SARTORIUS

Product Datasheet

4Cell® WFI-Quality Water

Bulk-packaged water for injection

Product Information

Our 4Cell® WFI-Quality Water* is aseptically processed from a validated water for injection (WFI) system that meets current United States Pharmacopeia (USP) and European Pharmacopeia (EP) specifications. Prepared through ultrafiltration, reverse osmosis, deionization, distillation, and sterile filtration, it provides immediate, off-the-shelf access to compliant WFI for off-loop applications, peak demand, maintenance, shutdown, or validation activities.

* Not for parenteral administration or in vitro diagnostics (IVD).

Features and Benefits

- Increase capacity instantly: Ensure continuous access to compliant WFI-quality water
- Simplify validation: Supplied in Flexsafe® bags with Certificate of Analysis and samples for incoming goods testing
- Meet the highest quality standards: Manufactured under certified ISO 13485 and ISO 9001 and in accordance with cGMP guidelines
- Achieve regulatory compliance: Released according to USP and EP specifications
- Maintain stored supply: Two-year shelf-life

Overview

Relevant applications
- 4Cell® WFI-Quality Water is intended for further manufacturing or research use only. It is not intended for parenteral or IVD use.
- 4Cell® WFI-Quality Water is distinct from sterile water for injection, which is intended for use in extemporaneous prescription compounding and as a diluent for injectable parenteral products.

Relevant process steps
- Hydration of cell culture media and buffers
- Rinsing of equipment or surfaces
- Downstream processing steps such as clarification and chromatography

4Cell® WFI-Quality Water provides an immediate supply of regulatory-compliant WFI to support increased demand or off-loop applications in bioprocessing workflows. It is supplied in Flexsafe® bags stored in different secondary packagings depending on the nominal volume. For large demand, it can be supplied in Palletank® containers with a returnable Palletank® shipping service available to support more sustainable logistics.

Proven and documented compatibility with Flexsafe® bags

Flexsafe® bags demonstrate excellent compatibility with 4Cell® WFI-Quality Water, achieving the highest performance rating with no impact on WFI quality over its two-year shelf life. Volatile and non-volatile extractables from Flexsafe® bags are not detected above reporting limits in 4Cell® WFI-quality water.

Technical Specifications

Release criteria	Specifications (at 25 °C)	Test method
Sterility	Sterile	USP <71> | EP 2.6.1
Conductivity	≤ 5 µS/cm*	USP <645> | EP 0169
pH	5 –7	USP <791> | EP 2.2.3
Endotoxin	< 0.25 EU/mL	USP <85> | EP 2.6.14
TOC before packaging	< 500 ppb in the loop**	USP <643> | EP 0169 | EP 2.2.44

Note. TOC = total organic carbon.

* ≤ 5 µS/cm corresponds to the conductivity specification for the packaged product, as defined in the USP and EP.

** < 500 ppb is the requirement for water in the recirculating loop, as specified in the USP and EP.

Ordering Information

Description	Region	Primary packaging	Material number	Secondary packaging	Order number
4Cell® WFI-Quality Water 20 L	Europe and Asia	Flexsafe® 2D Bag	FLS311046	Corrugated plastic box	CFB3FA3306
4Cell® WFI-Quality Water 1 L sample	Europe and Asia	Flexsafe® 2D Bag	FLS311043	Corrugated cardboard box	CFB3FA3306S*
4Cell® WFI-Quality Water 200 L	Europe and Asia	Flexsafe® 3D Bag	FIS311208	PE drum	CFB3FA3309**
4Cell® WFI-Quality Water 20 L	Americas	Flexsafe® 2D Bag	FLS308138	Corrugated plastic box	CFB3FA3206
4Cell® WFI-Quality Water 200 L	Americas	Flexsafe® 3D Bag	FIS307161	PE drum	CFB3FA3209**

* Material CFB3FA3306S cannot be ordered as a standalone item. It must be ordered together with item CFB3FA3306. If the same batch is required for the sample and CFB3FA3306, it must be clearly specified in the order.

** 1 sample is included in the drum.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Göttingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
sartorius.com

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