

WFI Quality Water, US

HYCLONE BUFFERS AND PROCESS LIQUIDS

HyClone™ HyPure WFI Quality Water undergoes extensive purification to meet or exceed the stringent specifications of United States Pharmacopeia (USP). Water for injection (WFI) is produced in our ISO 9001 certified facilities to ensure a high quality product (Fig 1).

Key features of HyPure WFI Quality Water:

- Meets stringent USP specifications
- Manufactured in our ISO 9001 certified facility
- Lot-specific certificate of analysis (CoA) for each lot of water produced

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 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 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. Actual test results on a CoA are not taken from system samples, but must be from actual packaged samples of the given lot



Fig 1. HyPure WFI Quality Water.

Quality control testing

Quality control test specifications are listed in Table 1.

Table 1. Test specifications (USP)*

Appearance	Clear liquid
Sterility testing	No growth (bacteria or fungi)
Endotoxin	< 0.25 EU/mL
Conductivity at 24°C–26°C (per current USP)	≤ 5 µS/cm
Oxidizable substances	Not Detected
Particulate matter for larwvolume injection	≤ 25/mL of ≥ 10 µm ≤ 3/mL of ≥ 25 µm

* Additional European Pharmacopoeia (EP) testing available upon request.

Applications

HyPure WFI Quality Water is intended for 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

Ordering information

HyPure WFI Quality Water is available in lot sizes up to 20 000 L and packaging configurations up to 1000 L.

Production

Production quantities are available in single-use bags.

Product	Size	Product code
HyClone HyPure WFI Quality Water, US Animal-derived component-free	10 L	SH30221.24
	20 L	SH30221.25
	50 L	SH30221.26
	100 L	SH30221.27
	200 L*	SH30221.28
	200 L†	SH30221.36
	500 L‡	SH30221.44
	1000 L‡	SH30221.45

* Supplied in container with a 4-port top drain with a dip tube.

† Supplied in container with a 2-port top drain.

‡ Requires purchase of reusable shipping container.

Research

Research quantities are available in bottles.

Product	Size	Product code
HyClone HyPure WFI Quality Water, US Animal-derived component-free	100 mL	SH30221.18
	500 mL	SH30221.17
	1000 mL	SH30221.10
	6 × 1000 mL	SH30221.LS

Related products	Size	Product code
HyClone HyPure WFI Quality Water, US Animal-derived component-free	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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