

Sievers solutions for pharmaceutical applications

industry challenges

Pharmaceutical and biopharmaceutical manufacturers across the globe are increasingly tasked to improve productivity without sacrificing quality. At the same time, budget pressures and resource consolidation continue to intensify, forcing manufacturers to do more with less in a highly regulated environment.

Faced with these demanding pressures, manufacturers turn to technologies and solutions that can help them improve output and increase efficiency. When it comes to compliance monitoring of ultrapure water (UPW) and validating or verifying cleaning samples, choosing the right analytical instrument is key.

solutions

Sievers* Total Organic Carbon (TOC) Analyzers offer time-tested dependability with fast analysis for UPW monitoring and other pharmaceutical testing. Boosting efficiency, the Sievers M9 TOC Analyzers reduce TOC result time by 50% compared to previous models and can measure Stage 1 Conductivity simultaneously. Additional features, such as automated reagent optimization and increased sample analysis capacity (when coupled with the Sievers Autosampler) enable greater productivity.

Designed to facilitate compliance within a highly regulated environment, Sievers TOC Analyzers exceed both regulatory and analytical requirements. The broad linear range allows for excellent low-level sensitivity when measuring UPW samples and high-level capability for cleaning validation and other applications.

application needs

Global Pharmacopeia Compliance

Sievers TOC Analyzers comply with United States Pharmacopeia (USP) <643> and European Pharmacopeia (EP) 2.2.44 for TOC measurement for Purified Water (PW) and Water for Injection (WFI). Sievers TOC Analyzers offer integrated samplers for standards, coupled with automated step-by-step routines, to provide unparalleled ease in applying

system suitability standards in an online or grab sample environment.

When coupled with the Sievers Autosampler and DataPro2 software, the Sievers M9 Laboratory and Portable TOC Analyzers offer automated system suitability protocols for the determination of response efficiency and limit response for ultrapure water.

Cleaning Validation and Verification

Cleaning validation applications offer an especially challenging situation, as the TOC concentration of these samples is often unknown, making optimal analysis conditions difficult to achieve. The Sievers M9 Autoreagent feature, used with or without the Sievers Autosampler, automatically optimizes reagent flow rates for the concentration and composition of samples. This eliminates time-consuming and labor-intensive steps by allowing samples to be run unattended, without user intervention. Sievers TOC Analyzers provide analytical accuracy and precision across a broad analytical range (0.03 ppb to 50 ppm) and complete oxidation of organics, regardless of their source.

Stage 1 Conductivity

USP <645> was introduced as a means to measure water purity of PW and WFI used in the manufacturing of drugs. Conductivity measurement is also used in cleaning applications to determine cleaning effectiveness and removal of harsh inorganic chemicals that may be left over from the cleaning process. The Sievers M9 Laboratory and M9 Portable Analyzers can simply and simultaneously measure TOC and sample conductivity for USP <643> and <645>. Readings are available in two minutes, saving manufacturers time and effort.

Data Integrity and Compliance

Sievers TOC Analyzers offer the most comprehensive support for compliance with FDA requirements for control of electronic records and signatures. Sievers TOC Analyzers and software comply with 21 CFR Part 11 and meet or exceed recent data integrity

guidelines from the FDA, European Medicines Agency, Pharmaceutical Inspection Co-operation Scheme (PICS) and others. Sievers DataPro2 and DataGuard software offer secure data storage and management, robust electronic signatures and data review, and comprehensive audit trails. When TOC and conductivity are measured simultaneously, the data are more reliable with improved traceability for out-of-specification (OOS) investigation reporting.

