SARTORIUS

Product Datasheet

Water for Injection

Bulk Packaged WFI-Quality Water

Product Information

Bulk Packaged for Commercial Use Elsewhere, Not for Parenteral Administration
Our WFI-Quality Water is aseptically processed from a validated Water For Injection System that meets current USP and EP specifications in the loop. Our WFI-Quality Water is not to be confused with Sterile Water for Injection which is intended for use in extemporaneous prescription compounding, and as a diluent for injectable parenteral products. We manufacture and test our Water For Injection (WFI)-quality products to strict industry standards. Prepared through a process of ultrafiltration, reverse osmosis, deionization, distillation and sterile filtration, we meet or exceed USP and EP requirements.

Benefits

- Highest quality standards: WFI-Quality Water is manufactured according to 21CFR820 guidelines
- Fast implementation: Flexsafe® bags can be used at every stage of the process for all applications
- Regulatory compliant: WFI-Quality Water is released based on EP and USP specifications

Derisking Media & Buffer Preparation by Outsourcing WFI-Quality Water

Release Criteria	Specifications (at 25 °C)	Test Method
Sterility	Sterile	<USP71> | EP 2.2.6.1
Conductivity	≤ 5 µS/cm*	<USP645> | EP 2.2.38
pH	5 to 7	<USP791> | EP 2.2.3
Endotoxin	< 0.25 EU/ml	<USP85> | EP 2.6.14
TOC**	< 500 ppb in the loop***	<USP643> | EP 2.2.44

Feature	Benefit
Packaged in Flexsafe® bags	Ready-to-use
Manufactured and released according to both EP | USP	Fast validation
Off-the-shelf 20 L and 200 L bags	Instant capacity increase
Standard and customized bag sizes and designs	Avoid CAPEX for installing onsite WFI loop and associated maintenance costs

* ≤ 5 µS/cm is corresponding to the Conductivity packaged as specified in the European and US pharmacopeias
** TOC: Total Organic Carbon
*** 500 ppb is the requirement for water in the recirculating loop as specified in the European and US pharmacopeias

Our dedicated team of Project Managers will help you select the best solution for the supply of your products and minimize the burden of transport logistics associated with large volumes of liquids.

WFI and Buffers in Biologics Manufacturing

All our liquid formulations are manufactured in ISO certified facilities following the strict guidelines and are packaged in our robust Flexsafe® bags. The complete range of scalable Flexsafe® bags enables you to implement single-use bioprocessing throughout all steps of drug manufacture, from process development to production – all using just one film.

- WFI-Quality Water
- Acids, Bases & Alcohols (HCl, NaOH, EtOH)
- Organic Solvents (Glycine, HEPES)
- Phosphate- and Amine-based (PBS, Tris)

Description	Primary Packaging	Secondary Packaging	Region	Material Number
WFI-Quality Water 20 L	Flexsafe® 2D Bag	Corrugated Plastic Box	Europe & Asia	CFB3FA3306
WFI-Quality Water 200 L	Flexsafe® 3D Bag	PE Drum	Europe & Asia	CFB3FA3309
WFI-Quality Water 20 L	Flexsafe® 2D Bag	Corrugated Plastic Box	Europe & Asia	CFB3FA3006
WFI-Quality Water 200 L	Flexsafe® 3D Bag	PE Drum	Europe & Asia	CFB3FA3009

Your Customized Formulations

Our buffer & media specialists will support you to create a solution that perfectly matches your expectations.
For critical raw materials you can either request specific suppliers or rely upon our established global network of qualified suppliers. Customized primary and secondary packaging and release assays are also available upon request to our Media Project Managers.

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Status: 08 | 2023