



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 **AQUALution** 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.

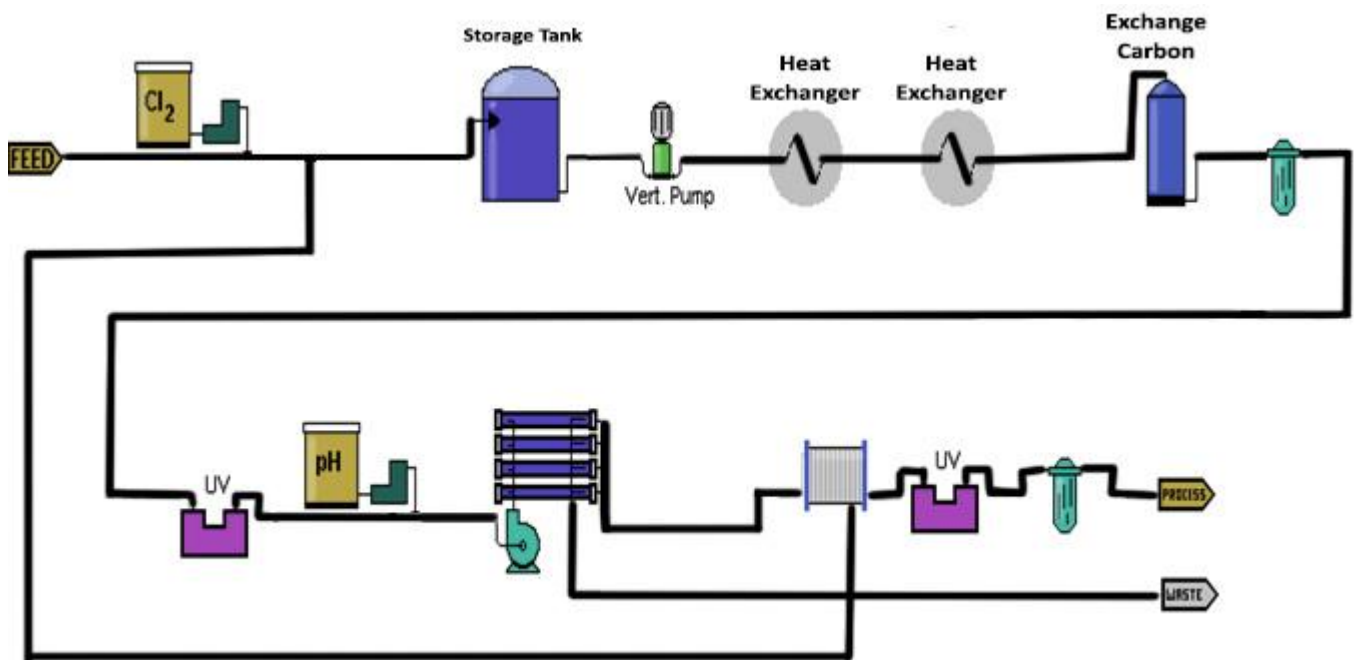
 **AQUAPure** High Purity Compendial Waters

 **AQUALutions** 0.9% Sodium Chloride + Custom Process Solutions

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 ($\mu\text{S}/\text{cm}$)	≤ 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

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






















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

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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	Sterile Water for Irrigation	Sterile Purified Water	Cell and Molecular Grade Water
Grade	AQUAPure USP & EP	AQUAPure USP	AQUAPure USP	AQUAPure USP	AQUAPure USP
Aquabiliti Product Code	HYPER	ULTRA	WIR	SPW	CMW
TOC					
Conductivity					
Endotoxin					
Sterility					
Particulate Matter					
RNase DNase & Protease					
Oxidizable Substances					
Residue on Evaporation					
Nitrates					

The following table shows the methodology used for testing **AQUABILITI's AQUAPure** compendial waters. Because critical processes require unmatched purity, AQUABILITI applies tightened specifications to TOC and endotoxin limits that exceed USP/EP criteria.

