

Validation documentation
Specific classifier 26188

HiperScan GmbH

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Contents

Introduction	5
Context of this document	5
Criteria for the inclusion of substances	6
Validation concept	7
Model creation procedure and validation runs	7
Particularities of individual substance classes	10
Significance of testing with <i>Apo-Ident</i>	11
Conclusion	11
Explanation of terminology	12
Summary	17
Validation samples	17
Validation results	17
Validation reports	19
Amygdalin	19
Amygdalin, bitter almond extract 98%	23
Calcium colamine phosphate	27
Deoxycholic acid	31
Dimercaptosuccinic acid	35
Glycyrrhizic acid	39
Griffonia seed extract	43
L-carnitine hydrochloride	47
L-carnitine tartrate	51
Mg-Ca-K colamine phosphate	57
Potassium orotate	61
Appendix	67
Additional calibration samples (<i>Type A</i>)	67
Additional validation samples (<i>Type B</i>)	113
Additional validation samples (<i>Type C</i>)	115
Requirements of validation	117
Conformity of <i>Apo-Ident</i> with the <i>European pharmacopeia</i>	118
References	119
Index	121

Introduction

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

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

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

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

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

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

Context of this document

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

- *NIR spectroscopy as a method for identity testing*: The *Ph. Eur.* [3] describes NIR spectroscopy in *Section 2.2.40* as an analytical method which is also suitable for the identification of raw materials. Therefore, validation of the method as such is not necessary.
- *Performance of the instrument*: The *Ph. Eur.* [3] furthermore describes the apparatus and the testing of its performance in *Section 2.2.40*. The document *Erfüllung von 2.2.40 Ph. Eur. durch Apo-Ident* [4] compares the implementation by *Apo-Ident* with this monograph in order to prove that *Apo-Ident* meets the specifications of the Pharmacopoeia. Each individual instrument delivered to a pharmacy is qualified in accordance with the tests described in “*Control of Instrument Performance*”. In this test, the unit consisting of analysis instrument hardware and the *QuickStep* spectroscopy software is assessed. The result is documented in a test protocol which is kept at the pharmacy.
- *Validation of the database* is documented separately for each substance class. The report at hand documents the substance class *Specific classifier 26188*.

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

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

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

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

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

Criteria for the inclusion of substances

This validation documentation describes the results of the validation of the reference database for the substance class *Specific classifier 26188*. Validation documentation is created for each published version of the reference database for all substance classes incorporated.

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

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

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

- Any positive result of *Apo-Ident* confirms the identity of the substance/substance group and distinguishes it from all other substances of the database. In the case of substance groups, the result is ambiguous: Distinction from all substances not belonging to the group is proven. The substance is identified as a member of this group. However, within the substance group, it is not possible to reliably classify which substance has been tested.
- The criteria for clear identifiability are a [specificity](#) of 100 % ([true negative rate](#)) and a minimum distance in the distance matrix. See 2. d) under [Model creation procedure and validation runs](#).

Validation concept

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

1. Collection of spectra for the *calibration sample*. The results (identities) of the calibration sample must be known. The calibration samples must be representative for the samples which are to be evaluated later. Therefore, they must take the various possible (physical) compositions into account. (Therefore, sourcing calibration samples for NIR from the specialist trade is superior to the use of CRS reference substances.)
2. The first mathematical step is *calibration*. Here, the [chemometric model](#) is calculated from the *calibration sample spectra* ([reference spectra](#)) and limits as well as some parameters are stipulated. The chemometric model is used later to calculate the analysis result (*prediction*).
3. Collection of further spectra for the *validation sample* which should be independent of the *calibration sample*. The results (identities) of the *validation sample* must also be known. The textbook suggests a random sample with a normal scope of 25 % to 50 % of the *calibration sample* [8].
4. The second technical data step is *validation*. Here, the [chemometric model](#) created is evaluated based on the spectra of the *validation samples*. As validation parameters for the identification, the *Ph. Eur. Section 2.2.40* [3] specifies the [specificity](#) and [robustness](#).

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

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

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

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

Model creation procedure and validation runs

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

1. Collecting the reference spectra (calibration sample)

- a) Procurement of the samples from the same sources from which pharmacies source their raw material for compounding (Caelo, Fagron, Euro-OTC, ..., see also *DAC III.2. Bezugsquellen-nachweis für Rezepturbestandteile* [Sources of supply for compounding] [7]).
- b) Testing the suitability according to *ApBetrO* [Pharmacies Rules and Regulations] §§ 6, 11, that is to say the availability of a valid manufacturer certificates via identity, purity and contents of the batch.
- c) Recording standard 40 spectra of the sample in different positions, as a standard on four instruments. Here, handling and presentation of the samples as later in the pharmacy.
- d) Visual checking for anomalies in the spectra. In case of indications of measurement errors, measurement must be repeated. If a signature is missing in the spectrum, the substance may be excluded from the start as not promising (the spectra are nonetheless entered in the database validation as independent *Type B* spectra).
- e) Testing identity. For each substance, a certificate of correct identity is obtained from an independent GMP-certified test laboratory. If the identity of the sample can be provided using NIR on an independently tested reference sample, in the respective following substance page of this validation documentation the *Mahalanobis distance* to this reference sample is specified as well as the *Mahalanobis distance* to the next non-identical substance. Such samples underline the statistical spread of the original reference substance, but cannot add any new characteristics of the substance.

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

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

2. Generating the chemometric models (calibration)

- a) Determination of the transformation matrix from the reference spectra using variance maximisation [8, 9]. (All reference spectra are always included, even if only a few spectra are added for an update.) All reference spectra receive the same data pre-treatment, which is also later applied to all measurement spectra in the field (in the pharmacies).
- b) Checking that the number of principal components used is still sufficient.
- c) Calculating the limits for each substance from the spread of the reference spectra. The calculation regulation is identical for each substance in a substance class.
- d) Überprüfen der Abstände zwischen den Grenzen der trennbaren Substanzen: Die Distanzmatrix enthält die *Mahalanobis-Abstände* von jeder Substanz zu jeder anderen. Die Werte hin und zurück sind jeweils unterschiedlich, weil die Streuung der Ausgangssubstanz eingeht. Ist eine Distanz kleiner als der Mindestabstand, so gelten die Substanzen als nicht sicher trennbar. Der Mindestabstand ist auf 9 festgelegt. Der Entwickler des Modells darf einen größeren Mindestabstand festlegen (ein Wert für das gesamte *chemometrische Modell*), um die Trennschärfe zu erhöhen.
- e) Überprüfung des Modells anhand der Referenzspektren. Es sind keine *falsch-positiven* Ergebnisse erlaubt.

f) Wird eines der Kriterien verletzt (d) *Unterschnittener Mindestabstand zwischen zwei Substanzen* oder (e) *Eine Substanz wird als eine andere identifiziert*, entscheidet der Entwickler der Datenbank, welche der folgenden Optionen er anwendet:

- Er nimmt beide Substanzen aus der Datenbank. (Die Spektren bleiben in der Validierung und dürfen auch in den Aufbau eingehen. Sie werden aber nicht zur Prüfung angeboten.)
- Er bildet eine Substanzgruppe mehrerer nicht sicher trennbarer Substanzen. Dann ist das Ergebnis mehrdeutig: Das chemometrische Modell stellt fest, dass es sich bei der Probe um eine der Substanzen aus der Gruppe handelt und dass es sich um keine andere Substanz handelt. Es kann aber nicht sagen, um welche der Substanzen es sich handelt. Um die eindeutige Identität festzustellen, muss der Anwender eine geeignete ergänzende Prüfung durchführen.
- Er erstellt ein weiteres *chemometrisches Modell* mit geringerem Umfang, in das mindestens alle Substanzen der nicht sicher trennbaren Substanzgruppe eingehen (Zweite-Stufe-Modell). Zweite-Stufe-Modelle werden nur aufgerufen, wenn die erste Stufe festgestellt hat, dass es sich nur um eine der Substanzen handeln kann, die in den Aufbau der Zweiten Stufe eingegangen ist.

3. Set of validation spectra (validation samples)

The following is provided for validation:

- a) *Type A*: The reference spectra = calibration spectra from which the database was generated. These also include spectra from substances which the *chemometric model* should not identify, but were also recorded during generation in order to increase selectivity. (As a result, the model “learns” to differentiate from other substances which are actually unknown to it.)
- b) *Type B*: Spectra recorded under the control of *HiperScan GmbH* and not used for the generation of the database. These also include reference spectra of other substance classes, and spectra that are not used as reference spectra. Samples are considered to be independent, if they originate from a batch, of which no spectra have been used for the generation of the database. (Up to *IdentModule 2018-01*, samples were still considered independent if the sampling was done independently, i.e. if they originate from another sales container.)
- c) *Type C*: Spectra from the field, which have not been recorded under the control of *HiperScan GmbH* and have not been used for the generation of the database. The spectra include not only substances of the substance class to be tested, but also substances from other classes.

All manufacturers’ batches from which spectra are used for the validation are listed by substance in this document: for substances included in the substance class *Specific classifier 26188* in the respective validation reports; otherwise in attachments *A*, *B* and *C*.

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

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

4. Validation runs and approval

- a) Validation spectra are transferred holistically to the *IdentModule* for evaluation in the same way as the spectroscopy software *QuickStep* transfers measured spectra.
- b) Following the provision of each spectrum, the *IdentModule* responds as to whether it has recognised a substance and which substance was recognised.
- c) The correctness of this response is checked for each possible initial assumption (each measurable substance with the substance class) and counted according to *true negative*, *false negative*, *true positive* and *false positive*. These figures are provided for each substance and additionally in the section *Summary*, separated according to types *A*, *B* and *C*.

- d) No *false positive* results whatsoever are permissible.
- e) If the criterion is also met for all substance classes, the *IdentModule* is approved.

Particularities of individual substance classes

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

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

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

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

Also, for the substance class **PhytoComm** (TCM-Granulated herbal extracts of the manufacturer *PhytoComm*) spectra for all useable batches are recorded by *HiperScan GmbH* and entered in the database. The supplier organises the respective tests themselves and keeps the test certificates.

A new evaluation option was created for the class *PhytoComm* with the update 2016-01. As the risks are considerably fewer than those from chemical agents, the pharmacist can specify a reasonable criterion for the *specificity* in accordance with internal risk estimation. The database for this is created without taking safety distances into account and no criterion is determined in advance for the *specificity*. Instead, the *specificity* for testing the identity with this concrete substance is calculated in the validation for each substance and provided with the measurement result. The pharmacist then judges himself whether this safety is reasonable with regard to the risk of the substance.

Additionally, a statistical forecast is provided for the *specificity* which is determined according to the *Rule of Three* [10, 11]. For this forecast, it is assumed that there would have been three wrong results more and is provided with a lower limit for *specificity*. This value has a special meaning if a *specificity* of 100 % is achieved for a substance during validation. In this case, the lower limit allows conclusions regarding the scale of existing safety for which with an endless number of validation spectra a value of less than 100 % is to be assumed.

If, for example 14 000 spectra not belonging to the substance are presented and no *false positive* classification is made, a hypothetical number of three *false positive* results is assumed (*Rule of Three* [10, 11]) and the *specificity* is defined with 100.0000 % (> 99.9786 %). Here, it applies that the higher the number of validation spectra which form the statistical basis, the better the *specificity* calculated via the lower *specificity* limit will be approximated.

The positive result of the identity test using *Apo-Ident* establishes that the sample spectrum is in accordance with a batch of the specified granulate from the supplier *PhytoComm*, whereby all useable batches from the supplier are known.

The *PhytoComm* class can only confirm the identity of batches that have been used for the generation of the database. As a consequence there cannot be any validation spectra of other batches. Therefore, the criterion reads that two samples (from different sales containers) from each batch must exist, one for the structure of the database (*Type A*) and one for the validation (*Type B*).

Significance of testing with *Apo-Ident*

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

Verbally, the statement of the analysis result can be expressed as follows. Here “*the spectra match*” means that the criteria *Mahalanobis distance*, *outlier analysis* and *correlation* are met as shown in *Erfüllung von 2.2.40 Ph. Eur. durch Apo-Ident* [4]. “The spectra do not match”, on the other hand, means that at least the criterion *Mahalanobis distance* is not met.

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

1. The spectrum of the sample measured matches spectra of the defined substance.
2. The spectrum of the sample measured does not match any spectrum of any other substance in this substance class. Therefore, all other substances can be clearly ruled-out.
3. As the spectra from other substance classes were used for validation, it is proven that no spectrum of one of these other substances matches the defined substance. (All substance classes with which a spectrum comparison is possible and makes sense are used for validation. This is documented for each substance class in the section *Summary*.)
4. If the defined substance belongs to a *substance group* which in itself is not clearly separable with *Apo-Ident*, matching with the spectra of one or several substances in this group is confirmed. Which of these substances it actually is cannot be determined clearly. All other substances are excluded analogous to 2 and 3.

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

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

Conclusion

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

Explanation of terminology

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

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

Substance classes are units of the organisational structure of the *IdentModule*. The substance classes are substance [databases](#) which are also broadly independently subscribable. On the one hand, the liquid and semi-solid substances are separated from the solid powders because they are measured against different references and therefore the spectra cannot be compared. On the other hand, for example the Pharmacopoeia substances are kept separated from the manufacturer-specific database *PhytoComm* for TCM (traditional Chinese medicine) raw materials.

The individual substance classes need only be limited against each other in-part. Often, no risk of confusion exists because they can only be procured from different sources. On the other hand, in several cases we handle substances which need not be distinguished. For example, em Huang Qi granulate from the company *PhytoComm* neither needs to be delimited from *Huang Qi* granulate from the company *HerbaSinica* nor is matching required. Respectively one single [chemometric model](#) is behind a substance class. (Even if several reciprocally secured chemometric models would be permissible.) The terms *substance class*, *chemometric model* and *databases* are mostly used here as synonyms.

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

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

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

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

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

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

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

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

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

The specificity of a classification (of a [chemometric model](#)) is the [true negative rate](#).

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

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

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

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

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

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

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

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

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

with r_p as the total number of *true positive* classifications and f_n as the total number of *false negative* classifications. The *true positive rate* is a measure for the recognition rate of the validated *Apo-Ident IdentModule*.

In order to ensure that each substance is received with the same weight, the spectra are weighted as described for the [true negative rate](#).

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

The false positive result describes a spectrum falsely classified as non-identity during validation. This is the most critical type of possible false classification. It means that a substance *A* within identity checking as substance *B* is judged as “*identified*”. For successful validation of an *IdentModule*, a number of false positive events of zero are demanded for all spectra entering the validation. The exception to this restriction is the class of TCM granulates from the company *PhytoComm* as described under [Particularities of individual substance classes](#).

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

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

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

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

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

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

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

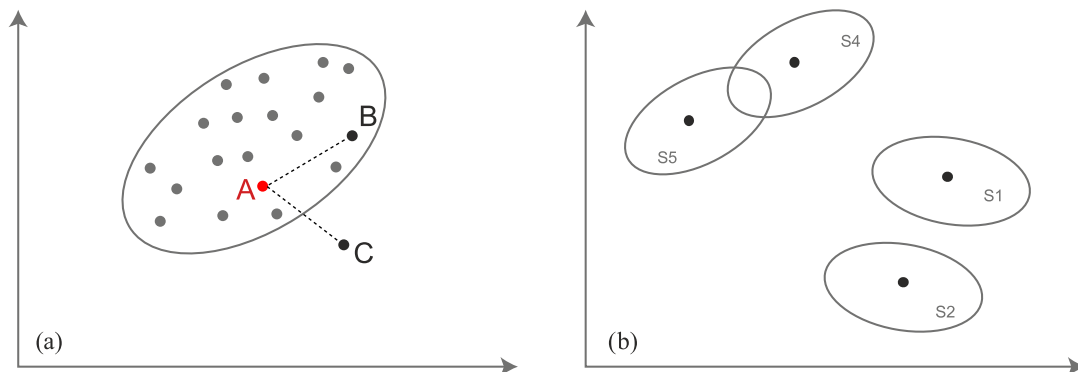


Figure 1: (a) The *Mahalanobis distance* from *A* to *B* is less than from *A* to *C*. However, the Euclidean distances are identical. (b) The *Mahalanobis distance* between the two measurement series *S4* and *S5* is smaller than between *S1* and *S2*. However, the Euclidean distances are identical.

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

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

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

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

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

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

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

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

Summary

A total of 111 543 spectra from 1988 different batches for a total of 393 substances were used to validate the substance class *Specific classifier 26188*.

Validation samples

The validation samples can be categorised as follows:

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

Substance class	Substances	Batches	Spectra
Specific classifier 26188	11	23	1140
APIs & excipients, solid	348	1848	101 728
Narcotic substances, solid	15	75	6951
Drugs	17	20	870

From category *A* a total of 110 689 spectra from 1966 batches for a total of 391 substances were taken into account for validation.

Typ B Spectra from independent samples which are not included in database generation. These spectra were recorded by *HiperScan GmbH*. Detailed information regarding the batches or samples can be found in the following validation reports in the section *Type B* or in [Appendix B](#).

Substance class	Substances	Batches	Spectra
Specific classifier 26188	12	19	849

From category *B* a total of 849 spectra from 19 batches for a total of 12 substances were taken into account for validation.

Typ C Spectra from independent samples which are not included in database generation. *Apo-Ident* customers carried out the measurements. Detailed information regarding the batches or samples can be found in the following validation reports in the section *Type C* or in [Appendix C](#).

Substance class	Substances	Batches	Spectra
Specific classifier 26188	2	5	5

From category *C* a total of 5 spectra from 5 batches for a total of 2 substances were taken into account for validation.

Validation results

The validation runs checked whether all substances/substance groups in the substance class *Specific classifier 26188* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, the matching of all relevant spectra of various substances with the substances/substance groups in the substance class *Specific classifier 26188* was checked and the correctness of the results was evaluated. The following table breaks down the numbers of correct and

incorrect results according to the expected result (*positive/negative*) and the validation spectrum type (*A/B/C*).

	False positive	True positive	False negative	True negative
Type A	0	1138	2	1 216 439
Type B	0	451	278	8610
Type C	0	5	0	50

All substances/substance groups in the substance class *Specific classifier 26188* can be clearly distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. In order to make these figures comparable, the weighted *true negative rate* (*specificity*) and the weighted *true positive rate* (*recognition rate*) are determined:

	Specificity	Recognition rate
Typ A	100.000 00 % (> 99.999 13 %)	99.870 13 % (> 99.506 89 %)
Typ B	100.000 00 % (> 99.913 77 %)	54.388 19 % (> 53.870 21 %)
Typ C	100.000 00 % (> 81.250 00 %)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	Amygdalin
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	23000-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

Amygdalin; Amygdalinum

Special notes

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

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]

Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]

AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Amygdalin	1	2	0

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Amygdalin*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Flora Apothek...	Amygdalin	13121802	21105	40	1405619

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 40 spectra of 1 reference samples from the substance/substance group *Amygdalin*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 1 different batches.
- 110 649 spectra from a total of 1965 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

- 80 spectra of 2 reference samples from the substance/substance group *Amygdalin*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

Supplier	Substance	Batch	Sample ID	Spectra
abcr GmbH	Amygdalin	1310927	21337	40
abcr GmbH	Amygdalin	1310579	21343	40

- 769 spectra from a total of 17 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Amygdalin*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	40	0	110 649
Type B	0	0	80	769
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9905 %)	100.0000 % (> 85.0000 %)
Type B	100.0000 % (> 99.0199 %)	0.0000 % (≥ 0.0000 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra ([Rule of Three](#) [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Amygdalin* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Levothyroxin sodium	25.97	—
Sodium cromoglicate	27.54	—
Vancomycin hydrochloride	40.15	—
Sodium tetraborate	45.31	—
Oxytetracycline hydrochloride	49.56	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
21105	21105	0.00	33.48

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group **Amygdalin, bitter almond extract 98%**
Substance class Specific classifier 26188
Report date 14/07/2020
Report number 21929-2020-07-14
Executing company HiperScan GmbH
Weißeritzstraße 3
01067 Dresden
Germany

Relevant substance names

Amygdalin, bitter almond extract 98%

Special notes

When selecting the *Amygdalin, bitter almond extract 98%* substance/substance group, the following information is displayed to the user:

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Amygdalin, bitter almond extract 98%	2	1	0

Second-stage model

For differentiation of the substance/substance group *Amygdalin, bitter almond extract 98%* the following second-stage model is used:

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Amygdalin, bitter almond extract 98%*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Auropure Life...	Amygdalin, bitte...	PA02099-17102131	24431	40	from supplier
Safic-Alcan	Amygdalin, bitte...	BAE150902	21929	60	from supplier
Safic-Alcan	Amygdalin, bitte...	BAE150902	21930	60	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 160 spectra of 3 reference samples from the substance/substance group *Amygdalin, bitter almond extract 98%*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 2 different batches.
- 110 529 spectra from a total of 1964 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

- 30 spectra of 1 reference samples from the substance/substance group *Amygdalin, bitter almond extract 98%*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

Supplier	Substance	Batch	Sample ID	Spectra
Auropure LifeScience	Amygdalin, bitter almond ext...	PA02099-160822	23605	30

- 819 spectra from a total of 18 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Amygdalin, bitter almond extract 98%*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

The validation runs checked whether the substance/substance group *Amygdalin, bitter almond extract 98%* can clearly be distinguished from all other substances using NIR spectroscopy with *Apo-Ident*. For this purpose, all relevant spectra of the various substances were compared with *Amygdalin, bitter almond extract 98%* and it was evaluated how many matches (positive) and rejections (negative) were correct or incorrect. The following table breaks down the numbers of correct and incorrect results according to the expected result (*positive/negative*) and the validation spectrum type (*A/B/C*).

	False positive	True positive	False negative	True negative
Type A	0	160	0	110 529
Type B	0	30	0	819
Type C	0	0	0	5

The substance/substance group *Amygdalin, bitter almond extract 98%* can be clearly distinguished from all other substances. In order to make these figures comparable, the weighted *true negative rate (specificity)* and the weighted *true positive rate (recognition rate)* are determined:

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	100.0000 % (> 96.2500 %)
Type B	100.0000 % (> 99.1232 %)	100.0000 % (> 80.0000 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Amygdalin, bitter almond extract 98%* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Levothyroxin sodium	22.45	—
Vancomycin hydrochloride	32.33	—
Hydrochlorothiazide	33.32	—
Sodium cromoglicate	34.16	—

The list stops after the first substance with a *Mahalanobis distance* greater than 50. If the substance/substance group *Amygdalin, bitter almond extract 98%* is separated from critical neighbours in a second-stage model, all the remaining substances in the second-stage model follow.

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
21929	21929	0.00	24.46
21930	21930	0.00	25.83
24431	24431	0.00	25.98

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	Calcium colamine phosphate
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	20536-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

Calcium colamine phosphate

Special notes

When selecting the *Calcium colamine phosphate* substance/substance group, the following information is displayed to the user:

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Calcium colamine phosphate	3	1	0

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Calcium colamine phosphate*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Flora Apothek...	Calcium colamine...	14384	21112	40	from supplier
Th. Geyer	Calcium colamine...	33299	22337	60	from supplier
Th. Geyer	Calcium colamine...	66606	24432	40	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 140 spectra of 3 reference samples from the substance/substance group *Calcium colamine phosphate*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 3 different batches.
- 110 549 spectra from a total of 1963 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

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

Supplier	Substance	Batch	Sample ID	Spectra
Th. Geyer	Calcium colamine phosphate	36986	24110	40

- 809 spectra from a total of 18 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Calcium colamine phosphate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	140	0	110 549
Type B	0	30	10	809
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	100.0000 % (> 95.7143 %)
Type B	100.0000 % (> 99.0819 %)	75.0000 % (> 67.5000 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Calcium colamine phosphate* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Riboflavin phosphate sodium	26.04	—
Carbomers 35000 / 50000	28.23	—
Magnesium hydrogen citrate	29.75	—
Magnesium citrate	30.24	—
Gentamicin sulfate	31.51	—
Dihydrocodeine hydrogen tartrate	32.97	—
Mg-Ca-K colamine phosphate	35.09	—
Levothyroxin sodium	45.97	—
L-glutathione	46.00	—
Estradiol hemihydrate	56.82	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
21112	21112	0.00	35.09
22337	22337	0.00	28.12
24432	24432	0.00	46.88

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	Deoxycholic acid
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	20412-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

Deoxycholic acid; Deoxycholic acidum

Special notes

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

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Deoxycholic acid	2	1	3

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Deoxycholic acid*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Euro OTC	Deoxycholic acid	1305051-01	22575	40	from supplier
New Zealand P...	Deoxycholic acid	0416720	24875	40	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 80 spectra of 2 reference samples from the substance/substance group *Deoxycholic acid*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 2 different batches.
- 110 609 spectra from a total of 1964 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

- 100 spectra of 2 reference samples from the substance/substance group *Deoxycholic acid*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

Supplier	Substance	Batch	Sample ID	Spectra
Fagron	Deoxycholic acid	14A02-B32-303429	21967	60
Fagron	Deoxycholic acid	14A02-B32-303429	23014	40

- 749 spectra from a total of 18 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 4 spectra from 2 *Apo-Ident* customers from 4 batches from the substance/substance group *Deoxycholic acid*.
- Among them are spectra of independent samples from 3 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

Supplier	Substance	Batch	Spectra
Fagron	Deoxycholic acid	13J21-N14	1
Gehe	Deoxycholic acid	2012060253	1
GEHE 21.10.2014	Deoxycholic acid	13F13-N06	1
Euro OTC	Deoxycholic acid	1305051-01	1

- 1 spectra from 1 *Apo-Ident* customers from a total of 1 batches from a further 1 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	80	0	110 609
Type B	0	100	0	749
Type C	0	4	0	1

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	100.0000 % (> 92.5000 %)
Type B	100.0000 % (> 99.0075 %)	100.0000 % (> 94.0000 %)
Type C	n/a (n/a)	n/a (n/a)

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

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

exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Deoxycholic acid* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Menthol	34.15	—
Soy lecithin (instant form)	40.86	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
22575	22575	0.00	37.51
24875	24875	0.00	36.66

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	Dimercaptosuccinic acid
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	21345-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

Dimercaptosuccinic acid

Special notes

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

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Dimercaptosuccinic acid	1	2	1

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Dimercaptosuccinic acid*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Safic-Alcan	Dimercaptosuccin...	20170210	23604	40	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 40 spectra of 1 reference samples from the substance/substance group *Dimercaptosuccinic acid*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 1 different batches.
- 110 649 spectra from a total of 1965 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

- 79 spectra of 2 reference samples from the substance/substance group *Dimercaptosuccinic acid*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

Supplier	Substance	Batch	Sample ID	Spectra
abcr GmbH	Dimercaptosuccinic acid	1005874	21345	39
Safic-Alcan	Dimercaptosuccinic acid	20180130	24109	40

- 770 spectra from a total of 17 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 1 spectra from 1 *Apo-Ident* customers from 1 batches from the substance/substance group *Dimercaptosuccinic acid*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.

