

Sievers*

Cleaning Validation Support Package (CVSP)

The Sievers Cleaning Validation Support Package (CVSP) from GE Analytical Instruments is a comprehensive set of documentation providing guidance for the use of Total Organic Carbon (TOC) methodology in laboratory, at-line, and on-line cleaning validation applications. The Sievers CVSP includes guidance, examples, worksheets, templates, and sample protocols that will significantly reduce the time and effort required to define and execute cleaning validation requirements. The CVSP is a powerful document package that greatly simplifies implementing Sievers Laboratory, Portable, and On-Line TOC Analyzers in cleaning validation and cleaning verification applications.



Key Features and Benefits

Application-Specific Protocols

Many pharmaceutical manufacturers seek to increase efficiency in the validation process while maintaining the highest levels of quality and regulatory compliance. In addition to laboratory-based cleaning validation support, the Sievers CVSP guides users through the steps and documentation necessary to validate methodology and cleaning processes to achieve on-line, real-time release of production equipment.

Inspection-Ready Documentation

The Sievers CVSP provides a science-based approach to cleaning validation and includes validation tools that can be applied to multiple aspects of pharmaceutical quality and ongoing quality control, such as:

- Cleaning process development
- Manufacturing
- Change control processes for active pharmaceutical ingredients, drug products, and biological and biotechnology products

Regulatory Document Structure

A key benefit of the Sievers CVSP is its systematic approach to cleaning validation documentation. The CVSP serves as a foundation document that is independent of, yet supportive of, other regulatory documents such as CFRs, PIC/S, ICH Guidelines, ASTM and Process Analytical Technology (PAT) guidance documents, cGMP Drug Notes, FDA guidance and USP Guidelines. In addition, the CVSP complements existing quality practices, requirements, standards and guidelines commonly utilized within the pharmaceutical and biotechnology industries.

Time-Saving Templates

The Sievers CVSP assists customers beyond process development and cleaning validation testing. It facilitates a science-based approach to defining key elements of a cleaning validation program, providing the user with templates for:

- Acceptance criteria calculations
- Test plans — Percent recovery studies
- Protocols and reports that encompass all aspects of process development, validation, manufacturing and process monitoring.





Sievers 900 Series and 500 RL TOC Analyzers

CVSP Contents

The three-phase CVSP supports the pharmaceutical cleaning validation process from validation planning through execution and maintenance. Following is a partial table of contents that outlines the phases.

Phase I – Validation Planning

- Pre-validation activities
- Analytical method performance characteristics
- Establishing acceptance criteria for use of TOC
- TOC prequalification study of proteins and cleaning agents
- Generating validation protocols and reports for using Sievers TOC Analyzers for cleaning validation

Phase II – Validation Execution

- Qualification activities
- Test the method, validate the method, and verify the method
- Validating a CIP process:
 - On-line TOC method for equipment release
 - Performance qualification for production equipment

Phase III – Validation Maintenance

- Monitor the cleaning validation program to eliminate risk
- Validation maintenance activities with the use of TOC

Additional Resources

For more information, visit www.geinstruments.com and go to *Applications – Pharmaceutical – Cleaning Validation*.



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