

# Pharma Compliance

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



# 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\*.

## United States Pharmacopeia (USP) Standards

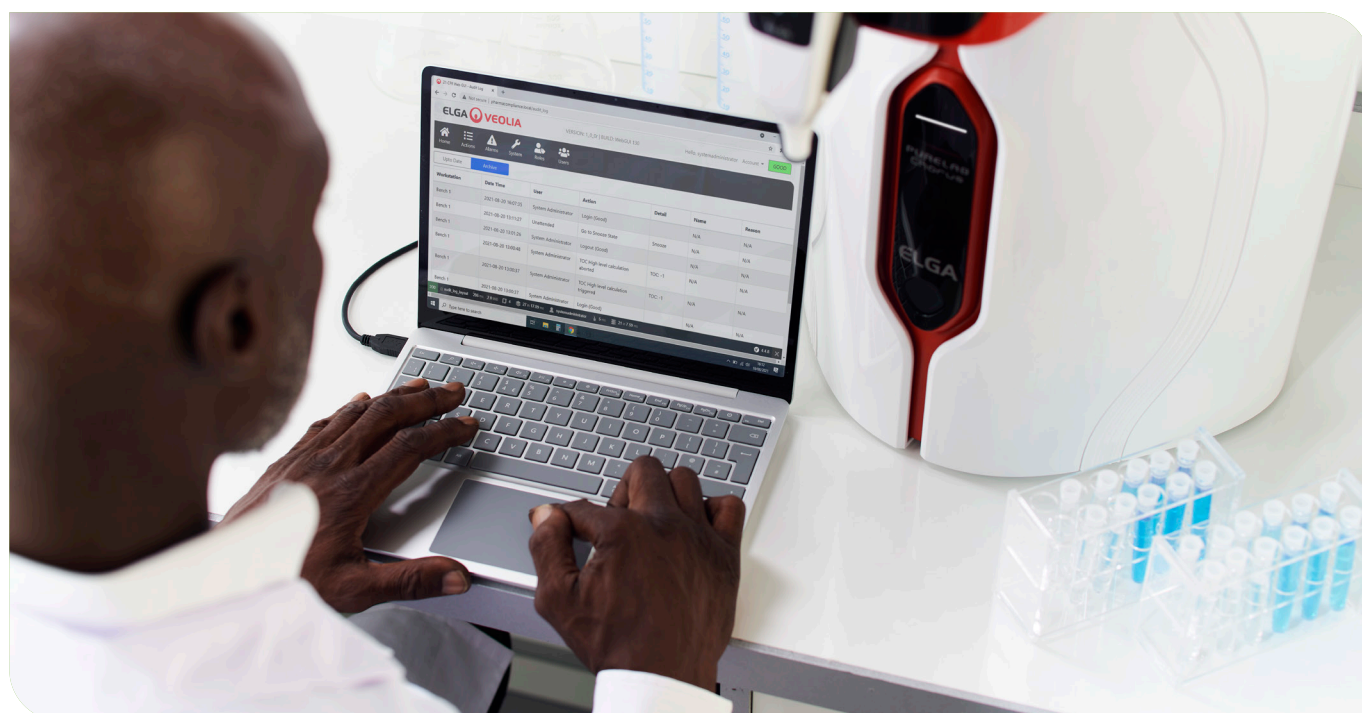
Purification and servicing processes support the total organic carbon measurement and water conductivity measurement required by USP643 and 645.

## 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.



\*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
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)



# 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.

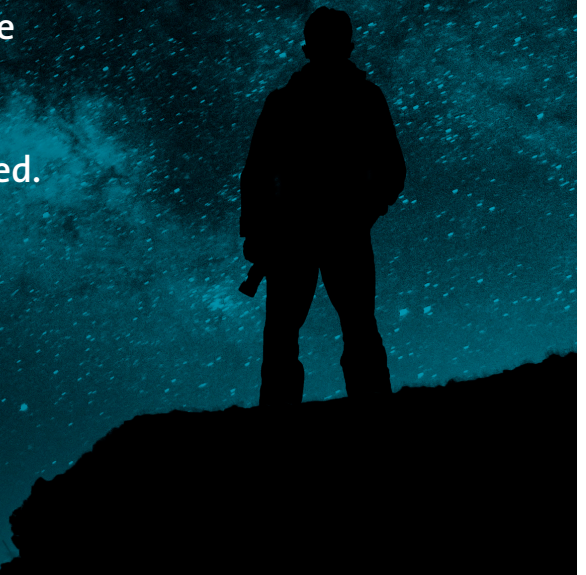
Worldwide technical service teams support science  
& healthcare globally with specialist expertise.

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,  
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