Sievers 500 RL On-Line TOC Analyzer for pharmaceutical applications

overview

The Sievers* 500 RL On-Line Total Organic Carbon (TOC) Analyzer delivers high quality online results, consistent with regulatory requirements for both process control and real-time testing (RTT). The highly automated Sievers 500 RL, which uses the proven Sievers laboratory TOC methodology, continuously provides exceptional analytical performance at a significantly lower cost than laboratory testing.

The Sievers 500 RL offers specific features for pharmaceutical applications, such as the innovative Super iOS* (Integrated On-Line Sampling System) for automating system protocols. The Sievers 500 RL also offers extended calibration stability and the unsurpassed ease of operation found in all Sievers TOC Analyzers.

key applications

Regulatory Compliance

The Sievers 500 RL provides online TOC analysis for compliance with the following:

- US Pharmacopeia (USP) <643>
- European Pharmacopeia (EP) 2.2.44 Total Organic Carbon
- Indian Pharmacopeia (IP) 2.4.30
- Chinese Pharmacopeia (CP) Appendix VIII R
- Japanese Pharmacopeia 16 (JP16) 2.59 monographs for Purified Water and Water for Injection

The robust Sievers 500 RL performance ensures all the new regulatory expectations can be met that are outlined in the FDA Process Validation Guidance document; ASTM E2656; and the ICH Q8, Q9, and Q10 international guidance.

Real-Time Testing and Process Control of Pharmaceutical Waters

The Sievers 500 RL provides low-risk, continuous online TOC measurements required to scientifically justify a reduction or elimination of costlier laboratory-based sampling processes. The Sievers 500 RL can also provide continuous, online quality assurance for pharmaceutical real-time testing and can be provided with the critical protocols required for RTT process validation. The Sievers 500 RL is also an optimal choice if the intended use is focused only on process control.

The Sievers 500 RL also measures USP <645> conductivity, which provides added assurance that the purified water and water for injection used in production meets quality requirements.

features and benefits

Science-Based Design

The Sievers 500 RL was designed to deliver exceptional analytical process capability. The Sievers Membrane Conductometric design eliminates false positive and false negative readings to which other technologies are susceptible.

Additionally, the Sievers technology ensures accurate recovery of all classes of organic compounds commonly found in UPW waters.

In a process capability study comparing online UPW TOC analyzers, the Sievers 500 RL demonstrated the highest degree of suitability for the intended use, making it a clear winner in delivering the highest quality results in pharmaceutical water applications.

Automation

The Sievers 500 RL features automated system protocols, such as validation and system suitability testing, as well as automated recording of production information for Sievers Standards. Data encryption facilitates secure distribution of analytical data for review. The Sievers 500 RL is available with a Super iOS (Integrated On-Line Sampling System) that fully automates all validation protocols, including system suitability.

Applications Versatility

The Sievers 500 RL's wide applications range includes high and/or unstable conductivity waters. A maximum sample conductivity specification of 25 µS/cm facilitates extremely reliable performance with all types of pharmaceutical water.

Conductivity

The Sievers 500 RL meets all USP <645> Stage 1 regulatory monitoring requirements, reporting raw conductivity, temperature, and temperature-compensated conductivity. Procedures compliant with USP <645> enable temperature accuracy verification. The 500 RL also supports conductivity testing in accordance with JP <2.51>.

Security

The Sievers 500 RL Analyzer protects data and the analyzer from unauthorized user access. The Sievers 500 RL outputs encrypted data files for analysis and system protocol results to a USB Flash memory drive or serial port. The encrypted files can be opened only in the Sievers DataShare* 500 program and cannot be modified. The optional Sievers DataGuard* software facilitates compliance with 21 CFR Part 11 electronic records regulations. DataGuard provides an administratively controlled user-access system supporting multiple users with unique passwords and full audit trail functionality.

