102 | 1 |
| Caelo | Gentian root | Int.Ch:313091 | 1 |
| Caelo | Gentian root | 12244607 | 1 |
| Caesar & Loretz Gm… | Gentian root | 12244603 | 2 |
| Galke | Gentian root | 19192 | 2 |
| Klenk | Gentian root | 6311B120315 | 8 |
| Klenk | Gentian root | 6311B130205 | 2 |
| Klenk | Gentian root | 6311B140704 | 1 |
| Klenk | Gentian root | 6311A120723 | 3 |
| Klenk | Gentian root | 6311a120723 | 2 |
| Klenk | Gentian root | 1911E-02142 | 1 |
| kräuter schulte | Gentian root | 52348 | 1 |
| Phoenix | Gentian root | 6311B120104 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Gentian root | 269197 | 2 |
| Richter | Gentian root | P200907 | 1 |
| - | Gentian root, powdered | 130063 | 1 |
| Caelo | Gentian root, powdered | 15011403 | 1 |
| Caelo | Gentian root, powdered | 14215601 | 1 |
| Caelo | Gentian root, powdered | 12007106 | 1 |
| Galke | Geum urbanum herb, cut | 20881 | 1 |
| Kräuter Schulte | Geum urbanum herb, cut | 51737 | 1 |
| Caelo | Ginger | 13100602 | 2 |
| Caelo | Ginger | 13100605 | 4 |
| Caelo | Ginger | 13310604 | 4 |
| Caelo | Ginger | 19121201 | 1 |
| Caelo | Ginger | 11325716 | 1 |
| Caelo | Ginger | 11325719 | 3 |
| Caelo | Ginger | 12180604 | 1 |
| Caelo | Ginger | 11325715 | 2 |
| Caelo | Ginger | 13100604 | 1 |
| Caelo | Ginger | 11325703 | 2 |
| Caelo | Ginger | 11325712 | 1 |
| Caelo | Ginger | 13310602 | 2 |
| Caelo | Ginger | 12164911-3368319002 | 1 |
| Galke | Ginger | 21766 | 2 |
| Galke | Ginger | 20633 | 1 |
| Klenk | Ginger | 6951B110119 | 1 |
| Klenk | Ginger | 6951B110822 | 1 |
| Klenk | Ginger | 6951B100302 | 1 |
| Klenk | Ginger | 6951B130110 | 1 |
| Phönix | Ginger | 13310601 | 1 |
| Richter | Ginger | KR27992 | 1 |
| Caelo | Ginger, peeled, powdered | 13092013B | 1 |
| Caelo | Ginger, peeled, powdered | 12164901 | 1 |
| Caelo | Ginger, peeled, powdered | 12164911 | 1 |
| Klenk | Ginger, peeled, powdered | 6954B170127 | 1 |
| Klenk | Ginger, peeled, powdered | 6954B16029 | 1 |
| Klenk | Ginger, peeled, powdered | B121030 | 2 |
| Klenk | Ginger, peeled, powdered | 6954B110801 | 1 |
| Klenk | Ginger, peeled, powdered | 6954B130418 | 2 |
| Klenk | Ginger, peeled, powdered | 6954B160429 | 5 |
| Klenk | Ginger, peeled, powdered | 6954B160929 | 2 |
| Klenk | Ginger, peeled, powdered | KS200260 | 1 |
| kräuter schulte | Ginger, peeled, powdered | 6954B121030 | 2 |
| Caelo | Ginkgo leaf | 12151709 | 2 |
| Caelo | Ginkgo leaf | 15077407 | 1 |
| Caelo | Ginkgo leaf | 13340907 | 1 |
| Caelo | Ginkgo leaf | 13340904 | 1 |
| Caelo | Ginkgo leaf | 13340906 | 1 |
| Caelo | Ginkgo leaf | 15077410 | 1 |
| Caelo | Ginkgo leaf | 12373604 | 1 |
| Nachprüfung | Ginkgo leaf | 2461A100429 | 11 |
| Bombastus | Ginseng root | 13150903 | 1 |
| Caelo | Ginseng root | 13341001 | 1 |
| Caelo | Ginseng root | 12080218 | 1 |
| Caelo | Goat's rue, cut | 12017913 | 2 |
| Caelo | Goat's rue, cut | 12343302 | 4 |
| Caelo | Goat's rue, cut | 5122013e | 1 |
| Caelo | Goat's rue, cut | 12343305 | 3 |
| Caelo | Goat's rue, cut | 12343303 | 6 |
| Caelo | Goat's rue, cut | 11307903 | 1 |
| Caelo | Goat's rue, cut | 11307901 | 1 |
| Caelo | Goat's rue, cut | 11175104 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Goat's rue, cut | 12017914 | 1 |
| Caelo | Goat's rue, cut | 12343308 | 1 |
| Galke | Goat's rue, cut | 8378 | 2 |
| Hepart AG | Goat's rue, cut | 12017907 | 3 |
| Klenk | Goat's rue, cut | 3901C110905 | 1 |
| Klenk | Goat's rue, cut | 3901B140801 | 1 |
| Caelo | Goat's rue, cut | 12017912 | 1 |
| Sanacorp | Goat's rue, cut | 12017911 | 1 |
| Anzag 17.04.13 ek:... | Goldenrod | 4521A110816 | 2 |
| Aurica | Goldenrod | 521201267 | 1 |
| Aurica | Goldenrod | 224133 | 1 |
| Bomba/AHD | Goldenrod | 279526 | 1 |
| Bombastus | Goldenrod | 270047 | 2 |
| Bombastus | Goldenrod | 271460 | 1 |
| Bombastus | Goldenrod | 261756 | 1 |
| Bombastus | Goldenrod | 271459 | 1 |
| Bombastus | Goldenrod | 278697 | 2 |
| Bombastus | Goldenrod | 209974 | 1 |
| Caelo | Goldenrod | 314050-1-p | 1 |
| Caelo | Goldenrod | 11280311 | 2 |
| Caelo | Goldenrod | 4021405 | 1 |
| Caelo | Goldenrod | 6081302 | 1 |
| Caelo | Goldenrod | 15061203 | 1 |
| Caelo | Goldenrod | 27121302 | 1 |
| Caelo | Goldenrod | 4091302 | 1 |
| Caelo | Goldenrod | 20111209 | 1 |
| Caelo | Goldenrod | 17091203 | 1 |
| Caelo | Goldenrod | 28051302 | 1 |
| Caelo | Goldenrod | 14018404 | 1 |
| Caelo | Goldenrod | 11280310 | 6 |
| Caelo | Goldenrod | 11280301 | 4 |
| Caelo | Goldenrod | 12343104 | 5 |
| Caelo | Goldenrod | 13386901 | 1 |
| Caelo | Goldenrod | 12343109 | 1 |
| Caelo | Goldenrod | 13386903 | 1 |
| Caelo | Goldenrod | 14112012 | 1 |
| Caelo | Goldenrod | 265283 | 1 |
| Caelo | Goldenrod | 112080308 | 1 |
| Caelo | Goldenrod | 12343101 | 3 |
| Caelo | Goldenrod | 2656153 | 1 |
| Caelo | Goldenrod | 12343105 | 1 |
| Caelo | Goldenrod | 12319004 | 10 |
| Caelo | Goldenrod | 11280309 | 1 |
| Caelo | Goldenrod | 12336801 | 1 |
| Caelo | Goldenrod | 12319007 | 21 |
| Caelo | Goldenrod | 12343103 | 17 |
| Caelo | Goldenrod | 12343102 | 3 |
| Caelo | Goldenrod | 12319006 | 3 |
| Caelo | Goldenrod | 12319002 | 2 |
| Caelo | Goldenrod | 11280308 | 9 |
| Caelo | Goldenrod | 12319003 | 22 |
| Caelo | Goldenrod | 4113A-01684 | 1 |
| Caelo | Goldenrod | 12343106 | 1 |
| Caesar & Loretz Gm... | Goldenrod | 11207010 | 3 |
| Galke | Goldenrod | 21079 | 2 |
| Gehe | Goldenrod | 11207011 | 1 |
| Klenk | Goldenrod | A110209 | 1 |
| Klenk | Goldenrod | 4521A-110816 | 1 |
| Klenk | Goldenrod | 4521A110209 | 4 |
| Klenk | Goldenrod | 4521A100414 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Goldenrod | 11280306 | 3 |
| Noweda | Goldenrod | 11207014 | 3 |
| Bombastus | Goldenrod | 274290 | 1 |
| Caelo | Goldenrot, European | 13386908 | 1 |
| Caelo | Goldenrot, European | 12343102 | 1 |
| Caelo | Goldenrot, European | 12343103-3466312121 | 1 |
| Klenk | Goldenrot, European | 1781B110706 | 1 |
| Kenk / Phoenix | Goldenrot, European | 1781B110826 | 1 |
| Sanacorp | Goldenrot, European | 12343103 | 1 |
| - | Greater celandine herb | 810I-01632 | 1 |
| Klenk | Greater celandine herb | 1406111632 | 1 |
| Caelo | Greater celandine herb | 311092 | 1 |
| Galke | Greater celandine herb | 20937 | 3 |
| Klenk | Greater celandine herb | 3731A130904 | 5 |
| Klenk | Greater celandine herb | 3731K120904 | 4 |
| Klenk | Greater celandine herb | 3731A110301 | 6 |
| Klenk | Greater celandine herb | 4711E-01632 | 1 |
| Klenk | Greater celandine herb | 3731A120611 | 4 |
| Klenk | Greater celandine herb | 3731B100205 | 1 |
| Aurica/Phönix | Green bean pod | 5052301 | 1 |
| Bombastus | Green bean pod | 272781 | 3 |
| Bombastus | Green bean pod | 278686 | 1 |
| Bombastus | Green bean pod | 282475 | 1 |
| Bombastus | Green bean pod | 278696 | 2 |
| Bombastus | Green bean pod | 270517 | 1 |
| Bombastus | Green bean pod | 240503 | 1 |
| Cae | Green bean pod | Int.Ch.313011 | 1 |
| Caelo | Green bean pod | 6031301 | 1 |
| Caelo | Green bean pod | 29091201 | 1 |
| Caelo | Green bean pod | 15060905 | 1 |
| Caelo | Green bean pod | 13333803 | 1 |
| Caelo | Green bean pod | 1333802 | 1 |
| Caelo | Green bean pod | 14080002 | 1 |
| Caelo | Green bean pod | 12358703 | 5 |
| Caelo | Green bean pod | 8301004 | 1 |
| Caelo | Green bean pod | 13333801 | 1 |
| Caelo | Green bean pod | 11030601 | 1 |
| Caelo | Green bean pod | 1103061 | 1 |
| Caelo | Green bean pod | 10006507 | 1 |
| Caelo | Green bean pod | 11030605 | 1 |
| Caelo | Green bean pod | 11030602 | 5 |
| Caelo | Green bean pod | 11233603 | 1 |
| Caelo | Green bean pod | 11030604 | 6 |
| Galke | Green bean pod | 21219 | 1 |
| Klenk | Green bean pod | 671C130620 | 6 |
| Klenk | Green bean pod | 671C121105 | 8 |
| Klenk | Green bean pod | C120321 | 2 |
| Klenk | Green bean pod | C121105 | 2 |
| Klenk | Green bean pod | C130620 | 1 |
| Klenk | Green bean pod | 671A110420 | 9 |
| Klenk | Green bean pod | 171A110301 | 1 |
| Klenk | Green bean pod | 671C120321 | 16 |
| Klenk | Green bean pod | 671B180726 | 1 |
| Klenk | Green bean pod | 671A180925 | 1 |
| Klenk | Green bean pod | 671A-110420 | 1 |
| Klenk | Green bean pod | 671A110301 | 1 |
| Klenk | Green bean pod | 671A100816 | 2 |
| Caelo | Ground ivy herb | 11052315 | 1 |
| Caelo | Ground ivy herb | 11374611 | 2 |
| Caelo | Ground ivy herb | 11052314 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ground ivy herb | 11374615 | 1 |
| Caelo | Ground ivy herb | 11374606 | 1 |
| Caelo | Ground ivy herb | 11374602 | 1 |
| Caelo | Ground ivy herb | 11374609 | 1 |
| Caelo | Ground ivy herb | 11052318 | 2 |
| Gutenberg-Apotheke | Ground ivy herb | 11374610 | 3 |
| Klenk | Ground ivy herb | 3991B110304 | 1 |
| Klenk | Ground ivy herb | 3991B130502 | 2 |
| Phönix | Ground ivy herb | 11374608 | 1 |
| Richter | Ground ivy herb | s99/09 | 1 |
| Caelo | Guaiacum wood | 8041401 | 1 |
| Caelo | Guaiacum wood | 11352008 | 1 |
| Caelo | Guaiacum wood | 4011M-01778 | 1 |
| Caelo | Guaiacum wood | 16136708 | 1 |
| Caelo | Guaiacum wood | 10353102 | 1 |
| Caelo | Guaiacum wood | 11352001 | 1 |
| Caelo | Guaiacum wood | 11352010 | 1 |
| Caelo | Guaiacum wood | 16136710 | 1 |
| Caelo | Guaiacum wood | 14008203 | 1 |
| Caelo | Guaiacum wood | 16136705 | 1 |
| Caelo | Guaiacum wood | 16136706 | 1 |
| Caelo | Guaiacum wood | 11352012 | 1 |
| sana 09.12.14 3,75 | Guaiacum wood | 13343802 | 1 |

## H

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hamamelis bark, cut | 13123701 | 1 |
| Caelo | Hamamelis bark, cut | 12361301 | 1 |
| Caelo | Hamamelis bark, cut | 13123703 | 1 |
| Caelo | Hamamelis leaf | 10102915 | 1 |
| Caelo | Hamamelis leaf | 12165805 | 1 |
| Caelo | Hamamelis leaf | 14356103 | 1 |
| Caelo | Hamamelis leaf | 12164802 | 1 |
| Caelo | Hamamelis leaf | 30287394 | 1 |
| Caelo | Hamamelis leaf | 13269904 | 1 |
| Caelo | Hamamelis leaf | 12164804 | 1 |
| Caelo | Hamamelis leaf | 13269902 | 2 |
| Euro OTC | Hamamelis leaf | 12164805 | 1 |
| Klenk | Hamamelis leaf | B110214 | 1 |
| Klenk | Hamamelis leaf | 2051B110214 | 1 |
| Caelo | Hamamelis leaf | 13269905 | 1 |
| Alliance | Hawthorn flower | 13010403 | 1 |
| Caelo | Hawthorn flower | 13010403 | 5 |
| Caelo | Hawthorn flower | 21051301 | 1 |
| Caelo | Hawthorn flower | 7121201 | 1 |
| Caelo | Hawthorn flower | 25101301 | 1 |
| Caelo | Hawthorn flower | 13010402 | 3 |
| Caelo | Hawthorn flower | 11068208 | 1 |
| Caelo | Hawthorn flower | 11068202 | 1 |
| Caelo | Hawthorn flower | 13010402 | 2 |
| Caelo | Hawthorn flower | 13253303 | 1 |
| Caelo | Hawthorn flower | 11068206 | 1 |
| Caelo | Hawthorn flower | 11068209 | 1 |
| Caelo | Hawthorn flower | 13253304 | 1 |
| Caesar & Loretz GmbH | Hawthorn flower | 11068206 | 3 |
| Hepart AG | Hawthorn flower | 13010401 | 1 |
| Klenk | Hawthorn flower | 1351B130819 | 3 |
| Klenk | Hawthorn flower | B1112107 | 1 |
| Klenk | Hawthorn flower | 1351B111207 | 4 |
| Caelo | Hawthorn fruit | 13101402 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hawthorn fruit | 11278202 | 1 |
| Caelo | Hawthorn fruit | 13367203 | 1 |
| Caelo | Hawthorn fruit | 12326308 | 1 |
| Caelo | Hawthorn fruit | 12326306 | 1 |
| Caelo | Hawthorn fruit | 12326307 | 2 |
| Klenk | Hawthorn fruit | 2806B121203 | 2 |
| Klenk | Hawthorn fruit | 2806B110818 | 2 |
| Caelo | Hawthorn fruit | 12326304 | 1 |
| an | Hawthorn leaf with flower | 1971A130930 | 2 |
| Bahnhof-Apotheke | Hawthorn leaf with flower | 7-121011 | 1 |
| Bombastus | Hawthorn leaf with flower | 267000 | 1 |
| Bombastus | Hawthorn leaf with flower | 273287 | 1 |
| Bombastus | Hawthorn leaf with flower | 275310 | 2 |
| Bombastus | Hawthorn leaf with flower | 278756 | 1 |
| Bombastus | Hawthorn leaf with flower | 267551 | 1 |
| Bombastus | Hawthorn leaf with flower | 272881 | 1 |
| Bombastus | Hawthorn leaf with flower | 264044 | 1 |
| Caelo | Hawthorn leaf with flower | 15188802 | 1 |
| Caelo | Hawthorn leaf with flower | 1518802 | 1 |
| Caelo | Hawthorn leaf with flower | 16025802 | 1 |
| Caelo | Hawthorn leaf with flower | 10273512 | 2 |
| Caelo | Hawthorn leaf with flower | 11068206 | 1 |
| Caelo | Hawthorn leaf with flower | 11366001 | 1 |
| Caelo | Hawthorn leaf with flower | 13276703 | 3 |
| Caelo | Hawthorn leaf with flower | IntCh:313082 | 1 |
| Caelo | Hawthorn leaf with flower | 1222514 | 1 |
| Caelo | Hawthorn leaf with flower | 12225108 | 7 |
| Caelo | Hawthorn leaf with flower | 2225104 | 1 |
| Caelo | Hawthorn leaf with flower | 12225104 | 12 |
| Caelo | Hawthorn leaf with flower | 109076 | 1 |
| Caelo | Hawthorn leaf with flower | 1225107 | 1 |
| Caelo | Hawthorn leaf with flower | 12225107 | 5 |
| Caelo | Hawthorn leaf with flower | 12225207 | 1 |
| Caelo | Hawthorn leaf with flower | 52467476 | 1 |
| Caelo | Hawthorn leaf with flower | 12225103 | 4 |
| Caelo | Hawthorn leaf with flower | 1221707 | 1 |
| Galke | Hawthorn leaf with flower | 21126 | 3 |
| Gehe | Hawthorn leaf with flower | 1351B111207 | 2 |
| Gehe | Hawthorn leaf with flower | 10273515 | 6 |
| Klenk | Hawthorn leaf with flower | 1971A120813 | 20 |
| Klenk | Hawthorn leaf with flower | 1971A130307 | 6 |
| Klenk | Hawthorn leaf with flower | 28101307 | 1 |
| Klenk | Hawthorn leaf with flower | 20121302 | 1 |
| Klenk | Hawthorn leaf with flower | 14101301 | 1 |
| Klenk | Hawthorn leaf with flower | A130307 | 1 |
| Klenk | Hawthorn leaf with flower | 1971A120215 | 3 |
| Klenk | Hawthorn leaf with flower | 1971a120813 | 2 |
| Klenk | Hawthorn leaf with flower | 1971A120727 | 13 |
| Klenk | Hawthorn leaf with flower | 1972A120727 | 1 |
| Klenk | Hawthorn leaf with flower | 1971A110620 | 5 |
| Klenk | Hawthorn leaf with flower | 1971a120215 | 1 |
| Klenk | Hawthorn leaf with flower | 1971A120813-34103101 | 1 |
| Klenk | Hawthorn leaf with flower | 1971A130307-35014110 | 1 |
| Klenk | Hawthorn leaf with flower | 1971A130307-3447 | 1 |
| Bahnhof-Apotheke | Hay flowers | 13-121105 | 1 |
| Caelo | Hay flowers | 11099912 | 1 |
| Caelo | Hay flowers | 11099914 | 1 |
| Caelo | Hay flowers | 12317110 | 2 |
| Caelo | Hay flowers | 1231702 | 1 |
| Caelo | Hay flowers | 12317102 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hay flowers | 13097302 | 9 |
| Caelo | Hay flowers | 12317101 | 8 |
| Caelo | Hay flowers | 25101202 | 1 |
| Caelo | Hay flowers | 14121301 | 1 |
| Caelo | Hay flowers | 12317104 | 10 |
| Caelo | Hay flowers | 11099916 | 1 |
| Caelo | Hay flowers | 13097301 | 1 |
| Caelo | Hay flowers | 13099205 | 1 |
| Caelo | Hay flowers | 11099909 | 1 |
| Caelo | Hay flowers | 11099902 | 1 |
| Caelo | Hay flowers | 12317107 | 14 |
| Caelo | Hay flowers | 3713F-01459 | 1 |
| Caelo | Hay flowers | 3713E-01459 | 1 |
| Caelo | Hay flowers | 12371707 | 1 |
| Galke | Hay flowers | 21926 | 1 |
| Klenk | Hay flowers | A130304 | 1 |
| Klenk | Hay flowers | 10192103 | 1 |
| Klenk | Hay flowers | 1400A120116 | 1 |
| Nachprüfung | Hay flowers | 1911E01459 | 1 |
| Phönix | Hay flowers | 12317108 | 3 |
| Caelo | Hay flowers | 11099915 | 1 |
| Caelo | Heather flower, rubbed | 10270516 | 1 |
| Caelo | Heather flower, rubbed | 13014204 | 5 |
| Caelo | Heather flower, rubbed | 13014206 | 1 |
| Klenk | Heather flower, rubbed | 13014202 | 1 |
| Alliance | Heather, cut | 255389 | 1 |
| Bombastus | Heather, cut | 278314 | 1 |
| Caelo | Heather, cut | 11011209 | 3 |
| Caelo | Heather, cut | 28061201 | 1 |
| Caelo | Heather, cut | 19111203 | 1 |
| Caelo | Heather, cut | 13367502 | 1 |
| Caelo | Heather, cut | 11102901 | 1 |
| Caelo | Heather, cut | 9291512 | 1 |
| Caesar/Noweda | Heather, cut | 4911I-03224 | 1 |
| Nachprüfung | Heather, cut | 5110A03224 | 1 |
| Caelo | Henna powder | 12122301 | 2 |
| Caelo | Henna powder | 13262803 | 2 |
| Caelo | Henna powder | 12122310 | 3 |
| Caelo | Henna powder | 12267311 | 1 |
| Klenk | Henna powder | 20747A111004 | 1 |
| Klenk | Henna powder | 2074A111004 | 1 |
| Bombaltus | Hop strobile | 274724 | 1 |
| Bombastus | Hop strobile | 276976 | 1 |
| Bombastus | Hop strobile | 271870 | 1 |
| Bombastus | Hop strobile | 208502 | 1 |
| Caelo | Hop strobile | 13123803 | 1 |
| Caelo | Hop strobile | 12221807 | 1 |
| Caelo | Hop strobile | 13123902 | 1 |
| Caelo | Hop strobile | 12008309 | 3 |
| Caelo | Hop strobile | 12380103 | 2 |
| Caelo | Hop strobile | 5021306 | 1 |
| Caelo | Hop strobile | 4111304 | 1 |
| Caelo | Hop strobile | 30121301 | 1 |
| Caelo | Hop strobile | 15061211 | 1 |
| Caelo | Hop strobile | 6091303 | 1 |
| Caelo | Hop strobile | 14068007 | 1 |
| Caelo | Hop strobile | 12008307 | 2 |
| Caelo | Hop strobile | 13123807 | 1 |
| Caelo | Hop strobile | 1451b120817 | 1 |
| Caelo | Hop strobile | 131223805 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hop strobile | 13123804 | 3 |
| Caelo | Hop strobile | 12221804 | 1 |
| Caelo | Hop strobile | 12008302 | 1 |
| Caelo | Hop strobile | 12008315 | 1 |
| Caelo | Hop strobile | 4756769 | 1 |
| Caelo | Hop strobile | 12008317 | 6 |
| Caelo | Hop strobile | 13123802 | 3 |
| Caelo | Hop strobile | 10240308 | 1 |
| Caelo | Hop strobile | 13187602 | 1 |
| Caelo | Hop strobile | 12008305 | 1 |
| Caelo | Hop strobile | 12008310 | 3 |
| Caelo | Hop strobile | 120008312 | 1 |
| Caelo | Hop strobile | 12221805 | 3 |
| Caelo | Hop strobile | 12221802 | 2 |
| Caelo | Hop strobile | 12092001 | 2 |
| Caelo | Hop strobile | 12008310 | 3 |
| Caelo | Hop strobile | 12380101 | 6 |
| Caelo | Hop strobile | 12006305 | 1 |
| Caelo | Hop strobile | 12008313 | 2 |
| Caelo | Hop strobile | 13123803-3505411011 | 1 |
| Caelo | Hop strobile | 13123804-3563412081 | 1 |
| Caelo | Hop strobile | 12008317 | 1 |
| Galke | Hop strobile | 20928 | 2 |
| Galke | Hop strobile | 20928 | 3 |
| Galke | Hop strobile | 23363 | 1 |
| Gehe | Hop strobile | 1451B120202 | 6 |
| Caelo | Hop strobile | 13123803 | 9 |
| Caelo | Hop strobile | 13123802 | 9 |
| Caelo | Hop strobile | 13123806 | 1 |
| Klenk | Hop strobile | 1451b130409 | 1 |
| Klenk | Hop strobile | 1451B130409 | 9 |
| Klenk | Hop strobile | 20071301 | 1 |
| Klenk | Hop strobile | B130409 | 1 |
| Klenk | Hop strobile | 1451B130107 | 6 |
| Klenk | Hop strobile | 1451B111004 | 1 |
| Klenk | Hop strobile | 1451B140408 | 1 |
| Klenk | Hop strobile | 1450A110712 | 1 |
| Klenk | Hop strobile | 1451B130409 | 1 |
| Klenk | Hop strobile | 1451b130107 | 1 |
| Klenk | Hop strobile | 1451B-120817 | 1 |
| Klenk | Hop strobile | 1451B120817 | 7 |
| Noweda | Hop strobile | 274725 | 1 |
| Galke | Horse chestnut flower, cut | 2614 | 1 |
| Klenk | Horse chestnut flower, cut | 1440A110311 | 3 |
| Richter | Horse chestnut flower, cut | s-09/09 | 1 |
| Apotheke Bühlau | Horse chestnut leaf | 100416 | 1 |
| Caelo | Horse chestnut leaf | 11063503 | 2 |
| Gehe | Horse chestnut leaf | 2551B131024 | 1 |
| Klenk | Horse chestnut leaf | 255100903 | 1 |
| Klenk | Horse chestnut leaf | 2551B111013 | 7 |
| Klenk | Horse chestnut leaf | N130124 | 2 |
| Klenk | Horse chestnut leaf | 2551N130124 | 3 |
| Klenk | Horse chestnut leaf | 2551B081223 | 1 |
| Fagron | Hydrocortisone butyrate | 16j21-b01 | 1 |
| Fagron | Hydrocortisone butyrate | 15G08-B16-314883 | 1 |
|  | Hydromorphone hydrochloride | 21002482008 | 1 |
| Caelo | Hydromorphone hydrochloride | 15393604 | 1 |
| Caelo | Hydromorphone hydrochloride | 18316002 | 2 |
| Caelo | Hydromorphone hydrochloride | 14210405 | 1 |
| Caelo | Hydromorphone hydrochloride | 16123805 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Hydromorphone hydrochloride | 16273607 | 3 |
| Caelo | Hydromorphone hydrochloride | 18188403 | 1 |
| Caelo | Hydromorphone hydrochloride | 1623604 | 1 |
| Caelo | Hydromorphone hydrochloride | 16273606 | 1 |
| Caelo | Hydromorphone hydrochloride | 16273602 | 1 |
| Caelo | Hydromorphone hydrochloride | 16273604 | 2 |
| Caelo | Hydromorphone hydrochloride | 18188402 | 2 |
| Caelo | Hydromorphone hydrochloride | 21002482004 | 3 |
| Caesar & Loretz GmbH | Hydromorphone hydrochloride | 18316005 | 3 |
| Caesar & Loretz GmbH | Hydromorphone hydrochloride | 21002482001 | 8 |
| Caesar & Loretz GmbH | Hydromorphone hydrochloride | 20004514004 | 2 |
| Caesar & Loretz GmbH | Hydromorphone hydrochloride | 20004514008 | 1 |
| Caesar & Loretz Gm... | Hydromorphone hydrochloride | 20004514001 | 14 |
| Caesar & Loretz Gm... | Hydromorphone hydrochloride | 20004525001 | 4 |
| Caesar & Loretz Gm... | Hydromorphone hydrochloride | 20004514009 | 3 |
| Fagron | Hydromorphone hydrochloride | 17F0-B01-337510 | 2 |
| Fagron | Hydromorphone hydrochloride | 18I27-B01-364198 | 1 |
| Fagron | Hydromorphone hydrochloride | 13I27-N05 | 1 |
| Fagron | Hydromorphone hydrochloride | 18I27-B01 | 1 |
| Fagron | Hydromorphone hydrochloride | 21F03-F01-379168 | 1 |
| Fagron | Hydromorphone hydrochloride | 15L08-B08 | 1 |
| Fagron | Hydromorphone hydrochloride | 17F01-B01-337510 | 1 |
| Fargon - Phoenix | Hydromorphone hydrochloride | 17F01-B01-3375510 | 1 |
| Caelo | Hydromorphone hydrochloride | 15393605 | 1 |
| Fagron | Hydromorphone hydrochloride | 15L08-B08-316877 | 1 |
| Phönix | Hydromorphone hydrochloride | 13E16-No2 | 1 |
| Fagron | Hydromorphone hydrochloride | 12G05-N02 | 1 |
| Caelo | Hyssop herb, cut | 11374303 | 2 |
| Caelo | Hyssop herb, cut | 13336101 | 7 |
| Caelo | Hyssop herb, cut | 11374304 | 1 |
| Caelo | Hyssop herb, cut | 13143902 | 1 |
| Caesar & Loretz/ Noweda | Hyssop herb, cut | 11374301 | 1 |
| Galke | Hyssop herb, cut | 20939 | 1 |
| Phönix | Hyssop herb, cut | 11374306 | 1 |

**I**

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| - | Iceland moss | 4711E-01774 | 1 |
| Anzag ek: 15,60 20... | Iceland moss | 11101605 | 1 |
| Bombastus | Iceland moss | 13357802 | 1 |
| Caelo | Iceland moss | 12187104 | 3 |
| Caelo | Iceland moss | 12187103 | 1 |
| Caelo | Iceland moss | 14304409 | 6 |
| Caelo | Iceland moss | 12187002 | 1 |
| Caelo | Iceland moss | 14304404 | 3 |
| Caelo | Iceland moss | 11053916 | 1 |
| Caelo | Iceland moss | 4912E-01774 | 1 |
| Caelo | Iceland moss | 15297601 | 1 |
| Caelo | Iceland moss | 12187109 | 4 |
| Caelo | Iceland moss | 13350807 | 4 |
| Caelo | Iceland moss | 11101601 | 1 |
| Caelo | Iceland moss | 12382806 | 1 |
| Caelo | Iceland moss | 14304403 | 2 |
| Caelo | Iceland moss | 12187107 | 1 |
| Caelo | Iceland moss | 14304402 | 1 |
| Caelo | Iceland moss | 14304401 | 1 |
| Caelo | Iceland moss | 18078207 | 1 |
| Caelo | Iceland moss | 12197002 | 1 |
| Caelo | Iceland moss | 15297606 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Iceland moss | 711906 | 1 |
| Caelo | Iceland moss | 12187108 | 4 |
| Caelo | Iceland moss | 12187106 | 3 |
| Caelo | Iceland moss | 12187102 | 21 |
| Caelo | Iceland moss | 13350805 | 4 |
| Caelo | Iceland moss | 15297605 | 4 |
| Caelo | Iceland moss | 11053911 | 1 |
| Caelo | Iceland moss | 1287102 | 1 |
| Caelo | Iceland moss | 9052804 | 2 |
| Caelo | Iceland moss | 15297603 | 1 |
| Caelo | Iceland moss | 11101607 | 8 |
| Euroct/Gehe | Iceland moss | 14304407 | 2 |
| Galke | Iceland moss | 12369 | 1 |
| Gehe | Iceland moss | 18079703 | 1 |
| Gehe | Iceland moss | 11053915 | 1 |
| Gehe | Iceland moss | 11101603 | 1 |
| Klenk | Iceland moss | 5191N110609 | 1 |
| Klenk | Iceland moss | 13350803 | 4 |
| Klenk | Iceland moss | 5191A140828 | 2 |
| noweda | Iceland moss | | 1 |
| Fagron | Indigo carmine | 12K06-N11 | 1 |
| Fagron | Indigo carmine | 12A20-N067-16 | 1 |
| Fagron | Indigo carmine | 5132316 | 1 |
| Fagron | Indigo carmine | 13K12-N01 | 1 |
| Fagron | Indigo carmine | 11F09-N06 | 1 |
| Caelo | Iron(III) sulfate hydrate | 12175908 | 1 |
| Caelo | Iron(III) sulfate hydrate | 1512210007 | 1 |
| Caelo | Iron(III) sulfate hydrate | 12175906 | 1 |
| Caelo | Iron(III) sulfate hydrate | 10354412 | 1 |
| Caelo | Iron(III) sulfate hydrate | 10354404 | 1 |
| Caelo | Iron(III) sulfate hydrate | 10354415 | 1 |
| Anzag | Ispaghula seed | 11185818 | 1 |
| Caelo | Ispaghula seed | 10011303 | 1 |
| Caelo | Ispaghula seed | 14031408 | 1 |
| Caelo | Ispaghula seed | 9011302 | 1 |
| Caelo | Ispaghula seed | 18071301 | 1 |
| Caelo | Ispaghula seed | 30101302 | 1 |
| Caelo | Ispaghula seed | 3051302 | 1 |
| Caelo | Ispaghula seed | 18061804 | 1 |
| Caelo | Ispaghula seed | 28111703 | 1 |
| Caelo | Ispaghula seed | 15081503 | 1 |
| Caelo | Ispaghula seed | 8041702 | 1 |
| Caelo | Ispaghula seed | 19061308 | 1 |
| Caelo | Ispaghula seed | 11061405 | 1 |
| Caelo | Ispaghula seed | 16121302 | 1 |
| Caelo | Ispaghula seed | 4121202 | 1 |
| Caelo | Ispaghula seed | 4121201 | 1 |
| Caelo | Ispaghula seed | 29061510 | 1 |
| Caelo | Ispaghula seed | 5091319 | 1 |
| Caelo | Ispaghula seed | 4114001 | 1 |
| Caelo | Ispaghula seed | 23011505 | 1 |
| Caelo | Ispaghula seed | 26011401 | 1 |
| Caelo | Ispaghula seed | 413E-03369 | 1 |
| Caelo | Ispaghula seed | 14246602 | 3 |
| Caelo | Ispaghula seed | 142660 | 1 |
| Caelo | Ispaghula seed | 15121901 | 1 |
| Caelo | Ispaghula seed | 12276527 | 1 |
| Caelo | Ispaghula seed | 15249315 | 1 |
| Caelo | Ispaghula seed | 12252709 | 1 |
| Caelo | Ispaghula seed | 12276511 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ispaghula seed | 1227506 | 1 |
| Caelo | Ispaghula seed | 15249319 | 2 |
| Caesar/Noweda | Ispaghula seed | 12276516 | 1 |
| Caesar/Noweda | Ispaghula seed | 12276509 | 3 |
| Caesar/Noweda | Ispaghula seed | 12276503 | 1 |
| Caesar/Noweda | Ispaghula seed | 12276501 | 2 |
| Cealo | Ispaghula seed | 12276502 | 4 |
| Klenk | Ispaghula seed | 7560A130710 | 1 |
| Klenk | Ispaghula seed | 20071302 | 1 |
| Klenk | Ispaghula seed | 7560A120828 | 7 |
| Klenk | Ispaghula seed | 7560A130418 | 2 |
| Klenk | Ispaghula seed | 7560A160229 | 1 |
| Klenk | Ispaghula seed | 7560A140203 | 1 |
| Klenk | Ispaghula seed | 7560A150420 | 3 |
| Caelo | Ispaghula seed | 11185811 | 2 |
| Caelo | Ivy leaf, cut | 23121303 | 1 |
| Caelo | Ivy leaf, cut | 23121305 | 1 |
| Caelo | Ivy leaf, cut | 12225603 | 2 |
| Caelo | Ivy leaf, cut | 2031301 | 1 |
| Caelo | Ivy leaf, cut | 11101205 | 1 |
| Caelo | Ivy leaf, cut | 4011301 | 1 |
| Caelo | Ivy leaf, cut | 15101203 | 1 |
| Caelo | Ivy leaf, cut | 8061205 | 1 |
| Caelo | Ivy leaf, cut | 20111211 | 1 |
| Caelo | Ivy leaf, cut | 10011401 | 1 |
| Caelo | Ivy leaf, cut | 27111301 | 1 |
| Caelo | Ivy leaf, cut | 11041303 | 1 |
| Caelo | Ivy leaf, cut | 11229505 | 5 |
| Caelo | Ivy leaf, cut | 12225602 | 1 |
| Caelo | Ivy leaf, cut | 12225605 | 5 |
| Caelo | Ivy leaf, cut | 12225606 | 5 |
| Gehe | Ivy leaf, cut | 2061B080402 | 1 |
| Klenk | Ivy leaf, cut | B130118 | 1 |
| Phönix | Ivy leaf, cut | 11101102 | 1 |

**J**

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Jasmine flower | 12143203 | 3 |
| Klenk | Jasmine flower | 1460A110505 | 1 |
| Phönix | Jasmine flower | 12143206 | 1 |
| Caelo | Java tea | 12225704 | 3 |
| Caelo | Java tea | 21061304 | 1 |
| Caelo | Java tea | 28101305 | 1 |
| Caelo | Java tea | 31121203 | 1 |
| Caelo | Java tea | 20111207 | 1 |
| Caelo | Java tea | 12225702 | 1 |
| Caelo | Java tea | 13258802 | 2 |
| Caelo | Java tea | 13258804 | 3 |
| Caelo | Java tea | 11212901 | 1 |
| Klenk | Java tea | 2221B12112 | 1 |
| Klenk | Java tea | 2221B110718 | 6 |
| Klenk | Java tea | 17121304 | 1 |
| Klenk | Java tea | B121112 | 3 |
| Klenk | Java tea | B110718 | 1 |
| Klenk | Java tea | 2221A110825 | 2 |
| Klenk | Java tea | 2221B121112 | 16 |
| VDL | Java tea | 2221B101213 | 1 |
| Aurica / 11 | Juniper berry | 521301390 | 1 |
| Aurica/Phönix | Juniper berry | 521006043 | 1 |
| Caelo | Juniper berry | 12028610 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Juniper berry | 12330505 | 2 |
| Klenk | Juniper berry | A120709 | 3 |
| Klenk | Juniper berry | 2890a101201 | 3 |
| Klenk | Juniper berry | 2890a120709 | 1 |
| Klenk | Juniper berry | 2890A120709 | 14 |
| Klenk | Juniper berry | 2890A101201 | 5 |
| Klenk | Juniper berry | 2890A130513 | 2 |
| Phoenix | Juniper berry | | 1 |
| Phönix | Juniper berry | 13020903 | 1 |
| Sanacorp | Juniper berry | 12330509 | 1 |
| Caelo | Juniper berry, pounded | 14149502 | 1 |
| Caelo | Juniper berry, pounded | 13031302 | 1 |
| Caelo | Juniper berry, pounded | 13367302 | 1 |
| Gehe | Juniper berry, pounded | 13020903 | 1 |
| Gehe am 27.03.2014 | Juniper berry, pounded | 2890A130513 | 1 |
| Klenk | Juniper berry, pounded | 2896B121016 | 7 |

## K

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Kaolin, heavy | 11350106 | 2 |
| Caelo | Kaolin, heavy | 13041801 | 2 |
| Caelo | Kaolin, heavy | 11350124 | 4 |
| Caelo | Kaolin, heavy | 11350107 | 1 |
| Caelo | Kaolin, heavy | 82043269 | 1 |
| Caelo | Kaolin, heavy | 11350125 | 4 |
| Caelo | Kaolin, heavy | 11350115 | 1 |
| Caelo | Kaolin, heavy | 13041803 | 1 |
| Caelo | Kaolin, heavy | 10176518 | 1 |
| Caelo | Kaolin, heavy | 13041834 | 1 |
| Caelo | Kaolin, heavy | 11041610 | 1 |
| Caelo | Kaolin, heavy | 13041803 | 1 |
| Caelo | Kaolin, heavy | 13041835 | 1 |
| Caelo | Kaolin, heavy | 63033516 | 1 |
| Caelo | Kaolin, heavy | 11350107 | 5 |
| Gehe | Kaolin, heavy | 13041835 | 2 |
| Klenk | Kaolin, heavy | 45131I01190 | 1 |
| Klenk | Kaolin, heavy | 424A130507 | 4 |
| Klenk | Kaolin, heavy | 424A100819 | 2 |
| Klenk | Kaolin, heavy | 424A130507 | 2 |
| Caelo | Kap-Aloe | 12338201 | 4 |
| Caelo | Kap-Aloe | 12338206 | 2 |
| Caelo | Kap-Aloe | 12232102 | 1 |
| Caelo | Kap-Aloe | 15283001 | 2 |
| Caelo | Kap-Aloe | 12338209 | 1 |
| Caelo | Kap-Aloe | 25071402 | 1 |
| Caelo | Kap-Aloe | 11061406 | 1 |
| Caelo | Kap-Aloe | 25111303 | 1 |
| Caelo | Kap-Aloe | 11041402 | 1 |
| Caelo | Kap-Aloe | 15283006 | 1 |
| Caelo | Kap-Aloe | 16202404 | 2 |
| Caelo | Kap-Aloe | 505125 | 1 |
| Caelo | Kap-Aloe | 16202407 | 1 |
| Caelo | Kap-Aloe | 16202403 | 1 |
| Caelo | Kap-Aloe | 15283010 | 2 |
| Caelo | Kap-Aloe | 12338203 | 4 |
| Caelo | Kap-Aloe | 16202401 | 2 |
| Caesar/Noweda | Kap-Aloe | 2013E-01089 | 1 |
| Caesar/Noweda | Kap-Aloe | 12338211 | 1 |
| Gehe | Kap-Aloe | 18235801 | 1 |
| Caelo | Kap-Aloe | 16202406 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Kap-Aloe | 15283007 | 1 |
| Caelo | Kap-Aloe | 15283011 | 2 |
| Caelo | Kelp, cut | 14071502 | 1 |
| Caelo | Kelp, cut | 11351109 | 1 |
| Caelo | Kelp, cut | 11352209 | 1 |
| Gehe | Kelp, cut | 280172 | 4 |
| Klenk | Kelp, cut | 1051A110920 | 1 |
| Sanacorp | Kelp, cut | 11351105 | 1 |
| Caelo | Kidney vetch, coarsely rubbed | 13104301 | 2 |
| AHD | Knotgrass | 4301A150527 | 1 |
| Caelo | Knotgrass | 12295702 | 3 |
| Caelo | Knotgrass | 4301A100126 | 2 |
| Caelo | Knotgrass | 8111202 | 1 |
| Caelo | Knotgrass | 4312M-01674 | 1 |
| Caelo | Knotgrass | 14079304 | 1 |
| Caelo | Knotgrass | 12368904 | 1 |
| Caelo | Knotgrass | 12295704 | 4 |
| Caelo | Knotgrass | 12368902 | 5 |
| Caelo | Knotgrass | 12368903 | 1 |
| Caelo | Knotgrass | 7102427 | 1 |
| Finze | Knotgrass | 10237202 | 1 |
| Gehe | Knotgrass | 12368906 | 3 |
| Klenk | Knotgrass | 4301A120912 | 1 |
| Klenk | Knotgrass | 4301A121120 | 4 |

