thermo scientific

Guide to pharmaceutical standards for Thermo Scientific UV-Vis Spectrophotometers

Solutions for pharmacopeia compliance support

ThermoFisher SCIENTIFIC

Testing parameters for pharmaceutical compliance

Thermo Scientific™ Evolution™ UV-Visible Spectrophotometers with Thermo Scientific™ INSIGHT™ Software offer an easy-to-use, reliable solution for pharmacopeia compliance support. INSIGHT software performs all the tests according to USP <857> 2015.

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

- Wavelength accuracy
- Absorbance accuracy
- Stray light
- Resolution

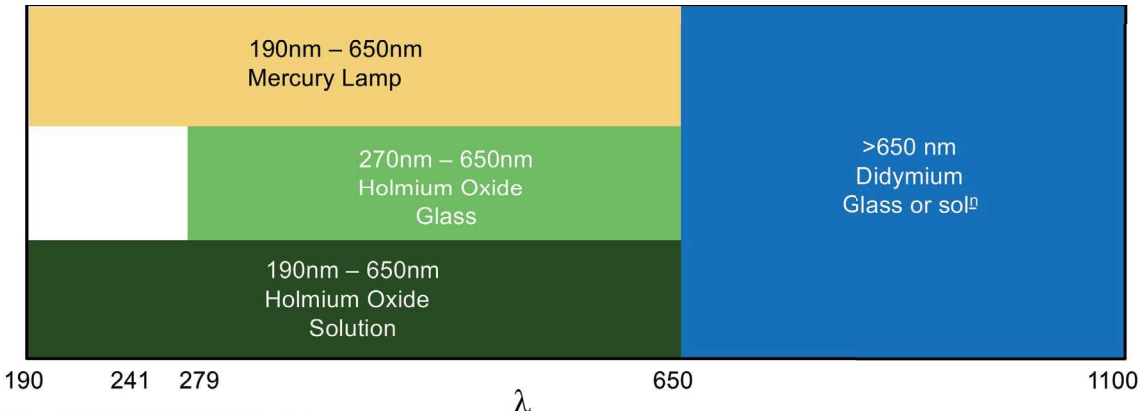
As the selection of standards can be somewhat challenging, we have prepared an overview of options that are available for use in PV testing. To help simplify the selection process, there are two kits available that include some or all of the standards needed to complete PV tests. Standards may also be purchased individually. In the following sections of this guide, we will also 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
840-289000	Liquid Standard Set for EP and USP-2015	Wavelength Accuracy	Calibrated holmium oxide solution for wavelength accuracy from 241 nm to 641 nm
		Photometric Accuracy	Calibrated 60 mg/L and 140mg/L potassium dichromate with blank: UV absorbance accuracy to 2A
		Stray Light	Certified potassium chloride solution for stray light measurement at 198 nm
		Resolution	Certified toluene in hexane solution with hexane blank for resolution (spectral bandwidth) testing
840-285200	UV-Vis Qualification Filter Kit, Calibrated	Wavelength Accuracy	Holmium glass and didymium glass filters
		Photometric Accuracy	4 neutral density filter 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

Wavelength accuracy and precision 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 (Ho) or a mercury lamp
- If you measure at >650 nm you also need didymium oxide (Dy)

Products containing Ho and Dy	Part Number
Qualification Filter Kit for UV-Vis* (Holmium glass and didymium glass filters)	840-285200
Liquid Standard Set for EP and USP-2015* (includes calibrated holmium oxide solution for wavelength accuracy from 241 nm to 641 nm)	840-289000
Wavelength Standard – Didymium Glass	840-266800
Wavelength Standards, Holmium and Didymium	840-253200

*Recommended

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."

A mercury lamp can also be used to measure spectral bandwidth, which is the primary scale used to quantify the resolution capability of the instrument.

