APPLICATION NOTE

UV/Vis Spectroscopy


**AUTHOR**

**Valentina Paolucci**
*Application Scientist*
*PerkinElmer, Milan, Italy*


# Pharmacopoeia Compliance – Operational Qualification of the LAMBDA 365+ UV/Vis Spectrophotometer

## Introduction

In Pharmaceutical Industries, analytical instruments are routinely used to assess that a certain product meets the required specification to guarantee quality and safety. In the US Pharmacopoeia, the general chapter USP <1058> describes the guidelines for the analytical instruments qualification (AIQ) to ensure that all the instruments are able to generate reliable and consistent data. The AIQ process involves interconnected activities over the lifetime of the instrument to establish fitness of purpose. These activities can be grouped into the following four categories (see Figure 1):

- **DQ:** Design Qualification contains the functional and operational specifications required for the instrument and the suitability for its intended purpose.
- **IQ:** Installation Qualification ensures that the instrument and the software are installed and configured as designed and specified. All the activities are documented.
- **OQ:** Operational Qualification verifies that the instrument operates as expected. The software functions including secure data storage, backup and archiving are also tested. All the activities are documented.
- **PQ:** Performance Qualification controls that the instrument performs as specified under real-world conditions of use.

In this work, the Operational Qualification of the PerkinElmer Lambda 365+ UV/Vis Spectrophotometer is carried out.

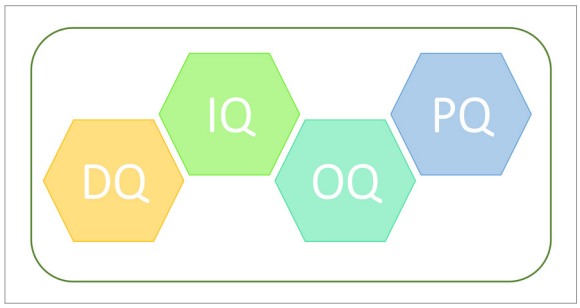


*Figure 1. Analytical Instrument Qualification Process.*

PerkinElmer®
*For the Better*

## Operational Qualification

UV/Vis spectrophotometers are highly versatile instruments that find a wide range of applications in the pharma space. When operated in regulated environment, UV/Vis spectrophotometers, such as any other instrumentations applied, need to be qualified and guarantee that the analytical results are reliable and consistent to meet the quality requirements. Guidelines have been set out in specific chapters of international pharmacopoeias including the United States Pharmacopoeia (USP <857>) and the European Pharmacopoeia (EP 2.2.25) where procedures are detailed to validate the performance of the UV/Vis spectrophotometer. While the EP 2.2.25 was revised in 2019, the latest version of the USP <857> is from December 2022. In these guidelines, the performance of the UV/Vis spectrophotometer is validated to confirm that the following parameters meet the specified requirements:

- Control of Wavelength
- Control of Absorbance
- Photometric linearity (no longer required in the USP <857>)
- Limit of stray light
- Spectral resolution

It is highly recommended that the tests are run using Certified Reference Materials (CRMs) recognized by national and international regulators or accreditation bodies, rather than homemade standards which are more prone to errors.

In this work, the tests were performed on the LAMBDA 365+ UV/Vis Spectrophotometer according to the USP<857> and EP 2.2.5 (similar results can be obtained for the LAMBDA 365+ Touch). The results of each test are shown using the secure, encrypted reporting system provided by the PerkinElmer One Source service as part of the Universal Operational Qualification (UOQ) Program. The UOQ program also includes the Japanese Pharmacopoeia Compliance as the LAMBDA 365+ can fully comply with the Japanese Pharmacopoeia standards too. The report includes pass/fail results and built-in calculations

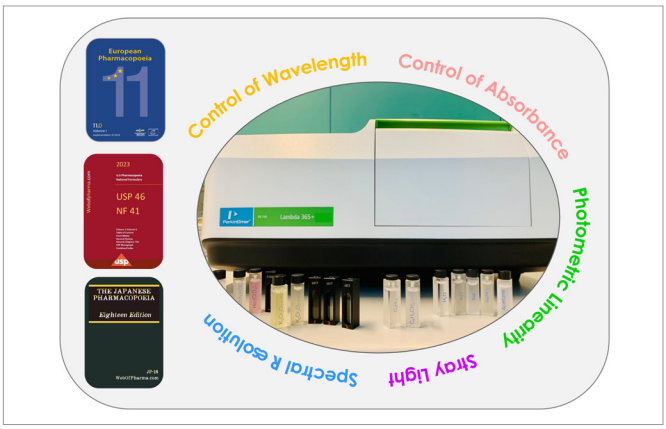


*Figure 2. Lambda 365+ UV/Vis Spectrophotometer with the CRM standards used for the Operational Qualification. Image source: www.pharmasopworld.com/.*

compliant with ASTM-E-29[1] and FDA MAN-000048[2] using the digital certificate technology to prevent duplication and tampering, while meeting 21 CFR Part 11 standards.

