ELGA VEOLIA

PURELAB®

Pharma Compliance

GMP ready: Ultrapure water, Passcode access, Validation support & TOC verification

WATER TECHNOLOGIES

GMP & QC Ready Ultrapure Lab Water

The PURELAB Pharma Compliance delivers 18.2MΩ ultrapure water from a reliable, intuitive & simple to use system designed to meet GMP requirements.

Easily integrated into existing workflows, the PURELAB Pharma Compliance uses a passcode access system, validation support documentation and complies with the TOC verification and water conductivity measurements required under US pharmacopeia 643 and 645.

The Validation Support Portfolio	
Meets the ultrapure water needs of laboratories operating under the validation conditions stipulated by GMP and Good Documentation Practise.	✓
Meets FDA & EU requirements for digital records.	✓
Supports the TOC suitability test required by the USP 643.	✓
Meets the line cell constant required by USP 645.	✓
Includes all the qualification documentation required to meet the validation stipulated by GMP.	✓
Is supported by a global network of service teams with significant experience of supporting laboratory equipment subject to validation under GMP.	✓
Is designed, manufactured and tested within a Quality Management System is approved by Lloyd's Register Quality Assurance (LRQA) and complies with ISO 9001.	✓

Assured Traceability, Proven Compliance

The PURELAB Pharma Compliance offers all the necessary purification features, software capabilities, qualification documentation and services required to meet GMP.

Digital Record Keeping

The PURELAB Pharma Compliance's admin functions, security and data integrity capabilities, password accessibility, audit trail procedures & permissions all meet national regulators best practice for data management in QC labs following GMP standards.

Qualification Documents

Installation Qualification (IQ) and Operational Qualification (OQ) documents are supplied as part of ELGA's standard offerings*.

Quality Management System

ELGA Labwater is a subsidiary of the Veolia group, whose Quality Management System is approved by Lloyd's Register Quality Assurance (LRQA) and CISO 9001.

Global Service Report

To support clients' Performance Qualification (PQ) procedures ELGA and the Veolia service teams manage annual servicing and calibration with minimised disruption.

United States Pharmacopeia (USP) Standards

Purification and servicing processes support the total organic carbon measurement and water conductivity measurement required by USP643 and 645.

*Design Qualification (DQ) documents can also be supplied.

Enhanced QC Output, Cost Effective Design

Cost Effective

The PURELAB Pharma Compliance delivers the water to support the QC tests necessary to validate drug purity in pharma manufacturing. Consumables are designed to minimise cost and waste.

Designed to Comply

Designed to meet FDA, United States Pharmacopeia, EUDRALEX, European Pharmacopoeia and all GMP requirements for Quality Control laboratories.

Proven Globally

Components have been proven in thousands of water systems globally and result from over a decade of user experience and feedback. ELGA's quality systems ensure that volume manufacturing sites with high frequency batch sampling and mandatory quality control function without unplanned interventions.

Internationally Trusted

Simplicity

ELGAs human centered design ethos delivers a user experience that drives productivity and excellence in today’s QC labs.

Reliability

Quality engineering, outstanding build quality and access to quick actioning service engineers worldwide.

Quality

Smart, intuitive software means our equipment integrates seamlessly into the lab and the quality of our water is guaranteed.

Global Validation Support

ELGA and its service partners deliver complete solutions that meet and exceed the compliance standards regulated and recommended by the FDA, EU, ISPE Engineering Guides, GMP & GAMP.

ELGA Labwater are specialists in the engineering, service & support of high quality water purification systems. Teams of certified ELGA representatives support pharmaceutical organisations globally everyday.

- Certified ELGA service representatives are trained to conduct comprehensive installation and operational qualification of purification systems on-site.
- Support teams are fully trained on industry standards and regulations.
- Certified ELGA service representatives provide user training to optimize equipment use.
- Certified ELGA service representatives can perform Installation Qualification, Operational Qualification and ongoing testing.
- All appropriate documentation and certificates are provided.
- Service support engineers can also perform field verification, calibration and US Pharmacopeia suitability tests.
- Service support engineers will also supply validation support documentation and test result reports.
- Service support is enabled using an ISO-9001 certified quality control system.

Technical Specification

PURELAB Pharma Compliance – VCLSDM1	
Purified Type 1 Treated Water Output Specifications	
Resistivity	18.2 MΩ-cm
Dispenser flow-rate	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 Requirements	
Water Source	Pre-treated preferably RO, SDI or distilled
Fouling Index (max)	1 for all models. A 5-10 micron pre-filter is recommend for all non RO feeds
Service Deionization (SDI)	1MΩ.cm minimum at exhaustion
Reverse Osmosis (RO)	Recommend <30 µs/cm
Free Chlorine (max)	0.05 ppm
TOC	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 and 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 gap) Max during service

Optimize your water purity at the point of use:

- Biofilter: Endotoxin removal (<0.001 EU/ml), DNase removal (<20pg/ml), RNase removal (<0.002ng/ml)
- Microfilter: Particulate removal (≥0.2 µm)

ELGA VEOLIA

Dedicated to Discovery

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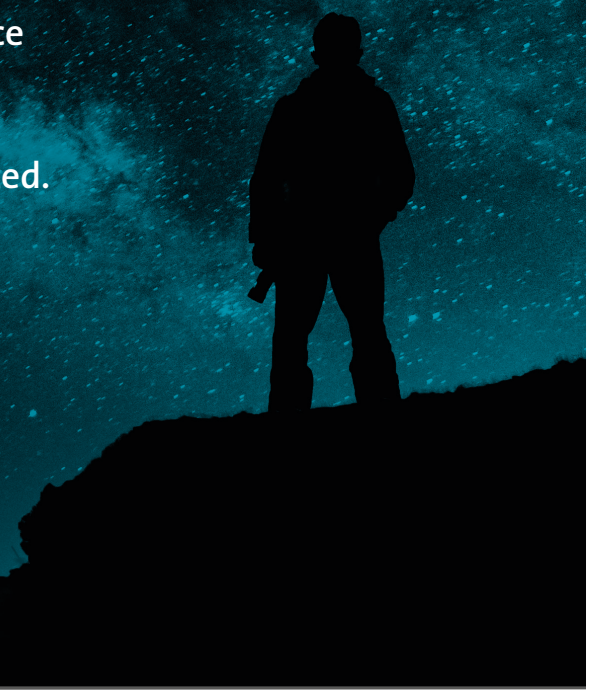
ELGA Labwater are specialists in the engineering, service & support of water purification systems.

Unrivalled product design has achieved international recognition and awards.

Worldwide technical service teams support science & healthcare globally with specialist expertise.

Global digital performance monitoring from Hubgrade ensures laboratory work is uninterrupted.

A global supply chain supports clients from regional centres on every continent.



To find your nearest ELGA representative, go to www.elgalabwater.com and select your country for contact details.

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2nd Place GIT Innovations Award 2010

reddot design award winner 2011

GOOD DESIGN AWARD 2014

Design Award Gold 2015 TBO

Hubgrade

OVER 80 INTERNATIONAL PATENTS