

SPECORD® Validation



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® 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 precision 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.



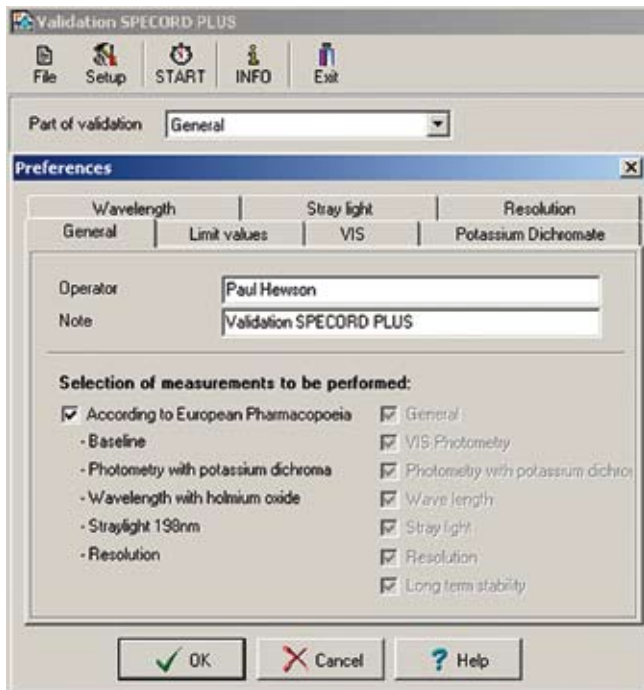
SPECORD® – Validation

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 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® FDA 21 part 11	820-60205-0
	WinASPECT® Validation software	820-60077-0
	Validation set	820-60073-0
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

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

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