

Chorus® Pharma System

DELIVERING COMPLIANT WATER FOR YOUR QUALITY CONTROL LAB

The Chorus® Pharma System delivers 18.2MΩ ultrapure water from a reliable, efficient and simple to use system designed to meet Good Manufacturing Practices (GMP) requirements. Easily integrated into existing workflows, this smart pharmaceutical lab water system provides digital record keeping, qualification documentation, and total organic carbon (TOC) and water conductivity measurements required by US pharmacopeia 643 and 645.

CFR 21 Part 11

• An FDA regulation that defines the processes for organizations to use e-signatures in place of handwritten signatures for government documents.

U.S. Pharmacopeia 643

- Outlines the general method for Total Organic Carbon (TOC) testing in pharmaceutical applications.
- Provides guidance on how to qualify the analytical technique for use, and guidance on how to interpret TOC instrumental results for use as a limit test.

U.S. Pharmacopeia 645

- Primary method for the determination of inorganic/ionic impurities.
- Determines that there is sufficient control/reduction of chemicals in the water purification system.

Good Manufacturing Practices (GMP)

 Good Manufacturing Practices or GMP is a system that consists of processes, procedures and documentation that ensures manufacturing products, such as food, cosmetics, and pharmaceutical goods, are consistently produced and controlled according to set quality standards

Total Organic Carbon

• An analytical parameter representing the concentration of organic carbon in a sample.



FEATURES & BENEFITS

- Complies with USD Regulation CFR 21 Part 11, USP 643, and USP 645
- Easily integrated into workflows
- Secure access with passcode
- Meets GMP ultra-pure water needs
- Complies with TOC verification
- Digital record keeping
- Qualification documentation
- Comprehensive installation and operational qualification by certified AQUA pro service professionals
- Fully trained service support teams

APPLICATIONS

- Mass Spectrometry
- Ion & Has Chromatography
- Ultra-trace and Qualitative Analyses
- Molecular Biology
- Cell Cultures
- Electrochemistry
- Immunochemistry
- Laboratory Water Purification

VALIDATIONS

The Chorus® Pharma system meets the ultrapure water needs of laboratories operating under the validation conditions stipulated by GMP and Good Documentation Practice.

It also meets FDA and EU requirements for digital records. In addition, the system provides data to support the TOC suitability test required by the USP 643 and meets the line cell constant required by UPS 645.

The Chorus Pharma system includes all the qualification documentation for typical validation requirements. It is also designed, manufactured and tested within a Quality Management System and is approved by Lloyds Register Quality Assurance (LRQA), complying with ISO 9001.

THE EVOQUA DIFFERENCE

Evoqua improves upon traditional approaches to water management by leveraging decades of experience in water system design, an unmatched local service network and highly trained service technicians, engineers and customer service representatives to help with all your water needs.

The Chorus Pharma System is supported by Evoqua's comprehensive local service network with significant experience in pharmaceutical laboratory water production.

TECHNICAL SPECIFICATIONS

CHORUS PHARMA COMPLIANCE (W2T935105)

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Purified Type 1 Treated Water Output Specifications	
Resistivity	18.2 M Ω- cm
Dispenser flowrate	up to 2 L/min
Total Organic Carbon (TOC)	1-3 ppb
Bacterial Endotoxin	<0.001 EU/ml with a LC197 Point-of Use Biofilter fitted
Bacterial Spec	<0.001 Cfu/ml with a LC134 or LC145 or LC197 Point-of-use 0.2µm Micron filter fitted
DNases	<5 pg/ml
RNases	<1 pg/ml
Particles	<0.01 µm
Recirculation Mode	During periods of non-use the unit will automatically operate in intermittent (10 minutes every 1 hours) re-circulation mode to maintain water purity with maximum efficiency
Feedwater Requiremen	nts
Water Source	Pre-treated preferably RO, SDI or distilled
Fouling Index (max)	1 for all models. A 5-10 micron pre-filter is recommended for all non-RO feeds
Service Deionization (SDI)	1M Ω cm minimum at exhaustion
Reverse Osmosis (RO)	Recommend <30 μs/cm
Free Chlorine (max)	0.05 ppm
ТОС	0.05 ppm max
Carbon Dioxide	30 ppm max
Silica	2 ppm max
Particulates	Filtration down to 0.2 micron advisable
Temperature	1-40°C (Recommended 10-15°C)
Feedwater Pressure an	d Flowrate
Maximum Inlet Pressure	0.7 bar (10 psi) Fit a LA652 Pressure Regulator where feedwater exceeds specified limits
Minimum Inlet Pressure	0.07 bar (1 psi)
Flowrate	130 l/hr (34 USG)
Drain Requirements	Up to 2 l/min (0.5 USG) (Gravity fall with air

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gap) Max during service



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