

## USP-NF Chapter Revisions for 857 and 1058 Kit Compliance - Tech Information

Date: 14-APRIL-2015 Last Updated: 5-JULY-2025

### **NIST Traceability & USP Compliance in Chemical Solutions™ Qualification Kits**

The Chemical Solutions™ Performance Qualification (PQ) and HSQ™ Kits, manufactured by MICROSOLV Technology Corporation, are designed to support laboratories in qualifying their HPLC and UV-Vis instrumentation with confidence and precision.

#### **NIST Traceability**

All materials in the kits are NIST traceable, meaning their concentrations and performance characteristics are linked to standards established by the National Institute of Standards and Technology. This traceability ensures:

- High accuracy and reproducibility
- Regulatory confidence
- Reliable instrument qualification

NIST traceability is especially critical when demonstrating compliance with regulatory standards and internal quality systems.

### **USP Compliance: What the Kits Support**

While the kits themselves are not USP-certified products, they are designed to be used as part of a user-defined protocol to meet relevant USP requirements, including:

- USP <1058>: Analytical Instrument Qualification
- USP <857>: UV-Visible Spectroscopy – Performance Verification

These chapters outline the framework and performance expectations for instrument qualification, but do not prescribe specific materials or methods. That's where the Chemical Solutions™ kits come in — providing reliable, traceable standards to support your qualification process.

### **HPLC PQ Kits: Comprehensive System Qualification Aligned with <1058>**

The HPLC Kits are now more than ever, designed to fully support both the current revisions to USP <1058>, offering a holistic approach to system qualification—including hardware, software, and data integrity.

This kit is especially valuable for organizations aiming to standardize their Performance Qualification (PQ) process. Companies adopting the Kits on an ongoing basis typically integrate it into their SOPs. This may involve the use of custom-written and validated report templates for chromatographic data

systems such as Empower or OpenLab, which automatically calculate and document the required results.

For smaller laboratories or those without the resources to develop custom software solutions, the kit includes a validated Excel template that fulfills documentation requirements. Ultimately, each organization's internal QA team will determine the level of documentation needed, but the PQ Kit provides a robust foundation for building SOPs that ensure compliance with both current and future <1058> expectations.

---

### **Note on USP <857> and UV Accuracy**

The updated USP <857> standard requires absorbance agreement within < 0.01 AU. However:

- Most routine UV-Vis spectrophotometers cannot achieve this level of accuracy.
- Only high-end, research-grade instruments typically meet this requirement consistently.

While the Chemical Solutions™ UV kits can be used to qualify your instrument, achieving full compliance with USP <857> may require:

- Additional calculations
- Supplemental procedures
- Instrument-specific validation beyond the scope of the kit

---

 Click [\*\*HERE\*\*](#) for PQ & HSQ Kit ordering information and product images

For technical support or guidance on integrating these kits into your qualification protocol, our team — including experts formerly from Chemical Solutions, Inc. — is here to help.

Printed from the Chrom Resource Center

Copyright 2025, All Rights Apply

**MicroSolv Technology Corporation**

9158 Industrial Blvd. NE, Leland, NC 28451

Tel: (732) 380-8900

Fax: (910) 769-9435

Email: [customers@mtc-usa.com](mailto:customers@mtc-usa.com)

Website: [www.mtc-usa.com](http://www.mtc-usa.com)