Supplier	Substance	Batch	Spectra
Dr. Behr	Dimercaptosuccinic acid	WE14020002	1

- 4 spectra from 2 *Apo-Ident* customers from a total of 4 batches from a further 1 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	40	0	110 649
Type B	0	61	18	770
Type C	0	1	0	4

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9905 %)	100.0000 % (> 85.0000 %)
Type B	100.0000 % (> 99.0207 %)	77.2152 % (> 73.4177 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Dimercaptosuccinic acid* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Bismuth gallath, basic	89.94	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
23604	23604	0.00	104.99

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	Glycyrrhizic acid
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	23001-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

Glycyrrhizic acid; Acidum glycyrrhiza

Special notes

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

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Glycyrrhizic acid	1	1	0

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Glycyrrhizic acid*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Flora Apothek...	Glycyrrhizic acid	10588	24175	40	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 40 spectra of 1 reference samples from the substance/substance group *Glycyrrhizic acid*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 1 different batches.
- 110 649 spectra from a total of 1965 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

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

Supplier	Substance	Batch	Sample ID	Spectra
abcr GmbH	Glycyrrhizic acid	1222024	21344	40

- 809 spectra from a total of 18 batches from further 11 substances. These spectra were recorded

by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Glycyrrhizic acid*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	40	0	110 649
Type B	0	0	40	809
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9905 %)	100.0000 % (> 85.0000 %)
Type B	100.0000 % (> 99.0819 %)	0.0000 % (≥ 0.0000 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra ([Rule of Three](#) [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Glycyrrhizic acid* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Bacitracin	17.80	—
Methylcobalamin	22.11	—
Cyanocobalamin	25.58	—
Calcium citrate tetrahydrate	38.58	—
Magnesium citrate	39.92	—
Minoxidil	43.06	—
L-glutathione	45.40	—
Nystatin	45.88	—
Prednisolon dihydrogen phosphate dinat...	50.20	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
24175	24175	0.00	17.80

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	Griffonia seed extract
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	23002-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

Griffonia seed extract; Griffonia extract; Griffonia simplicifolia

Special notes

When selecting the *Griffonia seed extract* substance/substance group, the following information is displayed to the user:

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Griffonia seed extract	4	1	0

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Griffonia seed extract*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Euro OTC	Griffonia seed e...	1205027	21109	40	from supplier
Euro OTC	Griffonia seed e...	1705007	23420	40	20170601*
Euro OTC	Griffonia seed e...	1905017	24808	40	20190709*
Pharmorgana	Griffonia seed e...	1000200297	25138	40	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 160 spectra of 4 reference samples from the substance/substance group *Griffonia seed extract*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 4 different batches.
- 110 529 spectra from a total of 1962 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

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

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

Supplier	Substance	Batch	Sample ID	Spectra
Euro OTC	Griffonia seed extract	1810009	24303	40

- 809 spectra from a total of 18 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Griffonia seed extract*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	160	0	110 529
Type B	0	0	40	809
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	100.0000 % (> 96.2500 %)
Type B	100.0000 % (> 99.0819 %)	0.0000 % (≥ 0.0000 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Griffonia seed extract* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Sodium cromoglicate	25.66	—
Paracetamol	32.61	—
Sulfogaiacol hydrate	33.19	—
Serine	69.95	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
21109	21109	0.00	49.52
25138	25138	0.00	55.38
24808	24808	0.00	50.11
23420	23420	0.00	32.61

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	L-carnitine hydrochloride
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	20356-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

L-carnitine hydrochloride; L-Carnitine hydrochloricum

Special notes

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

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
L-carnitine hydrochloride	1	0	0

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *L-carnitine hydrochloride*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Dr. Behr	L-carnitine hydr...	WE11030091	21569	60	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 60 spectra of 1 reference samples from the substance/substance group *L-carnitine hydrochloride*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 1 different batches.
- 110 629 spectra from a total of 1965 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

- 0 spectra of 0 reference samples from the substance/substance group *L-carnitine hydrochloride*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.
- 849 spectra from a total of 19 batches from further 12 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *L-carnitine hydrochloride*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	60	0	110 629
Type B	0	0	0	849
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	100.0000 % (> 90.0000 %)
Type B	100.0000 % (> 99.1243 %)	n/a (n/a)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra ([Rule of Three](#) [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *L-carnitine hydrochloride* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Folic acid hydrate	51.21	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
21569	21569	0.00	66.76

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	L-carnitine tartrate
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	21107-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

L-carnitine tartrate

Special notes

When selecting the *L-carnitine tartrate* substance/substance group, the following information is displayed to the user:

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
L-carnitine tartrate	3	3	0

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *L-carnitine tartrate*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Dr. Behr	L-carnitine tart...	WE11060069	21107	40	from supplier
Dr. Behr	L-carnitine tart...	WE15080050	22265	60	from supplier
Euro OTC	L-carnitine tart...	1302017-01	21206	40	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 140 spectra of 3 reference samples from the substance/substance group *L-carnitine tartrate*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 3 different batches.
- 110 549 spectra from a total of 1963 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

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

Supplier	Substance	Batch	Sample ID	Spectra
Euro OTC	L-carnitine tartrate	1708023	23697	40
Pharmorgana	L-carnitine tartrate	1000160672	22957	40
Pharmorgana	L-carnitine tartrate	1000170113	24108	40

- 729 spectra from a total of 16 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *L-carnitine tartrate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	138	2	110 549
Type B	0	120	0	729
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	98.5714 % (> 96.4286 %)
Type B	100.0000 % (> 98.9992 %)	100.0000 % (> 95.0000 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra ([Rule of Three](#) [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *L-carnitine tartrate* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Levothyroxin sodium	52.39	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
21107	21107	0.00	66.06
21206	21206	0.00	65.30
22265	22265	0.00	66.08

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group	Mg-Ca-K colamine phosphate
Substance class	Specific classifier 26188
Report date	14/07/2020
Report number	20423-2020-07-14
Executing company	HiperScan GmbH Weißeritzstraße 3 01067 Dresden Germany

Relevant substance names

Mg-Ca-K colamine phosphate

Special notes

When selecting the *Mg-Ca-K colamine phosphate* substance/substance group, the following information is displayed to the user:

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Mg-Ca-K colamine phosphate	4	1	0

Second-stage model

For differentiation of the substance/substance group *Mg-Ca-K colamine phosphate* the following second-stage model is used:

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Mg-Ca-K colamine phosphate*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Flora Apothek. ...	Mg-Ca-K colamine...	1000190952	25137	40	from supplier
Th. Geyer	Mg-Ca-K colamine...	36985	22336	60	from supplier
Th. Geyer	Mg-Ca-K colamine...	46816	22814	40	from supplier
Th. Geyer	Mg-Ca-K colamine...	80919	24433	40	from supplier

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 180 spectra of 4 reference samples from the substance/substance group *Mg-Ca-K colamine phosphate*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 4 different batches.
- 110 509 spectra from a total of 1962 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

- 80 spectra of 2 reference samples from the substance/substance group *Mg-Ca-K colamine phosphate*.
- Among them are spectra of independent samples from 1 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

Supplier	Substance	Batch	Sample ID	Spectra
Th. Geyer	Mg-Ca-K colamine phosphate	54610	23202	40
Th. Geyer	Mg-Ca-K colamine phosphate	54610	23603	40

- 769 spectra from a total of 18 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Mg-Ca-K colamine phosphate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	180	0	110 509
Type B	0	0	80	769
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	100.0000 % (> 96.6667 %)
Type B	100.0000 % (> 99.0199 %)	0.0000 % (≥ 0.0000 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Mg-Ca-K colamine phosphate* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Calcium colamine phosphate	26.09	—
Carbomers 35000 / 50000	35.04	—
Calcium lactate pentahydrate	38.27	—
Levothyroxin sodium	40.10	—
Magnesium citrate	40.82	—
Dihydrocodeine hydrogen tartrate	45.32	—
Ambroxol hydrochloride	47.15	—
Menthol	47.84	—
Oxalic acid	48.63	—
Magnesium hydrogen citrate	49.02	—
Riboflavin phosphate sodium	49.70	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
24433	24433	0.00	38.32
22814	22814	0.00	26.09
22336	22336	0.00	37.57
25137	25137	0.00	36.17

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

VALIDATION REPORT

IdentModule 2.2-2020-04

Validated substance/substance group **Potassium orotate**
Substance class Specific classifier 26188
Report date 14/07/2020
Report number 10003680-2020-07-14
Executing company HiperScan GmbH
Weißeritzstraße 3
01067 Dresden
Germany

Relevant substance names

Potassium orotate; Kalii oroticum

Special notes

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

no information

Applicable documents

978-3-7692-6679-5 *European Pharmacopoeia 9th Edition, Basic Version 2017* [3]
Komm2.2.40 *Erfüllung von Ph. Eur. 2.2.40 durch Apo-Ident* [4]
AA004 *Erstellung und Validierung eines IdentModul-Updates*

Validation method

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

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

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

Number of independent samples (batches) in calibration and validation

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

Substance	Type A	Type B	Type C
Potassium orotate	1	2	0

Second-stage model

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

no second-stage model

Calibration samples

Only spectra which have been recorded by *HiperScan GmbH* from traceable samples are used for the generation of the [chemometric models](#). The following samples have been obtained from the substance/substance group *Potassium orotate*:

Supplier	Substance	Batch	Sample ID	Spectra	Certificate
Euro OTC	Potassium orotate	1203038V-02	22335	60	from supplier
Euro OTC	Potassium orotate	1203038V-02	22498	40	9757

Validation samples

A total of 111 543 spectra were provided for validation. The results were evaluated separately according to the following sample categories:

Type A All calibration spectra.

- 100 spectra of 2 reference samples from the substance/substance group *Potassium orotate*. These samples are listed above in the [calibration samples](#) section. The reference samples come from 1 different batches.
- 110 589 spectra from a total of 1965 batches from further 390 substances. These spectra were recorded by *HiperScan GmbH*. *Type A* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type A* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix A](#). The samples in [Appendix A](#) were added for model generation not with the intention to have the model identify these substances, but with the intention to make the model reject them despite their similarity to substances identifiable.

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

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

- 120 spectra of 3 reference samples from the substance/substance group *Potassium orotate*.
- Among them are spectra of independent samples from 2 batches from which no spectra have been included in the database structure. They are sorted upwards in the following table and separated from the additional samples by a line.

Supplier	Substance	Batch	Sample ID	Spectra
Flora Apotheke Pharmaci...	Potassium orotate	ORK00119	25139	40
Flora Apotheke Pharmaci...	Potassium orotate	ORK00117	25140	40
Euro OTC	Potassium orotate	1203038V-02	22808	40

- 729 spectra from a total of 16 batches from further 11 substances. These spectra were recorded by *HiperScan GmbH*. *Type B* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type B* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix B](#).

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

- 0 spectra from 0 *Apo-Ident* customers from 0 batches from the substance/substance group *Potassium orotate*.
- Among them are spectra of independent samples from 0 batches from which no spectra have been included in the database structure. These are sorted upwards in the following table.
- 5 spectra from 3 *Apo-Ident* customers from a total of 5 batches from a further 2 substances. These spectra were recorded by *Apo-Ident* customers. *Type C* samples are documented within this entire report. If the substance can be identified with this [chemometric model](#), the samples are listed in the *Type C* section of each substance page. If the substance cannot be identified by this model, the samples are listed in [Appendix C](#).

Validation results

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

	False positive	True positive	False negative	True negative
Type A	0	100	0	110 589
Type B	0	110	10	729
Type C	0	0	0	5

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

	Specificity	Recognition rate
Type A	100.0000 % (> 99.9904 %)	100.0000 % (> 94.0000 %)
Type B	100.0000 % (> 98.9992 %)	91.6667 % (> 89.1667 %)
Type C	n/a (n/a)	n/a (n/a)

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

In order to illustrate the impact of the number of spectra, a comparison is made in parentheses as to how the *specificity* or *recognition rate* would worsen if three additional incorrect results were to exist amongst the spectra (*Rule of Three* [10, 11]). The larger the number of spectra, the lower the deterioration if the three hypothetical *incorrect results* were added.

Where the number of spectra does not exceed 20, no *recognition rate* is provided.

Nearest chemometric neighbours

The following table lists the closest chemometric neighbours of the substance/substance group *Potassium orotate* in the substance class *Specific classifier 26188*. Furthermore, their *Mahalanobis distance* is specified within the main model and, where appropriate, within the second-stage model.

Substance	Distance in main model	Distance in second-stage model
Miconazole nitrate	99.57	—

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

Identity according to identity test using NIR spectroscopy

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

Sample ID	Reference sample ID	Distance to reference sample	Distance to next foreign sample
22335	22335	0.00	114.83
22498	22498	0.00	115.44

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

Appendix A: Additional calibration samples (*Type A*)

Substance spectra also enter the generation of the [chemometric model](#) which cannot be identified with this model. This serves the purpose that substances which the model is not supposed to recognise are safely rejected. The spectra of these samples are entered into the validation as *Type A*. They were recorded by *HiperScan GmbH*.

The samples originate from 2361 batches. From these, 109 549 spectra were recorded. The calibration spectra of substances which can be identified with the model are listed respectively in the section *calibration samples* for the individual substances and do not appear again elsewhere in this list.

Supplier	Substance	Batch	Spectra	Certificate
Caelo	5-aminolevulinic acid hydrochloride	16357904	40	1707616
Caelo	5-aminolevulinic acid hydrochloride	16357904	40	20170324
Caelo	5-aminolevulinic acid hydrochloride	190219	40	20190312*
Fagron	5-aminolevulinic acid hydrochloride	13K27-N02	40	20131125
Fagron	5-aminolevulinic acid hydrochloride	17A12-B07-332960	40	20170131
Fagron	5-aminolevulinic acid hydrochloride	17A12-B07-332960	40	20170131
Caelo	Acacia, dried dispersion	14141901	120	AR-15-FG-006809-01
Caelo	Acacia, dried dispersion	15413201	40	AR-17-FG-000844-01
Caelo	Acacia, dried dispersion	181860	40	20180725*
Caelo	Acetylcysteine	12299020	40	20121026
Caelo	Acetylcysteine	161398	60	20160520*
Euro OTC	Acetylcysteine	1208026-01	60	20121116
Euro OTC	Acetylcysteine	1510016	60	20151116*
Euro OTC	Acetylcysteine	1610011	40	20161107*
Fagron	Acetylcysteine	15C16-B06-308039	40	20150402
Caelo	Acetylsalicylic acid	13297509	40	20131014
Caelo	Acetylsalicylic acid	161316	40	20160825*
Euro OTC	Acetylsalicylic acid	1307024-01	45	20130904
Euro OTC	Acetylsalicylic acid	1407026-01	60	20140801
Euro OTC	Acetylsalicylic acid	1601042	40	20160204*
Euro OTC	Acetylsalicylic acid	1608037	40	20160921*
Fagron	Acetylsalicylic acid	14E02-B04-297099	40	20140515
Fagron	Aciclovir	13B04-B40-294559	60	AR-15-FG-002570-01
Fagron	Aciclovir	13B04-B40-302333	60	20131217
Fagron	Aciclovir	14G07-B05-296462	60	20140728
Fagron	Aciclovir	19I17-F02-366255	40	20191202
Fagron	Albendazole	12J25-B40-293217	45	AR-15-FG-002571-01
Fagron	Albendazole	16B04-B06-322057	40	20160302
Audor	Alfatradiol	AP33-16-I-62P2985A	40	20161017
Audor	Alfatradiol	AP33-18-I-68P3620A	40	20180804
Caelo	Alfatradiol	13201601	120	20130812
Caelo	Alfatradiol	13201601	60	20130812
Caelo	Alfatradiol	191599	40	20190812*
Euro OTC	Alfatradiol	1404001-01	50	1509288
Euro OTC	Alfatradiol	1603019	40	20160419*
Euro OTC	Alfatradiol	1404001-01	60	1509288
Euro OTC	Alfatradiol	1603019	40	20160419*
Fagron	Alfatradiol	13G19-N06	40	1402683
Fagron	Alfatradiol	15J27-B08-323877	40	20151117
Fagron	Alfatradiol	15J27-B08-323877	40	20151117
Fagron	Alfatradiol	15J27-B08-323877	40	20151117
Caelo	Allantoin	162289	40	20160815*

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Supplier	Substance	Batch	Spectra	Certificate
Caelo	Allantoin	172346	40	20171019*
Caelo	Allantoin	172346	40	20171019*
Euro OTC	Allantoin	1406011-01	60	20140718
Euro OTC	Allantoin	1609012	40	20161006*
Euro OTC	Allantoin	1609012-01	40	20161006
Euro OTC	Allantoin	1406011-04	40	20170213
Fagron	Allantoin	13I03-B05	40	20130927
Fagron	Allopurinol	14E15-B05-307746	60	AR-16-FG-004367-01
Fagron	Allopurinol	14E15-B05-315557	60	20140611
Fagron	Allopurinol	14E15-B05-307746	40	20140611
Euro OTC	alpha-tocopheryl acetate	1110021-02	40	20120104
	dry concentrate			
Euro OTC	alpha-tocopheryl acetate	1305032-01	60	AR-15-FG-001194-01
	dry concentrate			
Euro OTC	alpha-tocopheryl acetate	1507001	60	20130708*
	dry concentrate			
Euro OTC	alpha-tocopheryl acetate	1603046	40	20160429*
	dry concentrate			
Euro OTC	alpha-tocopheryl acetate	1907033	40	20190820*
	dry concentrate			
Fagron	alpha-tocopheryl acetate	13H30-B02-287169	60	AR-15-FG-006388-01
	dry concentrate			
Fagron	alpha-tocopheryl acetate	14B03-B04-295113	60	20140224
	dry concentrate			
Caelo	Aluminium potassium sulfate dodecahydrate	12144605	40	from supplier
Caelo	Ambroxol hydrochloride	161996	40	20160810*
Caelo	Ambroxol hydrochloride	171582	40	20170607*
Euro OTC	Ambroxol hydrochloride	11110008-01	40	1401146
Euro OTC	Ambroxol hydrochloride	1311032-01	40	20131219
Euro OTC	Ambroxol hydrochloride	1509032	60	20151027*
Euro OTC	Ambroxol hydrochloride	1601008	60	20160119*
Euro OTC	Ambroxol hydrochloride	1602015	60	20160217*
Euro OTC	Ambroxol hydrochloride	1604035	40	20160428*
Fagron	Ambroxol hydrochloride	13I24-N02	40	20131017
Fagron	Ambroxol hydrochloride	19E01-B02-361735	40	20190606
Caelo	Amifampridine	17251208	40	20171117
Fagron	Amifampridine	13F05-N01	41	20130606
Fagron	Amifampridine	16A22-B04-317264	60	20160204
Inresa	Amifampridine	0631350001	60	8899
Inresa	Amifampridine	33-15-IV-56P2749B	40	20160822
Fagron	Amitriptyline hydrochloride	16C31-B01-325540	40	20160425
Fagron	Amitriptyline hydrochloride	18A16-B06-348643	40	1909242
Inresa	Amitriptyline hydrochloride	005669/17112016	40	1705099
Inresa	Amitriptyline hydrochloride	005669/06022017	40	20160524
Caelo	Amphetamine sulfate	13344603	40	0814J-03361
Caelo	Amphetamine sulfate	16153902	40	2017A-03361
Caelo	Amphetamine sulfate	13344603	60	0814J-03361
Fagron	Amphetamine sulfate	13G08-N11	40	0814K-03361
Fagron	Amphetamine sulfate	15L01-B05-315291	60	1316Q-03361
Fagron	Amphetamine sulfate	13G08-N11	60	0814K-03361
Fagron	Amphetamine sulfate	15L01-B05-315291	60	1316Q-03361
Th. Geyer	Amphetamine sulfate	67002	40	0814I-03361
Th. Geyer	Amphetamine sulfate	067043	40	2017C-03361
Th. Geyer	Amphetamine sulfate	67002	60	0814I-03361
Euro OTC	Amphotericin B	1305033-02	40	1403224
Euro OTC	Amphotericin B	1512026-01	40	20160121
Fagron	Amphotericin B	13I16-N02	40	1508271
Fagron	Amphotericin B	13I16-N02	60	20130911
Fagron	Amphotericin B	16L06-B04-333234	40	20170103

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Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Arginine	1604003	40	20160425*
Euro OTC	Arginine	1608031	40	20160916*
Euro OTC	Arginine	1702014	40	20170316*
Euro OTC	Arginine	2001001	40	20200122*
Fagron	Arginine	13J28-B02	40	AR-15-FG-008045-01
Fagron	Arginine	16H24-B04-335673	40	20161010
Euro OTC	Arginine hydrochloride	L1103042-01	40	20110325
Euro OTC	Arginine hydrochloride	L1212009-01	40	1402430
Euro OTC	Arginine hydrochloride	1306023-01	60	AR-15-FG-008412-01
Euro OTC	Arginine hydrochloride	1603033	40	20160425*
Euro OTC	Arginine hydrochloride	1610042	40	20161128*
Euro OTC	Arginine hydrochloride	1904014	40	20190509*
Caelo	Ascorbic acid	12350011	40	20121122
Caelo	Ascorbic acid	163452	40	20170125*
Caelo	Ascorbic acid	171358	40	20170524*
Caelo	Ascorbic acid	171358	40	20170524*
Euro OTC	Ascorbic acid	1607025	40	20160801*
Euro OTC	Ascorbic acid	1605024	40	20160617*
Euro OTC	Ascorbic acid	1609015	40	20161006*
Euro OTC	Ascorbic acid	1612018	40	20170109*
Euro OTC	Ascorbic acid	1911012	40	20191204*
Fagron	Ascorbic acid	13G29-B07	40	1410500
Fagron	Ascorbyl palmitate	13K04-N01	40	1403226
Fagron	Ascorbyl palmitate	13C06-B40-291206	60	20140306
Fagron	Ascorbyl palmitate	15F01-B99-309774	60	20150615
Fagron	Ascorbyl palmitate	17E18-B06-335527	40	20170606
Fagron	Ascorbyl palmitate	19D25-B04-361254	40	20190517
Fagron	Ascorbyl palmitate	17E18-B06-335527	40	20170606
Caelo	Atropine sulfate	11180602	30	1405538
Caelo	Atropine sulfate	13173808	40	1403483
Caelo	Atropine sulfate	13357405	50	1504594
Caelo	Atropine sulfate	14336806	60	1510209
Caelo	Atropine sulfate	15301601	60	20150930
Caelo	Atropine sulfate	14336806	60	1510209
Caelo	Atropine sulfate	15301601	60	20150930
Fagron	Atropine sulfate	16G20-B06-328437	40	20160823
Fagron	Bacitracin	13A-03-N11	40	1401189
Fagron	Bacitracin	14A21-B09-292909	60	1511741
Fagron	Bacitracin	14E23-B03-296243	60	1503715
Fagron	Bacitracin	15C12-B06-309185	60	20150324
Fagron	Bacitracin	15C12-B06-309185	60	9466
Fagron	Bacitracin	16B17-B03-322939	40	20160421
Fagron	Barbital sodium	12F27-N02	40	0814I-07775
Fagron	Barbital sodium	14K14-B04-303353	60	1516I-07775
Fagron	Barbital sodium	12F27-N02	60	0814I-07775
Fagron	Barbital sodium	14K14-B04-303353	60	1516I-07775
Euro OTC	Beclometasone dipropionate	1203022-03	55	1509281
Euro OTC	Beclometasone dipropionate	1203022-03	60	20120424
Euro OTC	Beclometasone dipropionate	1502032	40	20150327*
Euro OTC	Beclometasone dipropionate	1502032	40	20190828*
Euro OTC	Beclometasone dipropionate	1502032	30	20150327*
Fagron	Beclometasone dipropionate	13I05-N03	60	1511689
Fagron	Beclometasone dipropionate	13E02-B40-293328	40	20140508
Fagron	Beclometasone dipropionate	13E02-B40-296353	60	20140508
Fagron	Beclometasone dipropionate	13E02-B40-296353	29	20140508
Caelo	Benzocaine	12341904	40	1411055
Caelo	Benzocaine	13213509	60	1706017
Fagron	Benzocaine	14G02-B01-306980	40	20140723
Fagron	Benzocaine	16D13-B01-342411	40	1807429
Caelo	Benzoic acid	13391310	60	20131216

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Benzoic acid	15084614	40	20150318
Caelo	Benzoic acid	15084611	40	20150318
Caelo	Benzoic acid	15084614	40	1707644
Caelo	Benzoic acid	15084614	40	20150318
Audor	Benzydamine hydrochloride	AP300111801004B	40	20180418
Fagron	Benzydamine hydrochloride	14I30-B04-300713	45	AR-15-FG-015977-01
Fagron	Benzydamine hydrochloride	15I17-B02-315060	60	20151211
Caelo	Betaine monohydrate	12336602	40	1403327
Fagron	Betaine monohydrate	14I26-B06-309878	60	20141212
Fagron	Betaine monohydrate	18H13-B01-355585	40	20180907
Sigma-Aldrich	Betamethasone acetate	LRAA8500	40	CRS
Caelo	Betamethasone dipropionate, micronized	13372501	40	AR-15-FG-005428-01
Caelo	Betamethasone dipropionate, micronized	13236803	50	20130730
Caelo	Betamethasone dipropionate, micronized	13236803	40	20130730
Caelo	Betamethasone dipropionate, micronized	13372501	45	AR-15-FG-005428-01
Caelo	Betamethasone dipropionate, micronized	13236803	46	20130730
Euro OTC	Betamethasone dipropionate, micronized	1311023-01	60	1505455
Euro OTC	Betamethasone dipropionate, micronized	1601034	45	20160204*
Euro OTC	Betamethasone dipropionate, micronized	1311023-01	46	1505455
Euro OTC	Betamethasone dipropionate, micronized	1601034	45	20160204*
Fagron	Betamethasone dipropionate, micronized	13I17-N05	40	1401377
Fagron	Betamethasone dipropionate, micronized	13I17-N05	80	20130926
Fagron	Betamethasone dipropionate, micronized	16C04-B03-324513	40	20160421
Fagron	Betamethasone dipropionate, micronized	16C04-B03-324513	39	20160421
Sigma-Aldrich	Betamethasone sodium phosphate	MKBS9676V	40	CRS
Caelo	Betamethasone valerate	13091213	40	20130506
Caelo	Betamethasone valerate	13225507	54	1706018
Euro OTC	Betamethasone valerate	1208014-01	40	20120928
Euro OTC	Betamethasone valerate	1406019-01	60	20140725
Euro OTC	Betamethasone valerate	1510037	60	20151215*
Euro OTC	Betamethasone valerate	1610010	40	20161116*
Euro OTC	Betamethasone valerate	1811008	40	20181207*
Euro OTC	Betamethasone valerate	1510037	30	20151215*
Euro OTC	Betamethasone valerate	1811008	30	20181207*
Fagron	Betamethasone valerate	12K07-N23	40	20121119
Fagron	Betamethasone valerate	13K29-B32-288243	60	20131210
Fagron	Betamethasone valerate	13K05-B08-292651	60	1511154
Fagron	Betamethasone, micronized	12D26-N08	40	1402096
Fagron	Betamethasone, micronized	13H08-N06	60	1411037
Fagron	Betamethasone, micronized	11H31-B06-288219	40	1608324
Caelo	Bifonazole	15152701	40	20150703
Caelo	Bifonazole	15152702	40	20150703
Caelo	Bifonazole	15152702	40	20150703
Caelo	Bifonazole	151527	40	20150703*
Euro OTC	Bifonazole	1206027-01	40	1312397
Euro OTC	Bifonazole	1401031-01	60	20140220

