

Evolution UV-Visible Spectrophotometers

Pharmaceutical standards guide for UV-Vis spectrophotometers

Solutions for pharmacopeia compliance support



Testing parameters for pharmaceutical compliance

Thermo Scientific™ Evolution™ UV-Visible Spectrophotometers with Thermo Scientific™ Insight™ Pro Software offer an easy-to-use, reliable solution for pharmacopeia compliance support.

Both the USP and the EP call out the following for parameters for performance verification (PV) testing:

- Wavelength accuracy (USP and EP) and repeatability (USP only)
- Absorbance accuracy (USP and EP), repeatability (USP only), and linearity (EP only)
- Stray light (USP and EP)
- Resolution (USP and EP)

As the selection of standards can be somewhat challenging, we have prepared an overview of options that are available for use in PV testing. To help simplify the selection process, there are two kits available that include the essential standards for PV testing. Standards may also be purchased individually. In the following sections of this guide, we will describe the individual needs for each test and offer guidance on the selection of standards to complete the PV testing.



Part number	Standards kit	Performance verification test	Reference materials
222-327200	USP and EP UV Standards Set	Wavelength accuracy	Calibrated holmium oxide solution for wavelength accuracy from 241 nm to 641 nm
		Photometric accuracy and linearity	Calibrated 60 mg/L, 80 mg/L and 140 mg/L potassium dichromate with blank: UV absorbance accuracy to 2A
		Stray light	Certified potassium chloride, sodium iodide, and sodium nitrate for stray light measurements
		Resolution	Certified toluene in hexane solution with hexane blank for resolution (spectral bandwidth) testing
222-327300	USP and EP Vis Standards Set	Wavelength accuracy	Didymium glass filter
		Photometric accuracy and linearity	4 neutral density filters calibrated for absorbance at 440, 465, 546.1, 590 and 635 nm. Absorbance values approximately 0.5, 1.0, 1.5 and 2.0

Wavelength accuracy and repeatability

Wavelength accuracy and repeatability are to be determined over the operational range.

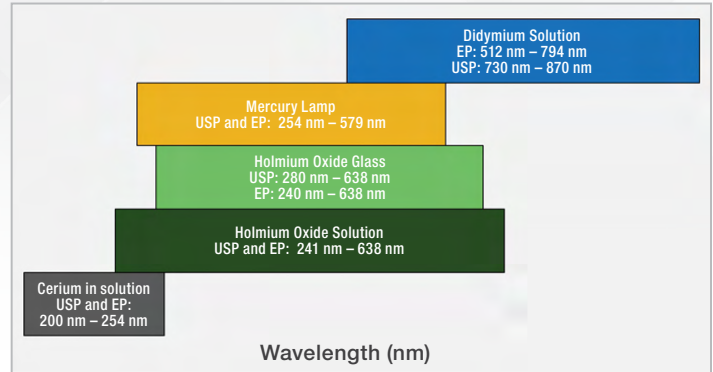
Operation range = *the wavelengths where samples are measured in your lab.*

What you will need:

- Either holmium oxide or a mercury lamp
- If you measure at >650 nm you also need didymium
- Cerium in solution is recommended if measuring in the far UV

Mercury lamp options for wavelength accuracy

Mercury vapor lamps present a number of advantages over other “standards” used in PV testing. These lamps produce atomic emission lines that do not change, and they are very well characterized. Every low pressure mercury lamp produces emission lines at exactly the same wavelengths. Mercury lamps never need to be re-calibrated and mercury vapor emission spectra are what other standards, such as holmium oxide solutions, are calibrated against as a standard. The USP lists atomic line spectra as its first choice for wavelength accuracy testing, stating: “This procedure is described as the primary application because the emission lines produced from a



discharge lamp are characteristic of the source element and, as a fundamental physical standard; these wavelengths have been measured with an uncertainty of not more than ± 0.01 nm.”

The EP also calls out atomic line spectra for this purpose: “Control the wavelength accuracy of an appropriate number of peaks in the intended spectral range...by measuring the emission from a light source for the verification of emission-line position.”

