



HyClone™ buffers and process liquids

WFI Quality Water, EP

HyPure WFI Quality Water undergoes extensive purification to meet or exceed the stringent specifications of European Pharmacopoeia (EP) and United States Pharmacopeia (USP). Water for injection (WFI) is produced in our facility in Pasching, Austria.

Key features of HyPure WFI Quality Water:

- Manufactured in our ISO 9001 certified facility.
- Meets stringent USP and EP specifications.
- Certificate of analysis (CoA) included with product and available electronically for future reference.

Specifications

The definition for HyPure WFI Quality Water includes the following:

- Must be produced from a validated water purification system that meets or exceeds current EP and USP requirements for HyPure WFI Quality Water.
- Must have a quality assurance monitoring system that ensures continuous compliance and incorporates system test and action limits.
- Must meet all applicable chemical, purity, and other acceptance criteria as outlined in the current USP and EP for both system and packaged water.
- Must include a lot-specific CoA for each lot of water produced, listing both acceptance criteria and actual test results.



Fig 1. HyPure WFI Quality Water.

Quality control testing

Quality control test specifications are listed in Table 1.

Table 1. Test specifications (EP)

Appearance	Clear, colorless liquid
Sterility testing	No growth (bacteria or fungi)
Chemical tests	
Ammonium	Pass
Calcium/magnesium	Pass
Chloride	Pass
Nitrates	Pass
Sulfates	Pass
Physical tests	
Acidity/alkalinity	Pass
Residue on evaporation	Pass
Endotoxin	< 0.25 EU/mL
Conductivity at 25°C–30°C (on day of fill)	≤ 1.3 µS/cm
Oxidizable substances	Pass
Total organic carbon (on day of fill)	< 500 ppb

Applications

HyPure WFI Quality Water is intended for further manufacturing or research use. Not for diagnostic or therapeutic use.

Applications for HyPure 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 rinse, purification, and chromatography buffers.
- Further manufacturing of finished product.

Ordering information

HyPure WFI Quality Water is available in lot sizes up to 10 000 L and packaging configurations up to 1000 L.

Production quantities of HyClone HyPure WFI Quality Water, EP are available in single-use bags.

Product	Product Size	Product code
HyClone HyPure WFI Quality Water, EP Animal-derived component-free	10 L	CH30154.01
	20 L	CH30154.02
	50 L	CH30154.03
	100 L	CH30154.04
	200 L	CH30154.05
	500 L*	CH30154.06
	1000 L*	CH30154.09

*Requires purchase of reusable shipping container

Research quantities of HyClone HyPure WFI Quality Water, USP are available in bottles.

Related products	Size	Product code
HyClone HyPure WFI Quality Water, USP Animal-derived component-free	100 mL	SH30221.18
	500 mL	SH30221.17
	1000 mL	SH30221.10
	6 × 1000 mL	SH30221.LS
HyClone HyPure Molecular Biology Grade Water	100 mL	SH30538.01
	500 mL	SH30538.02
	1000 mL	SH30538.03
	6 × 500 mL	SH30538.FS
	6 × 1000 mL	SH30538.LS
HyClone HyPure Cell Culture Grade Water	100 mL	SH30529.01
	500 mL	SH30529.02
	1000 mL	SH30529.03
	6 × 500 mL	SH30529.FS
	6 × 1000 mL	SH30529.LS

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