



SPECIFICATION SHEET

Product Name Water for Injection (WFI) - packaged
Grade Pharmaceutical Grade
Catalog # 2333991
Date 06-Mar-2025
Manufactured by: Greenfield Global LFS Ireland Limited, IDA Business & Technology Park Mountrath Road, Portlaoise, Laois, R32 PXV6, Ireland
Packaged by: Greenfield Global LFS Ireland Limited, IDA Business & Technology Park Mountrath Road, Portlaoise, Laois, R32 PXV6, Ireland

TEST	METHOD	SPECIFICATION
Appearance	Internal	Clear and Colourless
Total Aerobic Microbial Count (TAMC)	USP/EP	NMT 10 CFU/100 mL
Endotoxin	USP/EP	<0.25 EU/mL
Total Organic Carbon (TOC)	USP/EP	Max. 0.50 mg/L
Water Conductivity	USP/EP	Meet Requirements
Nitrates	EP	0.2 ppm max.
pH	Internal	4.0 – 7.5

Certification and Compliance Statements

This WFI water product complies with all the above-mentioned specifications as per USP and EP Water for injection monographs. TOC and Conductivity test results are reported from online instruments. Online conductivity is measured at Stage 1 as per USP/EP.

GMP compliance: This product is processed and packaged in compliance with excipient Good Manufacturing Practices.

This product is not sterile. This product contains no antimicrobial or other substance and is not intended for direct parenteral administration. USP <1231>: It is the user's responsibility to ensure fitness for use of this packaged product when it is used in manufacturing, clinical, or analytical applications where the purer bulk form of the water is indicated.