## L

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Lady's bedstraw herb | 12369004 | 2 |
| Caelo | Lady's bedstraw herb | 2401311647 | 1 |
| Caelo | Lady's bedstraw herb | 11265106 | 3 |
| Caelo | Lady's bedstraw herb | 24101201 | 1 |
| Caelo | Lady's bedstraw herb | 7011301 | 1 |
| Caelo | Lady's bedstraw herb | 22041303 | 1 |
| Caelo | Lady's bedstraw herb | 15029906 | 1 |
| Caelo | Lady's bedstraw herb | 11265103 | 5 |
| Caelo | Lady's bedstraw herb | 14019202 | 1 |
| Caelo | Lady's bedstraw herb | 10375707 | 2 |
| Caelo | Lady's bedstraw herb | 11265104 | 1 |
| Caelo | Lady's bedstraw herb | 11265102 | 9 |
| Caelo | Lady's bedstraw herb | 10375702 | 1 |
| Caelo | Lady's bedstraw herb | 12369006 | 5 |
| Caelo | Lady's bedstraw herb | 12369002 | 3 |
| Caelo | Lady's bedstraw herb | 12369003 | 8 |
| Caesar&loretz,Phoenix | Lady's bedstraw herb | 14019206 | 1 |
| Caesar&loretz,Phoenix | Lady's bedstraw herb | 14019215 | 1 |
| Finze | Lady's bedstraw herb | 12369001 | 3 |
| Galke | Lady's bedstraw herb | 21942 | 2 |
| Caelo | Lady's bedstraw herb | 12369007 | 3 |
| Klenk | Lady's bedstraw herb | 3921C130226 | 1 |
| Klenk | Lady's bedstraw herb | 3921B12030 | 1 |
| Sanacorp | Lady's bedstraw herb | 11265109 | 1 |
| Caelo | Lapacho wood, cut | 19061301 | 1 |
| Caelo | Lapacho wood, cut | 13298308 | 1 |
| Caelo | Lapacho wood, cut | 11154506 | 1 |
| Caelo | Lapacho wood, cut | 2x11154506 | 1 |
| Caelo | Lapacho wood, cut | 12239303 | 2 |
| Caelo | Lapacho wood, cut | 12239305 | 8 |
| Kenk / Phoenix | Lapacho wood, cut | 5161A110204 | 1 |
| Klenk | Lapacho wood, cut | 13298302 | 1 |
| Caelo | Lapacho wood, cut | 13298305 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Large waybread herb | 14125907 | 1 |
| Caelo | Large waybread herb | 10349610 | 1 |
| Caelo | Large waybread herb | 12374106 | 2 |
| Caelo | Large waybread herb | 123741004 | 1 |
| Caelo | Large waybread herb | 10349614 | 1 |
| Caelo | Large waybread herb | 13232401 | 1 |
| Caelo | Large waybread herb | 13232404 | 1 |
| Caelo | Large waybread herb | 10349603 | 2 |
| Caelo | Large waybread herb | 10349605 | 1 |
| Caelo | Large waybread herb | 12374101 | 4 |
| Caelo | Large waybread herb | 9311208 | 1 |
| Gehe | Large waybread herb | 12374104 | 7 |
| Klenk | Large waybread herb | N111121 | 1 |
| Klenk | Large waybread herb | 4281N110404 | 1 |
| Klenk | Large waybread herb | 4281N111121 | 5 |
| Caelo | Laurel leaf | 12299106 | 3 |
| Caelo | Laurel leaf | 12299101 | 1 |
| Klenk | Laurel leaf | B110809 | 1 |
| Klenk | Laurel leaf, cut | B110809 | 2 |
| Anzag | Lavender flower | 1488A12803 | 1 |
| Bombastus | Lavender flower | 268832 | 1 |
| Bombastus | Lavender flower | 274469 | 1 |
| Bombastus | Lavender flower | 279213 | 1 |
| Caelo | Lavender flower | 13185001 | 28 |
| Caelo | Lavender flower | 6091304 | 1 |
| Caelo | Lavender flower | 19071303 | 1 |
| Caelo | Lavender flower | 15061209 | 1 |
| Caelo | Lavender flower | 15061201 | 1 |
| Caelo | Lavender flower | 12031302 | 1 |
| Caelo | Lavender flower | 27091202 | 1 |
| Caelo | Lavender flower | 13387204 | 1 |
| Caelo | Lavender flower | 13336008 | 1 |
| Caelo | Lavender flower | 12088002 | 4 |
| Caelo | Lavender flower | 13159601 | 1 |
| Caelo | Lavender flower | 11327905 | 2 |
| Caelo | Lavender flower | 13185002 | 1 |
| Caelo | Lavender flower | 11054107 | 1 |
| Caelo | Lavender flower | 11054106 | 2 |
| Caelo | Lavender flower | 1318501 | 1 |
| Caelo | Lavender flower | 13185001-3415310152 | 1 |
| Caelo | Lavender flower | 13185001-3389311070 | 1 |
| Caelo | Lavender flower | 13185006 | 1 |
| Caelo | Lavender flower | 11327903 | 6 |
| Caelo | Lavender flower | 12088003 | 8 |
| Fagron | Lavender flower | 12088005 | 3 |
| Finze | Lavender flower | 11054104 | 2 |
| Galke | Lavender flower | 21416 | 2 |
| Herbasinica | Lavender flower | 1488A130830 | 1 |
| Caelo | Lavender flower | 13185003 | 10 |
| Klenk | Lavender flower | 1489A1203 | 1 |
| Klenk | Lavender flower | 1489A120103 | 19 |
| Klenk | Lavender flower | 1489A130214 | 16 |
| Klenk | Lavender flower | 1489A120919 | 6 |
| Klenk | Lavender flower | A130214 | 4 |
| Klenk | Lavender flower | 1488A111201 | 2 |
| Klenk | Lavender flower | 313U-01462 | 1 |
| Klenk | Lavender flower | 1489A100125 | 1 |
| Klenk | Lavender flower | 1488B130604 | 5 |
| Nachprüfung | Lavender flower | 12088006 | 3 |
| Phönix | Lavender flower | 1488A120803 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Lavender flower | 1488B130111 | 2 |
| Caelo | Lemon grass, cut | 11301509 | 2 |
| Caelo | Lemon grass, cut | 13149701 | 4 |
| Caelo | Lemon grass, cut | 13149703 | 1 |
| Caelo | Lemon grass, cut | 13341301 | 1 |
| Caelo | Lemon grass, cut | 11301501 | 1 |
| Klenk | Lemon grass, cut | 7721A130708 | 1 |
| Klenk | Lemon grass, cut | A120906 | 1 |
| Klenk | Lemon grass, cut | A130907 | 1 |
| Klenk | Lemon grass, cut | 7721A120906 | 1 |
| Caelo | Lemon grass, cut | 11301503 | 1 |
| Wolf | Lemon grass, cut | B654 | 1 |
| Caelo | Lemon peel, cut | 12217401 | 1 |
| Caelo | Lemon peel, cut | 12217402 | 1 |
| Caelo | Lemon peel, cut | 12217404 | 1 |
| Galke | Lemon peel, cut | 22975 | 1 |
| Klenk | Lemon peel, cut | 621A091016 | 1 |
| Klenk | Lemon peel, cut | 621A130221 | 1 |
| Klenk | Lemon peel, cut | A130221 | 3 |
| Klenk | Lemon peel, cut | B130521 | 1 |
| Caelo | Lemon verbena leaf, cut | 13037702 | 1 |
| Caelo | Lemon verbena leaf, cut | 12137505 | 1 |
| Caelo | Lemon verbena leaf, cut | 12137507 | 3 |
| Caelo | Lemon verbena leaf, cut | 10018208 | 1 |
| Klenk | Lemon verbena leaf, cut | 2411B110408 | 2 |
| Wolf | Lemon verbena leaf, cut | E-587 | 1 |
| Wolf | Lemon verbena leaf, cut | B-312 | 1 |
| Wolf | Lemon verbena leaf, cut | 23635 | 1 |
| Bahnhof-Apotheke | Lime flower | 7-121011 | 1 |
| Bombastus | Lime flower | 272958 | 7 |
| Bombastus | Lime flower | 275129 | 2 |
| Bombastus | Lime flower | 280678 | 3 |
| Caelo | Lime flower | 12170701 | 1 |
| Caelo | Lime flower | 28031302 | 1 |
| Caelo | Lime flower | 15111301 | 1 |
| Caelo | Lime flower | 15068302 | 1 |
| Caelo | Lime flower | 13101708 | 1 |
| Caelo | Lime flower | 1210702 | 1 |
| Caelo | Lime flower | 10273608 | 2 |
| Caelo | Lime flower | 9206604 | 1 |
| Caelo | Lime flower | 12170703 | 1 |
| Caelo | Lime flower | 10273606 | 1 |
| Caelo | Lime flower | Int.Ch:210140 | 1 |
| Caelo | Lime flower | 268709 | 2 |
| Caelo | Lime flower | 13337403 | 5 |
| Caelo | Lime flower | 13101702 | 8 |
| Caelo | Lime flower | 12170702 | 2 |
| Caelo | Lime flower | 13101701 | 7 |
| Caelo | Lime flower | 11086307 | 3 |
| Caelo | Lime flower | 11086305 | 7 |
| Caelo | Lime flower | 12170702-3355319071 | 1 |
| Caelo | Lime flower | 13337403-348012102 | 1 |
| galke, | Lime flower | 2098 | 1 |
| Klenk | Lime flower | 1611B120827 | 11 |
| Klenk | Lime flower | Pr.Nr.4411A-01474 | 1 |
| Klenk | Lime flower | 1611B111011 | 6 |
| Klenk | Lime flower | 1611B1010004 | 1 |
| Klenk | Lime flower | B130307 | 2 |
| Klenk | Lime flower | B130905 | 4 |
| Klenk | Lime flower | 1611B131220 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Lime flower | 1611B110421 | 2 |
| Klenk | Lime flower | 1611a121120 | 2 |
| Klenk | Lime flower | 1611B121105 | 4 |
| Klenk | Lime flower | 1611A121120 | 7 |
| Klenk | Lime flower | 1611B130905 | 5 |
| Klenk | Lime flower | 1611B130307 | 4 |
| Phönix | Lime flower | 2090413 | 1 |
| Phönix | Lime flower | 1611A12120 | 1 |
| Sanacorp | Lime flower | 264045 | 1 |
| Wolf | Lime flower | 22094 | 1 |
| Wolf | Lime flower | B449 | 1 |
| Caelo | Lime leaf, cut | 1611A121120 | 1 |
| Klenk | Lime leaf, cut | 2471B120502 | 1 |
| Akazie | Linseed | 20.09.2015 | 2 |
| Akazie | Linseed | 7300A141201 | 6 |
| Anzag | Linseed | 12137105 | 1 |
| Bombastus | Linseed | 1610 | 1 |
| Bombastus | Linseed | 295376 | 1 |
| Bombastus | Linseed | 274032 | 1 |
| Bombastus | Linseed | 278457 | 6 |
| Bombastus | Linseed | 269500 | 1 |
| Bombastus | Linseed | 282734 | 3 |
| Caelo | Linseed | 13296702 | 3 |
| Caelo | Linseed | 13140305 | 1 |
| Caelo | Linseed | 13296705 | 5 |
| Caelo | Linseed | 16011403 | 3 |
| Caelo | Linseed | 16011405 | 4 |
| Caelo | Linseed | 13296707 | 1 |
| Caelo | Linseed | 15006605 | 1 |
| Caelo | Linseed | 15006602 | 2 |
| Caelo | Linseed | 15006005 | 1 |
| Caelo | Linseed | 18111302 | 1 |
| Caelo | Linseed | 21081703 | 1 |
| Caelo | Linseed | 15061201 | 1 |
| Caelo | Linseed | 28051403 | 1 |
| Caelo | Linseed | 28051303 | 1 |
| Caelo | Linseed | 15321902 | 1 |
| Caelo | Linseed | 17067203 | 1 |
| Caelo | Linseed | 7370A131104 | 1 |
| Caelo | Linseed | 1326703 | 2 |
| Caelo | Linseed | 13412804 | 1 |
| Caelo | Linseed | 13262704 | 2 |
| Caelo | Linseed | 11365508 | 1 |
| Caelo | Linseed | 12092103 | 3 |
| Caelo | Linseed | 12321602 | 4 |
| Caelo | Linseed | 12321607 | 1 |
| Caelo | Linseed | 15053702 | 1 |
| Caelo | Linseed | 13262703 | 3 |
| Caelo | Linseed | 13262702 | 1 |
| Caelo | Linseed | 12321604 | 2 |
| Caelo | Linseed | 12321606 | 2 |
| Caelo | Linseed | 12092102 | 4 |
| Caelo | Linseed | 11365507 | 1 |
| Caelo | Linseed | 12092104 | 2 |
| Caelo | Linseed | 13296703 | 3 |
| Caelo | Linseed | 1232006 | 1 |
| Caelo | Linseed | 11199006 | 1 |
| Caelo | Linseed | 3923 | 1 |
| Caelo | Linseed | 12321601 | 1 |
| Caelo | Linseed | 18145601 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Linseed | 18007801 | 2 |
| Caelo | Linseed | 16355404 | 1 |
| Caelo | Linseed | 12382002 | 2 |
| Caelo | Linseed | 17067204 | 1 |
| Caelo | Linseed | 16040002 | 1 |
| Caelo | Linseed | 16040005 | 1 |
| Caelo | Linseed | 12186901 | 2 |
| Caelo | Linseed | 16040001 | 1 |
| Caelo | Linseed | 16355401 | 2 |
| Caelo | Linseed | 15006601 | 2 |
| Caelo | Linseed | 15006607 | 1 |
| Caelo | Linseed | 4713U02240 | 1 |
| Caelo | Linseed | 7307A170619 | 2 |
| Caelo | Linseed | 18145603 | 2 |
| Caelo | Linseed | 3615A-02240 | 1 |
| Caelo | Linseed | 11199003 | 1 |
| Caelo | Linseed | 12382006 | 3 |
| Caelo | Linseed | 7307A141201 | 3 |
| Finze | Linseed | 3607E-02240 | 1 |
| Gehe | Linseed | 16355402 | 7 |
| Gehe | Linseed | 18145605 | 1 |
| Hedinger | Linseed | 16011402 | 1 |
| Heinrich Kle/Sanacor | Linseed | 7307A170111 | 3 |
| Klenk | Linseed | 7300A170306 | 7 |
| Klenk | Linseed | 903312240 | 1 |
| Klenk | Linseed | 1910212240 | 1 |
| Klenk | Linseed | 7307A140526 | 3 |
| Klenk | Linseed | 7308A111107 | 3 |
| Klenk | Linseed | 7308A130110 | 4 |
| Klenk | Linseed | 1913Q-02240 | 1 |
| Klenk | Linseed | 7300A111107 | 4 |
| Klenk | Linseed | 7307A160414 | 4 |
| Klenk | Linseed | 7300A130110 | 7 |
| Klenk | Linseed | 7300A140526 | 1 |
| Klenk | Linseed | A130110 | 1 |
| Klenk | Linseed | 7307A-130722 | 1 |
| Klenk | Linseed | 7307A130722 | 5 |
| Klenk | Linseed | 7307A131104 | 8 |
| Klenk | Linseed | 7300A170306-1 | 1 |
| Klenk | Linseed | 7300A180523 | 2 |
| Klenk | Linseed | 7308A150710 | 2 |
| Klenk | Linseed | 7308A150414 | 2 |
| Klenk | Linseed | 7307A170110 | 2 |
| Klenk | Linseed | 7307A130124 | 1 |
| Klenk | Linseed | 7307A130110 | 15 |
| Klenk | Linseed | 7307A150710 | 6 |
| Klenk | Linseed | 7307a131104 | 1 |
| Klenk | Linseed | 2002285 | 1 |
| Klenk | Linseed | 3707A140526 | 1 |
| Klenk | Linseed | 7307A-130110 | 1 |
| Klenk | Linseed | 7500A140556 | 1 |
| Klenk | Linseed | 7300A130722 | 8 |
| Midas | Linseed | 7308A161208 | 1 |
| Klenk | Linseed | 7307a111107 | 1 |
| Klenk | Linseed | 7307A121212 | 1 |
| Caelo | Linseed | 12382004 | 1 |
| Klenk | Linseed | 7307A131021 | 1 |
| Phönix | Linseed | 7307A111107 | 7 |
| Klenk | Linseed | 7307A150414 | 1 |
| aurica/phoenix | Liqourice root | 521206925 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Liqourice root | 279409 | 2 |
| Bombastus | Liqourice root | 2901312151 | 1 |
| Bombastus | Liqourice root | 903312151 | 1 |
| Bombastus | Liqourice root | 278377 | 3 |
| Bombastus | Liqourice root | 5091305 | 1 |
| Bombastus | Liqourice root | 284243 | 2 |
| Bombastus | Liqourice root | 285185 | 2 |
| Bombastus | Liqourice root | 286584 | 1 |
| Bombastus | Liqourice root | 274921 | 3 |
| Bombastus | Liqourice root | 3713Q2151 | 1 |
| Caelo | Liqourice root | 13037904 | 1 |
| Caelo | Liqourice root | 12267104 | 2 |
| Caelo | Liqourice root | 12267103 | 1 |
| Caelo | Liqourice root | 13037902 | 1 |
| Caelo | Liqourice root | 10110912 | 1 |
| Caelo | Liqourice root | | 1 |
| Gehe | Liqourice root | 283316 | 1 |
| Klenk | Liqourice root | 6391A110421 | 4 |
| Klenk | Liqourice root | 6391A080905 | 4 |
| Klenk | Liqourice root | 6390A101020 | 1 |
| PHOENIX am 27.12.2013 | Liqourice root | 281844 | 1 |
| Phönix | Liqourice root | 277004 | 2 |
| Phönix | Liqourice root | 276425 | 1 |
| Caelo | Liqourice root | 276468 | 6 |
| Bahnhof-Apotheke | Liqourice root, peeled | 17-121112 | 1 |
| Bombastus | Liqourice root, peeled | 268001 | 1 |
| Bombastus | Liqourice root, peeled | 270192 | 1 |
| Caelo | Liqourice root, peeled | 13104503 | 3 |
| Caelo | Liqourice root, peeled | 10011301 | 1 |
| Caelo | Liqourice root, peeled | 18121302 | 1 |
| Caelo | Liqourice root, peeled | 1135904 | 1 |
| Caelo | Liqourice root, peeled | 11351906 | 3 |
| Caelo | Liqourice root, peeled | 13194101 | 5 |
| Caelo | Liqourice root, peeled | 638a120806 | 1 |
| Caelo | Liqourice root, peeled | 11351910 | 2 |
| Caelo | Liqourice root, peeled | 11351913 | 1 |
| Caelo | Liqourice root, peeled | 1351911 | 1 |
| Caelo | Liqourice root, peeled | 11351911 | 4 |
| Caelo | Liqourice root, peeled | 13104504 | 4 |
| Caesar & Loretz Gm... | Liqourice root, peeled | 11034014 | 1 |
| Defektur | Liqourice root, peeled | 270853 | 3 |
| Galke | Liqourice root, peeled | 23538 | 1 |
| Gehe | Liqourice root, peeled | 1250213 | 1 |
| Gehe | Liqourice root, peeled | 268835 | 1 |
| Caelo | Liqourice root, peeled | 12227112 | 1 |
| Klenk | Liqourice root, peeled | 6381a111004 | 1 |
| Klenk | Liqourice root, peeled | 6381A120806 | 3 |
| Klenk | Liqourice root, peeled | 6381A130426 | 21 |
| Klenk | Liqourice root, peeled | A130820 | 3 |
| Klenk | Liqourice root, peeled | A130426 | 1 |
| Klenk | Liqourice root, peeled | 6381A130820 | 4 |
| Klenk | Liqourice root, peeled | 6381A140109 | 2 |
| Klenk | Liqourice root, peeled | 6381A130425 | 1 |
| Klenk | Liqourice root, peeled | 6381A111004 | 14 |
| Klenk | Liqourice root, peeled | 6381A120611 | 12 |
| Klenk | Liqourice root, peeled | 6381A121126 | 27 |
| Klenk | Liqourice root, peeled | 6381A110531 | 2 |
| Klenk | Liqourice root, peeled | 638A130820 | 1 |
| Klenk | Liqourice root, peeled | 6381a121126 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Liqourice root, peeled | 70226/1 | 1 |
| Caelo | Liqourice root, peeled | 277004 | 1 |
| Caelo | Liqourice root, peeled | 11351905 | 3 |
| Bombastus | Lovage root | 273001 | 1 |
| Caelo | Lovage root | 12169007 | 1 |
| Caelo | Lovage root | 4312M-02150 | 1 |
| Caelo | Lovage root | 11181611 | 3 |
| Caelo | Lovage root | 12189001 | 1 |
| Caelo | Lovage root | 11181609 | 3 |
| Caelo | Lovage root | 13385005 | 1 |
| Caelo | Lovage root | 12169012 | 1 |
| Caelo | Lovage root | 12169009 | 1 |
| Caelo | Lovage root | 12169008 | 4 |
| Caelo | Lovage root | 12189002 | 1 |
| Caelo | Lovage root | 107063 | 1 |
| Caelo | Lovage root | 12169006 | 3 |
| Caelo | Lovage root | 12169010 | 2 |
| Klenk | Lovage root | B110228 | 1 |
| Klenk | Lovage root | B121029 | 1 |
| Klenk | Lovage root | 6371A080508 | 1 |
| Klenk | Lovage root | 6371B121029 | 3 |
| Klenk | Lovage root | 6371B-121029 | 1 |
| Sanacorp | Lovage root | 12169002 | 2 |
| Caelo | Lungwort herb, cut | 13029306 | 3 |
| Caelo | Lungwort herb, cut | 11134203 | 12 |
| Caelo | Lungwort herb, cut | 13355801 | 2 |
| Caelo | Lungwort herb, cut | 11134202 | 3 |
| Caelo | Lungwort herb, cut | 4331b111205 | 1 |
| Caelo | Lungwort herb, cut | 11134201 | 1 |
| Caelo | Lungwort herb, cut | 11021707 | 1 |
| Caelo | Lungwort herb, cut | 11134205 | 3 |
| Caelo | Lungwort herb, cut | 11021709 | 2 |
| Caelo | Lungwort herb, cut | 13029302 | 25 |
| Fagron | Lungwort herb, cut | Nachprüfung | 1 |
| Galke | Lungwort herb, cut | 19511 | 4 |
| Caelo | Lungwort herb, cut | 13029304 | 5 |
| Klenk | Lungwort herb, cut | 4331B111205 | 1 |
| Klenk | Lungwort herb, cut | 4331A120813 | 1 |
| Richter | Lungwort herb, cut | P195884 | 1 |
| Bahnhof-Apotheke | Lycopodium herb | 17-121112 | 1 |
| Caelo | Lycopodium herb | 11255003 | 1 |
| Caelo | Lycopodium herb | 11255012 | 2 |
| Caelo | Lycopodium herb | 11255009 | 3 |
| Caelo | Lycopodium herb | 11255016 | 2 |
| Caelo | Lycopodium herb | 11255010 | 1 |
| Caelo | Lycopodium herb | 11255014 | 7 |
| Caelo | Lycopodium herb | 11255018 | 1 |
| Caelo | Lycopodium herb | 9378812 | 1 |
| Caelo | Lycopodium herb | 11255017 | 6 |
| Caelo | Lycopodium herb | 13101501 | 1 |
| Caelo | Lycopodium herb | 11255011 | 6 |
| Caelo | Lycopodium herb | 1310502 | 1 |
| Caelo | Lycopodium herb | 11255008 | 12 |
| Caesar/Noweda | Lycopodium herb | 1255008 | 1 |
| Finze | Lycopodium herb | 9378803 | 1 |
| Galke | Lycopodium herb | 16913 | 3 |
| Klenk | Lycopodium herb | 4111B120220 | 1 |
| Klenk | Lycopodium herb | 4111B110428 | 1 |
| Sanacorp | Lycopodium herb | 13101502 | 2 |
| Sanacorp | Lycopodium herb | 11255005 | 3 |