Test	Methodology	USP/EP Specifications	Aquabiliti Tightened Specifications
Appearance	Visual Inspection	Clear and Colorless Liquid	Clear and Colorless Liquid
TOC	USP<643>	Before Packaging: < 0.50 mg/L Packaged: < 8.00 mg/L	Before Packaging: ≤ 0.05 mg/L Packaged: ≤ 2.00 mg/L
Conductivity	USP<645>	Before Packaging: ≤ 1.3 µS/cm Packaged: ≤ 5 µS/cm	Before Packaging: ≤ 1.3 µS/cm Packaged: ≤ 5 µS/cm
Endotoxin	USP<85>	≤ 0.25 EU/mL	≤ 0.05 EU/mL
Sterility	USP<71>	No Growth	No Growth
Particulate Matter	USP<788>	≤ 3 particles/mL ≥ 25 µm in size ≤ 25 particles/mL ≥ 10 µm in size	≤ 3 particles/mL ≥ 25 µm in size ≤ 25 particles/mL ≥ 10 µm in size
Oxidizable Substances	EP Sterilized WFI	Solution remains faintly pink	Solution remains faintly pink
Residue on Evaporation	EP Sterilized WFI	≤ 3 mg (0.003%)	≤ 3 mg (0.003%)
Nitrates	EP WFI in Bulk	≤ 0.2 ppm	≤ 0.2 ppm

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
AQUAPure HYPER Water for Injection (WFI) Quality Water (USP/EP Grade)	HYPER-0010-01	Bioprocess 2D Container (BPC)	10L
	HYPER-0020-01	Bioprocess 2D Container (BPC)	20L
	HYPER-0050-01	Bioprocess 3D Container (BPC)	50L
	HYPER-0100-01	Bioprocess 3D Container (BPC)	100L
	HYPER-0200-01	Bioprocess 3D Container (BPC)	200L
	HYPER-1100-01	Bioprocess 3D Container (BPC)	1100L

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
AQUAPure ULTRA Water for Injection (WFI) Quality Water (USP Grade)	ULTRA-0010-01	Bioprocess 2D Container (BPC)	10L
	ULTRA-0020-01	Bioprocess 2D Container (BPC)	20L
	ULTRA-0050-01	Bioprocess 3D Container (BPC)	50L
	ULTRA-0100-01	Bioprocess 3D Container (BPC)	100L
	ULTRA-0200-01	Bioprocess 3D Container (BPC)	200L
	ULTRA-1100-01	Bioprocess 3D Container (BPC)	1100L

Sterile Water for Irrigation (USP Grade)

AQUABILITI's Sterile Water for Irrigation 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 Sterile Water for Irrigation (USP Grade)

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

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
AQUAPure SPW Sterile Purified Water (USP Grade)	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
AQUAPure CMW Cell and Molecular Grade Water (USP Grade)	CMW-0010-01	Bioprocess 2D Container (BPC)	10L
	CMW-0020-01	Bioprocess 2D Container (BPC)	20L



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.

