

# Will the Chem Solutions Kit for UV-vis be appropriate for my spectrophotometer - FAQ

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The short answer is: It depends on the type of applications your laboratory is working on.

# **Understanding the Context**

The USP <857> monograph outlines a comprehensive set of tests and reference materials for qualifying UV-Vis spectrophotometers, tailored to meet the specific analytical needs of each laboratory. Several of these qualification tests also align with the guidelines found in **Ph. Eur. Chapter 2.2.25**.

To ensure compliance, company SOPs will be developed to align regulatory requirements with the analytical methods employed in each lab. The verification process includes the following key performance checks:

- Wavelength Accuracy
- Absorbance Accuracy
- Photometric Linearity
- Stray Light Evaluation
- Spectral Resolution

#### What Should Your Lab Consider?

We recommend that your laboratory first determine:

- Whether the instrument will be used in the UV range (200–400 nm), the visible range (400–780 nm), or both.
- The absorbance range required for your applications. While 0–1 AU is common, if your work involves 1–3 AU, different reference materials may be needed.

The Chemical Solutions UV-Vis kit includes seven concentrations of potassium dichromate, designed to assess absorbance accuracy within the 0–1 AU range, as well as to evaluate precision and linearity. It also contains holmium perchlorate, which supports wavelength accuracy verification up to 780 nm. Additionally, an iodide solution is provided for stray light testing. Stray light is measured only once and applies across all wavelengths. In this context, USP <857> serves more as a flexible framework, offering a menu of qualification options that allows laboratories to choose tests based on their instrument's intended use.

# **Instrument Capability Considerations**

For laboratories that must strictly adhere to USP <857> or Ph. Eur. 2.2.25, instruments are expected to deliver absolute absorbance accuracy within ±0.01 AU. Achieving this level of precision may be challenging for older models, particularly single-beam diode array spectrophotometers.

This is an important factor to consider when assessing your current instrumentation or planning future upgrades.

However, if strict USP compliance is not required for your applications, you may define a more practical tolerance based on a risk assessment aligned with your laboratory's analytical needs.

## **About the Kit and Compliance**

The Chemical Solutions UV/Vis Qualification Kit includes NIST-traceable solutions, providing high-quality reference standards for spectrophotometer verification.

However, it's important to note:

 The included instructions and software are not specifically designed to guide users through a complete USP <857> qualification process.

As such, while the materials in the kit are valuable, we strongly recommend developing internal SOPs tailored to your lab's specific compliance requirements.

## Do You Need to Follow USP <857>?

If your laboratory does not perform official USP release testing, then compliance with USP <857> is not mandatory.

The UV/Vis Qualification Kit includes general instructions and suggested test protocols to help you quickly and effectively qualify your spectrophotometer. It also comes with supporting software to streamline the process.

Each kit contains sufficient quantities of solution to support multiple qualifications, and includes protocols for:

- Wavelength accuracy and precision
- · Absorbance accuracy and precision
- Absorbance linearity
- Stray light determination

The validated software automatically calculates and prints all results and raw data, generating a final report ready for review and sign-off. A typical qualification, including instrument warm-up, can be completed in under an hour.

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Click <u>HERE</u> for PQ Kits for UV-vis Ordering Information.

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