## M

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Macrogols 6000 powder | 14J17-B01 | 1 |
| Fagron | Macrogols 6000 powder | 12J22-N02 | 1 |
| Fagron | Macrogols 6000 powder | 11G14-N03 | 1 |
| Fagron | Magnesium aspartate dihydrate | 17C21-B05-333111 | 1 |
| Caelo | Magnesium carbonate, heavy | 7011404 | 1 |
| Caelo | Magnesium carbonate, heavy | 2091303 | 1 |
| Caelo | Magnesium carbonate, heavy | 13123502 | 1 |
| Caelo | Magnesium carbonate, heavy | 13123505 | 1 |
| Caelo | Magnesium carbonate, heavy | 13123504 | 2 |
| Caelo | Magnesium carbonate, heavy | 12135404 | 1 |
| Euro OTC | Magnesium carbonate, heavy | 1211005-01 | 4 |
| Euro OTC | Magnesium carbonate, heavy | 1305024-01 | 1 |
| Fagron | Magnesium carbonate, heavy | 12F20-N04 | 1 |
| Euro OTC | Magnesium oxide, heavy | 1205012-01 | 1 |
| Euro OTC | Magnesium oxide, heavy | 1012033-01 | 1 |
| Caelo | Magnesium sulfate, dried | M-220413-2 | 1 |
| Caelo | Magnesium sulfate, dried | 12157207 | 1 |
| Caelo | Magnesium sulfate, dried | 11265903 | 1 |
| Caelo | Magnesium sulfate, dried | 11265902 | 1 |
| Caelo | Magnesium sulfate, dried | 12157202 | 1 |
| Caelo | Magnesium sulfate, dried | 10213213 | 2 |
| Caelo | Magnesium sulfate, dried | 12157208 | 1 |
| Caelo | Magnesium sulfate, dried | 11265908 | 2 |
| Anzag | Maize style | 274920 | 1 |
| Aurica/Phönix | Maize style | 520901387 | 1 |
| Bahnhof-Apotheke | Maize style | 20-121018 | 1 |
| Bombastus | Maize style | 282574 | 1 |
| Bombastus | Maize style | 285912 | 1 |
| Bombastus | Maize style | 276776 | 1 |
| Bombastus | Maize style | 81113a | 1 |
| Bombastus | Maize style | 19002817 | 1 |
| Bombastus | Maize style | 17001482 | 1 |
| Caelo | Maize style | 10325904 | 1 |
| Caelo | Maize style | 13277207 | 1 |
| Caelo | Maize style | 10325907 | 4 |
| Caelo | Maize style | 10325905 | 1 |
| Caelo | Maize style | 280363 | 1 |
| Caelo | Maize style | 13277201 | 1 |
| Caelo | Maize style | 13277202 | 1 |
| Caelo | Maize style | 13277205 | 1 |
| Caelo | Maize style | 11280405 | 11 |
| Caelo | Maize style | 11280404 | 2 |
| Caelo | Maize style | 10325902 | 2 |
| Caelo | Maize style | 15226103 | 1 |
| Caelo | Maize style | 15226102 | 1 |
| Caelo | Maize style | 10325906 | 7 |
| Gehe | Maize style | 18041004 | 1 |
| Klenk | Maize style | A110411 | 1 |
| Klenk | Maize style | 5581A111206 | 1 |
| Klenk | Maize style | 5581A081204 | 1 |
| Richter | Maize style | B189316 | 1 |
| Sana 21.10.14 Ek 3.57 | Maize style | 13381603 | 2 |
| A.H. 27.05.13 ek: 6,75EUR | Male speedwell wort | 274239 | 1 |
| Aurica/Phönix | Male speedwell wort | 520708362 | 1 |
| Bahnhof-Apotheke | Male speedwell wort | 4-121002 | 1 |
| Bombastus | Male speedwell wort | 274238 | 1 |
| Caelo | Male speedwell wort | 13089201 | 4 |
| Caelo | Male speedwell wort | 12162504 | 13 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Male speedwell wort | 3091305 | 1 |
| Caelo | Male speedwell wort | 28061303 | 1 |
| Caelo | Male speedwell wort | 20111303 | 1 |
| Caelo | Male speedwell wort | 11061305 | 1 |
| Caelo | Male speedwell wort | 14111303 | 1 |
| Caelo | Male speedwell wort | 3051306 | 1 |
| Caelo | Male speedwell wort | 11265502 | 1 |
| Caelo | Male speedwell wort | 4661c111011 | 1 |
| Caelo | Male speedwell wort | 11265503 | 5 |
| Caelo | Male speedwell wort | 1216504 | 1 |
| Caelo | Male speedwell wort | 12162503 | 1 |
| Caelo | Male speedwell wort | 13166701 | 3 |
| Caelo | Male speedwell wort | 12162505 | 2 |
| Finze | Male speedwell wort | 4661B110121 | 2 |
| Finze | Male speedwell wort | 4661B080915 | 1 |
| Klenk | Male speedwell wort | 4661A090318 | 1 |
| Klenk | Male speedwell wort | 4661C130226 | 27 |
| Klenk | Male speedwell wort | 4661C111011 | 13 |
| Klenk | Male speedwell wort | C130226 | 5 |
| Klenk | Male speedwell wort | C120321 | 1 |
| Klenk | Male speedwell wort | 4661C13026 | 1 |
| Klenk | Male speedwell wort | 4661C131104 | 1 |
| Klenk | Male speedwell wort | 4661B110916 | 1 |
| Klenk | Male speedwell wort | 4661B101011 | 1 |
| Klenk | Male speedwell wort | 4661C120321 | 10 |
| Klenk | Male speedwell wort | 4661c130226-34343111 | 1 |
| Klenk | Male speedwell wort | 4661C130226-32743106 | 1 |
| Klenk | Male speedwell wort | 4661C2004 | 1 |
| Klenk | Male speedwell wort | 4661C-111011 | 1 |
| Klenk | Male speedwell wort | 4661C120802 | 13 |
| Klenk | Male speedwell wort | 6661C130226 | 1 |
| Klenk | Male speedwell wort | 4661c120802 | 1 |
| Klenk | Male speedwell wort | 4661c120321 | 1 |
| Bombastus | Mallow flower | 273803 | 1 |
| Bombastus | Mallow flower | 13267304 | 1 |
| Caelo | Mallow flower | 20061201 | 1 |
| Caelo | Mallow flower | 12187501 | 6 |
| Caelo | Mallow flower | 18111303 | 1 |
| Caelo | Mallow flower | 27021301 | 1 |
| Caelo | Mallow flower | 8121202 | 1 |
| Caelo | Mallow flower | 13267302 | 1 |
| Caelo | Mallow flower | 12187405 | 4 |
| Caelo | Mallow flower | 13351309 | 1 |
| Caelo | Mallow flower | 13040402 | 1 |
| Caelo | Mallow flower | 10357902 | 1 |
| Caelo | Mallow flower | 13351307 | 1 |
| Caelo | Mallow flower | 13267303 | 2 |
| Caelo | Mallow flower | 12187404 | 4 |
| Caelo | Mallow flower | 11040106 | 4 |
| Caelo | Mallow flower | 12187502 | 1 |
| Caelo | Mallow flower | 12187505 | 3 |
| Caelo | Mallow flower | 12187402 | 8 |
| Caelo | Mallow flower | 10357904 | 1 |
| Caelo | Mallow flower | 13351301 | 2 |
| Caelo | Mallow flower | 9311104 | 1 |
| Caelo | Mallow flower | 13267301-3409310112 | 1 |
| Caelo | Mallow flower | 12187501-3414310132 | 1 |
| Galke | Mallow flower | 21119 | 1 |
| Gehe | Mallow flower | 1501B110207 | 1 |
| Klenk | Mallow flower | 10357908 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mallow flower | 13267301 | 6 |
| Klenk | Mallow flower | 1910211464 | 1 |
| Klenk | Mallow flower | B130829 | 3 |
| Klenk | Mallow flower | B120427 | 1 |
| Klenk | Mallow flower | 1501B-120427 | 1 |
| Klenk | Mallow flower | 1501B111215 | 1 |
| Klenk | Mallow flower | 1501B130829 | 3 |
| Klenk | Mallow flower | 1501b111215 | 1 |
| Klenk | Mallow flower | 1501B120508 | 6 |
| Klenk | Mallow flower | 150B111215 | 1 |
| Klenk | Mallow flower | 13351303 | 2 |
| Klenk | Mallow flower | 1501B120427 | 10 |
| Klenk | Mallow flower | 1501B100408 | 1 |
| Nachprüfung 29.10.12 | Mallow flower | C1316 | 1 |
| Klenk | Mallow flower | 1501b110207 | 1 |
| Caelo | Mallow leaf | 12310009 | 2 |
| Caelo | Mallow leaf | 20111302 | 1 |
| Caelo | Mallow leaf | 28061203 | 1 |
| Caelo | Mallow leaf | 14073902 | 1 |
| Caelo | Mallow leaf | 12310008 | 1 |
| Caelo | Mallow leaf | 13174213 | 1 |
| Caelo | Mallow leaf | 12153403 | 1 |
| Caelo | Mallow leaf | 12310001 | 3 |
| Caelo | Mallow leaf | 10290515 | 1 |
| Caelo | Mallow leaf | 10290502 | 1 |
| Caelo | Mallow leaf | 13174207 | 1 |
| Galke | Mallow leaf | 17133 | 1 |
| Galke | Mallow leaf | 21445 | 1 |
| Galke | Mallow leaf | 21454 | 1 |
| Gehe | Mallow leaf | 12310004 | 4 |
| Gehe | Mallow leaf | 10290512 | 1 |
| Gehe | Mallow leaf | 2131B110420 | 2 |
| Klenk | Mallow leaf | B130225 | 1 |
| Klenk | Mallow leaf | 2131B120529 | 3 |
| Klenk | Mallow leaf | 2131B10529 | 1 |
| Klenk | Mallow leaf | 2131B130225 | 4 |
| Sanacorp | Mallow leaf | 278925 | 1 |
| Caelo | Mallow leaf | 13174217 | 1 |
| Caelo | Mallow leaf | 12310006 | 1 |
| Caelo | Manna | 15219010 | 3 |
| Caelo | Manna | 11041401 | 1 |
| Caelo | Manna | 25111301 | 1 |
| Caelo | Manna | 15111738 | 1 |
| Caelo | Manna | 11061404 | 1 |
| Caelo | Manna | 28101404 | 1 |
| Caelo | Manna | 13041712 | 1 |
| Caelo | Manna | 25071403 | 1 |
| Caelo | Manna | 11308909 | 2 |
| Caelo | Manna | 14001310 | 3 |
| Caelo | Manna | 15219003 | 3 |
| Caelo | Manna | 15219008 | 3 |
| Caelo | Manna | 11308904 | 2 |
| Caelo | Manna | 11308907 | 2 |
| Caelo | Manna | 13127003 | 5 |
| Caelo | Manna | 11308911 | 2 |
| Caelo | Manna | 15219005 | 1 |
| Caelo | Manna | 11308901 | 2 |
| Caelo | Manna | 14001303 | 3 |
| Klenk | Manna | 5221A120509 | 10 |
| Klenk | Manna | 5221A110817 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Manna | 5221A140210 | 5 |
| Klenk | Manna | 5221A150107 | 2 |
| Caelo | Manna | 15219012 | 1 |
| Caelo | Manna | 15219009 | 1 |
| Caelo | Manna, powdered | 11071311 | 1 |
| Caelo | Manna, powdered | 15101306 | 1 |
| Caelo | Manna, powdered | 15101312 | 1 |
| Caelo | Manna, powdered | 11003611 | 1 |
| Caelo | Manna, powdered | 14001408 | 1 |
| Caelo | Manna, powdered | 14001402 | 1 |
| Caelo | Manna, powdered | 11308802 | 2 |
| Caelo | Manna, powdered | 11308807 | 1 |
| Galke | Manna, powdered | 20669 | 1 |
| Galke | Manna, powdered | 19784 | 1 |
| Noweda | Manna, powdered | 11170102 | 1 |
| Bombastus | Marian thistle fruit | 299483 | 1 |
| Bombastus | Marian thistle fruit | 296193 | 1 |
| Bombastus | Marian thistle fruit | 296535 | 1 |
| Bombastus | Marian thistle fruit | 278379 | 1 |
| Bombastus | Marian thistle fruit | 282283 | 1 |
| Bombastus | Marian thistle fruit | 280304 | 1 |
| Bombastus | Marian thistle fruit | 269499 | 1 |
| Bombastus | Marian thistle fruit | 282034 | 2 |
| Bombastus | Marian thistle fruit | 279405 | 3 |
| Bombastus | Marian thistle fruit | 278378 | 1 |
| Bombastus | Marian thistle fruit | 277720 | 3 |
| Bombastus | Marian thistle fruit | 284420 | 1 |
| Bombastus | Marian thistle fruit | 13122013a | 1 |
| Caelo | Marian thistle fruit | 12189113 | 6 |
| Caelo | Marian thistle fruit | 12189116 | 2 |
| Caelo | Marian thistle fruit | 18111301 | 1 |
| Caelo | Marian thistle fruit | 27111203 | 1 |
| Caelo | Marian thistle fruit | 15409204 | 2 |
| Caelo | Marian thistle fruit | 11126701 | 1 |
| Caelo | Marian thistle fruit | 12189105 | 1 |
| Caelo | Marian thistle fruit | 10270614 | 2 |
| Caelo | Marian thistle fruit | 12189111 | 3 |
| Caelo | Marian thistle fruit | 10270613 | 1 |
| Caelo | Marian thistle fruit | 1126705 | 1 |
| Caelo | Marian thistle fruit | 11126705 | 1 |
| Caelo | Marian thistle fruit | 12189106 | 4 |
| Caelo | Marian thistle fruit | 13326202 | 3 |
| Caelo | Marian thistle fruit | 12189108 | 4 |
| Caelo | Marian thistle fruit | 1126703 | 1 |
| Caelo | Marian thistle fruit | 12189109 | 2 |
| Caelo | Marian thistle fruit | 12189112 | 5 |
| Caelo | Marian thistle fruit | 12198107 | 1 |
| Caelo | Marian thistle fruit | 12189107 | 2 |
| Caelo | Marian thistle fruit | 12189104 | 2 |
| Caelo | Marian thistle fruit | 11126703 | 2 |
| Caelo | Marian thistle fruit | 12189115 | 2 |
| Caelo | Marian thistle fruit | 1289112 | 1 |
| ebert u.jacobi | Marian thistle fruit | 287527 | 1 |
| Galke | Marian thistle fruit | 22187 | 4 |
| Gehe | Marian thistle fruit | 11126702 | 9 |
| Klenk | Marian thistle fruit | A120725 | 1 |
| Klenk | Marian thistle fruit | 7180A120725 | 1 |
| Klenk | Marian thistle fruit | 7180A130219 | 1 |
| Klenk | Marian thistle fruit | 7180A090929 | 1 |
| Klenk | Marian thistle fruit | 7180A132019 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Marian thistle fruit | 7180A110209 | 2 |
| Caelo | Marian thistle herb | 13130703 | 2 |
| Caelo | Marian thistle herb | 10315911 | 4 |
| Caelo | Marian thistle herb | 10315909 | 1 |
| Caelo | Marian thistle herb | 10365604 | 4 |
| Caelo | Marian thistle herb | 17121204 | 1 |
| Caelo | Marian thistle herb | 30101306 | 1 |
| Caelo | Marian thistle herb | 18041303 | 1 |
| Caelo | Marian thistle herb | 1035911 | 1 |
| Caelo | Marian thistle herb | 10365601 | 4 |
| Caelo | Marian thistle herb | 1313702 | 1 |
| Caelo | Marian thistle herb | 10315907 | 1 |
| Caelo | Marian thistle herb | intch:318080 | 1 |
| Caelo | Marian thistle herb | 13130704 | 5 |
| Caelo | Marian thistle herb | 10365605 | 1 |
| Caelo | Marian thistle herb | 62607127 | 1 |
| Caelo | Marian thistle herb | 13130701-3492411030 | 1 |
| Caelo | Marian thistle herb | 13386703-3543411013 | 1 |
| Euro OTC | Marian thistle herb | 3701A-111207 | 1 |
| Gehe | Marian thistle herb | 10365602 | 2 |
| Klenk | Marian thistle herb | 3701B120717 | 3 |
| Klenk | Marian thistle herb | 3701B130318 | 5 |
| Klenk | Marian thistle herb | 11041310 | 1 |
| Klenk | Marian thistle herb | 2011402 | 1 |
| Klenk | Marian thistle herb | B110728 | 1 |
| Klenk | Marian thistle herb | 3701B111117 | 1 |
| Klenk | Marian thistle herb | 3701a111207 | 1 |
| Klenk | Marian thistle herb | 3701A100916 | 2 |
| Klenk | Marian thistle herb | 3701A111207 | 11 |
| Klenk | Marian thistle herb | 913E-01627 | 1 |
| Phönix 28.12.2013 | Marian thistle herb | 13130701 | 2 |
| Sanacorp | Marian thistle herb | 13130702 | 3 |
| Caelo | Marjoram herb | 12168908 | 6 |
| Caelo | Marjoram herb | 12168907 | 3 |
| Caelo | Marjoram herb | 13113303 | 3 |
| Caelo | Marjoram herb | 12168912 | 1 |
| Caelo | Marjoram herb | 12168909 | 6 |
| Caelo | Marjoram herb | 6051302 | 1 |
| Caelo | Marjoram herb | 27011402 | 1 |
| Caelo | Marjoram herb | 12168904 | 1 |
| Caelo | Marjoram herb | 11212707 | 1 |
| Caelo | Marjoram herb | 12168901 | 3 |
| Caelo | Marjoram herb | 12168906 | 1 |
| Caelo | Marjoram herb | 12168910 | 8 |
| Caelo | Marjoram herb | 13113304 | 3 |
| Caelo | Marjoram herb | 12168903 | 10 |
| Caelo | Marjoram herb | 12168905 | 2 |
| Caelo | Marjoram herb | 12168902 | 1 |
| Caelo | Marjoram herb | 9292602 | 1 |
| Caesar&loretz,Phoenix | Marjoram herb | 14181005 | 1 |
| Galke | Marjoram herb | 23241 | 1 |
| Galke | Marjoram herb | 22401 | 1 |
| Klenk | Marjoram herb | 4881A100929 | 3 |
| Klenk | Marjoram herb | 4881A101025 | 15 |
| Klenk | Marjoram herb | A101025 | 2 |
| Klenk | Marjoram herb | 4881A1311105 | 1 |
| Klenk | Marjoram herb | 4881a101025 | 1 |
| Klenk | Marjoram herb | 12345678 | 1 |
| Caelo | Marjoram herb | 11212711 | 3 |
| Wolf | Marjoram herb | P232243 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Wolf | Marjoram herb | B163516 | 6 |
| Wolf | Marjoram herb | 163516 | 1 |
| Caelo | Marrubium vulgare herb, cut | 12231601 | 4 |
| Caelo | Marrubium vulgare herb, cut | 12231604 | 4 |
| Caelo | Marrubium vulgare herb, cut | 13289109 | 1 |
| Caelo | Marrubium vulgare herb, cut | 1153803 | 1 |
| Caelo | Marrubium vulgare herb, cut | 11253802 | 1 |
| Caelo | Marrubium vulgare herb, cut | 313091 | 1 |
| Caelo | Marrubium vulgare herb, cut | 12231603 | 1 |
| Caelo | Marrubium vulgare herb, cut | 11253803 | 1 |
| Caelo | Marrubium vulgare herb, cut | 12231605 | 4 |
| Klenk | Marrubium vulgare herb, cut | 4141A130110 | 1 |
| Klenk | Marrubium vulgare herb, cut | 13289102 | 1 |
| Noweda | Marrubium vulgare herb, cut | 4141A080513 | 1 |
| Caelo | Marshmallow leaf | 12328202 | 3 |
| Caelo | Marshmallow leaf | 12328206 | 3 |
| Caelo | Marshmallow leaf | 13199604 | 4 |
| Caelo | Marshmallow leaf | 12328207 | 2 |
| Bombastus | Marshmallow root | 273458 | 1 |
| Caelo | Marshmallow root | 26091201 | 1 |
| Caelo | Marshmallow root | 15104503 | 1 |
| Caelo | Marshmallow root | 11101804 | 1 |
| Caelo | Marshmallow root | 13057103 | 1 |
| Caelo | Marshmallow root | 12147311 | 1 |
| Caelo | Marshmallow root | 12368906 | 1 |
| Caelo | Marshmallow root | 11101905 | 1 |
| Caelo | Marshmallow root | 11101907 | 7 |
| Caelo | Marshmallow root | 11101804 | 1 |
| Gehe | Marshmallow root | 6071A120306 | 2 |
| Klenk | Marshmallow root | 6071A130612 | 4 |
| Klenk | Marshmallow root | 6071A-130408 | 1 |
| Klenk | Marshmallow root | A130408 | 3 |
| Klenk | Marshmallow root | 6074B100416 | 1 |
| Klenk | Marshmallow root | 6071A-120314 | 1 |
| Klenk | Marshmallow root | 130116 | 1 |
| Klenk | Marshmallow root | 6071A120314 | 10 |
| Klenk | Marshmallow root | 6071a130408 | 1 |
| Klenk | Marshmallow root | 6071A130116 | 10 |
| Klenk | Marshmallow root | 6071A130408 | 14 |
| Klenk | Marshmallow root | 12147311 | 7 |
| Klenk | Marshmallow root | 6071B091207 | 1 |
| Phönix | Marshmallow root | 2090413 | 1 |
| Phönix | Marshmallow root | 6071a120314 | 1 |
| Bombastus | Marshmallow root, natural | 276741 | 1 |
| Bombastus | Marshmallow root, natural | 270467 | 1 |
| Caelo | Marshmallow root, natural | 270114 | 1 |
| Caelo | Masterwort root, cut | 13132002 | 1 |
| Caelo | Masterwort root, cut | 13341201 | 1 |
| Caelo | Masterwort root, cut | 12101808 | 1 |
| Caelo | Masterwort root, cut | 1210801 | 1 |
| Caelo | Masterwort root, cut | 12101807 | 2 |
| Fagron | Masterwort root, cut | 12101806 | 2 |
| Galke | Masterwort root, cut | 23074 | 1 |
| Galke | Masterwort root, cut | 18411 | 1 |
| Caelo | Maté leaf | 2141A120821 | 2 |
| Caelo | Maté leaf | 13118002 | 10 |
| Caelo | Maté leaf | 13061202 | 1 |
| Caelo | Maté leaf | 12133806 | 1 |
| Caelo | Maté leaf | 13118003 | 4 |
| Caelo | Maté leaf | 12133803 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Maté leaf | 12133804 | 7 |
| Caelo | Maté leaf | 12133801 | 3 |
| Caelo | Maté leaf | 11091710 | 1 |
| Caelo | Maté leaf | 13118001 | 1 |
| Caelo | Maté leaf | 12133807 | 7 |
| Galke | Maté leaf | 22365 | 1 |
| Klenk | Maté leaf | 2141A-111213 | 1 |
| Klenk | Maté leaf | 2141A111213 | 16 |
| Klenk | Maté leaf | 2131A111213 | 1 |
| Klenk | Maté leaf | 2141a111213 | 1 |
| Klenk | Matricaria flower | 1290A-120620 | 1 |
| Bahnhof-Apotheke | Matricaria flower | 11-121024 | 1 |
| Bombastus | Matricaria flower | 299185 | 1 |
| Bombastus | Matricaria flower | 268712 | 1 |
| Bombastus | Matricaria flower | 274106 | 1 |
| Bombastus | Matricaria flower | 276095 | 5 |
| Bombastus | Matricaria flower | 277959 | 2 |
| Bombastus | Matricaria flower | 287855 | 1 |
| Bombastus | Matricaria flower | 281103 | 2 |
| Bombastus | Matricaria flower | 271781 | 1 |
| Bombastus | Matricaria flower | 273667 | 1 |
| Bombastus | Matricaria flower | 276307 | 1 |
| Bombastus | Matricaria flower | 283710 | 2 |
| Bombastus | Matricaria flower | 274105 | 1 |
| Bombastus | Matricaria flower | 273388 | 1 |
| Bombastus | Matricaria flower | 277997 | 1 |
| Bombastus | Matricaria flower | 268408 | 1 |
| Bombastus | Matricaria flower | 268408 | 1 |
| Bombastus | Matricaria flower | 265419 | 1 |
| Bombastus | Matricaria flower | 292757 | 1 |
| Bombastus | Matricaria flower | 264997 | 1 |
| Caelo | Matricaria flower | 12294804 | 1 |
| Caelo | Matricaria flower | 12294809 | 3 |
| Caelo | Matricaria flower | 13014501 | 1 |
| Caelo | Matricaria flower | 20021313 | 1 |
| Caelo | Matricaria flower | 13111201 | 1 |
| Caelo | Matricaria flower | 10081201 | 1 |
| Caelo | Matricaria flower | 19111207 | 1 |
| Caelo | Matricaria flower | 27091203 | 1 |
| Caelo | Matricaria flower | 22111202 | 1 |
| Caelo | Matricaria flower | 13031306 | 1 |
| Caelo | Matricaria flower | 19041306 | 1 |
| Caelo | Matricaria flower | 26081303 | 1 |
| Caelo | Matricaria flower | 22111201 | 1 |
| Caelo | Matricaria flower | 22011303 | 1 |
| Caelo | Matricaria flower | 22081202 | 1 |
| Caelo | Matricaria flower | 13011406 | 1 |
| Caelo | Matricaria flower | 11101203 | 1 |
| Caelo | Matricaria flower | 16111202 | 1 |
| Caelo | Matricaria flower | 17101204 | 1 |
| Caelo | Matricaria flower | 13061201 | 1 |
| Caelo | Matricaria flower | 5081201 | 1 |
| Caelo | Matricaria flower | 14276804 | 3 |
| Caelo | Matricaria flower | 15090003 | 2 |
| Caelo | Matricaria flower | 15258505 | 1 |
| Caelo | Matricaria flower | 15258504 | 1 |
| Caelo | Matricaria flower | 12244802 | 4 |
| Caelo | Matricaria flower | 12299701 | 1 |
| Caelo | Matricaria flower | 12337608 | 1 |
| Caelo | Matricaria flower | 12059606 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Matricaria flower | 12299703 | 2 |
| Caelo | Matricaria flower | 13288405 | 3 |
| Caelo | Matricaria flower | 12361704 | 1 |
| Caelo | Matricaria flower | 12244803 | 3 |
| Caelo | Matricaria flower | 11169607 | 1 |
| Caelo | Matricaria flower | 11214810 | 1 |
| Caelo | Matricaria flower | 12111903 | 2 |
| Caelo | Matricaria flower | 12337610 | 1 |
| Caelo | Matricaria flower | 12337601 | 1 |
| Caelo | Matricaria flower | IntCh:313011 | 1 |
| Caelo | Matricaria flower | 12361706 | 1 |
| Caelo | Matricaria flower | 11218501 | 1 |
| Caelo | Matricaria flower | 12361701 | 3 |
| Caelo | Matricaria flower | 13210906 | 1 |
| Caelo | Matricaria flower | 13210905 | 3 |
| Caelo | Matricaria flower | 12294802 | 15 |
| Caelo | Matricaria flower | 12361702 | 6 |
| Caelo | Matricaria flower | 12361707 | 4 |
| Caelo | Matricaria flower | 18290002 | 1 |
| Caelo | Matricaria flower | 17338903 | 1 |
| Caelo | Matricaria flower | 13210901-3478312171 | 1 |
| Caelo | Matricaria flower | 13210901 | 3 |
| Caelo | Matricaria flower | 12244803 | 1 |
| Caelo | Matricaria flower | 12294804 | 6 |
| Caelo | Matricaria flower | 12244805 | 4 |
| Caelo | Matricaria flower | 12244804 | 2 |
| Caelo | Matricaria flower | 12361706 | 3 |
| Caelo | Matricaria flower | 13210905 | 1 |
| Caelo | Matricaria flower | 18193705 | 1 |
| Caelo | Matricaria flower | 13210901-3546411013 | 1 |
| Caelo | Matricaria flower | 13210903 | 1 |
| Caelo | Matricaria flower | AKD5 | 1 |
| Defektur | Matricaria flower | 29/13 | 1 |
| Defektur | Matricaria flower | 59/13 | 1 |
| Defektur | Matricaria flower | 10/13 | 1 |
| Defektur | Matricaria flower | 56/12 | 1 |
| Fagron | Matricaria flower | | 1 |
| Finze | Matricaria flower | 1290B101122 | 1 |
| Finze | Matricaria flower | 12361703 | 6 |
| Galke | Matricaria flower | 18471 | 5 |
| Galke | Matricaria flower | 21652 | 1 |
| Galke | Matricaria flower | 18803 | 1 |
| Gehe | Matricaria flower | 12337607 | 2 |
| Gehe | Matricaria flower | 12337605 | 2 |
| Gehe | Matricaria flower | 11255204 | 1 |
| Gehe | Matricaria flower | 12133009 | 1 |
| Hepart AG | Matricaria flower | B-477,kbA | 1 |
| Klenk | Matricaria flower | 1290B140123 | 2 |
| k | Matricaria flower | 1290A140513 | 1 |
| Klenk | Matricaria flower | 1290A150618 | 1 |
| Klenk | Matricaria flower | 1290A120601 | 14 |
| Klenk | Matricaria flower | 1290A130516 | 9 |
| Klenk | Matricaria flower | 1290A140508 | 1 |
| Klenk | Matricaria flower | 1290A130516 | 3 |
| Klenk | Matricaria flower | 1290B140624 | 1 |
| Klenk | Matricaria flower | 1290B140123 | 2 |
| Klenk | Matricaria flower | 1290A130502 | 1 |
| Klenk | Matricaria flower | 2310211452 | 1 |
| Klenk | Matricaria flower | 14111314 | 1 |
| Klenk | Matricaria flower | 16121301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Matricaria flower | 11101302 | 1 |
| Klenk | Matricaria flower | 27111204 | 1 |
| Klenk | Matricaria flower | B130415 | 2 |
| Klenk | Matricaria flower | A120529 | 1 |
| Klenk | Matricaria flower | A120529 | 1 |
| Klenk | Matricaria flower | A130502 | 1 |
| Klenk | Matricaria flower | A130516 | 1 |
| Klenk | Matricaria flower | 1290A20404 | 1 |
| Klenk | Matricaria flower | 1290A120404 | 6 |
| Klenk | Matricaria flower | 1290A110825 | 1 |
| Klenk | Matricaria flower | 1290A120403 | 3 |
| Klenk | Matricaria flower | 1290A120601 | 2 |
| Klenk | Matricaria flower | 1290A120404 | 1 |
| Klenk | Matricaria flower | 1290A12061 | 1 |
| Klenk | Matricaria flower | 1290A130502 | 1 |
| Klenk | Matricaria flower | 1290A120529 | 1 |
| Klenk | Matricaria flower | 4100113002 | 2 |
| Klenk | Matricaria flower | 1290A120620 | 13 |
| Klenk | Matricaria flower | 1290A180709 | 1 |
| Klenk | Matricaria flower | 1290A120529 | 5 |
| Klenk | Matricaria flower | 1290B130415 | 39 |
| Klenk | Matricaria flower | 1290A110421 | 1 |
| Klenk | Matricaria flower | 1290B130415 | 3 |
| Klenk | Matricaria flower | 1290a120620 | 1 |
| Noweda | Matricaria flower | 12361707 | 2 |
| Klenk | Matricaria flower | 1290A110607 | 1 |
| Phoenix | Matricaria flower | 11214802 | 2 |
| Phönix | Matricaria flower | 1300A120725 | 2 |
| Phönix | Matricaria flower | 1300A120426 | 1 |
| Spangropharm | Matricaria flower | 11169606 | 1 |
| Wolf | Matricaria flower | 23242 | 1 |
| - | Meadowsweet | 1511M-01685 | 1 |
| - | Meadowsweet | 130849 | 1 |
| Caelo | Meadowsweet | 12188801 | 1 |
| Caelo | Meadowsweet | 12188803 | 10 |
| Caelo | Meadowsweet | 4912E-01685 | 1 |
| Caelo | Meadowsweet | 12188704 | 2 |
| Caelo | Meadowsweet | 10381601 | 1 |
| Caelo | Meadowsweet | 12188807 | 1 |
| Caelo | Meadowsweet | 12188703 | 1 |
| Caelo | Meadowsweet | 12188805 | 13 |
| Caelo | Meadowsweet | 12188702 | 1 |
| Caelo | Meadowsweet | 10381602 | 3 |
| Caelo | Meadowsweet | 62487517 | 1 |
| Caelo | Meadowsweet | 12188806 | 3 |
| Galke | Meadowsweet | 20358 | 1 |
| Caelo | Meadowsweet | 10381604 | 5 |
| Sanacorp | Meadowsweet | 4541A120313 | 2 |
| Weltecke | Meadowsweet | 67010413 | 1 |
| Caelo | Meadowsweet flower, rubbed | 1225702 | 1 |
| Caelo | Meadowsweet flower, rubbed | 12275702 | 1 |
| Caelo | Meadowsweet flower, rubbed | 10349308 | 1 |
| Caelo | Meadowsweet flower, rubbed | 10051301 | 1 |
| Caelo | Meadowsweet flower, rubbed | 1227501 | 1 |
| Caelo | Meadowsweet flower, rubbed | 12275701 | 2 |
| Caelo | Meadowsweet flower, rubbed | 12275704 | 4 |
| Caelo | Meadowsweet flower, rubbed | 10349305 | 1 |
| Caelo | Meadowsweet flower, rubbed | 9326211 | 2 |
| Caelo | Meadowsweet flower, rubbed | 10349302 | 2 |
| Caelo | Meadowsweet flower, rubbed | 9326213 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Meadowsweet flower, rubbed | 10349307 | 2 |
| Caelo | Meadowsweet flower, rubbed | 12275704-3372319032 | 1 |
| Gehe | Meadowsweet flower, rubbed | 12275703 | 3 |
| Klenk | Meadowsweet flower, rubbed | A120312 | 1 |
| Kräuter Schulte | Meadowsweet flower, rubbed | 53473 | 1 |
| Kräuter Schulte | Meadowsweet flower, rubbed | 51369 | 1 |
| - | Melilot | 811Q-01664 | 1 |
| Caelo | Melilot | 11307607 | 1 |
| Caelo | Melilot | 11307606 | 6 |
| Caelo | Melilot | 122891202 | 1 |
| Caelo | Melilot | 8061204 | 1 |
| Caelo | Melilot | 19071201 | 1 |
| Caelo | Melilot | 25091301 | 1 |
| Caelo | Melilot | 22111303 | 1 |
| Caelo | Melilot | 24081202 | 1 |
| Caelo | Melilot | 12231703 | 3 |
| Caelo | Melilot | 12289203 | 5 |
| Caelo | Melilot | 11307605 | 4 |
| Caelo | Melilot | 12289206 | 1 |
| Caelo | Melilot | 12289207 | 1 |
| Caelo | Melilot | 11307601 | 1 |
| Caelo | Melilot | 12289201 | 1 |
| Caelo | Melilot | 107063 | 1 |
| Caelo | Melilot | 12231701 | 3 |
| Gehe | Melilot | 110324 | 1 |
| Hepart AG | Melilot | A110324 | 6 |
| Caelo | Melilot | 12289205 | 4 |
| Caelo | Melilot | 12289202 | 8 |
| Klenk | Melilot | 4151A110324 | 8 |
| Klenk | Melilot | 4151A120912 | 1 |
| Phönix | Melilot | 1237903 | 1 |
| - | Mellisa leaf | 131146 | 1 |
| Alfred Galke | Mellisa leaf | D-NI-1-9516-BC | 1 |
| Bahnhof-Apotheke | Mellisa leaf | 17-120917 | 1 |
| Bombastus | Mellisa leaf | 277722 | 1 |
| Bombastus | Mellisa leaf | 271499 | 2 |
| Bombastus | Mellisa leaf | 270044 | 1 |
| Caelo | Mellisa leaf | 1009 | 1 |
| Caelo | Mellisa leaf | | 1 |
| Caelo | Mellisa leaf | CH.111111 | 1 |
| Caelo | Mellisa leaf | 13214720 | 1 |
| Caelo | Mellisa leaf | 13214705 | 1 |
| Caelo | Mellisa leaf | 24011407 | 1 |
| Caelo | Mellisa leaf | 25021301 | 1 |
| Caelo | Mellisa leaf | 19041303 | 1 |
| Caelo | Mellisa leaf | 14111319 | 1 |
| Caelo | Mellisa leaf | 25061303 | 1 |
| Caelo | Mellisa leaf | 12032314 | 4 |
| Caelo | Mellisa leaf | 12032312 | 1 |
| Caelo | Mellisa leaf | 12032303 | 1 |
| Caelo | Mellisa leaf | 12032316 | 3 |
| Caelo | Mellisa leaf | 12032309 | 1 |
| Caelo | Mellisa leaf | 13030805 | 1 |
| Caelo | Mellisa leaf | 10310919 | 1 |
| Caelo | Mellisa leaf | 12032318 | 1 |
| Caelo | Mellisa leaf | 12032319 | 5 |
| Caelo | Mellisa leaf | 12032307 | 2 |
| Caelo | Mellisa leaf | 13030803 | 2 |
| Caelo | Mellisa leaf | 2161a121009 | 1 |
| galke | Mellisa leaf | 20867 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Mellisa leaf | 2161A151209 | 1 |
| Klenk | Mellisa leaf | 2161A121029 | 4 |
| Klenk | Mellisa leaf | 2807211503 | 1 |
| Klenk | Mellisa leaf | 2161A121009/PN:1198 | 1 |
| Klenk | Mellisa leaf | 27091201 | 1 |
| Klenk | Mellisa leaf | 2161A110818 | 1 |
| Klenk | Mellisa leaf | 111207 | 1 |
| Klenk | Mellisa leaf | 2161A121206 | 2 |
| Klenk | Mellisa leaf | 2161A121009 | 14 |
| Klenk | Mellisa leaf | 2161A101216 | 1 |
| Klenk | Mellisa leaf | 2161A120718 | 11 |
| Noweda | Mellisa leaf | 2161A111207 | 15 |
| Caelo | Mellisa leaf | 13214707 | 1 |
| Caelo | Mellisa leaf | 12032310 | 1 |
| | Methadone hydrochloride | 23003258002 | 4 |
| | Methadone hydrochloride | 23001356001 | 7 |
| | Methadone hydrochloride | 23001353005 | 4 |
| | Methadone hydrochloride | 21003277024 | 14 |
| | Methadone hydrochloride | 23001356002 | 4 |
| | Methadone hydrochloride | 23003258001 | 1 |
| | Methadone hydrochloride | 23003258005 | 7 |
| | Methadone hydrochloride | 23001356006 | 4 |
| | Methadone hydrochloride | 22E02-F04 | 2 |
| | Methadone hydrochloride | 23001353003 | 2 |
| | Methadone hydrochloride | 23G28-F02-386059 | 2 |
| | Methadone hydrochloride | 23A25-F02-384693 | 2 |
| | Methadone hydrochloride | 22E02-F04-382503 | 4 |
| | Methadone hydrochloride | 23G28-F02-385325 | 1 |
| | Methadone hydrochloride | 2314H055 | 1 |
| | Methadone hydrochloride | 23003258007 | 2 |
| | Methadone hydrochloride | 23G28-F02-385303 | 2 |
| | Methadone hydrochloride | 23A25-F02-384702 | 2 |
| | Methadone hydrochloride | 22E02-F04-382620 | 2 |
| | Methadone hydrochloride | 21003277011 | 2 |
| | Methadone hydrochloride | 23001353006 | 1 |
| | Methadone hydrochloride | 40125-P1 | 1 |
| | Methadone hydrochloride | 23001353004 | 1 |
| AHD | Methadone hydrochloride | 12344812 | 2 |
| Fagron | Methadone hydrochloride | 18C01-B05-346737 | 7 |
| Bombastus | Methadone hydrochloride | 14C24-B01-292858 | 6 |
| Caelo | Methadone hydrochloride | 1081801 | 1 |
| Caelo | Methadone hydrochloride | 15244702 | 1 |
| Caelo | Methadone hydrochloride | 16135311 | 4 |
| Caelo | Methadone hydrochloride | 16135305 | 6 |
| Caelo | Methadone hydrochloride | 16135312 | 3 |
| Caelo | Methadone hydrochloride | 17239504 | 9 |
| Caelo | Methadone hydrochloride | 19000787003 | 6 |
| Caelo | Methadone hydrochloride | 17239512 | 12 |
| Caelo | Methadone hydrochloride | 15244713 | 4 |
| Caelo | Methadone hydrochloride | 13266502 | 2 |
| Caelo | Methadone hydrochloride | 16135317 | 2 |
| Caelo | Methadone hydrochloride | 18186601 | 13 |
| Caelo | Methadone hydrochloride | 18132417 | 13 |
| Caelo | Methadone hydrochloride | 19000787001 | 9 |
| Caelo | Methadone hydrochloride | 17239507 | 4 |
| Caelo | Methadone hydrochloride | 19000787013 | 2 |
| Caelo | Methadone hydrochloride | 12171907 | 1 |
| Caelo | Methadone hydrochloride | 10076407 | 1 |
| Caelo | Methadone hydrochloride | 12171914 | 1 |
| Caelo | Methadone hydrochloride | 17239508 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Methadone hydrochloride | 17239510 | 6 |
| Caelo | Methadone hydrochloride | 21003277014 | 4 |
| Caelo | Methadone hydrochloride | 1613529 | 1 |
| Caelo | Methadone hydrochloride | 31011901 | 1 |
| Caelo | Methadone hydrochloride | 23021802 | 1 |
| Caelo | Methadone hydrochloride | 17011406 | 1 |
| Caelo | Methadone hydrochloride | 7091708 | 1 |
| Caelo | Methadone hydrochloride | 25111701 | 1 |
| Caelo | Methadone hydrochloride | 28041725 | 1 |
| Caelo | Methadone hydrochloride | 28061702 | 1 |
| Caelo | Methadone hydrochloride | 19011913 | 1 |
| Caelo | Methadone hydrochloride | 3111806 | 1 |
| Caelo | Methadone hydrochloride | 17051801 | 1 |
| Caelo | Methadone hydrochloride | 16135324 | 6 |
| Caelo | Methadone hydrochloride | 16135303 | 1 |
| Caelo | Methadone hydrochloride | 16135316 | 4 |
| Caelo | Methadone hydrochloride | 11227507 | 1 |
| Caelo | Methadone hydrochloride | 17239502 | 3 |
| Caelo | Methadone hydrochloride | 15244710 | 4 |
| Caelo | Methadone hydrochloride | 18132407 | 3 |
| Caelo | Methadone hydrochloride | 18132416 | 4 |
| Caelo | Methadone hydrochloride | 16135307 | 2 |
| Caelo | Methadone hydrochloride | 15244718 | 1 |
| Caelo | Methadone hydrochloride | 15244715 | 3 |
| Caelo | Methadone hydrochloride | 1723509 | 1 |
| Caelo | Methadone hydrochloride | 1816601 | 1 |
| Caelo | Methadone hydrochloride | 18132405 | 5 |
| Caelo | Methadone hydrochloride | 19149406 | 4 |
| Caelo | Methadone hydrochloride | 12344819 | 1 |
| Caelo | Methadone hydrochloride | 12344818 | 1 |
| Caelo | Methadone hydrochloride | 12344814 | 2 |
| Caelo | Methadone hydrochloride | 2912161 | 1 |
| Caelo | Methadone hydrochloride | 1729504 | 1 |
| Caelo | Methadone hydrochloride | 177239518 | 1 |
| Caelo | Methadone hydrochloride | 19149404 | 1 |
| Caelo | Methadone hydrochloride | 12171902 | 1 |
| Caelo | Methadone hydrochloride | 16135301 | 1 |
| Caelo | Methadone hydrochloride | 16135323 | 1 |
| Caelo | Methadone hydrochloride | 1723 | 1 |
| Caelo | Methadone hydrochloride | 15244717 | 6 |
| Caelo | Methadone hydrochloride | 18g02-b02-355992 | 1 |
| Caelo | Methadone hydrochloride | 17239501 | 1 |
| Caelo | Methadone hydrochloride | 18g02-b02355992 | 1 |
| Caelo | Methadone hydrochloride | 16135315 | 1 |
| Caelo | Methadone hydrochloride | 18c01b05350572 | 1 |
| Caelo | Methadone hydrochloride | 15244701 | 1 |
| Caelo | Methadone hydrochloride | 17239514 | 1 |
| Caelo | Methadone hydrochloride | 13266511 | 2 |
| Caelo | Methadone hydrochloride | 17239506 | 11 |
| Caelo | Methadone hydrochloride | 16135318 | 8 |
| Caelo | Methadone hydrochloride | 19149402 | 9 |
| Caelo | Methadone hydrochloride | 15244720 | 1 |
| Caelo | Methadone hydrochloride | 20170728/Ma2 | 1 |
| Caelo | Methadone hydrochloride | 19000787016 | 2 |
| Caelo | Methadone hydrochloride | 21000271019 | 7 |
| Caelo | Methadone hydrochloride | 18186601P-181001-4 | 1 |
| Caelo | Methadone hydrochloride | 18132405P-190225-10 | 1 |
| Caelo | Methadone hydrochloride | 18132413P-190916-1 | 1 |
| Caelo | Methadone hydrochloride | 19149402P-191223-1 | 1 |
| Caelo | Methadone hydrochloride | 18132405P-190527-1 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Methadone hydrochloride | 19000787001P2006221 | 1 |
| Caelo | Methadone hydrochloride | 19149406P-200323-2 | 1 |
| Caelo | Methadone hydrochloride | 18132413P-190709-2 | 1 |
| Caelo | Methadone hydrochloride | 57(18132413) | 1 |
| Caelo | Methadone hydrochloride | 61(19000787001) | 1 |
| Caelo | Methadone hydrochloride | 59(18132417) | 1 |
| Caelo | Methadone hydrochloride | 60(19000787001) | 1 |
| Caelo | Methadone hydrochloride | 14C24-B01-292860 | 2 |
| Caelo | Methadone hydrochloride | 11021904 | 1 |
| Caelo | Methadone hydrochloride | 18132408/ | 1 |
| Caelo | Methadone hydrochloride | M260813 | 1 |
| Caelo | Methadone hydrochloride | 19000787002 | 1 |
| Caelo | Methadone hydrochloride | 1327H051 | 1 |
| Caelo | Methadone hydrochloride | 13266521 | 1 |
| Caelo | Methadone hydrochloride | 15244705 | 2 |
| Caelo | Methadone hydrochloride | 19000824003 | 1 |
| Caelo | Methadone hydrochloride | 19149403 | 1 |
| Caelo | Methadone hydrochloride | 190603141F | 1 |
| Caelo | Methadone hydrochloride | 21003277006 | 15 |
| Caelo | Methadone hydrochloride | 21003277009 | 8 |
| Caelo | Methadone hydrochloride | 16135327 | 12 |
| Caelo | Methadone hydrochloride | 16135332 | 11 |
| Caelo | Methadone hydrochloride | 16135322 | 1 |
| Caelo | Methadone hydrochloride | 13266515 | 1 |
| Caelo | Methadone hydrochloride | 16135326 | 11 |
| Caelo | Methadone hydrochloride | 58(18132417) | 1 |
| Caelo | Methadone hydrochloride | 16135304 | 5 |
| Caelo | Methadone hydrochloride | 16135309 | 3 |
| Caelo | Methadone hydrochloride | 18186607 | 5 |
| Caelo | Methadone hydrochloride | 17239503 | 4 |
| Caelo | Methadone hydrochloride | 18186604 | 4 |
| Caelo | Methadone hydrochloride | 16135302 | 1 |
| Caelo | Methadone hydrochloride | 172329504 | 1 |
| Caelo | Methadone hydrochloride | 16135328 | 1 |
| Caelo | Methadone hydrochloride | 21000271002 | 4 |
| Caelo | Methadone hydrochloride | 21003277001 | 1 |
| Caelo | Methadone hydrochloride | 180219MC/17239506 | 1 |
| Caelo | Methadone hydrochloride | 16135325,170814MHC | 1 |
| Caelo | Methadone hydrochloride | 21000271001 | 1 |
| Caelo | Methadone hydrochloride | 19D09-B03-3645508 | 1 |
| Caelo | Methadone hydrochloride | 18186608 | 11 |
| Caelo | Methadone hydrochloride | 17239518 | 6 |
| Caelo | Methadone hydrochloride | 18132412 | 11 |
| Caelo | Methadone hydrochloride | 16135330 | 5 |
| Caelo | Methadone hydrochloride | 12344816 | 3 |
| Caelo | Methadone hydrochloride | 12344802 | 1 |
| Caelo | Methadone hydrochloride | 171920-0004 | 1 |
| Caelo | Methadone hydrochloride | 21000271011 | 5 |
| Caelo | Methadone hydrochloride | 16F24-B02-323184 | 1 |
| Caelo | Methadone hydrochloride | 15I24-B07-317266 | 1 |
| Caelo | Methadone hydrochloride | 19149409 | 3 |
| Caelo | Methadone hydrochloride | 18132409 | 1 |
| Caelo | Methadone hydrochloride | 13266514 | 1 |
| Caelo | Methadone hydrochloride | 190000787013 | 1 |
| Caelo | Methadone hydrochloride | 220901smi//21000271019 | 1 |
| Caelo | Methadone hydrochloride | 15244709 | 2 |
| Caelo | Methadone hydrochloride | 70925 | 1 |
| Caelo | Methadone hydrochloride | LOT067055 | 1 |
| Caelo | Methadone hydrochloride | 18132408 | 17 |
| Caelo | Methadone hydrochloride | 16135329 | 12 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Methadone hydrochloride | 18132404 | 3 |
| Caelo | Methadone hydrochloride | 19149401 | 3 |
| Caelo | Methadone hydrochloride | 12171906 | 2 |
| Caelo | Methadone hydrochloride | 15244706 | 3 |
| Caelo | Methadone hydrochloride | 15215501 | 1 |
| Caelo | Methadone hydrochloride | 13266501 | 1 |
| Caelo | Methadone hydrochloride | 16208016 | 1 |
| Caelo | Methadone hydrochloride | 15215505 | 3 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 18132403 | 11 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 18132413 | 11 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 191494001 | 9 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 18132406 | 4 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 21000271004 | 2 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 21000271017 | 4 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 19000787005 | 3 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 19000824004 | 3 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 21000271012 | 1 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 21003277015 | 1 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 21000271010 | 1 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 21003277010 | 1 |
| Caesar & Loretz GmbH | Methadone hydrochloride | F01-3764906 | 2 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 20D09-F05-371481 | 1 |
| Caesar & Loretz GmbH | Methadone hydrochloride | f05-3714801 | 1 |
| Caesar & Loretz GmbH | Methadone hydrochloride | 18186605 | 1 |
| Caesar & Loretz Gm… | Methadone hydrochloride | 21000271009 | 4 |
| Caesar & Loretz Gm… | Methadone hydrochloride | 19149407 | 2 |
| Caesar & Loretz GmbH/ | Methadone hydrochloride | 191494 | 2 |
| Caesar & Loretz Gm… | Methadone hydrochloride | 19000787012 | 2 |
| Caesar & Loretz Gm… | Methadone hydrochloride | 21000271013 | 3 |
| Caesar & Loretz Gm… | Methadone hydrochloride | 18186603 | 2 |
| Caesar & Loretz Gm… | Methadone hydrochloride | 19149405 | 1 |
| Cealo | Methadone hydrochloride | 21000271007 | 4 |
| Cordes/Alia | Methadone hydrochloride | 19000787008 | 9 |
| Dr. Wolff | Methadone hydrochloride | 16F24-B02 | 1 |
| Ebert & Jacobi | Methadone hydrochloride | 16135308 | 5 |
| Ebert-Jacobi | Methadone hydrochloride | 16135306 | 1 |
| Fagron | Methadone hydrochloride | 21G14-F06-379152 | 2 |
| Fa.Phönix | Methadone hydrochloride | 18c01-b05 | 1 |
| Faagron | Methadone hydrochloride | 1437H011 | 1 |
| Fagro/ Noweda | Methadone hydrochloride | 17/15-B02-339527 | 1 |
| Fagro//Noweda | Methadone hydrochloride | 15/24-B07-317267 | 1 |
| Fagro/Jenne | Methadone hydrochloride | 17I15-B02-339525 | 2 |
| Fagron | Methadone hydrochloride | 12B21N03 | 1 |
| Fagron | Methadone hydrochloride | 17l15-B02-339521 | 1 |
| Fagron | Methadone hydrochloride | 11G11-N02 | 1 |
| Fagron | Methadone hydrochloride | 21A06-F02-376492 | 3 |
| Fagron | Methadone hydrochloride | 1718H028 | 14 |
| Fagron | Methadone hydrochloride | 15/24-B07-313517 | 1 |
| Fagron | Methadone hydrochloride | 1814H016 | 1 |
| Fagron | Methadone hydrochloride | 17I15-B02-343150 | 5 |
| Fagron | Methadone hydrochloride | 16K01-B04 | 2 |
| Fagron | Methadone hydrochloride | 18G02-B02 | 7 |
| Fagron | Methadone hydrochloride | 20A09-F05 | 5 |
| Fagron | Methadone hydrochloride | 21A06-F01-376497 | 2 |
| Fagron | Methadone hydrochloride | 19D09-B03 | 7 |
| Fagron | Methadone hydrochloride | 12H07-N07 | 1 |
| Fagron | Methadone hydrochloride | 171920-0009 | 1 |
| Fagron | Methadone hydrochloride | 13B06-N02 | 5 |
| Fagron | Methadone hydrochloride | 1608H002 | 3 |
| Fagron | Methadone hydrochloride | 339527 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Methadone hydrochloride | 13I24-B06-286908 | 1 |
| Fagron | Methadone hydrochloride | 21H25-F02-380956 | 1 |
| Fagron | Methadone hydrochloride | 19D09-B03-364516 | 2 |
| Fagron | Methadone hydrochloride | 21G14-F06 | 2 |
| Fagron | Methadone hydrochloride | 2117H030 | 3 |
| Fagron | Methadone hydrochloride | 17I15-B02-343154 | 2 |
| Fagron | Methadone hydrochloride | 18G02-B02-355994 | 1 |
| Fagron | Methadone hydrochloride | 17I15-B02-339521 | 6 |
| Fagron | Methadone hydrochloride | 29051502 | 1 |
| Fagron | Methadone hydrochloride | 25091307 | 1 |
| Fagron | Methadone hydrochloride | 4031517 | 1 |
| Fagron | Methadone hydrochloride | 9041306 | 1 |
| Fagron | Methadone hydrochloride | 25091406 | 1 |
| Fagron | Methadone hydrochloride | 8081501 | 1 |
| Fagron | Methadone hydrochloride | F05-3705809 | 3 |
| Fagron | Methadone hydrochloride | 2877 | 1 |
| Fagron | Methadone hydrochloride | 21G14-F06-379955 | 4 |
| Fagron | Methadone hydrochloride | 19D09-B03_364513 | 1 |
| Fagron | Methadone hydrochloride | 13J24B06286910 | 1 |
| Fagron | Methadone hydrochloride | 12H07-N05 | 4 |
| Fagron | Methadone hydrochloride | 16K01-B04-329934 | 2 |
| Fagron | Methadone hydrochloride | 17/15-B02-339521 | 4 |
| Fagron | Methadone hydrochloride | 17\|15-B02-339521 | 1 |
| Fagron | Methadone hydrochloride | 20130912-6 | 1 |
| Fagron | Methadone hydrochloride | 1213E-02949 | 1 |
| Fagron | Methadone hydrochloride | 17C24-B05-334309 | 6 |
| Fagron | Methadone hydrochloride | 21G14-F06-379151 | 1 |
| Fagron | Methadone hydrochloride | 13J24-B06-286906 | 1 |
| Fagron | Methadone hydrochloride | 18C01-B05-350571 | 11 |
| Fagron | Methadone hydrochloride | 1914H016 | 3 |
| Fagron | Methadone hydrochloride | 21A06-F01 | 3 |
| Fagron | Methadone hydrochloride | 20A09-F05-370759 | 1 |
| Fagron | Methadone hydrochloride | 17/15-B02-343153 | 1 |
| Fagron | Methadone hydrochloride | 1225H008 | 1 |
| Fagron | Methadone hydrochloride | 17c24b05334309 | 1 |
| Fagron | Methadone hydrochloride | 15E29-B02-313031 | 1 |
| Fagron | Methadone hydrochloride | 20D09F05 | 3 |
| Fagron | Methadone hydrochloride | 16K01B04 | 1 |
| Fagron | Methadone hydrochloride | 19D09-B03-364518 | 1 |
| Fagron | Methadone hydrochloride | 17I15-B02-339529 | 2 |
| Fagron | Methadone hydrochloride | 16K01-B04-329936 | 1 |
| Fagron | Methadone hydrochloride | 17I15-B02-343151 | 4 |
| Fagron | Methadone hydrochloride | 16F24-B02-323185 | 1 |
| Fagron | Methadone hydrochloride | 18G02-B02-355993 | 2 |
| Fagron | Methadone hydrochloride | 17I15-B02-343153 | 1 |
| Fagron | Methadone hydrochloride | 14H15-B01-299381 | 1 |
| Fagron | Methadone hydrochloride | 13J24-B06-286907 | 1 |
| Fagron | Methadone hydrochloride | 14C24-B01-292857 | 4 |
| Fagron | Methadone hydrochloride | 1327h051 | 1 |
| Fagron | Methadone hydrochloride | 11D07-N09 | 1 |
| Fagron | Methadone hydrochloride | 16-k01-B04-329937 | 1 |
| Fagron | Methadone hydrochloride | 17I15-B02-343153 | 1 |
| Fagron | Methadone hydrochloride | 14C24-B01 | 2 |
| Fagron | Methadone hydrochloride | 67047 | 2 |
| Fagron | Methadone hydrochloride | 17105-B02 | 1 |
| Fagron | Methadone hydrochloride | 17/15-B02-343150 | 1 |
| Fagron | Methadone hydrochloride | 18C01-B05-350572 | 1 |
| Fagron | Methadone hydrochloride | 18gb02-35599202- | 1 |
| Fagron | Methadone hydrochloride | 1801h11 | 1 |
| Fagron | Methadone hydrochloride | 1801h011 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Methadone hydrochloride | 18c01-b05-350572 | 1 |
| Fagron | Methadone hydrochloride | 414022-1-P | 1 |
| Fagron | Methadone hydrochloride | 21A06-F01-376496 | 1 |
| Fagron | Methadone hydrochloride | 17I15-B02-339528 | 1 |
| Fagron | Methadone hydrochloride | 19D09-B03-364519 | 1 |
| Fagron | Methadone hydrochloride | 18C01-B05-350573 | 2 |
| Fagron | Methadone hydrochloride | 1316H037 | 4 |
| Fagron | Methadone hydrochloride | 13J24-B06-286908 | 1 |
| Fagron | Methadone hydrochloride | F04-3825003 | 1 |
| Fagron | Methadone hydrochloride | 15244704 | 4 |
| Fagron | Methadone hydrochloride | 21H25-F02-380953 | 1 |
| Fagron | Methadone hydrochloride | 1409H043 | 1 |
| Fagron | Methadone hydrochloride | 17I15-B02-339523 | 8 |
| Fagron | Methadone hydrochloride | 19D09-B03-364514 | 3 |
| Fagron | Methadone hydrochloride | 13F17-N02 | 6 |
| Fagron | Methadone hydrochloride | 20D09-F05-370590 | 1 |
| Fagron | Methadone hydrochloride | 20A09-F05-370758 | 1 |
| Fagron | Methadone hydrochloride | 23A25-F02-384698 | 3 |
| Fagron | Methadone hydrochloride | 21G14-F06-379154 | 1 |
| Fagron | Methadone hydrochloride | 21H25-F02-380954 | 1 |
| Fagron | Methadone hydrochloride | 21H25-F02-380291 | 2 |
| Fagron | Methadone hydrochloride | 15B24-B02-313097 | 1 |
| Fagron | Methadone hydrochloride | 17c24-bo5334311 | 1 |
| Fagron | Methadone hydrochloride | 20D09-F05-371480 | 1 |
| Fagron | Methadone hydrochloride | 15E29_B02_309070 | 1 |
| Fagron | Methadone hydrochloride | 17115-B02 | 1 |
| Fagron | Methadone hydrochloride | 19D09-B03-364558 | 4 |
| Fagron | Methadone hydrochloride | 211BH003 | 1 |
| Fagron | Methadone hydrochloride | 17C24-B05-335712 | 1 |
| Fagron | Methadone hydrochloride | 1715-B02-343151 | 1 |
| Fagron | Methadone hydrochloride | 19D09-B03-364517 | 4 |
| Fagron | Methadone hydrochloride | 20D09-F05-370589 | 4 |
| Fagron | Methadone hydrochloride | 15I24-B07 | 1 |
| Fagron | Methadone hydrochloride | 20A09-F05-370757 | 2 |
| Fagron | Methadone hydrochloride | 19D09-B03-364560 | 1 |
| Fagron | Methadone hydrochloride | 21A06-F02 | 1 |
| Fagron | Methadone hydrochloride | 17C24-B05-334311 | 2 |
| Fagron | Methadone hydrochloride | 18G02-B02-351285 | 1 |
| Fagron | Methadone hydrochloride | 16F24-B02-323186 | 1 |
| Fagron | Methadone hydrochloride | 21002144002 | 1 |
| Fagron | Methadone hydrochloride | 17C24-B05-335711 | 11 |
| Fagron | Methadone hydrochloride | 17I15W02 | 1 |
| Fagron | Methadone hydrochloride | 350571 | 1 |
| Fagron | Methadone hydrochloride | 16f24-b02-323184 | 1 |
| Fagron | Methadone hydrochloride | 16k01-b04-329933 | 1 |
| Fagron | Methadone hydrochloride | 1715-B02-339523 | 1 |
| Fagron | Methadone hydrochloride | 19D9-B03-364514 | 1 |
| Fagron | Methadone hydrochloride | 12A05-No2 | 1 |
| Fagron | Methadone hydrochloride | 18G02-B02-355991 | 1 |
| Fagron | Methadone hydrochloride | 17C24-B05 | 2 |
| Fagron | Methadone hydrochloride | 16F24-B02-323182 | 1 |
| Fagron | Methadone hydrochloride | 19D09-B03_364514 | 1 |
| Fagron | Methadone hydrochloride | 170427MH/1608H002 | 1 |
| Fagron | Methadone hydrochloride | 16F24-B02-329935 | 1 |
| Fagron | Methadone hydrochloride | 20A09F05 | 1 |
| Fagron | Methadone hydrochloride | 17C24-B-335711 | 1 |
| Fagron | Methadone hydrochloride | 14H15-B01 | 1 |
| Fagron | Methadone hydrochloride | B03-3645508 | 1 |
| Fagron | Methadone hydrochloride | 16K01-B04-329933 | 3 |
| Fagron | Methadone hydrochloride | F05-3714709 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Methadone hydrochloride | 18G02-B02-355990 | 8 |
| Fagron | Methadone hydrochloride | 15E29-B02-313098 | 3 |
| Fagron | Methadone hydrochloride | 14H15-B01-299382 | 6 |
| Fagron | Methadone hydrochloride | 15B24-B02-304724 | 6 |
| Fagron | Methadone hydrochloride | 1718H028 | 1 |
| Fagron | Methadone hydrochloride | 15E29-B02-309070 | 2 |
| Fagron | Methadone hydrochloride | 16B16-B02-318420 | 3 |
| Fagron | Methadone hydrochloride | 1514H042 | 3 |
| Fagron | Methadone hydrochloride | 1437H012 | 2 |
| Fagron | Methadone hydrochloride | 200000000 | 1 |
| Fagron | Methadone hydrochloride | 19D09-B03-364559 | 1 |
| Fagron | Methadone hydrochloride | 17/15-B02 | 1 |
| Fagron | Methadone hydrochloride | 16F24-B02-326207 | 3 |
| Fagron | Methadone hydrochloride | 1207h057 | 1 |
| Fagron | Methadone hydrochloride | 12b21-n03 | 1 |
| Fagron | Methadone hydrochloride | 1847H015 | 6 |
| Fagron | Methadone hydrochloride | 21H25-F02 | 2 |
| Fagron | Methadone hydrochloride | 1801H011 | 3 |
| Fagron | Methadone hydrochloride | 15-B02-343150 | 1 |
| Fagron | Methadone hydrochloride | 1715-B02-339525 | 2 |
| Fagron | Methadone hydrochloride | 1715-B02-343150 | 1 |
| Fagron | Methadone hydrochloride | 15-B02-339525 | 1 |
| Fagron | Methadone hydrochloride | 18G02-B02-35590 | 1 |
| Fagron | Methadone hydrochloride | 20A09-F05-371479 | 1 |
| Fagron | Methadone hydrochloride | 20A09-F05-370755 | 5 |
| Fargon/Noweda | Methadone hydrochloride | 18G02-B02-355989 | 9 |
| Gatt-Koller | Methadone hydrochloride | 1801702 | 1 |
| Gehe | Methadone hydrochloride | 23001353007 | 2 |
| Gehe | Methadone hydrochloride | 17115-B02-339523 | 1 |
| Gehe | Methadone hydrochloride | 24002906001 | 1 |
| Caelo | Methadone hydrochloride | 21003277005 | 1 |
| Fagron | Methadone hydrochloride | 16K01-B04-329937 | 2 |
| Gehe/Noweda | Methadone hydrochloride | 16135319 | 3 |
| Geilenkirchen | Methadone hydrochloride | | 2 |
| Hedinger/Sanacorp | Methadone hydrochloride | 13266518 | 3 |
| Jenne | Methadone hydrochloride | 15B24-B02 | 1 |
| Caelo | Methadone hydrochloride | 16135310 | 4 |
| NOW | Methadone hydrochloride | 23A25-F-02-384693 | 1 |
| noweda | Methadone hydrochloride | 3072001 | 1 |
| Noweda | Methadone hydrochloride | 23003258008 | 2 |
| Noweda | Methadone hydrochloride | 20a09f05370755 | 1 |
| Fagron | Methadone hydrochloride | 17c24-b05 | 1 |
| Caelo | Methadone hydrochloride | 16135325 | 4 |
| Caelo | Methadone hydrochloride | 21003277020 | 2 |
| Caelo | Methadone hydrochloride | 13266504 | 2 |
| Caelo | Methadone hydrochloride | 12171918 | 1 |
| Caelo | Methadone hydrochloride | 12344807 | 1 |
| Phoenix | Methadone hydrochloride | 191494003 | 12 |
| Phoenix | Methadone hydrochloride | 20D09-F05 | 3 |
| Phoenix | Methadone hydrochloride | 16125317 | 1 |
| Phönix | Methadone hydrochloride | 2100327706 | 1 |
| Caelo | Methadone hydrochloride | 19000787004 | 5 |
| Fagron | Methadone hydrochloride | 16F24B02323184 | 2 |
| Fagron | Methadone hydrochloride | 17I15-B02 | 8 |
| Sanacorp | Methadone hydrochloride | 12344806 | 2 |
| Sanacorp | Methadone hydrochloride | 12171913 | 1 |
| Caelo | Methadone hydrochloride | 13266505 | 4 |
| Sanarcorp | Methadone hydrochloride | 17115-b02-339521 | 1 |
| Siegfried Ltd | Methadone hydrochloride | 12B21-N03 | 1 |
| Siegfried Ltd, Div… | Methadone hydrochloride | 15244712 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Methadone hydrochloride | F01-3764907 | 1 |
| Fagron | Methadone hydrochloride | F05-3707509 | 3 |
| Siegfried Ltd. Dev… | Methadone hydrochloride | 17186104 | 1 |
| Siegfried/Fiebig-BTM | Methadone hydrochloride | 19D09-B03-364513 | 10 |
| Th. Geyer | Methadone hydrochloride | 18G02B02351285 | 2 |
| Th. Geyer | Methadone hydrochloride | 70617 | 19 |
| Th. Geyer | Methadone hydrochloride | 70873 | 6 |
| Th. Geyer | Methadone hydrochloride | 70245 | 87 |
| Th. Geyer | Methadone hydrochloride | 56(070245) | 1 |
| Th. Geyer | Methadone hydrochloride | 70246 | 1 |
| Th. Geyer | Methadone hydrochloride | 67055 | 26 |
| VDL;87,00EUR;08.09.14 | Methadone hydrochloride | 12344821 | 1 |
| Caelo | Methylrosanilinium chloride | 3455360 | 1 |
| Caelo | Methylrosanilinium chloride | 12H28-N06 | 1 |
| Caelo | Methylrosanilinium chloride | 13184801 | 1 |
| Caelo | Methylrosanilinium chloride | 9238107 | 1 |
| Caelo | Methylrosanilinium chloride | 12H28-No6 | 1 |
| Caelo | Methylrosanilinium chloride | 9238109 | 1 |
| Caelo | Methylrosanilinium chloride | 13H28-N03 | 18 |
| Caelo | Methylrosanilinium chloride | 9238106 | 1 |
| Fagron | Methylrosanilinium chloride | 13H28-N03 | 2 |
| Fagron | Methylrosanilinium chloride | 12H28_N06 | 1 |
| Fagron | Methylrosanilinium chloride | 13G03-N11 | 1 |
| Fagron | Methylrosanilinium chloride | 1989 | 2 |
| Fagron | Methylrosanilinium chloride | 13G03N11 | 1 |
| Fagron | Methylrosanilinium chloride | 13H28-No3 | 1 |
| Fagron | Methylrosanilinium chloride | 2159 | 2 |
| Fagron | Methylrosanilinium chloride | 13G03-N011 | 1 |
| Fagron | Methylrosanilinium chloride | 13H28-N03-0161-1030 | 1 |
| Fagron | Methylrosanilinium chloride | 12-17-N050109-140 | 1 |
| Fagron | Methylrosanilinium chloride | 12D19-N01 | 1 |
| Fagron | Methylrosanilinium chloride | 13H28-NO3 | 1 |
| Fagron | Methylrosanilinium chloride | 13G03-N11 | 1 |
| Fagron | Methylrosanilinium chloride | 12I17-N05 | 1 |
| Noweda | Methylrosanilinium chloride | 9238104 | 1 |
| Noweda | Methylrosanilinium chloride | 12H28-NO6 | 1 |
| Caelo | Methylrosanilinium chloride | 12/17-N05 | 1 |
| phönix | Methylrosanilinium chloride | 13184811 | 1 |
| Fagron | Midazolam | 14C12-B31-313222 | 1 |
| Fagron | Midazolam | 16J03-B09-326963 | 1 |
| | Midazolam hydrochloride | 21B03-F50-384896 | 1 |
| | Midazolam hydrochloride | 24B16-F02_386031 | 1 |
| | Midazolam hydrochloride | 24B16-F02-386031 | 7 |
| | Midazolam hydrochloride | 20002613005 | 1 |
| | Midazolam hydrochloride | 21B03-F50-384281 | 3 |
| | Midazolam hydrochloride | 24B16-F02-36031 | 1 |
| | Midazolam hydrochloride | F02-3860301 | 1 |
| | Midazolam hydrochloride | 24B16-F02-386034 | 4 |
| | Midazolam hydrochloride | F02-3860304 | 1 |
| | Midazolam hydrochloride | 24B16-F02-386032 | 1 |
| | Midazolam hydrochloride | 21B03 | 1 |
| Caelo | Midazolam hydrochloride | 14339015 | 2 |
| Caelo | Midazolam hydrochloride | 17168003 | 5 |
| Caelo | Midazolam hydrochloride | 14339002 | 1 |
| Caelo | Midazolam hydrochloride | 15224616 | 3 |
| Caelo | Midazolam hydrochloride | 2061508 | 1 |
| Caelo | Midazolam hydrochloride | 15224603 | 1 |
| Caelo | Midazolam hydrochloride | 17168011 | 5 |
| Caelo | Midazolam hydrochloride | 15224614 | 2 |
| Caelo | Midazolam hydrochloride | 17168001 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Midazolam hydrochloride | 11184705 | 1 |
| Caelo | Midazolam hydrochloride | 17168005 | 1 |
| Caelo | Midazolam hydrochloride | 143339009 | 1 |
| Caelo | Midazolam hydrochloride | 17168007 | 7 |
| Caelo | Midazolam hydrochloride | 2100053006 | 1 |
| Caelo | Midazolam hydrochloride | 15224605 | 1 |
| Caelo | Midazolam hydrochloride | 14339009 | 1 |
| Caelo | Midazolam hydrochloride | 83600116001 | 1 |
| Caelo | Midazolam hydrochloride | 16290605 | 10 |
| Caelo | Midazolam hydrochloride | 21003167008 | 3 |
| Caelo | Midazolam hydrochloride | 17168006 | 7 |
| Caelo | Midazolam hydrochloride | 17168009 | 4 |
| Caelo | Midazolam hydrochloride | 71680091 | 1 |
| Caelo | Midazolam hydrochloride | 192213002 | 5 |
| Caesar & Loretz GmbH | Midazolam hydrochloride | 21000038007 | 4 |
| Caesar & Loretz GmbH | Midazolam hydrochloride | 21003167002 | 11 |
| Caesar & Loretz GmbH | Midazolam hydrochloride | 20002613010 | 1 |
| Caesar & Loretz GmbH | Midazolam hydrochloride | 20002613009 | 1 |
| Caesar & Loretz GmbH | Midazolam hydrochloride | 21003167004 | 1 |
| Caesar & Loretz GmbH | Midazolam hydrochloride | 21000535006 | 2 |
| Caesar & Loretz Gm… | Midazolam hydrochloride | 21000038005 | 1 |
| Caesar & Loretz Gm… | Midazolam hydrochloride | 2100003807 | 1 |
| Caesar & Loretz Gm… | Midazolam hydrochloride | 20002613002 | 6 |
| Eurho/Phoenix | Midazolam hydrochloride | 12L17-N10 | 1 |
| Euro OTC | Midazolam hydrochloride | 15224607 | 2 |
| Fagron | Midazolam hydrochloride | 9D27-N01 | 2 |
| Fagron | Midazolam hydrochloride | 15H04-B03-314396 | 9 |
| Fagron | Midazolam hydrochloride | 18B28-B05-354856 | 2 |
| Fagron | Midazolam hydrochloride | 20D21-F02-370326 | 2 |
| Fagron | Midazolam hydrochloride | 17K21-B05-347538 | 2 |
| Fagron | Midazolam hydrochloride | 18F19B02 | 1 |
| Fagron | Midazolam hydrochloride | 20D21-F02 | 1 |
| Fagron | Midazolam hydrochloride | 18F19-B02 | 1 |
| Fagron | Midazolam hydrochloride | 940112 | 2 |
| Fagron | Midazolam hydrochloride | 11A31-N01 | 1 |
| Fagron | Midazolam hydrochloride | 400101 | 1 |
| Fagron | Midazolam hydrochloride | 14H05-B08-297982 | 1 |
| Fagron | Midazolam hydrochloride | 20F11-F04-374727 | 1 |
| Fagron | Midazolam hydrochloride | 20I24-F01-374730 | 3 |
| Fagron | Midazolam hydrochloride | 20I24-F01-374728 | 7 |
| Fagron | Midazolam hydrochloride | 18F19B02-354857 | 1 |
| Fagron | Midazolam hydrochloride | 18F19-B02-354857 | 4 |
| Fagron | Midazolam hydrochloride | 19I25-F03-365483 | 1 |
| Fagron | Midazolam hydrochloride | 16C14-B12-332469 | 1 |
| Fagron | Midazolam hydrochloride | 20I24-F01 | 3 |
| Fagron | Midazolam hydrochloride | 20D21-F02-370327 | 1 |
| Fagron | Midazolam hydrochloride | 30916 | 1 |
| Fagron | Midazolam hydrochloride | F01-3747208 | 2 |
| Fagron | Midazolam hydrochloride | 20124-F01-374730 | 1 |
| Caelo | Midazolam hydrochloride | 20002613004 | 2 |
| Noweda | Midazolam hydrochloride | 2100003805 | 1 |
| PHÖNIX | Midazolam hydrochloride | 18B28-B05 | 2 |
| Anzag ek:2,64EUR 16.07.12 | Mistletoe | 10273417 | 1 |
| Aurica/Phönix | Mistletoe | 6110801 | 1 |
| Bombastus | Mistletoe | 277432 | 2 |
| Caelo | Mistletoe | 11266709 | 10 |
| Caelo | Mistletoe | 11266708 | 8 |
| Caelo | Mistletoe | 24011401 | 1 |
| Caelo | Mistletoe | 29061201 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mistletoe | 23111204 | 1 |
| Caelo | Mistletoe | 28101304 | 1 |
| Caelo | Mistletoe | 10081205 | 1 |
| Caelo | Mistletoe | 26071302 | 1 |
| Caelo | Mistletoe | 6061306 | 1 |
| Caelo | Mistletoe | 18031303 | 1 |
| Caelo | Mistletoe | 11021303 | 1 |
| Caelo | Mistletoe | 10091201 | 1 |
| Caelo | Mistletoe | 29071302 | 1 |
| Caelo | Mistletoe | 17061304 | 1 |
| Caelo | Mistletoe | 12011301 | 1 |
| Caelo | Mistletoe | 29101302 | 1 |
| Caelo | Mistletoe | 20121303 | 1 |
| Caelo | Mistletoe | 29081302 | 1 |
| Caelo | Mistletoe | 27121305 | 1 |
| Caelo | Mistletoe | 14292506 | 2 |
| Caelo | Mistletoe | 14292514 | 1 |
| Caelo | Mistletoe | 10273420 | 5 |
| Caelo | Mistletoe | 11294003 | 2 |
| Caelo | Mistletoe | 11266710 | 7 |
| Caelo | Mistletoe | 10273412 | 1 |
| Caelo | Mistletoe | 10273418 | 1 |
| Caelo | Mistletoe | 11266704 | 14 |
| Caelo | Mistletoe | 11266714 | 4 |
| Caelo | Mistletoe | 11266712-3450311162 | 1 |
| Caelo | Mistletoe | 10273407 | 1 |
| Caelo | Mistletoe | 11294004 | 5 |
| Caelo | Mistletoe | 11266703 | 3 |
| Caelo | Mistletoe | 3813E-01695 | 1 |
| Caelo | Mistletoe | 4313E-01695 | 1 |
| Caelo | Mistletoe | 11266713 | 2 |
| Galke | Mistletoe | 20328 | 1 |
| Galke | Mistletoe | 22012 | 2 |
| Gehe | Mistletoe | 11266702 | 4 |
| Gesundform | Mistletoe | 216482 | 1 |
| Haustee | Mistletoe | 57010507 | 1 |
| Caelo | Mistletoe | 11294005 | 15 |
| Klenk | Mistletoe | 2901311695 | 1 |
| Klenk | Mistletoe | 1512211695 | 1 |
| Klenk | Mistletoe | 4691A121122 | 11 |
| Klenk | Mistletoe | 110816 | 1 |
| Klenk | Mistletoe | 4691A110816 | 2 |
| Klenk | Mistletoe | 4691A120507 | 2 |
| Klenk | Mistletoe | 4961A120419 | 1 |
| Klenk | Mistletoe | 4691a130307 | 1 |
| Klenk | Mistletoe | 4691A120419 | 6 |
| Klenk | Mistletoe | 4691A-120507 | 1 |
| Klenk | Mistletoe | 4691A130307 | 7 |
| Klenk | Mistletoe | 4691a121122 | 1 |
| Klenk | Mistletoe | 4691A121122-35454110 | 1 |
| Noweda | Mistletoe | 11294001 | 1 |
| Noweda | Mistletoe | 11266705 | 3 |
| Caelo | Mistletoe | 11266712 | 8 |
| Spangropharm | Mistletoe | 10273408 | 1 |
| Caelo | Molecular distilled glycero… | 11160012 | 1 |
| Noweda | Molecular distilled glycero… | 11160010 | 1 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 17331510 | 4 |
| Caelo | Morphine hemisulfate 2.5-hydrate | 17331507 | 1 |
| | Morphine hydrochloride trih… | 2300328004 | 1 |
| | Morphine hydrochloride trih… | 20003757010 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| | Morphine hydrochloride trih… | 23003282004 | 5 |
| | Morphine hydrochloride trih… | 25001073004 | 1 |
| | Morphine hydrochloride trih… | 23003282006 | 2 |
| | Morphine hydrochloride trih… | 212337009 | 1 |
| | Morphine hydrochloride trih… | 21002337005 | 4 |
| | Morphine hydrochloride trih… | 21002337009 | 2 |
| | Morphine hydrochloride trih… | 20003757015 | 1 |
| | Morphine hydrochloride trih… | Retest:170525 | 1 |
| 04655198 | Morphine hydrochloride trih… | 2003757008 | 1 |
| Caelo | Morphine hydrochloride trih… | 18188601 | 4 |
| Caelo | Morphine hydrochloride trih… | 13125208 | 1 |
| Caelo | Morphine hydrochloride trih… | 16184605 | 2 |
| Caelo | Morphine hydrochloride trih… | 13081310 | 1 |
| Caelo | Morphine hydrochloride trih… | 14081701 | 1 |
| Caelo | Morphine hydrochloride trih… | 12104409 | 1 |
| Caelo | Morphine hydrochloride trih… | 16184610 | 2 |
| Caelo | Morphine hydrochloride trih… | 118188607 | 2 |
| Caelo | Morphine hydrochloride trih… | 14238619 | 2 |
| Caelo | Morphine hydrochloride trih… | 20003757006 | 2 |
| Caelo | Morphine hydrochloride trih… | 15439413 | 2 |
| Caelo | Morphine hydrochloride trih… | 18188606 | 5 |
| Caelo | Morphine hydrochloride trih… | 18188612 | 3 |
| Caelo | Morphine hydrochloride trih… | 48188601 | 1 |
| Caelo | Morphine hydrochloride trih… | 15199711 | 4 |
| Caelo | Morphine hydrochloride trih… | 15199705Nr.3 | 1 |
| Caelo | Morphine hydrochloride trih… | 15199705 | 1 |
| Caelo | Morphine hydrochloride trih… | 15199705Nr.2 | 1 |
| Caelo | Morphine hydrochloride trih… | 12318101 | 1 |
| Caelo | Morphine hydrochloride trih… | 1543904 | 1 |
| Caelo | Morphine hydrochloride trih… | 15439409 | 1 |
| Caelo | Morphine hydrochloride trih… | 14238604 | 1 |
| Caelo | Morphine hydrochloride trih… | 16184609 | 2 |
| Caelo | Morphine hydrochloride trih… | 18188611 | 2 |
| Caelo | Morphine hydrochloride trih… | 16184614 | 3 |
| Caelo | Morphine hydrochloride trih… | 18188603 | 3 |
| Caelo | Morphine hydrochloride trih… | 16184602 | 2 |
| Caelo | Morphine hydrochloride trih… | 15439406 | 3 |
| Caelo | Morphine hydrochloride trih… | 193085012 | 1 |
| Caelo | Morphine hydrochloride trih… | 20001998002 | 2 |
| Caelo | Morphine hydrochloride trih… | 20003757003 | 2 |
| Caelo | Morphine hydrochloride trih… | 193085009 | 1 |
| Caelo | Morphine hydrochloride trih… | 15199709 | 1 |
| Caelo | Morphine hydrochloride trih… | 15439402 | 1 |
| Caelo | Morphine hydrochloride trih… | 16184607 | 1 |
| Caelo | Morphine hydrochloride trih… | 15199707 | 1 |
| Caelo | Morphine hydrochloride trih… | 1818866 | 1 |
| Caelo | Morphine hydrochloride trih… | 18188602 | 2 |
| Caelo | Morphine hydrochloride trih… | 12104403 | 1 |
| Caelo | Morphine hydrochloride trih… | 15439405 | 2 |
| Caelo | Morphine hydrochloride trih… | 18188613 | 3 |
| Caelo | Morphine hydrochloride trih… | 17258002NR:51/18 | 1 |
| Caelo | Morphine hydrochloride trih… | 14055084 | 1 |
| Caelo | Morphine hydrochloride trih… | 193085008 | 1 |
| Caelo | Morphine hydrochloride trih… | 20003757001 | 5 |
| Caelo | Morphine hydrochloride trih… | 20003757008 | 3 |
| Caelo | Morphine hydrochloride trih… | 193085014 | 2 |
| Caelo | Morphine hydrochloride trih… | 193085002 | 3 |
| Caelo | Morphine hydrochloride trih… | 13125206 | 1 |
| Caelo | Morphine hydrochloride trih… | 15199713 | 1 |
| Caelo | Morphine hydrochloride trih… | 17258002 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Morphine hydrochloride trih… | 16184613 | 7 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 193085005 | 1 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 20003757004 | 9 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 193085006 | 4 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 18188617 | 2 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 18188614 | 6 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 18188610 | 2 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 15199711 | 1 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 20003757002 | 2 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 193085003 | 3 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 18188607 | 1 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 15199711(1) | 1 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 15199712 | 1 |
| Caesar & Loretz GmbH | Morphine hydrochloride trih… | 15199711(2) | 1 |
| Fagron | Morphine hydrochloride trih… | 15A12-B04-303137 | 1 |
| Fagron | Morphine hydrochloride trih… | 11A27-N04 | 1 |
| Fagron | Morphine hydrochloride trih… | 18F11-B03-357051 | 2 |
| Fagron | Morphine hydrochloride trih… | 17F22-B01-338170 | 2 |
| Fagron | Morphine hydrochloride trih… | 15J27_B01_316889 | 1 |
| Fagron | Morphine hydrochloride trih… | 12E10N04 | 1 |
| Fagron | Morphine hydrochloride trih… | 13D09-N04 | 1 |
| Fagron | Morphine hydrochloride trih… | 18F11-B03-361065 | 1 |
| Fagron | Morphine hydrochloride trih… | 16D21-B02-322087 | 1 |
| Fagron | Morphine hydrochloride trih… | 20E28-F06 | 1 |
| Fagron | Morphine hydrochloride trih… | 18B26-B04-351286 | 1 |
| Fagron | Morphine hydrochloride trih… | 20E28-F06-372132 | 3 |
| Fagron | Morphine hydrochloride trih… | 12E10-N04 | 2 |
| Fagron | Morphine hydrochloride trih… | 17C24-B03-334287 | 1 |
| Fagron | Morphine hydrochloride trih… | 15/09-B08-312693 | 1 |
| Fagron | Morphine hydrochloride trih… | 15I09-B08-312693 | 2 |
| Fagron | Morphine hydrochloride trih… | B02-3220808 | 1 |
| Fagron | Morphine hydrochloride trih… | 13H22-N12 | 1 |
| Th. Geyer | Morphine hydrochloride trih… | PH120087 | 1 |
| Th. Geyer | Morphine hydrochloride trih… | 1415E-01879 | 1 |
| Th. Geyer | Morphine hydrochloride trih… | 2615M-01879 | 1 |
| Jenne | Morphine hydrochloride trih… | 20001998001 | 1 |
| Caelo | Morphine hydrochloride trih… | 193085007 | 9 |
| Caelo | Morphine hydrochloride trih… | 14238617 | 1 |
| Sanacorp | Morphine hydrochloride trih… | 16184612 | 2 |
| Caelo | Morphine hydrochloride trih… | 15439411 | 1 |
| Synop | Morphine hydrochloride trih… | 15I09-B08 | 1 |
| Th. Geyer | Morphine hydrochloride trih… | 67036 | 5 |
| Th. Geyer | Morphine hydrochloride trih… | 3518M-01879 | 1 |
| Th. Geyer | Morphine hydrochloride trih… | 4117A-01879 | 1 |
| Caelo | Motherwort | 5061203 | 1 |
| Caelo | Motherwort | 12376408 | 2 |
| Caelo | Motherwort | 12231503 | 2 |
| Caelo | Motherwort | 12376403 | 1 |
| Caelo | Motherwort | 12231502 | 3 |
| Caelo | Motherwort | 12376407 | 1 |
| Caelo | Motherwort | 11293004 | 1 |
| Klenk | Motherwort | 4071A-100707 | 1 |
| Caelo | Mullein flower, cut | 12317104 | 1 |
| Caelo | Mullein flower, cut | 521505390 | 1 |
| Caelo | Mullein flower, cut | 12192907 | 3 |
| Caelo | Mullein flower, cut | 18031301 | 1 |
| Caelo | Mullein flower, cut | 16081201 | 1 |
| Caelo | Mullein flower, cut | 12192904 | 1 |
| Caelo | Mullein flower, cut | 11020714 | 4 |
| Caelo | Mullein flower, cut | 11233401 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Mullein flower, cut | 12192901 | 3 |
| Caelo | Mullein flower, cut | 11233402 | 1 |
| Caelo | Mullein flower, cut | 11333402 | 1 |
| Caelo | Mullein flower, cut | 11020802 | 2 |
| Caelo | Mullein flower, cut | 11366402 | 1 |
| Caelo | Mullein flower, cut | 11020902 | 1 |
| Caelo | Mullein flower, cut | 13229702 | 1 |
| Caelo | Mullein flower, cut | 12170901 | 1 |
| Caelo | Mullein flower, cut | 11020713 | 2 |
| Caelo | Mullein flower, cut | 1219203 | 1 |
| Caelo | Mullein flower, cut | 12192905 | 5 |
| Caelo | Mullein flower, cut | 11366403 | 1 |
| Caelo | Mullein flower, cut | 12170906 | 1 |
| Caelo | Mullein flower, cut | 12192903 | 3 |
| Caelo | Mullein flower, cut | 13229701 | 2 |
| Caesar/Noweda | Mullein flower, cut | 2810E-01475 | 1 |
| Hepart AG | Mullein flower, cut | 12170904 | 2 |
| Klenk | Mullein flower, cut | 1651B110203 | 2 |
| Klenk | Mullein flower, cut | A120612 | 1 |
| Klenk | Mullein flower, cut | 1650A111018 | 3 |
| Klenk | Mullein flower, cut | 1650A100608 | 1 |
| Klenk | Mullein flower, cut | 1650A120612 | 1 |
| Klenk | Mullein flower, cut | 1651B150722 | 1 |
| Klenk | Mullein flower, cut | 1651B140324 | 2 |
| Klenk | Mullein flower, cut | 1651B121109 | 22 |
| Klenk | Mullein flower, cut | 1651B130820 | 5 |
| Klenk | Mullein flower, cut | 1651b130820 | 2 |
| Klenk | Mullein flower, cut | 1651B120315 | 3 |
| Caelo | Myrrh | 11276810 | 1 |
| Caelo | Myrrh | 12269904 | 4 |
| Caelo | Myrrh | 11276806 | 1 |
| Caelo | Myrrh | 14347509 | 1 |
| Caelo | Myrrh | 28101401 | 1 |
| Caelo | Myrrh | 30121413 | 1 |
| Caelo | Myrrh | 25071404 | 1 |
| Caelo | Myrrh | 15312606 | 1 |
| Caelo | Myrrh | 12269907 | 1 |
| Caelo | Myrrh | 15021410 | 1 |
| Caelo | Myrrh | 12269901 | 2 |
| Caelo | Myrrh | 11277111 | 1 |
| Caelo | Myrrh | 12269913 | 1 |
| Caelo | Myrrh | 14244602 | 1 |
| Caelo | Myrrh | 11277111 | 1 |
| Caelo | Myrrh | 12244404 | 1 |
| Caelo | Myrrh | 12244406 | 1 |
| Caelo | Myrrh | 13108701 | 2 |
| Caelo | Myrrh | 11277105 | 1 |
| Caelo | Myrrh | 15021402 | 1 |
| Klenk | Myrrh | 3351A121004 | 1 |
| Klenk | Myrrh | 3351A160330 | 4 |
| Klenk | Myrrh | 3351A130902 | 1 |
| Klenk | Myrrh | 3355B140723 | 1 |
| Klenk | Myrrh | 3351A120514 | 1 |
| Klenk | Myrrh | 3355B161010 | 1 |
| phönix | Myrrh | 3351a160330 | 1 |
| phönix | Myrrh | 15021411 | 1 |



