



hiperscan

apo-ident

Operating manual

+ Additional functions + Instructions

For *Apo-Ident* NIR spectrometer

Based on version 1.2



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Quick Reference User Guide

1. Starting the software

Start the *Apo-Ident* software by double-clicking the icon which is on the desktop.

The *Apo-Ident* user interface will open.

In case of low internal instrument temperature a warm-up phase will start automatically. Once the respective message has disappeared, the system is ready to start the measuring process.



2. Select substances

The first step is to choose your user profile under **Configuration profile**. Afterwards, select the category to be examined under **Substance selection**, e.g. "API's & excipients, solid".

Then enter the English or Pin Yin name of the substance. Optionally, the Latin name may be entered in the line below if available.

After entering the first letters the software will provide suggestions.

Note: In order to learn how to create a configuration profile, refer to page 8 of our detailed manual.

Class:	APIs & excipients, solid
Name:	Tetraca
Latin:	<input checked="" type="radio"/> Tetracaine base <input checked="" type="radio"/> Tetracaine hydrochloride

3. Transflectance reference measurement (only "APIs & excipients, liquid/semi-solid")

Please ensure that the sample container is placed inside the black **distance ring**.

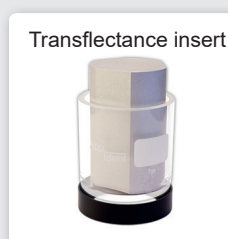
Place the transflectance insert with the feet facing downwards into a clean, empty sample container. Place the sample container with the transflectance insert onto the measurement window of the *Apo-Ident* instrument.

Important: Both the initial transflectance reference measurement as well as the measurement of liquids/semi-solid samples must be performed with the same transflectance insert and sample container. Otherwise this may result in non-identification.

Having successfully completed the reference measurement a substance measurement must be commenced within five minutes. Failure to take a sample measurement within five minutes means that the transflectance reference measurement will need to be repeated.

Class:	APIs & excipients, liquid/semi-solid (with analysis certificate)
Name:	Dexpanthenol
Latin:	Dexpanthenolum

Transflectance reference  Please use the same transflectance insert for the following sample measurement.



4. Start measurement

Place the **sample container with the substance onto the measurement window**

(With liquids and ointments use the transflectance insert in the sample container.)

and **start the measuring process** by clicking the green button next to **<Start measurement>** or by pressing the measurement button (green light) directly on top of the instrument.

Start measurement  Please use the same transflectance insert for the reference and sample measurement.



Quick Reference User Guide

5. Starting analysis

Before taking the first sample measurement after switching on *Apo-Ident*, the system requires that you run the external black and white (Zenith) reference standards.

Please follow the on-screen instructions and always use the distance ring as supplied.

These reference measurements will be repeated from time to time as prompted by the software.



6. Result presentation

After few seconds the instrument will show whether the substance has been identified or not.


Note: In the event of non-identification, repeat the measurement and if the answer is still the same please refer to section 2.4 of this manual before investigating possible causes for incorrect analysis.

Result	Name:	Glucose monohydrate
	NIRS Result:	Match
	Value:	99.9% (Limits 98% to 100%)
	Validation:	Available

7. Data for the report

Fill in the following data:

- Operator name
- Manufacturer/supplier
- Use-by date or shelf life (selection via blue hyperlink)
- Batch number
- PPN (optional)
- Additional tests (optional) – click [<Additional tests>](#) (text limited to 10 short lines)
- Comment (optional)





As long as this symbol  is visible, additional input data is missing and the analytical report cannot be generated.

Operator name:	<input type="text" value="Smith"/>
Manufacturer/Supplier:	<input type="text" value="Sample supplier"/>
Use-by date:	<input type="text" value="November"/> <input type="text" value="2016"/>
Batch number:	<input type="text" value="1234567"/>
PPN:	<input type="text"/>
Additional tests:	<input type="text" value="(empty)"/>
Comment:	<input type="text"/>
Test number:	10

8. Create report

The measurement report may now be saved as a PDF and printed if required.

Note: Irrespective of which of the four functions are selected, the measurement data and result will be saved automatically. Additionally, a label can be printed via a label printer (small printer icon).

Create report	   
---------------	---

1. First steps

1.1. Safety instructions

Please read the complete safety instructions carefully before using the *Apo-Ident* system.

- Make sure that the input voltage matches the specification on the rating label.
- Avoid using the instrument in high temperatures and high humidity or dusty and aggressive environments.
- The installation location should be well ventilated and the instrument should not be placed in direct sunlight. Install the instrument on a nonflammable, flat surface that does not transfer vibrations to instrument.
- Do not use if the power cord or plug is damaged or the wall socket is loose in any way. If the power cable is defective or shows faults, please replace it with a new one. Working with a defective cable can be hazardous as the instrument works with 230 Volts.
- Please ensure that no liquids or other materials get into the instrument. In the event of material ingress please disconnect the instrument from the electrical supply and contact customer services.
- Do not open the instrument by yourself.
- Do not operate the instrument in an explosive or flammable environment.
- *Apo-Ident* is frequently used for identification of dangerous substances. Only trained and qualified staff should operate the system. If unsure please contact the laboratory manager or the responsible person.

