



# Pristine Quality Waters and Aqueous Solutions to Enhance Your Workflow and Hyper-Accelerate New Projects

**AQUABILITI** enables the **life sciences, CGT, biotechnology, pharmaceutical and medical device industries** to propel productivity at sonic speed.

**Trust AQUABILITI** – We seek to support life sciences, CGT, biotechnology, pharmaceutical and medical device researchers, developers, and manufacturers in their innovative quest for life sustaining therapies. With a wide range of high purity waters and aqueous solutions, AQUABILITI is ready to support your most demanding manufacturing workflows.

## The Right **AQUA**Lution for Your Workflow

AQUABILITI offers a variety of high purity waters and aqueous solutions to meet your needs. Our products are manufactured in our 60,000 square foot ISO 13485:2016, cGMP compliant and animal origin-free (AOF) aqueous solutions facility and available in multiple packaging configurations based on industry demands. For customers with unique needs, AQUABILITI offers custom manufacturing to accommodate packaging, testing, and/or lot size requirements. Additionally, AQUABILITI's manufacturing capabilities extend to custom cGMP process solutions.

**Leverage our on-site Single-Use System (SUS) design and manufacturing coupled with continuous manufacturing capabilities to enhance your process needs.**



Discover **Unmatched Purity** with AQUABILITI.



**AQUA**Pure

High Purity Compendial Waters



**AQUA**Lutions

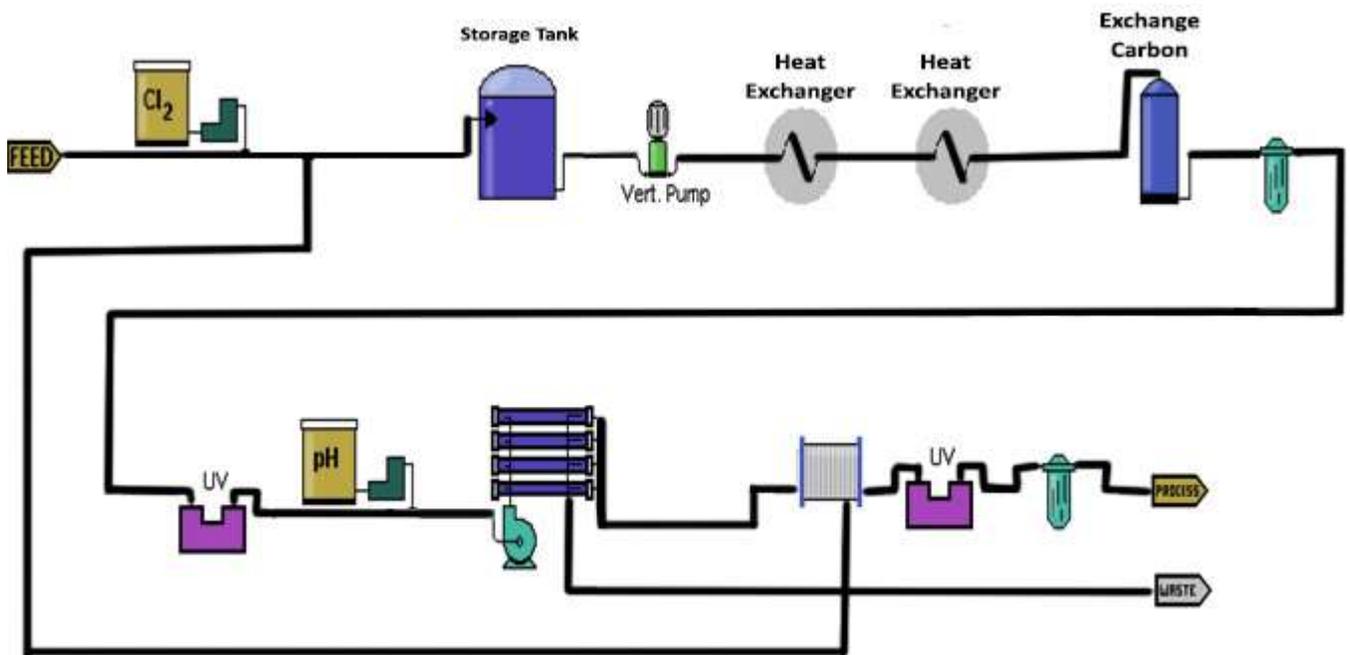
0.9% Sodium Chloride + Custom Process Solutions