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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alliance | Nettle leaf | 2381A120619 | 14 |
| Anzag | Nettle leaf | 2381-A130122 | 1 |
| Anzag | Nettle leaf | 10282807 | 2 |
| Bahnhof-Apotheke | Nettle leaf | 7-121109 | 1 |
| Bombastus | Nettle leaf | 273229 | 2 |
| Bombastus | Nettle leaf | 270987 | 3 |
| Bombastus | Nettle leaf | 276407 | 2 |
| Bombastus | Nettle leaf | 266638 | 1 |
| Bombastus | Nettle leaf | 280305 | 2 |
| Bombastus | Nettle leaf | 266099 | 1 |
| Bombastus | Nettle leaf | 275763 | 1 |
| Bombastus | Nettle leaf | 275848 | 3 |
| Caelo | Nettle leaf | 12183901 | 2 |
| Caelo | Nettle leaf | 12184005 | 7 |
| Caelo | Nettle leaf | 12195001 | 7 |
| Caelo | Nettle leaf | 12184001 | 6 |
| Caelo | Nettle leaf | 20111306 | 1 |
| Caelo | Nettle leaf | 18071202 | 1 |
| Caelo | Nettle leaf | 2051302 | 1 |
| Caelo | Nettle leaf | 7031302 | 1 |
| Caelo | Nettle leaf | 17121205 | 1 |
| Caelo | Nettle leaf | | 3 |
| Caelo | Nettle leaf | 3021401 | 1 |
| Caelo | Nettle leaf | 29071303 | 1 |
| Caelo | Nettle leaf | 13091302 | 1 |
| Caelo | Nettle leaf | 14344907 | 1 |
| Caelo | Nettle leaf | 12034414 | 1 |
| Caelo | Nettle leaf | 13386801 | 1 |
| Caelo | Nettle leaf | 10291411 | 2 |
| Caelo | Nettle leaf | 12195101 | 3 |
| Caelo | Nettle leaf | 10375901 | 2 |
| Caelo | Nettle leaf | 12183911 | 16 |
| Caelo | Nettle leaf | 12184706 | 3 |
| Caelo | Nettle leaf | 10291413 | 1 |
| Caelo | Nettle leaf | 120375901 | 1 |
| Caelo | Nettle leaf | 12183909 | 1 |
| Caelo | Nettle leaf | 10282806 | 1 |
| Caelo | Nettle leaf | 10291405 | 2 |
| Caelo | Nettle leaf | 12184702 | 2 |
| Caelo | Nettle leaf | 1283910 | 1 |
| Caelo | Nettle leaf | 12184502 | 2 |
| Caelo | Nettle leaf | 12814001 | 1 |
| Caelo | Nettle leaf | intch:313011 | 1 |
| Caelo | Nettle leaf | 10162712 | 1 |
| Caelo | Nettle leaf | 10291414 | 3 |
| Caelo | Nettle leaf | 12184004 | 9 |
| Caelo | Nettle leaf | 12183910 | 11 |
| Caelo | Nettle leaf | 12195002 | 2 |
| Caelo | Nettle leaf | 12184003 | 17 |
| Caelo | Nettle leaf | 10291422 | 3 |
| Caelo | Nettle leaf | 12184503 | 3 |
| Caelo | Nettle leaf | 12184707 | 11 |
| Caelo | Nettle leaf | 17337321 | 2 |
| Caelo | Nettle leaf | 83142389 | 1 |
| Caelo | Nettle leaf | 72085497 | 1 |
| Caelo | Nettle leaf | 83374109 | 1 |
| Caelo | Nettle leaf | 12183908 | 5 |
| Caelo | Nettle leaf | 12034402 | 3 |
| Caelo | Nettle leaf | 12183908-3443311112 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Nettle leaf | 12183908-3391311070 | 1 |
| Caelo | Nettle leaf | 12183908-3405310181 | 1 |
| Caesar & Loretz Gm… | Nettle leaf | 10291423 | 6 |
| Galke | Nettle leaf | 21238 | 1 |
| Galke | Nettle leaf | 20956 | 1 |
| Galke | Nettle leaf | 23302 | 1 |
| Gehe | Nettle leaf | 10162701 | 1 |
| Gehe | Nettle leaf | 12034403 | 8 |
| Gehe | Nettle leaf | 2381a120619 | 4 |
| Gutenberg-Apotheke | Nettle leaf | 18897 | 1 |
| Hepart AG | Nettle leaf | P234605kbA | 1 |
| Klenk | Nettle leaf | 2381A151012 | 1 |
| Klenk | Nettle leaf | 2381A150109 | 1 |
| Klenk | Nettle leaf | 2381A-120619 | 1 |
| Klenk | Nettle leaf | 2381A141124 | 1 |
| Klenk | Nettle leaf | 1913A-03054 | 1 |
| Klenk | Nettle leaf | 1107211689 | 1 |
| Klenk | Nettle leaf | A130703 | 1 |
| Klenk | Nettle leaf | A110913 | 1 |
| Klenk | Nettle leaf | A130122 | 1 |
| Klenk | Nettle leaf | 2372A130703 | 1 |
| Klenk | Nettle leaf | 2381A140221 | 1 |
| Klenk | Nettle leaf | 2381a130703 | 1 |
| Klenk | Nettle leaf | 2381A130703 | 15 |
| Klenk | Nettle leaf | 114Q-03054 | 1 |
| Klenk | Nettle leaf | 2381A121010 | 1 |
| Klenk | Nettle leaf | 4513E3054 | 1 |
| Klenk | Nettle leaf | 2381a130122 | 1 |
| Klenk | Nettle leaf | 2381A-121010 | 1 |
| Klenk | Nettle leaf | 2381A110913 | 19 |
| Klenk | Nettle leaf | 2381A110809 | 1 |
| Klenk | Nettle leaf | 2381A130122 | 27 |
| Nachprüfung 8.2.13 | Nettle leaf | C1081 | 1 |
| Noweda | Nettle leaf | 270854 | 3 |
| Phoenix | Nettle leaf | 12183914 | 9 |
| Caelo | Nettle leaf | 33/AD1 | 1 |
| Wolf | Nettle leaf | B-821 | 1 |
| Wolf | Nettle leaf | P234605 | 10 |
| Wolf | Nettle leaf | B821 | 1 |
| Caelo | Nettle root | 11265003 | 2 |
| Caelo | Nettle root | 11254902 | 3 |
| Caelo | Nettle root | 11254904 | 3 |
| Caelo | Nettle root | 10081202 | 1 |
| Caelo | Nettle root | 11254903 | 5 |
| Caelo | Nettle root | 6631B130610 | 1 |
| Caelo | Nettle root | 11265006 | 1 |
| Caelo | Nettle root | 11265004 | 4 |
| Caelo | Nettle root | 11265002 | 5 |
| Gehe | Nettle root | 6631B120927 | 5 |
| Caelo | Nettle root | 6441A121024 | 1 |
| Klenk | Nettle root | 6631N110513 | 1 |
| Klenk | Nettle root | 6631B120416 | 1 |
| Klenk | Nettle root | 9931B120927 | 1 |
| Sanacorp | Nettle root | 11265001 | 2 |
| Caelo | Nettle seed | 20111301 | 1 |
| Caelo | Nettle seed | 12131507 | 2 |
| Caelo | Nettle seed | 12131505 | 1 |
| Caelo | Nettle seed | 13010612 | 2 |
| Caelo | Nettle seed | 17282601 | 1 |
| Caelo | Nettle seed | 16327001 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Nettle seed | 13010607 | 1 |
| Caelo | Nettle seed | 15261608 | 1 |
| Caelo | Nettle seed | 15290602 | 1 |
| Caelo | Nettle seed | 16327003 | 1 |
| Euro OTC | Nettle seed | 7470A141021 | 2 |
| Klenk | Nettle seed | 7470A110418 | 1 |
| Klenk | Nettle seed | 2021505 | 1 |
| Klenk | Nettle seed | 7470A151009 | 2 |
| Klenk | Nettle seed | 7470A160928 | 2 |
| Klenk | Nettle seed | 7470A170130 | 1 |
| Sanacorp | Nettle seed | 13010602 | 1 |
| Caelo | Nutmeg | 12376805 | 1 |
| Caelo | Nutmeg | 12376802 | 2 |
| Caelo | Nutmeg, powdered (spice) | 12102305 | 2 |
| Galke | Nutmeg, powdered (spice) | 22739 | 1 |
| Klenk | Nutmeg, powdered (spice) | A130304 | 2 |
| Klenk | Nutmeg, powdered (spice) | 7325A120903 | 2 |
| Klenk | Nutmeg, powdered (spice) | 7325A130304 | 1 |
| Klenk | Nutmeg, powdered (spice) | 7325A130515 | 1 |

## O

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Alte Apotheke | Oak bark | 15314904 | 4 |
| apomix | Oak bark | 9357419 | 2 |
| Bahnhof-Apotheke | Oak bark | 17-121106 | 1 |
| Berkel AHK | Oak bark | 13360310 | 1 |
| Bombastus | Oak bark | 265717 | 1 |
| Bombastus | Oak bark | 274392 | 1 |
| Bombastus | Oak bark | 272704 | 1 |
| Bombastus | Oak bark | 274611 | 1 |
| Bombastus | Oak bark | 279525 | 2 |
| Bombastus | Oak bark | 229090 | 1 |
| Bombastus | Oak bark | 286297 | 1 |
| Caelo | Oak bark | 13360302 | 6 |
| Caelo | Oak bark | 11351209 | 10 |
| Caelo | Oak bark | 123test | 1 |
| Caelo | Oak bark | 1135121o | 1 |
| Caelo | Oak bark | 10238612 | 1 |
| Caelo | Oak bark | 16081305 | 1 |
| Caelo | Oak bark | 5091302 | 1 |
| Caelo | Oak bark | 22081204 | 1 |
| Caelo | Oak bark | 3041301 | 1 |
| Caelo | Oak bark | 1081401 | 1 |
| Caelo | Oak bark | 7021302 | 1 |
| Caelo | Oak bark | 26081302 | 1 |
| Caelo | Oak bark | 14111316 | 1 |
| Caelo | Oak bark | 10061504 | 1 |
| Caelo | Oak bark | 15146110 | 1 |
| Caelo | Oak bark | 15146105 | 4 |
| Caelo | Oak bark | 11351208 | 3 |
| Caelo | Oak bark | 12221105 | 2 |
| Caelo | Oak bark | 10348613 | 2 |
| Caelo | Oak bark | 161212 | 1 |
| Caelo | Oak bark | 280814A | 1 |
| Caelo | Oak bark | 11351203 | 1 |
| Caelo | Oak bark | 14277004 | 1 |
| Caelo | Oak bark | 13360301 | 1 |
| Caelo | Oak bark | 10348612 | 1 |
| Caelo | Oak bark | 10348615 | 1 |
| Caelo | Oak bark | 19032013 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Oak bark | 15146103 | 1 |
| Caelo | Oak bark | 13360304 | 1 |
| Caelo | Oak bark | 15314906 | 1 |
| Caelo | Oak bark | 18014702 | 1 |
| Caelo | Oak bark | 19133902 | 1 |
| Caelo | Oak bark | 15314912 | 3 |
| Caelo | Oak bark | 13360311 | 1 |
| Caelo | Oak bark | 14277004 | 2 |
| Caelo | Oak bark | 13360309 | 1 |
| Caelo | Oak bark | 15314904 | 1 |
| Caelo | Oak bark | 15146110 | 1 |
| Caelo | Oak bark | 41109-4-P | 1 |
| Caelo | Oak bark | 501919 | 1 |
| Caelo | Oak bark | 11351207 | 11 |
| Caelo | Oak bark | 18014701 | 1 |
| Caelo | Oak bark | 15314903 | 1 |
| Caelo | Oak bark | 15146109 | 2 |
| Caelo | Oak bark | 11351210 | 8 |
| Caelo | Oak bark | 11351207-3384310110 | 1 |
| Caelo | Oak bark | 15146105 | 1 |
| Caelo | Oak bark | 14277004 | 1 |
| Caelo | Oak bark | 13360305 | 1 |
| Caelo | Oak bark | 13360308 | 1 |
| Caelo | Oak bark | 15314910 | 6 |
| Caelo | Oak bark | 15314908 | 2 |
| Caelo | Oak bark | 11351201 | 3 |
| Caelo | Oak bark | 11351206 | 13 |
| Caelo | Oak bark | 15146102 | 1 |
| Caelo | Oak bark | 15146101 | 2 |
| Caelo | Oak bark | 13360306 | 2 |
| Caelo | Oak bark | 12221101 | 9 |
| Caelo | Oak bark | 10348605 | 1 |
| Caelo | Oak bark | 10348616 | 6 |
| Caelo | Oak bark | 16305701 | 1 |
| Caelo | Oak bark | 15314901 | 1 |
| Caelo | Oak bark | 15314911 | 1 |
| Caelo | Oak bark | 15146104 | 4 |
| Caelo | Oak bark | 13360312 | 5 |
| Caelo | Oak bark | 12221102 | 1 |
| Caelo | Oak bark | 13360303 | 1 |
| Caelo | Oak bark | 13360306 | 1 |
| Caelo | Oak bark | 15314905 | 3 |
| Caelo | Oak bark | 12221104 | 2 |
| Caelo | Oak bark | 11351205 | 3 |
| Euro OTC | Oak bark | | 1 |
| Galke | Oak bark | 17824 | 2 |
| Gehe | Oak bark | 10348609 | 2 |
| GEHE 10.03.2014 | Oak bark | 761A11816 | 1 |
| Klenk | Oak bark | C-280513-2 | 1 |
| Klenk | Oak bark | 761A110816 | 1 |
| Klenk | Oak bark | 761A090420 | 1 |
| Klenk | Oak bark | 761A110816 | 10 |
| Noweda | Oak bark | 10348617 | 8 |
| Klenk | Oak bark | 761A110816 | 1 |
| Phönix | Oak bark | 11351202 | 5 |
| Caelo | Oak bark, powdered | 10261513 | 1 |
| Caelo | Oat straw | 11280008 | 2 |
| Caelo | Oat straw | 11280014 | 1 |
| Caelo | Oat straw | 11280015 | 3 |
| Caelo | Oat straw | 11280012 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Oat straw | 11280017 | 2 |
| Noweda | Oat straw | 11280003 | 1 |
| Caelo | Olive leaf | 12159805 | 1 |
| Caelo | Olive leaf | 18100501 | 1 |
| Caelo | Olive leaf | 15254406 | 1 |
| Klenk | Olive leaf | 2211B131025 | 1 |
| Klenk | Olive leaf | 2211B120417 | 2 |
| Klenk | Olive leaf | 2211B130425 | 3 |
| Klenk | Olive leaf | 2211B150818 | 1 |
| Klenk | Orange peel, cut | 531A130204 | 5 |
| Klenk | Orange peel, cut | 531A091125 | 3 |
| Klenk | Orange peel, cut | 531a130204 | 1 |
| Caelo | Oregano herb | 12360904 | 1 |
| Caelo | Oregano herb | 12360902 | 3 |
| Caelo | Oregano herb | 11340705 | 1 |
| Caelo | Oregano herb | 12360901 | 6 |
| Caelo | Oregano herb | 11340703 | 2 |
| Caelo | Oregano herb | 11340709 | 1 |
| Caelo | Oregano herb | 11340708 | 1 |
| Klenk | Oregano herb | 4221A120315 | 2 |
| Caelo | Orris root | 11026706 | 1 |
| Caelo | Orris root | 11026704 | 2 |
| Caelo | Orris root | 13113401 | 2 |
| Caelo | Orris root | 1026706 | 1 |
| Caelo | Orris root | 13113404 | 1 |
| Fagron | Orris root | 11026705 | 3 |
| Galke | Orris root | 21303 | 1 |
| Klenk | Orris root | B130102 | 1 |
| Klenk | Orris root | B111013 | 1 |
| Klenk | Orris root | 6831B111013 | 1 |
| Sanacorp | Orris root | 11026701 | 1 |
| Caelo | Orris root | 13113402 | 1 |
| Caelo | Oxycodone hydrochloride | 17270202 | 2 |
| Caelo | Oxycodone hydrochloride | 12268912 | 1 |
| Caelo | Oxycodone hydrochloride | 15220205 | 1 |

