Will your qualification kits for UV-vis be appropriate for my spectrophotometer – FAQ

The USP <857> guidelines are somewhat complicated, such that it is not easy to provide a simple answer.

As an overview, in the old monograph, it was possible to simply qualify a spectrophotometer using a single stray light, wavelength and absorbance accuracy solution. The recent changes in the USP<857> states one must qualify over wavelength and absorbance ranges suitable to its intended use.

We would suggest that your laboratory decide if your SOPs only intend to use the instrument in the UV range of 200-400 nm, or visible 400-780nm. The absorbance range can be 0-1 absorbance unit (AU), but if it is necessary to operate from 1-3 AU, your team would need to use different materials.

Stray light also needs to be evaluated in the wavelength range of interest. So <857> is now more of a selection of menu items, to decide over what range is to be used on the instrument.

We also add that most routine spectrophotometers are unable to meet a 0.01 AU accuracy. Only high quality, research grade instruments can routinely achieve that. Here is why you will see many instrument companies such as Agilent (Carey) discontinuing a number of their older instruments. (Just something to keep in mind in regards to your current instruments.)

The solutions are NIST traceable, however, the instructions and software are not really written to guide the user through a current <857> qualification. As such, your company could certainly use the materials in our UV/Vis kit, but we would suggest your laboratory understand and write independent internal procedures.

Lastly, if your team does not need USP compliance (does not perform official USP release testing) it is not necessary that they follow <857>. Here is where you can use the kit to qualify your instrument, and the materials are NIST traceable.

Click *HERE* for PQ Kits for UV-vis Ordering Information.

MicroSolv Technology Corporation
9158 Industrial Blvd. NE, Leland, NC 28451
tel. (732) 380-8900, fax (910) 769-9435
Email: customers@mtc-usa.com
Website: www.mtc-usa.com