## Control of Wavelength

The LAMBDA 365+ UV/Vis spectrophotometer is a monochromator-based spectrophotomer where the wavelength is selected through electro-mechanical drives that move mirrors and gratings. The accuracy of this selection is highly important and becomes even more critical when samples exhibiting narrow absorption peaks are measured. Wavelength accuracy for both UV and Visible regions of the wavelength spectrum can be controlled using one or more of the followings standards:

- **Discharge Lamps** (mercury, deuterium, neon, and xenon) that produce atomic line spectra based on characteristic emission peaks of the source element as physical standard.
- **Rare Earth Oxide Solutions** (Cerium Oxide, Holmium Oxide, Didymium dissolved in acid media)
- **Rare Earth Glasses** (Holmium Glass, Didymium glass)

In this work, cerium oxide in perchloric acid solution, holmium oxide in perchloric acid solution and didymium glass filter were used to cover the UV and Visible regions. For each standard, six absorption spectra were collected to evaluate the precision of the peaks observed. The peak wavelengths are extracted using a simple processing equation created directly in the UV WinLab Software. In Figures 3, 4 and 5, one of the six absorption spectra collected for each CRM are reported. The wavelength obtained for the different peaks are reported in the report in figure 6 with corresponding difference between the mean obtained from the six spectra and the certificate wavelength value ("Diff Mean vs Cert") to evaluate the accuracy. As required, in the case of USP <857> (left section of the report), precision of the measurement is also specified as standard deviation ("SD") and its rounded value. All the results were abundantly better than the limits sets by both pharmacopoeias and the tests confirmed the wavelength accuracy of the Lambda 365+ UV/Vis Spectrophotometer.

*Table 1. Instrument parameters used for the control of wavelength – Cerium Oxide Solution, Holmium Oxide Solution, Didymium Glass*

| Internal Standards Obtained from LGC | |
|---|---|
| Method | Scan |
| Ordinate Mode | A |
| Wavelength Range (nm) | Cerium Oxide<br>190 – 280<br>Holmium Oxide<br>200 – 700<br>Didymium Glass<br>650 – 900 |
| Slit width (nm) | 1 |
| Scan Speed (nm/min) | 480 |
| Number of Cycles | 6 |
| Data Interval (nm) | 0.5 |

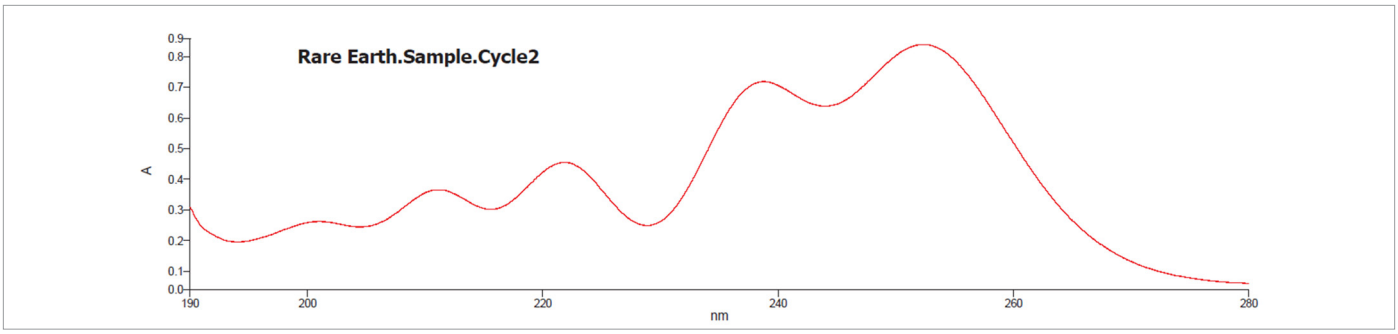


*Figure 3. Absorption spectra of cerium oxide in perchloric acid for wavelength accuracy control (one of the six spectra collected for this standard).*