The Thermo Scientific™ Evolution™ Pro UV-Vis Spectrophotometer is available with an optional factory installed mercury lamp. A mercury lamp accessory is also available for the Evolution One series instruments.

Products containing wavelength standards	Part number
USP and EP UV Standards Set* (Holmium oxide solution)	222-327200
USP and EP Vis Standards Set* (Didymium glass filter)	222-327300
Qualification Filter Kit for UV-Vis (Holmium glass and didymium glass filters)	840-326000
Wavelength standard – didymium glass	840-325800
Wavelength standards, holmium and didymium	840-325700
Cerium oxide standard	222-327400

*Recommended

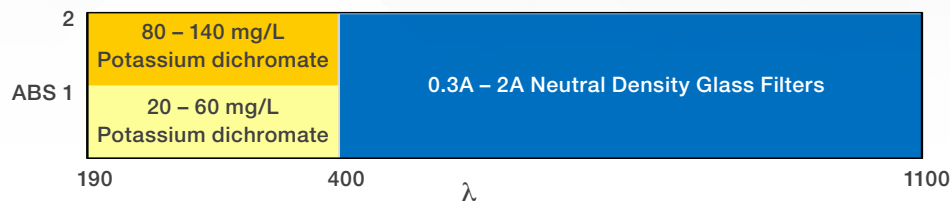
Instrument	Mercury lamp accessory part number
Evolution One, One Plus	840-211300
Evolution Pro	840-310900

Absorbance (photometric) accuracy, repeatability, and linearity

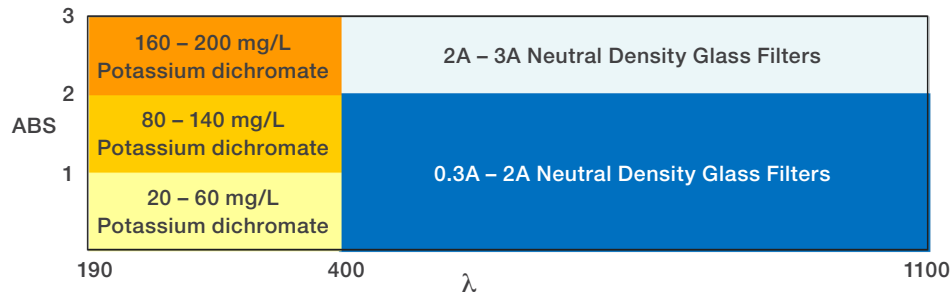
It is necessary to verify the absorbance accuracy of a system over its intended operational range for the wavelength and absorbance ranges required.

Operational Range = *the absorbance range where you measure samples in your lab, measured near the wavelength where you measure the samples.*

USP Absorbance accuracy and repeatability



EP Absorbance accuracy and linearity



What you will need for absorbance accuracy and precision:

For USP, select at least three standards at different absorbance levels that span the operational range measured.

- One standard must be in the 0 – 2.00A region
- If measuring >2.00A, standards evaluating this region must be selected

For EP, absorbance repeatability is not required.

- At a minimum the two limits of the absorbance range should be verified
- It is recommended not to test >2.00 A
- Tolerances at higher absorbance values (> 2A) should be defined on the basis of a risk assessment

For UV wavelength absorbance (<400 nm)

- Select at least three potassium dichromate standards
 - <1A 20-60 mg/L $K_2Cr_2O_7$
 - 1A – 2A samples: add a 80 – 140 mg/L $K_2Cr_2O_7$
 - 2A – 3A samples: add a 160 – 200 mg/L $K_2Cr_2O_7$

For visible wavelength absorbance (>400 nm)

- Select at least three neutral density glass filters
 - One between 0-2.00A
 - At least two more additional filters depending on the operational range

What you will need for absorbance linearity:

For USP, at least three standards must be measured over each wavelength range spanning operational range.

- At least one of the three standards must be within 0 – 2A region
- If absorbance for quantitation is measured at > 2 A, absorbance must be evaluated >2A also
 - Individual absorbance values need to be within correct limits

For EP, linearity must be measured over intended spectral range.

