

Buyers Guide

Quality Control

Choosing the right water purification system for scientific research.

Choosing the right water purification system for pharmaceutical quality control

Quality control (QC) testing is essential in the pharmaceutical industry to ensure that medicines are safe for use and have optimal therapeutic performance. Water plays a vital role in the analytical techniques at the heart of a QC laboratory, but its ability to dissolve a range of compounds and gases makes it susceptible to

contamination. The risks that insufficiently pure water pose for a QC laboratory are extensive; impurities in water can damage lab equipment, distort data and disrupt analyses.

Here are the main questions you should ask yourself when choosing the right water purification system for your laboratory:

1	What water purity do I require?
2	How much water do I require and how many users or applications require purified water?
3	How critical is the purity of my water?
4	What level of compliance is required for my work and systems?
5	What is the quality of my feedwater?
6	How much space can I spare for my water purification system?
7	Are my water purification requirements likely to grow?
8	How can the new equipment contribute to the environmental sustainability credentials of my laboratory operations?
9	What would be the scope and cost associated with obtaining poor results due to choosing a poor quality water generation system?

The following pages will guide your answers to these questions, but for further information, take a look at the resources available on the ELGA website, or speak directly to a member of the ELGA team.

1. Water Purity

	Type III	Type II	Type II+	Type I	Type I+
	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p>Type II water Pure water</p> <p>Used in general laboratory steps like media preparation and buffer creation</p> </div> <div style="width: 30%;"> <p>Type I water Ultrapure water</p> <p>Used for highly sensitive procedures like HPLC, AAS and mammalian cell culture</p> </div> <div style="width: 30%;"> <p>Type III water Primary grade water</p> <p>Used for non-critical work like rinsing beakers, filling water baths or feeding autoclaves</p> </div> </div>				
Inorganics (resistivity at 25 °C)	>0.05 MΩ.cm	>1 MΩ.cm	>10 MΩ.cm	>18 MΩ.cm	18.2 MΩ.cm
Total organic carbon (TOC)	<200 ppb	<50 ppb	<50 ppb	<10 ppb	<5 ppb
Bacteria	<1000 CFU/ml	<100 CFU/ml	<10 CFU/ml	<1 CFU/ml	<1 CFU/ml
Endotoxin	-	-	-	<0.03 EU/ml	<0.03 EU/ml

Choosing the ideal water purification system for QC procedures

Some applications are more sensitive to impurities than others, and laboratories must make sure that they use the appropriate grade of water for their QC tests to minimize contamination during analysis. For example, ultrapure water (Type I+ water) must be

used for highly sensitive endotoxin analysis, liquid chromatography and cell cultures, while apyrogenic water (Type II or Type II+ water) can be used for general chemistry and microbiological analysis.

Method	Sensitivity	Resistivity (MΩ.cm)	TOC (ppb)	Filter (µm)	Bacteria (CFU/ml)	Endotoxin (EU/ml)	Nuclease	Water Grade
HPLC	General	>5.0	<20	<0.2	<10	NA	NA	Type II+
	High	>18.0	<2	<0.2	<1	<0.03	NA	Type I+
IC	General	>5.0	<50	<0.2	<10	NA	NA	Type II+
	High	18.2	<10	<0.2	<1	<0.03	NA	Type I+
LC-MS	High	>18.0	<2	<0.2	<1	<0.03	NA	Type I+
ICP-MS		18.2	<10	<0.2	<1	NA	NA	Type I+
ICP-OES		>18.0	<10	<0.2	<1	NA	NA	Type I

2. Water Volume Requirements

What is your daily purified water consumption?

What is the peak flow rate of purified water you require?

What size reservoir might you require to provide this volume of water?

Storage reservoirs should be equipped with a composite vent filter (CVF) to protect stored water from airborne CO₂ and bacteria, guaranteeing a supply of purified water in sufficient volumes when required to ensure laboratory productivity. Stored water should be regularly recirculated through the purification process to prevent deterioration in purity.

Do you require several dispensing points to deliver water for multiple uses?

Do you require flexible dispensers that cater to your team and your laboratory?

What different applications require purified water in your laboratory?

Different applications may require different purity water at different locations within your facility. See Q1. You might be able to feed multiple applications with different water purity requirements through engineering dispense points into your comprehensive water purification system. Be sure to provide all of your requirements to your provider to ensure they can create a bespoke solution for your laboratory in the most cost effective manner.