**AQUABILITI**<sup>™</sup>  
IMPACTING LIVES

# Superb Process for Impeccable Quality

Commissioned in 2023, Aquabiliti's high-capacity on-demand reverse osmosis water generation system was specifically designed to produce ASTM Type 1A\* water – the highest purity water reserved for the most critical applications – a claim that few water systems can make. This level of purity significantly exceeds Water for Injection (WFI) specifications and requirements\*\*. Furthermore, our innovative modeled system is capable of **continuous manufacturing**.

## Process Overview:



Routine testing of Aquabiliti's generated water demonstrates unmatched quality compared to the requirements for Water for Injection (WFI) prior to packaging:

Analysis	Aquabiliti	Type 1A Water	USP/EP WFI
Conductivity (µS/cm)	≤ 0.06	≤ 0.06	≤ 1.3
TOC (ppb)	≤ 20	≤ 50	< 500
Endotoxin (EU/mL)	< 0.01	< 0.03	< 0.25

\* In-line Testing

\*\*Per USP <1231> Water for Pharmaceutical Purposes

A person wearing a white full-body protective suit, a white face mask, and blue gloves is working in a laboratory. They are holding a blue-handled tool or pipette. The background is a blurred laboratory environment with various pieces of equipment.

High Purity Waters  
that provide the versatility  
required for the most  
demanding workflows.

**AQUABILITI™**  
IMPACTING LIVES

# Compendial **Waters** for Life Sciences, CGT, Biotechnology, Pharmaceutical and Medical Device Industries

**AQUABILITI's AQUAPure** compendial waters are available in a wide range of packaging and testing options to support your research, development, or manufacturing workflows. Our innovative continuous filling process is fully closed-loop maintaining end-to-end, uncompromised purity.

Description	Water For Injection (WFI) Quality Water	Water For Injection (WFI) Quality Water	Water For Irrigation Quality Water	Sterile Purified Water	Cell and Molecular Grade Water
Grade	<b>AQUAPure</b> USP & EP	<b>AQUAPure</b> USP	<b>AQUAPure</b> USP	<b>AQUAPure</b> USP	<b>AQUAPure</b> USP
Aquabiliti Product Code	HYPER	ULTRA	WIR	SPW	CMW
TOC					
Conductivity					
Endotoxin					
Sterility					
Particulate Matter					
RNase DNase & Protease					
Oxidizable Substances					
Residue on Evaporation					
Nitrates					

## Water For Injection (WFI) Quality Water

AQUABILITI's HYPER water is available in multi-compendial USP/EP Grades for Water for Injection (WFI) Quality Water packaged in bulk for commercial use. Our WFI quality water meets the needs of upstream and downstream bioprocessing and manufacturing applications and complies with the United States Pharmacopeia (USP) and European Pharmacopeia (EP) as indicated.

### AQUAPure HYPER Water for Injection (WFI) Quality Water (USP/EP Grade)

Meets the USP/EP monograph for Water for Injection quality water packaged in bulk for commercial use.

Product	Aquabiliti Catalog Code	Container Type	Size
<b>AQUAPure HYPER Water for Injection (WFI) Quality Water (USP/EP Grade)</b>	<b>HYPER-0010-01</b>	Bioprocess 2D Container (BPC)	<b>10L</b>
	<b>HYPER-0020-01</b>	Bioprocess 2D Container (BPC)	<b>20L</b>
	<b>HYPER-0050-01</b>	Bioprocess 3D Container (BPC)	<b>50L</b>
	<b>HYPER-0100-01</b>	Bioprocess 3D Container (BPC)	<b>100L</b>
	<b>HYPER-0200-01</b>	Bioprocess 3D Container (BPC)	<b>200L</b>
	<b>HYPER-1100-01</b>	Bioprocess 3D Container (BPC)	<b>1100L</b>

### AQUAPure ULTRA Water for Injection (WFI) Quality Water (USP Grade)

Meets the USP monograph for Water for Injection quality water packaged in bulk for commercial use.