1.2. Software installation

- Insert the provided USB stick in your PC.
- Double click on the file QuickStep_*.exe and accept the license terms and conditions. Follow the setup instructions as directed by the software.
- Double click on the file named IdentModul_*.exe and accept the license terms and conditions. Follow the setup instructions as directed by the software.
- Following a successful installation of the software a certificate will be produced that may be saved or printed as part of your quality system.

1.3. Connecting the analytical instrument

Apo-Ident requires a power supply and a PC/Laptop with installed *Apo-Ident* software.

Please follow these steps:

- Insert the power supply cable in the socket at the back of the instrument (left side) and connect to an earthed socket of 230 Volts power supply. (The analytical instrument can also work with other power supply systems with earthed connection of 100V - 230 V and 50/60 Hz.)
- Connect *Apo-Ident* with the USB cable provided to a convenient USB port on the computer. The *Apo-Ident* USB port is at the back right-hand side of the unit.
- Switch on the instrument. The power switch is at the back left-hand side of the unit.
 - The indicator light on the top front panel will now show red indicating the system is live.

Apo-Ident is now ready to use.

1. First steps

1.4. Starting the software

Start the *Apo-Ident* software by double-clicking the icon which is on the desktop.

The *Apo-Ident* user interface will open.

In case of low internal instrument temperature a warm-up phase will start automatically. Once the respective message has disappeared, the system is ready to start the measuring process.

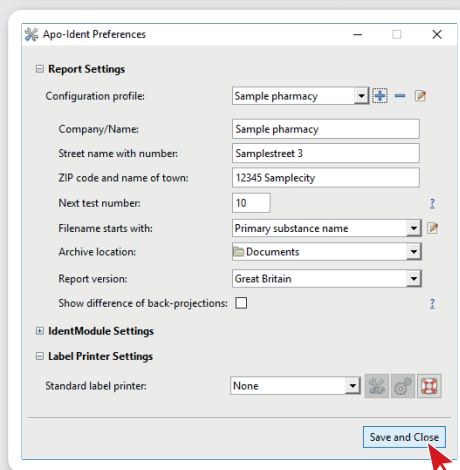
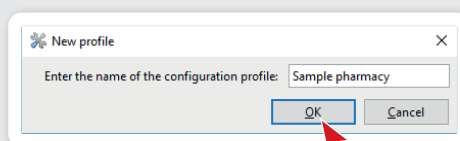
1.5. Creating a new configuration profile

When starting the program you will be prompted to create your configuration profile (= user profile). Preferably enter the name of your pharmacy or department as the profile name and confirm with **<OK>**.

Complete your profile with the address of your pharmacy and the next test number. Additionally, you may modify the following:

- How the filename of the test report created by *Apo-Ident* begins → **section 1.6**
- Where the file of the test reports is located → **section 1.7**
- Language or form of the test report (according to corresponding legal procedures or requirements) → **section 1.8**
- Settings for label printing → **section 1.10**

Once you have modified the settings click on **<Save and Close>**. Your user profile is now saved and available for sample analysis.



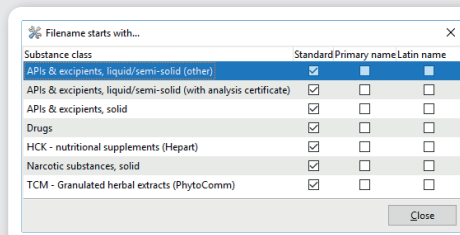
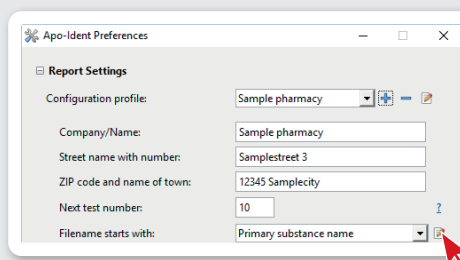
1.6. Selection of naming structure in archive folder

Select the classification for every substance, in order to save the substance name in archives in its particular form. By default, the primary substance name is stored.

Click on the icon with the pen next to **<Filename starts with>**, to adjust settings for the currently selected user profile.

Individually set for every substance category, whether the file name of the test protocol for the primary substance shall be defined in English, PIN YIN or in Latin. This setting is only applied for the currently selected user profile. Please consider that the latin name is not available for all substances in the database.

Note: You can always modify the name format in the menu bar by selecting **<Preferences>**.



1. First steps

1.7. Selection of an individualised save location of test reports

For every user profile you must select an individual save location for test reports inside settings for problem free archiving.

Note: Learn how to create additional user profiles in **section 1.9**.

If you want to create a new save folder, Select **<Archive location>** and then **<Other>**. Another window opens in which you can allocate your individual save location or create a new folder.

1.8. Language and form of the test report

Click right on the arrow next to **<Report version>** and choose language or form of the test report. This setting will only be used for the currently chosen user profile.

This setting affects the test report header as well as the label printout and the ranking display in the PDF.

