

# Securing a quality water supply

HyClone™ WFI quality water





# 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 collaborator 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

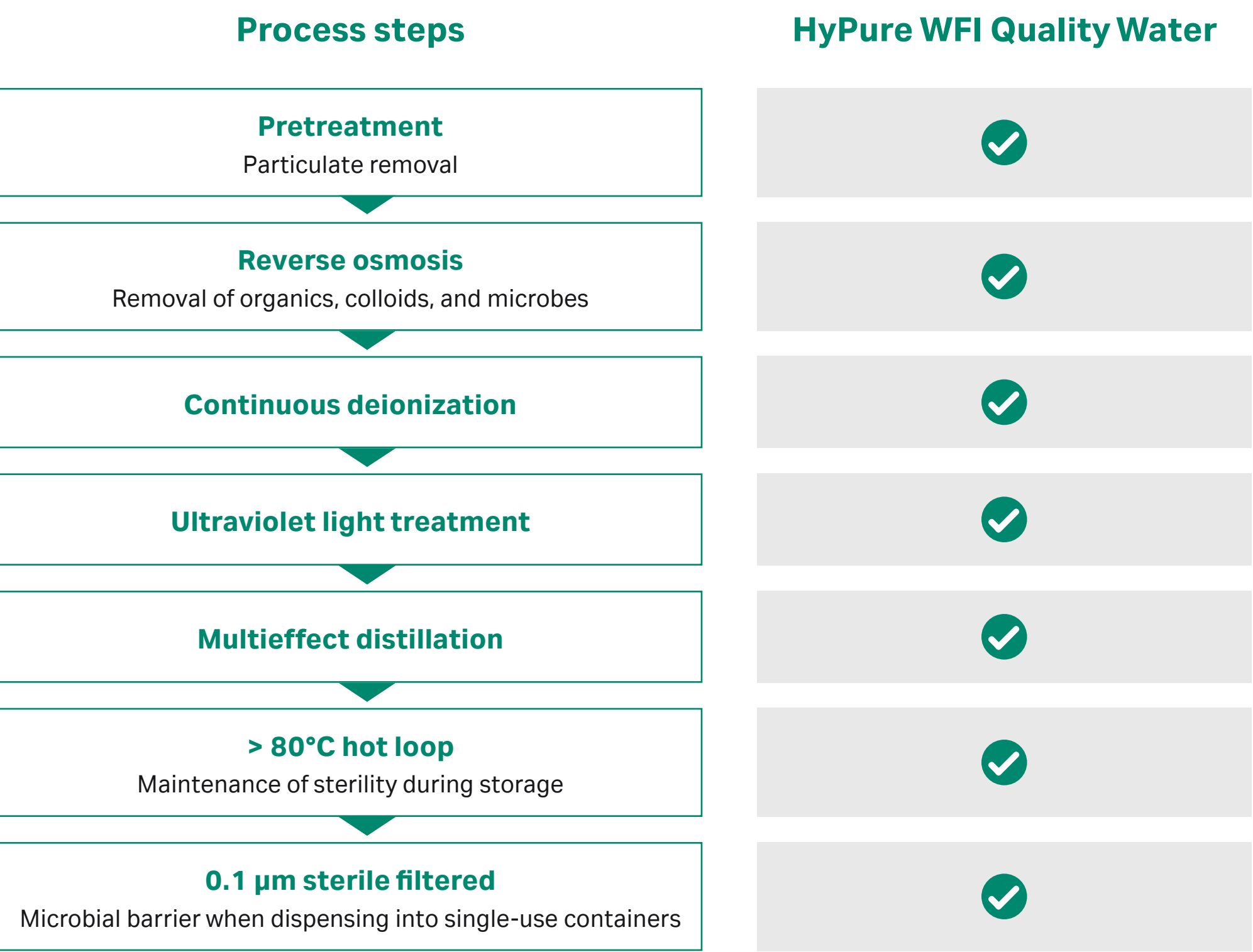
Installation or scale-up of a WFI system represents a major capital expenditure for any biopharmaceutical company. In addition to the initial investment and dedication of space, an even higher cost comes from validation, maintenance, and monitoring of buildings and equipment as well as from training 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 water.

HyPure 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.





# 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 HyPure WFI Quality Water

HyPure WFI Quality Water is produced in Logan, Utah, USA, and Pasching, Austria and tested to USP and EP monograph for packaged sterilized water for injection.

HyPure WFI Quality Water*	
Intended use	For manufacturing or research use only, not for diagnostic, therapeutic, or parenteral use.
Appearance	Clear colorless liquid
Sterility (USP/EP)	No Growth
Endotoxin (USP/EP)	< 0.25 EU/mL
Conductivity (USP/EP)	Not more than 5 µS/cm at 25 ± 1°C
Total organic carbon (USP)	Not more than 8.00 mg/L
Particulate matter (USP/EP)	Meets requirements as per USP <788>/EP2.9.19

\* Applicable to only bagged presentations of HyPure WFI Quality Water product.

Sterilized WFI chemical tests	
Acidity/alkalinity	Meets requirements <sup>†</sup>
Oxidizable substances	Not detected
Residue on evaporation	Not more than 3 mg (0.003%)
Chlorides	Meets requirements
Nitrates	≤ 0.2 ppm
Sulfates	Meets requirements
Ammonium	≤ 0.2 ppm
Calcium and magnesium	Meets requirements

<sup>†</sup> 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 collaborators. Logistics experts manage regulatory agencies and requirements to ensure domestic and international trade compliance by coordinating shipments with regulatory agencies or collaborating with customer-coordinated transportation.

# Standard packaging

HyPure WFI 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.

Product	Packaging	Volume	Product code
HyClone™ HyPure WFI Quality Water	Bottle*	100 mL	SH31191.01
		500 mL	SH31191.02
		1000 mL	SH31191.03
		1000 mL – 6 pack	SH31191.LS
		2000 mL	SH31191.04
	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‡	SH30221.44
		1000 L‡	SH30221.45

\*Bottled products are USP-tested only.  
† Made to order.  
‡ Requires purchase of reusable shipping container.

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

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