



Aurora 1030W TOC Validation Package

Complete IQ, OQ, PQ Documentation with On-Site Support

Description

The Aurora 1030W Validation Package provides complete documentation for validating a 1030W TOC (Total Organic Carbon) instrument for use in pharmaceutical and biotechnology GLP/GMP applications.

Aurora 1030W TOC Analyzers employ heated persulfate wet oxidation to perform the high sensitivity measurements required in Cleaning Validation (CV), Purified Water (PW), and Water for Injection (WFI) applications. The 21 CFR Part II compliant software and Aurora 1030W validation package ensure the instrument meets all requirements for operation in GLP and GMP environments.



Deliverables & Support

The Aurora 1030W Validation Package consists of instrument validation protocols for installation qualifications (IQ), operation qualifications (OQ), and performance qualifications (PQ) and matching certification documents to record successful completion of each step with a signature and date.

An OI Analytical technician is available to install the Aurora 1030W TOC analyzer and perform the IQ, OQ, PQ validations, providing certifications to be maintained with instrument records for inspections or audits. Organizations that use in-house personnel to conduct instrument validations may obtain the validation package separately.

The validation package and on-site installation ensure the Aurora 1030W is properly installed, verify operation of all critical sub-components using NIST-certified meters, and confirm system performance to manufacturer specifications, including accuracy and reproducibility, using a test standard supplied by OI Analytical.

The validation documents support the initial validation of an Aurora 1030W instrument and continuing validations over the lifetime of the instrument.

Principal Application

Validation of Aurora 1030W TOC Analyzers for GLP/GMP compliance supporting:

- Cleaning Validation (CV)
- Purified Water (PW)
- Water for Injection (WFI)

Protocols & Documentation

- Installation Qualifications (IQ)
- Operation Qualifications (OQ)
- Performance Qualifications (PQ)
- Standard Operating Procedures (SOPs)
- Certification Documentation