3. Importance of water purity

Do you need water purity monitored in real time right up to the point of use?

For applications that are sensitive to ionic contaminants, it is essential to monitor water resistivity to ensure water of adequate purity is used. Likewise, if experiments could be affected by organic contaminants, you may want to rely on a system that monitors total organic content (TOC). Many monitoring approaches have significant delays inherent to the method meaning values displayed are only relevant to water quality several minutes ago.

Do you require alerts when components are nearing the end of their life cycle to minimize disruption to laboratory processes?

Do you require a water purification system with enhanced DI technologies, such as EDI or PureSure DI technology, to prevent unexpected drops in water purity?

Do you require efficient service provision to maximise the uptime of your water purification system?

4. Compliance

Is your laboratory required to comply with GMP requirements?

Is your laboratory required to maintain records or submit designated information electronically in line with FDA 21 CFR Part 11?

Is your laboratory water purification system required to support validation activities?

Is your laboratory water purification system required to meet USP 643 and USP 645?

USP 643 and 645 are primary chemical limit tests that determine whether there is sufficient control/reduction of chemicals in a water purification system. USP 643 specifies a 'System Suitability Test' designed to confirm that TOC monitoring meets criteria for qualification. USP 645 specifies the verification of the cell constant and resistance measurement of the line cell to confirm that resistivity monitoring meets criteria for qualification.

5. Feedwater Quality

Do you know the quality of your feedwater?

Do you need this to be tested to allow you to choose the appropriate water purification system and any requisite pre-treatment?

Prefiltration can be required to deal with a number of impurities that can be found in municipal water, protecting purification technologies and mechanical parts of the water purification system from damage. ELGA's technical team can test your feedwater for you, ensuring that your water purification system can work at optimal efficiency.

What is the pressure of your feedwater? Might you require a system with a boost pump?

6. Footprint

How much space do you have on or under the bench or on the wall to situate your water purification system?

Do you require a compact, low-volume system with a built-in wrap-around reservoir?

Do you require a larger system with external reservoir for high volumes of water that you can situate under the bench with remote dispensers on the bench?

7. Scalability & Future Planning

Might you require additional capacity without extensively increasing the footprint of your water purification system in the future?

8. Sustainability

Do you want to minimise the water and energy consumption of your laboratory?

Do you have internal or external environmental targets to achieve?

Do you want to reduce plastic use and chemical waste?

9. Budget

Do you want a reliable pure water generator with the lowest total cost of ownership, and predictable operational costs, without forgoing product quality?

Do you want a reliable and helpful global service network, to maximise the up-time and efficiency of your water purification system, and minimise potential costly disruptions?



ELGA LabWater: Dedicated to Discovery

ELGA has been working with scientists since 1937 to guarantee pure and ultrapure water for their experiments and laboratory work. We designed the

PURELAB® product range to meet any one of your requirements for water quality, giving you peace of mind that your water purity is in good hands.

What can you expect from ELGA?

Absolute focus on water purification

The quality of ELGA water is guaranteed to the very last drop, so you can be confident you are receiving consistent optimum water purity.

Proven efficacy

ELGA is a trusted name and supplier with proven efficacy in helping to progress a wide range of scientific disciplines worldwide.

Smart and simple design

ELGA water purification systems fit seamlessly into the lab without taking up valuable bench space.

Ease of use and simplicity

Minimal training is required to quickly get your teams using ELGA products efficiently. Ease of use also minimizes the risk of user error.

Equipment that is easy to self-maintain

Any minor issues can be resolved quickly, without interruptions to your workflow.

Maximal uptime

ELGA's global service network ensures your water purification system operates at maximum efficiency.

