

# SPECTORD® PLUS Validation



PHARMACY



PETROCHEMISTRY



COSMETICS



CLINICAL CHEMISTRY



MATERIAL ANALYSIS



CHEMISTRY/POLYMER INDUSTRY



ENVIRONMENT/WATER/WASTE



FOOD/AGRICULTURE

Diverse quality standards, such as Ph.Eur., USP, TGA and ASTM and of course the demand of the analysis reliability require a regular validation. This means a regular check of the device parameters to ensure accurate and reproducible results.

The WinASPECT® PLUS validation software offers the user to perform the validation comfortably and easy on his own.

The following parameters can be tested all together or individually:

- Zero transmission
- Baseline stability
- Baseline noise
- Photometric accuracy in UV and Vis range
- Wavelength accuracy
- Wavelength reproducibility
- Stray light
- Resolution
- Long-term stability

The necessary parameters according to the European Pharmacopoe will even be selected automatically with one mouse click in the software.

In addition to the possibility of an electronic record, several documentation masters for the print out of the validation results as a brief protocol or a complete measurement protocol is possible.

The user furthermore is free to decide whether to perform device validation himself or have it done by service specialists.



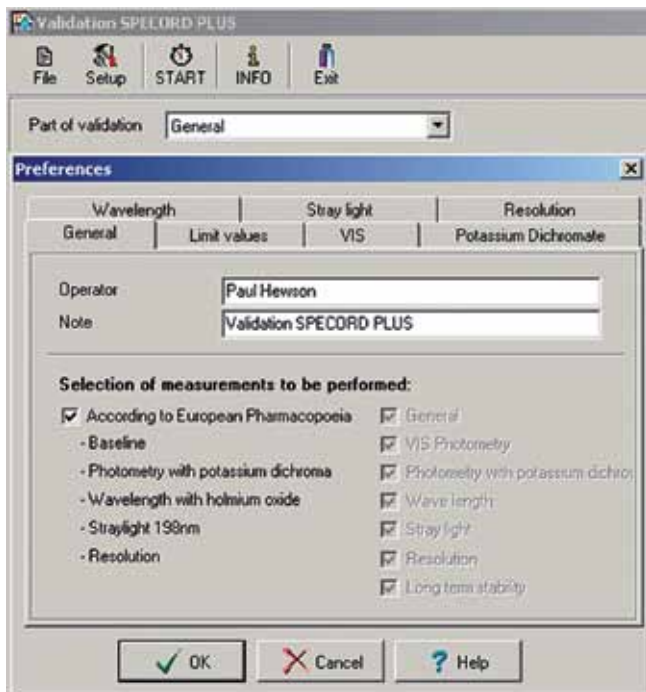
# SPECORD® PLUS – Validation

Independent from the software solution Analytik Jena offers a validation by own qualified experts for all devices. This way the user is free to decide whether to perform device validation himself or have it done by service specialists.

Furthermore Analytik Jena offers a complete IQ/OQ documentation.

The IQ is a regular service of Analytik Jena AG serving for the verification and documentation that the instrument system delivered agrees with the order. The IQ includes all requirements and actions of installation that may be of relevance for the analytical result.

The OQ may be performed as an additional service of Analytik Jena AG serving to furnish proof that the SPECORD® PLUS comes up to the analytical performance data guaranteed by Analytik Jena AG. The Guidelines in hand have both an instructive and documentary character. The qualified personnel of Analytik Jena AG by signing with their initials certify the conditions found at the time of installation. These Guidelines, checked and signed by the responsible head of the laboratory or his/her deputy, shall help to achieve the highest possible degree of reliability in terms of accuracy and reproducibility of measurement results.



|                  |   |             |
|------------------|---|-------------|
| Device option    | SPECORD® 200 PLUS   | 823-0200P-2 |
|                  | SPECORD® 210 PLUS   | 823-0210P-2 |
|                  | SPECORD® 250 PLUS   | 823-0250P-2 |
| Accessory option | Hellma test filter set, certified   | 820-60012-0 |
|                  | UV standard set - Merck, certified for validation   | 820-60129-0 |
| Software option  | WinASPECT® PLUS validation software   | 820-60077-P |
|                  | WinASPECT® FDA 21 part 11   | 820-60205-P |
|                  | Validation set (validation software with Hellma test filter set)  | 820-60073-P |
| Documentation    | IQ/OQ with certificated standards   | 820-60011-2 |
|                  | IQ/OQ with standards provided by customer   | 820-60010-2 |
|                  | Installation, start-up, instructions including software validation compliant to FDA 21 CFR part 11 guide Europe | 820-60207-0 |
|                  | Outside Europe  | 820-60208-0 |

**Analytik Jena AG | Analytical Instrumentation**

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Subject to changes in design  
and scope of delivery as well as  
further technical development!