- At least three standards in each wavelength range must be used
- The coefficient of determination must not be less than 0.999

Potassium dichromate solutions (K ₂ Cr ₂ O ₇)	Concentration (mg/L)	Part number
USP and EP UV Standards Set*	60 mg/L, 80 mg/L and 140 mg/L	222-327200
UV Photometric Accuracy Stds Kit for USP-2015 to 2A*	60 mg/L and 140 mg/L	840-288900
Potassium dichromate	100 mg/L	840-288300
Potassium dichromate	120 mg/L	840-288400
Potassium dichromate	160 mg/L	840-288600
Potassium dichromate	180 mg/L	840-288700
Potassium dichromate	200 mg/L	840-288800
Potassium Dichromate 5 Stds Kit (from 0.1A to 1.5A)	20 mg/L – 100 mg/L	9423UV95200E

*Recommended

Neutral density filters	Part number
USP and EP Vis Standards Set*	222-327300
Qualification Filter Kit for UV-Vis	840-326000
Photometric (Absorbance) accuracy and Linearity Test Kit calibrated ND filters (6 filters from 0.3 A to 2 A)	840-253000

*Recommended

Resolution

What you will need:

Determine the resolution of the spectrometer in the UV region using a 0.020% (v/v) solution of toluene in n-hexane with n-hexane as the reference. The spectrum of this solution

has an absorbance maximum at 269 nm and a minimum at approximately 266 nm. Resolution is reported as a ratio of these absorbance values. For USP, this test is required for PV. For EP, this test is only required where minimum ratio will be stated.

Reference materials	Standard	Part number
Certified toluene in hexane solution with hexane blank	USP and EP UV Standards Set	222-327200
Certified toluene in hexane solution with hexane blank	Resolution standard – toluene in hexane	222-226600

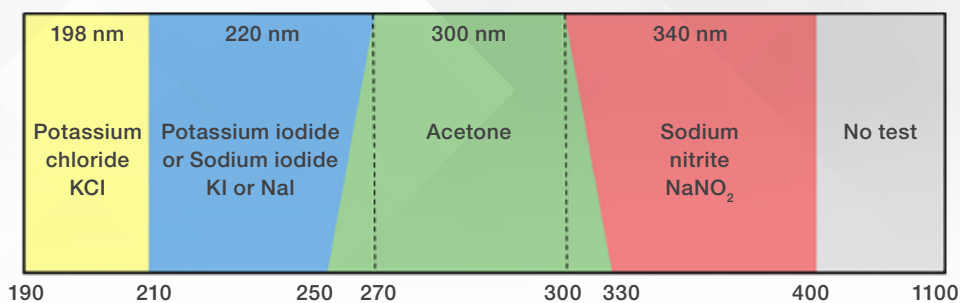
Stray light

The level of stray light must be monitored at appropriate wavelength(s) as part of performance qualification (PQ). Analysts

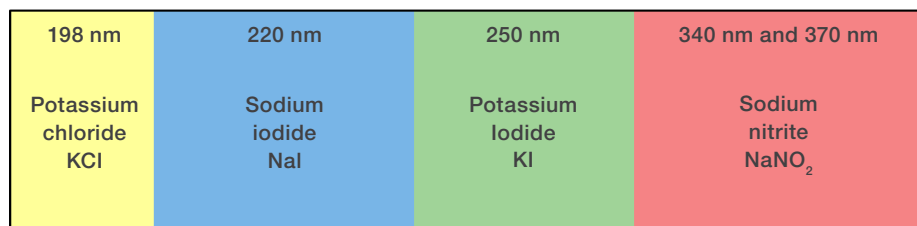
can measure the absorbance of the filters specified against the appropriate reference and record the maximum absorbance value.