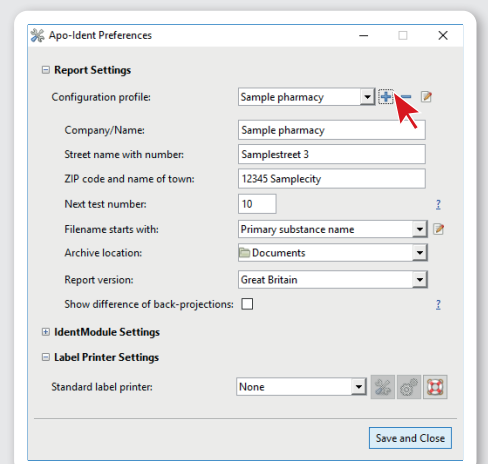
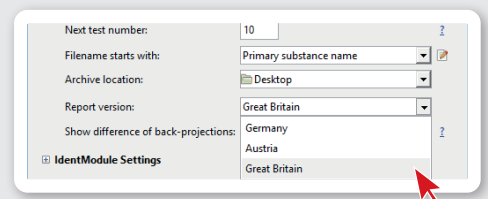
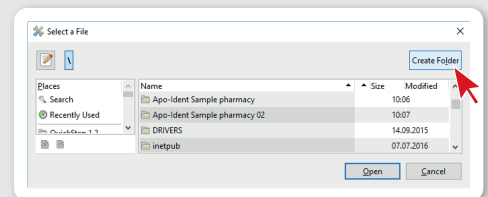
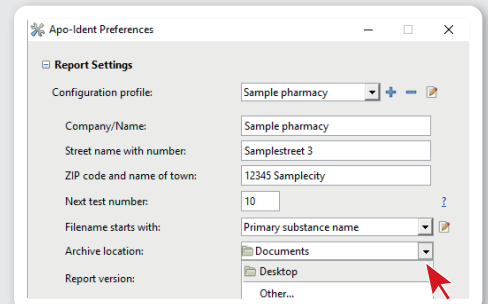
1.9. Assigning different user/pharmacy branches

You can assign various user profiles with this function, e.g. when the identification tests are carried out in different franchised pharmacies. Please note that according to the license agreement the software shall be used in a maximum of four pharmacies (main and franchise pharmacies). In case of more than four pharmacies, purchase of further licenses is required.

Click on the **<Preferences>** button in the menu bar above. A window opens as shown on the right.

Click the button with the plus icon to create a new user profile. Type in the name of the new pharmacy and press the **<OK>** button. As a result, a new user profile will be created.

Please type in your address for the new profile as well as the next test number. In regard to the other settings, proceed as described in section 1.6 to 1.8 and save your settings by clicking **<Save and Close>**. The profile is now available for additional users.



1. First steps

Prior to beginning the measurement, the selected profile may always be chosen in the upper part of the user interface under **Configuration profile**. Please ensure the correct user profile is selected prior to a measurement. Changing the user profile after a measurement results in the data being discarded and so the sample measurement must be repeated.

1.10. Settings for label printers

Brother QL 560 and QL 570 with fanfold paper

Installation of driver software

Before turning on the label printer, please install the device drivers for the *Brother QL 560* or *QL 570* on your computer (follow the instructions of the software).

Note: In Windows 10, the drivers are automatically installed after plugging in and turning on the printer.

Apo-Ident software settings

Choose your printer from the **<Standard label printer>** list and then click the **<tool-icon>** on the right side of the list.

Change the following settings in the open dialog box*:

- Format: Normal Format
- Bandwidth: 62 mm
- Length: 35 mm
- Orientation: Portrait

Click on **<Apply>** and confirm with **<OK>**.

* These figures refer to the use of the continuous label roll type DK-22205.

You are now back to the *Apo-Ident* software settings. Change further information here if it is not set by default already:

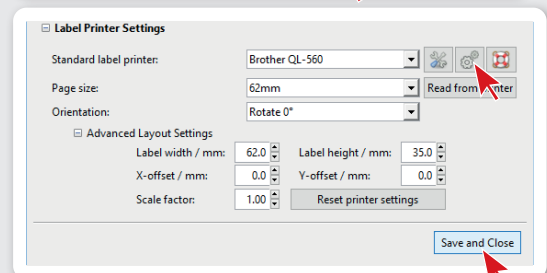
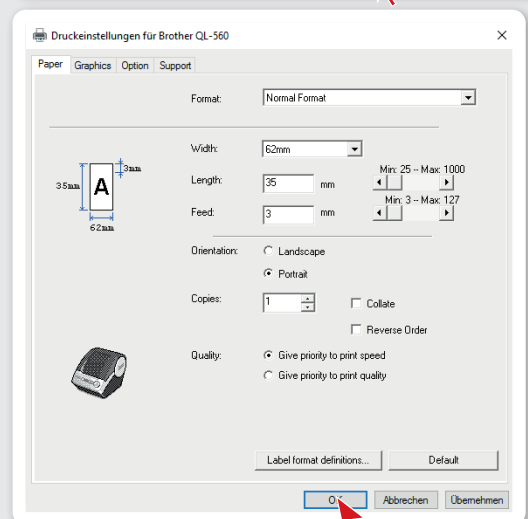
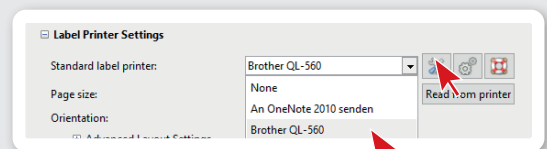
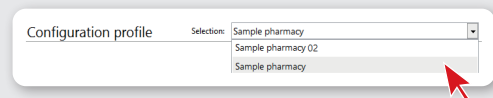
- Page size: 62 mm
- Orientation: check rotate 0°

Advanced Layout Settings:

- Label bandwidth / mm: 62 mm
- Label height / mm: 35 mm

Note: Before you save your settings, you may do a test print. In order to do that, click the middle button next to the description of the chosen printer.