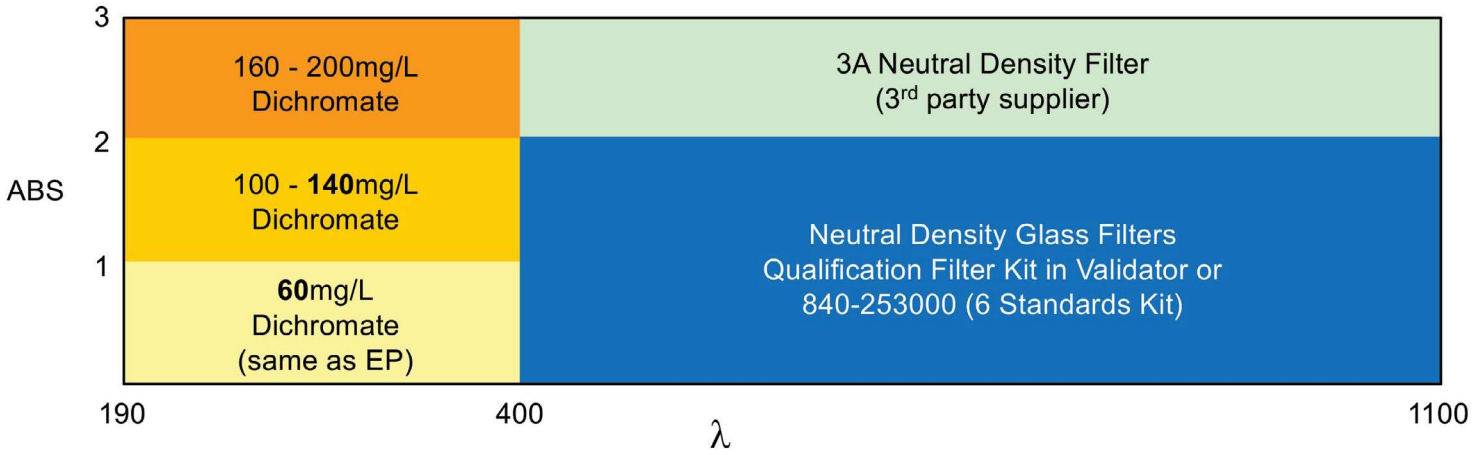
The Thermo Scientific™ Evolution™ 350 UV-Vis Spectrophotometer is available with an optional factory installed mercury lamp. If you already own an Evolution UV-Vis spectrophotometer, mercury lamp accessories are available for the Evolution 200 series instruments and the Evolution 300 instrument (recently discontinued).

Instrument	Mercury Lamp Accessory Part Number
Evolution 201, 220, 260	840-211300
Evolution 300	10020201
Evolution 350	840-310900

Photometric (absorbance) accuracy

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.*



What you will need:

For UV Wavelength Absorbance (<400 nm)

- <1A 60 mg/L $K_2Cr_2O_7$ only
- 1A – 2A samples: add a 140 mg/L $K_2Cr_2O_7$ solution
- 2A – 3A samples: add a 160 - 200 mg/L $K_2Cr_2O_7$ solution

For Visible Wavelength Absorbance (>400 nm)

- At least two neutral density glass filters
  - One slightly higher than the operational maximum
  - One or more across the operational range

Potassium Dichromate solutions ($K_2Cr_2O_7$)	Concentration (mg/L)	Part Number
Liquid Standard Set for EP and USP-2015*	60 mg/L and 140 mg/L or	840-289000
UV Photometric Accuracy Stds for USP-2015 to 2A*	60 mg/L and 140 mg/L	840-288900
Potassium Dichromate	160 mg/L	840-288600
Potassium Dichromate	180 mg/L	840-288700
Potassium Dichromate	200 mg/L	840-288800