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Bifonazole	1510001	60	20151203*
Fagron	Bifonazole	12G11-N09	40	20120807
Fagron	Bifonazole	16D07-B10-324381	40	20160419
Caelo	Bilberry fruit, dried	10265602	40	20101206
Caelo	Biotin	16164313	40	20160616
Caelo	Biotin	16164313	40	20160216
Caelo	Biotin	163432	40	20170119*
Caelo	Biotin	163432	40	20170119*
Euro OTC	Biotin	1402028-01	60	20140404
Euro OTC	Biotin	1508030	60	20150925*
Euro OTC	Biotin	1610003	40	20161110*
Fagron	Biotin	13K29-N02	40	20131204
Fagron	Biotin	17K20-B03-351524	40	20180108
Caelo	Bismuth gallath, basic	13179105	40	1412254
Caelo	Bismuth gallath, basic	13179105	60	20130701
Caelo	Bismuth gallath, basic	170041	40	20170214*
Caelo	Bismuth gallath, basic	17004102	40	20170214
Fagron	Bismuth gallath, basic	15B02-B04-309481	40	20150226
Fagron	Bismuth gallath, basic	15J26-B02-317883	40	20151102
Caelo	Black mustard seed, powdered	12350204	80	1403711
Caelo	Boric acid	14133119	60	20140509
Caelo	Boric acid	15425112	40	20160104
Caelo	Boric acid	170613	40	20170316*
Fagron	Boric acid	13I04-N06	40	20130920
Fagron	Boric acid	15L09-B07-322988	40	20151222
Caelo	Budesonide, micronized	11351704	40	AR-15-FG-005286-01
Caelo	Budesonide, micronized	161431	40	20160606*
Caelo	Budesonide, micronized	15344004	40	20151116
Caelo	Budesonide, micronized	161431	25	20160606*
Caelo	Budesonide, micronized	15344004	23	20151116
Euro OTC	Budesonide, micronized	1311022-01	60	20140113
Euro OTC	Budesonide, micronized	1604018	40	20160509*
Euro OTC	Budesonide, micronized	1311022-01	37	20140113
Euro OTC	Budesonide, micronized	1604018	23	20160509*
Fagron	Budesonide, micronized	16J04-B01-326581	40	20161026
Fagron	Budesonide, micronized	16J04-B01-326581	40	20161026
Fagron	Budesonide, micronized	18C15-B03-355399	40	20180409
Fagron	Budesonide, micronized	16J04-B01-326581	30	20161026
Caelo	Butylated hydroxytoluene	13354602	40	20131105
Caelo	Butylated hydroxytoluene	13354604	40	AR-15-FG-007846-02
Caelo	Butylated hydroxytoluene	15172103	60	20150529
Caelo	Butylated hydroxytoluene	15172103	60	20150529
Caelo	Butylated hydroxytoluene	15172103	60	20150529
Caelo	Butylated hydroxytoluene	190749	40	20190405*
Caelo	Caffeine	12317911	40	20121113
Caelo	Caffeine	12317911	40	20121113
Caelo	Caffeine	13233105	60	20131008
Caelo	Caffeine	13233104	60	20131008
Euro OTC	Caffeine	1211012-01	40	1412248
Euro OTC	Caffeine	1808017	40	20180905*
Euro OTC	Caffeine	1909022	40	20191022*
Caelo	Calcium ascorbate	13105624	40	20130620
Caelo	Calcium ascorbate	163111	40	20161207*
Caelo	Calcium ascorbate	16311101	40	20161207
Euro OTC	Calcium ascorbate	1612003	40	20170110*
Euro OTC	Calcium ascorbate	1709005	40	20170914*
Euro OTC	Calcium ascorbate	1709004	40	20170914*
Euro OTC	Calcium ascorbate	1801010	40	20180115*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Calcium citrate tetrahydrate	13391203	40	20131205
Caelo	Calcium citrate tetrahydrate	13391203	40	20131205
Caelo	Calcium citrate tetrahydrate	171768	40	20170713*
Euro OTC	Calcium citrate tetrahydrate	1305018-01	40	20130528
Euro OTC	Calcium citrate tetrahydrate	1509039	60	20151013*
Euro OTC	Calcium citrate tetrahydrate	1509039-01	60	20151013
Euro OTC	Calcium citrate tetrahydrate	1701001	40	20170124*
Caelo	Calcium gluconate	12236502	40	1401575
Caelo	Calcium gluconate	12335829	40	20121121
Euro OTC	Calcium gluconate	1304012-01	40	AR-15-FG-008127-01
Euro OTC	Calcium gluconate	1407041-01	60	20140818
Euro OTC	Calcium gluconate	1911017	40	20200123*
Euro OTC	Calcium gluconate	1712007	40	20200203*
Caelo	Calcium glycerophosphate	13007912	40	20130124
Caelo	Calcium glycerophosphate	14341007	60	AR-16-FG-005932-01
Caelo	Calcium glycerophosphate	191007	40	20190502*
Fagron	Calcium glycerophosphate	13I17-N04	40	20131016
Fagron	Calcium glycerophosphate	15B03-B03-305050	60	1706313
Caelo	Calcium lactate pentahydrate	15101401	60	20150407
Caelo	Calcium lactate pentahydrate	15101405	60	20150407
Caelo	Calcium lactate pentahydrate	161313	60	20160513*
Fagron	Calcium lactate pentahydrate	12E10-N03	40	20120704
Fagron	Calcium lactate pentahydrate	12I12-N06	40	AR-15-FG-007939-01
Euro OTC	Calcium orotate dihydrate	1401006-01	40	1412540
Euro OTC	Calcium orotate dihydrate	1603003	40	20160329*
Euro OTC	Calcium orotate dihydrate	1603003	40	20180615*
Fagron	Calcium orotate dihydrate	12L04-N07	40	20121207
Fagron	Calcium orotate dihydrate	13J23-N05	40	20131111
Caelo	Calcium pantothenate	14208012	60	20140722
Caelo	Calcium pantothenate	173352	40	20180202*
Euro OTC	Calcium pantothenate	1305034-01	40	20130617
Euro OTC	Calcium pantothenate	1509024	60	20151005*
Euro OTC	Calcium pantothenate	1603042	40	20160429*
Euro OTC	Calcium pantothenate	1607023	40	20160809*
Euro OTC	Calcium pantothenate	1702018	40	20170330*
Euro OTC	Calcium pantothenate	1711003	40	20171123*
Fagron	Calcium pantothenate	13H28-N11	40	20130916
Caelo	Camphor, racemic	15316801	60	20151029
Caelo	Camphor, racemic	170043	40	20170220*
Euro OTC	Camphor, racemic	1406029-01	60	20140708
Fagron	Camphor, racemic	14E19-B07-300365	60	20140527
Fagron	Camphor, racemic	16E23-B08-336937	40	20160627
THC-Pharma GmbH	Cannabidiol	15-7221-80338	60	1316Q-07806
THC-Pharma GmbH	Cannabidiol	15-7221-80338	60	1316Q-07806
THC-Pharma GmbH	Cannabidiol	15-7221-80338	60	1316Q-07806
THC-Pharma GmbH	Cannabidiol	15-7221-80338	60	1316Q-07806
THC-Pharma GmbH	Cannabidiol	15-7221-80338	60	1316Q-07806
THC-Pharma GmbH	Cannabidiol	CBD-API17-003	40	20170609

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
THC-Pharma GmbH	Cannabidiol	CBD-API17-003	40	20170609
THC-Pharma GmbH	Cannabidiol	CBD-API16-003	40	2017B-03911
THC-Pharma GmbH	Cannabidiol	CBD-API16-004	40	2017A-03911
THC-Pharma GmbH	Cannabidiol	15-7221-80338	60	1316Q-07806
Euro OTC	Capsaicin	1703023	40	20170407*
Euro OTC	Capsaicin	1811009	40	20181207*
Fagron	Capsaicin	13J07-N07	40	AR-15-FG-007151-01
Caelo	Captopril	12339610	40	1403227
Caelo	Captopril	15189502	60	AR-15-FG-014855-01
Caelo	Captopril	190118	40	20190312*
Fagron	Captopril	12G25-N08	40	20120814
Fagron	Captopril	14B26-B01-312221	60	20140317
Caelo	Carbomers 35000 / 50000	13135601	40	1403767
Caelo	Carbomers 35000 / 50000	13186207	40	1403768
Caelo	Carbomers 35000 / 50000	14057902	40	20140228
Caelo	Carbomers 35000 / 50000	14057903	60	20140228
Caelo	Carbomers 35000 / 50000	162530	40	20161011*
Euro OTC	Carbomers 35000 / 50000	1311027-02	60	20131205
Euro OTC	Carbomers 35000 / 50000	1512010	60	20151216*
Euro OTC	Carbomers 35000 / 50000	1604032	40	20160428*
Euro OTC	Carbomers 35000 / 50000	1607028	40	20160804*
Euro OTC	Carbomers 35000 / 50000	1610024	40	20161102*
Caelo	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	12354404	40	1401185
Caelo	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	13104807	40	1401186
Caelo	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	14029211	40	20140127
Caelo	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	13299310	60	20131002
Caelo	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	161714	40	20160713*
Caelo	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	16171406	40	AR-17-FG-015964-01
Caelo	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	180486	40	20180228*
Fagron	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	13D22-N02	40	1401187
Fagron	Carmellose sodium (400 / 450 / 500 / 600 / 1600 / 2000 mPa · s)	18E15-B04-354617	40	20180620
Euro OTC	Cellulose, microcrystalline	1201004-01	40	20120201
Euro OTC	Cellulose, microcrystalline	1211037-01	30	20121207
Euro OTC	Cellulose, microcrystalline	1211037-01	40	20121207
Euro OTC	Cellulose, microcrystalline	1507022	60	20150805*
Euro OTC	Cellulose, microcrystalline	1604029	40	20160512*
Fagron	Cellulose, microcrystalline	12C23-N06	70	1403080
Fagron	Cellulose, microcrystalline	16B24-B11-323324	40	20160311
Caelo	Cetomacrogol emulsifying wax 1000 NI	14055001	40	20140225
Caelo	Cetomacrogol emulsifying wax 1000 NI	15277504	40	20150828

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Fagron	Cetomacrogol emulsifying wax 1000 NI	12H07-N06	40	20120905
Fagron	Cetomacrogol emulsifying wax 1000 NI	13C05-B40-289262	40	1408003
Caelo	Cetostearyl alcohol	14054504	40	20140226
Caelo	Cetostearyl alcohol	14054504	60	20140226
Caelo	Cetostearyl alcohol	17049205	40	20170302
Fagron	Cetostearyl alcohol	13C13-N13	40	1402265
Caelo	Cetyl alcohol	13096901	40	1405179
Caelo	Cetyl alcohol	13286502	40	20130925
Caelo	Cetyl alcohol	13286502	60	20130925
Caelo	Cetyl alcohol	15323301	60	AR-16-FG-008835-01
Caelo	Cetyl alcohol	161063	40	20160420*
Caelo	Cetyl alcohol	161063	40	20160420*
Caelo	Cetyl alcohol	161063	40	20160420*
Caelo	Cetyl alcohol	161063	40	20160420*
Caelo	Cetyl alcohol	161063	40	20160420*
Caelo	Cetyl alcohol	161063	40	20160420*
Euro OTC	Cetyl alcohol	1508014-01	40	20150821
Caelo	Cetyl palmitate 15	12331916	40	1402429
Caelo	Cetyl palmitate 15	14351606	60	20141219
Caelo	Cetyl palmitate 15	15301703	60	AR-16-FG-007435-01
Caelo	Cetyl palmitate 15	15301703	60	20151013
Caelo	Cetyl palmitate 15	160538	60	20160323*
Caelo	Cetyl palmitate 15	17043503	40	20170306
Caelo	Cetyl palmitate 15	171640	40	20170719*
Caelo	Cetyl palmitate 15	172715	40	20171124*
Caelo	Cetyl palmitate 15	191390	40	20190702*
Caelo	Chicory root, cut	11374504	40	20120112
Caelo	Chloral hydrate	13213311	40	20130712
Caelo	Chloral hydrate	15448318	40	1704462
Caelo	Chloral hydrate	16355802	40	20170112
Fagron	Chloral hydrate	13F06-N07	40	20130626
Fagron	Chloral hydrate	17E05-B05-335580	40	20170623
Caelo	Chloramphenicol	11370716	40	20120202
Caelo	Chloramphenicol	12248507	40	20120831
Caelo	Chloramphenicol	13080924	60	1509287
Caelo	Chloramphenicol	14346908	60	20150115
Euro OTC	Chloramphenicol	1209019-02	80	20130408
Euro OTC	Chloramphenicol	1209019-02	80	20130408
Euro OTC	Chloramphenicol	1407043-01	60	20140903
Euro OTC	Chloramphenicol	1602002	45	20160309*
Fagron	Chloramphenicol	11F20-N05	120	1412249
Fagron	Chloramphenicol	13A11-N02	40	20130125
Fagron	Chloramphenicol	14E01-B02-308559	60	20140513
Caelo	Chlorhexidine diacetate	12142726	40	1402685
Caelo	Chlorhexidine diacetate	12142727	40	20120711
Caelo	Chlorhexidine diacetate	154389	60	20160309*
Caelo	Chlorhexidine diacetate	15438914	40	1704392
Caelo	Chlorhexidine diacetate	15438914	40	20160309
Caelo	Chlorhexidine diacetate	15438913	40	20160309*
Caelo	Chlorhexidine diacetate	154389	40	20160309*
Caelo	Chlorhexidine diacetate	154389	40	20160309*
Caelo	Chlorhexidine diacetate	15438909	40	20160309*
Caelo	Chlorhexidine diacetate	154389	40	20160309*
Fagron	Chlorhexidine diacetate	14I08-B02-306223	60	20140922
Fagron	Chlorhexidine diacetate	15J02-B08-322916	40	20151104
Fagron	Chlorhexidine diacetate	15J02-B08-322916	40	20151104
Fagron	Chlorhexidine diacetate	14I08-B02-306223	40	20140922
Caelo	Chlorocresol	13275106	60	20130828

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Chlorocresol	13275106	60	20130828
Caelo	Chlorocresol	163378	40	20170124*
Caelo	Chlorocresol	182523	40	20180919*
Caelo	Chlorocresol	190837	40	20190508*
Euro OTC	Chlortetracycline chloride	hydro-1108051-02	40	20111013
Euro OTC	Chlortetracycline chloride	hydro-1604015	40	20160510*
Euro OTC	Chlortetracycline chloride	hydro-1910002	40	20191107*
Fagron	Chlortetracycline chloride	hydro-12K30-N07	40	1405318
Fagron	Chlortetracycline chloride	hydro-12K30-N07	40	20121210
Fagron	Chlortetracycline chloride	hydro-14J08-B07-307742	60	20141029
Euro OTC	Cholecalciferol dry concentrate	2001007	40	20200316*
Caelo	Cholesterol	160444	60	20160222*
Caelo	Cholesterol	16044415	40	1804387
Fagron	Cholesterol	13F10-B40	40	20131223
Fagron	Cholesterol	15J23-B03-325106	40	20151103
Fagron	Cholesterol	17E17-B05-339074	40	20170620
Caelo	Choline chloride	162092	40	20160801*
Caelo	Choline chloride	14273819	40	20141002
Caelo	Choline chloride	14273819	40	20141002
Caelo	Choline chloride	16209209	40	20160801
Euro OTC	Choline hydrogen tartrate	1603044	40	20160429*
Euro OTC	Choline hydrogen tartrate	1607020	40	20160808*
Euro OTC	Choline hydrogen tartrate	1603044-01	40	20160429
Euro OTC	Choline hydrogen tartrate	1603044-01	40	20160429
Euro OTC	Choline hydrogen tartrate	1702005	40	20170307*
Euro OTC	Choline hydrogen tartrate	1901053	40	20190228*
Euro OTC	Choline hydrogen tartrate	1910013	40	20191107*
Caelo	Ciclopirox olamine	13343209	40	AR-15-FG-016214-01
Caelo	Ciclopirox olamine	14147406	60	AR-15-FG-014857-01
Caelo	Ciclopirox olamine	14378809	60	20150227
Caelo	Ciclopirox olamine	15364408	40	20151201
Caelo	Ciclopirox olamine	14147406	60	AR-15-FG-014857-01
Caelo	Ciclopirox olamine	14378809	60	20150227
Caelo	Ciclopirox olamine	15364408	40	20151201
Fagron	Ciclopirox olamine	13A16-N04	40	20130117
Fagron	Ciclopirox olamine	14F13-B03-302340	60	1608170
Fagron	Ciclopirox olamine	16G26-B02-324884	40	20160907
Fagron	Ciclopirox olamine	16G26-B02-324884	40	20160907
Fagron	Ciclopirox olamine	14F13-B03-302340	60	1608170
Caelo	Ciclosporin	13148604	60	1412541
Caelo	Ciclosporin	13148604	60	20130613
Caelo	Ciclosporin	173327	35	20180111*
Fagron	Ciclosporin	13D26-N07	40	1402057
Fagron	Ciclosporin	13D26-N07	42	1508429
Fagron	Ciclosporin	18G30_B04-354759	40	20181115
Fagron	Ciprofloxacin hydrochloride	12B08-N03	40	1401421
Fagron	Ciprofloxacin hydrochloride	14B25-B02	40	20140324
Fagron	Ciprofloxacin hydrochloride	18F27-B01-353346	40	20180814
Caelo	Citric acid	11380204	40	20120127
Caelo	Citric acid	12043112	40	20120229
Caelo	Citric acid	13396502	60	20140110
Caelo	Citric acid	13243213	40	20130821
Caelo	Citric acid	160386	60	20160315*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Fagron	Citric acid	12F18-N03	40	20120628
Fagron	Citric acid	13G24-N13	40	20130827
Caelo	Citric acid monohydrate	15185301	60	20150708
Caelo	Citric acid monohydrate	17085602	40	20170410
Caelo	Citric acid monohydrate	181305	40	20180606*
Fagron	Citric acid monohydrate	12D26-N02	40	20120515
Hedinger	Citric acid monohydrate	202029	40	20161110
Hedinger	Citric acid monohydrate	202029	40	1908675
Hedinger	Citric acid monohydrate	202030	40	20180727
Euro OTC	Citrulline	1310015-01	40	20131120
Euro OTC	Citrulline	1403021-01	59	1411031
Euro OTC	Citrulline	1506014	60	20150624*
Euro OTC	Citrulline	1604038	40	20160523*
Euro OTC	Citrulline	1703036	40	20170418*
Euro OTC	Citrulline	1811028	40	20181127*
Fagron	Citrulline	16D11-B02-326797	40	20160421
Fagron	Citrulline	18K15-B01-356962	40	20190123
Caelo	Clindamycin hydrochloride	15392809	40	20151204
Caelo	Clindamycin hydrochloride	15392817	40	20151204
Euro OTC	Clindamycin hydrochloride	1111058-01	80	20120516
Euro OTC	Clindamycin hydrochloride	1511004	60	20151123*
Euro OTC	Clindamycin hydrochloride	1510038	60	20151120*
Euro OTC	Clindamycin hydrochloride	2001044	40	20200303*
Fagron	Clindamycin hydrochloride	13G24-N09	40	1412075
Fagron	Clindamycin hydrochloride	16D05-B08-332106	40	20160504
Caelo	Clioquinol	11304120	40	20111208
Caelo	Clioquinol	163072	40	20161202*
Euro OTC	Clioquinol	1309009-02	40	AR-15-FG-009542-01
Euro OTC	Clioquinol	1509038	60	20151009*
Fagron	Clioquinol	13I26-N15	40	20131028
Fagron	Clioquinol	14I11-B03-300049	60	20140926
Fagron	Clioquinol	14I11-B03-300049	60	20140926
Caelo	Clobetasol propionate	13134705	80	AR-15-FG-005328-01
Caelo	Clobetasol propionate	13269505	60	AR-15-FG-000622-02
Caelo	Clobetasol propionate	14338001	60	AR-16-FG-008581-01
Caelo	Clobetasol propionate	14338001	59	1607072
Caelo	Clobetasol propionate	15439504	40	20160204
Caelo	Clobetasol propionate	192245	40	20200127*
Caelo	Clobetasol propionate	14338001	59	AR-16-FG-008581-01
Caelo	Clobetasol propionate	14338001	45	1607072
Caelo	Clobetasol propionate	15439504	37	20160204
Euro OTC	Clobetasol propionate	1211021-04	60	1605044
Euro OTC	Clobetasol propionate	1606022	40	20160713*
Euro OTC	Clobetasol propionate	1606022	40	20160713*
Fagron	Clobetasol propionate	18I12-B02-357669	40	20181001
Fagron	Clonidine hydrochloride	13I25-B07	40	20131009
Fagron	Clonidine hydrochloride	14H11-B04-311163	60	AR-18-FG-006797-02
Fagron	Clonidine hydrochloride	14H11-B04-311163	40	20140929
Fagron	Clonidine hydrochloride	19B27-B02-361777	40	20190607
Fagron	Clonidine hydrochloride	14H11-B04-311163	40	20140929
Caelo	Clotrimazole	13184113	40	20130614
Caelo	Clotrimazole	13224204	40	20130815
Caelo	Clotrimazole	13224220	40	20130815
Caelo	Clotrimazole	13224220	40	20130815
Caelo	Clotrimazole	153956	40	20151215*
Euro OTC	Clotrimazole	1306036-01	40	20130823
Euro OTC	Clotrimazole	1510003	60	20151111*
Fagron	Clotrimazole	12I21-N01	40	20120322
Fagron	Clotrimazole	14B05-B36	40	20140225
Fagron	Clotrimazole	14C04-B31	40	20140319