Apply with **<Save and Close>** if your test print was successful. If the test print failed then please contact customer service.



2. Measurement operation

2.1. Substances which can be clearly identified with Apo-Ident

First, select your user profile under **Configuration profile**. Next, select the category to be examined under **Substance selection**, e.g. "API's & excipients, solid".

Enter the English or Pin Yin name of the substance. Optionally, the Latin name may be entered in the line below if required (if available).

Note: After entering the first letters the software will provide suggestions.

The substance is distinctly identifiable if there is a **green button** in front of the name. If the button is yellow or red, please continue reading under section 2.4 or 2.5.

Select the according substance and place the **sample container with the substance on the measuring window**. Start the **measurement procedure** by clicking the green button next to **Start measurement** or by clicking the measurement button (illuminated green button) on the top panel of the instrument.

Please make sure to always use the distance ring.

Following the first measurement after switching on *Apo-Ident* you will be requested to run the black and white (Zenith) external reference standards. Please follow the instructions on the screen.

The measurement of the references will have to be repeated upon request by the software from time to time.

A result will be displayed after a few seconds stating if the substance has been identified.

Note: If the result is negative some additional information will be displayed. Please check measurement parameters and repeat your sample measurement before further investigation.

Enter the following data after your measurement:

- Operator name
- Manufacturer/supplier
- Use-by date or shelf life (selection via blue hyperlink)
- Batch number
- PPN (optional)
- Additional tests (optional) – click **<Additional tests>** (text limited to 10 short lines)
- Comment (optional)

Class:	APIs & excipients, solid
Name:	Tetraca
Latin:	<input checked="" type="radio"/> Tetracaine base <input checked="" type="radio"/> Tetracaine hydrochloride

Start measurement




Please use the same transreflectance insert for the reference and sample measurement.



Name:	Glucose monohydrate
Result	Match
NIRS Result:	
Value:	99.9% (Limits 98% to 100%)
Validation:	Available

Operator name:	Smith
Manufacturer/Supplier:	Sample supplier
Use-by date:	November 2016
Batch number:	1234567
PPN:	
Additional tests:	(empty)
Comment:	
Test number:	10

As long as this symbol  is visible, additional input data is missing and the measuring report cannot be generated.

2. Measurement operation

Now you can save the measurement protocol, open a PDF file or print.

Note: No matter which of the functions you choose, the measurement data and result will be saved automatically. In addition you may also print your test label on the label printer (small printer icon)

2.2. Measurement with transfectance insert (only "APIs & excipients, liquid/semi-solid")

Transflectance reference measurement

Please ensure that the sample container is placed in the **black distance ring** prior to measurement.

Place the transfectance insert with the little feet facing the bottom into an empty sample container. Position the sample container with the transfectance insert onto the measurement window of the *Apo-Ident* instrument.

! **Important:** Both, the initial transfectance reference measurement as well as measuring liquids/semi-solids must be performed with the same transfectance insert and sample container. Otherwise this may result in non-identification.

Having successfully completed the reference measurement a substance measurement must be commenced **within five minutes**. Failure to take a sample measurement within five minutes means that the transfectance reference measurement will need to be repeated.

2.3. Measurement with sample insert (for small amounts of substances)

Some substances can also be identified with small amounts of sample. For this application you need to use a sample insert. After selecting such a substance, the checkbox **<Use sample insert>** will appear. Check the box if you use the sample insert.

An overview of all substances which may be measured with the sample insert, may be found under **<Help>** - **<Subscribed substances with sample insert>**.

The sample should be filled to a height of about 0.5 cm in the sample insert. Place the sample container on the measurement window and start the measurement process as usual.

As a next step you will be requested for references. First measure the black reference followed by the white reference (with the insert) as directed by the software. The reference is valid for 60 minutes.

The result will now be displayed as usual.

Create report



Class: APIs & excipients, liquid/semi-solid (with analysis certificate)
Name: Dexpanthenol
Latin: Dexpanthenolum

Transflectance reference



Please use the same transfectance insert for the following sample measurement.

Transflectance insert



Substance selection
Class: APIs & excipients, solid
Name: Betamethasone valerate
Latin: Betamethasoni valeras

Transflectance reference ☒
Start measurement ☒

☒ Use sample insert



2. Measurement operation

2.4. Substances with indeterminate test result

Substances which are not clearly identified with *Apo-Ident* will be indicated by a yellow icon in front of the substance name.

For further information click on the icon .

Click **<Show as PDF>** if you want to print this information.

For exact identification, an additional test (or tests) may be required. The method and the result may be entered directly in the software (under **<Additional tests>**) or handwritten on the test report. The final result information should be completed in the appropriate fields.