*Recommended

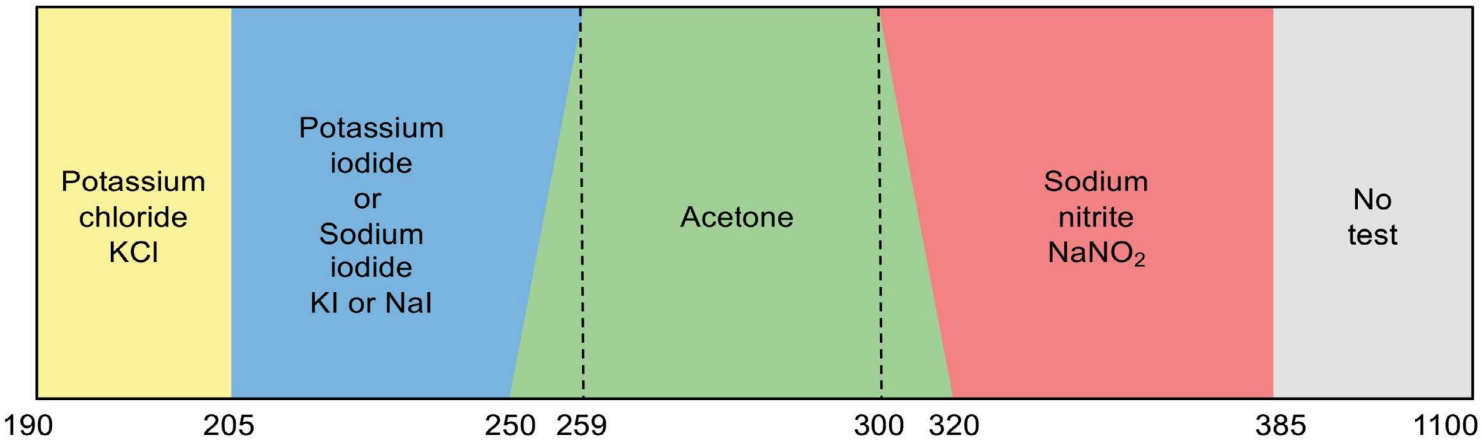
Neutral Density Filters	Mercury Lamp Accessory Part Number
Qualification Filter Kit for UV-Vis*	840-285200
Photometric accuracy and linearity test kit Calibrated ND filters (6 filters from 0.3 A to 2 A)	840-253000

*Recommended

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:



Reference Materials	Standard	Part Number
KCl 190-205 nm Measure at 198 nm	Liquid Standard Set for EP and USP-2015	840-289000
KCl 190-205 nm Measure at 198 nm	Stray light filter, potassium chloride, KCl	9423UV95520E
NaI 210-259 nm Measure at 220 nm	Stray light filter, sodium iodine, NaI	9423UV95500E
Acetone 250-320 nm Measure at 300 nm	Acetone stray light standard and blank	840-284400
NaNO2 300-385 nm Measure at 340 nm	Stray light standard, sodium nitrate	222-226500

Resolution

What you will need:

- Either a traditional standard or a mercury lamp

Please refer to the wavelength accuracy section for mercury lamp information.

Reference Materials	Standard	Part Number
Certified toluene in hexane solution with hexane blank	Liquid Standard Set for EP and USP-2015*	840-289000
Certified toluene in hexane solution with hexane blank	Resolution Standard – Toluene in Hexane	222-226600

Thermo Scientific Evolution UV-Vis Spectrophotometers

When meeting today's pharmacopeia standards is a top priority, choosing an UV-Visible spectrophotometer should be easy.

The versatile Evolution 200 series and Evolution 350 UV-Vis Spectrophotometers feature:

- 1 nm fixed or selectable bandwidths with double-beam optics
- Precision monochromator drive that delivers fast scanning and high accuracy
- INSIGHT 2 version 2.4 software with enhanced compliance features

Each Evolution UV-Vis Spectrophotometer is available in a Pharma Value package which includes:

- Your choice of an Evolution UV-Vis spectrophotometer with INSIGHT software including easy-to-use USP performance testing methods
- Thermo Scientific™ INSIGHT™ Security software for support of 21 CFR Part 11 Compliance
- Thermo Scientific™ Validator™ package featuring all of the documents for initial and re-qualification throughout the lifetime of your instrument

Description	Part Number
Evolution 201 Computer Control UV-Vis	840-210800
Evolution 220 Computer Control UV-Vis	840-210600
Evolution 260 Bio Computer Control UV-Vis	840-211000
Evolution 350 Computer Control UV-Vis	840-310800
Evolution 350 with Mercury Lamp	912A0959
Evolution 201 Pharmaceutical Value Bundle	840-260400
Evolution 220 Pharmaceutical Value Bundle	840-260600
Evolution 260 Bio Pharmaceutical Value Bundle	840-260800
Evolution 350 Pharma Value Bundle with Mercury Lamp	912A0973

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

Evolution 201 spectrophotometer features a 1.0 nm spectral bandwidth for high-resolution data in routine quality control and basic research applications.

Evolution 220 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.