Product	Aquabiliti Catalog Code	Container Type	Size
<b>AQUAPure ULTRA Water for Injection (WFI) Quality Water (USP Grade)</b>	<b>ULTRA-0010-01</b>	Bioprocess 2D Container (BPC)	<b>10L</b>
	<b>ULTRA-0020-01</b>	Bioprocess 2D Container (BPC)	<b>20L</b>
	<b>ULTRA-0050-01</b>	Bioprocess 3D Container (BPC)	<b>50L</b>
	<b>ULTRA-0100-01</b>	Bioprocess 3D Container (BPC)	<b>100L</b>
	<b>ULTRA-0200-01</b>	Bioprocess 3D Container (BPC)	<b>200L</b>
	<b>ULTRA-1100-01</b>	Bioprocess 3D Container (BPC)	<b>1100L</b>

## Water for Irrigation Quality Water (USP Grade)

AQUABILITI's **Water for Irrigation (WIR) Quality Water (USP Grade)** is a sterile non-pyrogenic water produced by our proprietary water purification system. Manufactured and tested in compliance with the USP monograph for bulk packaged water for irrigation, AQUAPure WIR, Water for Irrigation Quality Water (USP Grade) is ideal for use in the manufacture and testing of medical devices, and applications where Water For Injection may not be appropriate.

### AQUAPure WIR Water for Irrigation Quality Water (USP Grade)

Product	Aquabiliti Catalog Code	Container Type	Size
<b>AQUAPure WIR Water for Irrigation Quality Water (USP Grade)</b>	<b>WIR-0010-01</b>	Bioprocess 2D Container (BPC)	<b>10L</b>
	<b>WIR-0020-01</b>	Bioprocess 2D Container (BPC)	<b>20L</b>
	<b>WIR-0050-01</b>	Bioprocess 3D Container (BPC)	<b>50L</b>
	<b>WIR-0100-01</b>	Bioprocess 3D Container (BPC)	<b>100L</b>
	<b>WIR-0200-01</b>	Bioprocess 3D Container (BPC)	<b>200L</b>
	<b>WIR-1100-01</b>	Bioprocess 3D Container (BPC)	<b>1100L</b>

## Sterile Purified Water (USP Grade)

AQUABILITI's **Sterile Purified Water (USP Grade)** can be utilized for both Sterile and Non-Sterile applications. AQUAPure SPW Purified Water is manufactured and tested in accordance with USP monograph for Sterile Purified Water. Purified water is suitable in various non-parenteral applications including oral and topical products, non-active medical device manufacture and cleaning applications.

### AQUAPure SPW Sterile Purified Water (USP Grade)

Product	Aquabiliti Catalog Code	Container Type	Size
<b>AQUAPure SPW Sterile Purified Water (USP Grade)</b>	SPW-0010-01	Bioprocess 2D Container (BPC)	10L
	SPW-0020-01	Bioprocess 2D Container (BPC)	20L
	SPW-0050-01	Bioprocess 3D Container (BPC)	50L
	SPW-0100-01	Bioprocess 3D Container (BPC)	100L
	SPW-0200-01	Bioprocess 3D Container (BPC)	200L
	SPW-1100-01	Bioprocess 3D Container (BPC)	1100L

## Cell and Molecular Grade Water (USP Grade)

AQUABILITI's **Cell and Molecular Grade Water (USP Grade)** is manufactured specifically for your most stringent research applications. AQUAPure Cell and Molecular Grade Water is sterile and low endotoxin for your cell culture processes. Protease and nuclease free, it is perfect for any of your molecular biology needs as well as saving valuable lab space and simplifying your purchasing process.