## P

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Pale coneflower root | 11115206 | 1 |
| Caelo | Pale coneflower root | 12244504 | 1 |
| Caelo | Pancreas powder | 17322611 | 1 |
| Caelo | Pancreas powder | 17322602 | 1 |
| Caelo | Parsley herb, rubbed | 12376601 | 2 |
| Caelo | Parsley herb, rubbed | 12376602 | 2 |
| Caelo | Parsley herb, rubbed | 51978126 | 1 |
| Caelo | Parsley herb, rubbed | 12376603 | 2 |
| Caelo | Parsley root | 12080304 | 1 |
| Caelo | Parsley root | 12080309 | 1 |
| Caelo | Parsley root | 13156003 | 1 |
| Caelo | Parsley root | 13156005 | 1 |
| Caelo | Parsley root | 6441A120606 | 5 |
| Gahlke | Parsley root | 20872 | 1 |
| Gehe | Parsley root | 6441A110210 | 3 |
| Klenk | Parsley root | 6441A121024 | 4 |
| Klenk | Parsley root | 6441A150811 | 1 |
| Klenk | Parsley root | 6441A120283 | 1 |
| Caelo | Parsley seed | PrüfNr.2814A-01550 | 1 |
| Klenk | Parsley seed | 7370A09120 | 1 |
| Klenk | Parsley seed | 7370A091120 | 2 |
| an | Passionflower herb | 13141212 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Anzag | Passionflower herb | 1207211669 | 1 |
| Caelo | Passionflower herb | 12101301 | 1 |
| Caelo | Passionflower herb | 15085105 | 1 |
| Caelo | Passionflower herb | 13141203 | 2 |
| Caelo | Passionflower herb | 11049108 | 1 |
| Caelo | Passionflower herb | 1011A-01669 | 1 |
| Caelo | Passionflower herb | 11049116 | 4 |
| Caelo | Passionflower herb | 12031701 | 1 |
| Caelo | Passionflower herb | 13141201 | 1 |
| Caelo | Passionflower herb | 12031712 | 1 |
| Caelo | Passionflower herb | 12031704 | 1 |
| Caelo | Passionflower herb | 12031706 | 3 |
| Caelo | Passionflower herb | 12031703 | 2 |
| Caelo | Passionflower herb | 11049111 | 1 |
| Caelo | Passionflower herb | 13141202 | 7 |
| Caelo | Passionflower herb | 12031710 | 13 |
| Caelo | Passionflower herb | 12031716 | 3 |
| Caelo | Passionflower herb | 12031715 | 7 |
| Caelo | Passionflower herb | 12031705 | 4 |
| Caelo | Passionflower herb | 13141205 | 4 |
| Caelo | Passionflower herb | 12031714 | 2 |
| Caelo | Passionflower herb | 12031717 | 9 |
| Klenk | Passionflower herb | A120329 | 2 |
| Klenk | Passionflower herb | 4231A-110913 | 1 |
| Klenk | Passionflower herb | 4231A120329 | 2 |
| Klenk | Peony root, cut | 6421B120327 | 1 |
| Klenk | Peony root, cut | B110916 | 2 |
| Caelo | Pepper | 12192305 | 1 |
| Caelo | Pepper | 12192306 | 1 |
| Caelo | Pepper | 12192309 | 1 |
| Caelo | Pepper | 12192304 | 1 |
| Caelo | Pepper | 11193911 | 1 |
| Caelo | Pepper | 15395310 | 1 |
| Caelo | Pepper | 13221110 | 1 |
| Klenk | Pepper | A130415 | 2 |
| PHOENIX 19.05.2014 | Pepper | 13221105 | 1 |
| Bombast | Peppermint leaf | 278679 | 2 |
| Bombastus | Peppermint leaf | 279634 | 1 |
| Bombastus | Peppermint leaf | 266772 | 2 |
| Bombastus | Peppermint leaf | 246514 | 1 |
| Bombastus | Peppermint leaf | 281043 | 3 |
| Bombastus | Peppermint leaf | 285914 | 1 |
| Bombastus | Peppermint leaf | 271499 | 1 |
| Bombastus | Peppermint leaf | 281282 | 1 |
| Bombastus | Peppermint leaf | 272956 | 3 |
| Bombastus | Peppermint leaf | 279214 | 1 |
| Bombastus | Peppermint leaf | 276514 | 1 |
| Bombastus | Peppermint leaf | 286105 | 1 |
| Bombastus | Peppermint leaf | 275295 | 3 |
| Bombastus | Peppermint leaf | 279914 | 2 |
| Bombastus | Peppermint leaf | 255719 | 1 |
| Bombastus | Peppermint leaf | 282509 | 1 |
| Caelo | Peppermint leaf | 20061202 | 1 |
| Caelo | Peppermint leaf | 14339202 | 2 |
| Caelo | Peppermint leaf | 12266903 | 5 |
| Caelo | Peppermint leaf | 14083102 | 2 |
| Caelo | Peppermint leaf | 13030806 | 1 |
| Caelo | Peppermint leaf | 2181B090928 | 1 |
| Caelo | Peppermint leaf | 5091307 | 1 |
| Caelo | Peppermint leaf | 20111215 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Peppermint leaf | 8101301 | 1 |
| Caelo | Peppermint leaf | 6011403 | 1 |
| Caelo | Peppermint leaf | 14221701 | 1 |
| Caelo | Peppermint leaf | 161212 | 1 |
| Caelo | Peppermint leaf | 11327803 | 5 |
| Caelo | Peppermint leaf | 13214720 | 1 |
| Caelo | Peppermint leaf | 1132803 | 1 |
| Caelo | Peppermint leaf | 12266908 | 8 |
| Caelo | Peppermint leaf | 13030804 | 1 |
| Caelo | Peppermint leaf | 13030809 | 2 |
| Caelo | Peppermint leaf | 13214706 | 1 |
| Caelo | Peppermint leaf | 12266912 | 1 |
| Caelo | Peppermint leaf | 13030808 | 1 |
| Caelo | Peppermint leaf | 12032311 | 1 |
| Caelo | Peppermint leaf | 11294409 | 2 |
| Caelo | Peppermint leaf | 11327801 | 2 |
| Caelo | Peppermint leaf | Int.Ch.:313011 | 1 |
| Caelo | Peppermint leaf | ChB:311092 | 1 |
| Caelo | Peppermint leaf | 13214707 | 3 |
| Caelo | Peppermint leaf | 268320 | 1 |
| Caelo | Peppermint leaf | 12054149 | 1 |
| Caelo | Peppermint leaf | 13030807 | 3 |
| Caelo | Peppermint leaf | 11294401 | 3 |
| Caelo | Peppermint leaf | 13214705 | 1 |
| Caelo | Peppermint leaf | 12266904 | 3 |
| Caelo | Peppermint leaf | 11347609 | 1 |
| Caelo | Peppermint leaf | 2181A1209-13 | 1 |
| Caelo | Peppermint leaf | 12032319 | 2 |
| Caelo | Peppermint leaf | 13030805 | 5 |
| Caelo | Peppermint leaf | 12266913 | 9 |
| Caelo | Peppermint leaf | 13105001 | 1 |
| Caelo | Peppermint leaf | 13030803 | 3 |
| Caelo | Peppermint leaf | 17292709 | 1 |
| Caelo | Peppermint leaf | 17117806 | 1 |
| Caelo | Peppermint leaf | 18287701 | 1 |
| Caelo | Peppermint leaf | 17292702 | 1 |
| Caelo | Peppermint leaf | 13030808-3401310161 | 1 |
| Caelo | Peppermint leaf | 12266908-343431160 | 1 |
| Caesar & Loretz GmbH | Peppermint leaf | 11294411 | 1 |
| Fagron | Peppermint leaf | 1234567 | 2 |
| Galke | Peppermint leaf | 22783 | 3 |
| Galke | Peppermint leaf | 20975 | 3 |
| Galke | Peppermint leaf | 22218 | 1 |
| Gehe | Peppermint leaf | 2181B130717B | 1 |
| Gehe | Peppermint leaf | 2181B130717A | 1 |
| Klenk | Peppermint leaf | 2181A110512 | 5 |
| HiperScan | Peppermint leaf | | 1 |
| Klenk | Peppermint leaf | 2181B130717 | 10 |
| Klenk | Peppermint leaf | 2181A13020 | 1 |
| Klenk | Peppermint leaf | 2181A101013 | 6 |
| Klenk | Peppermint leaf | 2181A151119 | 1 |
| Klenk | Peppermint leaf | 1209211505 | 1 |
| Klenk | Peppermint leaf | 1913A-01505 | 1 |
| Klenk | Peppermint leaf | 1001311505 | 1 |
| Klenk | Peppermint leaf | 2161A120718 | 3 |
| Klenk | Peppermint leaf | 2161A130806 | 7 |
| Klenk | Peppermint leaf | 2181A130320 | 6 |
| Klenk | Peppermint leaf | 216A121029 | 1 |
| Klenk | Peppermint leaf | 2161 | 1 |
| Klenk | Peppermint leaf | A121009 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Peppermint leaf | A130806 | 1 |
| Klenk | Peppermint leaf | 2181A-101013 | 1 |
| Klenk | Peppermint leaf | 2183A120913 | 2 |
| Klenk | Peppermint leaf | 2161A110207 | 1 |
| Klenk | Peppermint leaf | 2161B140321 | 1 |
| Klenk | Peppermint leaf | 2161A111207 | 1 |
| Klenk | Peppermint leaf | CH.2161B080818 | 1 |
| Klenk | Peppermint leaf | 2181a120913 | 3 |
| Klenk | Peppermint leaf | 2181A120913 | 34 |
| Klenk | Peppermint leaf | 2181A190508-06 | 1 |
| Klenk | Peppermint leaf | 2161A121029 | 17 |
| Klenk | Peppermint leaf | 4513E1503 | 1 |
| Klenk | Peppermint leaf | 2161A07020203 | 1 |
| Klenk | Peppermint leaf | 2181A100323 | 1 |
| Klenk | Peppermint leaf | 2181A-120913 | 1 |
| Klenk | Peppermint leaf | 2161A121009 | 6 |
| Klenk | Peppermint leaf | 4113Q1505 | 1 |
| Klenk | Peppermint leaf | 2181A190508 | 2 |
| Klenk | Peppermint leaf | 2181a171109 | 1 |
| Klenk | Peppermint leaf | 2181A171025 | 1 |
| Klenk | Peppermint leaf | 2181B180727 | 2 |
| Klenk | Peppermint leaf | 2181A180130 | 2 |
| Klenk | Peppermint leaf | 2161A121206 | 14 |
| Klenk | Peppermint leaf | 2161A-121206 | 1 |
| Kräuter-Schulte | Peppermint leaf | 56254 | 1 |
| nachprüfung | Peppermint leaf | C1327 | 1 |
| Noweda | Peppermint leaf | 2911U-01505 | 1 |
| Bombastus | Peppermint leaf | 273843 | 2 |
| Phönix | Peppermint leaf | 11327808 | 3 |
| Probe | Peppermint leaf | 1223456 | 1 |
| Wolf | Peppermint leaf | P221379 | 7 |
| Wolf | Peppermint leaf | B-185 | 5 |
| Wolf | Peppermint leaf | B-120 | 1 |
| Wolf | Peppermint leaf | B-725 | 2 |
| Wolf | Peppermint leaf | B243 | 1 |
| Wolf | Peppermint leaf | B725 | 1 |
|  | Phenobarbital | 22D19-F03-384178 | 2 |
|  | Phenobarbital | 21K03-F02-385153 | 1 |
| Fagron | Phenobarbital | 13G05-N09 | 1 |
| Fagron | Phenobarbital | 21A19-F02-376671 | 5 |
| Fagron | Phenobarbital | B01-3639508 | 1 |
| Fagron | Phenobarbital | 15G07-B06-311718 | 1 |
| Fagron | Phenobarbital | 18H15-B01-354934 | 2 |
| Fagron | Phenobarbital | 16G20-B04-328344 | 3 |
| Fagron | Phenobarbital | F02-3766701 | 1 |
| Fagron | Phenobarbital | 19G23-B01-363958 | 1 |
| Fagron | Phenobarbital | B01-3655903 | 1 |
| Fagron | Phenobarbital | 18C07-B01-347288 | 4 |
| Fagron | Phenobarbital | 19G23-B01 | 1 |
| Fagron | Phenobarbital | 15I18-B08-318544 | 1 |
| Fagron | Phenobarbital | 21A19-F02 | 3 |
| Fagron | Phenobarbital | 19G23-B01-363364 | 1 |
| Fagron | Phenobarbital | B01-3549304 | 1 |
| Fagron | Phenobarbital | 19G23-B01-365593 | 3 |
| Th. Geyer | Phenobarbital | 70510 | 17 |
| Th. Geyer | Phenobarbital | 67045 | 3 |
| Th. Geyer | Phenobarbital | 67056 | 5 |
| Caelo | Phenol | 11163802 | 1 |
| Caelo | Phenol | 7061305 | 1 |
| Caelo | Phenol | 12223014 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Phenol | 11163809 | 1 |
| Caelo | Phenol | 11163801 | 1 |
| Caelo | Phenol | 12223020 | 1 |
| Caelo | Phenol | 12223022 | 1 |
| Caelo | Phenol | 12223001 | 1 |
| Caelo | Piper cubeba | 11081903 | 1 |
| Caelo | Podophyllum resin (from pod… | 12287805 | 1 |
| Caelo | Podophyllum resin (from pod… | 11085811 | 1 |
| Caelo | Podophyllum resin (from pod… | 11085807 | 4 |
| Caelo | Podophyllum resin (from pod… | 12379903 | 1 |
| Caelo | Podophyllum resin (from pod… | 12287810 | 1 |
| Caelo | Podophyllum resin (from pod… | 82433349 | 1 |
| | Potassium hydrogen tartrate | 22001645002 | 1 |
| Bären Apotheke | Potassium hydrogen tartrate | 15354613 | 3 |
| Caelo | Potassium hydrogen tartrate | 15354601 | 1 |
| Caelo | Potassium hydrogen tartrate | 13030006 | 2 |
| Caelo | Potassium hydrogen tartrate | 18205107 | 2 |
| Caelo | Potassium hydrogen tartrate | 15354614 | 2 |
| Caelo | Potassium hydrogen tartrate | 17061303 | 1 |
| Caelo | Potassium hydrogen tartrate | 11345807 | 1 |
| Caelo | Potassium hydrogen tartrate | 1534609 | 1 |
| Caelo | Potassium hydrogen tartrate | 15354609 | 4 |
| Caelo | Potassium hydrogen tartrate | 23062015A | 1 |
| Caelo | Potassium hydrogen tartrate | 17065603 | 2 |
| Caelo | Potassium hydrogen tartrate | 13133126 | 1 |
| Caelo | Potassium hydrogen tartrate | 18205104 | 1 |
| Caelo | Potassium hydrogen tartrate | 20004282003 | 2 |
| Caelo | Potassium hydrogen tartrate | 18205106 | 1 |
| Caelo | Potassium hydrogen tartrate | 11127417 | 1 |
| Caelo | Potassium hydrogen tartrate | 13133114 | 1 |
| Caelo | Potassium hydrogen tartrate | 15081005 | 1 |
| Caelo | Potassium hydrogen tartrate | 15081008 | 2 |
| Caelo | Potassium hydrogen tartrate | 15081010 | 3 |
| Caelo | Potassium hydrogen tartrate | 13133104 | 2 |
| Caelo | Potassium hydrogen tartrate | 160514b | 1 |
| Caelo | Potassium hydrogen tartrate | 90573259 | 1 |
| Caelo | Potassium hydrogen tartrate | 13133120 | 2 |
| Caesar & Loretz GmbH | Potassium hydrogen tartrate | 182051002 | 1 |
| Caesar & Loretz GmbH | Potassium hydrogen tartrate | 18205101 | 7 |
| Caesar & Loretz GmbH | Potassium hydrogen tartrate | 18205105 | 1 |
| Caesar & Loretz GmbH | Potassium hydrogen tartrate | 17366002 | 1 |
| Caleo/ Noweda | Potassium hydrogen tartrate | 18205103 | 3 |
| Gehe | Potassium hydrogen tartrate | 11345808 | 1 |
| Hänseler | Potassium hydrogen tartrate | 2020.01.0154 | 1 |
| Hänseler | Potassium hydrogen tartrate | 2020.12.0138 | 1 |
| Hänseler | Potassium hydrogen tartrate | 2018.12.0068 | 1 |
| Hänseler | Potassium hydrogen tartrate | 2021.10.0154 | 1 |
| Hänseler | Potassium hydrogen tartrate | 2019.03.0574 | 1 |
| Hänseler | Potassium hydrogen tartrate | 2020.07.0244 | 1 |
| Lamotte/Phönix | Potassium hydrogen tartrate | 17065602 | 1 |
| phönix | Potassium hydrogen tartrate | 15354604 | 4 |
| Sanacorp | Potassium hydrogen tartrate | 20001056005 | 2 |
| Sanacorp | Potassium hydrogen tartrate | 20001056003 | 2 |
| Sanacorp | Potassium hydrogen tartrate | 14115208 | 4 |
| Caelo | Potassium hydroxide | 12382606 | 2 |
| Caelo | Potassium hydroxide | 12057912 | 2 |
| Caelo | Potassium hydroxide | 13275201 | 2 |
| Caelo | Potassium hydroxide | 27111310 | 1 |
| Caelo | Potassium hydroxide | 17091202 | 1 |
| Caelo | Potassium hydroxide | 12057906 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Potassium hydroxide | 11165708 | 1 |
| Caelo | Potassium hydroxide | 12382611 | 1 |
| Caelo | Potassium hydroxide | 12382601 | 2 |
| Caelo | Potassium hydroxide | 11165705 | 1 |
| Caelo | Potassium hydroxide | 12057905 | 1 |
| Caelo | Potassium hydroxide | 12057908 | 2 |
| Caelo | Potassium hydroxide | 13275207 | 1 |
| Caesar & Loretz Gm… | Potassium hydroxide | 12057902 | 2 |
| Caelo | Potassium hydroxide | 12382603 | 4 |
| Caelo | Potassium sodium tartrate t… | 15375601 | 12 |
| Caelo | Potassium sodium tartrate t… | 17257701 | 4 |
| Caelo | Potassium tartrate hemihydrate | 17176007 | 1 |
| Caelo | Potassium tartrate hemihydrate | 17176004 | 1 |
| Caelo | Potassium tartrate hemihydrate | 19051804 | 1 |
| Caelo | Potassium tartrate hemihydrate | 27061304 | 1 |
| Caelo | Potassium tartrate hemihydrate | 13111415 | 1 |
| Caelo | Potassium tartrate hemihydrate | 24061705 | 1 |
| Caelo | Potassium tartrate hemihydrate | 11225007 | 1 |
| Caelo | Potassium tartrate hemihydrate | 193079002 | 1 |
| Caelo | Potassium tartrate hemihydrate | 12322110 | 1 |
| Caelo | Potassium tartrate hemihydrate | 15167703 | 1 |
| Caelo | Potassium tartrate hemihydrate | 13331113 | 1 |
| Caelo | Potassium tartrate hemihydrate | 193079004 | 1 |
| Caelo | Potassium tartrate hemihydrate | 18220301 | 2 |
| Caelo | Potassium tartrate hemihydrate | 17176002 | 2 |
| Caelo | Potassium tartrate hemihydrate | 18220305 | 2 |
| Caelo | Potassium tartrate hemihydrate | 17176001 | 2 |
| Alliance | Primrose flower | 11374401 | 10 |
| Aurica / 11 | Primrose flower | 521301234 | 1 |
| Aurica/Gehe | Primrose flower | 521203308 | 1 |
| Caelo | Primrose flower | 13086603 | 5 |
| Caelo | Primrose flower | 1308660 | 1 |
| Caelo | Primrose flower | 13086602 | 3 |
| Caelo | Primrose flower | 25091306 | 1 |
| Caelo | Primrose flower | 9021301 | 1 |
| Caelo | Primrose flower | 5021303 | 1 |
| Caelo | Primrose flower | 11374403 | 1 |
| Caelo | Primrose flower | 13276904 | 1 |
| Caelo | Primrose flower | 13086608 | 1 |
| Caelo | Primrose flower | 11206811 | 4 |
| Caelo | Primrose flower | 11206808 | 1 |
| Caelo | Primrose flower | 11206811 | 1 |
| Caelo | Primrose flower | 11206807 | 1 |
| Caelo | Primrose flower | 11374404 | 1 |
| Caelo | Primrose flower | 113744044 | 1 |
| Caelo | Primrose flower | 11374402 | 1 |
| Caelo | Primrose flower | 11206810 | 5 |
| Caelo | Primrose flower | 13086603 | 1 |
| Caelo | Primrose flower | 13086602 | 5 |
| Caelo | Primrose flower | 11206804 | 1 |
| Caelo | Primrose flower | 11206803 | 4 |
| Caelo | Primrose flower | 10207104 | 1 |
| Caelo | Primrose flower | 10072509 | 1 |
| Galke | Primrose flower | 22612 | 2 |
| Gehe | Primrose flower | 11374401 | 1 |
| Hepart AG | Primrose flower | 11374403 | 3 |
| Caelo | Primrose flower | 13086605 | 1 |
| Klenk | Primrose flower | 1541B100414 | 1 |
| Klenk | Primrose flower | B130808 | 1 |
| Klenk | Primrose flower | B110314 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Primrose flower | A111018 | 1 |
| Klenk | Primrose flower | B130808 | 1 |
| Klenk | Primrose flower | 1540A-100907 | 1 |
| Klenk | Primrose flower | 1540A100907 | 1 |
| Klenk | Primrose flower | 1541B130808 | 6 |
| Klenk | Primrose flower | 1541B110314 | 7 |
| VDL | Primrose flower | 11206806 | 1 |
| Weltecke / GEHE | Primrose flower | 63011112 | 1 |
| Caelo | Primrose root, cut | 13087005 | 3 |
| Caelo | Primrose root, cut | 12064506 | 4 |
| Caelo | Primrose root, cut | 24011301 | 1 |
| Caelo | Primrose root, cut | 4021410 | 1 |
| Caelo | Primrose root, cut | 5010E-02159 | 1 |
| Caelo | Primrose root, cut | 10382009 | 1 |
| Caelo | Primrose root, cut | 12064503 | 1 |
| Caelo | Primrose root, cut | 10382013 | 1 |
| Caelo | Primrose root, cut | 13087004 | 1 |
| Caelo | Primrose root, cut | 10382012 | 1 |
| Caelo | Primrose root, cut | Int.Ch:318090 | 1 |
| Caelo | Primrose root, cut | 10382010 | 1 |
| Caelo | Primrose root, cut | 13067001 | 1 |
| Caelo | Primrose root, cut | 13087001 | 1 |
| Caelo | Primrose root, cut | 71653517 | 1 |
| Caelo | Primrose root, cut | 13087005-3534411072 | 1 |
| Caelo | Primrose root, cut | 13087002 | 4 |
| Klenk | Primrose root, cut | B130218 | 3 |
| Klenk | Primrose root, cut | 6461A100511 | 1 |
| Noweda | Primrose root, cut | 12064504 | 4 |
| Caelo | Promethazine hydrochloride | 11352305 | 1 |
| Caelo | Promethazine hydrochloride | 19051805 | 1 |
| Caelo | Promethazine hydrochloride | 17058601 | 2 |
| Caelo | Promethazine hydrochloride | 13119211 | 1 |
| Audor Pharma | Psyllium seed | 15190313 | 2 |
| Bahnhof-Apotheke | Psyllium seed | 3-121005 | 1 |
| Caelo | Psyllium seed | 13305906 | 2 |
| Caelo | Psyllium seed | 13305904 | 2 |
| Caelo | Psyllium seed | 12140301 | 7 |
| Caelo | Psyllium seed | 10291204 | 1 |
| Caelo | Psyllium seed | 12185504 | 10 |
| Caelo | Psyllium seed | 12185508 | 4 |
| Caelo | Psyllium seed | 13305903 | 1 |
| Caelo | Psyllium seed | 10061503 | 1 |
| Caelo | Psyllium seed | 10291205 | 1 |
| Caelo | Psyllium seed | 13305910 | 4 |
| Caelo | Psyllium seed | 12276510 | 1 |
| Caelo | Psyllium seed | 10291206 | 1 |
| Caelo | Psyllium seed | 12185509 | 5 |
| Caelo | Psyllium seed | 13234310 | 3 |
| Caelo | Psyllium seed | 10291207 | 6 |
| Caelo | Psyllium seed | 15190304 | 3 |
| Caelo | Psyllium seed | 12185503 | 3 |
| Caelo | Psyllium seed | 13234309 | 1 |
| Caelo | Psyllium seed | 7380a120911 | 1 |
| Caelo | Psyllium seed | 11185803 | 1 |
| Caelo | Psyllium seed | 15321007 | 1 |
| Caelo | Psyllium seed | 15190306 | 2 |
| Caelo | Psyllium seed | 12185502 | 1 |
| Caesar/Noweda | Psyllium seed | 12276501 | 3 |
| Caesar/Noweda | Psyllium seed | 11185817 | 3 |
| Galke | Psyllium seed | 22989 | 7 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Galke | Psyllium seed | 20968 | 2 |
| Hedinger/Sanacorp | Psyllium seed | 15190303 | 4 |
| Klenk | Psyllium seed | 7380A130128 | 6 |
| Klenk | Psyllium seed | 7380A150520 | 7 |
| Klenk | Psyllium seed | 7380A120109 | 24 |
| Klenk | Psyllium seed | A120109 | 1 |
| Klenk | Psyllium seed | A130128 | 1 |
| Klenk | Psyllium seed | A120911 | 1 |
| Klenk | Psyllium seed | 7560A130418 | 1 |
| Klenk | Psyllium seed | 7380A161018 | 2 |
| Klenk | Psyllium seed | 7380A150929 | 4 |
| Klenk | Psyllium seed | 7560a120330 | 1 |
| Klenk | Psyllium seed | 7380A110317 | 1 |
| Klenk | Psyllium seed | 7380A111018 | 1 |
| Klenk | Psyllium seed | 7380A120911 | 16 |
| Klenk | Psyllium seed | 7380a120109 | 3 |
| Klenk | Psyllium seed | 7380a111018 | 1 |
| Klenk | Psyllium seed | 7560A140203 | 1 |
| Rondell Apotheke | Psyllium seed | 13305907 | 5 |
| Caelo | Psyllium seed | 11185811 | 4 |
| Allianz Healthcare | Pumpkin seed | 16081210 | 1 |
| Caelo | Pumpkin seed | 16081202 | 1 |
| Caelo | Pumpkin seed | 14186910 | 1 |
| Caelo | Pumpkin seed | 14186905 | 1 |
| Caelo | Pumpkin seed | 12249001 | 2 |
| Caelo | Pumpkin seed | 140736306 | 1 |
| Caelo | Pumpkin seed | 122490911 | 1 |
| Caelo | Pumpkin seed | 14073603 | 1 |
| Caelo | Pumpkin seed | 12249011 | 2 |
| sanacorp | Pumpkin seed | 14186909 | 1 |
| Sanacorp | Pumpkin seed | 16081206 | 2 |
| Sanacorp | Pumpkin seed | 16081212 | 1 |

## Q

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Quinolinol sulfate potassiu… | 16221809 | 6 |
| Caelo | Quinolinol sulfate potassiu… | 15147701 | 3 |
| Caelo | Quinolinol sulfate potassiu… | 13403513 | 2 |
| Caelo | Quinolinol sulfate potassiu… | 13403501 | 3 |
| Caelo | Quinolinol sulfate potassiu… | 7051305 | 1 |
| Caelo | Quinolinol sulfate potassiu… | 13403501 | 4 |
| Caelo | Quinolinol sulfate potassiu… | 15147714 | 1 |
| Caelo | Quinolinol sulfate potassiu… | 13071101 | 2 |
| Caelo | Quinolinol sulfate potassiu… | 13071104 | 4 |
| Caelo | Quinolinol sulfate potassiu… | 10281601 | 1 |
| Caelo | Quinolinol sulfate potassiu… | 15147708 | 4 |
| Caelo | Quinolinol sulfate potassiu… | 9106304 | 1 |
| Caelo | Quinolinol sulfate potassiu… | 16221807 | 6 |
| Caelo | Quinolinol sulfate potassiu… | 15147704 | 4 |
| Caelo | Quinolinol sulfate potassiu… | 13071106 | 2 |
| Caelo | Quinolinol sulfate potassiu… | 16221811 | 2 |
| Dermapharm | Quinolinol sulfate potassiu… | 140804 | 83 |
| Dermapharm | Quinolinol sulfate potassiu… | 100804 | 12 |
| Dermapharm | Quinolinol sulfate potassiu… | 1470804 | 1 |
| Dermapharm | Quinolinol sulfate potassiu… | 120905 | 43 |
| Ebert-Jacobi | Quinolinol sulfate potassiu… | 16221804 | 3 |
| GEHE | Quinolinol sulfate potassiu… | 15147706 | 6 |
| Gehe amax | Quinolinol sulfate potassiu… | 13403506 | 15 |
| Lieber Leyh | Quinolinol sulfate potassiu… | 1605110096 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Nachprüfung | Quinolinol sulfate potassiu… | 2812U03423 | 1 |
| Nachprüfung | Quinolinol sulfate potassiu… | 13071104 | 1 |
| Nachprüfung | Quinolinol sulfate potassiu… | 120905 | 10 |
| Noweda | Quinolinol sulfate potassiu… | 140804 | 2 |