Sievers TOC Methodology

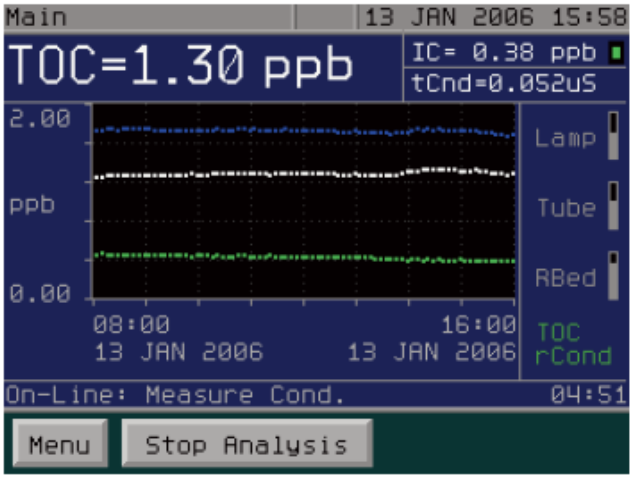
The Sievers Membrane Conductometric TOC Detection method has proven to be an extremely reliable technique for measuring TOC. The Sievers technology utilizes a gas-permeable membrane that selectively passes only the CO_2 produced from the oxidation of organics. By preventing acids, bases, and halogenated compounds from interfering with the measurement of CO_2 from oxidation, the Membrane Conductometric Method delivers unmatched selectivity, sensitivity, stability, accuracy, and precision.

Comprehensive Validation Support

Professional and comprehensive IQ (Installation Qualification) and OQ (Operation Qualification) documents are available for the 500 RL. Optional PQ (Performance Qualification) documentation is also available for a complete validation solution.

Simplicity

The Sievers 500 RL is extremely easy to install, operate, and maintain. The large, color touch-screen menu provides access to all Sievers 500 RL functions. In addition to displaying TOC data, trend graphs, and analyzer status, the color interface provides real-time status of consumables and prompts the user when semi-annual maintenance is due.



Main analyzer display screen

Easy, Stable Calibration

With 12-month calibration stability and easy screen prompts to perform single-point or multi-point calibration protocols, the Sievers 500 RL makes on-site calibration simple and convenient. Super iOS models allow for vial set cartridge insertion, with no further operator action needed once the protocols are started.

accessories and options

The Sievers 500 RL is available in two iOS (Integrated On-Line Sampling System) configurations: the Sievers Standard iOS and the Sievers Super iOS.

Sievers Standard iOS

The Sievers Standard iOS accommodates grab samples and standards used for calibration and system protocols. The single-port Standard iOS automatically activates the calibration and verification protocols in the Sievers 500 RL firmware.

Sievers Super iOS

The optional Super iOS, together with the Sievers vial set cartridges, provide a robust solution for secure data management. The Super iOS has four vial ports and uses a unique vial cartridge to automate calibration and pharmaceutical system protocols, eliminating human error and substantially reducing labor costs.

Sievers Super iOS and Vial Cartridge

Each vial set cartridge includes an embedded memory chip that transfers data about the standards—including type, concentration, lot number, and expiration—to the Analyzer.

This information is stored with the protocol results, creating a detailed protocol record and eliminating the need to manually document standards information. For added convenience, the Sievers 500 RL with Super iOS can be configured to automatically restart TOC analysis following successful system suitability testing.

DataShare 500

The Sievers DataShare 500 PC-based program allows multiple parties to securely share and review protocol data and reports with signature fields. Data cannot be modified, ensuring data security consistent with 21 CFR Part 11 requirements. On Super iOS models, information embedded in the vial set cartridge is automatically imported into the report.

DataGuard

Sievers DataGuard software facilitates compliance with 21 CFR Part 11 and electronic records control requirements. DataGuard provides administratively controlled, multi-level and multi-user access, and complete audit trail functionality.

Sievers Certified Reference Materials

Sievers is the leading global brand of TOC and conductivity standards. Sievers Certified Reference Materials are available for all validation protocols, including calibration, verification, linearity, specificity, robustness, and USP system suitability tests.

Manufactured in a stringent cleanroom environment and using ISO 9001 guidelines, Sievers Standards provide the accuracy, stability, and NIST/USP traceability required to provide superior performance in demanding pharmaceutical applications.

technical support and services

SUEZ provides ongoing technical support and on-site installation, maintenance, calibration, and training services for its Sievers product line. Together, these services and support ensure optimal performance of the Sievers 500 RL for pharmaceutical applications.

Find a contact near you by visiting www.sieversinstruments.com and clicking on "Contact Us."

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