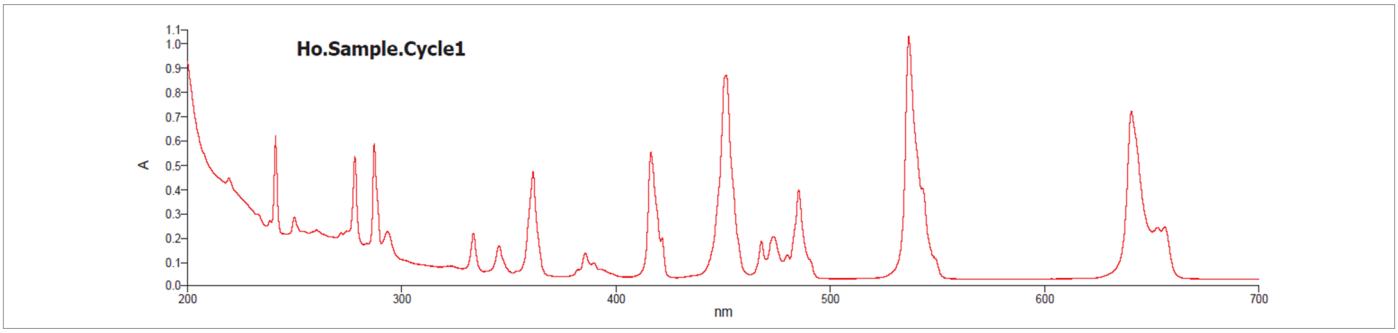


*Figure 4. Absorption spectra of a 4% solution of holmium oxide in perchloric acid for wavelength accuracy control (one of the six spectra collected for this standard).*

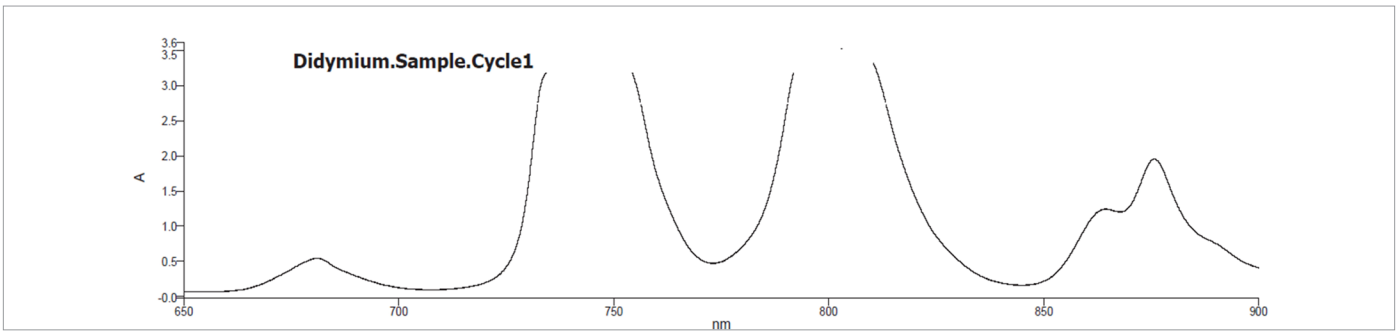


*Figure 5. Absorption spectra of didymium glass for wavelength accuracy control (one of the six spectra collected for this standard). The absorption peaks used for the wavelength control are positioned at 681.02 nm and 875.74 nm.*

