

Pharma Compliance

GMP ready: Ultrapure water, passcode access, validation support and TOC verification.

The PURELAB® Pharma Compliance delivers $18.2 M\Omega$ water from a reliable, intuitive and simple to use system designed to meet GMP requirements.

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

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

Cost effective

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

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.

Digital record keeping

The PURELAB Pharma Compliance's admin functions, security and data integrity capabilities, password accessibility, audit trail

procedures and permissions all meet global 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.¹

United States Pharmacopeia (USP) Standards

Purification and servicing processes support the total organic carbon (TOC) measurement and water conductivity measurement required by USP 643 and 645.

Designed to comply

Designed to meet FDA, USP, EUDRALEX, EP and GMP requirements for Quality Control laboratories.

Reference

1. Design qualification (DQ) documents can also be supplied.



For further information, visit:

www.elgalabwater.com

1