**R**

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ramsons herb | 11182207 | 1 |
| Caelo | Ramsons herb | 12380801 | 2 |
| Caelo | Ramsons herb | 11182204 | 1 |
| Caelo | Ramsons herb | 12380803 | 1 |
| Caelo | Ramsons herb | 11182203 | 1 |
| Caelo | Ramsons herb | 12380802 | 2 |
| Caelo | Ramsons herb | 14343305 | 1 |
| Klenk | Ramsons herb | 3511B111005 | 2 |
| Klenk | Ramsons herb | 712914 | 1 |
| - | Raspberry leaf | 130849 | 1 |
| AHD | Raspberry leaf | 300696 | 1 |
| Alfred Galke | Raspberry leaf | 19851 | 1 |
| Alliance Health 23… | Raspberry leaf | 13101604 | 3 |
| an | Raspberry leaf | 13086708 | 1 |
| Caelo | Raspberry leaf | 1236705 | 1 |
| Caelo | Raspberry leaf | 10136412 | 1 |
| Bahnhof-Apotheke | Raspberry leaf | 17-120917 | 1 |
| Bombastus | Raspberry leaf | 279686 | 3 |
| Bombastus | Raspberry leaf | 274507 | 1 |
| Bombastus | Raspberry leaf | 269870 | 1 |
| Bombastus | Raspberry leaf | 291500 | 1 |
| Bombastus | Raspberry leaf | 272898 | 1 |
| Bombastus | Raspberry leaf | 273778 | 1 |
| Bombastus | Raspberry leaf | 248586 | 1 |
| Bombastus | Raspberry leaf | 273668 | 2 |
| Bombastus | Raspberry leaf | 267122 | 1 |
| Caelo | Raspberry leaf | 1310603 | 1 |
| Caelo | Raspberry leaf | 12103108 | 8 |
| Caelo | Raspberry leaf | 13038003 | 1 |
| Caelo | Raspberry leaf | 12362710 | 14 |
| Caelo | Raspberry leaf | 2909211511 | 1 |
| Caelo | Raspberry leaf | 307211511 | 1 |
| Caelo | Raspberry leaf | 12103105 | 18 |
| Caelo | Raspberry leaf | 12103101 | 7 |
| Caelo | Raspberry leaf | 12362703 | 10 |
| Caelo | Raspberry leaf | 12103107 | 11 |
| Caelo | Raspberry leaf | 11071301 | 1 |
| Caelo | Raspberry leaf | 30011408 | 1 |
| Caelo | Raspberry leaf | 9081205 | 1 |
| Caelo | Raspberry leaf | 20081311 | 1 |
| Caelo | Raspberry leaf | 8031307 | 1 |
| Caelo | Raspberry leaf | 11121201 | 1 |
| Caelo | Raspberry leaf | 17121203 | 1 |
| Caelo | Raspberry leaf | 9101204 | 1 |
| Caelo | Raspberry leaf | 7011402 | 1 |
| Caelo | Raspberry leaf | 18101203 | 1 |
| Caelo | Raspberry leaf | 18041304 | 1 |
| Caelo | Raspberry leaf | 21051302 | 1 |
| Caelo | Raspberry leaf | 25091201 | 1 |
| Caelo | Raspberry leaf | 22081201 | 1 |
| Caelo | Raspberry leaf | 9011404 | 1 |
| Caelo | Raspberry leaf | 14018803 | 1 |
| Caelo | Raspberry leaf | 10013406 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Raspberry leaf | 10136408 | 1 |
| Caelo | Raspberry leaf | 12362701 | 7 |
| Caelo | Raspberry leaf | 12362707 | 5 |
| Caelo | Raspberry leaf | 12362708 | 4 |
| Caelo | Raspberry leaf | 12103109 | 2 |
| Caelo | Raspberry leaf | 13101803 | 1 |
| Caelo | Raspberry leaf | 10013410 | 1 |
| Caelo | Raspberry leaf | 10013411 | 1 |
| Caelo | Raspberry leaf | 11030706 | 3 |
| Caelo | Raspberry leaf | 10013407 | 1 |
| Caelo | Raspberry leaf | 1210315 | 1 |
| Caelo | Raspberry leaf | IntCh:311090 | 1 |
| Caelo | Raspberry leaf | 13038002 | 1 |
| Caelo | Raspberry leaf | 13127901 | 3 |
| Caelo | Raspberry leaf | 10013409 | 2 |
| Caelo | Raspberry leaf | 2271C120508 | 5 |
| Caelo | Raspberry leaf | 713E-01511 | 1 |
| Caelo | Raspberry leaf | 12362706 | 29 |
| Caelo | Raspberry leaf | 11030704 | 2 |
| Caelo | Raspberry leaf | 314U1511 | 1 |
| Caelo | Raspberry leaf | 12392709 | 1 |
| Caelo | Raspberry leaf | 6859427 | 1 |
| Caelo | Raspberry leaf | 12368706 | 1 |
| Caelo | Raspberry leaf | 13038001 | 6 |
| Caelo | Raspberry leaf | 12103111 | 15 |
| Caelo | Raspberry leaf | 231013c | 1 |
| Caelo | Raspberry leaf | 10136404 | 1 |
| Caelo | Raspberry leaf | 12362704 | 5 |
| Caelo | Raspberry leaf | 12362711 | 9 |
| Caelo | Raspberry leaf | 13101602-347312141 | 1 |
| Caelo | Raspberry leaf | 12362710-3432311160 | 1 |
| Caesar & Loretz Gm… | Raspberry leaf | 10013408 | 1 |
| China Medica | Raspberry leaf | 13086703 | 1 |
| Galke | Raspberry leaf | 18060 | 2 |
| Galke | Raspberry leaf | 19499 | 2 |
| Galke | Raspberry leaf | 21244 | 1 |
| Galke | Raspberry leaf | 23532 | 1 |
| Gehe | Raspberry leaf | 11030707 | 4 |
| gehe 10.12.13 | Raspberry leaf | 229117121120 | 1 |
| Gutenberg-Apotheke | Raspberry leaf | 28911 | 1 |
| Klenk | Raspberry leaf | 2291A12112o | 1 |
| Caelo | Raspberry leaf | 12362709 | 7 |
| Caelo | Raspberry leaf | 11030705 | 1 |
| Caelo | Raspberry leaf | 13101605 | 1 |
| Caelo | Raspberry leaf | 12362705 | 9 |
| Kenk / Phoenix | Raspberry leaf | 22781C120508 | 1 |
| Klenk | Raspberry leaf | 2291A-120806 | 1 |
| Klenk | Raspberry leaf | 2291A120813 | 2 |
| Klenk | Raspberry leaf | 2291A130320 | 1 |
| Klenk | Raspberry leaf | A130430 | 1 |
| Klenk | Raspberry leaf | 2291A120806 | 2 |
| Klenk | Raspberry leaf | 12273107 | 1 |
| Klenk | Raspberry leaf | 2291A121120 | 4 |
| Klenk | Raspberry leaf | 2291a111124 | 1 |
| Klenk | Raspberry leaf | 2291A120507 | 5 |
| Klenk | Raspberry leaf | 2291A110125 | 1 |
| Phoenix | Raspberry leaf | 10136409 | 1 |
| Caelo | Raspberry leaf | 12130107 | 1 |
| Klenk | Raspberry leaf | 2291A111124 | 1 |
| Caelo | Raspberry leaf | 13101603 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| vedono | Raspberry leaf | 12362702 | 7 |
| Wolf | Raspberry leaf | P201727 | 19 |
| Wolf | Raspberry leaf | B-457 | 1 |
| Wolf | Raspberry leaf | P222676 | 1 |
| Aurica | Red clover flower | 521203442 | 1 |
| Aurica | Red clover flower | 521206331 | 1 |
| Aurica/Anzag | Red clover flower | 521303918 | 1 |
| Galke | Red clover flower | 23128 | 2 |
| Klenk | Red clover flower | 7470A130311 | 1 |
| Klenk | Red clover flower | 1640A130122 | 15 |
| Klenk | Red clover flower | 811Q-07163 | 1 |
| Klenk | Red clover flower | 1640A110727 | 1 |
| Klenk | Red clover flower | 1640a130122 | 1 |
| Kräuter Schulte | Red clover flower | 53778 | 1 |
| Caelo | Red poppy petals, cut | 12330205 | 1 |
| Kräuter Schulte | Red tea | 52029 | 1 |
| Galke | Red-rose Flower | 22641 | 2 |
| Klenk | Red-rose Flower | 1561A121016 | 1 |
| Phönix | Red-rose Flower | 12380008 | 2 |
| Caelo | Red-rose Flower | 12380004 | 1 |
| Klenk | Red-rose petal | 1561A110404 | 1 |
| Caelo | Red-rose petal | 12380008 | 1 |
| Caelo | Red-rose petal | 11011301 | 1 |
| Caelo | Red-rose petal | 11304906 | 1 |
| Caelo | Red-rose petal | 11304901 | 3 |
| Caelo | Red-rose petal | 10306514 | 1 |
| Caelo | Red-rose petal | 11304912 | 2 |
| Caelo | Red-rose petal | 11304904 | 4 |
| Caelo | Red-rose petal | 13194403 | 4 |
| Caelo | Red-rose petal | 10113211 | 1 |
| Caelo | Red-rose petal | 12380007-3357319071 | 1 |
| Caelo | Red-rose petal | 12380001 | 4 |
| Caelo | Red-rose petal | 12380004 | 2 |
| Caelo | Red-rose petal | 13194402 | 1 |
| Klenk | Red-rose petal | 1561B101210 | 2 |
| Klenk | Red-rose petal | 1561A121016-34023101 | 1 |
| kräuter schulte | Red-rose petal | 47543 | 1 |
| Richter | Red-rose petal | P236157 | 1 |
| Caelo | Redwood, cut | 12041403 | 1 |
| Caelo | Redwood, cut | 13106901 | 1 |
| Caelo | Redwood, cut | 12049607 | 2 |
| Klenk | Redwood, cut | 5961B111219 | 1 |
| Caelo | Redwood, cut | 12049608 | 2 |
| Caelo | Restharrow root | 71035467 | 1 |
| Bombastus | Restharrow root | 274421 | 1 |
| Bombastus | Restharrow root | 272831 | 2 |
| Bombastus | Restharrow root | 283708 | 1 |
| Caelo | Restharrow root | 12330001 | 14 |
| Caelo | Restharrow root | 1233001 | 2 |
| Caelo | Restharrow root | 15101313 | 1 |
| Caelo | Restharrow root | 6101201 | 1 |
| Caelo | Restharrow root | 21011306 | 1 |
| Caelo | Restharrow root | 20111213 | 1 |
| Caelo | Restharrow root | 4021406 | 1 |
| Caelo | Restharrow root | 12330003 | 2 |
| Caelo | Restharrow root | 11103105 | 2 |
| Caelo | Restharrow root | Int.Ch:212150 | 1 |
| Caelo | Restharrow root | 12330005 | 5 |
| Caelo | Restharrow root | 1230004 | 1 |
| Caelo | Restharrow root | 12330002 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Restharrow root | 11247302 | 2 |
| Caelo | Restharrow root | 72439069 | 1 |
| Caesar/Noweda | Restharrow root | 71015/3 | 2 |
| Galke | Restharrow root | 12700 | 1 |
| Klenk | Restharrow root | 4296345 | 1 |
| Klenk | Restharrow root | B130404 | 3 |
| Klenk | Restharrow root | B111110 | 1 |
| Klenk | Restharrow root | 6411B111110 | 1 |
| Klenk | Restharrow root | 6411B130404 | 2 |
| Klenk | Restharrow root | 6411111110 | 1 |
| Klenk | Restharrow root | 6411B101216 | 2 |
| Caelo | Restharrow root | 11103107 | 2 |
| Caelo | Rhubarb | 11057818 | 2 |
| Caelo | Rhubarb | 12211903 | 4 |
| Caelo | Rhubarb | 15101301 | 1 |
| Caelo | Rhubarb | 25111305 | 1 |
| Caelo | Rhubarb | 10071302 | 1 |
| Caelo | Rhubarb | 12211907 | 6 |
| Caelo | Rhubarb | 14155404 | 1 |
| Caelo | Rhubarb | 11057810 | 1 |
| Caelo | Rhubarb | 12211908 | 1 |
| Caelo | Rhubarb | 11265902 | 1 |
| Caelo | Rhubarb | 11321806 | 1 |
| Caelo | Rhubarb | 13235201 | 2 |
| Caelo | Rhubarb | 12211902 | 3 |
| Caelo | Rhubarb | 12211904 | 2 |
| Caelo | Rhubarb | 11057817 | 3 |
| Caelo | Rhubarb | 13235205 | 1 |
| Caelo | Rhubarb | 11057804 | 1 |
| Caelo | Rhubarb | 12211906 | 1 |
| Caelo | Rhubarb | 13235203 | 1 |
| Klenk | Rhubarb | 6891B111118 | 1 |
| Klenk | Rhubarb | 7761B130514 | 2 |
| Phönix | Rhubarb | 12211905 | 3 |
| Phönix | Rhubarb | 13235208 | 2 |
| Bombastus | Rhubarb, powdered | 11043806 | 1 |
| Caelo | Rhubarb, powdered | 11043825 | 2 |
| Caelo | Rhubarb, powdered | 9071201 | 1 |
| Caelo | Rhubarb, powdered | 23061402 | 1 |
| Caelo | Rhubarb, powdered | 11043826 | 1 |
| Caelo | Rhubarb, powdered | 11043816 | 1 |
| Caelo | Rhubarb, powdered | 13193106 | 2 |
| Caelo | Rhubarb, powdered | 11043818 | 1 |
| Caelo | Rhubarb, powdered | 11043817 | 1 |
| Caelo | Rhubarb, powdered | 11043809 | 1 |
| Caelo | Rhubarb, powdered | 11043816 | 2 |
| Caelo | Rhubarb, powdered | 11043818 | 1 |
| Caelo | Rhubarb, powdered | 13193104 | 4 |
| Caelo | Rhubarb, powdered | 13193109 | 1 |
| Caelo | Rhubarb, powdered | 11043822 | 1 |
| Caelo | Rhubarb, powdered | 11043819 | 2 |
| Fagron | Rhubarb, powdered | 11043821 | 1 |
| Hedinger | Rhubarb, powdered | 13193110 | 1 |
| Bahnhof-Apotheke | Ribwort plantain | 7-121011 | 1 |
| Bombastus | Ribwort plantain | 276453 | 1 |
| Bombastus | Ribwort plantain | 275479 | 1 |
| Caelo | Ribwort plantain | 13113008 | 5 |
| Caelo | Ribwort plantain | 23121304 | 1 |
| Caelo | Ribwort plantain | 12225802 | 5 |
| Caelo | Ribwort plantain | 13113001 | 8 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ribwort plantain | 12225803 | 2 |
| Caelo | Ribwort plantain | 13410612 | 1 |
| Caelo | Ribwort plantain | 13410601 | 1 |
| Caelo | Ribwort plantain | 15096308 | 1 |
| Caelo | Ribwort plantain | 12362903 | 33 |
| Caelo | Ribwort plantain | 10315712 | 2 |
| Caelo | Ribwort plantain | 13113005 | 5 |
| Caelo | Ribwort plantain | 25041301 | 1 |
| Caelo | Ribwort plantain | 28061301 | 1 |
| Caelo | Ribwort plantain | 4021411 | 1 |
| Caelo | Ribwort plantain | 2031302 | 1 |
| Caelo | Ribwort plantain | 20111304 | 1 |
| Caelo | Ribwort plantain | 16101304 | 1 |
| Caelo | Ribwort plantain | 8061208 | 1 |
| Caelo | Ribwort plantain | 22021302 | 1 |
| Caelo | Ribwort plantain | 10011402 | 1 |
| Caelo | Ribwort plantain | 15111302 | 1 |
| Caelo | Ribwort plantain | 19121202 | 1 |
| Caelo | Ribwort plantain | 17071201 | 1 |
| Caelo | Ribwort plantain | 25091305 | 1 |
| Caelo | Ribwort plantain | 15101204 | 1 |
| Caelo | Ribwort plantain | 20111208 | 1 |
| Caelo | Ribwort plantain | 11061304 | 1 |
| Caelo | Ribwort plantain | 13410603 | 3 |
| Caelo | Ribwort plantain | 14199202 | 1 |
| Caelo | Ribwort plantain | 15096301 | 1 |
| Caelo | Ribwort plantain | 10315711 | 4 |
| Caelo | Ribwort plantain | 10315707 | 2 |
| Caelo | Ribwort plantain | 12225804 | 1 |
| Caelo | Ribwort plantain | 1362903 | 1 |
| Caelo | Ribwort plantain | 13232401 | 1 |
| Caelo | Ribwort plantain | 12362907 | 2 |
| Caelo | Ribwort plantain | 10315705 | 1 |
| Caelo | Ribwort plantain | 13113006 | 6 |
| Caelo | Ribwort plantain | 12362902 | 7 |
| Caelo | Ribwort plantain | 13113010 | 4 |
| Caelo | Ribwort plantain | 1313007 | 1 |
| Caelo | Ribwort plantain | 10315714 | 2 |
| Caelo | Ribwort plantain | 10328702 | 2 |
| Caelo | Ribwort plantain | 13113007 | 6 |
| Caelo | Ribwort plantain | 12362906 | 7 |
| Caelo | Ribwort plantain | 10315715 | 9 |
| Caelo | Ribwort plantain | 12362903-3388311070 | 1 |
| Caelo | Ribwort plantain | 13113004-3488312172 | 1 |
| Galke | Ribwort plantain | 20832 | 5 |
| Galke | Ribwort plantain | 21598 | 1 |
| Galke | Ribwort plantain | 20259 | 1 |
| Gehe | Ribwort plantain | 1080413 | 1 |
| Klenk | Ribwort plantain | A110816 | 1 |
| Klenk | Ribwort plantain | 4271A130716 | 1 |
| Klenk | Ribwort plantain | 4271A-110816 | 1 |
| Klenk | Ribwort plantain | 4281N111121 | 1 |
| Klenk | Ribwort plantain | 4271A100615 | 2 |
| Klenk | Ribwort plantain | 4271A110816 | 2 |
| Klenk | Ribwort plantain | 4271A130115 | 6 |
| Klenk | Ribwort plantain | 4271A111125 | 2 |
| Klenk | Ribwort plantain | 427A111125 | 1 |
| Phoenix | Ribwort plantain | 4271A11016 | 1 |
| Phönix | Ribwort plantain | 13113004 | 13 |
| Sanacorp | Ribwort plantain | 263401 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Ribwort plantain | 12362901 | 1 |
| Alliance | Robert herb | 3951A110621 | 7 |
| Caelo | Robert herb | 11147804 | 1 |
| Caelo | Robert herb | 8121203 | 1 |
| Caelo | Robert herb | 12319304 | 2 |
| Caelo | Robert herb | 11147807 | 3 |
| Caelo | Robert herb | 11147813 | 2 |
| Caelo | Robert herb | 12319305 | 1 |
| Caelo | Robert herb | 12319302 | 1 |
| Caelo | Robert herb | 11147812 | 3 |
| Caelo | Robert herb | 11147810 | 3 |
| Klenk | Robert herb | A110621 | 6 |
| Klenk | Robert herb | 3951B121218 | 2 |
| Klenk | Robert herb | 3951B12118 | 1 |
| Caelo | Rose hips peel | 12064207 | 1 |
| Bombastus | Rose hips peel | 283458 | 1 |
| Bombastus | Rose hips peel | 275394 | 2 |
| Bombastus | Rose hips peel | 257166 | 1 |
| Bombastus | Rose hips peel | 277431 | 3 |
| Bombastus | Rose hips peel | 285184 | 1 |
| Bombastus | Rose hips peel | 231013A | 1 |
| Caelo | Rose hips peel | 25061203 | 1 |
| Caelo | Rose hips peel | 15061210 | 1 |
| Caelo | Rose hips peel | 9121301 | 1 |
| Caelo | Rose hips peel | 7031305 | 1 |
| Caelo | Rose hips peel | 5091301 | 1 |
| Caelo | Rose hips peel | 10101206 | 1 |
| Caelo | Rose hips peel | 11301401 | 1 |
| Caelo | Rose hips peel | 12288301 | 1 |
| Caelo | Rose hips peel | 12357501 | 1 |
| Caelo | Rose hips peel | 14050704 | 1 |
| Caelo | Rose hips peel | 14050705 | 1 |
| Caelo | Rose hips peel | 11301405 | 2 |
| Caelo | Rose hips peel | 2851A120904konv. | 1 |
| Caelo | Rose hips peel | 10157309 | 1 |
| Caelo | Rose hips peel | 13317805 | 1 |
| Caelo | Rose hips peel | 11301407 | 12 |
| Caelo | Rose hips peel | 12288302 | 7 |
| Caelo | Rose hips peel | 11301403 | 2 |
| Caelo | Rose hips peel | 12357502 | 3 |
| Caelo | Rose hips peel | 12357504 | 2 |
| Caelo | Rose hips peel | 13317801 | 2 |
| Caelo | Rose hips peel | 12357505 | 6 |
| Klenk | Rose hips peel | 2851A150310 | 4 |
| Klenk | Rose hips peel | 2851A120102 | 5 |
| Klenk | Rose hips peel | A120904 | 3 |
| Klenk | Rose hips peel | 2851A120904 | 2 |
| Klenk | Rose hips peel | 2851A101119 | 3 |
| Klenk | Rose hips peel | 2851A110202 | 1 |
| Klenk | Rose hips peel | 2851A-110202 | 1 |
| Klenk | Rose hips peel | 3613M-01543 | 1 |
| Phönix | Rose hips peel | 2841B111019 | 2 |
| Aurica | Rose hips with peel, cut | 521201801 | 1 |
| Caelo | Rose hips with peel, cut | 1512211542 | 1 |
| Caelo | Rose hips with peel, cut | 307211542 | 1 |
| Caelo | Rose hips with peel, cut | 2103311542 | 1 |
| Caelo | Rose hips with peel, cut | 19111204 | 1 |
| Caelo | Rose hips with peel, cut | 16111201 | 1 |
| Caelo | Rose hips with peel, cut | 12064209 | 4 |
| Caelo | Rose hips with peel, cut | 12029011 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Rose hips with peel, cut | 12064210 | 2 |
| Caelo | Rose hips with peel, cut | 12064213 | 1 |
| Caelo | Rose hips with peel, cut | 12064207 | 2 |
| Caelo | Rose hips with peel, cut | 13048704 | 3 |
| Caelo | Rose hips with peel, cut | 13048704 | 1 |
| Caelo | Rose hips with peel, cut | 13048703 | 1 |
| Caelo | Rose hips with peel, cut | 12029008 | 1 |
| Caelo | Rose hips with peel, cut | 12064212 | 3 |
| Caelo | Rose hips with peel, cut | 12064210 | 3 |
| Caelo | Rose hips with peel, cut | 12064209 | 1 |
| Caelo | Rose hips with peel, cut | 13048703 | 1 |
| Caelo | Rose hips with peel, cut | 12064201 | 1 |
| Caelo | Rose hips with peel, cut | 12064213 | 1 |
| Caelo | Rose hips with peel, cut | 12064202 | 1 |
| Caelo | Rose hips with peel, cut | 12064207 | 3 |
| Caelo | Rose hips with peel, cut | 114Q-01542 | 1 |
| Caelo | Rose hips with peel, cut | 13048701 | 2 |
| Caelo | Rose hips with peel, cut | 13097405 | 1 |
| Caelo | Rose hips with peel, cut | 12064212 | 2 |
| Klenk | Rose hips with peel, cut | A120904 | 1 |
| Klenk | Rose hips with peel, cut | B111019 | 1 |
| Klenk | Rose hips with peel, cut | A120719 | 1 |
| Klenk | Rose hips with peel, cut | B130523 | 1 |
| Klenk | Rose hips with peel, cut | 2841B081210 | 1 |
| Klenk | Rose hips with peel, cut | 3613M-01542 | 1 |
| Klenk | Rose hips with peel, cut | 2841B111019 | 3 |
| Klenk | Rose hips with peel, cut | 2851A120904 | 1 |
| Phönix | Rose hips with peel, cut | 10281021 | 1 |
| Phönix | Rose hips with peel, cut | 2841B130523 | 1 |
| Phönix | Rose hips with peel, cut | 2841B130523 | 1 |
| Caelo | Rose hips with peel, cut | 12064202 | 1 |
| Caelo | Rose hips with peel, cut | 12064206 | 1 |
| Caelo | Rose mallow flower, cut | 13040402 | 1 |
| Caelo | Rose mallow flower, cut | 10244507 | 1 |
| Caelo | Rose mallow flower, cut | 13040401 | 2 |
| an | Roselle | 14018101 | 1 |
| Caelo | Roselle | 7121301 | 1 |
| Caelo | Roselle | 11036504 | 1 |
| Caelo | Roselle | 12267507 | 2 |
| Caelo | Roselle | 11036512 | 1 |
| Caelo | Roselle | 12007306 | 1 |
| Caelo | Roselle | 11036509 | 2 |
| Caelo | Roselle | 12267503 | 2 |
| Caelo | Roselle | 12267501 | 3 |
| Caelo | Roselle | 12267502 | 3 |
| Caelo | Roselle | 12267504 | 1 |
| Caelo | Roselle | 12267504-3428311150 | 1 |
| Caelo | Roselle | 11036511 | 1 |
| Caelo | Roselle | 12267504 | 3 |
| Klenk | Roselle | 1431B130205 | 1 |
| Klenk | Roselle | B130205 | 1 |
| Klenk | Roselle | 1431B-110519 | 1 |
| Klenk | Roselle | 1431B131015 | 2 |
| Klenk | Roselle | 1431B111122 | 1 |
| phoenix | Roselle | 12267502 | 4 |
| Sanacorp | Roselle | 12267508 | 2 |
| vedono | Roselle | 12007313 | 1 |
| Akazie | Rosemary leaf | 20.09.2015 | 1 |
| Bahnhof-Apotheke | Rosemary leaf | 7-120915 | 1 |
| Bombastus | Rosemary leaf | 293920 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Rosemary leaf | 277128 | 1 |
| Bombastus | Rosemary leaf | 281248 | 1 |
| Bombastus | Rosemary leaf | 298424 | 2 |
| Bombastus | Rosemary leaf | 287805 | 1 |
| Bombastus | Rosemary leaf | 270171 | 1 |
| Bombastus | Rosemary leaf | 281843 | 1 |
| Caelo | Rosemary leaf | 13128806 | 2 |
| Caelo | Rosemary leaf | 14159601 | 1 |
| Caelo | Rosemary leaf | 28051404 | 1 |
| Caelo | Rosemary leaf | 5041302 | 1 |
| Caelo | Rosemary leaf | 11193404 | 1 |
| Caelo | Rosemary leaf | 13128802 | 2 |
| Caelo | Rosemary leaf | 13128805 | 1 |
| Caelo | Rosemary leaf | 13128801 | 1 |
| Caelo | Rosemary leaf | 14082901 | 1 |
| Caelo | Rosemary leaf | 12225902 | 1 |
| Caelo | Rosemary leaf | 11193402 | 2 |
| Caelo | Rosemary leaf | 1415901 | 1 |
| Caelo | Rosemary leaf | IntCh:313060 | 1 |
| Caelo | Rosemary leaf | 2261A7020901 | 1 |
| Caelo | Rosemary leaf | 11193405 | 1 |
| Caelo | Rosemary leaf | 17352502 | 1 |
| Caelo | Rosemary leaf | 11193406 | 1 |
| Caelo | Rosemary leaf | 11193405 | 1 |
| Caelo | Rosemary leaf | 2261A150622 | 6 |
| Caelo | Rosemary leaf | 15125001 | 2 |
| Caelo | Rosemary leaf | 15125008 | 1 |
| Caelo | Rosemary leaf | 15428003 | 1 |
| Caelo | Rosemary leaf | 11193408 | 6 |
| Fagron | Rosemary leaf | 2261A130201 | 29 |
| Galke | Rosemary leaf | 22777 | 1 |
| Galke | Rosemary leaf | 19813 | 1 |
| Galke | Rosemary leaf | 21390 | 1 |
| Klenk | Rosemary leaf | 2261A140910 | 4 |
| Klenk | Rosemary leaf | 301401 | 1 |
| Klenk | Rosemary leaf | A130201 | 2 |
| Klenk | Rosemary leaf | 61A131118 | 1 |
| Klenk | Rosemary leaf | | 1 |
| Klenk | Rosemary leaf | 2261A170803 | 1 |
| Klenk | Rosemary leaf | 2216A170803 | 1 |
| Klenk | Rosemary leaf | 2261A160329 | 2 |
| Klenk | Rosemary leaf | 112E-01510 | 1 |
| Klenk | Rosemary leaf | 2261A131118 | 13 |
| Klenk | Rosemary leaf | 2261A160905 | 6 |
| Klenk | Rosemary leaf | 2261A081117 | 1 |
| Klenk | Rosemary leaf | 2261a120224 | 2 |
| Klenk | Rosemary leaf | 2261A120224 | 18 |
| Klenk | Rosemary leaf | 2261a160329 | 1 |
| Noweda | Rosemary leaf | 15428011 | 1 |
| Noweda | Rosemary leaf | 2261A100916 | 1 |
| Klenk | Rosemary leaf | 2261A170317 | 1 |
| Caelo | Rue herb, cut | 12148806 | 1 |
| Caelo | Rue herb, cut | 11371803 | 1 |
| Caelo | Rue herb, cut | 12148801 | 1 |
| Caelo | Rue herb, cut | 12148804 | 1 |
| Caelo | Rue herb, cut | 9336802 | 1 |
| Caelo | Rue herb, cut | | 1 |
| Caelo | Rue herb, cut | 12148803 | 2 |
| Gehe | Rue herb, cut | 12148802 | 1 |
| Klenk | Rue herb, cut | A120207 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Rue herb, cut | 4361A120207 | 1 |
| Klenk | Rue herb, cut | 4361A07020601 | 1 |
| Klenk | Rue herb, cut | 4361A100707 | 3 |
| Fagron | Rutoside trihydrate | 13K12B06295483 | 1 |
| Fagron | Rutoside trihydrate | 13K12-B06295483 | 1 |
| Fagron | Rutoside trihydrate | 13K12-B06 | 1 |
| Fagron | Rutoside trihydrate | L14050127 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Saffron | 384A110608 | 1 |
| Klenk | Saffron | 384A-120410 | 1 |
| Klenk | Saffron | 384A130320 | 2 |
| Klenk | Saffron | 384a120410 | 1 |
| Caelo | Saffron filaments | 11071310 | 1 |
| Caelo | Saffron filaments | 21011403 | 1 |
| Caelo | Saffron filaments | 15101305 | 1 |
| Caelo | Saffron filaments | 10184811 | 2 |
| Caelo | Saffron filaments | 12108311 | 2 |
| Caelo | Saffron filaments | 10184822 | 1 |
| Fagron | Saffron filaments | 380A120416 | 1 |
| Gehe | Saffron filaments | 12108308 | 2 |
| Klenk | Saffron filaments | 380A130613 | 1 |
| Aurica | Sage leaf | 521204613 | 1 |
| Bahnhof-Apotheke | Sage leaf | 3-121018 | 1 |
| Bombastus | Sage leaf | 271253 | 1 |
| Bombastus | Sage leaf | 277512 | 1 |
| Bombastus | Sage leaf | 270115 | 1 |
| Bombastus | Sage leaf | 255381 | 1 |
| Caelo | Sage leaf | 12370010 | 16 |
| Caelo | Sage leaf | 12370002 | 4 |
| Caelo | Sage leaf | 13266606 | 1 |
| Caelo | Sage leaf | 13266621 | 1 |
| Caelo | Sage leaf | 12370017 | 1 |
| Caelo | Sage leaf | 1209211513 | 1 |
| Caelo | Sage leaf | 410211513 | 1 |
| Caelo | Sage leaf | 103311513 | 1 |
| Caelo | Sage leaf | 12370006 | 8 |
| Caelo | Sage leaf | 11347513 | 1 |
| Caelo | Sage leaf | 11347508 | 3 |
| Caelo | Sage leaf | 31081202 | 1 |
| Caelo | Sage leaf | 26081301 | 1 |
| Caelo | Sage leaf | 8011420 | 1 |
| Caelo | Sage leaf | 9121302 | 1 |
| Caelo | Sage leaf | 14111315 | 1 |
| Caelo | Sage leaf | 22061201 | 1 |
| Caelo | Sage leaf | 22111203 | 1 |
| Caelo | Sage leaf | 25061302 | 1 |
| Caelo | Sage leaf | 12112101 | 1 |
| Caelo | Sage leaf | 20121201 | 1 |
| Caelo | Sage leaf | 22081203 | 1 |
| Caelo | Sage leaf | 111012004 | 1 |
| Caelo | Sage leaf | 17061302 | 1 |
| Caelo | Sage leaf | 13011405 | 1 |
| Caelo | Sage leaf | 12021302 | 1 |
| Caelo | Sage leaf | 15121201 | 1 |
| Caelo | Sage leaf | 15041304 | 1 |
| Caelo | Sage leaf | 13266626 | 1 |
| Caelo | Sage leaf | 12370016 | 9 |
| Caelo | Sage leaf | 13266605 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sage leaf | 13266603 | 2 |
| Caelo | Sage leaf | 11347509 | 4 |
| Caelo | Sage leaf | 12370004 | 2 |
| Caelo | Sage leaf | 12370015 | 2 |
| Caelo | Sage leaf | 312010 | 1 |
| Caelo | Sage leaf | 12370013 | 3 |
| Caelo | Sage leaf | 279939 | 1 |
| Caelo | Sage leaf | 11347503 | 1 |
| Caelo | Sage leaf | 11056123 | 5 |
| Caelo | Sage leaf | 12370001 | 18 |
| Caelo | Sage leaf | 11347511 | 9 |
| Caelo | Sage leaf | 12370014 | 8 |
| Caelo | Sage leaf | 12370011 | 11 |
| Caelo | Sage leaf | 12380009 | 1 |
| Caelo | Sage leaf | 1237003 | 1 |
| Caelo | Sage leaf | 12370009 | 12 |
| Caelo | Sage leaf | 123770010 | 1 |
| Caelo | Sage leaf | 12370003-3359319071 | 1 |
| Caelo | Sage leaf | 12370014-3477312161 | 1 |
| Caelo | Sage leaf | 11056125 | 3 |
| Caesar & Loretz Gm… | Sage leaf | 11056121 | 3 |
| Caesar & Loretz Gm… | Sage leaf | 11056109 | 5 |
| Caesar & Loretz Gm… | Sage leaf | 11347502 | 5 |
| Galke | Sage leaf | 21015 | 3 |
| gehe 07.12.2013 | Sage leaf | 2301/7120403 | 1 |
| Klenk | Sage leaf | 2301A110204 | 7 |
| Klenk | Sage leaf | 2301A130904 | 2 |
| Klenk | Sage leaf | C120126 | 1 |
| Klenk | Sage leaf | 2301A110420 | 1 |
| Klenk | Sage leaf | 2301C12126 | 1 |
| Klenk | Sage leaf | 2301c120126 | 1 |
| Klenk | Sage leaf | 2301a120403 | 1 |
| Klenk | Sage leaf | 2301A120403 | 38 |
| Klenk | Sage leaf | 2301C120126 | 16 |
| Klenk | Sage leaf | 2301C12026 | 1 |
| Klenk | Sage leaf | 2301A110420 | 2 |
| Nachprüfung 21.11.11 | Sage leaf | C1247 | 1 |
| Phoenix | Sage leaf | 231C130326 | 1 |
| Caelo | Sage leaf | 12370003 | 4 |
| Wolf | Sage leaf | B735 | 1 |
| Galke | Sanicle herb, cut | 23097 | 1 |
| Kräuter Schulte | Saponaria root, cut | 54977 | 1 |
| Kräuter Schulte | Saponaria root, cut | 54500 | 1 |
| Kräuter Schulte | Saponaria root, cut | 54524 | 2 |
| Caelo | Sarsaparilla root, cut | 13079201 | 1 |
| Klenk | Sarsaparilla root, cut | B111108 | 1 |
| Klenk | Sarsaparilla root, cut | 6561B111108 | 1 |
| bohn | Savory, rubbed | 12177208 | 1 |
| Caelo | Savory, rubbed | 12177207 | 2 |
| Caelo | Savory, rubbed | 12177203 | 7 |
| Caelo | Savory, rubbed | 12177205 | 3 |
| Caelo | Savory, rubbed | 13172404 | 2 |
| Caelo | Savory, rubbed | 12200801 | 1 |
| Caelo | Savory, rubbed | 12177201 | 1 |
| Caelo | Selenium yeast | 13347906 | 1 |
| Caelo | Selenium yeast | 13347911 | 1 |
| Caelo | Selenium yeast | 15276208 | 1 |
| Caesar & Loretz Gm… | Selenium yeast | 11318111 | 1 |
| Euro OTC | Selenium yeast | L1910012-01 | 1 |
| Euro OTC | Selenium yeast | L1910012-1 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bomba/AHD | Senna leaflet | 280008 | 1 |
| Bombastus | Senna leaflet | 280448 | 1 |
| Bombastus | Senna leaflet | 278109 | 1 |
| Bombastus | Senna leaflet | 280581 | 2 |
| Bombastus | Senna leaflet | 273474 | 1 |
| Caelo | Senna leaflet | 12273120 | 5 |
| Caelo | Senna leaflet | 1803311514 | 1 |
| Caelo | Senna leaflet | 103311514 | 2 |
| Caelo | Senna leaflet | 2413Q01514 | 1 |
| Caelo | Senna leaflet | 806211514 | 1 |
| Caelo | Senna leaflet | 711211514 | 1 |
| Caelo | Senna leaflet | 2909211514 | 1 |
| Caelo | Senna leaflet | 12273104 | 2 |
| Caelo | Senna leaflet | 12273107 | 9 |
| Caelo | Senna leaflet | 12273115 | 11 |
| Caelo | Senna leaflet | 12273101 | 4 |
| Caelo | Senna leaflet | 15101303 | 1 |
| Caelo | Senna leaflet | 9071302 | 1 |
| Caelo | Senna leaflet | 5091306 | 1 |
| Caelo | Senna leaflet | 21011401 | 1 |
| Caelo | Senna leaflet | 18071201 | 1 |
| Caelo | Senna leaflet | 14306311 | 2 |
| Caelo | Senna leaflet | 14306324 | 1 |
| Caelo | Senna leaflet | 14306310 | 1 |
| Caelo | Senna leaflet | 12115502 | 1 |
| Caelo | Senna leaflet | 13136708 | 7 |
| Caelo | Senna leaflet | 14183805 | 2 |
| Caelo | Senna leaflet | 12273103 | 11 |
| Caelo | Senna leaflet | 11277314 | 5 |
| Caelo | Senna leaflet | 1273103 | 1 |
| Caelo | Senna leaflet | 111113a | 1 |
| Caelo | Senna leaflet | 13136705 | 4 |
| Caelo | Senna leaflet | 11041009 | 1 |
| Caelo | Senna leaflet | 12369903 | 1 |
| Caelo | Senna leaflet | 2231B13014 | 1 |
| Caelo | Senna leaflet | 11277305 | 1 |
| Caelo | Senna leaflet | 12273114 | 2 |
| Caelo | Senna leaflet | 11277304 | 4 |
| Caelo | Senna leaflet | 12273118 | 3 |
| Caelo | Senna leaflet | 313082 | 1 |
| Caelo | Senna leaflet | 12276111 | 1 |
| Caelo | Senna leaflet | 273547 | 3 |
| Caelo | Senna leaflet | 10126502 | 1 |
| Caelo | Senna leaflet | 12273105 | 6 |
| Caelo | Senna leaflet | 12273113 | 3 |
| Caelo | Senna leaflet | 19135519 | 2 |
| Caelo | Senna leaflet | 19135513 | 3 |
| Caelo | Senna leaflet | 191355003 | 1 |
| Caelo | Senna leaflet | 12273106 | 3 |
| Caelo | Senna leaflet | 3813E1514 | 1 |
| Caelo | Senna leaflet | 5013U01514 | 1 |
| Caelo | Senna leaflet | 4113Q1514 | 1 |
| Caelo | Senna leaflet | 131316701 | 1 |
| Caelo | Senna leaflet | 514R1514 | 1 |
| Caelo | Senna leaflet | 13136703 | 3 |
| Caelo | Senna leaflet | 18046209 | 1 |
| Caelo | Senna leaflet | 12273111 | 10 |
| Caelo | Senna leaflet | 13136704 | 13 |
| Caelo | Senna leaflet | 18046110 | 1 |
| Caelo | Senna leaflet | 19135501 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Senna leaflet | 18046104 | 2 |
| Caelo | Senna leaflet | 12115503 | 6 |
| Caelo | Senna leaflet | 12273119 | 4 |
| Caelo | Senna leaflet | 13136705-3489312103 | 1 |
| Caelo | Senna leaflet | 13136706 | 1 |
| Caelo | Senna leaflet | 1316706 | 1 |
| Caesar & Loretz Gm... | Senna leaflet | 11277303 | 3 |
| Caesar & Loretz Gm... | Senna leaflet | 11277308 | 3 |
| Caesar&Loretz GmbH... | Senna leaflet | 12115504 | 4 |
| Fagron | Senna leaflet | 314Q1514 | 1 |
| Galke | Senna leaflet | 21778 | 1 |
| Klenk | Senna leaflet | 2331B120403 | 1 |
| Klenk | Senna leaflet | 2331B120521 | 4 |
| Klenk | Senna leaflet | 2331C130326 | 16 |
| Klenk | Senna leaflet | 2331B150903 | 1 |
| Klenk | Senna leaflet | 2331B130214 | 5 |
| Klenk | Senna leaflet | B130214 | 1 |
| Klenk | Senna leaflet | 2331c130326 | 1 |
| Klenk | Senna leaflet | 2331B110907 | 2 |
| Klenk | Senna leaflet | 2331A110207 | 1 |
| Nachprüfung | Senna leaflet | 2331A100525 | 2 |
| Noweda | Senna leaflet | 11277316 | 4 |
| Caelo | Senna leaflet | 13136724 | 1 |
| Caelo | Senna leaflet | 13136718 | 1 |
| Phönix | Senna leaflet | 2331C120614 | 8 |
| Phönix 10.01.2014 | Senna leaflet | 13136707 | 1 |
| Sanacorp | Senna leaflet | 13136701 | 6 |
| Caelo | Senna leaflet | 11277307 | 1 |
| Caelo | Senna leaflet | 11277301 | 1 |
| Caelo | Senna leaflet | 12115501 | 5 |
| Caelo | Senna leaflet | 12273116 | 15 |
| Caelo | Senna leaflet | 1316703 | 2 |
| Caelo | Senna leaflet, powdered | 11193307 | 1 |
| Caelo | Senna leaflet, powdered | 17223202 | 1 |
| Caelo | Senna leaflet, powdered | 15363922 | 1 |
| Caelo | Senna leaflet, powdered | 14347606 | 1 |
| Caleo/ Fiebig | Senna leaflet, powdered | 15363902 | 1 |
| Fiebig | Senna leaflet, powdered | 15363920 | 1 |
| Klenk | Senna leaflet, powdered | 2331B150903 | 1 |
| Caelo | Senna pods, tinnevelly | 12267609 | 3 |
| Caelo | Senna pods, tinnevelly | 22061202 | 1 |
| Caelo | Senna pods, tinnevelly | 12267604 | 1 |
| Caelo | Senna pods, tinnevelly | 11003004 | 1 |
| Caelo | Senna pods, tinnevelly | 110030009 | 1 |
| Caelo | Senna pods, tinnevelly | 11003013 | 1 |
| Caelo | Senna pods, tinnevelly | 122676707 | 1 |
| Caelo | Senna pods, tinnevelly | 12267606 | 1 |
| Caelo | Senna pods, tinnevelly | 12267610 | 1 |
| Caelo | Senna pods, tinnevelly | 12267608 | 1 |
| Caelo | Senna pods, tinnevelly | 12267007 | 1 |
| Caelo | Senna pods, tinnevelly | 12267201 | 1 |
| Caelo | Senna pods, tinnevelly | 17030712 | 1 |
| Caelo | Senna pods, tinnevelly | 18240501 | 1 |
| Caelo | Senna pods, tinnevelly | 18240505 | 1 |
| Caelo | Senna pods, tinnevelly | 17030708 | 1 |
| Caelo | Senna pods, tinnevelly | 18240506 | 1 |
| Caelo | Senna pods, tinnevelly | 17030709 | 1 |
| Caelo | Senna pods, tinnevelly | 12267605 | 1 |
| Caesar & Loretz Gm... | Senna pods, tinnevelly | 12267601 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caesar & Loretz Gm… | Senna pods, tinnevelly | 11003014 | 1 |
| Caesar & Loretz Gm… | Senna pods, tinnevelly | 11003012 | 1 |
| Caesar & Loretz Gm… | Senna pods, tinnevelly | 11003009 | 2 |
| Caesar & Loretz Gm… | Senna pods, tinnevelly | 12267603 | 1 |
| Caelo | Senna pods, tinnevelly | 12267602 | 2 |
| Klenk | Senna pods, tinnevelly | 1041B120327 | 2 |
| Alfred Galke | Shepherd's purse | 20591 | 1 |
| Bahnhof-Apotheke | Shepherd's purse | 4-120924 | 1 |
| Bombastus | Shepherd's purse | 278856 | 2 |
| Bombastus | Shepherd's purse | 269594 | 4 |
| Bombastus | Shepherd's purse | 269977 | 1 |
| Bombastus | Shepherd's purse | 284136 | 1 |
| Bombastus | Shepherd's purse | 12345 | 2 |
| Bombastus | Shepherd's purse | 287350 | 1 |
| Caelo | Shepherd's purse | 11328204 | 3 |
| Caelo | Shepherd's purse | 11328208 | 6 |
| Caelo | Shepherd's purse | 269595 | 1 |
| Caelo | Shepherd's purse | 12354001 | 1 |
| Caelo | Shepherd's purse | 11091202 | 1 |
| Caelo | Shepherd's purse | 15101202 | 1 |
| Caelo | Shepherd's purse | 14061201 | 1 |
| Caelo | Shepherd's purse | 3121301 | 1 |
| Caelo | Shepherd's purse | 10061301 | 1 |
| Caelo | Shepherd's purse | 12354202 | 2 |
| Caelo | Shepherd's purse | 12354205 | 6 |
| Caelo | Shepherd's purse | 11328205 | 1 |
| Caelo | Shepherd's purse | 11328206 | 2 |
| Caelo | Shepherd's purse | 11328207 | 8 |
| Caelo | Shepherd's purse | 12354209 | 1 |
| Caelo | Shepherd's purse | 1132820111-14 | 1 |
| Caelo | Shepherd's purse | 12354206 | 5 |
| Caelo | Shepherd's purse | 11036401 | 1 |
| Caelo | Shepherd's purse | 12354204 | 16 |
| Caelo | Shepherd's purse | 12354503 | 1 |
| Caelo | Shepherd's purse | 11328201 | 6 |
| Caelo | Shepherd's purse | 12354203-3396310111 | 1 |
| Caelo | Shepherd's purse | 11328209 | 6 |
| Caelo | Shepherd's purse | 12254202 | 1 |
| Caelo | Shepherd's purse | 11328203 | 5 |
| Caelo | Shepherd's purse | 11036406 | 5 |
| Caelo | Shepherd's purse | 11036404 | 1 |
| Caelo | Shepherd's purse | 12354203 | 13 |
| Galke | Shepherd's purse | 19483 | 1 |
| Caelo | Shepherd's purse | 12354207 | 2 |
| Klenk | Shepherd's purse | 3671B111201 | 1 |
| Klenk | Shepherd's purse | B111201 | 1 |
| Klenk | Shepherd's purse | 3671A-100414 | 2 |
| Caelo | Shepherd's purse | 13344203 | 1 |
| Sanacorp | Shepherd's purse | 12354201 | 11 |
| Caelo | Shepherd's purse | 11036410 | 2 |
| Wolf | Shepherd's purse | 21719 | 2 |
| Wolf | Shepherd's purse | B449 | 2 |
| - | Silverweed | 711M-01619 | 1 |
| - | Silverweed | 130849 | 1 |
| Caelo | Silverweed | 11328112 | 2 |
| Caelo | Silverweed | 20081202 | 1 |
| Caelo | Silverweed | 8111204 | 1 |
| Caelo | Silverweed | 11328103 | 4 |
| Caelo | Silverweed | 11328105 | 7 |
| Caelo | Silverweed | 11016407 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Silverweed | 11328110 | 1 |
| Caelo | Silverweed | 11328109 | 13 |
| Caelo | Silverweed | 11016404 | 1 |
| Caelo | Silverweed | 11328107 | 7 |
| Galke | Silverweed | 12891 | 2 |
| Gehe | Silverweed | 11328101 | 1 |
| Klenk | Silverweed | 3551A110913 | 1 |
| Klenk | Silverweed | H-280513-3 | 1 |
| Klenk | Silverweed | A110913 | 2 |
| Klenk | Silverweed | 3551A130903 | 1 |
| Euro OTC | Sodium alginate | 1509036-01 | 1 |
| Fagron | Sodium alginate | 14G22-B99 | 1 |
| phönix | Sodium alginate | 11509036-02 | 1 |
| Sigma-Aldrich | Sodium butyrate | Lot.091M-5302V | 1 |
| Caelo | Sodium carbonate decahydrate | 11254708 | 1 |
| Caelo | Sodium carbonate decahydrate | 12239810 | 2 |
| Caelo | Sodium carbonate decahydrate | 13036910 | 1 |
| Caelo | Sodium carbonate decahydrate | 13036907 | 1 |
| Caelo | Sodium carbonate decahydrate | 80136179 | 1 |
| Caelo | Sodium carbonate decahydrate | 13036909 | 1 |
| Caelo | Sodium carbonate decahydrate | 11254706 | 1 |
| Caelo | Sodium carbonate decahydrate | 13036902 | 2 |
| Caelo | Sodium carbonate decahydrate | 12239806 | 1 |
| Caelo | Sodium carbonate decahydrate | 80136428 | 1 |
| Phönix | Sodium carbonate decahydrate | 13036904 | 2 |
| Audor Pharma | Sodium hyaluronate | AP30101305H | 2 |
| Audor Pharma | Sodium hyaluronate | AP30101404H | 1 |
| Audor Pharma | Sodium hyaluronate | A0397074 | 1 |
| Audor Pharma | Sodium hyaluronate | AP30101505H | 1 |
| Audor Pharma | Sodium hyaluronate | AP30101404H | 1 |
| Caelo | Sodium hyaluronate | 17234702 | 1 |
| Caelo | Sodium hyaluronate | 14364706 | 2 |
| Caelo | Sodium hyaluronate | 1263303 | 1 |
| Caelo | Sodium hyaluronate | 14188702 | 1 |
| Caelo | Sodium hyaluronate | 16246703 | 1 |
| Caelo | Sodium hyaluronate | 21002684002 | 4 |
| Caelo | Sodium hyaluronate | 15204901 | 1 |
| Caelo | Sodium hyaluronate | 15204903 | 3 |
| Caelo | Sodium hyaluronate | 193031002 | 1 |
| Caelo | Sodium hyaluronate | 17234701 | 1 |
| Caelo | Sodium hyaluronate | 15448803 | 1 |
| Calo/AHD | Sodium hyaluronate | 14364704 | 1 |
| Euro OTC | Sodium hyaluronate | L1512025-01 | 2 |
| Euro OTC | Sodium hyaluronate | L1907021-01 | 1 |
| Euro OTC | Sodium hyaluronate | L2103023-01 | 1 |
| Euro OTC | Sodium hyaluronate | L1710023-02 | 3 |
| Fagron | Sodium hyaluronate | L1311012-01 | 1 |
| Fisher Scientific | Sodium hyaluronate | A0387534 | 1 |
| Caelo | Sodium hyaluronate | 2100131002 | 1 |
| Caelo | Sodium hyaluronate | 21000131002 | 1 |
| Alliance | Sodium hydrocarbonate | 12324704 | 1 |
| Anzag/ Hedinger | Sodium hydrocarbonate | 206027 | 1 |
| Caelo | Sodium hydrocarbonate | 13060103 | 8 |
| Caelo | Sodium hydrocarbonate | 13101706 | 1 |
| Caelo | Sodium hydrocarbonate | 8101203 | 1 |
| Caelo | Sodium hydrocarbonate | 6011404 | 1 |
| Caelo | Sodium hydrocarbonate | 12324725 | 1 |
| Caelo | Sodium hydrocarbonate | 12132204 | 7 |
| Caelo | Sodium hydrocarbonate | 15328602 | 1 |
| Caelo | Sodium hydrocarbonate | 13390520 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium hydrocarbonate | 12132219 | 8 |
| Caelo | Sodium hydrocarbonate | 13186704 | 1 |
| Caelo | Sodium hydrocarbonate | 12324708 | 1 |
| Caelo | Sodium hydrocarbonate | 13060117 | 1 |
| Caelo | Sodium hydrocarbonate | 13060120 | 5 |
| Caelo | Sodium hydrocarbonate | 11304813 | 1 |
| Caelo | Sodium hydrocarbonate | 12356303 | 3 |
| Caelo | Sodium hydrocarbonate | 13234005 | 4 |
| Caelo | Sodium hydrocarbonate | 13234004 | 2 |
| Caelo | Sodium hydrocarbonate | 13234205 | 1 |
| Caelo | Sodium hydrocarbonate | 12132503 | 1 |
| Caelo | Sodium hydrocarbonate | 12356401 | 4 |
| Caelo | Sodium hydrocarbonate | 13234007 | 4 |
| Caelo | Sodium hydrocarbonate | 13234202 | 3 |
| Caelo | Sodium hydrocarbonate | 12356403 | 1 |
| Caelo | Sodium hydrocarbonate | 12356407 | 2 |
| Caelo | Sodium hydrocarbonate | 1203030-1 | 1 |
| Caelo | Sodium hydrocarbonate | 11304802 | 2 |
| Caelo | Sodium hydrocarbonate | 13186706 | 2 |
| Caelo | Sodium hydrocarbonate | 1234702 | 2 |
| Caelo | Sodium hydrocarbonate | 12324702 | 7 |
| Caelo | Sodium hydrocarbonate | 3012Q-01892 | 1 |
| Caelo | Sodium hydrocarbonate | 13390505 | 1 |
| Caelo | Sodium hydrocarbonate | 13186721 | 1 |
| Caelo | Sodium hydrocarbonate | 12132203 | 3 |
| Caelo | Sodium hydrocarbonate | 11304809 | 1 |
| Caelo | Sodium hydrocarbonate | 1219204 | 1 |
| Caesar & Loretz Gm... | Sodium hydrocarbonate | 13060102 | 1 |
| EuRho | Sodium hydrocarbonate | 1203030-01 | 8 |
| EuRho | Sodium hydrocarbonate | 1208008-01 | 9 |
| Euro OCT | Sodium hydrocarbonate | 1307017-01 | 1 |
| Euro OTC | Sodium hydrocarbonate | 120303001 | 1 |
| Euro OTC | Sodium hydrocarbonate | 120800801 | 1 |
| Euro OTC | Sodium hydrocarbonate | 1109029-01 | 8 |
| Euro OTC | Sodium hydrocarbonate | 1012011-01 | 1 |
| Euro OTC | Sodium hydrocarbonate | 1012011 | 1 |
| Euro OTC | Sodium hydrocarbonate | 1304017-01 | 5 |
| Euro OTC | Sodium hydrocarbonate | 1304017-02 | 2 |
| euroho/gehe | Sodium hydrocarbonate | 123030-02 | 1 |
| Euro OTC | Sodium hydrocarbonate | 1104013-01 | 2 |
| Fagron | Sodium hydrocarbonate | 13B18-N03 | 6 |
| Fagron | Sodium hydrocarbonate | 12D11-N02 | 9 |
| Fagron | Sodium hydrocarbonate | 12D11-No2 | 1 |
| Fagron | Sodium hydrocarbonate | 11/12-N16 | 1 |
| Fagron | Sodium hydrocarbonate | 11I12-N16 | 3 |
| Fagron | Sodium hydrocarbonate | 11K25-N05 | 3 |
| Fagron | Sodium hydrocarbonate | 13G11-N03 | 2 |
| Fagron | Sodium hydrocarbonate | RBA3421100 | 3 |
| Fagron | Sodium hydrocarbonate | RBA3651200 | 1 |
| Fagron | Sodium hydrocarbonate | 4413I01892 | 1 |
| fargon | Sodium hydrocarbonate | 12G11-N03 | 7 |
| Finze | Sodium hydrocarbonate | Pr.Nr.4311Q-01892 | 1 |
| Fischer/VDL | Sodium hydrocarbonate | 6521111 | 5 |
| Gehe | Sodium hydrocarbonate | 1203030-02 | 8 |
| Gehe | Sodium hydrocarbonate | 12k09-N05 | 1 |
| Gehe | Sodium hydrocarbonate | 11078315 | 1 |
| gehe 11.12.2013 | Sodium hydrocarbonate | 13D29-N09 | 4 |
| Caelo | Sodium hydrocarbonate | 13186711 | 1 |
| Caelo | Sodium hydrocarbonate | 13186705 | 4 |
| Otto Fischar Phönix | Sodium hydrocarbonate | 6522101 | 6 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Sodium hydrocarbonate | 13390515 | 1 |
| Caelo | Sodium hydrocarbonate | 12109205 | 6 |
| Caelo | Sodium hydrocarbonate | 12109204 | 3 |
| Caelo | Sodium hydroxide | 15312102 | 1 |
| Caelo | Sodium hydroxide | 11070821 | 1 |
| Fagron | Sodium hydroxide | 12E02-N15 | 1 |
| Fagron | Sodium hydroxide | 13F06-N02 | 3 |
| Fagron | Sodium hydroxide | 13k22-no5 | 1 |
| Caelo | Sodium hydroxide | 12368105 | 1 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 18060801 | 1 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 18060803 | 1 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 19143902 | 2 |
| Caelo | Sodium methyl-4-hydroxybenzoate | 17051903 | 2 |
| Bombastus | Sodium monohydrogenphosphat… | 11H04-N06 | 1 |
| Fagron | Sodium monohydrogenphosphat… | 13D24-N12 | 2 |
| Fagron | Sodium monohydrogenphosphat… | 13H01-B01 | 1 |
| Fagron | Sodium monohydrogenphosphat… | 613I-01914 | 1 |
| Fagron | Sodium monohydrogenphosphat… | 12L05-N04 | 2 |
| AHD | Sodium monohydrogenphosphat… | 112345013 | 1 |
| Alliance | Sodium monohydrogenphosphat… | 12256606 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 1169315 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12345013 | 6 |
| Caelo | Sodium monohydrogenphosphat… | 11169303 | 2 |
| Caelo | Sodium monohydrogenphosphat… | 12256602 | 2 |
| Caelo | Sodium monohydrogenphosphat… | 71199028 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12256606 | 3 |
| Caelo | Sodium monohydrogenphosphat… | 9302613 | 2 |
| Caelo | Sodium monohydrogenphosphat… | 11169309 | 3 |
| Caelo | Sodium monohydrogenphosphat… | 12345004 | 7 |
| Caelo | Sodium monohydrogenphosphat… | 12345001 | 2 |
| Caelo | Sodium monohydrogenphosphat… | 11169321 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 11169315 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 83002059 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12345025 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12345016 | 7 |
| Caelo | Sodium monohydrogenphosphat… | AKD7 | 1 |
| Fagron | Sodium monohydrogenphosphat… | 2111E-01914 | 1 |
| Fagron | Sodium monohydrogenphosphat… | 11K30-N01 | 1 |
| Fagron | Sodium monohydrogenphosphat… | 1513I-01914 | 1 |
| Fagron | Sodium monohydrogenphosphat… | B44888A | 1 |
| gebepharm | Sodium monohydrogenphosphat… | 20160909-2 | 1 |
| Gehe | Sodium monohydrogenphosphat… | 12345007 | 3 |
| ICHTHYOL-GESELLSCHAFT | Sodium monohydrogenphosphat… | Caelo | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12109002 | 2 |
| Caelo | Sodium monohydrogenphosphat… | 13028103 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12109109 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12109106 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 10135304 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12109003 | 3 |
| Caelo | Sodium monohydrogenphosphat… | 11109513 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 12109108 | 2 |
| Caelo | Sodium monohydrogenphosphat… | 13028001 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 72006059 | 1 |
| Gehe | Sodium monohydrogenphosphat… | 12109001 | 2 |
| Phönix | Sodium monohydrogenphosphat… | 1302800, | 1 |
| Phönix | Sodium monohydrogenphosphat… | 13028101 | 1 |
| Caelo | Sodium monohydrogenphosphat… | 13028003 | 1 |
| Caelo | Sodium perborate, hydrated | 13050801 | 2 |
| Caelo | Sodium perborate, hydrated | 13050807 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Sodium perborate, hydrated | 13050805 | 1 |
| Aldrich | Sodium proprionate | U02796-056 | 1 |
| Caelo | Sodium thiosulfate | 26041302 | 1 |
| Caelo | Sodium thiosulfate | 80426288 | 1 |
| Fagron | Sodium thiosulfate | 13092013E | 1 |
| Fagron | Sodium thiosulfate | 12F20-N20 | 1 |
| Fagron | Sodium thiosulfate | 12F20-N10 | 1 |
| Fagron | Sodium thiosulfate | 3313U-01922 | 1 |
| Caelo | Softisan® 601 | 15184901 | 1 |
| Caelo | Softisan® 601 | 13296104 | 1 |
| Caelo | Softisan® 601 | 14099608 | 1 |
| Caesar & Loretz GmbH | Softisan® 601 | 18197002 | 2 |
| Caelo | Solanum dulcamara stems, cut | 10375607 | 1 |
| Caelo | Solanum dulcamara stems, cut | 10375605 | 2 |
| Caelo | Solanum dulcamara stems, cut | 132564301 | 1 |
| Caelo | Solanum dulcamara stems, cut | 13254301 | 1 |
| Caelo | Solanum dulcamara stems, cut | 103745604 | 1 |
| Klenk | Solanum dulcamara stems, cut | 5601A080513 | 3 |
| Caelo | Sorrel herb, cut | 130546 | 1 |
| Gahlke | Sorrel herb, cut | 21479 | 1 |
| Caelo | Sorrel herb, cut | 13289502 | 2 |
| Kräuter-Schulte | Sorrel herb, cut | 55272 | 1 |
| Caelo | Sour cherry stems, cut | 10367019 | 1 |
| Caelo | Sour cherry stems, cut | 12042301 | 1 |
| Caelo | Sour cherry stems, cut | 10367014 | 1 |
| Caelo | Sour cherry stems, cut | 12042307 | 1 |
| AHD | Spearmint leaf | 14343404 | 1 |
| Caelo | Spearmint leaf | 13105001 | 10 |
| Caelo | Spearmint leaf | 12376706 | 1 |
| Caelo | Spearmint leaf | 11037409+110374 | 1 |
| Caelo | Spearmint leaf | 12133901 | 3 |
| Caelo | Spearmint leaf | 1512Q-01505 | 1 |
| Caelo | Spearmint leaf | 12133906 | 2 |
| Caelo | Spearmint leaf | 12133909 | 1 |
| Caelo | Spearmint leaf | 13105003 | 1 |
| AHD | St. John's wort | 11185608 | 2 |
| Caelo | St. John's wort | 12092201 | 1 |
| Aurica | St. John's wort | 521202559 | 1 |
| Aurica | St. John's wort | 521200778 | 1 |
| Bahnhof-Apotheke | St. John's wort | 4-121018 | 1 |
| Bombastus | St. John's wort | 275106 | 6 |
| Bombastus | St. John's wort | 268834 | 2 |
| Bombastus | St. John's wort | 265761 | 1 |
| Bombastus | St. John's wort | 268913 | 1 |
| Caelo | St. John's wort | 11185608 | 18 |
| Caelo | St. John's wort | 12092204 | 1 |
| Caelo | St. John's wort | 16041301 | 1 |
| Caelo | St. John's wort | 5021301 | 1 |
| Caelo | St. John's wort | 13091303 | 1 |
| Caelo | St. John's wort | 30011401 | 1 |
| Caelo | St. John's wort | 15068103 | 2 |
| Caelo | St. John's wort | 15068105 | 1 |
| Caelo | St. John's wort | 132203204 | 1 |
| Caelo | St. John's wort | 4021B110321 | 1 |
| Caelo | St. John's wort | 11185607 | 1 |
| Caelo | St. John's wort | 1185608 | 1 |
| Caelo | St. John's wort | 11185602 | 1 |
| Caelo | St. John's wort | 111185608 | 1 |
| Caelo | St. John's wort | 268913 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | St. John's wort | 13203204 | 6 |
| Caelo | St. John's wort | 13203205 | 1 |
| Finze | St. John's wort | 9297303 | 1 |
| Galke | St. John's wort | 21556 | 1 |
| Galke | St. John's wort | 23054 | 1 |
| Galke | St. John's wort | 21034 | 1 |
| Gehe | St. John's wort | 11185602 | 1 |
| Gehe | St. John's wort | 9297305 | 1 |
| Gehe | St. John's wort | 12092209 | 2 |
| Bombastus | St. John's wort | 281530 | 1 |
| Gutenberg-Apotheke | St. John's wort | 4021A100819914 | 2 |
| Hepart AG | St. John's wort | B-445,kbA | 1 |
| Klenk | St. John's wort | 4012A100819 | 1 |
| Klenk | St. John's wort | 4021A-100819 | 1 |
| Klenk | St. John's wort | A130612 | 3 |
| Klenk | St. John's wort | A121120 | 1 |
| Klenk | St. John's wort | 4021A100919 | 1 |
| Klenk | St. John's wort | 4021A100819 | 1 |
| Klenk | St. John's wort | 4021A130612 | 4 |
| Klenk | St. John's wort | 4021a120604 | 1 |
| Klenk | St. John's wort | 4021a100819 | 1 |
| Klenk | St. John's wort | 4021A120905 | 9 |
| Klenk | St. John's wort | 4021B110321 | 2 |
| Klenk | St. John's wort | 4021A120604 | 16 |
| Klenk | St. John's wort | 4021A100819 | 21 |
| Noweda | St. John's wort | 12092202 | 6 |
| Klenk | St. John's wort | 4021A00819 | 1 |
| Wolf | St. John's wort | 19468 | 2 |
| Wolf | St. John's wort | B-424 | 1 |
| Wolf | St. John's wort | B-455 | 2 |
| Wolf | St. John's wort | 21990 | 4 |
| Wolf | St. John's wort | B206152 | 1 |
| Wolf | St. John's wort | 206152 | 1 |
| Caelo | Star anise | 10169101 | 1 |
| Caelo | Star anise | 12226211 | 1 |
| Caelo | Star anise | 11314104 | 1 |
| Caelo | Star anise | 10376405 | 1 |
| Caelo | Star anise | 11314103 | 1 |
| Caelo | Star anise | 10376403 | 2 |
| Klenk | Star anise | 2696B111109 | 1 |
| Klenk | Star anise | B111109 | 1 |
| Klenk | Star anise | 2690A101026 | 1 |
| Klenk | Star anise | 2690A111013 | 3 |
| Klenk | Star anise | 2690A130903 | 2 |
| Klenk | Star anise | 2690A120809 | 1 |
| Caelo | Star anise, cut | 16253201 | 2 |
| Caelo | Stemless carline root | 13130301 | 6 |
| Caelo | Stemless carline root | 13130303 | 1 |
| Caelo | Stemless carline root | 23071203 | 1 |
| Caelo | Stemless carline root | 25111306 | 1 |
| Caelo | Stemless carline root | 14347401 | 1 |
| Caelo | Stemless carline root | 12144804 | 1 |
| Caelo | Stemless carline root | 13033501 | 1 |
| Caelo | Stemless carline root | 13130304 | 1 |
| Caelo | Stemless carline root | 12232803 | 1 |
| Hepart AG | Stemless carline root | B120726 | 1 |
| Klenk | Stemless carline root | B110831 | 1 |
| Klenk | Stemless carline root | 12097301 | 1 |
| Klenk | Stemless carline root | 6194b110831 | 1 |
| Klenk | Stemless carline root | 6194B110831 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Stemless carline root | 69191B120726 | 1 |
| Klnek | Stemless carline root | 6191B120726 | 3 |
| Nachprüfung | Stemless carline root | 2812U02133 | 1 |
| Noweda | Stemless carline root | 12163702 | 1 |
| Caelo | Strawberry leaf | 5122013c | 1 |
| Caelo | Strawberry leaf | 11117909 | 1 |
| Klenk | Strawberry leaf | B120925 | 1 |
| Klenk | Strawberry leaf | A130430 | 1 |
| Klenk | Strawberry leaf | 2031B110224 | 2 |
| Klenk | Strawberry leaf | 2031A130430 | 2 |
| Caelo | Sulfamerazine | 10218401 | 1 |
| Fagron | Sulfanilamide | 11L01-No8 | 1 |
| Klenk | Sunflower, cut | 1711I-07036 | 1 |
| Klenk | Sunflower, cut | 1701B091013 | 1 |
| Caelo | Sweet woodruff herb | 12103508 | 1 |
| Caelo | Sweet woodruff herb | 18031304 | 1 |
| Caelo | Sweet woodruff herb | 12103510 | 1 |
| Caelo | Sweet woodruff herb | 12103513 | 2 |
| Caelo | Sweet woodruff herb | 10375812 | 1 |
| Caelo | Sweet woodruff herb | 4409M-01621 | 1 |
| Caelo | Sweet woodruff herb | 52236077 | 1 |
| Caelo | Sweet woodruff herb | 12103509 | 1 |
| Caelo | Sweet woodruff herb | 10375802 | 1 |
| Caelo | Sweet woodruff herb | 12103504 | 2 |
| Caelo | Sweet woodruff herb | 12103514 | 1 |
| Gahlke | Sweet woodruff herb | 22100 | 1 |
| Klenk | Sweet woodruff herb | 3601B090114 | 1 |
| Klenk | Sweet woodruff herb | B090114 | 3 |
| Klenk | Sweet woodruff herb | 3601B140321 | 1 |
| Kräuter-Schulte | Sweet woodruff herb | 52878 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Talcum | 12267424 | 5 |
| Caelo | Talcum | 13146302 | 8 |
| Caelo | Talcum | 13146315 | 1 |
| Caelo | Talcum | 11318335 | 4 |
| Caelo | Talcum | 13146308 | 6 |
| Caelo | Talcum | 11164313 | 1 |
| Caelo | Talcum | 13146301 | 1 |
| Caelo | Talcum | 28121201 | 1 |
| Caelo | Talcum | 15061301 | 1 |
| Caelo | Talcum | 2011406 | 1 |
| Caelo | Talcum | 11318311 | 3 |
| Caelo | Talcum | 11318324 | 4 |
| Caelo | Talcum | 9218303 | 1 |
| Caelo | Talcum | 11318312 | 2 |
| Caelo | Talcum | 11164306 | 1 |
| Caelo | Talcum | 13146316 | 3 |
| Caelo | Talcum | 12267423 | 3 |
| Caelo | Talcum | 12267401 | 4 |
| Caelo | Talcum | 13146307 | 3 |
| Caelo | Talcum | 12267412 | 7 |
| Caelo | Talcum | 11318301 | 1 |
| Caelo | Talcum | 13146312 | 4 |
| EuRho | Talcum | 1105024-02 | 1 |
| Euro OTC | Talcum | 1305022-01 | 7 |
| Euro OTC | Talcum | 1205046-01 | 2 |
| Euro OTC | Talcum | 1210052-01 | 4 |
| Euro OTC | Talcum | 1305022-02 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Phönix | Talcum | 10148805Retest | 1 |
| Caelo | Tall hawkweed, cut | 3611b111005 | 1 |
| Klenk | Tall hawkweed, cut | B111005 | 1 |
| Klenk | Tall hawkweed, cut | 3611B11105 | 1 |
| Caelo | Tall nasturtium herb, cut | 12031606 | 1 |
| Caelo | Tall nasturtium herb, cut | 12031601 | 1 |
| Caelo | Tall nasturtium herb, cut | 12031602 | 1 |
| Caelo | Tall nasturtium herb, cut | 13104401 | 4 |
| Caelo | Tall nasturtium herb, cut | 12031603 | 1 |
| Caelo | Tall nasturtium herb, cut | 107063 | 1 |
| Caelo | Tall nasturtium herb, cut | 13104402 | 2 |
| Caelo | Tall nasturtium herb, cut | 13104404 | 2 |
| Caelo | Tall nasturtium herb, cut | 13104405 | 1 |
| Caelo | Tall nasturtium herb, cut | 12031605 | 1 |
| Caelo | Tall nasturtium herb, cut | 12031604 | 2 |
| Caelo | Tall nasturtium herb, cut | 13104403 | 5 |
| Caelo | Tall nasturtium herb, cut | 13104406 | 1 |
| Caelo | Thalidomide | 20081504 | 1 |
| Fagron | Thalidomide | 13K20-N01 | 1 |
| Fagron | Thalidomide | 14E27-B04-299297 | 1 |
| Caelo | Theriac | 12289307 | 8 |
| Caelo | Theriac | 12289301 | 4 |
| Caelo | Theriac | 15026405 | 1 |
| Caelo | Theriac | 11081515 | 1 |
| Caelo | Theriac | 2021301 | 1 |
| Caelo | Theriac | 15101307 | 1 |
| Caelo | Theriac | 15312511 | 2 |
| Caelo | Theriac | 11082413 | 1 |
| Caelo | Theriac | 1531501 | 1 |
| Caelo | Theriac | 12289312 | 1 |
| Caelo | Theriac | 13407304 | 2 |
| Caelo | Theriac | 15312501 | 2 |
| Caelo | Theriac | 412091-2P | 1 |
| Caelo | Theriac | 14156501 | 1 |
| Caelo | Theriac | 12189404 | 2 |
| Caelo | Theriac | 15312508 | 1 |
| Caelo | Theriac | 12289306 | 1 |
| Caelo | Theriac | 12289303 | 1 |
| Caelo | Theriac | 15026401 | 3 |
| Caelo | Theriac | 15312504 | 1 |
| Caelo | Theriac | 12189401 | 1 |
| Caelo | Theriac | 12289305 | 2 |
| Caesar/Noweda | Theriac | 12289309 | 1 |
| Klenk | Theriac | 12189403 | 1 |
| Aurica | Thyme | 521207003 | 1 |
| Bahnhof-Apotheke | Thyme | 17-121112 | 1 |
| Bombastus | Thyme | 277996 | 2 |
| Bombastus | Thyme | 277466 | 1 |
| Bombastus | Thyme | 243485 | 1 |
| Caelo | Thyme | 15104401 | 1 |
| Caelo | Thyme | 14119001 | 1 |
| Caelo | Thyme | 13048314 | 1 |
| Caelo | Thyme | 11345007 | 5 |
| Caelo | Thyme | 11345004 | 4 |
| Caelo | Thyme | 11021301 | 1 |
| Caelo | Thyme | 22021301 | 1 |
| Caelo | Thyme | 26021301 | 1 |
| Caelo | Thyme | 29101301 | 1 |
| Caelo | Thyme | 13081301 | 1 |
| Caelo | Thyme | 15101201 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Thyme | 23021304 | 1 |
| Caelo | Thyme | 29011303 | 1 |
| Caelo | Thyme | 25091304 | 1 |
| Caelo | Thyme | 4041301 | 1 |
| Caelo | Thyme | 8061206 | 1 |
| Caelo | Thyme | 12111201 | 1 |
| Caelo | Thyme | 11121306 | 1 |
| Caelo | Thyme | 4021512 | 1 |
| Caelo | Thyme | 13011402 | 1 |
| Caelo | Thyme | 21121204 | 1 |
| Caelo | Thyme | 16011401 | 1 |
| Caelo | Thyme | 25041302 | 1 |
| Caelo | Thyme | 11345001 | 1 |
| Caelo | Thyme | 13048308 | 2 |
| Caelo | Thyme | 10365816 | 1 |
| Caelo | Thyme | 1134514 | 1 |
| Caelo | Thyme | 11345002 | 1 |
| Caelo | Thyme | 11345006 | 3 |
| Caelo | Thyme | 13048302 | 2 |
| Caelo | Thyme | 13048301 | 14 |
| Caelo | Thyme | 11345010 | 6 |
| Caelo | Thyme | 11345011 | 13 |
| Caelo | Thyme | 13048309 | 4 |
| Caelo | Thyme | 11345014 | 12 |
| Caelo | Thyme | 11345013 | 9 |
| Caelo | Thyme | 10365815 | 2 |
| Caelo | Thyme | 10365807 | 2 |
| Caelo | Thyme | 13048309-3475312161 | 1 |
| Galke | Thyme | 20719 | 2 |
| Galke | Thyme | 19386 | 2 |
| Galke | Thyme | 1833 | 1 |
| Galke | Thyme | 28719 | 1 |
| Gehe | Thyme | 4622A110120 | 1 |
| Hepart AG | Thyme | A130109 | 2 |
| Klenk | Thyme | 1910211688 | 1 |
| Klenk | Thyme | 4622a110728 | 1 |
| Klenk | Thyme | 4622A141203 | 1 |
| Klenk | Thyme | 4622A110728 | 25 |
| Klenk | Thyme | 4622A130109 | 75 |
| Klenk | Thyme | 2103311688 | 1 |
| Klenk | Thyme | 4622A120111 | 35 |
| Klenk | Thyme | A130910 | 3 |
| Klenk | Thyme | 4622A130910 | 2 |
| Klenk | Thyme | 4622B110519 | 1 |
| Klenk | Thyme | 4622A12011 | 1 |
| Klenk | Thyme | 4622A-120111 | 1 |
| Klenk | Thyme | 4622a130109 | 2 |
| Klenk | Thyme | 4622A170207 | 1 |
| Klenk | Thyme | 4622A170905 | 3 |
| Klenk | Thyme | 4622a120111 | 3 |
| Noweda | Thyme | 521303908 | 1 |
| Bombastus | Thyme | 273909 | 3 |
| Caelo | Thyme | | 1 |
| Weltecke | Thyme | 67101212 | 1 |
| Caelo | Tonka beans | 12144101 | 1 |
| Caelo | Tonka beans | 20111312 | 1 |
| Caelo | Tonka beans | 1078C | 1 |
| Caelo | Tonka beans | 12145101 | 2 |
| Noweda | Tonka beans | 1040A111026 | 1 |
| Aurica | Tormentil | 521304332 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tormentil | 15085501 | 1 |
| Caelo | Tormentil | 30011405 | 1 |
| Caelo | Tormentil | 10081203 | 1 |
| Caelo | Tormentil | 12040712 | 3 |
| Caelo | Tormentil | 12040717 | 1 |
| Caelo | Tormentil | 2512A-02188 | 1 |
| Caelo | Tormentil | 25022014A | 1 |
| Caelo | Tormentil | 11102010 | 1 |
| Caelo | Tormentil | 12040704 | 2 |
| Caelo | Tormentil | 12216802 | 1 |
| Caelo | Tormentil | 14008005 | 1 |
| Caelo | Tormentil | 15364316 | 1 |
| Caelo | Tormentil | 12040707 | 1 |
| Caelo | Tormentil | 15178203 | 1 |
| Caelo | Tormentil | 411082-2-P | 1 |
| Caelo | Tormentil | 15178206 | 1 |
| Caelo | Tormentil | 12216806 | 1 |
| Caelo | Tormentil | 14360103 | 1 |
| Caelo | Tormentil | 12216803 | 4 |
| Caelo | Tormentil | 14008001 | 2 |
| Caelo | Tormentil | 15364302 | 5 |
| Caelo | Tormentil | 4753268 | 1 |
| Caelo | Tormentil | 12040708 | 9 |
| Caelo | Tormentil | 12040713 | 1 |
| Caelo | Tormentil | 1914A-02188 | 1 |
| Caelo | Tormentil | 6911B150825 | 4 |
| Caelo | Tormentil | 6911B140227 | 1 |
| Caelo | Tormentil | 14140006 | 3 |
| Caelo | Tormentil | 14140001 | 1 |
| Caelo | Tormentil | 12216805 | 1 |
| Caelo | Tormentil | 14008002 | 2 |
| Caelo | Tormentil | 12216801 | 4 |
| Galke | Tormentil | 21744 | 2 |
| Galke | Tormentil | 21091 | 1 |
| Caelo | Tormentil | 13220502 | 1 |
| Klenk | Tormentil | 6911B131029 | 4 |
| Klenk | Tormentil | 6911B141114 | 2 |
| Klenk | Tormentil | 6911B140227 | 1 |
| Klenk | Tormentil | 6911B111013 | 10 |
| Klenk | Tormentil | 6914b120112 | 1 |
| kräuter schulte | Tormentil | 51952 | 1 |
| Noweda 06.04.2016 | Tormentil | 15178202 | 2 |
| Noweda10.02.2017 | Tormentil | 15364313 | 3 |
| phönix | Tormentil | 15364343 | 1 |
| Phönix | Tormentil | 15364302 | 1 |
| Richter | Tormentil | P209904 | 1 |
| Caelo | Tragacanth | 12285403 | 4 |
| Caelo | Tragacanth | 16110802 | 2 |
| Caelo | Tragacanth | 13204705 | 1 |
| Caelo | Tragacanth | 9081202 | 1 |
| Caelo | Tragacanth | 7021402 | 1 |
| Caelo | Tragacanth | 14011302 | 1 |
| Caelo | Tragacanth | 8081201 | 1 |
| Caelo | Tragacanth | 20111305 | 1 |
| Caelo | Tragacanth | 15121203 | 1 |
| Caelo | Tragacanth | 15041302 | 1 |
| Caelo | Tragacanth | 12285402 | 1 |
| Caelo | Tragacanth | 15085602 | 4 |
| Caelo | Tragacanth | 13095208 | 3 |
| Caelo | Tragacanth | 13277804 | 4 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Tragacanth | 15085607 | 1 |
| Caelo | Tragacanth | 11128905 | 1 |
| Caelo | Tragacanth | 13204701 | 4 |
| Caelo | Tragacanth | 13277802 | 4 |
| Caelo | Tragacanth | 13095203 | 1 |
| Caelo | Tragacanth | 153799 | 1 |
| Caelo | Tragacanth | 1228503 | 1 |
| Caelo | Tragacanth | 14162207 | 1 |
| Caelo | Tragacanth | 15379907 | 1 |
| Caelo | Tragacanth | 15085606 | 7 |
| Caelo | Tragacanth | 14162205 | 7 |
| Caelo | Tragacanth | 15379906 | 5 |
| Caelo | Tragacanth | 15085602 | 1 |
| Caelo | Tragacanth | 12108806 | 1 |
| Caelo | Tragacanth | 13204705 | 5 |
| Caelo | Tragacanth | 1327802 | 1 |
| Caelo | Tragacanth | 16350004 | 1 |
| Caelo | Tragacanth | 16110807 | 3 |
| Caelo | Tragacanth | 12285408 | 1 |
| JENNE | Tragacanth | 16110801 | 1 |
| Noweda | Tragacanth | 14162207 | 2 |
| Fagron | Triamcinolone acetonide 1:1… | 12I07-N04 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 11G14-N02 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 14F17-N02 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 12F21-N01 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 12E23-N01 | 2 |
| Fagron | Triamcinolone acetonide 1:1… | 12A05-N07 | 3 |
| Fagron | Triamcinolone acetonide 1:1… | 11g14-n02 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 13F20-N010113/150 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 13A15-N05 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 12I07-N04022/359 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 12I07-No4 | 1 |
| Fagron | Triamcinolone acetonide 1:1… | 12G23-N06 | 3 |
| Fagron | Triamcinolone acetonide 1:1… | 13F21-N01 | 3 |
| Fagron | Triamcinolone acetonide 1:1… | 12I07-N04 | 1 |
| Fargon/17.07.2013/… | Triamcinolone acetonide 1:1… | 12\|07-N04 | 1 |
| Caelo | Tricalcium phosphate | 1056303 | 1 |
| EuRho | Tricalcium phosphate | 13031203 | 1 |
| EuRho /Phönix | Tricalcium phosphate | 1206002-01 | 3 |
| Euro OTC | Tricalcium phosphate | 1304025-01 | 2 |
| Fagron | Tricalcium phosphate | 12I13-N03 | 1 |
| apomix | Trichloroacetic acid | 12G04-M11 | 1 |
| Caelo | Trichloroacetic acid | 13056203 | 3 |
| Caelo | Trichloroacetic acid | 12135207 | 5 |
| Caelo | Trichloroacetic acid | 12135210 | 2 |
| Caelo | Trichloroacetic acid | 14101711 | 1 |
| Caelo | Trichloroacetic acid | 6091306 | 1 |
| Caelo | Trichloroacetic acid | 12135203 | 1 |
| Caelo | Trichloroacetic acid | 12135201 | 1 |
| Caelo | Trichloroacetic acid | 11294318 | 1 |
| Caelo | Trichloroacetic acid | 12g04m11 | 1 |
| Caelo | Trichloroacetic acid | 13056212 | 1 |
| Caelo | Trichloroacetic acid | 10379401 | 1 |
| Caelo | Trichloroacetic acid | 10130802 | 1 |
| Fagron | Trichloroacetic acid | 13B19-M04 | 1 |
| Fagron | Trichloroacetic acid | 13H22-M04 | 1 |
| Merck | Trichloroacetic acid | 12821 | 1 |
| Caelo | Trichloroacetic acid | 13056213 | 1 |
| Caelo | Trichloroacetic acid | 13056209 | 1 |
| Caelo | Trichloroacetic acid | 12135204 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Turmeric rhizome | 15158001 | 2 |
| Caelo | Turmeric rhizome | 12136507 | 1 |
| Caelo | Turmeric rhizome | 15372603 | 1 |
| Caelo | Turmeric rhizome | 13360204 | 2 |
| Caelo | Turmeric rhizome | 15158001 | 2 |
| Caelo | Turmeric rhizome | 12136504 | 1 |
| Caelo | Turmeric rhizome | 12136506 | 1 |
| Caelo | Turmeric rhizome | 1213650 | 1 |
| Caelo | Turmeric rhizome | 16344604 | 2 |
| Caelo | Turmeric rhizome | 15207601 | 1 |
| Caelo | Turmeric rhizome | 12136501 | 2 |
| Caelo | Turmeric rhizome | 12136503 | 2 |
| Galke | Turmeric rhizome | 23123 | 1 |
| Galke | Turmeric rhizome | 20184 | 1 |
| Klenk | Turmeric rhizome | 6741B121030 | 1 |
| Bombastus | Turmeric, javanese | 288629 | 1 |
| Bombastus | Turmeric, javanese | 282221 | 2 |
| Bombastus | Turmeric, javanese | 262792 | 1 |
| Bombastus | Turmeric, javanese | 28221 | 1 |
| Bombastus | Turmeric, javanese | 277130 | 1 |
| Bombastus | Turmeric, javanese | 284242 | 2 |
| Caelo | Turmeric, javanese | 25041313 | 1 |
| Caelo | Turmeric, javanese | 12319201 | 1 |
| Caelo | Turmeric, javanese | 13262907 | 1 |
| Caelo | Turmeric, javanese | 14309503 | 1 |
| Caelo | Turmeric, javanese | 16094101 | 1 |
| Caelo | Turmeric, javanese | 14017706 | 1 |
| Caelo | Turmeric, javanese | 11182903 | 1 |
| Caelo | Turmeric, javanese | 17042002 | 1 |
| Caelo | Turmeric, javanese | 17042003 | 1 |
| Caelo | Turmeric, javanese | 12319206 | 2 |
| Galke | Turmeric, javanese | 15540 | 1 |
| Galke | Turmeric, javanese | 15540 | 1 |
| Gehe | Turmeric, javanese | 12319206 | 2 |
| Klenk | Turmeric, javanese | 6731B160426 | 1 |
| Kenk / Phoenix | Turmeric, javanese | 6731B130117 | 1 |
| Klenk | Turmeric, javanese | B130117 | 1 |
| Klenk | Turmeric, javanese | 6731B150630 | 1 |
| Noweda | Turmeric, javanese | 6731B180412 | 1 |
| Caelo | Turmeric, javanese | 15120202 | 3 |