Substance selection

Class: APIs & excipients, liquid/semi-solid (with analysis certificate)

Name: Cool

Latin: Cooling cream DAB

Cooling cream DAB 6 (stabilised, contains rose oil)

Substance not conclusively distinguishable

The selected substance 'Cooling cream DAB 6 (stabilised, contains rose oil)' is not conclusively distinguishable by near-infrared spectroscopy (Apo-Ident) from following substances:

Substance name	Latin name
Cooling cream DAB	Unguentum leniens

Apo-Ident combines these substances in the classification 'Cooling cream / Cooling cream with rose oil'. In order to get a conclusive test result, additional tests are necessary to distinguish within this classification.


Show as PDF Close


Configuration profile Selection: Sample pharmacy

Substance selection Class: APIs & excipients, liquid/semi-solid (with analysis certificate)

Name: Cooling cream DAB 6 (stabilised, contains rose oil)

Latin: Unguentum leniens DAB 6

Transflectance reference 

Start measurement  Please use the same transflectance insert for the reference and sample measurement.

Result Name: Cooling cream / Cooling cream with rose oil

NIRS Result: Match (Additional Tests required)

Value: 99.5% (Limits 98% to 100%)

Validation: Available

Report details Operator name: Smith

Manufacturer/Supplier: Sample supplier

Use-by date: October 2016






Batch number: 1234567

PPN:

Additional tests: (empty)

Comment:

Test number: 10

Create report     Show group as PDF 

The method and the result of the measurement should be entered in the software under **<Additional tests>**.

If the additional test results are available you may confirm if the substance is positively identified by clicking the check box ☒ **<Identified>**.

Additional Tests (Method and Result)

Yellowish white paste, odour slightly like rose oil

Final result: ☒ Identified ☐ Discard

Approve Discard

2. Measurement operation

The text entry and the final result will be displayed in the report.

Result NIRS:

The sample has been identified as a substance within the group Cooling cream / Cooling cream with rose oil*.

Value: 99.5% (limits 98.0% to 100%)

All other substances of the database have been excluded on the basis of the NIR spectrum. The test result is only conclusive with additional tests which differentiates within the group.

** Cooling cream DAB 6 (stabilised, contains rose oil); Cooling cream DAB*

Additional tests:
(Method and result)

Yellowy white paste, odour slightly like rose oil

Conclusion:

Cooling cream DAB 6 (stabilised, contains rose oil) has been clearly identified.

Approved by:

Name

Date/Signature

Handwritten entry of additional testing results on printed report

If the additional testing will be carried out at a later time, the final result has to be checked on the printed test result when completed. The checkbox ☒ **<Identified>** must **not** be clicked in the software.

Result NIRS:

The sample has been identified as a substance within the group Cooling cream / Cooling cream with rose oil*.

Value: 99.5% (limits 98.0% to 100%)

All other substances of the database have been excluded on the basis of the NIR spectrum. The test result is only conclusive with additional tests which differentiates within the group.

** Cooling cream DAB 6 (stabilised, contains rose oil); Cooling cream DAB*

Additional tests:
(Method and result)

Conclusion:

Cooling cream DAB 6 (stabilised, contains rose oil) has been clearly identified.

☐ Yes ☐ No

Approved by:

Name

Date/Signature

2. Measurement operation

2.5. Substances which can not be identified by Apo-Ident

Substances which cannot be identified with *Apo-Ident*, e.g. because they do not have a sufficient signature in the NIR, will be clearly indicated in red after the substance name is entered. A message box with additional information will also be displayed.

For identification of this substance a different test method is required.

However the *Apo-Ident* software can provide you with the test report. Just click **<OK>**.

The method and the result may be entered directly in the software (under **<Tests>**) or handwritten on the test report. The final result information should be completed in the appropriate fields.

Substance selection

Class:	APIs & excipients, solid
Name:	selen
Latin:	Sodium selenate

Class: APIs & excipients, solid

Name: Sodium selenate

Latin: Natrii selenas

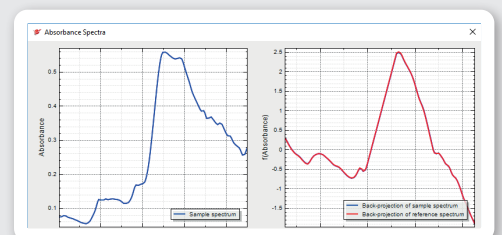
Message box:

Substance 'Sodium selenate' cannot be identified by Apo-Ident. Please use another identification method.

You can create a protocol anyway. Please complete the required fields for this substance.

Otherwise please select another substance.

OK



Test report for identity verification of raw substances

Sample pharmacy
Samplestreet 3, 12345 Samplecity

06/10/2016

Tested substance: Sodium selenate
 Natrii selenas

Batch number: 123

Manufacturer/Supplier: Sample supplier

Use-by date: October 2016

Test number: 11

Operator name: Smith

Report file: Sodium_sel__123__2016-10-06_15-04-42.pdf

Comment:

Tests:
 (Method and result)

Conclusion: Sodium selenate has been clearly identified.

☐ Yes ☐ No

Approved by:

 Name

 Date/Signature

3. Additional functions

3.1. Consistency percentage and control input

The confidence limits for identification are displayed after the reported value. If the measured spectrum is outside of the limits the substance will not be identified and designated as „No match“

By clicking on the hyperlink **<NIRS Result>** you may view the measured spectrum.