Access to a global network of water experts

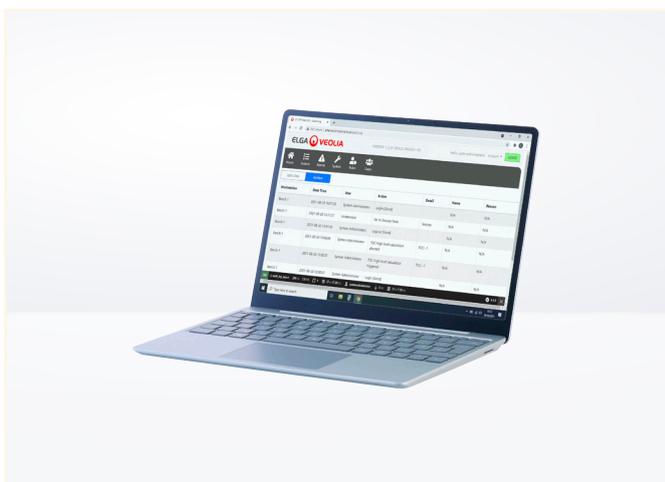
ELGA is part of Veolia, the largest environmental management agency in the world.



PURELAB® Water Purification Systems are engineered for simplicity of use, operation and maintenance, and designed to provide a constant and reliable supply of high quality water for QC applications

The PURELAB® range offers three levels of regulatory compliance:

Low-level compliance: PURELAB® Chorus 1 Life Science or Analytical Research	Mid-level compliance: PURELAB® Chorus 1 Life Science or Analytical Research + VSM	High-level compliance: PURELAB® Pharma Compliance
<ul style="list-style-type: none"> • Low or non-regulation control • Only require quality water 	<ul style="list-style-type: none"> • Require some level of documentation • Validated system • Basic data tracking 	<ul style="list-style-type: none"> • Require detailed documentation • Validated to USP 643 and 645 • Data tracking to comply with 'Part 11'



PURELAB® Pharma Compliance

- Consistently delivers Type I+ or Type I water
- Up to 2.0 l/min dispense flow rate
- Provides up to 120 l/day of ultrapure water
- Smart, intuitive software
- Digital record keeping
- Meets GxP requirements
- Complies with the TOC verification and water conductivity measurements required under USP 643 and 645



PURELAB® Chorus 1

- Consistently delivers Type I+ or Type I water
- Life Science or Analytical Research models are appropriate for QC labs
- Up to 2.0 l/min dispense flow rate
- PureSure® technology for optimal water purity
- Modular, configurable design to optimize valuable lab space
- Range of dispensing solutions, reservoir sizes and purification packs
- In-built auto-recirculation to manage biofilm, ensuring reliable water quality and optimal readings
- Real-time TOC monitoring
- Intuitive menu navigation to minimize the risk of error

The PURELAB® range offers a complete purification solution:

PURELAB® Chorus 1 Life Science, PURELAB® Flex 2 and PURELAB® Pharma Compliance need pretreated laboratory feed water.

- Preferably RO, service deionization (SDI) or distilled water
- PURELAB® Chorus 2/2+ provides Type II water directly from a potable water supply
- PURELAB® Chorus 3 provides Type III RO water

Key features of the PURELAB® range

Auto-recirculation	Water left for any period of time will drop in quality, so the auto-recirculation feature in PURELAB® purification systems pushes fresh cleaned water to the point of use, and provides a reading of the water purity. This reassures QC laboratories that the water used for their tests is of the highest quality – without any need to manually recirculate the water – and that the data will be sufficiently accurate to meet ‘Part 11’ requirements.
Real-time TOC Monitoring	PURELAB® systems continuously measure resistivity, and calculate the TOC value of water produced before it is dispensed, and display the value in real time. This method of TOC monitoring enables the unit to read all the water that is running through the system, rather than just a sample.
PureSure® Technology	PureSure® technology consists of a double purification pack and monitoring system, using an enhanced DI process that relies on ion exchange (IX) resins to guarantee water quality. The technology will provide advance warning when the first DI pack has been fully exhausted. When this occurs, the second DI pack ensures that water continues to meet the required specification. This allows the laboratory to replace the DI pack at a convenient time, without interrupting its workflow, causing downtime. The second DI pack can then be moved to the position of the first DI pack to maximise its use, avoiding the premature exchange of packs, wasting valuable resource.
Integrated Filtration	For complete assurance of quality, integrated filters with recirculation eliminate any concern about stagnant water in point of use filters. Further, POU filters have a limited lifespan, and typically need to be replaced every 1 to 3 months, depending on the usage. Instead, PURELAB® Chorus 1 and Pharma Compliance systems feature integrated filtration, ensuring that the quality of water meets specification with just annual replacements. With the addition of a service contract, the laboratory will never need to remember filter replacement dates.



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