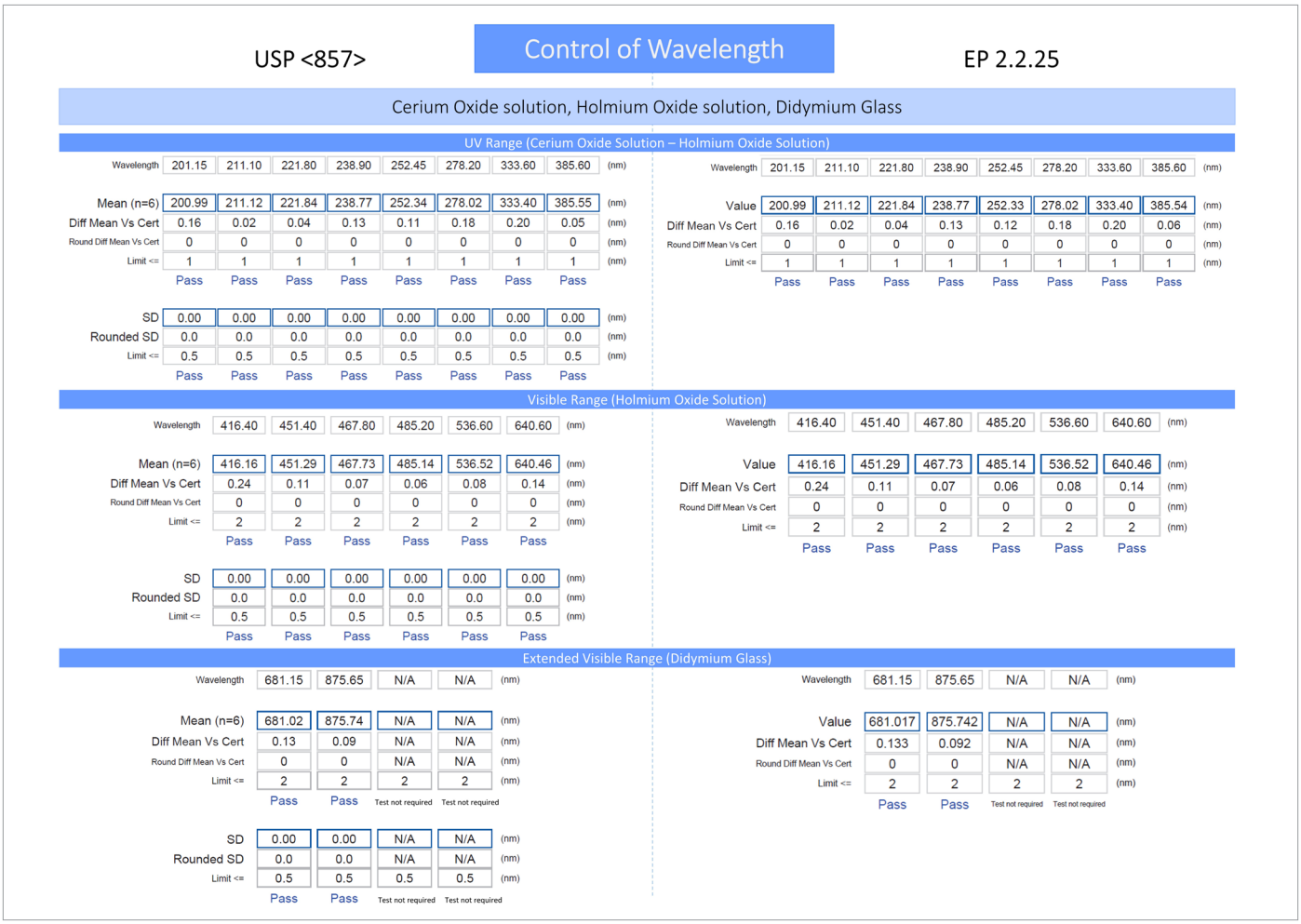


*Figure 6. Results obtained for the control of wavelength for UV, visible and extended visible region (USP<857> on the left and EP 2.2.25 on the right) using cerium oxide solution, holmium oxide solution and didymium glass.*

## Control of Absorbance

Assessment of the photometric response of a UV-Vis spectrophotometer is fundamental to ensure that the reading is accurate and precise. This becomes even more critical when quantification assays are carried out to determine analyte concentration following the Lambert-Beer's Law. The procedures for the control of absorbance require to measure the absorption values of standard materials at specific wavelengths to cover the intended spectral range of application, and at least two range of absorbance levels. The values obtained are compared with the values reported for the CRMs used and accuracy and precision are checked to be below the specified limits (see Figure 7).

The standards that can be used are the following:

- **Nicotinic Acid Solutions** (213 and 261 nm)
- **Potassium Dichromate Solutions** (235, 257, 313 and 350 nm)
- **Metal-on-Fused Silica Filters** (250, 280, 340, 360 and 400 nm for the UV region and 465, 500, 546.1, 590 and 635 nm for the Visible region)
- **Neutral Density Glass Filters** (440, 465, 546.1, 590 and 635 nm for the Visible region)

In this work, potassium dichromate (60 mg/L and 160 mg/L) and three neutral density glass filters were used. For each wavelength, six replicates were collected, and corresponding mean and standard deviation calculated as shown in Figures 7 and 8. All the tests were passed successfully with differences between the certified absorbances and the measured absorbances even one order of magnitude better than the limit required by the pharmacopoeia standards.

*Table 2. Instrument parameters used for the control of absorbance - Potassium Dichromate Solution.*

| Control of Absorbance – Potassium Dichromate | |
|---|---|
| Method | Wavelength Program |
| Ordinate Mode | A |
| Wavelength (nm) | 235<br>257<br>313<br>350 |
| Slit Width (nm) | 1 |
| Response (s) | 1 |
| Number of Cycles | 6 |

*Table 3. Instrument parameters used for the control of absorbance - Neutral Density Glass Filters.*

| Control of Absorbance – Neutral Density Glass Filters | |
|---|---|
| Method | Wavelength Program |
| Ordinate Mode | A |
| Wavelength (nm) | 440<br>465<br>546.1<br>590<br>635 |
| Slit Width (nm) | 1 |
| Response (s) | 1 |
| Number of Cycles | 6 |