## U

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Audor Pharma | Uridine | APIB1600169AU | 44 |
| Audor Pharma | Uridine | AP30514IB1500001AXU | 5 |
| Audor Pharma | Uridine | AP3015 | 1 |
| Audor Pharma | Uridine | APIB1600169AU/Re | 1 |
| Audor Pharma | Uridine | AP721060040/5U | 3 |
| Audor Pharma | Uridine | APIB1400280AU | 1 |
| Audor Pharma | Uridine | APIB1600182.11AU | 1 |
| Audor Pharma | Uridine | AP30514U | 5 |
| Audor Pharma | Uridine | APIB16001169 | 1 |
| Audor Pharma | Uridine | APIB1600182AU | 8 |
| Audor Pharma | Uridine | APIB1600169 | 2 |
| Audor Pharma | Uridine | IB1600169AU | 3 |
| Caelo | Uridine | AP1600169AU | 1 |
| Caelo | Uridine | IB1600169A | 1 |
| Fagron | Uridine | 11G07-N04 | 1 |
| Fagron | Uridine | 14051405 | 1 |
| Fagron | Uridine | 22041301 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Fagron | Uridine | 12091402 | 1 |
| Fagron | Uridine | 16101301 | 1 |
| Fagron | Uridine | 721110090 | 4 |
| Fagron | Uridine | 13D08-N26 | 1 |
| Fagron | Uridine | APIB16000169au | 1 |
| Fagron | Uridine | 13K18-B31 | 4 |
| Fagron | Uridine | 14F02-B09 | 1 |
| Fagron | Uridine | 13D29-N06 | 3 |
| Fagron | Uridine | 14F02-B09-305467 | 7 |
| Phönix | Uridine | 721010040 | 1 |
| Roth / Roth | Uridine | 410301476 | 1 |
| siehe WE-Prüfprotokoll | Uridine | 54/11 | 1 |

## V

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Valerian root, cut | 6641B120417 | 1 |
| Aurica | Valerian root, cut | 221838 | 2 |
| Bombastus | Valerian root, cut | 274722 | 1 |
| Bombastus | Valerian root, cut | 267863 | 1 |
| Bombastus | Valerian root, cut | 269457 | 1 |
| Caelo | Valerian root, cut | 12033809 | 9 |
| Caelo | Valerian root, cut | 13287402 | 3 |
| Caelo | Valerian root, cut | 13196802 | 4 |
| Caelo | Valerian root, cut | 13196806 | 6 |
| Caelo | Valerian root, cut | 12033810 | 1 |
| Caelo | Valerian root, cut | 12033808 | 8 |
| Caelo | Valerian root, cut | 1203381 | 1 |
| Caelo | Valerian root, cut | 20081303 | 1 |
| Caelo | Valerian root, cut | 3091202 | 1 |
| Caelo | Valerian root, cut | 31101202 | 1 |
| Caelo | Valerian root, cut | 29101303 | 1 |
| Caelo | Valerian root, cut | 31121201 | 1 |
| Caelo | Valerian root, cut | 28101303 | 1 |
| Caelo | Valerian root, cut | 15175205 | 1 |
| Caelo | Valerian root, cut | 2712A-02167 | 1 |
| Caelo | Valerian root, cut | 120338012 | 1 |
| Caelo | Valerian root, cut | 11103612 | 2 |
| Caelo | Valerian root, cut | 11349101 | 4 |
| Caelo | Valerian root, cut | 11103601 | 1 |
| Caelo | Valerian root, cut | 11035002 | 1 |
| Caelo | Valerian root, cut | 11103608 | 1 |
| Caelo | Valerian root, cut | 11103602 | 1 |
| Caelo | Valerian root, cut | 13119003 | 12 |
| Caelo | Valerian root, cut | 12033812 | 8 |
| Caelo | Valerian root, cut | 12033804 | 9 |
| Caelo | Valerian root, cut | 13119002 | 18 |
| Caelo | Valerian root, cut | 12033811 | 5 |
| Caelo | Valerian root, cut | 11103609 | 4 |
| Caelo | Valerian root, cut | 13119001 | 1 |
| Caelo | Valerian root, cut | 12033807 | 1 |
| Caelo | Valerian root, cut | 13119004 | 3 |
| Caelo | Valerian root, cut | 12033805 | 4 |
| Caelo | Valerian root, cut | 13196801-3564412081 | 1 |
| Galke | Valerian root, cut | 21798 | 4 |
| Galke | Valerian root, cut | 22070 | 1 |
| Klenk | Valerian root, cut | 13196808 | 1 |
| Klenk | Valerian root, cut | 6641B110317 | 2 |
| Klenk | Valerian root, cut | 6641B-110317 | 1 |
| Klenk | Valerian root, cut | 6645B130226 | 1 |
| Klenk | Valerian root, cut | 6641B130226 | 9 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Valerian root, cut | 6641B100823 | 1 |
| Caelo | Valerian root, cut | 1319003 | 1 |
| Sanacorp | Valerian root, cut | 11103607 | 3 |
| Berkel AHK | Valerian root, powdered | 13287406 | 1 |
| Caelo | Valerian root, powdered | 15175204 | 1 |
| Caelo | Valerian root, powdered | 14179403 | 2 |
| Caelo | Valerian root, powdered | 13287402 | 2 |
| an | Verbena herb | 12383007 | 1 |
| Aurica | Verbena herb | 521305668 | 1 |
| Caelo | Verbena herb | 4651b120611 | 1 |
| Caelo | Verbena herb | 12188202 | 14 |
| Caelo | Verbena herb | 19111205 | 1 |
| Caelo | Verbena herb | 6111301 | 1 |
| Caelo | Verbena herb | 15012405 | 1 |
| Caelo | Verbena herb | 11031103 | 1 |
| Caelo | Verbena herb | 12383005 | 1 |
| Caelo | Verbena herb | 13351401 | 1 |
| Caelo | Verbena herb | 12178601 | 1 |
| Caelo | Verbena herb | 12383002 | 2 |
| Caelo | Verbena herb | 11031105 | 2 |
| Caelo | Verbena herb | 11031106 | 5 |
| Caelo | Verbena herb | 13151001 | 18 |
| Caelo | Verbena herb | 12188203 | 6 |
| Caelo | Verbena herb | 11031108 | 5 |
| Caelo | Verbena herb | 2x12188202 | 1 |
| Caelo | Verbena herb | 11031110 | 6 |
| Caelo | Verbena herb | 13151003 | 5 |
| Finze | Verbena herb | 12187601 | 15 |
| Gehe | Verbena herb | 4651B110310 | 2 |
| Klenk | Verbena herb | 4654B120611 | 1 |
| Klenk | Verbena herb | 4651A070828 | 3 |
| Klenk | Verbena herb | A130923 | 1 |
| Klenk | Verbena herb | 4651B130611 | 2 |
| Klenk | Verbena herb | 4651B120611 | 17 |
| Caelo | Verbena herb | 110031110 | 1 |

## W

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Bombastus | Walnut bark | 711B1206130 | 1 |
| Caelo | Walnut bark | 11325606 | 2 |
| Caelo | Walnut bark | 11325605 | 1 |
| Caelo | Walnut bark | 11016604 | 1 |
| Caelo | Walnut bark | 11016605 | 1 |
| Caelo | Walnut bark | 11325603 | 1 |
| Gehe | Walnut bark | 711B110128 | 3 |
| Klenk | Walnut bark | 711B120906 | 2 |
| Klenk | Walnut bark | 711B111020 | 5 |
| Klenk | Walnut bark | 711B120613 | 3 |
| Klenk | Walnut bark | 711B080806 | 1 |
| Klenk | Walnut bark | 711b120613 | 1 |
| Caelo | Walnut leaf | 12124603 | 15 |
| ApoFit/Noweda | Walnut leaf | 271137 | 1 |
| Caelo | Walnut leaf | 12124605 | 8 |
| Caelo | Walnut leaf | 8071502 | 1 |
| Caelo | Walnut leaf | 25041404 | 1 |
| Caelo | Walnut leaf | 3051301 | 1 |
| Caelo | Walnut leaf | 12124602 | 3 |
| Caelo | Walnut leaf | 14064904 | 4 |
| Caelo | Walnut leaf | 11103004 | 2 |
| Caelo | Walnut leaf | 14064906 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Walnut leaf | 10050416 | 1 |
| Caelo | Walnut leaf | 11103001 | 1 |
| Caelo | Walnut leaf | 14064903 | 1 |
| Caelo | Walnut leaf | 15126004 | 1 |
| Caelo | Walnut leaf | 12124502 | 1 |
| Caelo | Walnut leaf | 1214603 | 1 |
| Caelo | Walnut leaf | 1005903 | 1 |
| Caelo | Walnut leaf | 16044008 | 1 |
| Caelo | Walnut leaf | 11103003 | 2 |
| Caelo | Walnut leaf | 15126002 | 1 |
| Caelo | Walnut leaf | 14064909 | 2 |
| Caelo | Walnut leaf | 15126003 | 6 |
| Caelo | Walnut leaf | 11103008 | 5 |
| Caelo | Walnut leaf | 12124603-341930192 | 1 |
| Caelo | Walnut leaf | 3712Q-01499 | 1 |
| Caelo | Walnut leaf | 11103010 | 5 |
| Caelo | Walnut leaf | 1414Q01499 | 1 |
| Caelo | Walnut leaf | 14064910 | 1 |
| Caelo | Walnut leaf | 14064902 | 5 |
| Caelo | Walnut leaf | 4713U01499 | 1 |
| Caelo | Walnut leaf | 414Q1499 | 1 |
| Caelo | Walnut leaf | 12124601 | 8 |
| Caelo | Walnut leaf | 15126008 | 6 |
| Galke | Walnut leaf | 21061 | 1 |
| Gehe | Walnut leaf | 2111B151028 | 3 |
| Gehe | Walnut leaf | 10050412 | 1 |
| Hepart AG | Walnut leaf | A120123 | 1 |
| Caelo | Walnut leaf | 11103009 | 1 |
| Klenk | Walnut leaf | 2111A110816 | 1 |
| Klenk | Walnut leaf | F-280513-1 | 1 |
| Klenk | Walnut leaf | A130410 | 1 |
| Klenk | Walnut leaf | 2111A131029 | 1 |
| Klenk | Walnut leaf | 2111A120123 | 9 |
| Klenk | Walnut leaf | 2111A130410 | 4 |
| Klenk | Walnut leaf | 2111A-120123 | 1 |
| Klenk | Walnut leaf | 211B151028 | 1 |
| noweda | Walnut leaf | | 1 |
| Noweda | Walnut leaf | 11103007 | 6 |
| Caelo | Walnut leaf | 16044002 | 4 |
| Caelo | White deadnettle flower | 10081206 | 1 |
| Caelo | White deadnettle flower | 2101301 | 1 |
| Caelo | White deadnettle flower | 15299101 | 1 |
| Caelo | White deadnettle flower | 11371610 | 5 |
| Caelo | White deadnettle flower | 12152402 | 2 |
| Caelo | White deadnettle flower | 11371613 | 2 |
| Caelo | White deadnettle flower | 52470437 | 1 |
| Galke | White deadnettle flower | 21691 | 4 |
| Galke | White deadnettle flower | 22704 | 1 |
| Caelo | White deadnettle flower | 11371611 | 2 |
| Caelo | White deadnettle flower | 11371609 | 3 |
| Caelo | White deadnettle flower | 12275802 | 1 |
| Klenk | White deadnettle flower | 1470A120111 | 4 |
| Klenk | White deadnettle flower | 1470A080103 | 1 |
| Caelo | White deadnettle herb | 11371711 | 2 |
| Caelo | White deadnettle herb | 11371705 | 1 |
| Caelo | White deadnettle herb | 11371702 | 1 |
| Caelo | White deadnettle herb | 11371709 | 2 |
| Caelo | White deadnettle herb | 11371712 | 1 |
| Caelo | White deadnettle herb | 11371703 | 1 |
| Gahlke | White deadnettle herb | 22253 | 2 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Galke | White deadnettle herb | 19706 | 1 |
| Caelo | White deadnettle herb | 11371706 | 3 |
| Caelo | White mustard seed | 15120304 | 1 |
| Caelo | White mustard seed, powdered | 12375706 | 2 |
| Caelo | White mustard seed, powdered | 12375704 | 1 |
| Caelo | White mustard seed, powdered | 12375701 | 1 |
| Caelo | White mustard seed, powdered | 7254a110823 | 1 |
| Caelo | White mustard seed, powdered | 12375705 | 1 |
| Caelo | White mustard seed, powdered | 12375705 | 4 |
| Caelo | White mustard seed, powdered | 13224804 | 3 |
| Caelo | White mustard seed, powdered | 13224801 | 1 |
| Caelo | White mustard seed, powdered | 12375702 | 1 |
| Klenk | White mustard seed, powdered | 7254A141202 | 1 |
| Caelo | White mustard seed, powdered | 11114409 | 1 |
| Caelo | Wild apple, sweet | 11229805 | 1 |
| Anzag | Wild pansy | 274237 | 2 |
| Bombastus | Wild pansy | 280890 | 1 |
| Bombastus | Wild pansy | 282661 | 2 |
| Bombastus | Wild pansy | 278106 | 2 |
| Bombastus | Wild pansy | 272832 | 1 |
| Bombastus | Wild pansy | 276259 | 3 |
| Bombastus | Wild pansy | 278106 | 2 |
| Bombastus | Wild pansy | 220232 | 1 |
| Caelo | Wild pansy | 10291009 | 3 |
| Caelo | Wild pansy | 14061311 | 1 |
| Caelo | Wild pansy | 17101205 | 1 |
| Caelo | Wild pansy | 7101303 | 1 |
| Caelo | Wild pansy | 13091205 | 1 |
| Caelo | Wild pansy | 15021301 | 1 |
| Caelo | Wild pansy | 5021304 | 1 |
| Caelo | Wild pansy | 11216103 | 3 |
| Caelo | Wild pansy | 11216103 | 2 |
| Caelo | Wild pansy | 12189204 | 10 |
| Caelo | Wild pansy | 12382806 | 1 |
| Caelo | Wild pansy | 10291007 | 1 |
| Caelo | Wild pansy | 12189203 | 4 |
| Caelo | Wild pansy | 4681A180411 | 1 |
| Caelo | Wild pansy | 12189204-3458312120 | 1 |
| Caelo | Wild pansy | 12189203 | 5 |
| Caelo | Wild pansy | 1289203 | 1 |
| Caelo | Wild pansy | 12189204 | 4 |
| Caelo | Wild pansy | 12382802 | 1 |
| Caelo | Wild pansy | 12189204-3463312101 | 1 |
| Fagron | Wild pansy | | 1 |
| Bombastus | Wild pansy | 279314 | 3 |
| Klenk | Wild pansy | 4681A120806 | 1 |
| Klenk | Wild pansy | B130715 | 1 |
| Klenk | Wild pansy | 4681A110303 | 2 |
| Klenk | Wild pansy | 4681A181105 | 1 |
| Klenk | Wild pansy | 4681B130715 | 5 |
| Klenk | Wild pansy | 4681A120806 | 15 |
| Klenk | Wild pansy | 4681A-120806 | 1 |
| Nachprüfung | Wild pansy | 10291007 | 1 |
| Sanacorp | Wild pansy | 12221-01694 | 1 |
| - | Wild thyme, cut | 131023 | 1 |
| - | Wild thyme, cut | 130685 | 1 |
| Caelo | Wild thyme, cut | 11374805 | 5 |
| Caelo | Wild thyme, cut | 11031203 | 1 |
| Caelo | Wild thyme, cut | 11374805i.O. | 1 |
| Caelo | Wild thyme, cut | 13086805 | 3 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Wild thyme, cut | 11374803 | 1 |
| Caelo | Wild thyme, cut | 11374807 | 2 |
| Caesar & Loretz Gm… | Wild thyme, cut | 11374802 | 1 |
| Finze | Wild thyme, cut | 11031204 | 1 |
| Gehe | Wild thyme, cut | 1090413 | 1 |
| Klenk | Wild thyme, cut | 4501A120813 | 2 |
| Bomba/AHD | Willow bark | 280362 | 1 |
| Bombastus | Willow bark | 261615 | 1 |
| Bombastus | Willow bark | 288869 | 1 |
| Bombastus | Willow bark | 277847 | 1 |
| Bombastus | Willow bark | 277005 | 3 |
| Bombastus | Willow bark | 278458 | 2 |
| Bombastus | Willow bark | 251385 | 1 |
| Bombastus | Willow bark | 292710 | 1 |
| Bombastus | Willow bark | 282270 | 1 |
| Bombastus | Willow bark | 281533 | 2 |
| Bombastus | Willow bark | 161594 | 1 |
| Caelo | Willow bark | 12185201 | 5 |
| Caelo | Willow bark | 12185206 | 5 |
| Caelo | Willow bark | 21011302 | 1 |
| Caelo | Willow bark | 9071301 | 1 |
| Caelo | Willow bark | 11073208 | 1 |
| Caelo | Willow bark | 11073210 | 3 |
| Caelo | Willow bark | 13180705 | 1 |
| Caelo | Willow bark | 11073201 | 1 |
| Caelo | Willow bark | 2185206 | 1 |
| Caelo | Willow bark | 12185204 | 4 |
| Caelo | Willow bark | 12185208 | 12 |
| Caelo | Willow bark | 12185207 | 3 |
| Caelo | Willow bark | 13180701 | 1 |
| Caelo | Willow bark | 13180705-3530411072 | 1 |
| Galke | Willow bark | 20338 | 1 |
| Caelo | Willow bark | 13180702 | 4 |
| Klenk | Willow bark | B100910 | 6 |
| Klenk | Willow bark | 811B100910 | 3 |
| Noweda | Willow bark | 4609A-01305 | 1 |
| Caelo | Willow herb | 11347318 | 2 |
| Caelo | Willow herb | 11347311 | 1 |
| Caelo | Willow herb | 13104702 | 1 |
| Caelo | Willow herb | 11347316 | 1 |
| Caelo | Willow herb | 13200203 | 1 |
| Caelo | Willowherb, small flowered | 12064506 | 1 |
| Bahnhof-Apotheke | Willowherb, small flowered | 17-121107 | 1 |
| Bombastus | Willowherb, small flowered | 281846 | 2 |
| Caelo | Willowherb, small flowered | 10326104 | 5 |
| Caelo | Willowherb, small flowered | 10326108 | 14 |
| Caelo | Willowherb, small flowered | 13200203 | 7 |
| Caelo | Willowherb, small flowered | 10326107 | 1 |
| Caelo | Willowherb, small flowered | 1031301 | 1 |
| Caelo | Willowherb, small flowered | 7071201 | 1 |
| Caelo | Willowherb, small flowered | 16081304 | 1 |
| Caelo | Willowherb, small flowered | 12041301 | 1 |
| Caelo | Willowherb, small flowered | 16081302 | 1 |
| Caelo | Willowherb, small flowered | 21061307 | 1 |
| Caelo | Willowherb, small flowered | 2081305 | 1 |
| Caelo | Willowherb, small flowered | 15011411 | 1 |
| Caelo | Willowherb, small flowered | 13071301 | 1 |
| Caelo | Willowherb, small flowered | 18031305 | 1 |
| Caelo | Willowherb, small flowered | 29121201 | 1 |
| Caelo | Willowherb, small flowered | 31101303 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Willowherb, small flowered | 15101302 | 1 |
| Caelo | Willowherb, small flowered | 28031318 | 1 |
| Caelo | Willowherb, small flowered | 14267909 | 1 |
| Caelo | Willowherb, small flowered | 9378908 | 1 |
| Caelo | Willowherb, small flowered | 2412E-01641 | 1 |
| Caelo | Willowherb, small flowered | 13355906 | 2 |
| Caelo | Willowherb, small flowered | 412041 | 1 |
| Caelo | Willowherb, small flowered | 4721C110701 | 4 |
| Caelo | Willowherb, small flowered | 13200202-3481312102 | 1 |
| Caelo | Willowherb, small flowered | 13200201 | 3 |
| Caelo | Willowherb, small flowered | 12117701 | 8 |
| Caelo | Willowherb, small flowered | 12117701-3371319012 | 1 |
| Galke | Willowherb, small flowered | 22347 | 4 |
| Galke | Willowherb, small flowered | 47502 | 1 |
| Klenk | Willowherb, small flowered | 4721C2120321 | 1 |
| Hepart AG | Willowherb, small flowered | 10326110 | 2 |
| Klenk | Willowherb, small flowered | 4721A120418 | 11 |
| Klenk | Willowherb, small flowered | A120418 | 1 |
| Klenk | Willowherb, small flowered | C120321 | 1 |
| Klenk | Willowherb, small flowered | 4721B130528 | 1 |
| Klenk | Willowherb, small flowered | 4721A101010 | 2 |
| Klenk | Willowherb, small flowered | 4721C120321 | 10 |
| Klenk | Willowherb, small flowered | 4721A120903 | 7 |
| Klenk | Willowherb, small flowered | 2512U-01641 | 1 |
| Phoenix | Willowherb, small flowered | 4721C130618 | 4 |
| Bahnhof-Apotheke | Wormwood | 17-121107 | 1 |
| Bombastus | Wormwood | 265417 | 2 |
| Bombastus | Wormwood | 281000 | 1 |
| Bombastus | Wormwood | 221868 | 1 |
| Caelo | Wormwood | 12355807 | 10 |
| Caelo | Wormwood | 12355803 | 27 |
| Caelo | Wormwood | 13174401 | 3 |
| Caelo | Wormwood | 12103003 | 8 |
| Caelo | Wormwood | 7011401 | 1 |
| Caelo | Wormwood | 7031301 | 1 |
| Caelo | Wormwood | 6101203 | 1 |
| Caelo | Wormwood | 15408304 | 1 |
| Caelo | Wormwood | 12355805 | 4 |
| Caelo | Wormwood | 13381905 | 1 |
| Caelo | Wormwood | 11285802 | 2 |
| Caelo | Wormwood | 13174402 | 2 |
| Caelo | Wormwood | 12355801 | 20 |
| Caelo | Wormwood | 12355806 | 7 |
| Caelo | Wormwood | 11285805 | 2 |
| Caelo | Wormwood | 12355804 | 8 |
| Caelo | Wormwood | 12355808 | 2 |
| Caelo | Wormwood | 11285810 | 6 |
| Caelo | Wormwood | 11285803 | 1 |
| Caelo | Wormwood | 272957 | 1 |
| Caelo | Wormwood | 277513 | 1 |
| Galke | Wormwood | 21330 | 1 |
| Gehe | Wormwood | 11285811 | 1 |
| Gehe | Wormwood | 13381901 | 1 |
| Caelo | Wormwood | 13381902 | 3 |
| Caelo | Wormwood | 12355802 | 3 |
| Klenk | Wormwood | 3461A121130 | 2 |
| Klenk | Wormwood | 3461A110324 | 2 |
| Klenk | Wormwood | A110324 | 1 |
| Klenk | Wormwood | 3461A1100324 | 1 |
| Sanacorp | Wormwood | 12103002 | 2 |