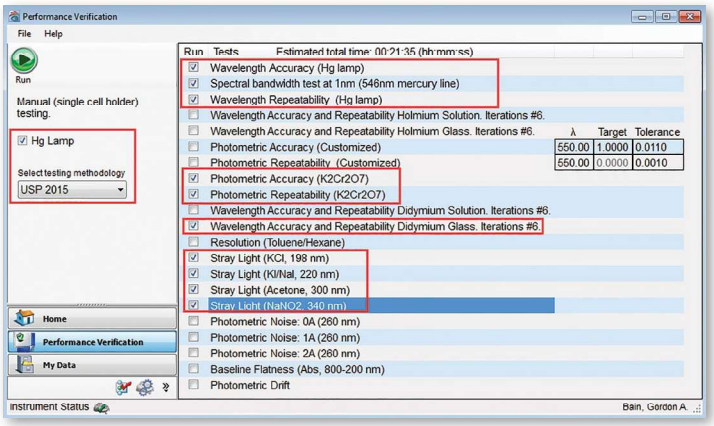
Evolution 260 Bio spectrophotometer adds the convenience of pre-programmed Bio Applications for increased productivity in your life science laboratory to the Evolution 220 platform.

Evolution 350 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.

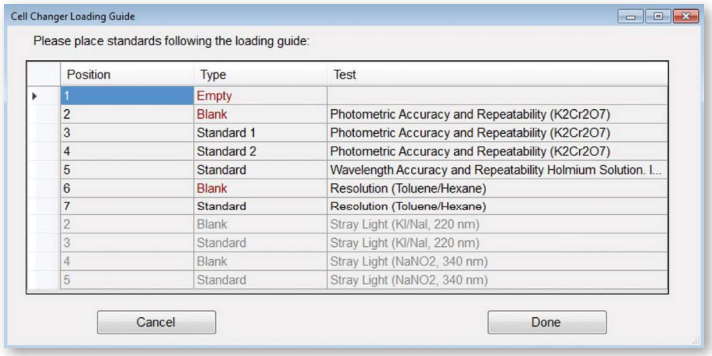
INSIGHT Software

INSIGHT software provides correct test methodologies for measuring standards one at a time and provides semi-automated testing of multiple samples using a cell changer accessory.

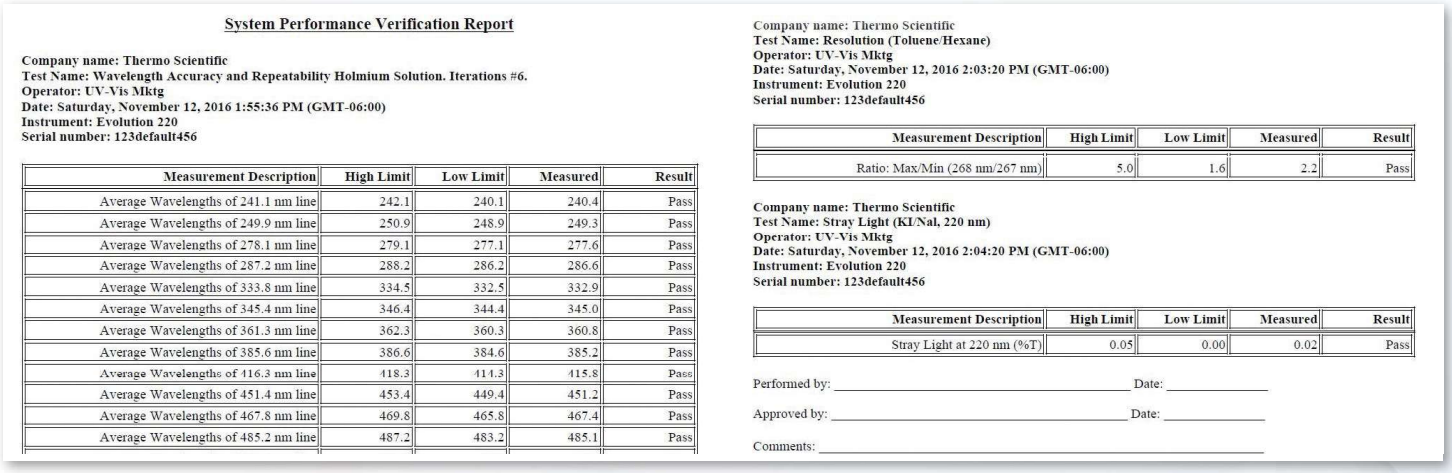
All data is retained in the PV application as it is running. Complete test results are arranged in a single report.