USP <857> | Control of Absorbance | EP 2.2.25

Potassium Dichromate

60 mg/L

| Performed at | 235 | 257 | 313 | 350 | 430 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 0.7425 | 0.8642 | 0.2908 | 0.6432 | N/A | (Au) |
| Mean (n=6) | 0.7438 | 0.8661 | 0.2929 | 0.6450 | N/A | (Au) |
| Diff Mean Vs Cert | 0.0013 | 0.0019 | 0.0021 | 0.0018 | N/A | (Au) |
| Round Diff Mean Vs Cert | 0.001 | 0.002 | 0.002 | 0.002 | N/A | (Au) |
| Limit <= | 0.010 | 0.010 | 0.010 | 0.010 | 0.010 | (Au) |
| | Pass | Pass | Pass | Pass | Test not required | |
| SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Rounded SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Limit <= | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | (Au) |
| | Pass | Pass | Pass | Pass | Test not required | |

| Performed at | 235 | 257 | 313 | 350 | 430 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 0.7425 | 0.8642 | 0.2908 | 0.6432 | N/A | (Au) |
| Value | 0.7438 | 0.8661 | 0.2929 | 0.6450 | N/A | (Au) |
| Diff Mean Vs Cert | 0.0013 | 0.0019 | 0.0021 | 0.0018 | N/A | (Au) |
| Round Diff Mean Vs Cert | 0.001 | 0.002 | 0.002 | 0.002 | N/A | (Au) |
| Limit <= | 0.010 | 0.010 | 0.010 | 0.010 | 0.010 | (Au) |
| | Pass | Pass | Pass | Pass | Test not required | |

160 mg/L

| Performed at | 235 | 257 | 313 | 350 | (nm) |
|---|---|---|---|---|---|
| Absorbance Cert. | 2.016 | 2.347 | 0.776 | 1.720 | (Au) |
| Mean (n=6) | 2.017 | 2.345 | 0.7780 | 1.720 | (Au) |
| Diff Mean Vs Cert | 0.001 | 0.002 | 0.0020 | 0.000 | (Au) |
| Round Diff Mean Vs Cert | 0.001 | 0.002 | 0.002 | 0.000 | (Au) |
| Limit (Aλ) <= | 0.010 | 0.010 | 0.010 | 0.010 | (Aλ) |
| Limit <= | 0.020 | 0.023 | 0.008 | 0.017 | (Au) |
| | Pass | Pass | Pass | Pass | |
| SD | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Rounded SD | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Limit (Aλ/100) <= | 0.50 | 0.50 | 0.50 | 0.50 | (Aλ/100) |
| Limit <= | 0.010 | 0.012 | 0.004 | 0.009 | (Au) |
| | Pass | Pass | Pass | Pass | |

| Performed at | 235 | 257 | 313 | 350 | (nm) |
|---|---|---|---|---|---|
| Absorbance Cert. | 2.016 | 2.347 | 0.776 | 1.720 | (Au) |
| Value | 2.0169 | 2.3449 | 0.7780 | 1.7201 | (Au) |
| Diff Mean Vs Cert | 0.0009 | 0.0021 | 0.0020 | 0.0001 | (Au) |
| Round Diff Mean Vs Cert | 0.001 | 0.002 | 0.002 | 0.000 | (Au) |
| Limit (Aλ) <= | 0.010 | 0.010 | 0.010 | 0.010 | (Aλ) |
| Limit <= | 0.020 | 0.023 | 0.008 | 0.017 | (Au) |
| | Pass | Pass | Pass | Pass | |

*Figure 7. Values obtained for the control of absorbance – Potassium Dichromate solutions.*

USP <857> **Control of Absorbance** EP 2.2.25

Neutral Density Glass Filters

**G1**

| Performed at | 440 | 465 | 546.1 | 590 | 635 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 0.2888 | 0.2541 | 0.2539 | 0.2729 | 0.2737 | (Au) |
| Mean (n=6) | 0.2887 | 0.2530 | 0.2542 | 0.2732 | 0.2739 | (Au) |
| Diff Mean Vs Cert | 0.0001 | 0.0011 | 0.0003 | 0.0003 | 0.0002 | (Au) |
| Round Diff Mean Vs Cert | 0.000 | 0.001 | 0.000 | 0.000 | 0.000 | (Au) |
| Limit <= | 0.008 | 0.008 | 0.008 | 0.008 | 0.008 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |
| SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Rounded SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Limit <= | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |

| Performed at | 440 | 465 | 546.1 | 590 | 635 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 0.2888 | 0.2541 | 0.2539 | 0.2729 | 0.2737 | (Au) |
| Value | 0.2887 | 0.2530 | 0.2542 | 0.2732 | 0.2739 | (Au) |
| Diff Mean Vs Cert | 0.0001 | 0.0011 | 0.0003 | 0.0003 | 0.0002 | (Au) |
| Round Diff Mean Vs Cert | 0.000 | 0.001 | 0.000 | 0.000 | 0.000 | (Au) |
| Limit <= | 0.008 | 0.008 | 0.008 | 0.008 | 0.008 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |