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Cocaine hydrochloride	13259305	40	0814J-01278
Caelo	Cocaine hydrochloride	15224802	60	1316Q-01278
Caelo	Cocaine hydrochloride	15224802	60	1316Q-01278
Caelo	Cocaine hydrochloride	17003902	40	1917S-01278
Caelo	Cocaine hydrochloride	13259305	60	0814J-01278
Caelo	Cocaine hydrochloride	15224802	60	1316Q-01278
Caelo	Cocaine hydrochloride	15224802	60	1316Q-01278
Fagron	Cocaine hydrochloride	13I17-N02	40	0814I-01278
Fagron	Cocaine hydrochloride	16B11-B05-323386	40	1917Q-1278
Fagron	Cocaine hydrochloride	13I17-N02	60	0814I-01278
Th. Geyer	Cocaine hydrochloride	60145	40	0814K-01278
Th. Geyer	Cocaine hydrochloride	60145	60	0814K-01278
Caelo	Cocoa butter	13292013	40	20130924
Caelo	Cocoa butter	14348906	60	20150122
Caelo	Cocoa butter	163165	40	20161116*
Caelo	Cocoa butter	17055907	33	20170310
Caelo	Cocoa butter	190360	40	20190227*
Caelo	Codeine phosphate hemihydrate	13071504	40	0814J-01279
Caelo	Codeine phosphate hemihydrate	15350703	60	1316R-01279
Caelo	Codeine phosphate hemihydrate	13071504	60	0814J-01279
Caelo	Codeine phosphate hemihydrate	15350703	60	1316R-01279
Fagron	Codeine phosphate hemihydrate	13C11-N10	40	0814I-01279
Fagron	Codeine phosphate hemihydrate	15F09-B02-310520	60	1316Q-01279
Fagron	Codeine phosphate hemihydrate	16E17-B05-324109	40	2017A-01279
Fagron	Codeine phosphate hemihydrate	13C11-N10	60	0814I-01279
Fagron	Codeine phosphate hemihydrate	15F09-B02-310520	60	1316Q-01279
Th. Geyer	Codeine phosphate hemihydrate	67038	40	0814K-01279
Th. Geyer	Codeine phosphate hemihydrate	067054	40	2017D-01279
Th. Geyer	Codeine phosphate hemihydrate	67038	60	0814K-01279
Audor	Colistin sulfate	APKB-CS-1602026C	40	20160418
Audor	Colistin sulfate	APKB-CS-1603034C	40	20160627
Audor	Colistin sulfate	APKB-CS-1602026C	40	20160418
Euro OTC	Colistin sulfate	1406001-01	60	1508600
Euro OTC	Colistin sulfate	1507044	60	20150817*
Euro OTC	Colistin sulfate	1602021	60	20160307*
Euro OTC	Colistin sulfate	1606008	40	20160704*
Fagron	Colistin sulfate	13G05-N01	40	20130719
Fagron	Colistin sulfate	13G05-N01	40	20130719
Fagron	Colistin sulfate	14E02-B03	40	1501654
Fagron	Colistin sulfate	16F03-B01-324216	40	20160706
Caelo	Corn starch	13154914	60	20130529
Caelo	Corn starch	161385	60	20160621*
Caelo	Corn starch	182748	40	20181031*
Caelo	Cyanocobalamin	13342803	40	AR-15-FG-005429-01
Caelo	Cyanocobalamin	13342807	60	AR-15-FG-014917-01
Caelo	Cyanocobalamin	160154	60	20160309*
Caelo	Cyanocobalamin	13342807	30	AR-15-FG-014917-01
Caelo	Cyanocobalamin	160154	60	20160309*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Cyanocobalamin	1305040-01	60	AR-15-FG-005214-01
Euro OTC	Cyanocobalamin	1506035	60	20150708*
Euro OTC	Cyanocobalamin	1506035	60	0000010479
Euro OTC	Cyanocobalamin	1604017	30	20160509*
Euro OTC	Cyanocobalamin	1812011	40	20190205*
Euro OTC	Cyanocobalamin	1506035	60	20150708*
Euro OTC	Cyanocobalamin	1506035	45	0000010479
Euro OTC	Cyanocobalamin	1604017	30	20160509*
Audor	Cyproterone acetate	APCPA140201CP	40	20140617
Audor	Cyproterone acetate	APX03-181002-m0C	40	20181213
Euro OTC	Cyproterone acetate	1611003	40	20161201*
Euro OTC	Cyproterone acetate	1810017	40	20181108*
Fagron	Cyproterone acetate	13C11-N02	40	1501534
Fagron	Cyproterone acetate	13J16-No4	75	1602654
Fagron	Cyproterone acetate	15I11-B01-322117	40	20150921
Fagron	Cyproterone acetate	17D11-B07-333693	40	20170501
Fagron	Cyproterone acetate	17D11-B07-333693	20	20170501
Euro OTC	Cystine	1307052-01	40	20130918
Euro OTC	Cystine	1408016-01	60	20140911
Euro OTC	Cystine	1603010	40	20160406*
Euro OTC	Cystine	1610013	40	20161110*
Euro OTC	Cystine	1801016	40	20180126*
Fagron	Cystine	15F08-B05-310685	40	20150616
Caelo	Dapsone	160735	60	20160405*
Caelo	Dapsone	170311	39	20170221*
Caelo	Dapsone	191135	40	20190726*
Caelo	Dequalinium chloride	12361908	40	1412076
Caelo	Dequalinium chloride	12361906	60	20121228
Caelo	Dequalinium chloride	15218406	40	20150622
Caelo	Dequalinium chloride	15402803	40	1707614
Caelo	Dequalinium chloride	154028	40	20160219*
Caelo	Dequalinium chloride	154028	40	20160219*
Euro OTC	Dequalinium chloride	1405012-01	60	20140623
Euro OTC	Dequalinium chloride	1512032	60	20160121*
Euro OTC	Dequalinium chloride	1512032-02	40	1809202
Fagron	Dequalinium chloride	13I26-N10	40	20130121
Fagron	Dequalinium chloride	15B16-B04-332113	40	20150226
Caelo	Dexamethasone	13084315	60	AR-15-FG-006810-01
Caelo	Dexamethasone	15054627	40	20150420
Caelo	Dexamethasone	190221	40	20190214*
Caelo	Dexamethasone	190221	40	20190214*
Euro OTC	Dexamethasone	1303007-01	40	1407432
Euro OTC	Dexamethasone	1303007-01	60	20130328
Euro OTC	Dexamethasone	1601052	45	20160225*
Euro OTC	Dexamethasone	1611001	40	20161212*
Euro OTC	Dexamethasone	1601052	45	20160225*
Euro OTC	Dexamethasone	1611001	37	20161212*
Fagron	Dexamethasone	16F02-B05-324844	40	20160711
Fagron	Dexamethasone	19A24-B01-361445	40	20190403
Caelo	Dexamethasone acetate	13260703	40	1412430
Caelo	Dexamethasone acetate	13260706	60	1502537
Caelo	Dexamethasone acetate	14200207	60	20140807
Caelo	Dexamethasone acetate	14200207	30	20140807
Euro OTC	Dexamethasone acetate	1405024-01	60	20140620
Euro OTC	Dexamethasone acetate	1708011	40	20171002*
Euro OTC	Dexamethasone acetate	1405024-01	45	20140620
Fagron	Dexamphetamine sulfate	13I23-N01	40	0814M-03582
Fagron	Dexamphetamine sulfate	15H06-B04-313862	60	1316Q-03582
Fagron	Dexamphetamine sulfate	16D20-B01-321049	40	2017B-03582
Fagron	Dexamphetamine sulfate	13I23-N01	60	0814M-03582

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Fagron	Dexamphetamine sulfate	15H06-B04-313862	60	1316Q-03582
Fagron	Dextromethorphan hydro-bromide monohydrate	15D23-B07-308849	60	AR-16-FG-008487-02
Fagron	Dextromethorphan hydro-bromide monohydrate	15D23-B07-308849	60	20150508
Fagron	Dextromethorphan hydro-bromide monohydrate	16A22-B03-321371	40	20160205
Fagron	Dextromethorphan hydro-bromide monohydrate	17B28-B01-341594	40	20170612
Fagron	Dextromethorphan hydro-bromide monohydrate	19A08-B03-363561	40	20190201
Sigma-Aldrich	Diclofenac potassium	D1039990	40	CRS
Caelo	Diclofenac sodium	12214219	20	20120815
Caelo	Diclofenac sodium	13214311	60	20130826
Caelo	Diclofenac sodium	13214311	60	20130826
Caelo	Diclofenac sodium	163492	40	20170112*
Euro OTC	Diclofenac sodium	1403013-01	40	20140401
Euro OTC	Diclofenac sodium	1607016	40	20160808*
Fagron	Diclofenac sodium	13E03-N02	40	20130515
Fagron	Diclofenac sodium	12L28-B05	40	20130123
Caelo	Dihydrocodeine hydrogen tartrate	13267601	40	0914A-03065
Caelo	Dihydrocodeine hydrogen tartrate	12142506	40	0914B-03065
Caelo	Dihydrocodeine hydrogen tartrate	15295901	60	1316Q-03065
Caelo	Dihydrocodeine hydrogen tartrate	13267601	60	0914A-03065
Caelo	Dihydrocodeine hydrogen tartrate	12142506	60	0914B-03065
Caelo	Dihydrocodeine hydrogen tartrate	15295901	60	1316Q-03065
Fagron	Dihydrocodeine hydrogen tartrate	13H19-N03	40	0914C-03065
Fagron	Dihydrocodeine hydrogen tartrate	14K26-B04-306298	60	1516I-03065
Fagron	Dihydrocodeine hydrogen tartrate	15F18-B07-323388	40	2017A-03065
Fagron	Dihydrocodeine hydrogen tartrate	13H19-N03	60	0914C-03065
Th. Geyer	Dihydrocodeine hydrogen tartrate	67035	40	0914D-03065
Th. Geyer	Dihydrocodeine hydrogen tartrate	067052	40	2017D-03065
Th. Geyer	Dihydrocodeine hydrogen tartrate	67035	60	0914D-03065
Caelo	Diltiazem hydrochloride	13346914	40	20131028
Caelo	Diltiazem hydrochloride	13346914	60	20131028
Caelo	Diltiazem hydrochloride	13346914	60	20131028
Caelo	Diltiazem hydrochloride	161908	40	20160715*
Fagron	Diltiazem hydrochloride	14C12-B04	40	20140417
Fagron	Diltiazem hydrochloride	16G20-B03-328133	40	20160829
Fagron	Diltiazem hydrochloride	16G20-B03-328133	40	20160829
Caelo	Dimethyl fumarate	13269801	60	1506634
Euro OTC	Dimethyl fumarate	1410013-01	60	20141125
Caelo	Diphenhydramine hydro-chloride	12329816	40	20121119
Caelo	Diphenhydramine hydro-chloride	12329816	60	20121119

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Diphenhydramine chloride	hydro- 16004901	40	20160122
Caelo	Diphenhydramine chloride	hydro- 180082	40	20180126*
Fagron	Diphenhydramine chloride	hydro- 16C25-B03-331026	40	AR-17-FG-015432-02
Fagron	Diphenhydramine chloride	hydro- 18K28-B02-358954	40	20181219
Caelo	Dithranol	18115302	40	1811302
Caelo	Dithranol	18190604	40	1904372
Caelo	Dithranol	190868	40	20190426*
Caelo	Dithranol	190550	40	20190426*
Euro OTC	Dithranol	1702022-01	40	1809448
Fagron	Dithranol	18B23-B05-348137	40	20180430
Fagron	Doxycycline hyclate	12G12-N15	40	1404233
Fagron	Doxycycline hyclate	12G12-N15	40	20120807
Fagron	Doxycycline hyclate	14K28-B05-312218	60	20150216
Fagron	Doxycycline hyclate	19A30-B01-360207	40	20190412
Fagron	Doxycycline hyclate	19I12-F01-366406	40	20191204
Caelo	Doxylamine hydrogen succinate	15203906	40	20151112
Caelo	Doxylamine hydrogen succinate	15203906	40	20151112
Caelo	Doxylamine hydrogen succinate	183312	40	20190219*
Fagron	Doxylamine hydrogen succinate	14F03-B01-293498	60	1410524
Fagron	Doxylamine hydrogen succinate	15F01-B04-309189	40	AR-16-FG-011361-01
Caelo	Emulsifying cetostearyl alcohol (type A)	13233005	30	1506057
Caelo	Emulsifying cetostearyl alcohol (type A)	13233005	60	20130816
Caelo	Emulsifying cetostearyl alcohol (type A)	14322505	60	20141031
Caelo	Emulsifying cetostearyl alcohol (type A)	153857	60	20151202*
Caelo	Emulsifying cetostearyl alcohol (type A)	153857	60	20151202*
Caelo	Emulsifying cetostearyl alcohol (type A)	153856	60	20160210*
Caelo	Emulsifying cetostearyl alcohol (type A)	153856	60	20160210*
Euro OTC	Emulsifying cetostearyl alcohol (type A)	1510043	60	20151124*
Euro OTC	Emulsifying cetostearyl alcohol (type A)	1504010-01	60	20150423
Fagron	Emulsifying cetostearyl alcohol (type A)	13L17-B05	40	1505070
Fagron	Emulsifying cetostearyl alcohol (type A)	16I13-B01-326511	40	20161024
Fagron	Enalapril maleate	16K14-B02-336220	40	1801425
Fagron	Enalapril maleate	17J18-B03-347278	40	20171208
Fagron	Eosin Y	12E25-N01	60	20120607
Fagron	Eosin Y	15G01-T03-025958	60	1604114
Fagron	Eosin Y	13F14-T01-017395	40	1608469
Fagron	Eosin Y	13F14-T01-017395	40	20141219
Fagron	Eosin Y	13F14-T01-017395	40	1801115
Fagron	Eosin Y	13F14-T01-017395	40	1705197
Fagron	Eosin Y	17K21-T07-042542	40	1805338

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Ephedrine hydrochloride	12017217	40	1511635
Caelo	Ephedrine hydrochloride	13323305	40	20131113
Caelo	Ephedrine hydrochloride	14378502	60	20150106
Caelo	Ephedrine hydrochloride	161197	60	20160420*
Fagron	Ephedrine hydrochloride	15H28-B02-316349	40	20150924
Fagron	Ephedrine hydrochloride	17G05-B05-337987	40	20170901
Caelo	Epinephrine hydrogen tartrate	12120202	40	1405614
Caelo	Epinephrine hydrogen tartrate	12337804	40	20121128
Caelo	Epinephrine hydrogen tartrate	14007802	60	1603180
Caelo	Epinephrine hydrogen tartrate	14007802	60	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	20	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	20	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	20	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	60	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	20	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	20	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	20	20140130
Caelo	Epinephrine hydrogen tartrate	14007802	60	1603180
Fagron	Epinephrine hydrogen tartrate	12L22-N04	40	20120106
Fagron	Epinephrine hydrogen tartrate	18K30-B03-358514	40	20190320
Caelo	Erythromycin	13175601	40	20130620
Caelo	Erythromycin	160792	60	20160408*
Euro OTC	Erythromycin	1308016-02	60	1412542
Euro OTC	Erythromycin	1508034	60	20150925*
Euro OTC	Erythromycin	1607038	40	20160831*
Euro OTC	Erythromycin	1705038	40	20170705*
Euro OTC	Erythromycin	1811019	40	20190114*
Fagron	Erythromycin	12E24-N04	60	20120607
Fagron	Erythromycin	14B06-B35-290872	60	20140225
Euro OTC	Escin, water-soluble	1310020-01	40	AR-15-FG-005777-01
Euro OTC	Escin, water-soluble	1506038	60	20150708*
Euro OTC	Escin, water-soluble	1605021	40	20160609*
Fagron	Escin, water-soluble	12K22-N13	40	20121127
Fagron	Escin, water-soluble	12I07-B40-306607	40	1610369
Caelo	Estradiol benzoate	15078608	40	20150415
Caelo	Estradiol benzoate	181444	40	20180614*
Euro OTC	Estradiol benzoate	1301006-02	40	1507405
Euro OTC	Estradiol benzoate	1507009	60	0000010566
Euro OTC	Estradiol benzoate	1507009	60	0000010566
Fagron	Estradiol benzoate	12H02-N02	40	20120817
Fagron	Estradiol benzoate	14B20-B02	40	20140327
Fagron	Estradiol benzoate	12H02-N02	60	20120817
Fagron	Estradiol benzoate	14B20-B02	60	20140327
Caelo	Estradiol hemihydrate	12268016	40	1410502

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Estradiol hemihydrate	13285802	60	20130913
Caelo	Estradiol hemihydrate	13285802	60	1510622
Caelo	Estradiol hemihydrate	13285802	20	20130913
Caelo	Estradiol hemihydrate	13285802	20	20130913
Caelo	Estradiol hemihydrate	13285802	20	20130913
Caelo	Estradiol hemihydrate	13285802	20	20130913
Caelo	Estradiol hemihydrate	13285802	20	20130913
Caelo	Estradiol hemihydrate	13285802	20	20130913
Caelo	Estradiol hemihydrate	13285802	20	20130913
Caelo	Estradiol hemihydrate	13285802	60	1410504
Euro OTC	Estradiol hemihydrate	1208022-01	40	20121012
Euro OTC	Estradiol hemihydrate	1507013	60	1510623
Euro OTC	Estradiol hemihydrate	1510039	60	20151103*
Euro OTC	Estradiol hemihydrate	1601017	45	20160122*
Euro OTC	Estradiol hemihydrate	1612008	40	20170117*
Euro OTC	Estradiol hemihydrate	1507013	60	1510623
Euro OTC	Estradiol hemihydrate	1510039	89	20151103*
Euro OTC	Estradiol hemihydrate	1612008	40	20170117*
Fagron	Estradiol hemihydrate	14G24-B04-297404	55	20140825
Fagron	Estradiol hemihydrate	16H04-B01-328738	40	20160915
Caelo	Estradiol valerate	13264001	60	1410503
Caelo	Estradiol valerate	13264001	120	1510624
Caelo	Estradiol valerate	13264001	20	20130920
Caelo	Estradiol valerate	13264001	20	20130920
Caelo	Estradiol valerate	13264001	20	20130920
Caelo	Estradiol valerate	13264001	20	20130920
Caelo	Estradiol valerate	13264001	20	20130920
Caelo	Estradiol valerate	13264001	60	1410503
Caelo	Estradiol valerate	13264001	20	20130920
Caelo	Estradiol valerate	13264001	20	20130920
Caelo	Estradiol valerate	15194802	60	20150708
Caelo	Estradiol valerate	163277	40	20161221*
Caelo	Estradiol valerate	13264001	45	1410503
Caelo	Estradiol valerate	13264001	45	1510624
Caelo	Estradiol valerate	15194802	30	20150708
Caelo	Estradiol valerate	163277	40	20161221*
Fagron	Estradiol valerate	12D18-N02	40	20120426
Fagron	Estradiol valerate	12D18-N02	40	20120118
Fagron	Estradiol valerate	14E26-B02-294846	60	20140616
Caelo	Estriol	12298706	40	20121106
Caelo	Estriol	13256001	55	1511155
Caelo	Estriol	13256001	60	20130821
Caelo	Estriol	13256001	20	20130821
Caelo	Estriol	13256001	60	20130821
Caelo	Estriol	13256001	20	20130821
Caelo	Estriol	13256001	20	20130821
Caelo	Estriol	13256001	20	20130821
Caelo	Estriol	13256001	20	20130821
Caelo	Estriol	13256001	20	20130821
Caelo	Estriol	13256001	20	20130821
Caelo	Estriol	13256001	60	1511155
Euro OTC	Estriol	1507026	60	0000010671
Euro OTC	Estriol	1509042	60	20151009*
Euro OTC	Estriol	1703044	40	20170502*
Euro OTC	Estriol	1507026	60	0000010671
Euro OTC	Estriol	1509042	60	20151009*
Fagron	Estriol	11J13-N07	40	1412180
Fagron	Estriol	16D15-B03-322957	40	20160711
Fagron	Estriol	16I19-B01-331468	40	20170301
Fagron	Estriol	16D15-B03-322957	40	20160711

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Ethacridine lactate monohydrate	12149507	40	20120619
Caelo	Ethacridine lactate monohydrate	16273403	40	20161122
Euro OTC	Ethacridine lactate monohydrate	1206016-02	60	20121019
Euro OTC	Ethacridine lactate monohydrate	1412034-02	40	20150223
Fagron	Ethacridine lactate monohydrate	13I24-N03	40	AR-15-FG-007011-02
Fagron	Ethacridine lactate monohydrate	15A29-B02-306219	40	20150205
Fagron	Ethinylestradiol	13I09-N04	40	1402058
Fagron	Ethinylestradiol	14E15-B03-296049	55	1507109
Fagron	Ethinylestradiol	14E15-B03-310270	60	20140708
Fagron	Ethinylestradiol	14E15-B03-310270	60	20140708
Fagron	Ethinylestradiol	18E25-B01-355721	40	20180810
Fagron	Ethinylestradiol	14E15-B03-296049	56	1507109
Fagron	Ethinylestradiol	14E15-B03-310270	60	20140708
Katwijk Chemi...	Ethosuximide	451717	40	20180509
Katwijk Chemi...	Ethosuximide	451645	40	1807457
Euro OTC	Ethyl hydrogen fumarate calcium	1310029-01	60	20131126
Euro OTC	Ethyl hydrogen fumarate calcium	1306012-01	60	1505456
Euro OTC	Ethyl hydrogen fumarate calcium	1510005	60	20151030*
Euro OTC	Ethyl hydrogen fumarate calcium	2001042	40	20200331*
Fagron	Ethyl hydrogen fumarate calcium	13B25-N08	60	1411090
Caelo	Fampridine	16276001	40	20161024
Caelo	Fampridine	16276001	40	20161024
Caelo	Fampridine	16276001	40	20161024
Caelo	Fampridine	16276001	40	20161024
Caelo	Fampridine	190675	40	20190506*
Caelo	Fampridine	180219	40	20180214*
Caelo	Fampridine	180219	40	20180214*
Fagron	Fampridine	13G26-N06	40	1402686
Fagron	Fampridine	14D11-B06-293750	60	20140113
Fagron	Fampridine	16D11-B07-318220	40	AR-16-FG-011566-01
Fagron	Fampridine	16E25-B03-324097	40	20160609
Fagron	Fampridine	16E25-B03-324097	40	20160609
Fagron	Fampridine	17K20-B02-349165	40	20180103
Fagron	Fampridine	17K20-B02-349165	40	20180103
Fagron	Fentanyl citrate	13G30-N06	40	0814M-07678
Fagron	Fentanyl citrate	15F18-B01-525098	60	1316R-03686
Fagron	Fentanyl citrate	15F18-B01-525166	60	1316Q-03686
Fagron	Fentanyl citrate	13G30-N06	60	0814M-07678
Fagron	Fentanyl citrate	15F18-B01-525098	60	1316R-03686
Fagron	Fentanyl citrate	15F18-B01-525166	60	1316Q-03686
EDQM	Fenticonazole nitrate	1.3	40	CRS
Euro OTC	Finasteride (form III)	1403016-01	60	1506004
Euro OTC	Finasteride (form III)	1403016-02	60	20140505
Euro OTC	Finasteride (form III)	1605020	40	20160613*
Euro OTC	Finasteride (form III)	1610012	40	20161116*
Euro OTC	Finasteride (form III)	1403016-02	51	20140505
Euro OTC	Finasteride (form III)	1605020	40	20160613*
Euro OTC	Finasteride (form III)	1610012	33	20161116*
Fagron	Finasteride (form III)	13I03-N01	40	1411272

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Fagron	Finasteride (form III)	14A16-B40-295980	60	20140317
Fagron	Finasteride (form III)	14A16-B40-295980	45	20140317
Caelo	Fluocinolonacetomid, cronized	mi- 12035003	60	20120321
Caelo	Fluocinolonacetomid, cronized	mi- 162281	40	20160907*
Caelo	Fluocinolonacetomid, cronized	mi- 12035003	48	20120321
Caelo	Fluocinolonacetomid, cronized	mi- 162281	30	20160907*
Euro OTC	Fluocinolonacetomid, cronized	mi- 2804013E-01	60	1404008
Euro OTC	Fluocinolonacetomid, cronized	mi- 2804013E-01	60	20121206
Euro OTC	Fluocinolonacetomid, cronized	mi- 2804013E-01	60	20121206
Euro OTC	Fluocinolonacetomid, cronized	mi- 2804013E-01	60	20121206
Fagron	Fluocinolonacetomid, cronized	mi- 14L19-B04-307101	45	20150219
Fagron	Fluocinolonacetomid, cronized	mi- 14L19-B04-307101	40	20150219
Fagron	Fluocinolonacetomid, cronized	mi- 17F14-B08-350105	40	20171221
Fagron	Fluocinolonacetomid, cronized	mi- 14L19-B04-307101	45	20150219
Euro OTC	Folic acid hydrate	1401005-01	40	20140131
Euro OTC	Folic acid hydrate	1508024	60	20150902*
Euro OTC	Folic acid hydrate	1604036	40	20160429*
Euro OTC	Folic acid hydrate	1611009	40	20161201*
Euro OTC	Folic acid hydrate	1911019	40	20191216*
Fagron	Folic acid hydrate	12G17-N05	40	20120727
Fagron	Folic acid hydrate	16C03-B06-322513	40	20160411
Caelo	Fructose	160667	60	20160425*
Caelo	Fructose	15084311	40	20150316
Euro OTC	Fructose	1212015-01	40	20130111
Euro OTC	Fructose	1509037	60	20151027*
Euro OTC	Fructose	1512009	60	20160113*
Euro OTC	Fructose	1701049	40	20170213*
Fagron	Fructose	16H05-B01-326259	40	20160926
Fagron	Fructose	16H05-B01-326259	40	20160926
Fagron	Furosemide	13A22-N08	40	1401379
Fagron	Furosemide	14K10-B02-301746	60	20141215
Fagron	Furosemide	17D06-B01-338982	40	20170626
Fagron	Furosemide	19I27-F04-366906	40	20191218
Fagron	Fusidic acid	12G04-N01	40	1401162
Fagron	Fusidic acid	13L13-B01-289513	60	20140113
Fagron	Fusidic acid	14E01-B08-299791	60	20140605
Fagron	Galactose	13I13-B40-287993	60	AR-15-FG-008936-01
Fagron	Galactose	14H05-B09-310972	60	20140818
Caelo	Gelatine, white	11334025	40	20111214
Caelo	Gelatine, white	15320504	40	AR-16-FG-014461-01
Caelo	Gelatine, white	15320504	45	AR-16-FG-011564-01
Caelo	Gentamicin sulfate	13205003	60	20130723
Caelo	Gentamicin sulfate	14353504	40	20150119
Euro OTC	Gentamicin sulfate	1305047-01	30	20130919
Euro OTC	Gentamicin sulfate	1305047-03	60	1411076
Euro OTC	Gentamicin sulfate	1305047-03	45	AR-15-FG-012403-01
Euro OTC	Gentamicin sulfate	1506016	60	0000010321
Euro OTC	Gentamicin sulfate	1610036	40	20161124*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Gentamicin sulfate	1610036-01	40	1804343
Euro OTC	Gentamicin sulfate	1711025	40	20171206*
Euro OTC	Gentamicin sulfate	1907036	40	20190823*
Euro OTC	Gentamicin sulfate	1711025	40	20171206*
Fagron	Gentamicin sulfate	12B21-N02	40	1411075
Fagron	Gentamicin sulfate	14E08-B03-294848	60	20140616
Fagron	Gentamicin sulfate	16B29-B01-328731	40	20160411
Caelo	Ginger, peeled	11325715	40	20111205
Caelo	Glucose	12294514	40	1402475
Caelo	Glucose	14033901	40	20140214
Caelo	Glucose	14142310	45	20140523
Caelo	Glucose	16050501	40	20160317
Caelo	Glucose	190380	40	20190411*
Caelo	Glucose monohydrate	171368	40	20170601*
Caelo	Glucose monohydrate	173050	40	20171110*
Euro OTC	Glucose monohydrate	1509006	60	20150914*
Euro OTC	Glucose monohydrate	1601016	60	20160129*
Euro OTC	Glucose monohydrate	1604006	40	20160511*
Euro OTC	Glucose monohydrate	1701002	40	20170213*
Euro OTC	Glucose monohydrate	1807005	40	20180718*
Fagron	Glucose monohydrate	11L19-N13	40	20120105
Fagron	Glucose monohydrate	14B04-B01	40	20140304
Euro OTC	Glutamic acid	L1405023-01	60	20140627
Euro OTC	Glutamic acid	1604056	40	20160523*
Euro OTC	Glutamic acid	1604056	40	20180613*
Fagron	Glutamic acid	11I30-N02	40	AR-15-FG-010446-02
Fagron	Glutamic acid	15G31-B08-311884	40	20150817
Euro OTC	Glutamine	1702007	40	20170322*
Euro OTC	Glutamine	1706010	40	20170802*
Fagron	Glutamine	17E05-B06-334869	40	20170601
Fagron	Glutamine	17E05-B06-334869	40	AR-17-FG-016178-01
Caelo	Glycerol monostearate 40-55%	12105705	80	20120424
Caelo	Glycerol monostearate 40-55%	12105720	40	20120424
Caelo	Glycerol monostearate 40-55%	14099903	60	AR-15-FG-000732-02
Caelo	Glycerol monostearate 40-55%	154450	60	20160225*
Fagron	Glycerol monostearate 40-55%	14C12-B40-292622	60	20140404
Fagron	Glycerol monostearate 40-55%	15E13-B03-305532	60	20150703
Caelo	Glycerol monostearate 60	13109304	40	1407633
Caelo	Glycerol monostearate 60	13232604	60	1504599
Caelo	Glycerol monostearate 60	15286302	60	20150911
Caelo	Glycerol monostearate 60	15286302	60	AR-16-FG-009226-01
Caelo	Glycerol monostearate 60	16233804	40	10052
Caelo	Glycerol monostearate 60	180683	40	20180430*
Caelo	Glycerol monostearate 60	182462	40	20181008*
Caelo	Glycerol monostearate 60	190547	40	20190423*
Caelo	Glycerol monostearate, emulsifying	12210401	80	1407214
Caelo	Glycerol monostearate, emulsifying	12210401	40	20120726
Caelo	Glycerol monostearate, emulsifying	14240607	60	1412120
Caelo	Glycerol monostearate, emulsifying	14240607	60	20140815