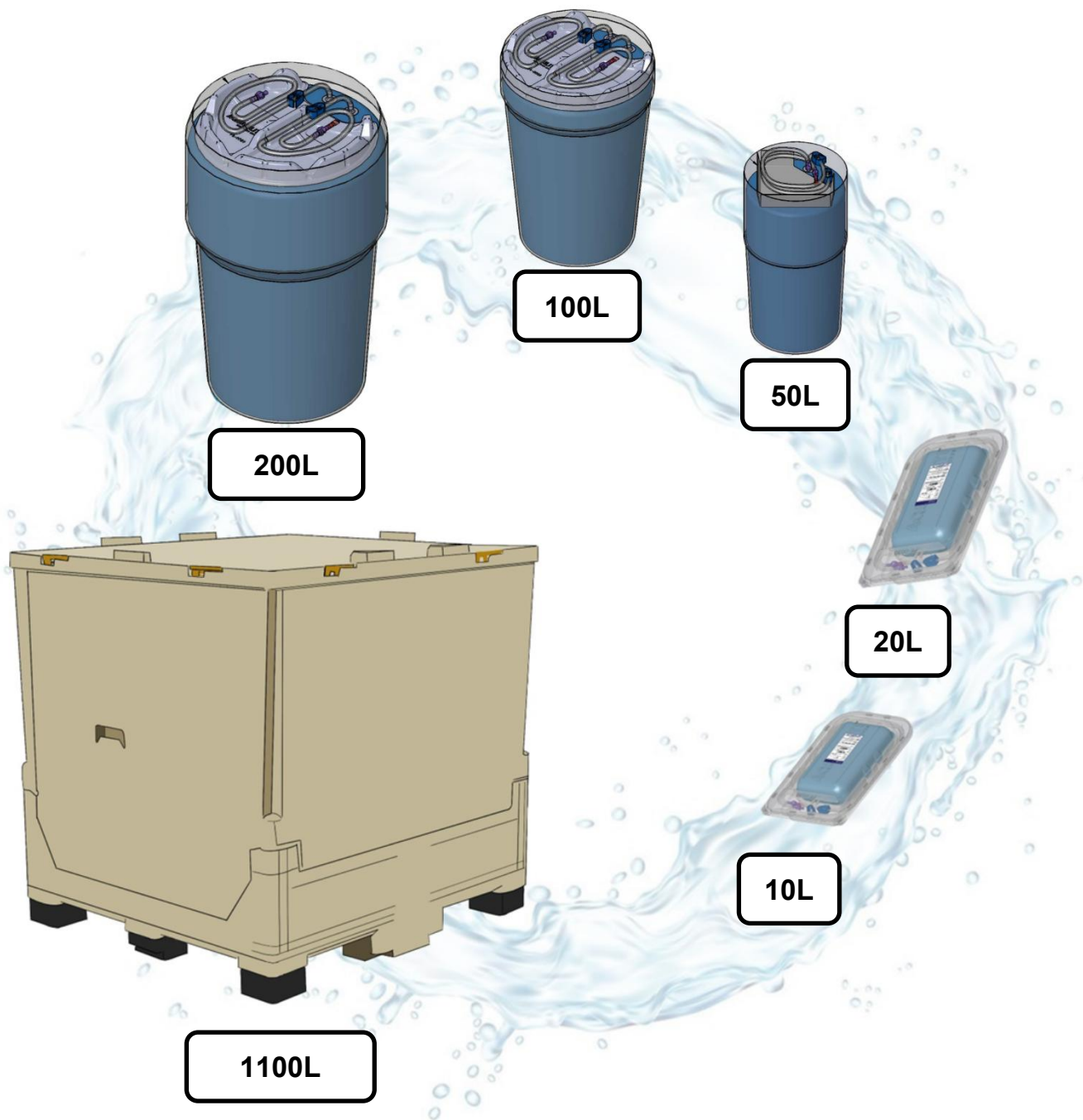
AQUALutions 0.9% Sodium Chloride (Normal Saline)

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

Description	USP Specifications	Aquabiliti Tightened Specifications
pH	4.5 – 7.0	4.5 – 7.0
Concentration	0.855 – 0.945 %	0.855 – 0.945%
Endotoxin	≤ 0.5 EU/mL	≤ 0.05 EU/mL
Sterility	No Growth	No Growth
Particulate Matter	≤ 3 particles/mL ≥ 25 µm in size ≤ 25 particles/mL ≥ 10 µm in size	≤ 3 particles/mL ≥ 25 µm in size ≤ 25 particles/mL ≥ 10 µm in size
Sodium Identification	Present	Present
Chloride Identification	Present	Present
Iron	≤ 2 ppm	≤ 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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