**G2**

| Performed at | 440 | 465 | 546.1 | 590 | 635 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 1.0016 | 0.9291 | 0.9369 | 1.001 | 0.9743 | (Au) |
| Mean (n=6) | 1.001 | 0.9289 | 0.9373 | 1.001 | 0.9754 | (Au) |
| Diff Mean Vs Cert | 0.0006 | 0.0002 | 0.0004 | 0.000 | 0.0011 | (Au) |
| Round Diff Mean Vs Cert | 0.001 | 0.000 | 0.000 | 0.000 | 0.001 | (Au) |
| Limit <= | 0.008 | 0.008 | 0.008 | 0.008 | 0.008 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |
| SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Rounded SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Limit <= | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |

| Performed at | 440 | 465 | 546.1 | 590 | 635 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 1.0016 | 0.9291 | 0.9369 | 1.001 | 0.9743 | (Au) |
| Value | 1.0013 | 0.9289 | 0.9373 | 1.0012 | 0.9754 | (Au) |
| Diff Mean Vs Cert | 0.0003 | 0.0002 | 0.0004 | 0.0002 | 0.0011 | (Au) |
| Round Diff Mean Vs Cert | 0.000 | 0.000 | 0.000 | 0.000 | 0.001 | (Au) |
| Limit <= | 0.008 | 0.008 | 0.008 | 0.008 | 0.008 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |

**G3**

| Performed at | 440 | 465 | 546.1 | 590 | 635 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 0.4912 | 0.4476 | 0.4561 | 0.5071 | 0.5041 | (Au) |
| Mean (n=6) | 0.4915 | 0.4482 | 0.4569 | 0.5078 | 0.5047 | (Au) |
| Diff Mean Vs Cert | 0.0003 | 0.0006 | 0.0008 | 0.0007 | 0.0006 | (Au) |
| Round Diff Mean Vs Cert | 0.000 | 0.001 | 0.001 | 0.001 | 0.001 | (Au) |
| Limit <= | 0.008 | 0.008 | 0.008 | 0.008 | 0.008 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |
| SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Rounded SD | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | (Au) |
| Limit <= | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |

| Performed at | 440 | 465 | 546.1 | 590 | 635 | (nm) |
|---|---|---|---|---|---|---|
| Absorbance Cert. | 0.4912 | 0.4476 | 0.4561 | 0.5071 | 0.5041 | (Au) |
| Value | 0.4915 | 0.4482 | 0.4569 | 0.5078 | 0.5047 | (Au) |
| Diff Mean Vs Cert | 0.0003 | 0.0006 | 0.0008 | 0.0007 | 0.0006 | (Au) |
| Round Diff Mean Vs Cert | 0.000 | 0.001 | 0.001 | 0.001 | 0.001 | (Au) |
| Limit <= | 0.008 | 0.008 | 0.008 | 0.008 | 0.008 | (Au) |
| | Pass | Pass | Pass | Pass | Pass | |

*Figure 8. Values obtained for the control of absorbance - Neutral Density Glass Filters.*

## Absorbance Linearity

Absorbance linearity test is an extension of the absorbance control where the linearity of the photometric response is tested in the intended spectral range. The CRMs recommended for the control of absorbance and the same instrument setting parameters (see Table 3) can also be used for the control of absorbance linearity in the UV and Visible regions. The acceptance criterion states that the coefficient of determination ($R^2$) needs to be higher than 0.999. The absorbance values obtained during the control of absorbance test are plotted against the certified absorbance values to calculate $R^2$ which was found to be 1.000 confirming the absorbance linearity (see Figure 9). This test is no longer required in the latest version of the USP <857>.

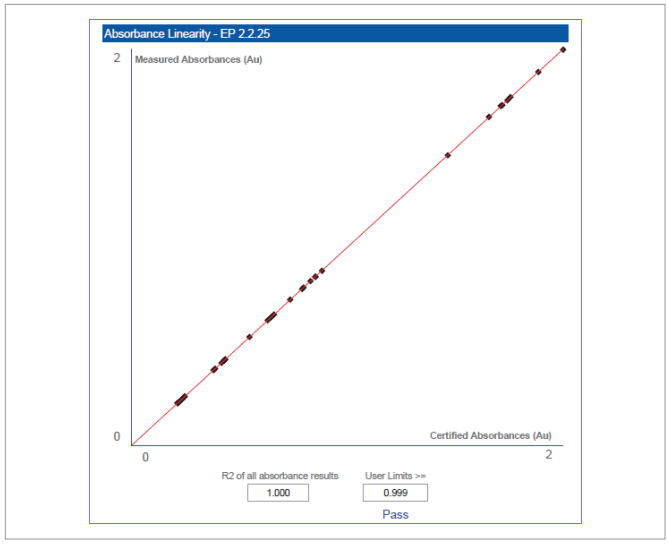


*Figure 9. Results obtained for the absorbance linearity test. The absorbance values were obtained from the control of absorbance test.*