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Glycerol monostearate, emulsifying	161646	40	20160727*
Caelo	Glycerol monostearate, emulsifying	16030301	40	20160204
Caelo	Glycine	13157303	60	20130625
Caelo	Glycine	14147006	60	AR-16-FG-012263-01
Caelo	Glycine	15262518	40	20150910
Caelo	Glycine	170265	40	20170315*
Caelo	Glycine	173493	40	20180117*
Euro OTC	Glycine	1402022-01	40	20140328
Euro OTC	Glycine	1402022-01	60	AR-15-FG-005430-01
Euro OTC	Glycine	1801005	40	20180125*
Fagron	Glycine	12G13-N04	40	1401163
Fagron	Glycine	13G09-N03	40	20120711
Fagron	Glycopyrronium bromide	16E09-B08-331027	40	1707615
Fagron	Glycopyrronium bromide	16E09-B08-331027	40	20160530
Fagron	Glycopyrronium bromide	18C30-B07-350744	40	20180502
Fagron	Glycopyrronium bromide	18G25-B01-356318	40	20180907
Fagron	Gramicidin	13J15-N02	40	AR-15-FG-000813-01
Fagron	Gramicidin	17E09-B02-341211	40	AR-18-FG-008970-02
Fagron	Gramicidin	18A19-B14-350428	40	20180704
Fagron	Gramicidin	18L20-B01-358528	40	20190320
Fagron	Griseofulvin	13D19-N03	40	1401419
Fagron	Griseofulvin	14E16-B01-296834	60	20140526
Fagron	Griseofulvin	16F13-B06-330832	40	20160713
Caelo	Guaifenesin	163333	40	20161221*
Caelo	Guaifenesin	172496	40	20171005*
Euro OTC	Guaifenesin	1212002-01	40	20121214
Euro OTC	Guaifenesin	1506044	60	20150708*
Euro OTC	Guaifenesin	1605005	40	20160525*
Euro OTC	Guaifenesin	1910023	40	20191114*
Bombastus	Hard fat in pastilles	306363	34	20161213
Bombastus	Hard fat in pastilles	308558	40	20170321
Caelo	Hard fat in pastilles	12158122	40	20120627
Caelo	Hard fat in pastilles	160278	60	20160407*
Fagron	Hard fat W35	15A07-B12-302751	60	1604639
Fagron	Hard fat W35	15A07-B12-309245	60	20150115
Fagron	Hard fat W35	16K08-B10-334910	40	20161229
Fagron	Hard fat W35	19C04-B09-191420	40	20190330
Caelo	Hay flower	12317104	40	20121122
Klenk	Hay flower	1400A130304	40	20130403
Euro OTC	Heparin sodium	12050009-03	40	AR-15-FG-007427-02
Euro OTC	Heparin sodium	1605022-01	40	9699
Fagron	Heparin sodium	12H30-N07	40	1404230
Fagron	Heparin sodium	12L20-B01-317990	40	20130312
Yino Pharma	Heparin sodium	YN01011170904	40	20180411*
Yino Pharma	Heparin sodium	YN01011170904	40	20180411*
Yino Pharma	Heparin sodium	YN01011170502	40	20180411*
Yino Pharma	Heparin sodium	YN01011170502	40	20180411*
Yino Pharma	Heparin sodium	YN01011170904	40	20180531*
Euro OTC	Histamine dihydrochloride	1111004-02	40	1403674
Euro OTC	Histamine dihydrochloride	1506030	60	20150706*
Fagron	Histamine dihydrochloride	14G16-B02-299175	100	20140729
Fagron	Histamine dihydrochloride	19D19-B02-361228	40	20190516
Euro OTC	Histidine	1703022	40	20170405*
Fagron	Histidine	15I01-B12-329082	40	20150921
Fagron	Histidine	18J03-B02-355093	40	20181123
Audor	Hyaluronic acid sodium salt	AP30101404H	60	20141203
Audor	Hyaluronic acid sodium salt	AP30101702H	40	1802037
Caelo	Hydrochlorothiazide	13008505	60	AR-15-FG-014461-01

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Hydrochlorothiazide	182649	40	20181127*
Fagron	Hydrochlorothiazide	11L01-N02	40	20111209
Fagron	Hydrochlorothiazide	17L20-B02-345079	40	20180125
Caelo	Hydrocortisone	13341502	60	20131203
Caelo	Hydrocortisone	13341502	60	20131203
Caelo	Hydrocortisone	180915	40	20180412*
Euro OTC	Hydrocortisone	1206018-01	40	20130727
Euro OTC	Hydrocortisone	1509029	60	20151014*
Euro OTC	Hydrocortisone	1611016	40	20161220*
Euro OTC	Hydrocortisone	1509029	51	20151014*
Fagron	Hydrocortisone	16A19-B06-320970	40	20160204
Fagron	Hydrocortisone	16A19-B06-321981	40	20160204
Fagron	Hydrocortisone	16A19-B06-321981	40	1702302
Fagron	Hydrocortisone	16H01-B01-326071	40	20160907
Fagron	Hydrocortisone	16A19-B06-320970	30	20160204
Fagron	Hydrocortisone	16H01-B01-326071	40	20160907
Caelo	Hydrocortisone acetate	13291708	60	20130926
Caelo	Hydrocortisone acetate	182780	40	20181210*
Euro OTC	Hydrocortisone acetate	1209003-01	40	20121108
Euro OTC	Hydrocortisone acetate	1508029	60	20150902*
Euro OTC	Hydrocortisone acetate	1604052	40	20160525*
Euro OTC	Hydrocortisone acetate	1209003-01	45	20121108
Euro OTC	Hydrocortisone acetate	1508029	44	20150902*
Fagron	Hydrocortisone acetate	15A30-B09-307090	60	20150226
Fagron	Hydrocortisone acetate	18H07-B03-356259	40	20180829
Fagron	Hydrocortisone butyrate	15J12-B03-322394	40	20151028
Caelo	Hydromorphone chloride	13267702	40	0914A-01334
Caelo	Hydromorphone chloride	15393602	60	1516J-01334
Caelo	Hydromorphone chloride	13267702	60	0914A-01334
Caelo	Hydromorphone chloride	15393602	60	1516J-01334
Fagron	Hydromorphone chloride	13E16-N02	40	0914B-01334
Fagron	Hydromorphone chloride	13I25-N05	60	1516I-01334
Fagron	Hydromorphone chloride	15L08-B08-316877	40	1917Q-01334
Fagron	Hydromorphone chloride	13E16-N02	60	0914B-01334
Fagron	Hydromorphone chloride	13I25-N05	60	1516I-01334
Caelo	Hydroquinone	12288505	40	20121015
Caelo	Hydroquinone	14026904	60	20140122
Caelo	Hydroquinone	14281501	60	AR-15-FG-008058-01
Caelo	Hydroquinone	14280110	60	20141017
Caelo	Hydroquinone	15057004	60	20150306
Caelo	Hydroquinone	15057001	60	20150306
Caelo	Hydroquinone	15057001	60	20150306
Caelo	Hydroquinone	182306	40	20181008*
Caelo	Hydroquinone	192642	40	20191115*
Caelo	Hydroxyethylcellulose (aparent viscosity 300 mPas)	12249204	40	20120830
Caelo	Hydroxyethylcellulose (aparent viscosity 300 mPas)	13378506	40	1507205
Caelo	Hydroxyethylcellulose (aparent viscosity 300 mPas)	161006	60	20160426*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Hydroxyethylcellulose (apparent viscosity 300 mPas)	16278705	40	20161014
Caelo	Hydroxyethylcellulose (apparent viscosity 300 mPas)	16278705	40	20161014
Euro OTC	Hydroxyethylcellulose (apparent viscosity 300 mPas)	1110024-04	40	20120110
Euro OTC	Hydroxyethylcellulose (apparent viscosity 300 mPas)	1804003	40	20180413*
Euro OTC	Hydroxyethylcellulose (apparent viscosity 300 mPas)	1911004	40	20191122*
Fagron	Hydroxyethylcellulose (apparent viscosity 300 mPas)	13H22-N11	40	20130826
Fagron	Hydroxyethylcellulose (apparent viscosity 300 mPas)	16E09-B05-327042	40	20160530
Caelo	Hydroxyethylcellulose (apparent viscosity 5000 mPas)	171151	40	20170523*
Caelo	Hydroxyethylcellulose (apparent viscosity 5000 mPas)	190769	40	20190425*
Caelo	Hydroxyethylcellulose (apparent viscosity 9000 mPas)	03936475	20	20121001
Caelo	Hydroxyethylcellulose (apparent viscosity 9000 mPas)	14352504	60	AR-15-FG-009318-01
Caelo	Hydroxyethylcellulose (apparent viscosity 9000 mPas)	16252008	40	20160907
Caelo	Hydroxypropylcellulose (300 mPa · s)	12093107	40	1402049
Caelo	Hydroxypropylcellulose (300 mPa · s)	14189804	60	AR-15-FG-014922-01
Caelo	Hydroxypropylcellulose (300 mPa · s)	15345001	60	20151104
Caelo	Hydroxypropylcellulose (300 mPa · s)	181146	40	20180618*
Fagron	Hyoscine butylbromide	12K01-N07	40	1406057
Fagron	Hyoscine butylbromide	12K01-N07	40	20121102
Fagron	Hyoscine butylbromide	13K22-N03	40	20131126
Fagron	Hyoscine butylbromide	15I09-B04-312245	60	20150921
Fagron	Hyoscine butylbromide	18A03-B01-352889	40	20180122
Caelo	Hyoscine hydrobromide	14278801	60	1504154
Caelo	Hyoscine hydrobromide	15054501	60	1511156
Caelo	Hyoscine hydrobromide	190869	40	20190604*
Caelo	Hyoscine hydrobromide	172303	40	20170926*
Caelo	Hyoscine hydrobromide	15054501	28	1511156
Caelo	Hyoscine hydrobromide	190869	40	20190604*
Fagron	Hyoscine hydrobromide	15L09-B04-334706	40	20151228
Fagron	Hyoscine hydrobromide	15L09-B04-334706	40	20151228
Fagron	Hyoscine hydrobromide	19G29-B02-367045	40	20191223
Fagron	Hyoscine hydrobromide	15L09-B04-334706	40	20151228
Fagron	Hyoscine hydrobromide	15L09-B04-334706	40	20151228
Caelo	Hypromellose 4000	13155006	40	1402056
Caelo	Hypromellose 4000	13155006	40	20130529
Caelo	Hypromellose 4000	14338801	45	20141217
Fagron	Hypromellose 4000	15G08-B14-314845	40	20150727
Fagron	Hypromellose 4000	19G17-B04-194255	40	20190830
Caelo	Ibuprofen	11352219	40	20120124
Caelo	Ibuprofen	172271	40	20170831*
Euro OTC	Ibuprofen	1211011-02	40	1501533
Euro OTC	Ibuprofen	1410025-02	40	20141125
Euro OTC	Indometacin	1012009-02	40	1402050
Euro OTC	Indometacin	1205002-01	40	20120521
Euro OTC	Indometacin	1512031	60	20160122*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Indometacin	1612017	40	20170209*
Fagron	Indometacin	18H14-B04-365453	40	20180920
Euro OTC	Inositol	1206032-01	40	20120814
Fagron	Inositol	13D15-B40-328250	40	20140812
Fagron	Inositol	13D15-B40-328250	40	AR-17-FG-016393-01
Caelo	Iodoform	12283206	40	20130709
Caelo	Iodoform	16012302	40	AR-17-FG-012459-01
Caelo	Iodoform	16012302	40	20160211
Caelo	Iodoform	191132	40	20190524*
Fagron	Iodoform	12L11-B41	40	20140113
Fagron	Ipratropium bromide	12C15-N01	40	1403675
Fagron	Ipratropium bromide	12K01-N08	40	20121025
Fagron	Ipratropium bromide	18H30-B09-359179	40	20180918
Euro OTC	Isoleucine	1604057	40	20160601*
Euro OTC	Isoleucine	1704022	40	20170612*
Euro OTC	Isoleucine	1909025	40	20191015*
Fagron	Isoleucine	13E02-B01-286930	40	1403154
Fagron	Isoleucine	13E02-B01	40	20130621
Fagron	Isosorbide dinitrate 40%	12F08-N04	40	20120801
Fagron	Isosorbide dinitrate 40%	13D15-N02	39	20130410
Fagron	Isosorbide dinitrate 40%	15I10-B01-328577	40	1709092
Fagron	Isosorbide dinitrate 40%	15I10-B01-328577	30	20150922
Fagron	Isosorbide dinitrate 40%	17C29-B01-339447	40	20170517
Caelo	Isoxuprine hydrochloride	161770	40	20160818*
Caelo	Isoxuprine hydrochloride	16177001	40	20160818
Caelo	Isoxuprine hydrochloride	181078	40	20180719*
Euro OTC	Isoxuprine hydrochloride	1503008-01	40	20150430
Euro OTC	Isoxuprine hydrochloride	1905019	40	20191128*
Caelo	Ispaghula husk	13238005	40	20130816
Caelo	Juniper, pounded	13367302	40	20131122
Caelo	Kelp, cut	13230805	40	AR-15-FG-007678-01
Caelo	Kelp, cut	15418801	60	AR-17-FG-007505-01
Fagron	Ketamine hydrochloride	13H19-N01	40	8931
Fagron	Ketamine hydrochloride	14I03-B02-303165	60	20140926
Fagron	Ketamine hydrochloride	14I03-B02-311706	40	20140926
Caelo	Ketoconazole	12171007	30	1401554
Caelo	Ketoconazole	13179612	60	20130613
Caelo	Ketoconazole	13179612	60	20130613
Caelo	Ketoconazole	153477	40	20151113*
Fagron	Ketoconazole	12A16-N06	40	20120123
Fagron	Ketoconazole	16A26-B01-322982	40	20160210
Caelo	Lactose monohydrate	12139910	30	20120606
Caelo	Lactose monohydrate	14025601	40	20140207
Caelo	Lactose monohydrate	14025601	40	20140207
Caelo	Lactose monohydrate	14025601	40	20140207
Caelo	Lactose monohydrate	14025601	40	20140207
Caelo	Lactose monohydrate	14025601	40	20140207
Caelo	Lactose monohydrate	160277	60	20160321*
Euro OTC	Lactose monohydrate	1509030	60	20151013*
Euro OTC	Lactose monohydrate	1606025	40	20160628*
Euro OTC	Lactose monohydrate	1909014	40	20191015*
Euro OTC	Levocarnitine	1210029-01	40	20121130
Fagron	Levocarnitine	12H10-N07	40	20120830
Fagron	Levocarnitine	14A20-B11-290728	60	AR-15-FG-016322-01
Fagron	Levocarnitine	14A20-B11-290728	60	AR-16-FG-005969-01
Fagron	Levocarnitine	15L04-B05-319229	40	AR-17-FG-012937-01
Fagron	Levocarnitine	16L06-B03-338285	40	20161227
Fagron	Levothyroxin sodium	14E28-B05-298322	30	1506426
Fagron	Levothyroxin sodium	14E28-B05-306102	60	20140915
Fagron	Levothyroxin sodium	18G27-B02-352032	40	20180822

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Fagron	Levothyroxin sodium	14E28-B05-298322	47	1506426
Fagron	Levothyroxin sodium	14E28-B05-306102	53	20140915
Euro OTC	L-glutathione	1102019-02	60	AR-15-FG-008218-01
Euro OTC	L-glutathione	1703008	40	20170327*
Euro OTC	L-glutathione	1808036	40	20180919*
Fagron	L-glutathione	18C01-B08-347604	40	20180416
Caelo	Lidocaine	13352411	60	20131115
Caelo	Lidocaine	180444	40	20180419*
Euro OTC	Lidocaine	1310023-01	60	20131118
Euro OTC	Lidocaine	1612021	40	20170206*
Euro OTC	Lidocaine	1911005	40	20191129*
Fagron	Lidocaine	13H05-N05	40	1401378
Fagron	Lidocaine	16F21-B06-327232	40	20160728
Caelo	Lidocaine hydrochloride monohydrate	12135511	40	AR-15-FG-008867-01
Caelo	Lidocaine hydrochloride monohydrate	172923	40	20171122*
Euro OTC	Lidocaine hydrochloride monohydrate	1403025-02	60	20140516
Euro OTC	Lidocaine hydrochloride monohydrate	1411010	60	20150126*
Euro OTC	Lidocaine hydrochloride monohydrate	1907012	40	20190801*
Caelo	Liquorice root, peeled	11351911	40	20120102
Galke	Liquorice root, peeled	22728	40	from supplier
Fagron	Lithium orotate monohydrate	13J04-N01	40	1405616
Fagron	Lithium orotate monohydrate	13I09-B04-290311	60	20130927
Fagron	Lithium orotate monohydrate	15F25-B01-315219	40	20150716
Fagron	Lithium orotate monohydrate	18K21-B01-363417	40	20181231
Euro OTC	L-leucine	1302013-01	60	20130320
Euro OTC	L-leucine	1601032	40	20160308*
Fagron	L-leucine	13J09-N03	40	1402431
Fagron	L-leucine	15D09-B06-322249	40	20151030
Fagron	L-malic acid	15J09-B03-313987	60	9346
Fagron	L-malic acid	15J09-B03-313987	40	20151106
Fagron	L-malic acid	15J09-B03-313987	40	20151106
Fagron	L-malic acid	16J06-B98-327269	40	20161117
Fagron	L-malic acid	16J06-B98-327269	40	20161117
Caelo	L-phenylalanine	14088304	60	1501656
Euro OTC	L-phenylalanine	1212014-03	60	20130111
Euro OTC	L-phenylalanine	1704003	40	20170425*
Euro OTC	L-phenylalanine	1909032	40	20191017*
Fagron	L-phenylalanine	17B13-B03-343288	40	20170309
Fagron	L-phenylalanine	19J23-F10-366142	40	20191127
Euro OTC	L-proline	1606010	40	20160714*
Euro OTC	L-proline	1705021	40	20170720*
Fagron	L-proline	15D13-B02-308152	60	1704059
Fagron	L-proline	16J14-B01-327195	40	20161116
Euro OTC	L-threonine	1210027-01	40	1403152
Euro OTC	L-threonine	1210027-01	60	20121108
Euro OTC	L-threonine	1601031	40	20160225*
Euro OTC	L-threonine	1909003	40	20190913*
Fagron	L-threonine	12H02-N03	40	1402580
Euro OTC	L-tryptophan	1506003	60	20150630*
Euro OTC	L-tryptophan	1506003	60	20150630*
Euro OTC	L-tryptophan	1712006	40	20180105*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	L-tryptophan	1910016	40	20191106*
Fagron	L-tryptophan	14B05-B32-293485	60	AR-15-FG-009473-01
Fagron	L-tryptophan	17G19-B01-343931	40	20170919
Euro OTC	Lysine hydrochloride	1611021	40	20161202*
Euro OTC	Lysine hydrochloride	1708009	40	20170922*
Euro OTC	Lysine hydrochloride	1805030	40	20180611*
Euro OTC	Lysine hydrochloride	2003009	40	20200403*
Fagron	Lysine hydrochloride	15B09-B06-304170	60	20150220
Fagron	Lysine hydrochloride	14H20-B03-301894	60	AR-16-FG-005856-01
Caelo	Macrogols 1500	12324607	40	1403323
Caelo	Macrogols 1500	17120001	40	20170519
Caelo	Macrogols 1500	171200	40	20170519*
Euro OTC	Macrogols 1500	1508002	60	20150810*
Euro OTC	Macrogols 1500	1604005	40	20160512*
Caelo	Macrogols 4000	12074116	40	1401164
Caelo	Macrogols 4000	12318019	40	1403322
Caelo	Macrogols 4000	12361502	40	20130107
Caelo	Macrogols 4000	13356616	40	20131107
Euro OTC	Macrogols 4000	1507004	60	0000010550
Euro OTC	Macrogols 4000	1508031	60	20150914*
Euro OTC	Macrogols 4000	1605012	40	20160606*
Euro OTC	Macrogols 4000	1605025	40	20160603*
Euro OTC	Macrogols 4000	1702003	40	20170301*
Euro OTC	Macrogols 4000	1711016	40	20171214*
Fagron	Macrogols 4000	15B13-B04-305461	60	AR-16-FG-004020-01
Fagron	Macrogols 4000	16F10-B04-325645	40	20160822
Euro OTC	Magnesium citrate	1501031	60	AR-15-FG-007845-01
Euro OTC	Magnesium citrate	1506020	60	20150623*
Euro OTC	Magnesium citrate	1507019	60	20150722*
Euro OTC	Magnesium citrate	1511018	60	20151130*
Euro OTC	Magnesium citrate	1602028	40	20160314*
Euro OTC	Magnesium citrate	1706007	40	20170720*
Euro OTC	Magnesium citrate	1711018	40	20171129*
Euro OTC	Magnesium citrate	1803033	40	20180403*
Euro OTC	Magnesium citrate	1808020	40	20180827*
Euro OTC	Magnesium citrate	1902006	40	20190226*
Euro OTC	Magnesium hydrogen aspartate tetrahydrate	1204014-01	40	1404588
Euro OTC	Magnesium hydrogen aspartate tetrahydrate	1306045-01	60	20130708
Euro OTC	Magnesium hydrogen aspartate tetrahydrate	1605031	40	20160617*
Euro OTC	Magnesium hydrogen aspartate tetrahydrate	1901036	40	20190227*
Euro OTC	Magnesium hydrogen aspartate tetrahydrate	1906029	40	20190712*
Euro OTC	Magnesium hydrogen aspartate tetrahydrate	2002039	40	20200331*
Caelo	Magnesium hydrogen citrate	13389102	60	20131205
Caelo	Magnesium hydrogen citrate	15415014	40	20160105
Euro OTC	Magnesium hydrogen citrate	1507010	60	20150713*
Euro OTC	Magnesium hydrogen citrate	1510033	60	20151117*
Euro OTC	Magnesium hydrogen citrate	1601005	60	20160119*
Euro OTC	Magnesium hydrogen citrate	1701003	40	20170124*
Caelo	Magnesium orotate dihydrate	162227	40	20160809*
Caelo	Magnesium orotate dihydrate	16222701	40	20160809
Euro OTC	Magnesium orotate dihydrate	1511021	60	20151228*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Magnesium orotate dihydrate	1707018	40	20170907*
Euro OTC	Magnesium orotate dihydrate	1911024	40	20200107*
Caelo	Magnesium stearate	13095536	40	20130405
Caelo	Magnesium stearate	14136929	60	AR-15-FG-012028-01
Euro OTC	Magnesium stearate	1502033-01	40	20150317
Euro OTC	Magnesium stearate	1704002	40	20170622*
Fagron	Magnesium stearate	12C29-N06	110	20120418
Fagron	Magnesium stearate	12D26-B03	40	1407310
Euro OTC	Manganese orotate dihydrate	1601003	60	20160113*
Euro OTC	Manganese orotate dihydrate	1801031	40	20180131*
Euro OTC	Manganese orotate dihydrate	1907009	40	20190718*
Caelo	Mannitol	12305723	40	1402329
Caelo	Mannitol	15197305	40	20150720
Euro OTC	Mannitol	1508012	60	20150827*
Euro OTC	Mannitol	1511025	60	20151228*
Fagron	Mannitol	15A26-B01-305841	40	20150204
Fagron	Mannitol	15A26-B01-305841	40	20150204
Fagron	Mannitol	17B08-B04-352402	40	20170517
Caelo	Marshmallow root, peeled	13214804	40	20130806
Caelo	Matricaria flower	12337605	40	20121122
Caelo	Melatonin	12321404	40	20121107
Caelo	Melatonin	12321411	40	20121107
Caelo	Melatonin	12321415	80	20121107
Euro OTC	Melatonin	1305029-02	60	1411054
Euro OTC	Melatonin	1510041	60	20151123*
Euro OTC	Melatonin	1709020	40	20180105*
Euro OTC	Melatonin	1804015	40	20180522*
Euro OTC	Melatonin	1804015	40	20180522*
Fagron	Melatonin	15G06-B03-315183	40	20150717
Fagron	Melatonin	15G06-B03-323733	40	20150717
Caelo	Menthol	13377404	60	20131212
Caelo	Menthol	181522	40	20180625*
Euro OTC	Menthol	1403022-02	45	20140408
Euro OTC	Menthol	1509045	60	20151008*
Euro OTC	Menthol	1603024	40	20160429*
Euro OTC	Menthol	1608012	40	20160902*
Fagron	Menthol	16L20-T04-044769	40	20170116
Fagron	Menthol	18L04-T06-065445	40	20181217
Fagron	Mepivacaine hydrochloride	12A20-N12	40	1401555
Fagron	Mepivacaine hydrochloride	13L04-B07-297077	60	AR-15-FG-007876-01
Euro OTC	Mesalazine	1206029-04	60	AR-15-FG-011819-01
Euro OTC	Mesalazine	1206029-04	60	20140923
Euro OTC	Mesalazine	1602005	40	20160218*
Euro OTC	Mesalazine	1602005-01	40	20160218
Euro OTC	Mesalazine	1911016	40	20191218*
Fagron	Mesalazine	15H13-B06-317177	60	20150827
Fagron	Mesalazine	16I28-B02-327679	40	20161128
Caelo	Metamizol sodium monohydrate	161610	40	20160714*
Caelo	Metamizol sodium monohydrate	15362816	40	20151106
Caelo	Methacholine chloride	13260303	40	20130827
Caelo	Methacholine chloride	13260303	60	20130827
Caelo	Methacholine chloride	162293	40	20160815*
Caelo	Methacholine chloride	16229304	40	20160815