Analytical Instrument Qualification

One of the most costly, time-consuming activities within the pharmaceutical environment is system and instrument validation. Sievers TOC Analyzers greatly simplify this task. Offering a variety of calibration options, including multi-point and single-point calibration choices, the M9 Analyzers automatically analyze calibration standards, perform all necessary calculations, and apply them to the Analyzer. When paired with the Sievers Autosampler, the M9 Laboratory and M9 Portable Analyzers offer the ultimate in validation ease with a fully automated validation protocol. This enables the determination of system suitability, accuracy, precision, linearity, robustness, specificity, and LOD/LOQ, with the touch of a button. Easy-to-use validation documentation is available for all Sievers TOC Analyzers and has been enhanced to align with the most current global regulatory guidance.

Sievers M9 Analyzers

Sievers M9 Portable TOC Analyzer

The Sievers M9 Portable TOC Analyzer offers a lightweight, compact design for maximum versatility. It is engineered for ease of use and cost-effective operation, allowing it to be carried to various locations

for grab samples, used online for continuous measurements, or moved to the lab to work with the Sievers Autosampler. The flexibility of the M9 Portable makes it a powerful troubleshooting analysis tool that can be installed online or carried to any location in the water system. The M9 Portable uses the same Integrated On-Line Sampling (iOS) System as the M9 On-Line TOC Analyzer. Turbo mode is available for rapid, four-second analysis to quickly analyze samples or identify transient TOC excursions.

Sievers M9 On-Line TOC Analyzer

The Sievers M9 On-Line TOC Analyzer provides continuous monitoring with the ability to introduce discrete grab samples and standards. The Sievers M9 On-Line's patented Integrated On-Line Sampling (iOS) System allows users to directly introduce calibration, validation, and system suitability standards without removing the instrument from the continuous sample source or changing the sample inlet configuration. Housed in an IP-45 rated enclosure, the wall-mounted Sievers M9 On-Line is ideal for demanding environments or measuring incoming water into the production plant.

Sievers M9 Laboratory TOC Analyzer and Sievers Autosampler

Streamlined to occupy minimal bench space, the Sievers M9 Lab can be operated as a stand-alone unit or teamed with the Sievers Autosampler. It is well suited to analyze a variety of sample matrices and concentrations, and the Autoreagent feature optimizes analysis conditions for challenging samples. The M9 Lab has an option for simultaneous testing of TOC and conductivity, as well an optional Turbo mode for four-second analysis.



Sievers 500 RL On-Line TOC Analyzer

As a process tool to control high purity water systems, the Sievers 500 RL On-Line delivers high quality online results, consistent with regulatory requirements for both process control and real-time testing. Saving time and minimizing complications, the Sievers 500 RL not only provides the most robust analytical technology available, but it's also remarkably simple to operate and maintain. The Sievers Membrane Conductometric design eliminates false positive and false negative readings to which other technologies are susceptible, and it is designed to meet or exceed all relevant pharmaceutical regulatory requirements including global pharmacopeia, quality standards, and GMP's.

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. The Sievers 500 RL also offers extended calibration stability.

Sievers InnovOx TOC Analyzer

The advantages of clearly understanding water quality before and after wastewater treatment enable manufacturing facilities to work efficiently, while minimizing crisis efforts and, most importantly, remaining compliant. Sievers InnovOx TOC Analyzers are designed for harsh environments and challenging sample matrices. By using an ultra-efficient Supercritical Water Oxidation (SCWO) technique, the Sievers InnovOx can run hundreds of wastewater samples sequentially with extreme accuracy, precision, and speed.

CheckPoint Pharma TOC Sensor

The CheckPoint Pharma direct conductometric TOC sensor provides pharmaceutical manufacturers with a cost-effective and flexible tool for process trending, screening potential trouble areas, and diagnosing problems in real time. With a dynamic range of 0.21 to 1,000 ppb, it can measure TOC in hot WFI (up to 90 °C) or ozonated water and will operate at ambient temperatures up to 55°C. Its three analog outputs enable simultaneous measurement of TOC, raw conductivity, and temperature. Users can download data via USB or collect data using the standard Modbus TCP/IP or optional 4-20mA outputs. The CheckPoint Pharma comes with a simple and convenient Standard Operating Procedure (SOP) to meet installation, operation, and performance qualification requirements.



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