3.2. Display of the difference between the sample and the reference

If required, you are able to view the difference between the spectrum of the sample and the reference in the displayed graphs (this is only possible for positive substance identification). Please note that only the right-hand graph will display the difference spectrum for ease of interpretation.

Under **<Preferences>** check **<Show difference of back-projections>** to have the line displayed in the report. The button **<Save and Close>** completes the input.

3.3. Query operation (search function) for substance, expiration date or custom criteria

This feature lets you review test reports or labels and print them. Click the button **<Query>** in the menu bar.

The search window depicted on the right will open.

Adjust the user/configuration profile on top for the search query if necessary. For example, in the tab **<Substance>**, enter the name of the substance for which you want to find the test reports. Click **<Execute>**. All test reports containing the entered search text will be shown.

In order to search for the expiration date, click on the tab **<Use-by Date/Shelf Life>** and enter the data needed.

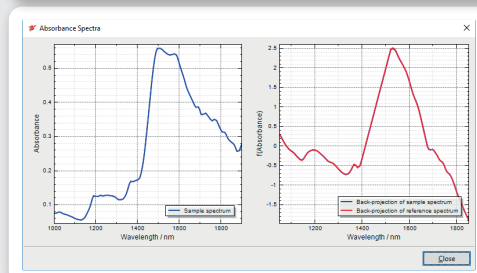
After running the query you may choose the relevant substance in the result window and view information about the measurement or report. Additionally, you may print the test report or label again.

Name: **Glucose monohydrate**

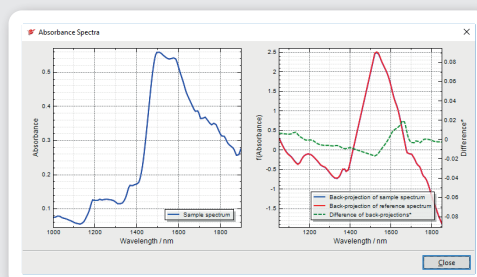
Result **NIRS Result** **Match**

Value: **99.9%** (Limits 98% to 100%)

Validation: Available



Graph without display of difference



Graph with display of difference

Archive Query

Configuration profile: Sample pharmacy

Substance Use-by Date/Shelf Life Advanced

Search for substance with given name, test number or PPN.

Substance name, test number or PPN:

Execute

Primary Name: Latin Name/Manufacturer/Supplier Batch Number Test number PPN Timestamp/Use-by Date/Shelf Life

Information Show Report Print Report Print Label

Save Copy to ... Close

Archive Query

Configuration profile: Sample pharmacy

Substance Use-by Date/Shelf Life Advanced

Search for substances with use-by date/shelf life in the time period

from October 2016 to October 2016

Execute 2 matches found.

Primary Name	Latin Name	Manufacturer/Supplier Batch Number	Test number	PPN
Cosling cream DAB 6 (stabilised, contains rose oil)	Unguentum Ierisens DAB 6	Sample supplier	1234567	10
Sodium selenate	Natrii selenas	Sample supplier	123	11

Information Show Report Print Report Print Label

Save Copy to ... Close

3. Additional functions

Under the tab **<Advanced>** you are able to define your own search criteria. You may also search for the operator, supplier or a batch number.

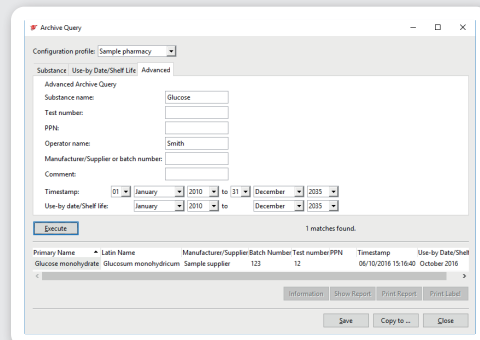
In the query **<Timestamp>** you are, for example, able to request all measurements starting from the 01-01-2016.

Export of query results in CSV format

Results of the query may be saved in CSV format by clicking **<Save>**. You may open these in a CSV compatible program (like MS Excel) to either print the list or continue using it.

Copy data to customised locations (e.g. onto a USB flash drive)

If you want to copy the found data to a custom location, please click the **<Copy to...>** button and select the desired location. All data pertinent to the search criteria will be copied.

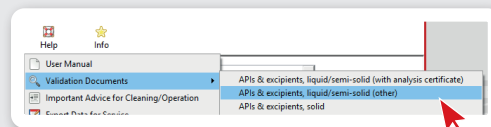


3.4. Display of validation documents

Click on **<Help>** in the menu bar on top.

Now choose the relevant document.

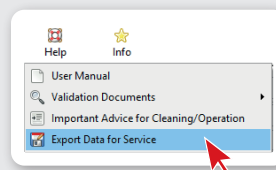
After a successful measurement, you may open the validation document of the presently identified substance directly via the *Apo-Ident* interface. To open the document, click on **<Validation>** in the result area.



3.5. Export data (e.g. for Apo-Ident customer service)

To send your test reports or to save for the purpose of data backup, click on **<Help>** in the menu bar on top.

