

# TOC solutions for pharma

## Ultrapure water monitoring in lab and process



## A strong alliance for lab and process TOC

Two partners, one standard: Analytik Jena and Endress+Hauser support pharmaceutical TOC monitoring with fast, sensitive and compliant solutions and services you can rely on.



With Endress+Hauser and Analytik Jena combining their TOC expertise, pharmaceutical manufacturers gain one integrated source for TOC monitoring both in online and in laboratory applications. We share aligned quality philosophies and commitment to a common goal: to make your TOC monitoring processes simpler, safer, and more efficient. As a family-owned company, we focus on reliable long-term partnerships supporting future-ready pharmaceutical production. Benefit from streamlined qualification and consistently high performance:

- High quality standards across lab and process instruments
- Highest process safety for critical pharmaceutical TOC applications
- One stable qualified supply chain
- Long-term availability of products, spare parts and services
- Future-proof investments backed by sustainable lifecycle concepts
- Global service and support network

## Compliance master plan

### Services

In pharmaceutical production, timelines are tight, and testing and monitoring systems must operate with consistently high reliability. Our service offering is designed to ensure full regulatory compliance, full traceability, and maximum instrument uptime.

We provide a comprehensive service package including:

- Installation (IQ) and operational qualification (OQ)
- Software validation
- Audit trail with detailed service reports
- Short reaction times for troubleshooting
- Tailored service and maintenance packages

Our service experts are trained and certified to deliver GMP-compliant services to make sure your processes and lab tests run safely and without interruption.

### Data integrity and compliance

Data integrity is a key success factor for compliance and product quality and is implemented in our software solutions for process monitoring and laboratory analysis. This ensures consistent, tamper-proof data, supporting confident quality decisions and audit safety.



- Transparent and fully traceable documentation
- FDA 21 CFR Part 11 compliance
- Compliance with European and US pharmacopeias
- Higher efficiency, less manual effort
- Best data quality to improve your processes

### For your process: Endress+Hauser CA79 online analyzers

All concepts for online TOC analyzers consider data integrity as a core feature, which was implemented in every function of the instrument. CA79 stores each user interaction, each parameter setting and all measured values permanently in an encrypted format. This data is completely tamper proof. It cannot be modified but displayed on the local display and visualized as graphs, providing a detailed overview of all actions and measurements. This ensures a high level of data security and integrity.

TOC analyzers of the Endress+Hauser group actively support customers in meeting industry requirements regarding validation and documentation. The System Suitability Test can be carried out semi or fully automated. It always delivers an unambiguous result like "passed" or "failed". The SST becomes part of the electronic audit trail.



### For your lab: Analytik Jena multi N/C 4300 UV

The UV digestion-based TOC analyzers are ideal for ultrapure water testing and cleaning validation, detecting TOC levels down to 1 ppb. The dual wavelength UV reactor completely oxidizes samples in the trace range without persulfate. Long-term warranties on core components (e.g. 3 years on the UV reactor) and low reagent consumption make multi N/C 4300 UV a sustainable choice. Fast measurement cycles, parallel purge and analysis in NPOC mode and extensive automation options streamline your workflows. The intuitive multiWin pro software guarantees compliance with FDA 21 CFR Part 11 and further regulatory frameworks:

- Role-based user management with Active Directory login
- Central data storage and access from multiple computers
- Audit trail and versioning: Tracking of time, author and details of action supported by filtering options
- Electronic signatures following the dual control principle and the three-step process „created / checked / released“





## CA79 low-range TOC analyzer

Online analyzer for continuous, accurate TOC monitoring of water for injection (WFI) based on UV oxidation and measurement of differential conductivity. Suitable for low conductivities < 2  $\mu\text{S}/\text{cm}$ . Fast response time for effective product protection and compact design for easy integration in ultrapure water installations. Compliant with European and US Pharmacopeias and FDA 21 CFR Part 11.

For more details see also:  
[www.endress.com/CA79](http://www.endress.com/CA79)



## Further solutions for pharma lab testing by multi N/C x300 series

Besides the UV digestion based trace detector for low level TOC applications, Analytik Jena also offers catalytic combustion based TOC/TN analyzers. The multi N/C 3300 supports TOC/TN cleaning validation, pure-water applications and extractables testing from plastic packaging materials, while the multi N/C 3300 HS offers great repeatability in the TOC trace range and supports direct swab combustion for TOC cleaning validation. The multi N/C 2300 N is our specialist for total protein determination in aqueous solutions (e.g. vaccines). With its direct injection principle, this analyzer supports handling of smallest sample volumes, while multiWin pro software takes care of automatic parameter conversion from total nitrogen readings into total protein results.

For more details check-out our E-book:  
[www.analytik-jena.com/toc-pharma](http://www.analytik-jena.com/toc-pharma)



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