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Methacholine chloride	16229301	40	20160815
Fagron	Methacholine chloride	12F01-N04	60	1403251
Fagron	Methacholine chloride	16L20-B01-329966	40	20170123
Fagron	Methacholine chloride	16L20-B01-329968	40	20170123
Caelo	Methadone hydrochloride	12344818	40	0914E-02949
Caelo	Methadone hydrochloride	15244715	60	1516A-02949
Caelo	Methadone hydrochloride	12344818	60	0914E-02949
Caelo	Methadone hydrochloride	15244715	60	1516A-02949
Fagron	Methadone hydrochloride	13J24-B06	40	0914F-02949
Fagron	Methadone hydrochloride	15E29-B02-313098	60	1516B-02949
Fagron	Methadone hydrochloride	16F24-B02-323183	40	1917Q-02949
Fagron	Methadone hydrochloride	13J24-B06	60	0914F-02949
Fagron	Methadone hydrochloride	15E29-B02-313098	60	1516B-02949
Th. Geyer	Methadone hydrochloride	67033	40	0914G-02949
Th. Geyer	Methadone hydrochloride	67047	40	0914H-02949
Th. Geyer	Methadone hydrochloride	67033	60	0914G-02949
Th. Geyer	Methadone hydrochloride	67047	60	0914H-02949
Caelo	Methionine	15404102	40	AR-17-FG-000285-02
Caelo	Methionine	16274007	40	20161014
Euro OTC	Methionine	L1404041-01	60	20140508
Euro OTC	Methionine	1602012	60	20160219*
Fagron	Methionine	12K01-N03	40	1402432
Fagron	Methionine	13L19-B36-295115	60	20140108
Caelo	Methoxsalen	16103003	40	20160415
Caelo	Methoxsalen	170781	40	20170427*
Caelo	Methoxsalen	170781	40	20170427*
Euro OTC	Methoxsalen	130604101	60	20130805
Euro OTC	Methoxsalen	1506013	60	20150706*
Euro OTC	Methoxsalen	1608019	40	20160913*
Fagron	Methoxsalen	15J15-B03-321321	40	20151124
Fagron	Methoxsalen	18A12-B50-355102	40	20181112
Caelo	Methyl-4-hydroxybenzoate	11090034	40	20110428
Caelo	Methyl-4-hydroxybenzoate	181769	40	20180824*
Euro OTC	Methyl-4-hydroxybenzoate	1205025-01	40	20120601
Euro OTC	Methyl-4-hydroxybenzoate	1601037	60	20160119*
Fagron	Methyl-4-hydroxybenzoate	14L30-T01-018345	40	20150309
Fagron	Methyl-4-hydroxybenzoate	19B05-T03-062158	40	20190228
Caelo	Methylcellulose	13130115	60	20130517
Caelo	Methylcellulose	160602	60	20160323*
Fagron	Methylcellulose	12D02-N09	40	1402447
Fagron	Methylcellulose	15H04-B07-331291	40	20150824
Euro OTC	Methylcobalamin	1207019-01	40	1402501
Euro OTC	Methylcobalamin	1401032-01	60	8778
Euro OTC	Methylcobalamin	1510002	60	20151201*
Euro OTC	Methylcobalamin	1401032	60	20151201*
Euro OTC	Methylcobalamin	1601043	60	20160209*
Euro OTC	Methylcobalamin	1804006	40	20180420*
Euro OTC	Methylcobalamin	1809001	40	20180925*
Euro OTC	Methylcobalamin	1904002	40	20190806*
Euro OTC	Methylcobalamin	2002014	40	20200401*
Fagron	Methylprednisolone	13G19-N05	40	1402438
Fagron	Methylprednisolone	15I04-B05-311572	45	AR-16-FG-009102-01
Fagron	Methylprednisolone	15I04-B05-311572	45	20151026
Fagron	Methylprednisolone	18E16-B02-B02-358166	40	20180611
Fagron	Methylprednisolone	15I04-B05-311572	45	AR-16-FG-009102-01
Fagron	Methylprednisolone	15I04-B05-311572	45	20151026
EDQM	Methylprednisolone acetate	2.0	20	CRS
Caelo	Metoclopramide hydrochloride	14193102	60	AR-15-FG-002889-01

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Metoclopramide chloride	hydro- 14193102	60	20140725
Caelo	Metoclopramide chloride	hydro- 15421101	40	20160226
Gatt-Koller	Metoclopramide chloride	hydro- 20170236	40	20170724
Audor	Metoprolol tartrate	APMTP02218MT	40	20190220
Euro OTC	Metoprolol tartrate	2001021	40	20200116*
Fagron	Metoprolol tartrate	16E31-B03-327107	40	20160627
Fagron	Metoprolol tartrate	16E31-B03-327107	40	20160627
Fagron	Metoprolol tartrate	16E31-B03-327107	40	20160627
Fagron	Metoprolol tartrate	19K20-F03-366934	40	20191218
Inresa	Metoprolol tartrate	309905RII	60	AR-15-FG-006635-01
Inresa	Metoprolol tartrate	405005RII	60	20140430
Caelo	Metronidazole	12110410	40	20120515
Caelo	Metronidazole	13095007	40	20130426
Caelo	Metronidazole	13095007	40	20130426
Caelo	Metronidazole	160892	60	20160413*
Euro OTC	Metronidazole	1212030-02	40	20130627
Euro OTC	Metronidazole	1508004	60	20150819*
Fagron	Metronidazole	13D10-N02	40	20130516
Fagron	Metronidazole	16I19-B04-326155	40	20161013
Caelo	Miconazole nitrate	13185601	40	20130704
Caelo	Miconazole nitrate	13185601	80	20130704
Caelo	Miconazole nitrate	13352802	39	1412250
Caelo	Miconazole nitrate	13352802	40	20131118
Caelo	Miconazole nitrate	161447	40	20160617*
Euro OTC	Miconazole nitrate	1307025-02	60	20130806
Euro OTC	Miconazole nitrate	1509014	60	20150930*
Fagron	Miconazole nitrate	13D22-N14	100	20130529
Fagron	Miconazole nitrate	18C23-B02-356141	40	20180416
Fagron	Midazolam	13K05-N01	40	0914E-07393
Fagron	Midazolam	14C12-B31-313222	60	1516A-07393
Fagron	Midazolam	13K05-N01	60	0914E-07393
Fagron	Midazolam	14C12-B31-313222	60	1516A-07393
Caelo	Midazolam hydrochloride	12215811	40	0914E-03538
Caelo	Midazolam hydrochloride	15224602	60	1516B-03538
Caelo	Midazolam hydrochloride	12215811	60	0914E-03538
Caelo	Midazolam hydrochloride	15224602	60	1516B-03538
Fagron	Midazolam hydrochloride	13E22-N09	40	0914F-03538
Fagron	Midazolam hydrochloride	14L23-B04-300245	60	1516A-03538
Fagron	Midazolam hydrochloride	15H04-B03-314396	40	1917R-03538
Fagron	Midazolam hydrochloride	16C14-B12-332469	40	0718E-03538
Fagron	Midazolam hydrochloride	13E22-N09	60	0914F-03538
Fagron	Midazolam hydrochloride	14L23-B04-300245	60	1516A-03538
Fagron	Midazolam hydrochloride	16C14-B12-332469	40	0718E-03538
Caelo	Minoxidil	13039501	40	20130306
Caelo	Minoxidil	14093701	40	20140428
Caelo	Minoxidil	14093701	40	20140428
Euro OTC	Minoxidil	1311038-01	59	AR-15-FG-007848-01
Euro OTC	Minoxidil	1411006-01	60	20141210
Euro OTC	Minoxidil	1509035	60	20151016*
Euro OTC	Minoxidil	1602013	60	20160225*
Euro OTC	Minoxidil	1612011	40	20170130*
Caelo	Mometasone furoate, micronized	160286	60	20160316*
Caelo	Mometasone furoate, micronized	163532	40	20170104*
Euro OTC	Mometasone furoate, micronized	1403015-01	60	20140503

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Mometasone furoate, mi-cronized	1510036	60	20151118*
Euro OTC	Mometasone furoate, mi-cronized	1610009	40	20170321*
Euro OTC	Mometasone furoate, mi-cronized	1403015-01	31	20140503
Euro OTC	Mometasone furoate, mi-cronized	1510036	30	20151118*
Fagron	Mometasone furoate, mi-cronized	13F17-N01	40	20130620
Fagron	Mometasone furoate, mi-cronized	16A20-B06-319750	40	20160209
Fagron	Mometasone furoate, mi-cronized	13F17-N01	44	20130620
Fagron	Mometasone furoate, mi-cronized	16A20-B06-319750	30	20160209
Caelo	Morphine hydrochloride	13125207	40	0914E-01879
Caelo	Morphine hydrochloride	13349505	40	0914F-01879
Caelo	Morphine hydrochloride	15439404	60	1416R-01879
Caelo	Morphine hydrochloride	16184605	40	1917S-01879
Caelo	Morphine hydrochloride	13125207	60	0914E-01879
Caelo	Morphine hydrochloride	13349505	60	0914F-01879
Caelo	Morphine hydrochloride	15439404	60	1416R-01879
Fagron	Morphine hydrochloride	13G08-N04	40	0914G-01879
Fagron	Morphine hydrochloride	15I09-B08-312694	60	1416Q-01879
Fagron	Morphine hydrochloride	13G08-N04	60	0914G-01879
Fagron	Morphine hydrochloride	15I09-B08-312694	60	1416Q-01879
Th. Geyer	Morphine hydrochloride	67036	40	0914H-01879
Th. Geyer	Morphine hydrochloride	67036	60	0914H-01879
Caelo	Morphine sulfate	12153212	40	0914F-07776
Caelo	Morphine sulfate	11333103	40	0914E-07776
Caelo	Morphine sulfate	15255703	60	1416Q-07776
Caelo	Morphine sulfate	11333103	31	0914E-07776
Fagron	Morphine sulfate	13J07-N04	40	0914G-07776
Fagron	Morphine sulfate	14F02-B06-315405	40	1917Q-07776
Fagron	Morphine sulfate	13J07-N04	60	0914G-07776
Caelo	Mupirocin calcium	14276602	60	20141103
Caelo	Mupirocin calcium	161184	60	20160504*
Fagron	Mupirocin calcium	12E02-N07	40	1401556
Fagron	Mupirocin calcium	15H13-B01-316111	40	20150909
Caelo	Myrrh	13108701	40	AR-15-FG-000946-01
Audor	Naloxone hydrochloride di-hydrate	AP13501078IIN	40	20160429
Audor	Naloxone hydrochloride di-hydrate	AP1547I022-1N	40	20180629
Caelo	Naloxone hydrochloride di-hydrate	163577	40	20170306*
Caelo	Naloxone hydrochloride di-hydrate	170441	40	20170306*
Fagron	Naloxone hydrochloride di-hydrate	13D22-N07	40	1402059
Fagron	Naloxone hydrochloride di-hydrate	13L12-B03	40	20140113
Caelo	Naphazoline hydrochloride	12375211	40	20130108
Caelo	Naphazoline hydrochloride	12375211	60	20130108
Caelo	Naphazoline hydrochloride	12375211	60	20130108
Caelo	Naphazoline hydrochloride	181193	40	20180504*
Euro OTC	Naphazoline hydrochloride	1407034-01	60	AR-15-FG-007847-01
Euro OTC	Naphazoline hydrochloride	1506015	60	20150727*
Euro OTC	Naphazoline nitrate	1512033	60	20160126*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Naphazoline nitrate	1810016	40	20181112*
Euro OTC	Naphazoline nitrate	1910029	40	20191125*
Fagron	Naphazoline nitrate	12L10-N03	40	20121217
Fagron	Naphazoline nitrate	12J08-B40-287904	60	20131129
Fagron	Naproxen	15F18-B03-309492	45	AR-16-FG-008486-02
Fagron	Naproxen	15F18-B03-315691	45	20150703
Fagron	Naproxen	16B04-B09-326261	40	20160229
Caelo	Neomycin sulfate	13062923	60	AR-15-FG-016581-01
Caelo	Neomycin sulfate	13062923	45	20130315
Caelo	Neomycin sulfate	161650	30	20160629*
Euro OTC	Neomycin sulfate	1303033-03	60	AR-15-FG-016582-01
Euro OTC	Neomycin sulfate	1601046	45	20160212*
Fagron	Neomycin sulfate	14C27-B05-302516	60	1604527
Fagron	Neomycin sulfate	14C27-B05-302517	60	20140418
Caelo	Neostigmine bromide	10144105	40	20100616
Caelo	Neostigmine bromide	12172304	40	1403163
Caelo	Neostigmine bromide	14256802	60	AR-15-FG-014460-01
Caelo	Neostigmine bromide	15228101	60	20151002
Caelo	Neostigmine bromide	14256802	60	AR-15-FG-014460-01
Caelo	Neostigmine bromide	15228101	60	20151002
Caelo	Nicotinamide	13097506	40	20130416
Caelo	Nicotinamide	163048	40	20161123*
Caelo	Nicotinamide	163048	40	20161123*
Euro OTC	Nicotinamide	1310025-01	60	20131121
Euro OTC	Nicotinamide	1511010	60	20151203*
Euro OTC	Nicotinamide	1601045	60	20160210*
Euro OTC	Nicotinamide	1610019	40	20161202*
Euro OTC	Nicotinamide	1906027	40	20190712*
Euro OTC	Nicotinic acid	1906026	40	20190711*
Fagron	Nicotinic acid	14E01-B09-293947	60	AR-15-FG-008938-01
Fagron	Nicotinic acid	16H19-B02-330121	40	AR-17-FG-016013-01
apomix	Non-ionic emulsifying alcohol	NS-8350010216	40	20160718
apomix	Non-ionic emulsifying alcohol	NS-8350010618	40	20180925
Bombastus	Non-ionic emulsifying alcohol	19001210	40	20190221
Bombastus	Non-ionic emulsifying alcohol	19001210	40	20190221
Caelo	Non-ionic emulsifying alcohol	13413001	40	1405257
Caelo	Non-ionic emulsifying alcohol	13413001	40	20140116
Caelo	Non-ionic emulsifying alcohol	182021	40	20180725*
Caelo	Norethisterone acetate	15417004	40	1711489
Caelo	Norethisterone acetate	182252	40	20181031*
Euro OTC	Norethisterone acetate	1306033-01	60	1511684
Fagron	Norethisterone acetate	12L14-N03	40	1401558
Fagron	Norethisterone acetate	17B21-B01-341608	40	20170619
Audor	Nystatin	AP4018717N	40	20160307
Caelo	Nystatin	16272214	40	20160929
Caelo	Nystatin	17025110	40	20170308
Euro OTC	Nystatin	1712010-01	40	1807445
Euro OTC	Nystatin	1905014	40	20190709*
Fagron	Nystatin	19B28-B05-191210	40	20190316
Caelo	Octenidine dihydrochloride	12115202	40	20120511
Caelo	Octenidine dihydrochloride	13071407	40	1407345
Caelo	Octenidine dihydrochloride	13166806	40	20130718
Caelo	Octenidine dihydrochloride	15275502	60	20150910

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Octenidine dihydrochloride	15356601	60	1604116
Caelo	Octenidine dihydrochloride	170423	40	20170214*
Caelo	Octenidine dihydrochloride	163355	40	20170403*
Caelo	Octenidine dihydrochloride	18223413	40	20181005
Caelo	Octenidine dihydrochloride	15356601	60	1604116
Caelo	Octenidine dihydrochloride	170423	40	20170214*
Caelo	Octenidine dihydrochloride	18223413	40	20181005
Fagron	Ofloxacin	13A17-N01	40	1403155
Fagron	Ofloxacin	13A17-N01	40	20130123
Fagron	Ofloxacin	13A17-N01	60	20130123
Fagron	Ofloxacin	15H19-B01-312926	60	20151006
Fagron	Ofloxacin	15H19-B01-325226	40	1707611
Fagron	Ofloxacin	18J30-B01-360431	40	20190419
Fagron	Omeprazole	15K12-B02-314608	40	20151124
Fagron	Omeprazole	15K12-B02-314608	40	20151124
Fagron	Omeprazole	19F14-B01-362735	40	1910227
Inresa	Omeprazole	OPFP14017	60	1507407
Inresa	Omeprazole	OPFP14017	60	20140228
Inresa	Omeprazole	OPFP14017	60	20140528
Inresa	Omeprazole	OPFP14017	40	20150428
Euro OTC	Ornithine aspartate	L1304034-01	40	1402571
Euro OTC	Ornithine aspartate	1312030-01	60	1506280
Euro OTC	Ornithine aspartate	1611018	40	20161213*
Euro OTC	Ornithine aspartate	1611018-01	40	20161213
Fagron	Ornithine aspartate	14A20-B07-296093	45	1506279
Fagron	Ornithine aspartate	14I24-B04-307758	40	20141110
Fagron	Ornithine aspartate	14I24-B04-307758	40	20141110
Fagron	Ornithine aspartate	17I21-B05-342561	40	1804455
Euro OTC	Ornithine hydrochloride	1307028-01	120	20130813
Euro OTC	Ornithine hydrochloride	1605011	40	20160601*
Euro OTC	Ornithine hydrochloride	2001004	40	20200123*
Fagron	Ornithine hydrochloride	13A03-N05	40	1403094
Caelo	Orris root	11026705	40	20110221
Caelo	Oxalic acid	13353901	40	20131029
Caelo	Oxalic acid	12212410	40	1403223
Caelo	Oxalic acid	13353918	60	20131029
Caelo	Oxalic acid	171140	40	20170426*
Caelo	Oxalic acid	171140	40	20170426*
Caelo	Oxalic acid	18202403	40	1905160
Audor	Oxetacaine	AP010-160120	40	1809415
Caelo	Oxetacaine	172498	40	20170925*
Caelo	Oxetacaine	191134	40	20190523*
Fagron	Oxybuprocaine hydrochloride	13D16-N12	40	1402060
Fagron	Oxybuprocaine hydrochloride	13J24-B07-295015	60	AR-15-FG-014812-02
Fagron	Oxybuprocaine hydrochloride	15A26-B07-306787	60	20150203
Fagron	Oxybuprocaine hydrochloride	17G21-B03-338576	40	20170823
Fagron	Oxybuprocaine hydrochloride	16L05-B06-334330	40	20170113
Fagron	Oxybutynin hydrochloride	13H26-B03-290572	60	AR-15-FG-002173-01
Fagron	Oxybutynin hydrochloride	14A29-B09-293841	45	20140227
Fagron	Oxybutynin hydrochloride	14I16-B03-312059	40	20141007
Fagron	Oxybutynin hydrochloride	18K22-B01-359482	40	20181217
Caelo	Oxycodone hydrochloride	12268908	40	0914E-07734
Caelo	Oxycodone hydrochloride	12034515	40	0914F-07734
Caelo	Oxycodone hydrochloride	12268914	60	1416Q-07734
Caelo	Oxycodone hydrochloride	12268913	60	1416R-07734

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Oxycodone hydrochloride	12268908	60	0914E-07734
Caelo	Oxycodone hydrochloride	12034515	60	0914F-07734
Caelo	Oxycodone hydrochloride	12268914	60	1416Q-07734
Caelo	Oxycodone hydrochloride	12268913	60	1416R-07734
Caelo	Oxytetracycline hydrochloride	12130001	60	20120530
Caelo	Oxytetracycline hydrochloride	12328103	40	20121214
Caelo	Oxytetracycline hydrochloride	16077002	40	AR-16-FG-011460-01
Euro OTC	Oxytetracycline hydrochloride	1306022-02	60	1507542
Euro OTC	Oxytetracycline hydrochloride	1506037	60	20150721*
Euro OTC	Oxytetracycline hydrochloride	1506037	60	20150721*
Euro OTC	Oxytetracycline hydrochloride	1602025	40	20160609*
Euro OTC	Oxytetracycline hydrochloride	1602025-01	40	AR-16-FG-014422-01
Euro OTC	Oxytetracycline hydrochloride	1602025	40	20160609*
Euro OTC	Oxytetracycline hydrochloride	1602025-02	40	20161021
Euro OTC	Oxytetracycline hydrochloride	1602025-02	40	20161021
Euro OTC	Oxytetracycline hydrochloride	1701034	40	20170314*
Euro OTC	Oxytetracycline hydrochloride	1701035-02	40	20170314
Fagron	Oxytetracycline hydrochloride	13D08-N11	60	20110131
Fagron	Oxytetracycline hydrochloride	15D29-B99-309066	60	20150522
Caelo	Pancreas powder	13118902	40	1402190
Caelo	Pancreas powder	13395203	60	20131218
Caelo	Pancreas powder	161397	60	20160527*
Caelo	Pancreas powder	16139708	40	20160527
Caelo	Pancreas powder	16139708	40	20160527
Caelo	Papaverine hydrochloride	13324310	60	20130920
Caelo	Papaverine hydrochloride	123161	40	20121127*
Caelo	Paracetamol	15075706	40	20150424
Caelo	Paracetamol	15075707	40	20150424
Caelo	Paracetamol	191851	40	20190827*
Euro OTC	Paracetamol	1111024-02	60	20120123
Fagron	Paracetamol	13D30-N03	40	1402271
Fagron	Paracetamol	13D16-N08	40	1402296
Fagron	Paracetamol	13G23-N03	40	1402297
Caelo	Paraffin, hard	13390413	60	20131213
Caelo	Paraffin, hard	15232004	60	1702507
Caelo	Paraffin, microcrystalline	14307104	60	AR-15-FG-005277-01
Caelo	Paraffin, microcrystalline	14307106	60	20141014
Caelo	Paraffin, microcrystalline	154128	60	20160112*
Caelo	Patent blue V	12364206	40	1508043
Caelo	Patent blue V	12364206	40	20130110
Caelo	Patent blue V	13351803	60	20131114
Caelo	Patent blue V	13351807	40	1702362
Caelo	Patent blue V	190746	40	20190425*
Caelo	Phenazone	15415101	40	20151215
Caelo	Phenazone	15415107	40	20151215

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Phenazone	181347	40	20180629*
Fagron	Phenazone	13G16-B07-287172	40	AR-16-FG-011360-01
Fagron	Phenazone	13G16-B07-287172	40	20130814
Fagron	Phenazone	15H28-B09-322944	40	20150916
Caelo	Pheniramine maleate	12200502	40	1401559
Caelo	Pheniramine maleate	15172702	40	1908273
Euro OTC	Pheniramine maleate	1910024	40	20191122*
Fagron	Pheniramine maleate	13D24-N04	40	20130530
Fagron	Pheniramine maleate	18C21-B02-362029	40	20180426
Caelo	Phenobarbital	12173202	40	0914E-01040
Caelo	Phenobarbital	12173202	60	0914E-01040
Fagron	Phenobarbital	15G07-B06-311718	60	1416Q-01040
Fagron	Phenobarbital	15G07-B06-311718	60	1416Q-01040
Th. Geyer	Phenobarbital	67045	40	0914F-01040
Th. Geyer	Phenobarbital	067056	40	2017A-01040
Th. Geyer	Phenobarbital	67045	60	0914F-01040
Caelo	Phenylbutazon	14057202	40	20140321
Caelo	Phenylbutazon	161121	60	20160331*
Euro OTC	Phenylbutazon	1305050-02	60	AR-15-FG-005687-01
Euro OTC	Phenylbutazon	1507023	60	20150805*
Euro OTC	Phenylbutazon	1908013	40	20190923*
Euro OTC	Phenylephrine hydrochlorid-e	1704009	40	20170524*
Euro OTC	Phenylephrine hydrochlorid-e	2001012	40	20200218*
Fagron	Phenylephrine hydrochlorid-e	12J19-B40-288254	40	20131210
Fagron	Phenylephrine hydrochlorid-e	14H13-B02-308438	60	AR-16-FG-008920-01
Fagron	Phenylephrine hydrochlorid-e	16A20-B07-317987	40	AR-16-FG-013385-01
Fagron	Phenytoin	13G26-N02	40	1401380
Fagron	Phenytoin	15E12-B05-312661	45	20150519
Fagron	Phenytoin	18F01-B02-350492	40	20180705
Fagron	Phenytoin	18F01-B02-350492	40	20180705
Fagron	Phenytoin	19E14-B02	40	20190722
Caelo	Pilocarpine hydrochloride	12217319	60	20120806
Caelo	Pilocarpine hydrochloride	12217319	60	1501660
Caelo	Pilocarpine hydrochloride	171595	40	20170606*
Caelo	Pilocarpine hydrochloride	17124208	40	20170607
Euro OTC	Pilocarpine hydrochloride	1305044-01	60	20130725
Euro OTC	Pilocarpine hydrochloride	1603047	40	20160429*
Euro OTC	Pilocarpine hydrochloride	1908008	40	20190830*
Euro OTC	Pilocarpine hydrochloride	1305044-01	60	20130725
Euro OTC	Pilocarpine hydrochloride	1603047	40	20160429*
Caelo	Poloxamers 407	14196101	60	AR-14-FG-013090-01
Caelo	Poloxamers 407	16242605	40	20160915
Fagron	Poloxamers 407	14G17-B03-296866	60	20140806
Caelo	Polymyxin B sulfate	153501	60	20160318*
Caelo	Polymyxin B sulfate	181154	40	20180507*
Euro OTC	Polymyxin B sulfate	1304033-01	40	20130829
Euro OTC	Polymyxin B sulfate	1202039-02	40	1411033
Euro OTC	Polymyxin B sulfate	1304033-02	60	20130612
Euro OTC	Polymyxin B sulfate	1505005-01	60	AR-16-FG-005387-01
Euro OTC	Polymyxin B sulfate	1604016	40	20160509*
Fagron	Polymyxin B sulfate	13C12-N02	40	1402691
Fagron	Polymyxin B sulfate	12G13-N05	40	1410347
Fagron	Polymyxin B sulfate	13I13-N05	45	AR-15-FG-001516-01
Fagron	Polymyxin B sulfate	14F04-B03-296722	60	20140708
Fagron	Polymyxin B sulfate	15H14-B01-314364	60	20150902

