USP General Chapter <857> and Ph. Eur. Chapter 2.2.25 10th Edition

Meeting requirements with the Cary 60 and Cary 3500 UV-Vis spectrophotometers

Qualification of instruments

Updates to the United States Pharmacopeia (USP) General Chapter <857> and the European Pharmacopoeia (Ph. Eur.) Chapter 2.2.25 will require some changes to the way users perform analytical instrument qualification for UV-Vis spectrophotometers. The Agilent Cary 60 and Cary 3500 UV-Vis systems are ready to meet these new requirements, which will be implemented from 1 December 2019 and 1 January 2020 respectively.

Both qualification chapters require qualification of UV-Vis systems over the intended operating range with new test limits and in some cases new reference materials. The tests control the UV-Vis spectrophotometer performance for wavelength and absorbance, as well as stray light and resolution. Both the Cary 60 and Cary 3500 UV-Vis systems demonstrate photometric performance to meet the updated requirements. In addition to this, both UV-Vis systems are supported by optional software packages that help meet the requirements of 21 CFR Part 11 and EU Annex 11 and other global regulatory requirements related to electronic records and electronic signatures. Agilent Cary 60 and Cary 3500 UV-Vis spectrophotometers are manufactured according to a quality management system certified to ISO 9001.

Agilent offers a comprehensive set of compliance services including instrument and software qualification. These are continuously updated to meet the latest pharmacopeia requirements (Table 1). In addition, the software used to deliver the qualification services has been developed and tested strictly using the Agilent life cycle quality systems. This approach complies with the industry quality requirements for commercial off-the-shelf software products.

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Table 1. USP and EP test requirements for UV-Vis spectrophotometer qualification.

Pharmacopeia Requirement	Test	Qualification Test Procedures Available for Agilent UV-Vis Spectrophotometers
Control of Wavelengths		
Wavelength Accuracy	Source line	√
Wavelength Accuracy and Reproducibility	Holmium Oxide in Perchloric Acid	√
	Didymium	√
	Cerium Sulfate	√
Control of Absorbance		
Photometric Accuracy and Reproducibility	Potassium Dichromate	√
	NIST Glass Filters	√
	Nicotinic Acid	√
Photometric Linearity	All samples	√
Limit of Stray Light		
Procedure A: Ratio Method	Potassium Chloride	√
	Acetone	√
	Sodium Iodide	√
	Sodium Nitrate	√
Procedure B: Maximum Absorbance/Minimum Transmittance Method	Potassium Chloride	√
	Acetone	√
	Sodium Iodide	√
	Sodium Nitrate	√
Control of Resolution		
	Toluene/Hexane Resolution	√

Both Cary 60 and Cary 3500 UV-Vis spectrophotometers are built with the unique Agilent Xenon flash lamp that lasts more than 10 years, thus minimizing lamp replacement and revalidation costs. It also offers efficiency savings such as no warm up time, and performance benefits for greater photometric range and fast scanning for improved productivity.

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