What you will need based on your operational wavelength:

USP Stray light standards depending on operational range



EP Stray light standards depending on operational range



Reference materials	Standard	Part number
KCl, NaI, and NaNO ₂	USP and EP UV Standards Set	222-327200
KCl • 190 – 210 nm Measure at 198 nm	Stray light filter, potassium chloride, KCl	9423UV95520E
NaI • 210 – 270 nm Measure at 220 nm	Stray light filter, sodium iodine, NaI	9423UV95500E
Acetone (USP only) • 250 – 330 nm Measure at 300 nm	Acetone stray light standard and blank	840-284400
NaNO ₂ • 300 – 400 nm Measure at 340 nm (USP and EP only) and 370 nm (EP only)	Stray light standard, sodium nitrate	222-226500

Thermo Scientific Evolution UV-Vis Spectrophotometers

Meeting today's pharmacopeia standards is a top priority, and choosing a UV-Visible spectrophotometer should be easy.

Each Evolution UV-Vis Spectrophotometer is available in both Security and Validator bundles and USP/EP Standards Pharma bundles. All bundles include:

- Your choice of an Evolution UV-Vis spectrophotometer
 - Thermo Scientific™ Insight™ Pro Security Software for support of 21 CFR Part 11 Compliance
 - Thermo Scientific™ Validator™ for Insight Pro documents for initial and re-qualification throughout the lifetime of your instrument
- The choice of performance verification standards kit:
 - USP and EP UV + Vis Standards Sets – Contains all the standards needed to meet the general USP and EP testing requirements
 - Qualification Filter Kit for UV-Vis – Contains the standards needed for general instrument qualification. Includes some standards utilized for pharma PV testing, but additional standards will be necessary for full compliance

Description	Part number
Evolution One UV-Vis Spectrophotometer	840-341400
Evolution One Plus UV-Vis Spectrophotometer	840-341500
Evolution Pro UV-Vis Spectrophotometer	840-340200
Evolution Pro UV-Vis Spectrophotometer w/ Mercury Lamp	840-340100

Choose the Evolution UV-Vis model that meets your requirements:



Evolution One Spectrophotometer features a 1.0 nm spectral bandwidth for high-resolution data in routine quality control and basic research applications.

Evolution One Plus Spectrophotometer increases the versatility of your system with a selectable bandwidth option for a wider variety of applications. Features Applications Focused Beam Geometry optimized for use with integrating sphere accessory (diffuse transmittance/reflectance), fiber optic probe, and microcells.



Evolution Pro Spectrophotometer is a high performance solution featuring a parallel beam design and an extra-large sample compartment for expanded accessory options. Includes a mercury lamp option for supporting pharmacopoeia wavelength and bandwidth accuracy testing.

Installation and support*

Validated installation

Our Unity Lab Services professionals can handle your installation offering:

Improved Productivity – Accurate installation scheduled at your convenience, optimizing both equipment and user performance.

Peace of Mind – Your equipment will be installed and configured to our manufacturing specifications ensuring optimal performance while users are trained on equipment operation and routine care.

Validated Installation includes:

- On-site installation of instrument
- Installation Qualification and Operational Qualification
- User orientation and instrument familiarization
- All engineer labor and travel charges for installation

Does not include instrument Performance Qualification (PQ)

Description	Part number
Evolution One/One Plus Validation Installation	701-059093
Evolution Pro Validation Installation	701-059157

Standards rental options

Thermo Fisher Scientific also offers the option to include the rental of standards for performance verification with service. Standards rental can be added to the following service options:

Description	Part number
USP Standards Rental with Validated Installation	701-055587
USP Standards Rental with Recertification Contract	701-055588
USP Standards Rental with Performance Verification	701-173000

Performance verification

Description	Part number
Performance verification for Evolution Spectrophotometers includes Validator qualification materials	701-023300

Annual recertification

Description	Part number
Optional annual recertification with contract for Evolution Spectrophotometers**	701-509300

** Models include Evolution One/One Plus, Evolution Pro, Evolution Array, Evolution 60S, Evolution 200 series, Evolution 300, Evolution 350 or Evolution 600 Spectrophotometers

* Unity Lab Services are not available in all countries. Please consult with your Thermo Fisher Scientific Sales Representative or authorized dealer from more information.

 Learn more at thermofisher.com/evolution

thermo scientific

For research use only. Not for use in diagnostic procedures. For current certifications, visit thermofisher.com/certifications.

© 2021 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **BR53063_E 1221 M**