### AQUAPure CMW Cell and Molecular Grade Water

Product	Aquabiliti Catalog Code	Container Type	Size
<b>AQUAPure CMW Cell and Molecular Grade Water (USP Grade)</b>	<b>CMW-0010-01</b>	Bioprocess 2D Container (BPC)	<b>10L</b>
	<b>CMW-0020-01</b>	Bioprocess 2D Container (BPC)	<b>20L</b>



**High Purity Solutions**  
that meet the needs of  
upstream and downstream  
**Bioprocessing and**  
**Manufacturing.**

## 0.9% Sodium Chloride (USP Grade)

AQUABILITI's **0.9% Sodium Chloride (USP Grade)** is produced via inline dilution of a concentrated Sodium Chloride mixture with Water for Injection quality water. Manufactured and tested in compliance with the USP monograph for Sodium Chloride Injection, AQUALutions 0.9% Sodium Chloride (USP Grade) is for further manufacturing use only and not for direct therapeutic use.

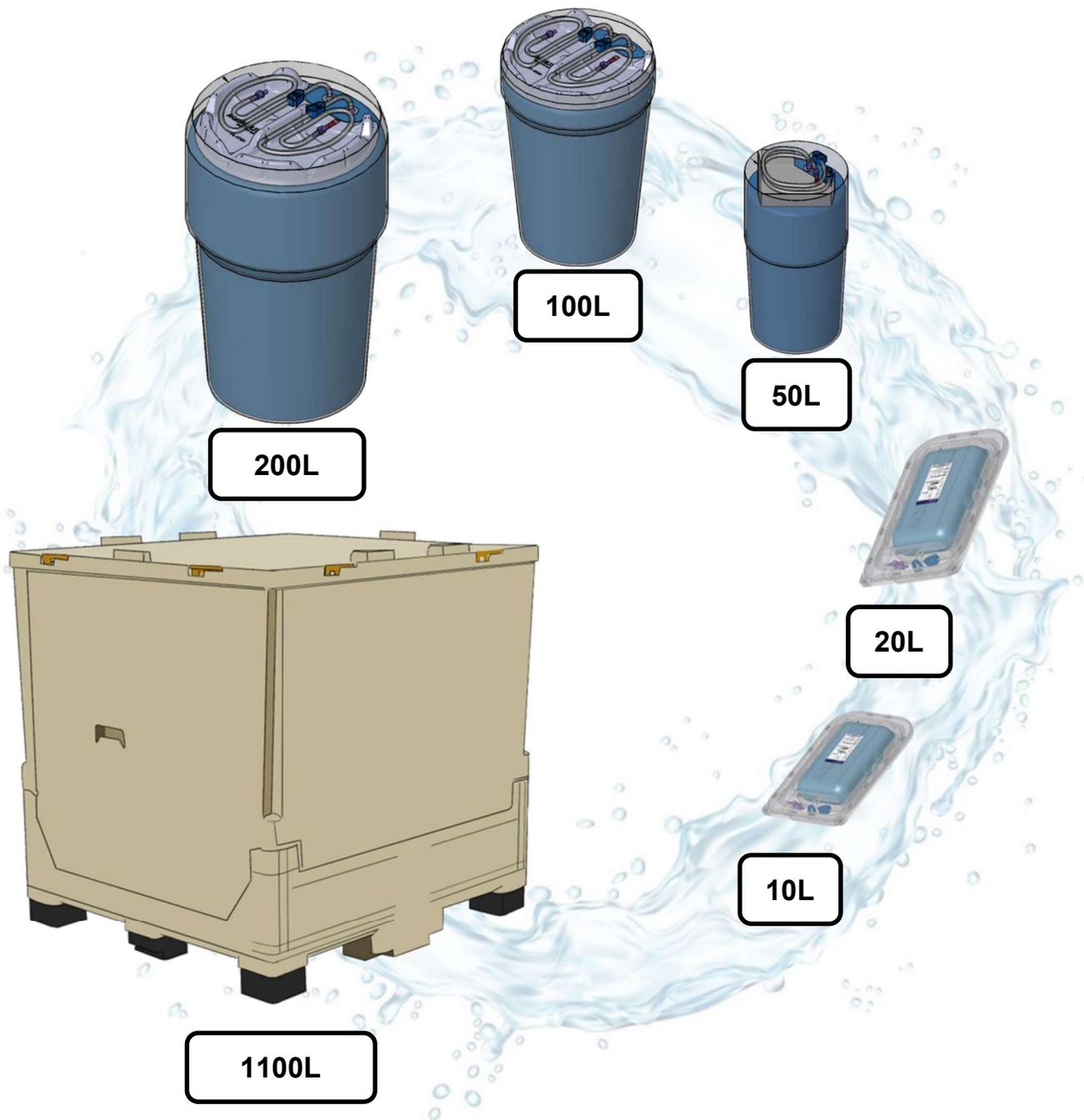
### AQUALutions 0.9% Sodium Chloride (Normal Saline)