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**Y**

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Klenk | Yarrow flower | 4181A121130 | 1 |
| Caelo | Yarrow flower | 12267703 | 2 |
| Caelo | Yarrow flower | 12267702 | 1 |
| Caelo | Yarrow flower | 13350507 | 1 |
| Caelo | Yarrow flower | 12363002 | 6 |
| Caelo | Yarrow flower | 12338306 | 1 |
| Caelo | Yarrow flower | 70139427 | 1 |
| Caelo | Yarrow flower | 12363005 | 5 |
| Klenk | Yarrow flower | A110816 | 3 |
| Alfred Galke | Yarrow herb | 19861 | 1 |
| Anzag 12.11.12 ek:3,85 | Yarrow herb | 11280513 | 1 |
| Bahnhof-Apotheke | Yarrow herb | 7-121011 | 1 |
| Bombastus | Yarrow herb | 279023 | 3 |
| Bombastus | Yarrow herb | 274284 | 1 |
| Bombastus | Yarrow herb | 15006702 | 1 |
| Bombastus | Yarrow herb | 274610 | 2 |
| Bombastus | Yarrow herb | 276498 | 1 |
| Bombastus | Yarrow herb | 275964 | 1 |
| Caelo | Yarrow herb | 13381804 | 2 |
| Caelo | Yarrow herb | 12338304 | 15 |
| Caelo | Yarrow herb | 12379606 | 9 |
| Caelo | Yarrow herb | 13029104 | 5 |
| Caelo | Yarrow herb | 13029105 | 4 |
| Caelo | Yarrow herb | 11218404 | 1 |
| Caelo | Yarrow herb | H-220313-1 | 1 |
| Caelo | Yarrow herb | 12379603 | 7 |
| Caelo | Yarrow herb | 12338305 | 7 |
| Caelo | Yarrow herb | 12338303 | 10 |
| Caelo | Yarrow herb | 16041302 | 1 |
| Caelo | Yarrow herb | 9101311 | 1 |
| Caelo | Yarrow herb | 5021302 | 1 |
| Caelo | Yarrow herb | 12041302 | 1 |
| Caelo | Yarrow herb | 10101205 | 1 |
| Caelo | Yarrow herb | 29071301 | 1 |
| Caelo | Yarrow herb | 8011421 | 1 |
| Caelo | Yarrow herb | 9121304 | 1 |
| Caelo | Yarrow herb | 27011404 | 1 |
| Caelo | Yarrow herb | 10081301 | 1 |
| Caelo | Yarrow herb | 15006720 | 1 |
| Caelo | Yarrow herb | 15006713 | 1 |
| Caelo | Yarrow herb | 15006708 | 1 |
| Caelo | Yarrow herb | 13381810 | 1 |
| Caelo | Yarrow herb | 13381805 | 1 |
| Caelo | Yarrow herb | 11280511 | 2 |
| Caelo | Yarrow herb | 12379607 | 1 |
| Caelo | Yarrow herb | 14018503 | 2 |
| Caelo | Yarrow herb | 16102013E | 1 |
| Caelo | Yarrow herb | 12338311 | 2 |
| Caelo | Yarrow herb | 11306301 | 1 |
| Caelo | Yarrow herb | 11280517 | 1 |
| Caelo | Yarrow herb | 1408510 | 1 |
| Caelo | Yarrow herb | 12338306 | 3 |
| Caelo | Yarrow herb | 13029103 | 13 |
| Caelo | Yarrow herb | 12336306 | 1 |
| Caelo | Yarrow herb | 11280514 | 2 |
| Caelo | Yarrow herb | 12379601 | 9 |
| Caelo | Yarrow herb | 13029106 | 10 |
| Caelo | Yarrow herb | 12338306-3358319071 | 1 |
| Caelo | Yarrow herb | 1309106 | 1 |

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| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Yarrow herb | 11280512 | 9 |
| Caelo | Yarrow herb | 12379602 | 9 |
| Caelo | Yarrow herb | 18304002 | 1 |
| Caelo | Yarrow herb | 18304016 | 1 |
| Caelo | Yarrow herb | 18088002 | 1 |
| Caelo | Yarrow herb | 18304013 | 1 |
| Caelo | Yarrow herb | 130929105 | 1 |
| Caelo | Yarrow herb | 13029107-3436311151 | 1 |
| Caelo | Yarrow herb | 13029107-3418310182 | 1 |
| Caelo | Yarrow herb | 13381806 | 2 |
| Caesar & Lorenz | Yarrow herb | 12379605 | 3 |
| Caesar & Loretz Gm… | Yarrow herb | 11306303 | 1 |
| Fagron | Yarrow herb | 3613M-0165 | 1 |
| Galke | Yarrow herb | 22048 | 7 |
| Galke | Yarrow herb | 23735 | 1 |
| Galke | Yarrow herb | 23318 | 1 |
| Gehe | Yarrow herb | 1128503 | 1 |
| Ichtyol/Phönix | Yarrow herb | 13029108 | 9 |
| Klenk | Yarrow herb | 15333007 | 1 |
| Klenk | Yarrow herb | A130709 | 1 |
| Klenk | Yarrow herb | 4181A130710 | 1 |
| Klenk | Yarrow herb | 4181A101102 | 1 |
| Klenk | Yarrow herb | 4181A121130 | 12 |
| Klenk | Yarrow herb | 4181A130513 | 10 |
| Klenk | Yarrow herb | 4181A111122 | 5 |
| Klenk | Yarrow herb | 4181130709 | 1 |
| Klenk | Yarrow herb | 4181B130709 | 2 |
| Klenk | Yarrow herb | 4181a11011 | 1 |
| Klenk | Yarrow herb | 4181a130513 | 1 |
| Klenk | Yarrow herb | 4181A110111 | 16 |
| nachprüfung | Yarrow herb | C1320 | 1 |
| Noweda | Yarrow herb | 12378603 | 1 |
| Phagron | Yarrow herb | | 3 |
| Caelo | Yarrow herb | 18088008 | 1 |
| Wolf | Yarrow herb | B230010 | 9 |
| Wolf | Yarrow herb | 230010 | 1 |
| Wolf | Yarrow herb | 21295 | 2 |
| Caelo | Yellow chaste weed | 11293101 | 4 |
| Caelo | Yellow chaste weed | 15029505 | 1 |
| Caelo | Yellow chaste weed | 12170605 | 2 |
| Caelo | Yellow chaste weed | 1024407 | 1 |
| Caelo | Yellow chaste weed | 10244407 | 1 |
| Caelo | Yellow chaste weed | 512U-01473 | 1 |
| Caelo | Yellow chaste weed | 12170603 | 1 |
| Klenk | Yellow chaste weed | 1591A110511 | 13 |
| Klenk | Yellow chaste weed | 1591A-110511 | 1 |
| Caelo | Yellow chaste weed | 12170602 | 2 |
| VDL | Yellow chaste weed | 10244406 | 1 |

## Z

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Caelo | Zedoary root | 13010104 | 1 |
| Caelo | Zedoary root | 25111304 | 1 |
| Caelo | Zedoary root | 11091603 | 1 |
| Caelo | Zedoary root | 12125301 | 3 |
| Caelo | Zedoary root | 12125304 | 2 |
| Caelo | Zedoary root | 13010102 | 3 |
| Caelo | Zedoary root | 13010106 | 3 |
| Klenk | Zedoary root | 6941B121025 | 3 |
| Klenk | Zedoary root | 6941B110329 | 2 |

*continued on the next page*



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*continued from previous page*

| Supplier | Substance | Batch | Spectra |
|---|---|---|---|
| Noweda | Zedoary root | 11091605 | 3 |
| Caelo | Zedoary root | 111091607 | 1 |
| Caelo | Zedoary root, powdered | 12007504 | 1 |
| Caelo | Zedoary root, powdered | 15277101 | 1 |
| Caelo | Zedoary root, powdered | 15352606 | 1 |
| Caelo | Zedoary root, powdered | 13165501 | 2 |
| Caelo | Zedoary root, powdered | 13165504 | 4 |
| Klenk | Zedoary root, powdered | 12007505 | 1 |

# *Appendix D:* Requirements of validation

In order to ensure adherence to the safe scientific status, the individual methods for manufacturing and testing must be validated under certain circumstances (compare § 34 para. 1 no. 3, § 35 para. 1 no. 4 and para. 4 sentence 1 no. 2 b, para. 6 sentence 3 *ApoBetrO* [Pharmacies Rules and Regulations]). The *ApoBetrO* [Pharmacies Rules and Regulations] incorporates a legal definition in § 1 a para. 16 (quotation translated):

> *"Validation is the provision of documented proof which with a high degree of safety documents that, via a specific process or standard work process, a medicinal product is manufactured and tested, which is in accordance with previously determined quality features."*

Validation documentation can be used to prove that methods or devices which are not described in the Pharmacopoeia within the meaning of § 6 para. 1 sentence 3 *ApBetrO* [Pharmacies Rules and Regulations] achieve the same results as those in the Pharmacopoeia. On the other hand, with the requirements of the demanded validation it must be observed whether the respective testing method is already incorporated in the Pharmacopoeia.

NIR spectroscopy as a general testing method need not be validated in accordance with the express ruling in the *Ph. Eur. Section 1.1* [3], as it is already described in *Section 2.2.40* of the *Ph. Eur.* as an area of application for the identification of raw materials.

However, a special validation requirement exists for the reference database. This requirement is met with the existing document. Further requirements or rules as to how this proof must be furnished do not exist. It is required that the processes guarantee the same results as the methods and devices in the Pharmacopoeia [17].

Carrying out identity tests with *Apo-Ident* is therefore also possible if the NIR spectroscopy process is not required in the Pharmacopoeia monograph of the substance for identity testing. All NIR analyses with *Apo-Ident* prove several, often all molecule groups and are therefore comparable with a series of individual, targeted chemical proofs [4]. Therefore, the identity proof with *Apo-Ident* replaces the monograph test series (with two or more test combinations).

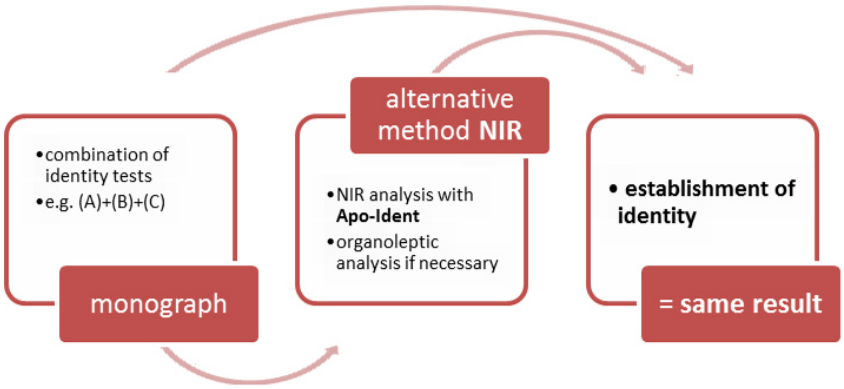



**Figure 2:** The combination of tests of the monograph is replaced by the alternative method NIR spectroscopy using *Apo-Ident*. This is permissible because both test procedures result in the establishment of the identity of the raw material.

With this validation documentation, proof is furnished that identical results are achieved with *Apo-Ident* and Pharmacopoeia methods, i.e. confirmation of the identity of the raw material [2].

# *Appendix E:* Conformity of *Apo-Ident* with the *European pharmacopeia*

According to *Ph. Eur. Section 2.2.40*, NIR spectroscopy is basically suitable for: "Identification of agents, excipients, dosage forms, intermediate manufacturing products, chemical raw materials and packaging materials" ([3], quotation translated).

The fact that *Apo-Ident* meets the further criteria of the European Pharmacopoeia under the headings in *Section 2.2.40*

- Apparatus
- Measurement methods
- Sample preparation and presentation
- Testing the functionality of the instrument
- Identification and characterisation (qualitative analysis)
- Quantitative analysis
- Ongoing model evaluation
- Transfer of databases
- Data storage

can be proven based on the *HiperScan GmbH* documentation of "Meeting *2.2.40 Ph. Eur.* by *Apo-Ident*" [4].


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# *Appendix F:* Explanation of the spectrum acquisition under the control of *HiperScan GmbH*

The spectra for the generation of the database (*type A*) and the spectra for the validation of the database (*type B*) are recorded exclusively under the control of *HiperScan GmbH*. This means that the spectra are recorded either by a qualified employee of *HiperScan GmbH* or by an employee of the *Fagron Group* who has been trained and authorised by *HiperScan GmbH*. Prior to inclusion in the database, the quality assurance of the spectra is carried out by a qualified employee of *HiperScan GmbH*.

# *Appendix G:* Addition to the second-stage models

As described in the general part of the *Apo-Ident* validation documentation, in the section Model creation procedure and validation runs, under *2. Generating the chemometric models (calibration)* in *f)*, it is possible to create a further chemometric model for certain substances (second-stage model) and to undertake the assessment in several steps.

## Substances in second-stage models

In the substance class *APIs & excipients, solid*, a distinction is made between the following substances in the listed second-stage models:

### Submodell - Submodel 01

Beeswax, white
Beeswax, yellow
Cetyl palmitate
Cocoa butter
Hard fat
Hard fat W35
Magnesium stearate
Paraffin, hard
Paraffin, microcrystalline
Sodium dodecyl sulfate

### Submodell - Submodel 02

Betamethasone
Dexamethasone
Fluocinolone acetonide
Gramicidin
Methylprednisolone
Prednisolone
Triamcinolone acetonide
Tyrothricin

### Submodell - Submodel 03

Acacia, dried dispersion
alpha-tocopheryl acetate dry concentrate
Amphotericin B
Bacitracin
Calcium glycerophosphate
Calcium pantothenate
Carmellose sodium
Cholecalciferol dry concentrate
Colistin sulfate
Corn starch
Cyanocobalamin
Erythromycin lactobionate
Estradiol hemihydrate
Estriol
Eucalyptus leaf
Fructose
Gelatine, white
Hyoscine hydrobromide

Maltodextrin
Methylcobalamin
Nystatin
Oxalic acid
Polymyxin B sulfate
Potato starch
Riboflavin
Rice starch
SyrSpend® SF Alka
SyrSpend® SF pH4
SyrSpend® SF pH4 neo (Maize starch)
Tosylchloramide sodium
Triamcinolone
Wheat starch

**Submodell - Submodel 04**

Carbomers
Finasteride
Gentamicin sulfate
Magnesium citrate
Mg-Ca-K colamine phosphate
Neomycin sulfate
Riboflavin sodium phosphate hydrate
Sodium tetraborate
Tobramycin sulfate
Zinc gluconate

**Submodell - Submodel 05**

Fusidic acid
Povidone
Povidone iodine
Progesterone
Spironolactone
Testosterone propionate
Ubidecarenone

**Submodell - Submodel 07**

Betamethasone valerate
Budesonide
Erythromycin

**Submodell - Submodel 08**

Ephedrine hydrochloride
Prednisolone acetate
Prednisone

**Submodell - Submodel 09**

Acetylsalicylic acid
Benzoic acid


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Dequalinium chloride
Dithranol
Eosin Y
Levothyroxin sodium
Oxytetracycline hydrochloride
Sodium salicylate
Tannin

**Submodell - Submodel 12**

Clioquinol
Mesalazine
Miconazole nitrate
Nicotinic acid
Theophylline-ethylenediamine hydrate

**Submodell - Submodel 13**

Alfatradiol
Amifampridine
Amitriptyline hydrochloride
Capsaicin
Ciprofloxacin hydrochloride
Cyproterone acetate
Heparin sodium
Levocarnitine
Methoxsalen
Norethisterone acetate
Oxybutynin hydrochloride
Prednicarbate
Pyridoxal-5-phosphate hydrate
Quinine hydrochloride dihydrate
Sodium citrate
Sucrose
Tetracaine
Triclosan
Valine

**Submodell - Submodel 14**

Atropine sulfate
Calcium orotate dihydrate
Hydrocortisone
Magnesium hydrogen citrate
Mometasone furoate
Phenytoin
Potassium sorbate
Propranolol hydrochloride
Quinoline yellow
Saccharin sodium

**Submodell - Submodel 15**

Beclometasone dipropionate
Betamethasone dipropionate

Clobetasol propionate

**Submodell - Submodel 18**

Diphenylcyclopropenone
Sodium benzoate


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# *Appendix H:* Module for Qualitative Analysis of Cannabis Flowers

The qualitative analysis of cannabis flowers is available only to subscribers of the corresponding reference database. This enables the use of an additional module as a second-stage model.

## Purpose of the Module

The module provides evidence of the presence of both $\Delta^9$-tetrahydrocannabinol (THC) and cannabidiol (CBD), as well as their acid forms, in cannabis flowers and essential oil-containing herbal drugs (e.g., hop strobiles, rosemary leaves, mate leaves, peppermint leaves, and many others). A result is considered positive if the mass fraction is at least 5 %.

A qualitative detection of THC and/or CBD is carried out using qualitative methods in accordance with *Ph. Eur. Section 5.21 Chemometric methods for the evaluation of analytical data.* Thus, the module for the qualitative analysis of cannabis flowers represents, in most cases, a complete alternative to the thin-layer chromatography (TLC) method described in the monograph for cannabis flowers. In cases where the module cannot deliver a fully reliable result, the use of another validated analytical method is recommended (see *Structure and Functionality*).

## Structure and Functionality

The spectrum of a cannabis flower undergoes the following steps within the IdentModule:

1. Upon selecting one of the three chemotypes of cannabis flowers, the sample spectrum is first analyzed using the model for *Solid APIs & excipients*.
2. If one of the three cannabis chemotypes is identified as the closest match in the *Solid APIs & excipients* model, the spectrum is forwarded to the module for qualitative analysis of cannabis flowers.
3. The spectrum is checked for similarity to known cannabis flower spectra. This test may also be passed for spectra from other essential oil-containing herbal drugs. Fundamentally dissimilar spectra are rejected at this stage.
4. The sample is analyzed in parallel using two specialized models that yield a positive or negative result for THC and/or CBD detection. If the model cannot provide a clearly reliable result (e.g., if cannabinoid content is near the 5 % threshold), a neutral result is returned.
5. Based on the results of the THC and CBD models, the substance is identified as follows:

| Model Result for THC | CBD | Substance |
|---|---|---|
| positive | positive | Cannabis flower, THC/CBD type |
| positive | negative | Cannabis flower, THC type |
| negative | positive | Cannabis flower, CBD type |
| negative | negative | Sample rejected, as it cannot be a defined and selectable medicinal substance |
| neutral | (...) | Recommendation to conduct another validated analysis, e.g., |
| (...) | neutral | TLC |

6. Finally, the result is compared with the initial assumption (selected substance).

## Cannabis Flower Substances and Samples

For model development and module optimization, cannabis flowers of pharmaceutical quality were primarily used. These cover the full range of THC/CBD content combinations available in pharmacies. The quality of these flowers is documented through appropriate manufacturer certificates. Additionally, CBD-type flowers from so-called CBD shops were recorded to supplement the data base. These samples mainly serve to improve model robustness and have limited relevance to the pharmacy market. Certificates are only partially available for these samples.

The THC and CBD content of all cannabis flower samples was determined via HPLC, in accordance with the valid monograph, using the same flower(s) from which the NIR spectra were obtained. The date of this analysis is listed in the validation report tables under *Certificate*. Based on these reference values, samples were classified as THC- or CBD-containing if the content (mass fraction) exceeded the 5 % threshold. Subsequently, the samples were grouped into substances by chemotype in accordance with point 5 of the table under *Structure and Functionality*.

- The following samples exhibit a THC content above and a CBD content below 5 %. They have been assigned to the *THC-dominant chemotype*.

| Sample ID | Producer | Brand | Contant / % | |
|---|---|---|---|---|
| | | | THC | CBD |
| B10001 | Weeco Pharma | 1A 18/1 Weeco | 13.91 | 0.07 |
| B10002 | Four 20 Pharma | 420 Evolution 25/1 CA ICC | 24.07 | 0.10 |
| B10003 | Four 20 Pharma | 420 Evolution 27/1 CA ICC | 25.65 | 0.12 |
| B10004 | Four 20 Pharma | 420 Evolution 27/1 CA WES | 26.21 | 0.14 |
| B10005 | Four 20 Pharma | 420 Natural 22/1 CA GG4 | 22.30 | 0.09 |
| B10006 | Four 20 Pharma | 420 Natural 27/1 CA ZRP | 22.87 | 0.10 |
| B10007 | ADREXpharma | Adrex 17/1 CAN | 13.37 | 0.09 |
| B10008 | ADREXpharma | Adrex 22/1 CAN | 22.04 | 0.11 |
| B10009 | AMP | AMP Classic 18/1 | 17.63 | 0.08 |
| B10010 | AMP | AMP Classic 25/1 | 23.23 | 0.10 |
| B10012 | Aurora Deutschland | Aurora 20/1 DNK | 18.13 | 0.14 |
| B10013 | Aurora Deutschland | Aurora 22/1 DNK | 16.93 | 0.11 |
| B10014 | Canopy Growth Corporation | Bakerstreet 20 | 21.75 | 0.08 |
| B10015 | Bedrocan International B.V. | Bedica | 13.43 | 0.12 |
| B10017 | Bedrocan International B.V. | Bedrocan | 16.48 | 0.15 |
| B10019 | Canopy Growth Corporation | Canopy AKH 22 | 24.66 | 0.13 |
| B10021 | Canopy Growth Corporation | Canopy Krypton 25 | 25.52 | 0.12 |
| B10022 | Canopy Growth Corporation | Canopy LSK 16 | 18.75 | 0.12 |
| B10023 | Tilray Deutschland | Navcora THC22 Porto | 19.65 | 0.10 |
| B10024 | Tilray Deutschland | Navcora THC22 Porto | 18.35 | 0.11 |
| B10025 | Aurora Deutschland | Pedanios 20/1 DNK | 18.63 | 0.09 |
| B10026 | Aurora Deutschland | Pedanios 22/1 DNK | 23.98 | 0.12 |
| B10027 | Aurora Deutschland | Pedanios 27/1 FRG-CA | 27.67 | 0.17 |
| B10028 | Aurora Deutschland | Pedanios 29/1 SRD-CA | 30.07 | 0.14 |
| B10029 | Pharmcann Deutschland | Pharmcann Silver THC22 | 22.95 | 0.18 |
| B10030 | Fette Pharma | RE:CANNIS Blüten 16/1 Sativa | 12.76 | 0.07 |
| B10031 | Fette Pharma | RE:CANNIS Blüten 21/1 Indica | 20.34 | 0.13 |
| B10033 | Remexian Pharma | Remexian 22/1 | 21.89 | 0.35 |
| B10034 | Remexian Pharma | Remexian 25/1 | 21.05 | 0.12 |
| B10035 | Remexian Pharma | Remexian 25/1 GAC | 22.55 | 0.10 |
| B10036 | WMG Pharma | Supreme 24/1 WMG Pharma | 24.12 | 0.11 |
| B10038 | Tilray Deutschland | Tilray THC18 Spotlight Porto | 12.63 | 0.31 |
| B10039 | Tilray Deutschland | Tilray THC18 Spotlight Porto | 13.89 | 0.08 |
| B10040 | Tilray Deutschland | Tilray THC22 Indica No. 2 | 16.41 | 0.10 |
| B10041 | Tilray Deutschland | Tilray THC22 Montevideo | 17.02 | 0.08 |
| B10042 | Tilray Deutschland | Tilray THC22 Sativa No. 2 | 19.94 | 0.09 |
| B10043 | Tilray Deutschland | Tilray THC25 Montevideo | 22.32 | 0.11 |
| B10044 | Tilray Deutschland | Tilray THC25 Sativa No. 2 | 17.42 | 0.10 |
| B10045 | Tilray Deutschland | Tilray THC25 Spotlight Porto | 19.08 | 0.12 |
| B10046 | Tilray Deutschland | Tilray THC25 Spotlight Porto | 20.17 | 0.10 |
| B10047 | Tilray Deutschland | Tilray THC25 Spotlight Porto | 17.16 | 0.07 |
| B10048 | Tilray Deutschland | Tilray THC25 Spotlight Porto | 19.31 | 0.09 |
| B10049 | Tilray Deutschland | Tilray THC25 Spotlight Porto | 20.14 | 0.12 |
| B10050 | Tilray Deutschland | TilrayTHC22 Spotlight Porto | 19.51 | 0.09 |
| B10051 | Tilray Deutschland | TilrayTHC22 Spotlight Porto | 15.71 | 0.09 |

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| Sample ID | Producer | Brand | Contant / % | |
|---|---|---|---|---|
| | | | THC | CBD |
| B10052 | Tilray Deutschland | TilrayTHC22 Spotlight Porto | 20.61 | 0.10 |
| B10053 | Vayamed | Vayamed 22/1 | 20.76 | 0.19 |
| B10054 | Weeco Pharma | Weeco 23/1 | 23.63 | 0.11 |
| B10055 | Weeco Pharma | Weeco 25/1 | 22.66 | 0.11 |
| B10057 | Four 20 Pharma | 420 Evolution 27/1 CA STR | 23.78 | 0.51 |
| B10058 | Four 20 Pharma | 420 Natural 17/1 CA TRP | 18.26 | 0.11 |
| B10059 | Four 20 Pharma | 420 Natural 20/1 CA GG4 | 21.94 | 0.10 |
| B10060 | ADREXpharma | Adrex 30/1 8BK CAN | 30.29 | 0.15 |
| B10061 | ADREXpharma | Adrex 26/1 AK COL | 24.45 | 0.15 |
| B10062 | Cansativa | AMICI SB 29/1 | 23.91 | 0.10 |
| B10064 | Vayamed | Avaay 23/1 CK Critical Kush | 18.58 | 0.29 |
| B10065 | WMG Pharma | Supreme 18/1 WMG | 15.28 | 0.11 |
| B10089 | Four 20 Pharma | 420 Evolution 27/1 CA ICC | 25.36 | 0.32 |
| B10090 | Four 20 Pharma | 420 Evolution 27/1 CA WES | 27.11 | 0.15 |
| B10091 | Four 20 Pharma | 420 Natural 27/1 CA ZRP | 24.02 | 0.11 |
| B10092 | ADREXpharma | Adrex 17/1 CAN | 13.75 | 0.09 |
| B10098 | Canopy Growth Corporation | Canopy LSK 16 | 19.72 | 0.29 |
| B10099 | Aurora Deutschland | Pedanios 27/1 FRG-CA | 25.77 | 0.19 |
| B10100 | Aurora Deutschland | Pedanios 29/1 SRD-CA | 30.81 | 0.15 |
| B10101 | Fette Pharma | RE:CANNIS Blüten 16/1 Sativa | 13.27 | 0.08 |
| B10104 | Weeco Pharma | Weeco 25/1 | 23.95 | 0.20 |
| B10106 | Four 20 Pharma | 420 Evolution 27/1 CA STR | 27.95 | 0.13 |
| B10107 | Four 20 Pharma | 420 Natural 17/1 CA TRP | 18.54 | 0.10 |
| B10108 | ADREXpharma | Adrex 30/1 8BK CAN | 29.25 | 0.15 |
| B10109 | ADREXpharma | Adrex 26/1 AK COL | 27.62 | 0.20 |
| B10110 | Cansativa | AMICI SB 29/1 | 26.73 | 0.15 |
| B10117 | Canopy Growth Corporation | Canopy LSK 16 | 10.59 | 0.16 |
| B10118 | Aurora Deutschland | Pedanios 29/1 SRD-CA | 29.59 | 0.18 |
| B10119 | Fette Pharma | RE:CANNIS Blüten 16/1 Sativa | 15.73 | 0.17 |
| B10123 | ADREXpharma | Adrex 30/1 8BK CAN | 27.28 | 0.19 |
| B10124 | Cansativa | AMICI SB 29/1 | 26.47 | 0.13 |
| B10126 | Weeco Pharma | 1A 18/1 Weeco | 17.19 | 0.11 |
| B10127 | AMP | AMP Classic 18/1 | 17.93 | 0.10 |
| B10128 | Tilray Deutschland | Tilray THC18 Spotlight Porto | 11.60 | 0.06 |
| B10129 | Tilray Deutschland | Tilray THC18 Spotlight Porto | 15.24 | 0.09 |
| B10130 | Aurora Deutschland | Pedanios 27/1 FRG-CA | 27.21 | 0.18 |
| B10131 | Four 20 Pharma | 420 Evolution 27/1 CA STR | 26.86 | 0.10 |

- The following samples exhibit both THC and CBD contents above 5 %. They have been assigned to the *THC/CBD intermediate type*.

| Sample ID | Producer | Brand | Contant / % | |
|---|---|---|---|---|
| | | | THC | CBD |
| B20016 | Bedrocan International B.V. | Bediol | 5.01 | 7.45 |
| B20020 | Canopy Growth Corporation | Canopy HSK 8/7 | 8.38 | 7.02 |
| B20032 | Fette Pharma | RE:CANNIS Blüten 9,5/10,5 Hybrid | 10.52 | 10.65 |
| B20037 | Tilray Deutschland | Tilray 9/9 No.2 | 9.02 | 8.46 |
| B20063 | Aurora Deutschland | Cannabis Pedanios 8/8 | 8.33 | 8.74 |
| B20097 | Canopy Growth Corporation | Canopy HSK 8/7 | 7.95 | 6.99 |
| B20102 | Fette Pharma | RE:CANNIS Blüten 9,5/10,5 Hybrid | 9.08 | 10.08 |
| B20103 | Tilray Deutschland | Tilray 9/9 No.2 | 8.78 | 8.82 |
| B20111 | Aurora Deutschland | Cannabis Pedanios 8/8 | 8.06 | 9.17 |
| B20116 | Canopy Growth Corporation | Canopy HSK 8/7 | 7.46 | 6.23 |

*continued on following page*

| Sample ID | Producer | Brand | Contant / % | |
|---|---|---|---|---|
| | | | THC | CBD |
| B20120 | Fette Pharma | RE:CANNIS Blüten 9,5/10,5 Hybrid | 10.11 | 10.68 |
| B20121 | Tilray Deutschland | Tilray 9/9 No.2 | 8.22 | 7.25 |
| B20125 | Aurora Deutschland | Cannabis Pedanios 8/8 | 7.73 | 8.35 |
| B20140 | Cannamedical Pharma | Cannamedical Balanced light | 5.38 | 9.76 |
| B20142 | Bedrocan International B.V. | Bediol | 6.33 | 9.56 |
| B20143 | Tilray Deutschland | Tilray THC9:CBD9 No.2 | 9.26 | 9.94 |
| B20144 | Aurora Deutschland | Pedanios 10/13 MBE-CA | 9.22 | 14.17 |
| B20145 | Aurora Deutschland | Pedanios 10/10 EQI-CA | 10.10 | 11.60 |
| B20154 | IMC (Adjupharm) | IMC balanced 7/8 B01 | 8.43 | 9.36 |

- The following samples exhibit a THC content below and a CBD content above 5 %. They have been assigned to the *CBD-dominant chemotype*.

| Sample ID | Producer | Brand | Contant / % | |
|---|---|---|---|---|
| | | | THC | CBD |
| B30011 | Aurora Deutschland | Aurora 1/12 DNK | 0.56 | 13.14 |
| B30018 | Bedrocan International B.V. | Bedrolite | 0.24 | 6.32 |
| B30056 | Fette Pharma | RE:CANNIS Blüten 1/15 | 1.40 | 14.53 |
| B30073 | Ecommerce Space | Sieved Mix Indoor | 0.14 | 5.00 |
| B30077 | Lucky Life | Strawberry Aroma | 0.15 | 5.47 |
| B30080 | bubatzbros.de | Cali Essentials "California Dream" | 0.68 | 16.50 |
| B30081 | bubatzbros.de | Cali Essentials "Mango Kush" | 0.58 | 11.69 |
| B30083 | HGV Kräutergarten | Tropical Haze Outdoor CBD Blüten | 0.39 | 11.87 |
| B30084 | HGV Kräutergarten | Sweet Babe Blüten | 0.19 | 5.22 |
| B30085 | HGV Kräutergarten | Blue Bear OG Premium Blüten | 0.09 | 5.64 |
| B30086 | HGV Kräutergarten | Northern Lights Premium CBD-Blüten | 0.49 | 14.78 |
| B30087 | HGV Kräutergarten | Purple Haze Premium Blüten | 0.17 | 5.47 |
| B30088 | HGV Kräutergarten | White Widow Premium Blüten | 0.07 | 6.78 |
| B30093 | Aurora Deutschland | Aurora 1/12 DNK | 0.59 | 11.75 |
| B30105 | Fette Pharma | RE:CANNIS Blüten 1/15 | 1.02 | 15.84 |
| B30112 | Aurora Deutschland | Aurora 1/12 DNK | 0.58 | 12.48 |
| B30122 | Fette Pharma | RE:CANNIS Blüten 1/15 | 0.93 | 16.07 |
| B30132 | CBD NOL | CBD Blüten Premium - Redwood Kush | 0.18 | 5.09 |
| B30135 | CBD NOL | CBD Blüten Premium - Purple Kush | 0.32 | 8.98 |
| B30146 | CBD Express | Gelato | 0.10 | 6.97 |
| B30147 | CBD Express | Skywalker OG | 0.26 | 10.94 |
| B30149 | CBD Express | Cameleon | 0.14 | 7.53 |
| B30150 | CBD Express | Harlequin | 0.07 | 10.53 |

- The following samples exhibit both THC and CBD contents below 5 %. They do not correspond to any cannabis flower chemotype according to the monograph, but were included in the model for demarcation purposes, similar to essential oil-containing herbal drugs.

| Sample ID | Producer | Brand | Contant / % | |
|---|---|---|---|---|
| | | | THC | CBD |
| B40066 | Malkmus Holistic | Space Grown Orbitz by Marvin Game | 0.47 | 2.76 |
| B40067 | Malkmus Holistic | Mexican Gold | 0.07 | 2.18 |

*continued on following page*


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| Sample ID | Producer | Brand | Contant / % | |
|---|---|---|---|---|
| | | | THC | CBD |
| B40068 | Malkmus Holistic | Cherry Calussi | 0.12 | 3.31 |
| B40069 | Malkmus Holistic | Melon Kush Deluxe | 0.06 | 2.70 |
| B40070 | Malkmus Holistic | Sweet Berry Jane | 0.01 | 2.02 |
| B40071 | Malkmus Holistic | Bubba Berry by AchtVier | 0.12 | 3.15 |
| B40072 | Malkmus Holistic | Super Lemon Haze 15% CBD | 0.00 | 1.47 |
| B40074 | Ecommerce Space | Sweet Berry | 0.08 | 3.25 |
| B40075 | Ecommerce Space | Gorilla Glue | 0.15 | 4.74 |
| B40076 | Lucky Life | California Blueberry | 0.02 | 2.61 |
| B40078 | Lucky Life | Orange Bud | 0.00 | 1.68 |
| B40079 | Lucky Life | Purple Touch | 0.13 | 4.01 |
| B40082 | HGV Kräutergarten | Lennon Haze CBD Blüten | 0.08 | 4.14 |
| B40133 | CBD NOL | CBD Blüten Premium - Super Lemon Haze | 0.04 | 2.18 |
| B40134 | CBD NOL | CBD Blüten - Cannatonic | 0.06 | 3.51 |
| B40136 | CBD NOL | CBD Blüten - Amnesia Haze | 0.12 | 4.17 |
| B40137 | CBD NOL | CBD Blüten - Pineapple Express | 0.20 | 4.46 |
| B40138 | CBD NOL | CBG Blüten Premium - Big Bud | 0.09 | 0.12 |
| B40139 | CBD NOL | CBD Blüten Premium - Bel Air | 0.19 | 2.84 |
| B40141 | Vayamed | avaay 5/1 THCV12 | 3.74 | 0.10 |
| B40148 | CBD Express | CBN Blüten V-One | 0.16 | 4.77 |

Each of these cannabis flowers was first measured with the Apo-Ident directly as taken from the package, without any pretreatment. Subsequently, spectra of ground flowers were also recorded. This approach is intended to increase the robustness of the model.

## Unambiguous Identifiability

A specificity of 100 % (true negative rate) is required for the module for qualitative analysis of cannabis flowers.

In contrast to other models, the distance to other substances is not evaluated directly. Instead, a probability value for a positive or negative result is calculated based on *Type A* spectra within a given distance from the sample spectrum. From all available cannabis flower samples, a threshold was determined for correct identifications. If the probability value of the sample exceeds this threshold plus a safety margin, the identification is considered unambiguous. Otherwise, a neutral result is issued. The probability thresholds used are summarized in the following table:

| Model | Classification | Probability Threshold |
|---|---|---|
| CBD Identification | positive | 0.92 |
| | negative | 0.82 |
| THC Identification | positive | 0.89 |
| | negative | 0.85 |

## Validation and Scope of the Models

The detection of THC and CBD, including their acid forms, is performed using two specialized PCA models. These are trained with spectra of cannabis flowers, pure cannabinoids, and selected herbal drugs.

To define the herbal drug selection, all pharmacy-relevant herbal drugs were initially considered together with cannabis flowers using the main model for *Solid APIs & excipients*. Herbal drugs whose spectral distance to cannabis flower samples was smaller than the distance to the next API were selected. After building the first generation of the THC and CBD models, the herbal drugs with the largest spectral distance to cannabis flower samples were successively removed until no further improvement in detection rate could be achieved.

The module for qualitative analysis of cannabis flowers is implemented as a second-stage model following the model for *Solid APIs & excipients* (analogous to the submodels). The main model acts as a prefilter, ensuring that only spectra similar to cannabis flower spectra are forwarded. This applies to cannabis flower spectra and certain essential oil-containing herbal drugs.

The restricted selection of substances for model calibration enables high performance, allowing even subtle spectral differences to be effectively evaluated. In combination with the prefiltering main model, this enables differentiation from a wide range of substances.

**The module for qualitative analysis of cannabis flowers has been fully validated against all substances of the classes *Solid APIs & excipients*, *Solid Narcotic Substances*, *Drugs*, and other *Chemicals*.**

## Ongoing Model Maintenance

According to *Ph. Eur.* [3], regular acquisition of new samples and re-evaluation of chemometric models is required. This necessitates batch maintenance for the cannabis flower analysis module. This also applies to the herbal drugs used for calibrating the PCA models for THC and CBD identification. The spectra of all other herbal drugs are considered sufficiently distinct (correlation $< 0.86$) from cannabis flower spectra and are thus filtered out beforehand, meaning they are not evaluated by the cannabinoid identification models.

Regular batch maintenance for calibration and validation of the cannabis flower analysis module is performed for the following herbal drugs:

- Nettle seeds
- Herniaria
- Cannabis flowers
- Bitter fennel
- Cloves
- Ginkgo leaves
- Hop strobiles
- Chamomile flowers
- Caraway
- Lavender flowers
- Mate leaves
- Lemon balm leaves
- Pepper
- Peppermint leaves
- Marigold flowers
- Rosemary leaves
- Celery fruits
- Black mustard seeds
- Senna leaflets
- Thyme


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