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Potassium citrate	11320212	40	20111201
Caelo	Potassium citrate	13317618	60	20130926
Caelo	Potassium citrate	15123103	60	20150414
Caelo	Potassium citrate	161130	60	20160602*
Euro OTC	Potassium citrate	1509044	60	20151013*
Euro OTC	Potassium citrate	1611017	40	20161207*
Euro OTC	Potassium citrate	1912008	40	20200115*
Caelo	Potassium hydrogen tartrate	11345805	40	20120103
Caelo	Potassium hydrogen tartrate	15354609	40	20151030
Caelo	Potassium hydrogen tartrate	170656	40	20170511*
Caelo	Potassium hydrogen tartrate	182051	40	20180903*
Caelo	Potassium sodium tartrate tetrahydrate	12030207	40	20120213
Caelo	Potassium sodium tartrate tetrahydrate	13216605	40	1404530
Caelo	Potassium sodium tartrate tetrahydrate	14376001	60	20150204
Caelo	Potassium sorbate	13224604	60	20130813
Caelo	Potassium sorbate	163266	40	20170105*
Caelo	Potassium sorbate	17170008	30	20170711
Euro OTC	Potassium sorbate	1508025	60	20150902*
Euro OTC	Potassium sorbate	1608013	40	20160819*
Euro OTC	Potassium sorbate	1907023	40	20190802*
Caelo	Potassium tartrate hemihydrate	13331104	60	20131002
Caelo	Potassium tartrate hemihydrate	15167701	60	20150608
Caelo	Potassium tartrate hemihydrate	160289	60	20160405*
Caelo	Potassium tartrate hemihydrate	192911	40	20191125*
Caelo	Potassium tartrate hemihydrate	193079	40	20191125*
Caelo	Potato starch	12360213	40	1403494
Caelo	Potato starch	14033815	60	20140207
Caelo	Potato starch	161237	60	20160621*
Klenk	Potato starch	0094A170123	40	20170309
Caelo	Povidone 25, soluble	12032714	40	1402437
Caelo	Povidone 25, soluble	14142103	40	AR-15-FG-000596-01
Caelo	Povidone 25, soluble	16307808	40	AR-17-FG-015299-02
Caelo	Povidone 25, soluble	180276	40	20180202*
Caelo	Povidone 25, soluble	191752	40	20190717*
Caelo	Povidone 25, soluble	191276	40	20190517*
Fagron	Povidone 25, soluble	12E22-N05	40	1411537
Fagron	Povidone 25, soluble	13J21-N02	40	AR-16-FG-019116-01
Fagron	Povidone 25, soluble	15C12-B02-323006	40	1710348
Caelo	Povidone iodine	13337205	60	20131021
Caelo	Povidone iodine	15234101	40	AR-17-FG-015433-02
Caelo	Povidone iodine	15234109	40	20150717
Caelo	Povidone iodine	182385	40	20180917*
Euro OTC	Povidone iodine	1501029-01	60	20150211
Euro OTC	Povidone iodine	1509009	60	20150918*
Euro OTC	Povidone iodine	1606026-02	40	20160708
Euro OTC	Povidone iodine	1805007	40	20180525*
Euro OTC	Povidone iodine	1905008	40	20190628*
Euro OTC	Povidone iodine	2001048	40	20200320*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Audor	Prasterone	APZDHA16003-M	40	1805404
Audor	Prasterone	APZDHAC17003MD	40	20180119
Audor	Prasterone	APZDHAC18004D	40	1906523
Euro OTC	Prasterone	1102036-01	40	1404310
Euro OTC	Prasterone	1506011	60	20150629*
Euro OTC	Prasterone	1602018	30	20160301*
Euro OTC	Prasterone	1704012	40	20170529*
Euro OTC	Prasterone	1707014	40	20170829*
Euro OTC	Prasterone	1710035	40	20171212*
Euro OTC	Prasterone	1712014	40	20180115*
Euro OTC	Prasterone	1907045	40	20190905*
Euro OTC	Prasterone	1809009	40	20191111*
Euro OTC	Prasterone	1910025	40	20191111*
Euro OTC	Prasterone	2001038	40	20200302*
Fagron	Prasterone	13J10-B02-287175	40	1404309
Fagron	Prasterone	15G14-B07-310827	60	20150814
Fagron	Prasterone	16L13-B01-330724	40	20161228
Euro OTC	Praziquantel	1908004	40	20190830*
Caelo	Prednicarbate, micronized	13119402	60	1501576
Caelo	Prednicarbate, micronized	13119402	60	20130517
Caelo	Prednicarbate, micronized	13372404	50	AR-15-FG-007941-02
Caelo	Prednicarbate, micronized	13372404	49	20131119
Caelo	Prednicarbate, micronized	13119402	30	20130517
Caelo	Prednicarbate, micronized	13372404	33	20131119
Euro OTC	Prednicarbate, micronized	1302033-02	60	1509286
Euro OTC	Prednicarbate, micronized	1507011	60	20150730*
Euro OTC	Prednicarbate, micronized	1601058	45	20160223*
Euro OTC	Prednicarbate, micronized	2001031	40	20200331*
Euro OTC	Prednicarbate, micronized	1601058	31	20160223*
Fagron	Prednicarbate, micronized	12D27-N04	40	20120509
Fagron	Prednicarbate, micronized	14A27-B02-291256	60	AR-16-FG-011442-01
Fagron	Prednicarbate, micronized	12D27-N04	48	20120509
Caelo	Prednisolon dihydrogen phosphate dinatrium	13304703	40	20130904
Caelo	Prednisolon dihydrogen phosphate dinatrium	13304704	60	1411052
Caelo	Prednisolon dihydrogen phosphate dinatrium	16174715	40	20160930
Fagron	Prednisolon dihydrogen phosphate dinatrium	14E07-B06-295251	60	20140623
Fagron	Prednisolon dihydrogen phosphate dinatrium	18D23-B08-351348	40	1812421
Caelo	Prednisolone acetate	12091814	80	20120416
Caelo	Prednisolone acetate	12324502	40	20121112
Caelo	Prednisolone acetate	13262605	60	20130923
Caelo	Prednisolone acetate	13262605	60	20130923
Caelo	Prednisolone acetate	13262605	47	20130923
Euro OTC	Prednisolone acetate	1306040	40	20130812
Euro OTC	Prednisolone acetate	1209028-03	60	AR-15-FG-010480-01
Euro OTC	Prednisolone acetate	1512020	45	20160119*
Euro OTC	Prednisolone acetate	1512020	44	20160119*
Fagron	Prednisolone acetate	12H14-N07	40	20120829
Fagron	Prednisolone acetate	15I23-B04-345785	40	20151014
Fagron	Prednisolone acetate	12H14-N07	49	20120829
Fagron	Prednisolone hydrogen succinate	13D16-N11	40	1509250
Fagron	Prednisolone hydrogen succinate	14G29-B07-304733	40	1701370
Fagron	Prednisolone hydrogen succinate	14G29-B07-304733	40	20140825

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Prednisolone, micronized	12324202	40	20121113
Caelo	Prednisolone, micronized	12324226	39	1411271
Caelo	Prednisolone, micronized	13343105	60	1411232
Caelo	Prednisolone, micronized	154000	60	20160225*
Caelo	Prednisolone, micronized	161343	60	20160601*
Caelo	Prednisolone, micronized	15400002	40	20160225
Caelo	Prednisolone, micronized	154000	59	20160225*
Caelo	Prednisolone, micronized	161343	44	20160601*
Caelo	Prednisolone, micronized	15400002	40	20160225
Euro OTC	Prednisolone, micronized	1212021-02	60	1411270
Euro OTC	Prednisolone, micronized	1501047-01	60	AR-15-FG-015509-01
Euro OTC	Prednisolone, micronized	1607011	40	20160818*
Euro OTC	Prednisolone, micronized	1212021-02	48	1411270
Euro OTC	Prednisolone, micronized	1501047-01	30	AR-15-FG-015509-01
Euro OTC	Prednisolone, micronized	1607011	40	20160818*
Fagron	Prednisolone, micronized	13H07-B02-285592	60	20130909
Fagron	Prednisolone, micronized	14I10-B03-302263	40	20141020
Fagron	Prednisolone, micronized	16C15-B01-320761	40	20160407
Fagron	Prednisolone, micronized	13H07-B02-285592	60	20130909
Fagron	Prednisolone, micronized	14I10-B03-302263	40	20141020
Fagron	Prednisolone, micronized	16C15-B01-320761	36	20160407
Caelo	Prednisone	12232716	60	20120829
Caelo	Prednisone	12232716	60	20120829
Caelo	Prednisone	192455	40	31102019*
Euro OTC	Prednisone	1401042-02	60	1605276
Euro OTC	Prednisone	1604051	40	20160523*
Euro OTC	Prednisone	1604051	40	20160523*
Fagron	Prednisone	13C14-B40-289148	60	20131223
Fagron	Prednisone	16J19-B02-328642	40	20161221
Euro OTC	Pregnenolone	1204040-01	40	1404311
Euro OTC	Pregnenolone	1312007-01	60	8985
Euro OTC	Pregnenolone	1602001	45	20160208*
Euro OTC	Pregnenolone	1612019	40	20170131*
Euro OTC	Pregnenolone	1908021	40	20190913*
Euro OTC	Pregnenolone	1908020	40	20191018*
Fagron	Pregnenolone	15B11-B07-310278	45	9338
Fagron	Pregnenolone	18L27-B02-357840	40	20190220
Caelo	Prilocaine hydrochloride	15230305	60	20150723
Fagron	Prilocaine hydrochloride	13I02-N03	40	1403257
Fagron	Prilocaine hydrochloride	13I02-N03	40	20130918
Fagron	Prilocaine hydrochloride	14H13-B03-297591	60	AR-15-FG-016323-01
Caelo	Procaine hydrochloride	13109906	60	AR-15-FG-008935-01
Caelo	Procaine hydrochloride	15006906	60	20150209
Euro OTC	Procaine hydrochloride	1601014	60	20160203*
Fagron	Procaine hydrochloride	13F12-B40-301798	60	20141210
Fagron	Procaine hydrochloride	15J27-B10-322937	40	20151113
Caelo	Progesterone, micronized	15319601	40	20151014
Caelo	Progesterone, micronized	17060903	40	20170315
Euro OTC	Progesterone, micronized	1111053-01	30	20120119
Euro OTC	Progesterone, micronized	1506033	60	0000010482
Euro OTC	Progesterone, micronized	1506034	60	0000010483
Euro OTC	Progesterone, micronized	1509008	60	20150914*
Euro OTC	Progesterone, micronized	1511008	60	20151119*
Euro OTC	Progesterone, micronized	1601009	45	20160128*
Euro OTC	Progesterone, micronized	1601001	45	20160128*
Euro OTC	Progesterone, micronized	1603004	40	20160406*
Euro OTC	Progesterone, micronized	1506033	30	0000010482
Euro OTC	Progesterone, micronized	1601009	45	20160128*
Fagron	Progesterone, micronized	16A20-B02-319103	40	20160209
Fagron	Progesterone, micronized	16A20-B02-319103	40	20160209

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Promethazine hydrochloride	13119214	60	20130506
Caelo	Promethazine hydrochloride	161466	40	20160621*
Caelo	Propranolol hydrochloride	12370712	60	20130116
Caelo	Propranolol hydrochloride	12370712	60	20130116
Caelo	Propranolol hydrochloride	15283302	40	20150929
Fagron	Propranolol hydrochloride	13I13-N04	40	1402307
Fagron	Propranolol hydrochloride	15F16-B02-312979	40	20150630
Caelo	Propyl-4-hydroxybenzoate	11373523	40	1402440
Caelo	Propyl-4-hydroxybenzoate	13365009	60	20131203
Caelo	Propyl-4-hydroxybenzoate	162595	40	20161005*
Caelo	Propyl-4-hydroxybenzoate	162595	40	20161005*
Caelo	Propyl-4-hydroxybenzoate	190732	40	20190404*
Caelo	Propyphenazone	12039103	40	1402051
Caelo	Propyphenazone	13332206	60	20131009
Fagron	Propyphenazone	16E02-B08-327928	40	20160602
Fagron	Propyphenazone	16H25-B01-334972	40	20161227
Euro OTC	Pyridoxal-5-phosphate	1302029-01	40	8897
Euro OTC	Pyridoxal-5-phosphate	1302029-01	40	20130315
Euro OTC	Pyridoxal-5-phosphate	1701015	40	20170220*
Euro OTC	Pyridoxal-5-phosphate	1701015-01	40	20170220
Euro OTC	Pyridoxal-5-phosphate	1808030	40	20181019*
Euro OTC	Pyridoxal-5-phosphate	1902022	40	20190320*
Euro OTC	Pyridoxal-5-phosphate	1908001	40	20190903*
Euro OTC	Pyridoxal-5-phosphate	1910027	40	20191217*
Caelo	Pyridoxine hydrochloride	14262302	60	20141002
Caelo	Pyridoxine hydrochloride	162225	40	20160825*
Euro OTC	Pyridoxine hydrochloride	1401044-01	60	20140221
Euro OTC	Pyridoxine hydrochloride	1407009-01	60	20140807
Euro OTC	Pyridoxine hydrochloride	1507012	60	20150721*
Euro OTC	Pyridoxine hydrochloride	1601039	60	20160203*
Fagron	Quinidine sulfate dihydrate	12L04-N10	40	AR-14-FG-013249-01
Fagron	Quinidine sulfate dihydrate	12J16-B03	39	1412323
Fagron	Quinidine sulfate dihydrate	14I04-B09-304357	60	AR-15-FG-015409-01
Caelo	Quinine dihydrochloride	172129	40	20173008*
Caelo	Quinine dihydrochloride	172072	40	20170830*
Caelo	Quinine hydrochloride	15376201	60	20151105
Caelo	Quinine hydrochloride	16283302	40	1802260
Fagron	Quinine hydrochloride	13G10-N07	30	20130809
Fagron	Quinine hydrochloride	13I30-B02-295630	60	AR-15-FG-015410-01
Caelo	Quinine sulfate	13024604	60	AR-16-FG-005472-01
Caelo	Quinine sulfate	15230005	40	20150729
Fagron	Quinine sulfate	13J23-N03	40	1404401
Fagron	Quinine sulfate	14B27-B01	40	AR-16-FG-009455-01
Caelo	Quinoline yellow	12042010	40	20120314
Caelo	Quinoline yellow	13109108	40	1711481
Caelo	Quinoline yellow	17034101	40	1709327
Caelo	Quinoline yellow	172277	40	20171020*
Caelo	Quinolinol sulfate potassium sulfate	13071104	40	1403095
Caelo	Quinolinol sulfate potassium sulfate	13403501	60	20131218
Caelo	Quinolinol sulfate potassium sulfate	15147704	40	20150618
Caelo	Quinolinol sulfate potassium sulfate	15147704	40	20150618
Caelo	Quinolinol sulfate potassium sulfate	162218	40	20160808*
Caelo	Resocrinol	13293108	60	AR-15-FG-006906-01
Caelo	Resocrinol	161533	40	20160524*
Fagron	Resocrinol	12G24-N04	40	1401462

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Fagron	Resocinol	13I18-B09-291533	45	20130606
Euro OTC	Ribavirin	1308001	45	20130902*
Euro OTC	Ribavirin	1604012	40	20160428*
Caelo	Riboflavin	12003317	40	1405155
Caelo	Riboflavin	13305203	60	AR-15-FG-005686-01
Caelo	Riboflavin	14322008	40	AR-16-FG-013669-01
Euro OTC	Riboflavin	1701050	40	20170214*
Euro OTC	Riboflavin	1701050-01	40	20170214
Fagron	Riboflavin	13D02-N03	40	AR-15-FG-000733-01
Fagron	Riboflavin	13D02-N03	40	20130405
Fagron	Riboflavin	15G20-B13-310997	60	20150819
Fagron	Riboflavin	16B18-B06-319026	40	AR-16-FG-014466-01
Fagron	Riboflavin	17G14-B05-337885	40	AR-18-FG-000141-01
Fagron	Riboflavin phosphate sodium	13I26-N06	40	1403705
Fagron	Riboflavin phosphate sodium	15J02-B03-313137	60	AR-16-FG-009883-02
Fagron	Riboflavin phosphate sodium	17A03-B01-335897	40	AR-18-FG-000920-01
Caelo	Rice starch	12068525	40	20120327
Caelo	Rice starch	16144501	40	20160504
Euro OTC	Rice starch	1912005	40	20200109*
Fagron	Rice starch	16B25-B01-327231	40	20160308
Fagron	Rice starch	16B25-B01-327231	40	AR-17-FG-015298-02
Caelo	Ropivacaine hydrochloride monohydrate	181569	40	20180802*
Euro OTC	Ropivacaine hydrochloride monohydrate	1707006	40	20171013*
Euro OTC	Ropivacaine hydrochloride monohydrate	1903027	40	20190416*
Caelo	Saccharin sodium	172110	40	20170831*
Caelo	Saccharin sodium	162210	39	20160811*
Caelo	Saccharin sodium	172592	40	20171206*
Fagron	Saccharin sodium	13I20-B06-291654	40	AR-17-FG-012457-01
Fagron	Saccharin sodium	14F30-B02-296322	40	AR-17-FG-022421-01
Fagron	Saccharin sodium	14F30-B02-296322	40	AR-18-FG-007117-02
Caelo	Salicylic acid	13344002	60	20131029
Caelo	Salicylic acid	13344018	60	20131020
Caelo	Salicylic acid	160109	60	20160229*
Euro OTC	Salicylic acid	1110020-01	40	20120125
Euro OTC	Salicylic acid	1509007	60	20150929*
Fagron	Salicylic acid	16I15-B08-333932	40	20170210
Fagron	Salicylic acid	190263	40	20190121
Caelo	Selenium yeast	13347911	40	1509355
Caelo	Selenium yeast	17002202	40	1707512
Caelo	Selenium yeast	17002208	40	20170126
Caelo	Selenium yeast	173332	40	20180207*
Euro OTC	Selenium yeast	L1204012-01	40	1403461
Euro OTC	Serine	1512012	60	20160112*
Euro OTC	Serine	1606020-01	40	20160714
Euro OTC	Serine	1606020	40	20160714*
Euro OTC	Serine	1711033	40	20171208*
Euro OTC	Serine	1904034	40	20190521*
Euro OTC	Serine	1909027	40	20191015*
Caelo	Siam benzoin	12321312	40	pending
Caelo	Sildenafil citrate	160498	60	20160307*
Caelo	Sildenafil citrate	170715	40	20170529*
Caelo	Sildenafil citrate	170715	40	20170529*
Euro OTC	Sildenafil citrate	1311010-01	60	20131209
Euro OTC	Sildenafil citrate	1311010-04	40	20150309

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Sildenafil citrate	1908006	40	20190906*
Fagron	Sildenafil citrate	13F24-N03	40	1402052
Fagron	Sildenafil citrate	13J15-N01	80	20131030
Caelo	Sodium acetate trihydrate	12316506	40	1402111
Caelo	Sodium acetate trihydrate	13411404	60	20140113
Caelo	Sodium acetate trihydrate	172003	40	20171107*
Euro OTC	Sodium acetate trihydrate	1507020	60	20150723*
Euro OTC	Sodium acetate trihydrate	1706008	40	20170710*
Euro OTC	Sodium acetate trihydrate	2002041	40	20200331*
Caelo	Sodium ascorbate	15429905	40	20160118
Caelo	Sodium ascorbate	182620	40	20181112*
Euro OTC	Sodium ascorbate	1406018-01	60	1411165
Euro OTC	Sodium ascorbate	1406018-01	60	20140724
Euro OTC	Sodium ascorbate	1507030	60	20150811*
Euro OTC	Sodium ascorbate	1506018	60	20150706*
Euro OTC	Sodium ascorbate	1510017	60	20151102*
Euro OTC	Sodium ascorbate	1601007	60	20160120*
Caelo	Sodium benzoate	11267016	40	20110923
Caelo	Sodium benzoate	13178619	60	20130624
Euro OTC	Sodium benzoate	1409040-01	60	20141021
Euro OTC	Sodium benzoate	1506019	60	20150623*
Euro OTC	Sodium benzoate	1510044	60	20151109*
Euro OTC	Sodium benzoate	1602020	60	20160225*
Euro OTC	Sodium benzoate	1610037	40	20161202*
Euro OTC	Sodium benzoate	1701045	40	20170207*
Euro OTC	Sodium benzoate	1711019	40	20171205*
Euro OTC	Sodium benzoate	2001018	40	20200205*
Yino Pharma	Sodium chondroitin sulfate	YN010511806006	40	20180912*
Caelo	Sodium citrate	12045026	40	20120307
Caelo	Sodium citrate	13089335	60	AR-15-FG-000405-01
Caelo	Sodium citrate	14112517	60	20140416
Euro OTC	Sodium citrate	1506041	60	0000010492
Euro OTC	Sodium citrate	1511017	60	20151130*
Euro OTC	Sodium citrate	1610016	40	20161102*
Euro OTC	Sodium citrate	1701029	40	20170126*
Fagron	Sodium citrate	12E04-N05	40	20120516
Fagron	Sodium citrate	14A13-B02-294541	60	20140424
Fagron	Sodium citrate	16F10-B01-326088	40	20160711
Caelo	Sodium cromoglicate	11114501	80	20110518
Caelo	Sodium cromoglicate	13232802	20	1505352
Caelo	Sodium cromoglicate	13232802	110	20130905
Caelo	Sodium cromoglicate	15224404	60	20150625
Euro OTC	Sodium cromoglicate	1403017-01	60	20140505
Euro OTC	Sodium cromoglicate	1510018	60	20151109*
Euro OTC	Sodium cromoglicate	1703027	40	20170405*
Fagron	Sodium cromoglicate	12C09-N02	79	1401553
Fagron	Sodium cromoglicate	13G24-N04	40	20130515
Caelo	Sodium cyclamate	12256803	40	1401418
Caelo	Sodium cyclamate	12105622	40	20120423
Caelo	Sodium cyclamate	182167	40	20181023*
Caelo	Sodium dodecyl sulfate	13099011	40	1403108
Caelo	Sodium dodecyl sulfate	15344503	60	20151022
Caelo	Sodium dodecyl sulfate	16229217	40	20160809
Caelo	Sodium dodecyl sulfate	170955	40	20170503*
Caelo	Sodium dodecyl sulfate	191243	40	20190521*
Caelo	Sodium dodecyl sulfate	190923	40	20190521*
Caelo	Sodium edetate	13142009	40	20130524
Caelo	Sodium edetate	161364	60	20160504*
Euro OTC	Sodium edetate	1609023	40	20170106*
Euro OTC	Sodium edetate	1812016	40	20190116*

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Fagron	Sodium edetate	13E15-N05	40	1402193
Fagron	Sodium edetate	16F21-B02-325085	40	20160713
Caelo	Sodium methyl-4-hydroxybenzoate	15358708	40	AR-16-FG-015095-01
Caelo	Sodium methyl-4-hydroxybenzoate	15358708	40	20151127
Caelo	Sodium methyl-4-hydroxybenzoate	15358713	40	20151127
Caelo	Sodium methyl-4-hydroxybenzoate	170519	40	20170308*
Caelo	Sodium methyl-4-hydroxybenzoate	191439	40	20190628*
Caelo	Sodium salicylate, powdered	12158307	40	1403225
Caelo	Sodium salicylate, powdered	13140513	60	20130531
Caelo	Sodium salicylate, powdered	163053	40	20161118*
Caelo	Sodium tetraborate	13290118	60	1412042
Caelo	Sodium tetraborate	161372	60	20160624*
Caelo	Sodium tetraborate	161372	40	20160624*
Euro OTC	Sodium tetraborate	1404025-01	60	20140514
Euro OTC	Sodium tetraborate	1507024	60	20150730*
Euro OTC	Sodium tetraborate	1510032	60	20151118*
Euro OTC	Sodium tetraborate	1711002	40	20171128*
Caelo	Softisan® 601	13296104	40	1403144
Caelo	Softisan® 601	15184905	60	20150611
Caelo	Softisan® 601	172178	40	20170817*
Caelo	Sorbic acid	12038025	40	20120315
Caelo	Sorbic acid	13334008	60	AR-15-FG-007849-01
Caelo	Sorbic acid	14176214	40	20140708
Caelo	Sorbic acid	14380714	40	20150209
Caelo	Sorbic acid	162080	40	20160722*
Caelo	Sorbic acid	15382002	40	20151112
Caelo	Sorbic acid	172056	40	20170823*
Caelo	Sorbic acid	162080	40	20160722*
Caelo	Sorbic acid	191114	40	20190502*
Caelo	Sorbitan stearate	12274801	40	20120924
Caelo	Sorbitan stearate	162352	40	20160826*
Caelo	Sorbitan stearate	17030805	40	20170210
Caelo	Sorbitan stearate	172564	40	20171027*
Caelo	Sorbitan stearate	192928	40	20191122*
Fagron	Sorbitan stearate	14J07-B02-299399	60	AR-16-FG-004368-01
Caelo	Sorbitol	13278217	40	20130920
Caelo	Sorbitol	16038501	40	20160315
Caelo	Sorbitol	163531	40	20170119*
Caelo	Sorbitol	16353107	40	20170119
Euro OTC	Sorbitol	1506052	60	20150713*
Euro OTC	Sorbitol	1512016	60	20160113*
Euro OTC	Sorbitol	1604007	40	20160428*
Euro OTC	Sorbitol	1610018	40	20161121*
Caelo	Soy lecithin (instant form)	13030504	40	1404399
Caelo	Soy lecithin (instant form)	13279813	40	20130903
Caelo	Soy lecithin (instant form)	17118101	40	20170620
Caelo	Soy lecithin (instant form)	191879	40	20190712*
Caelo	Spironolactone	14378715	40	20150211
Caelo	Spironolactone	160773	60	20160415*
Caelo	Spironolactone	190158	40	20190308*
Euro OTC	Spironolactone	1212034-01	50	1403151
Euro OTC	Spironolactone	1212034-01	42	20130215
Euro OTC	Spironolactone	1602006	45	20160309*
Fagron	Spironolactone	15G22-B10-311159	40	20150728
Fagron	Spironolactone	2294216E20-B06-322016	40	20160531

continued on the next page

continued from previous page

Supplier	Substance	Batch	Spectra	Certificate
Caelo	Star anise	11314104	30	20111121
Caelo	Stearic acid 50	12241910	40	AR-15-FG-007284-01
Caelo	Stearic acid 50	14359310	60	20150126
Caelo	Stearic acid 50	14359310	60	AR-16-FG-004044-01
Caelo	Stearic acid 50	14359314	60	20150126
Caelo	Stearic acid 50	170810	40	20170426*
Caelo	Stearic acid 50	170810	40	20170426*
Caelo	Stearic acid 50	192910	40	20191128*
Caelo	Stemless carline root	12232802	40	20120822
Caelo	Sucrose	13352909	40	1410501
Caelo	Sucrose	14340003	60	20141114
Caelo	Sucrose	161999	40	20160714*
Caelo	Sucrose	162060	40	20160808*
Caelo	Sucrose	163286	40	20161219*
Caelo	Sucrose	163081	40	20161115*
Caelo	Sucrose	171066	40	20170511*
Caelo	Sucrose	172133	40	20170817*
Caelo	Sucrose	173247	40	20180117*
Caelo	Sucrose	181582	40	20180605*
Caelo	Sulfacetamide	11085910	40	1402651
Caelo	Sulfacetamide	15445901	40	20160126
Caelo	Sulfacetamide	15445901	40	20160126
Euro OTC	Sulfacetamide	1312012-01	60	20140117
Euro OTC	Sulfacetamide	1509018	60	20150929*
Caelo	Sulfadiazine	12164101	40	1402053
Caelo	Sulfadiazine	13150011	60	20130708
Caelo	Sulfadiazine	170566	40	20170330*
Caelo	Sulfadiazine	17056602	40	20170330
Caelo	Sulfadiazine	17056602	40	20170330
Caelo	Sulfadiazine	191850	40	20190730*
Caelo	Sulfogaiacol hydrate	13405805	45	20140108
Caelo	Sulfogaiacol hydrate	190303	40	20190222*
Gatt-Koller	Sulfogaiacol hydrate	1156/04152115	60	20150410
Gatt-Koller	Sulfogaiacol hydrate	4543/01170317	40	AR-17-FG-012520-01
Fagron	SyrSpend [®] SF Alka	17D11-B04-332593	40	20170505
Fagron	SyrSpend [®] SF Alka	17D11-B04-332593	40	20170505
Fagron	SyrSpend [®] SF Alka	17F14-B02-335945	20	1804106
Fagron	SyrSpend [®] SF Alka	18B21-B08-347192	40	1809264
Fagron	SyrSpend [®] SF Alka	18C13-B11-350851	40	20180502
Fagron	SyrSpend [®] SF pH4	15A26-B04-311720	40	1608352
Fagron	SyrSpend [®] SF pH4	15A26-B04-311720	40	20150223
Fagron	SyrSpend [®] SF pH4	15A26-B04-305667	40	1701055
Caelo	Tannin	12336016	60	20121127
Caelo	Tannin	172092	40	20170829*
Fagron	Tannin	13H30-B03-287645	60	1711482
Fagron	Tannin	16D08-B04-328410	40	AR-17-FG-015963-01
Fagron	Tannin	16D08-B04-328410	40	20160425
Caelo	Tartaric acid	15130201	60	20150416
Caelo	Tartaric acid	15164001	60	1704461
Caelo	Tartaric acid	161468	40	20160607*
Euro OTC	Tartaric acid	1907022	40	20190813*
Fagron	Tartaric acid	13I25-B01-294093	60	1711509
Fagron	Tartaric acid	14G07-B02-308554	40	20140827
Euro OTC	Taurine	1306024-01	50	20130822
Euro OTC	Taurine	1504032-01	60	20150430
Euro OTC	Taurine	1504032-01	60	9167
Euro OTC	Taurine	1602011	60	20160218*
Euro OTC	Taurine	1607035	40	20160819*
Euro OTC	Taurine	1704001	40	20170426*
Euro OTC	Taurine	1904003	40	20190425*

