

HyClone™ HyPure Water for Injection (WFI) Quality Water

Support cell culture growth and biomanufacturing processes with Water for Injection (WFI) quality water.

Overview

Support cell culture growth and biomanufacturing processes with Water for Injection (WFI) quality water.

- Meets stringent USP and/or EP compendial grade specifications.
- Manufactured in ISO 9001 certified facility.
- Lot-specific certificate of analysis (CoA) for each lot of water produced.
- Intended for further manufacturing or research use. Not for diagnostic or therapeutic use.

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

HyPure WFI Quality Water meets the following criteria: Must be produced from a validated water purification system that meets or exceeds current USP and/or EP 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/or 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. Actual test results on a CoA are not taken from system samples but must be from actual packaged samples of the given lot.

Product specifications
HyClone™ HyPure WFI quality water, USP grade, 2000 mL

Catalog code	SH31191.04
Certifications/Compliance	Manufactured in cGMP (21 CFR 820) compliant and ISO90001 certified facilities
Format	Liquid
Shelf life	24 months
Sterilization	0.1 µm sterile filtered
Storage	2° to 30° C

DOMINIQUE DUTSCHER SAS