## Limit of Stray Light

Stray light refers to all the unwanted radiation that reaches the detector, even though it was not selected by the bandwidth at the chosen wavelength. Stray light is mainly caused by the imperfections in the dispersing elements such as the grating component of the monochromator, diffraction effects or from damaged/worn components. It results in a negative deviation from the Lambert-Beer's Law and sets the upper limit of the maximum absorbance value possible for the instrument. Stray light is more critical for highly concentrated samples for which the stray light component might represent the largest part of the radiation that reaches the detector. Cut-off filter solutions are used to determine the limit of stray light. These solutions absorb below a certain wavelength, while transmit light at higher wavelengths. The stray light can be obtained by measuring the absorbance below such cut-off wavelengths where any light transmitted is given by stray light. The recommended CRM cut-off filters are the following:

- **Aqueous Potassium Chloride** (KCl 12 g/L) - 198 nm
- **Aqueous Sodium Iodide** (NaI 10 g/L) - 220 nm
- **Acetone** - 300 nm
- **Aqueous Sodium Nitrite** ($NaNO_2$ 50 g/L) - 340 nm and 370 nm

In this work, all the above CRM standards were used. According to the USP <857>, two procedures are available for the control of stray light. Procedure A requires to collect the absorbance of the cut-off standard solution using a 5 mm cuvette and subtract the resulting value from the absorbance obtained using the same cut-off standard solution in a 10 mm cuvette. Procedure B requires to measure the absorbance of a 10 mm cuvette filled with the cut-off filter solution against a 10 mm cuvette filled with the appropriate reference solution. In this study, the procedure B was followed, which is the same as described in the EP.2.2.25 (see Table 4 for the instrument parameters). The resulting absorbance values collected for all CRMs were higher (the values of absorbance equal to 10 indicate that the instrument was saturated) than the acceptance limits confirming that the instrument passes the limit of stray light control (see Figure 10).

*Table 4. Instrument parameters used for the limit of stray light.*

| Limit of Stray Light | |
|---|---|
| Method | Wavelength Program |
| Ordinate Mode | A |
| Wavelength (nm) | 198<br>220<br>300<br>340<br>370 |
| Slit Width (nm) | 1 |
| Response (s) | 1 |
| Number of Cycles | 6 |

USP <857> — Limit of Stray Light — EP 2.2.25

Standards 10 mm vs Appropriate Reference

| | Found Wavelength of Peak (nm) | Found Absorbance (ΔA) | Rounded Result (ΔA) | Limit >= (ΔA) | |
|---|---|---|---|---|---|
| Aqueous potassium chloride (12 g/L)(EP @198) | 198 | 2.74 | 2.7 | 2.0 | Pass |
| Aqueous sodium iodide (10 g/L) (EP @220) | 220 | 4.35 | 4.4 | 3.0 | Pass |
| Acetone | 300 | 4.01 | 4.0 | 2.0 | Pass |
| Aqueous sodium nitrite (50 g/L) (EP @340) | 340 | 10.00 | 10.0 | 3.0 | Pass |
| Aqueous sodium nitrite (50 g/L) (EP @370) | 370 | 10.00 | 10.0 | 3.0 | Pass |

*Figure 10. Results obtained for the limit of stray light test. The values of absorbance equal to 10 indicate that the instrument was saturated.*

## Spectral Resolution

Spectral resolution of a spectrophotometer refers to its ability to resolve two neighboring peaks as separate peaks. The resolution is associated with the slit of the spectrophotometer and the data point interval used to collect the spectrum. The SBW (spectral bandwidth) is defined as the width measured at half the maximum intensity of the light band that comes from the monochromator and it relates to the physical slit of the instrument. Selecting lower SBW by setting lower slit values in the spectrophotometer will guarantee a better resolution, although it might lead to higher noise (less light will go through the sample). In general, it is suggested to set the slit at around 1/8th of the FWHM (full width at half maximum) of the analyte's absorption band. The CRM standard used to determine the spectral resolution of the spectrophotomer is the following:

- **Toluene in Hexane** - 0.020% (v/v) solution

The spectral resolution is determined by measuring the ratio between the absorption maximum collected at 269 nm and the absorption minimum collected at 266 nm (see Figure 11 for the toluene in hexane absorption spectrum). The instrument setting parameters used for the spectral resolution test are reported in Table 5. The absorption values at 266 nm and 269 nm are obtained using processing equations that extract them from the spectra and then subtracted by the baseline obtained at 300 nm. The processing equations are easily created directly in the UV WinLab software. The ratio was found to be equal to two and the test is successfully passed as the acceptance limit is $A_{269}/A_{266}$ >1.3 (see Figure 12).