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Supplier	Substance	Batch	Spectra	Certificate
Caelo	Testosterone	13406004	50	20131219
Caelo	Testosterone	13406004	50	20131219
Caelo	Testosterone	15244906	60	20150814
Caelo	Testosterone	16311506	40	20161123
Caelo	Testosterone	15244906	38	20150814
Euro OTC	Testosterone	1307001-01	40	1402309
Euro OTC	Testosterone	1511005	60	20151119*
Euro OTC	Testosterone	1604049	40	20160510*
Euro OTC	Testosterone	1910001	40	20191024*
Euro OTC	Testosterone	1912017	40	20191216*
Euro OTC	Testosterone	1511005	35	20151119*
Euro OTC	Testosterone	1604049	34	20160510*
Fagron	Testosterone	12F13-N02	40	20120628
Fagron	Testosterone	15E18-B08-307772	60	20150526
Fagron	Testosterone	17J26-B01-342032	40	20171205
Fagron	Testosterone	15E18-B08-307772	54	20150526
Caelo	Testosterone propionate	12163607	40	AR-15-FG-000623-01
Caelo	Testosterone propionate	15444709	40	1707612
Euro OTC	Testosterone propionate	1109024-02	60	1503607
Euro OTC	Testosterone propionate	1511003	60	20151111*
Euro OTC	Testosterone propionate	1512023	45	20151230*
Euro OTC	Testosterone propionate	2003011	40	20200408*
Euro OTC	Testosterone propionate	1511003	43	20151111*
Euro OTC	Testosterone propionate	1512023	45	20151230*
Caelo	Tetracaine base	171117	40	20170512*
Caelo	Tetracaine base	181249	40	20180605*
Euro OTC	Tetracaine base	1405025-01	60	AR-14-FG-012475-01
Euro OTC	Tetracaine base	1512022	45	20160128*
Fagron	Tetracaine base	12L19-N10	40	20130108
Fagron	Tetracaine base	14A16-B04-292915	60	20140205
Fagron	Tetracaine base	14A16-B04-292916	60	20140205
Caelo	Tetracaine hydrochloride	12019822	40	20120228
Caelo	Tetracaine hydrochloride	15437108	40	20160211
Euro OTC	Tetracaine hydrochloride	1506040	60	20150713*
Euro OTC	Tetracaine hydrochloride	1512019	45	20151228*
Euro OTC	Tetracaine hydrochloride	1612005	40	20170112*
Euro OTC	Tetracaine hydrochloride	1807017	40	20180730*
Fagron	Tetracaine hydrochloride	15K04-B03-322151	40	20160112
Fagron	Tetracaine hydrochloride	16G28-B03-327368	40	20160826
Caelo	Tetracycline hydrochloride	13201303	60	20130807
Caelo	Tetracycline hydrochloride	13201303	60	20130807
Caelo	Tetracycline hydrochloride	161167	60	20160504*
Caelo	Tetracycline hydrochloride	15230712	40	20150819
Euro OTC	Tetracycline hydrochloride	1302012-01	40	1411585
Euro OTC	Tetracycline hydrochloride	1506012	60	20150707*
Caelo	Thalidomide	13395704	60	20140207
Caelo	Thalidomide	15276711	40	1704508
Caelo	Thalidomide	182496	40	20181022*
Fagron	Thalidomide	14E27B04295348	60	1503608
Fagron	Thalidomide	15A13-B01-312230	40	1704509
Caelo	Theophylline	12166316	40	1402055
Caelo	Theophylline	12341101	60	20121115
Caelo	Theophylline	192563	40	20191120*
Caelo	Theophylline-ethylenediamine hydrate	12145301	40	20120628
Caelo	Theophylline-ethylenediamine hydrate	12363708	40	20130116
Caelo	Theophylline-ethylenediamine hydrate	13268609	40	1412133

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Supplier	Substance	Batch	Spectra	Certificate
Caelo	Theophylline-ethylenediamine hydrate	15380302	40	20160211
Caelo	Theophylline-ethylenediamine hydrate	17073707	30	20170323
Caelo	Theophylline-ethylenediamine hydrate	192220	40	20191204*
Caelo	Thiamine chloride hydro-chloride	14069502	60	20140321
Caelo	Thiamine chloride hydro-chloride	14069502	60	8986
Caelo	Thiamine chloride hydro-chloride	160156	60	20160316*
Caelo	Thiamine chloride hydro-chloride	192567	40	20191216*
Euro OTC	Thiamine chloride hydro-chloride	1211008-02	60	20121122
Euro OTC	Thiamine chloride hydro-chloride	1612004	40	20170117*
Caelo	Thymol	14025805	60	20140127
Caelo	Thymol	16144101	40	20160606
Euro OTC	Thymol	1312022-02	60	20131219
Euro OTC	Thymol	1510004	60	20151016*
Fagron	Thymol	15H13-B05-328912	40	20151118
Audor	Tobramycin sulfate	AP15061047002T	40	1608462
Audor	Tobramycin sulfate	AP15061047002T	40	20160322
Euro OTC	Tobramycin sulfate	1301011-02	60	1508071
Euro OTC	Tobramycin sulfate	1505015-01	60	8963
Euro OTC	Tobramycin sulfate	1510035-01	60	9202
Euro OTC	Tobramycin sulfate	1510035	60	20151208*
Euro OTC	Tobramycin sulfate	1807045	40	20180917*
Euro OTC	Tobramycin sulfate	2001010	40	20200113*
Fagron	Tobramycin sulfate	12G03-N03	40	1404541
Fagron	Tobramycin sulfate	15I17-B04-315697	45	20150928
Fagron	Tobramycin sulfate	16B05-B03-336397	40	1801385
Klenk	Tormentil	6911B141114	60	AR-15-FG-014020-01
Caelo	Tosylchloramide sodium	13103201	40	20130424
Caelo	Tosylchloramide sodium	13361602	40	1407634
Caelo	Tosylchloramide sodium	16236603	40	20160819
Caelo	Tosylchloramide sodium	172265	40	20170906*
Audor	Tranexamic acid	APX1508016MT	40	20170224
Audor	Tranexamic acid	APX1803027MT	40	20180430
Euro OTC	Tranexamic acid	2002005	40	20200219*
Euro OTC	Tranexamic acid	2001034	40	20200218*
Fagron	Tranexamic acid	14C21-B08-292225	60	AR-17-FG-016394-01
Fagron	Tranexamic acid	14L15-B06-3000036	60	AR-15-FG-008937-02
Caelo	Tretinoin	15028403	60	1507086
Caelo	Tretinoin	15239503	60	20150717
Caelo	Tretinoin	15028403	60	1507086
Caelo	Tretinoin	15239503	60	20150717
Euro OTC	Tretinoin	1402007-02	60	1507085
Euro OTC	Tretinoin	1510007	60	20151102*
Euro OTC	Tretinoin	1604059	40	20160603*
Euro OTC	Tretinoin	1402007-02	60	1507085
Euro OTC	Tretinoin	1510007	60	20151102*
Fagron	Tretinoin	15F01-B06-317884	40	20150619
Fagron	Tretinoin	15F01-B06-317884	40	20150619
Caelo	Triamcinolone acetonide	13256607	100	AR-15-FG-003755-01
Caelo	Triamcinolone acetonide	13379921	60	1503634
Euro OTC	Triamcinolone acetonide	1303001-02	40	20130815
Euro OTC	Triamcinolone acetonide	1211013-02	30	20130417

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Supplier	Substance	Batch	Spectra	Certificate
Euro OTC	Triamcinolone acetonide	1508008	60	20150902*
Euro OTC	Triamcinolone acetonide	1601021	45	20160119*
Euro OTC	Triamcinolone acetonide	1605010	40	20160531*
Euro OTC	Triamcinolone acetonide	1608005	40	20160906*
Euro OTC	Triamcinolone acetonide	1605010	25	20160531*
Euro OTC	Triamcinolone acetonide	1608005	22	20160906*
Fagron	Triamcinolone acetonide	12E15-N03	60	1412051
Fagron	Triamcinolone acetonide	15C19-B06-308572	60	20150402
EDQM	Triamcinolone hexacetonide	3.0	40	CRS
Caelo	Triamcinolone, micronized	15106905	45	20150527
Caelo	Triamcinolone, micronized	15106905	40	20150527
Caelo	Triamcinolone, micronized	15106911	40	20150527
Fagron	Triamcinolone, micronized	12A03-N09	40	20120117
Fagron	Triamcinolone, micronized	12K07-N13	80	AR-15-FG-003373-01
Fagron	Triamcinolone, micronized	14B13-B30-316101	40	20140311
Fagron	Triamcinolone, micronized	18A19-B05-351174	40	1811263
Fagron	Triamcinolone, micronized	18E09-B04-353921	40	1907730
Fagron	Triamcinolone, micronized	18J01-B05-364078	40	2004435
Fagron	Triamcinolone, micronized	18A19-B05-351174	32	1811263
Caelo	Triclosan	13391808	60	20131211
Caelo	Triclosan	14121209	45	20140718
Euro OTC	Triclosan	1406032-01	60	20140710
Euro OTC	Triclosan	1507041	60	20150804*
Euro OTC	Triclosan	1510045	60	20150511*
Euro OTC	Triclosan	1602003	45	20160204*
Euro OTC	Triclosan	1701032	40	20170207*
Fagron	Triclosan	17K02-B06-343548	40	20180105
Caelo	Trometamol	14050002	40	20140220
Caelo	Trometamol	161688	40	20160615*
Caelo	Trometamol	16168810	40	20160615
Euro OTC	Trometamol	1803016	40	20180320*
Fagron	Trometamol	13E22-N05	40	AR-17-FG-016395-01
Fagron	Trometamol	18A23-B10-351258	40	20180306
Fagron	Tropicamide	14D23-B04-293294	60	AR-15-FG-001641-01
Fagron	Tropicamide	16G19-B05-324829	40	20160905
Fagron	Tropicamide	17J06-B04-341322	40	1807428
Fagron	Tyrosine	13G24-N22	60	1411030
Fagron	Tyrosine	16B26-B01-322911	40	20160324
Fagron	Tyrosine	18E15-B02-359934	40	20181001
Fagron	Tyrothricin	12K14-N01	40	1509178
Fagron	Tyrothricin	12K14-N01	60	AR-15-FG-001172-01
Fagron	Tyrothricin	14A23-B05-294146	60	AR-15-FG-015005-01
Caelo	Ubidecarenone	14004504	60	AR-15-FG-009220-01
Caelo	Ubidecarenone	17209402	40	20170823
Caelo	Ubidecarenone	17209402	40	20170823
Caelo	Ubidecarenone	172094	35	20170823*
Euro OTC	Ubidecarenone	1205029-01	40	20121009
Euro OTC	Ubidecarenone	1605030	40	20160623*
Euro OTC	Ubidecarenone	1703026	40	20170406*
Euro OTC	Ubidecarenone	1801019	40	20180126*
Fagron	Ubidecarenone	16G26-B01-331742	40	20170110
Fagron	Ubidecarenone	18J24-B01-357225	40	20181121
Caelo	Urea	15154103	60	20150722
Caelo	Urea	161074	60	20160509*
Caelo	Urea	170216	40	20170202*
Caelo	Urea	18023003	40	20180216
Caelo	Urea	15154103	60	20150722
Euro OTC	Urea	1404024-01	60	20140519
Euro OTC	Urea	1601044	40	20160208*
Euro OTC	Urea	1604044	40	20160512*

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Supplier	Substance	Batch	Spectra	Certificate
Fagron	Urea	12F25-N05	40	20120724
Fagron	Urea	14I18-B03-303581	60	20141003
Fagron	Urea	14I18-B03-303581	60	20141003
Audor	Uridine	APIB160018211AU	40	20161118
Fagron	Uridine	11G07-N04	60	1402481
Fagron	Uridine	13K18-B31-288497	60	20131129
Euro OTC	Valine	1604055	40	20160601*
Euro OTC	Valine	1701026	40	20170222*
Euro OTC	Valine	1904006	40	20190423*
Euro OTC	Valine	1909028	40	20191015*
Fagron	Valine	15A14-B07-307756	60	9198
Audor	Vancomycin hydrochloride	APHAP1609006EV	40	AR-18-FG-000670-01
Euro OTC	Vancomycin hydrochloride	1407047-01	60	AR-15-FG-008950-01
Euro OTC	Vancomycin hydrochloride	1506029	60	AR-15-FG-009077-01
Euro OTC	Vancomycin hydrochloride	1610038	40	20161208*
Euro OTC	Vancomycin hydrochloride	1810013	40	20181029*
Euro OTC	Vancomycin hydrochloride	1908025	40	20190923*
Fagron	Vancomycin hydrochloride	17I18-B08-340944	40	20171109
Fagron	Vancomycin hydrochloride	18L18-B02-359948	40	20190207
Caelo	Vanillin	14044413	60	20140227
Caelo	Vanillin	15135302	60	AR-17-FG-022168-03
Caelo	Vanillin	160895	60	20160421*
Caelo	Vanillin	191201	40	20190515*
Fagron	Vanillin	13J01-N07	60	20130926
Caelo	Wax, bleached	13378619	20	1509364
Caelo	Wax, bleached	14336620	60	20141125
Caelo	Wax, bleached	15292022	40	20150827
Caelo	Wax, yellow	13335507	60	20131011
Caelo	Wax, yellow	15317602	60	20151007
Klenk	Wax, yellow	0290A170314	40	1908177
Klenk	Wax, yellow	0290A170915	40	20190507
Caelo	Wheat starch	14023203	60	AR-16-FG-011433-01
Caelo	Wheat starch	15124707	60	20150527
Klenk	Wheat starch	0104A141114	60	20141210
Klenk	Wheat starch	0104A160512	40	20160628
Caelo	Wool alcohols	13380601	40	1412037
Caelo	Wool alcohols	153703	60	20151111*
Caelo	Wool alcohols	153703	60	20151111*
Caelo	Wool alcohols	163530	40	20161223*
Caelo	Wool alcohols	191275	40	20190606*
Caelo	Xylitol	14068206	60	20140317
Caelo	Xylitol	15135405	60	20150417
Caelo	Xylitol	15135405	40	20150417
Fagron	Xylitol	14G04-B04-298356	60	AR-15-FG-008046-01
Fagron	Xylitol	14G04-B04-303524	60	20140919
Caelo	Xylometazoline chloride	hydro- 13344901	60	1501655
Caelo	Xylometazoline chloride	hydro- 13344901	60	20131119
Caelo	Xylometazoline chloride	hydro- 16074211	40	20160318
Fagron	Xylometazoline chloride	hydro- 13I18-B03-295481	60	AR-15-FG-007785-01
Fagron	Xylometazoline chloride	hydro- 14K19-B05-305006	60	20141128
Fagron	Xylometazoline chloride	hydro- 14K19-B05-305006	60	20141128
Caelo	Xylose	14218902	60	AR-14-FG-013086-01
Caelo	Xylose	17160902	40	20170704
Fagron	Xylose	13A31-B40-292395	60	20140407

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Supplier	Substance	Batch	Spectra	Certificate
Fagron	Xylose	16A25-B05-328261	40	20160215
Caelo	Zinc acetate dihydrate	15383301	40	20151127
Caelo	Zinc acetate dihydrate	153833	40	20151127*
Caelo	Zinc acetate dihydrate	170204	40	20170126*
Caelo	Zinc gluconate	170165	40	20170125*
Caelo	Zinc gluconate	170951	40	20170518*
Euro OTC	Zinc gluconate	1407033-02	60	20140902
Euro OTC	Zinc gluconate	1508007	60	20150827*
Euro OTC	Zinc gluconate	1603035	40	20160427*
Euro OTC	Zinc gluconate	1807019	40	20180725*
Caelo	Zinc stearate	180628	40	20180322*

Appendix B: Additional validation samples (Type B)

It is necessary that spectra also enter the validation which cannot be identified with this model. In this manner, it is verified that the model also rejects unknown substances. The spectra for these samples were recorded by *HiperScan GmbH*. They are allocated to the *Type B*. They also include the calibration spectra for other models.

The samples originate from 3 batches. From these 120 spectra were recorded. The spectra recorded on independent samples of substances which can be identified with the model are listed respectively in the section *Type B* for the individual substances and do not appear again elsewhere in this list.

Supplier	Substance	Batch	Spectra	Certificate
Flora Apothek. ...	Levamisole hydrochloride	LV17203	40	from supplier
Flora Apothek. ...	Levamisole hydrochloride	LV19305	40	from supplier
Pharmorgana	Sodium dichloroacetate	1000150016	40	from supplier

Appendix C: Additional validation samples (Type C)

Not required.

Appendix D: Requirements of validation

In order to ensure adherence to the safe scientific status, the individual methods for manufacturing and testing must be validated under certain circumstances (compare § 34 para. 1 no. 3, § 35 para. 1 no. 4 and para. 4 sentence 1 no. 2 b, para. 6 sentence 3 *ApoBetrO* [Pharmacies Rules and Regulations]). The *ApoBetrO* [Pharmacies Rules and Regulations] incorporates a legal definition in § 1 a para. 16 (quotation translated):

“Validation is the provision of documented proof which with a high degree of safety documents that, via a specific process or standard work process, a medicinal product is manufactured and tested, which is in accordance with previously determined quality features.”

Validation documentation can be used to prove that methods or devices which are not described in the Pharmacopoeia within the meaning of § 6 para. 1 sentence 3 *ApBetrO* [Pharmacies Rules and Regulations] achieve the same results as those in the Pharmacopoeia. On the other hand, with the requirements of the demanded validation it must be observed whether the respective testing method is already incorporated in the Pharmacopoeia.

NIR spectroscopy as a general testing method need not be validated in accordance with the express ruling in the *Ph. Eur. Section 1.1* [3], as it is already described in *Section 2.2.40* of the *Ph. Eur.* as an area of application for the identification of raw materials.

However, a special validation requirement exists for the reference database. This requirement is met with the existing document. Further requirements or rules as to how this proof must be furnished do not exist. It is required that the processes guarantee the same results as the methods and devices in the Pharmacopoeia [17].

Carrying out identity tests with *Apo-Ident* is therefore also possible if the NIR spectroscopy process is not required in the Pharmacopoeia monograph of the substance for identity testing. All NIR analyses with *Apo-Ident* prove several, often all molecule groups and are therefore comparable with a series of individual, targeted chemical proofs [4]. Therefore, the identity proof with *Apo-Ident* replaces the monograph test series (with two or more test combinations).

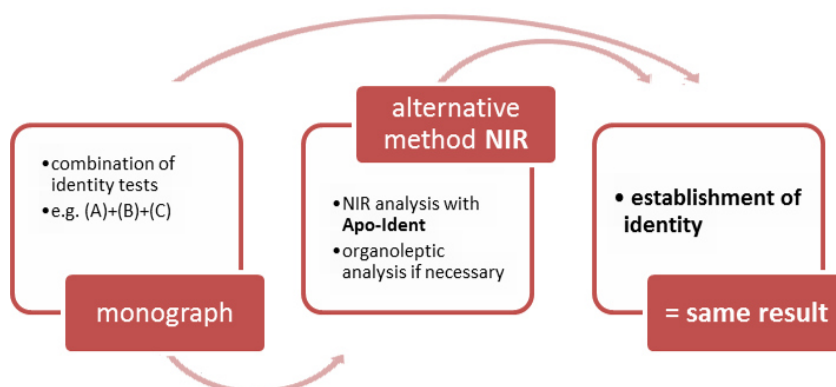


Figure 2: The combination of tests of the monograph is replaced by the alternative method NIR spectroscopy using *Apo-Ident*. This is permissible because both test procedures result in the establishment of the identity of the raw material.

With this validation documentation, proof is furnished that identical results are achieved with *Apo-Ident* and Pharmacopoeia methods, i.e. confirmation of the identity of the raw material [2].

Appendix E: Conformity of Apo-Ident with the European pharmacopeia

According to *Ph. Eur. Section 2.2.40*, NIR spectroscopy is basically suitable for: “Identification of agents, excipients, dosage forms, intermediate manufacturing products, chemical raw materials and packaging materials” ([3], quotation translated).

The fact that *Apo-Ident* meets the further criteria of the European Pharmacopoeia under the headings in *Section 2.2.40*

- Apparatus
- Measurement methods
- Sample preparation and presentation
- Testing the functionality of the instrument
- Identification and characterisation (qualitative analysis)
- Quantitative analysis
- Ongoing model evaluation
- Transfer of databases
- Data storage

can be proven based on the *HiperScan GmbH* documentation of “Meeting 2.2.40 *Ph. Eur.* by *Apo-Ident*” [4].

References

- [1] ABDA – BUNDESVEREINIGUNG DEUTSCHER APOTHEKERVERBÄNDE: Verordnung über den Betrieb von Apotheken (Apothekenbetriebsordnung – ApBetrO), 2012
- [2] REIMANN, B. ; REGIERUNGSPRÄSIDIUM DARMSTADT: Hinweise zur ordnungsgemäßen Prüfung von Arzneimitteln und Ausgangsstoffen (§§ 6 und 11 *ApBetrO*), 2007
- [3] *Europäisches Arzneibuch, Grundwerk 2017*. 9. Ausgabe. Deutscher Apotheker Verlag (978-3-7692-6679-5)
- [4] HIPERSCAN GMBH: Erfüllung von 2.2.40 Ph. Eur. durch Apo-Ident, 2013
- [5] ARBEITSGEMEINSCHAFT DER PHARMAZIERÄTE DEUTSCHLANDS (APD): Resolution in Verbindung mit §§ 6 und 11 *ApBetrO* Verwendung eines Nah-Infrarot-Spektrometers (NIR) zur Identitätsprüfung, 16. 10. 2013, DAZ 48, November 2013
- [6] ARBEITSGEMEINSCHAFT DER PHARMAZIERÄTE DEUTSCHLANDS (APD): Resolution 2014, Arbeitsgemeinschaft der Pharmazieräte Deutschlands (APD), Oktober 2014
- [7] *DAC/NRF*. Govi-Verlag (978-3-7741-0044-2)
- [8] KESSLER, W.: *Multivariate Datenanalyse*. WILEY-VCH Verlag, 2007 (978-3-527-31262-7)
- [9] NÆS, T. ; ISAKSSON, T. ; FEARN, T. ; DAVIES, T.: *Multivariate Calibration and Classification*. NIR Publications, 2002 (978 0 9528666 2 6)
- [10] HANLEY, J. A. ; LIPPMAN-HAND, A.: If nothing goes wrong, is everything all right? In: *Journal of the American Medical Association* 249 (1983), S. 1743–1745
- [11] JOVANOVIĆ, B. D. ; LEVY, P. S.: A Look at the Rule of Three. In: *The American Statistician* 51 (1997), S. 137–139
- [12] BRONSTEIN, I. N. ; SEMENDJAJEW, K. A. ; MUSIOL, G. ; MÜHLIG, H.: *Taschenbuch der Mathematik*. 5. überarbeitete und erweiterte Auflage. Verlag Harri Deutsch, 2000 (3-8171-2015-2)
- [13] MAHALANOBIS, P.: On the generalized distance in statistics. In: *Proc. Nat. Inst. Sci. India (Calcutta)* 2 (1936), S. 49–55
- [14] YAMBOR, B. ; DRAPER, W. ; BEVERIDGE, R.: Analyzing PCA-based face recognition algorithms: Eigenvector selection and distance measures. In: *Second Workshop Empirical Evaluation in Computer Vision* (2000)
- [15] HIPERSCAN GMBH: Identifikationsmethodik Apo-Ident, 2012
- [16] HIPERSCAN GMBH: Datenvorbehandlung des Identifikationssystems Apo-Ident, 2012
- [17] CYRAN ; ROTTA: Apothekenbetriebsordnung, Kommentar § 6 Rn. 10, 2010

Index

Acidum glycyrrhiza, *see* Glycyrrhizic acid, [39](#)

Amygdalin, [19](#)

Amygdalin, bitter almond extract 98%, [23](#)

Amygdalinum, *see* Amygdalin, [19](#)

Calcium colamine phosphate, [27](#)

Deoxycholic acid, [31](#)

Deoxycholic acidum, *see* Deoxycholic acid, [31](#)

Dimercaptosuccinic acid, [35](#)

Glycyrrhizic acid, [39](#)

Griffonia extract, *see* Griffonia seed extract,
[43](#)

Griffonia seed extract, [43](#)

Griffonia simplicifolia, *see* Griffonia seed
extract, [43](#)

Kalii oroticum, *see* Potassium orotate, [61](#)

L-Carnitine hydrochloricum, *see* L-carnitine
hydrochloride, [47](#)

L-carnitine hydrochloride, [47](#)

L-carnitine tartrate, [51](#)

Mg-Ca-K colamine phosphate, [57](#)

Potassium orotate, [61](#)