Choose **<Export Data for Service>** and continue as described in section 3.6



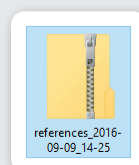
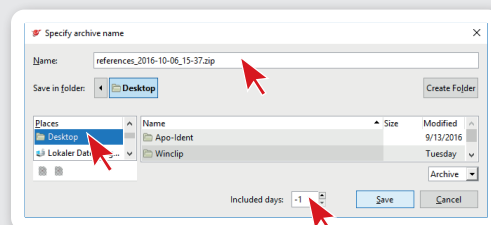
3.6. Custom selection of the number of measuring days for saving or sending data

This feature lets you save your spectra compressed in a ZIP file. You may set how many measurement days you want to summarise and send or save in the following way. Only whole days are possible for this feature:

- -1 = all days
- 1 = 1 day
- 2 = 2 days
- and so on

Click **<Save>**. Afterwards, the according archive file will be displayed on your desktop. Of course, you may choose another location as well.

This file is now available for forwarding by email if required.



3. Additional functions

3.7. Details of identification (ranking)

Apo-Ident compares the measured spectrum with the other samples saved in the spectral reference library. A maximum of 20 results of the highest consistency may be displayed in the ranking table. In order to view the ranking table, please click the hyperlink [<Value>](#) in the result section of the user interface.

A table will then be displayed which provides all the identification criteria. If you select the button [<Show as PDF>](#), you will get the displayed table in PDF format and you may print and file it together with the test report.

At the first position (rank 1) the reference substance with the **highest consistency with the sample** will be displayed. If the criteria for the identification of the substance are met, it will be displayed in **green**.

Thereafter, the nearest reference substances follow in **red**. These are not directly considered in the evaluation of the measured spectrum of the sample. Please note that the name in the ranked list (classification) may differ from the substance name for substances which are summarised in groups. The group name will then be displayed (e.g. "triglycerides").

This figure supports the confirmability and validation of the identification results by the user.

You can find an explanation of the particular terms on the next page.

Name: **Glucose monohydrate**
Result
NIRS Result: **Match**
Value: **99.9%** (Limits 98% to 100%)
Validation: Available

Identification details							
Ranking	Classification	Sample ID	Significance	Confidence	Correlation	Distance	Value
1	Glucose monohydrate	20031	0.9992	0.9992	0.9999	2.7	99.92%
2	Potassium tartrate hemihydrate	20999	0.9558	0.9076	0.9955	22.3	0.00%
3	Potassium tartrate hemihydrate	21440	0.9373	0.8063	0.9964	26.2	0.00%
4	Lactose monohydrate	20029	0.9309	0.9238	0.9905	30.3	0.00%
5	Levothyroxine sodium	21820SI	0.8920	0.7375	0.4612	41.5	0.00%
6	Borax	20179	0.8762	0.6258	0.8753	51.5	0.00%
7	Arginine	20391	0.8716	0.7486	0.8530	46.8	0.00%
8	Allantoin	20079	0.8561	0.5706	0.7040	63.1	0.00%
9	Levothyroxine sodium	21708	0.8496	0.4669	0.5237	68.3	0.00%
10	Aciclovir	21677	0.8481	0.8602	0.9089	33.0	0.00%
11	Levothyroxine sodium	21708SI	0.8421	0.1656	0.4582	73.1	0.00%
12	Calcium orotate dihydrate	20418	0.8417	0.2483	0.9431	74.8	0.00%
13	D-(-)-Mannose	21035	0.8379	0.3894	0.9617	75.4	0.00%
14	Potassium sodium tartrate tetrahydrate	20782	0.8349	0.2741	0.9798	75.2	0.00%
15	Glucose, anhydrous	20982	0.8280	0.4188	0.9749	57.1	0.00%
16	Tannin	20018	0.8279	0.2466	0.9345	85.7	0.00%
17	Starch	20181	0.8264	0.2812	0.9077	70.9	0.00%
18	Potassium sodium tartrate tetrahydrate	21801	0.8252	0.2044	0.9795	81.0	0.00%
19	Magnesium orotate dihydrate	20429	0.8236	0.0260	0.8795	95.5	0.00%
20	Morphine sulfate	21184SI	0.8220	0.3040	0.1360	100.9	0.00%

Help Show as PDF Close

4. Explanation of Terms

Name	Explanation	Valuation
Ranking	Determined degree of consistency of the measurement compared against the reference samples deposited in the database	
Classification	Substance or substance group clearly distinguishable by <i>Apo-Ident</i> ; A substance group represents several substances which are not distinguishable by <i>Apo-Ident</i> but are available for measurement (e.g. "triglycerides"). For a clear identification further tests are generally necessary	Indication green = identified red = not identified
Sample ID	Identification number of reference samples given by <i>HiperScan GmbH</i> to the spectra of substances which define the basis of the <i>Apo-Ident</i> library; Detailed information for all reference samples may be taken from the validation documentation	
Significance	Measure for the distance of the measurement result regarding to the mean value of the reference measurements of a sample or classification	The greater the value (maximum 1), the closer the spectrum of the sample lies to stored reference values.
Confidence	Outlier evaluation	The higher the value (maximum 1) the nearer the measured spectrum of the sample fits to the stored reference spectra.
Correlation	Statistical measure for the similarity between the back-projection of the mean of the stored reference spectra and the back-projection of the measured spectrum of the sample.	The higher the value (maximum 1) the greater the correlation of the back-projection.
Distance	Distance measure between the mean of the stored spectra of a reference sample and the measured spectrum as a function of the principal component space (Mahalanobis distance)	The smaller the value, the closer is the spectrum of the sample to the stored reference values.
Value	Uses the minimum of significance, confidence and correlation. Any rank after rank 1 forces evaluation to zero.	The greater the value (maximum 100 %), the closer the sample is to the stored reference values. The defined minimum value for an identification is 98 %.
Specificity (only for substance class of PhytoComm)	The specificity of a classification is the true negativ rate. Only if all false samples are rejected, specificity is 100 %.	
Recognition rate (only for substance class of PhytoComm)	This is the true positiv rate. It defines the amount of correctly classified spectra in the validation run.	