*Table 5. Instrument parameters for the Spectral Resolution test.*

| Limit of Stray Light | |
|---|---|
| Method | Wavelength Program |
| Ordinate Mode | A |
| Wavelength Range (nm) | 265 – 305 |
| Slit Width (nm) | 1 |
| Scan Speed (nm/min) | 60 |
| Number of Cycles | 1 |

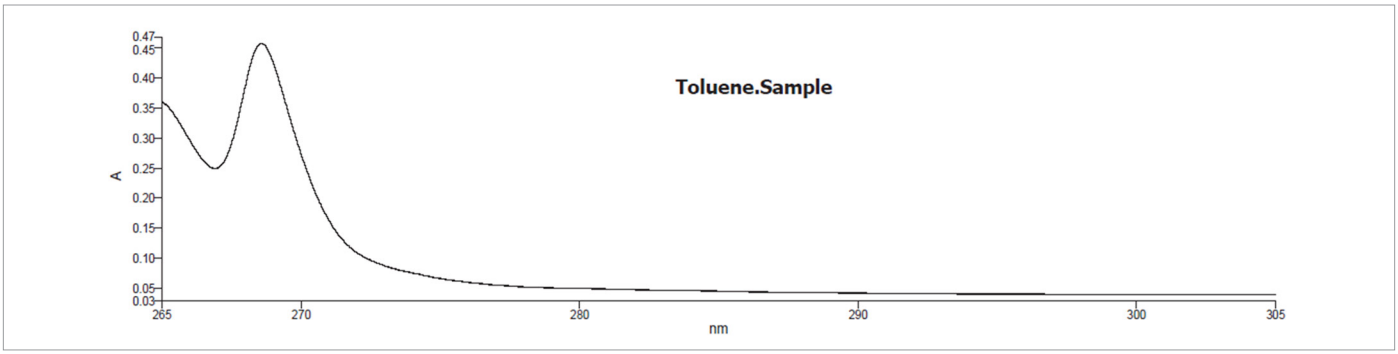


*Figure 11. Absorption spectrum of toluene in hexane (0.020% v/v) solution for the spectral resolution test.*

USP <857> — Spectral Resolution — EP 2.2.25

Toluene in Hexane 0.020% (v/v)

| | Wavelength (nm) | Found Absorbance (A) | Result (A) Adjusted for Base line | |
|---|---|---|---|---|
| Base line value at 300nm - if hexane blank not used | 300 | 0.0402 | | |
| 0.020% (v / v) solution of toluene in hexane (@266 nm) | 266.91 | 0.2499 | 0.2097 | |
| 0.020% (v / v) solution of toluene in hexane (@269 nm) | 268.57 | 0.4579 | 0.4177 | |
| | Result: Ratio | Rounded result (Ratio) | Limit >= (Ratio) | |
| Absorbance Ratio (A@269/A@266) | 1.99189318073 | 2 | 1.3 | Pass |

*Figure 12. Results obtained for the spectral resolution test.*

## Conclusion

The PerkinElmer LAMBDA 365+ UV/Vis spectrophotometer demonstrated not only to meet, but proved to exceed the requirements set by the guidelines of the global pharmacopoeia standards USP <857> and EP 2.2.25 (the instrument is also compliant with the Japanese Pharmacopoeia standards). All the control tests were successfully passed confirming that the Lambda 365+ will deliver reliable results and ensure high quality data. The results obtained for each test are shown using the ultra-secure report which is released as part of the UOQ (Universal Operational Qualification) performed by the PerkinElmer One Source Service. This document provides secure, encrypted reporting using digital certificate technology to prevent modifications, deletions or duplication, meeting 21 CFR Part 11 standards. Full compliance with 21 CFR Part 11 is also provided by the UV WinLab Enhanced Security (ES) software that controls the LAMBDA 365+ UV/Vis spectrophotometer offering the laboratories in the pharmaceutical industries the optimal solution to trust their results and rely on the integrity of their data.

## References

1. ASTM-E-29: "Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications".
2. FDA MAN-000048: "ORA Lab Manual Vol. III Section 4 - Basic Statistics and Data Presentation".

**PerkinElmer U.S. LLC**
710 Bridgeport Ave.
Shelton, CT 06484-4794 USA
(+1) 855-726-9377
**www.perkinelmer.com**



52376