

GE Healthcare

HyClone™ WFI quality and deionized waters

Securing a quality water supply



WFI quality water

Water for injection (WFI) quality water is widely used in the pharmaceutical industry. Today's rapid advances in biotechnology and biopharmaceutical manufacturing create an ever-increasing need for dependable sources of WFI quality water.

Whether your manufacturing need is large volumes of WFI quality water for cell culture processes, for cleaning and rinsing, or for buffer preparation, we have the resources, expertise, and capacity to be your partner of choice.

HyClone HyPure WFI Quality Water:

- Meets stringent Pharmacopeial specifications
- Manufactured in an ISO 9001 certified facility
- Certificate of analysis (CoA) for each lot of water produced
- Low levels of endotoxin
- Sterile filtered



Securing a supply

Installation or scale-up of a WFI system represents a major capital expenditure for any biopharmaceutical company. In addition to the initial investment and dedication of space, an even higher cost comes from validation, maintenance, and monitoring of buildings and equipment as well as from training of personnel. As a result, many leading biopharmaceutical manufacturers have audited and qualified our WFI Quality Water as the preferred outsourced supply or secondary source for large volume demands.

Establishing a supply of ready-to-use WFI quality water in packaging suitable for your application can save time and money.

Processing quality waters

A validated water purification system uses a sequential purification process that converts high-quality source water into ultrapure WFI quality or deionized water.

WFI Quality Water undergoes an extensive purification process to meet or exceed stringent specifications in our ISO 9001 certified facilities. Our cGMP compliant manufacturing and logistics facilities are strategically located to meet the needs of biopharmaceutical and research customers throughout the world.

Process steps	WFI Quality Water	Deionized Water
Pretreatment Particulate removal	✓	✓
Reverse osmosis Removal of organics, colloids, and microbes	✓	✓
Continuous deionization	✓	✓
Ultraviolet light treatment	✓	✓
Multieffect distillation	✓	
> 80°C hot loop Maintenance of sterility during storage	✓	
> 0.1 µm final filtration Microbial barrier when dispensing into single-use containers	✓	✓

Standards for WFI Quality Water

HyPure WFI Quality Water is tested to all applicable chemical, purity, and other acceptance criteria as outlined in the current U.S. Pharmacopeia (USP) or European Pharmacopoeia (EP) for both system and packaged water. Our quality assurance monitoring systems ensure continuous compliance and incorporate stringent action and alert limits. HyPure WFI Quality Water includes a lot-specific CoA for each lot of water produced, listing both acceptance criteria and actual test results.

Applications for WFI quality water include:

- Hydration of cell culture media, supplements, and salt solutions
- Rinsing of primary packaging, production vessels, equipment, and room surfaces
- Reconstitution and rehydration of product during synthesis
- Preparation of buffers for chromatographic purification



Specifications for WFI Quality Water

WFI Quality Water produced in Logan, Utah, USA, is tested to current USP monograph for sterile purified water. Water produced in Pasching, Austria is tested to EP monograph for sterilized water for injection.

US

WFI Quality Water*	Intended use	For manufacturing or research use only, not for diagnostic, therapeutic, or parenteral use.
	Purification method	Reverse osmosis/distillation
	Appearance	Clear liquid
	Sterility	Meets requirements as per USP <71>
	Endotoxin	< 0.25 EU/mL as per USP <85>
	Conductivity	Not more than 5 µS/cm at 25 ± 1°C as per USP <645>
	Oxidizable substances	Not detected
	Particulate matter	Meets requirements as per USP <788>
Deionized Water	Intended use	For manufacturing or research use only, not for diagnostic, therapeutic, or parenteral use.
	Appearance	Clear liquid
	Sterility: bacteria and fungi	No growth
	Endotoxin	≤ 0.25 EU/mL

EU

WFI Quality Water	Intended use	For manufacturing or research use only, not for diagnostic, therapeutic, or parenteral use.
	Purification method	Reverse osmosis/distillation
	Appearance	Clear, colourless liquid
	Sterility: bacteria and fungi	No growth
	Endotoxin	< 0.25 EU/mL
	Conductivity†	< 1.1 µS/cm at 20°C to 25°C
	Oxidizable substances	Meets requirements‡
	Acidity/alkalinity	Meets requirements‡
	Residue on evaporation	Not more than 3 mg (0.003%)
	Chlorides	≤ 0.5 ppm
	Nitrates	≤ 0.2 ppm
	Sulfates	Meets requirements‡
	Ammonium	≤ 0.2 ppm
	Calcium and magnesium	Meets requirements‡
Total organic carbon†	< 500 ppb	

*US manufactured HyPure WFI Quality Water can be tested to EP specifications upon request.

†results reported from BULK WFI on day of fill

‡as per EP monograph 0169

Global manufacturing, packaging, and logistics

Manufacturing facilities are designed to meet stringent regulatory requirements, while serving the global bioproduction market. With facilities and distribution sites around the world, we are able to provide quality waters in lot sizes and delivery systems suitable for your application.

Logistics

Our logistics experts arrange and ship more than 400 domestic and international shipments every month using air, land, and ocean containers and validated freight partners. Logistics experts manage regulatory agencies and requirements to ensure domestic and international trade compliance by coordinating shipments with regulatory agencies or partnering with customer-coordinated transportation.



Standard packaging

WFI Quality Water and Deionized Quality Water is available in the following volumes and packaging configurations. Custom volume, packaging, or testing options are provided on a made to order (MTO) basis.

US			
Product	Packaging	Volume	Product code
WFI Quality Water	Bottle	500 mL	SH30221.17
		1000 mL	SH30221.10
	Single-use bag	10 L	SH30221.24
		20 L	SH30221.25
	Single-use top drain bag	50 L	SH30221.26
		100 L	SH30221.27
		200 L	SH30221.28
	Single-use bottom drain bag	200 L	SH30221.32
		Single-use bag	500 L*
			1000 L*
Deionized Water	Single-use bag	20 L	SH30922.02
	Single-use top drain bag	200 L	SH30922.01

EU			
Product	Packaging	Volume	Product code
WFI Quality Water	Single-use bag	10 L	CH30154.01
		20 L	CH30154.02
	Single-use top drain bag	50 L	CH30154.03
		100 L	CH30154.04
		200 L	CH30154.05
	Single-use bag	500 L*	CH30154.06
		1000 L*	CH30154.09

*Requires purchase of reusable shipping container.

To order or receive additional information, please contact your local sales representative or visit us at [gelifesciences.com/hyclone](https://www.gelifesciences.com/hyclone).



gelifesciences.com/hyclone

GE Healthcare Bio-Sciences AB
Björkgatan 30
751 84 Uppsala
Sweden

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GE Healthcare UK Ltd., Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK
GE Healthcare Europe GmbH, Munzinger Strasse 5, D-79111 Freiburg, Germany
GE Healthcare Bio-Sciences Corp., 100 Results Way, Marlborough, MA 01752, USA
GE Healthcare Dharmacon Inc., 2650 Crescent Dr, Lafayette, CO 80026, USA
HyClone Laboratories Inc., 925 W 1800 S, Logan, UT 84321, USA
GE Healthcare Japan Corp., Sanken Bldg., 3-25-1, Hyakunincho Shinjuku-ku, Tokyo 169-0073, Japan
For local office contact information, visit gelifesciences.com/contact.

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