Product	Aquabiliti Catalog Code	Container Type	Size
<b>AQUALutions 0.9% Sodium Chloride (USP Grade)</b>	<b>SAL-0010-01</b>	Bioprocess 2D Container (BPC)	<b>10L</b>
	<b>SAL-0020-01</b>	Bioprocess 2D Container (BPC)	<b>20L</b>
	<b>SAL-0050-01</b>	Bioprocess 3D Container (BPC)	<b>50L</b>
	<b>SAL-0100-01</b>	Bioprocess 3D Container (BPC)	<b>100L</b>
	<b>SAL-0200-01</b>	Bioprocess 3D Container (BPC)	<b>200L</b>
	<b>SAL-1100-01</b>	Bioprocess 3D Container (BPC)	<b>1100L</b>

Description	Specification
pH	4.5 – 7.0
Concentration	0.855 – 0.945 %
Endotoxin	≤ 0.5 EU/mL
Sterility	No Growth
Particulate Matter	≤ 3 particles/mL ≥ 25 µm in size ≤ 25 particles/mL ≥ 10 µm in size
Sodium Identification	Present
Chloride Identification	Present
Iron	≤ 2 ppm

# AQUAPure and AQUALutions

## Packaging Options:



## Integrated Quality Approach

Whether for research, development, or commercial production, our products are designed and manufactured to meet the stringent quality requirements of our customers.

To achieve our quality objectives, AQUABILITI has developed and implemented a multi-tier **integrated quality approach** that includes Certifications, Registrations & Compliance, Manufacturing Design, and Risk Management.

### Closed System Filling

Large volume liquid suites use closed system manifold filling for all bioprocess containers.

### Supplier Qualification Program

Focused program to qualify and manage supplier quality performance.

### Change Management Program

Focused program to provide all stakeholders change notification.

### ISO 13485:2016 & 21 CFR 820

ISO 13485:2016 and FDA current Good Manufacturing Practice (cGMP) quality system regulation compliant.

Our quality system and processes are applied consistently across our product portfolio – spanning products used in research and applications to products used in the manufacturing process for commercial biologic therapies.

# Pristine Quality Solutions to Supercharge Your Workflow

**AQUABILITI** enables the life sciences CGT, biotechnology, pharmaceutical and medical device industries to improve productivity and speed.



-  **AQUAPure** **HYPER** Water for Injection (WFI) Quality Water (USP/EP Grade)
-  **AQUAPure** **ULTRA** Water for Injection (WFI) Quality Water (USP Grade)
-  **AQUAPure** **WIR** Water for Irrigation (WIR) Quality Water (USP Grade)
-  **AQUAPure** **SPW** Sterile Purified Water (USP Grade)
-  **AQUAPure** **CMW** Cell and Molecular Quality Water (USP Grade)
-  **AQUALutions** 0.9% Sodium Chloride (Normal Saline)

## How can we help you?

<https://www.aquabiliti.com/contact-us>

or contact your Aquabiliti Account Manager

All products shown are for research and further manufacturing use only.

Not for direct therapeutic use.

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**Aquabiliti Customer  
Service**

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