Verification tests specific to USP 2015 can be automatically selected to be used with or without a mercury lamp



A cell changer can be used to simplify and speed up tests



System Performance Verification Report

Company name: Thermo Scientific
Test Name: Wavelength Accuracy and Repeatability Holmium Solution. Iterations #6.
Operator: UV-Vis Mktg
Date: Saturday, November 12, 2016 1:55:36 PM (GMT-06:00)
Instrument: Evolution 220
Serial number: 123default456

Measurement Description	High Limit	Low Limit	Measured	Result
Average Wavelengths of 241.1 nm line	242.1	240.1	240.4	Pass
Average Wavelengths of 249.9 nm line	250.9	248.9	249.3	Pass
Average Wavelengths of 278.1 nm line	279.1	277.1	277.6	Pass
Average Wavelengths of 287.2 nm line	288.2	286.2	286.6	Pass
Average Wavelengths of 333.8 nm line	334.5	332.5	332.9	Pass
Average Wavelengths of 345.4 nm line	346.4	344.4	345.0	Pass
Average Wavelengths of 361.3 nm line	362.3	360.3	360.8	Pass
Average Wavelengths of 385.6 nm line	386.6	384.6	385.2	Pass
Average Wavelengths of 416.3 nm line	418.3	414.3	415.8	Pass
Average Wavelengths of 451.4 nm line	453.4	449.4	451.2	Pass
Average Wavelengths of 467.8 nm line	469.8	465.8	467.4	Pass
Average Wavelengths of 485.2 nm line	487.2	483.2	485.1	Pass

Company name: Thermo Scientific
Test Name: Resolution (Toluene/Hexane)
Operator: UV-Vis Mktg
Date: Saturday, November 12, 2016 2:03:20 PM (GMT-06:00)
Instrument: Evolution 220
Serial number: 123default456

Measurement Description	High Limit	Low Limit	Measured	Result
Ratio: Max/Min (268 nm/267 nm)	5.0	1.6	2.2	Pass

Company name: Thermo Scientific
Test Name: Stray Light (KI/NaI, 220 nm)
Operator: UV-Vis Mktg
Date: Saturday, November 12, 2016 2:04:20 PM (GMT-06:00)
Instrument: Evolution 220
Serial number: 123default456

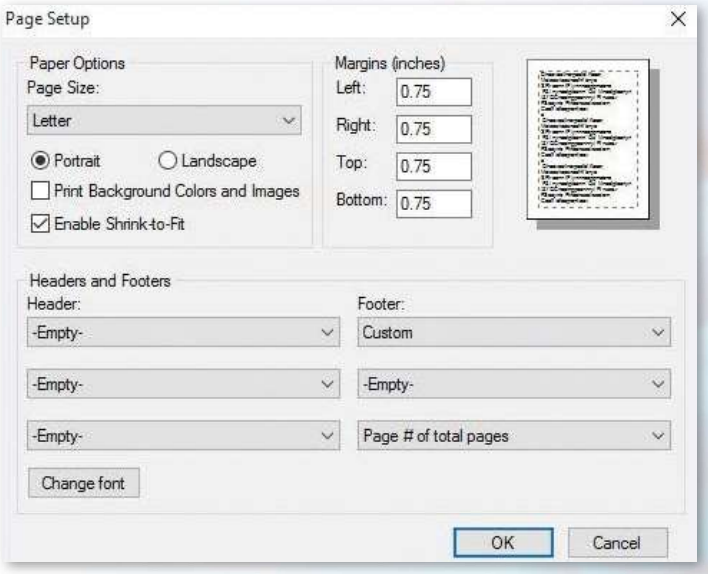
Measurement Description	High Limit	Low Limit	Measured	Result
Stray Light at 220 nm (%T)	0.05	0.00	0.02	Pass

Performed by: _____ Date: _____

Approved by: _____ Date: _____

Comments: _____

The results of each test will be displayed in a System Verification Report



Reports can be customized to add headers, footers, and watermarks

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.

Description	Part Number
Evolution 200 Validated Installation	701-674400
Evolution 350 Validated Installation	701-680300

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)

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 Array, Evolution 60S, Evolution 200, Evolution 300 or Evolution 600 Spectrophotometers

Find out more at **thermofisher.com/uv-vis**

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