5. Important note

5.1. Correct filling of sample container

Transflectance reference measurement

Please be careful that the sample container is placed inside **black distance ring**. Place the transflectance insert with the little feet facing the bottom into a clean, empty sample container. Then place the sample container with the transflectance insert onto the measurement window of the *Apo-Ident* instrument.



Important: The initial transflectance reference as well as measuring liquids/semi-solids must be performed with the same transflectance insert and sample container. Otherwise this may result in non-identification.

semi-solids: after the transflectance reference measurement, remove the transflectance insert from sample container and hold it in hands with little feet pointing upwards. Using a narrow spatula, take a pea sized sample of the substance to measured and place it on the top of the transflectance insert (as shown).

Place the sample container over the transflectance insert and rotate to evenly distribute the sample over the surface. Firmly press the insert so that **all three feet** may be seen touching the bottom of the container. Please make sure that there are **no air pockets** under the transflectance insert.

liquids: after the transflectance reference measurement remove the transflectance insert from the sample container. Pour a little liquid in the container so that it's **base is completely covered**. Place the transflectance insert with feet pointing downwards in the sample container. A small amount of the liquid sample should be visible between the transflectance insert and the sample container sides. Inspect the container to make sure there are **no trapped air bubbles** in the measurement area.



5. Important note

5.2. Cleaning/operation of sample container, transfectance insert and sample insert

Sample container

Cleaning:

- After every measurement clean the sample container first with tissue paper. This is especially recommended after the measurement of ointments and emulsion.
- Clean it with dishwashing liquid, warm water and with a soft cloth.
- Wash with mild detergent solution, rinse with warm deionised water and dry it with a lint-free cloth.
- Before using a sample container, rinse with 70 % isopropyl alcohol and dry it with a tissue paper.

Before measurement, please take care that the bottom of the container is clean and free of contamination.

No water marks should be visible.

Transfectance insert

Instructions for use:

Scratches between the transfectance insert feet or strong colour change can influence the identification process. Therefore please handle the transfectance insert carefully.

- Never clean the transfectance insert with a scourer, spatulas or other abrasive materials.
- The transfectance insert is not suitable for cleaning in a dishwasher.

Cleaning:

- Clean the transfectance insert after measurement with a tissue paper.
- Clean it with dishwashing liquid, warm water and with a soft cloth.
- Wash with mild detergent solution, rinse with warm deionised water and dry with a lint-free cloth.
- Before using the transfectance insert, rinse with 70 % isopropyl alcohol and dry it with a tissue paper.

Sample insert for the measurement of small samples

Cleaning:

- After a measurement using the sample insert, gently tap the sample container to release powder residues.
- Clean it with dishwashing liquid, warm water and with a soft cloth.
- Wash with mild detergent solution, rinse with warm deionised water and dry with a lint-free cloth.
- Before using the sample insert rinse with 70 % isopropyl alcohol and let it dry.

Measurement window

Please make sure that the measurement window of the *Apo-Ident* instrument is always clean and free from contamination. We recommend a lint free cloth soaked in 70 % isopropyl alcohol for cleaning purposes.

If you use the sample container to prepare a pharmaceutical product please ensure that all surfaces that come into contact with the substance is free from any microbial contamination.

6. Technical data and disposal

6.1. Technical data

Analytical method	Near-infrared spectroscopy
Measuring time	< 15 seconds
Spectral range	1,000 - 1,900 nm
Spectral resolution	10 nm
Wavelength accuracy	± 1 nm
Wavelength reproducibility	± 0.3 nm
Automatic recalibration/ equipment check	integrated wavelength and white standard
Operating temperature	15 - 35 °C
Dimensions	232 x 210 x 282 mm
Weight	5.2 kg
Interface	USB, Typ B
Operating voltage	100 - 240 V~/50/60 Hz/60 W
Software	<i>QuickStep Apo-Ident</i>
System requirements	<ul style="list-style-type: none">• PC with Windows Vista, Windows 7 (except Starter version), Windows 8, Windows 10, Linux• min. 1 GB RAM• min. 1.6 GHz Pentium• 0.5 GB disk space



The instrument complies with the following EG-Standards:

- EMC Directive 2014/30/EU
- Low voltage directive 2014/35/EU
- RoHS Directive 2011/65/EU

6.2. Disposal



According to European WEEE standards, the electrical and electronics instruments are not allowed to be disposed of in domestic waste. Recycling or disposing would be carried out because incorrect disposal can sustainably damage the health and environment, created by toxic and dangerous components.

Please do not hesitate to contact us if you have any further questions.



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