



Certificate of Analysis

Water for Injection, USP Sterile Grade

Product Number: WFI-USP-2XL

Lot Number: 31304211
Date of Manufacture: 2021-04-13
Expiration Date: 2024-04-13
Storage Temperature: 2 - 30 °C

BASIS FOR RELEASE

Test	Method	Specification	Result
Appearance	Visual	Clear and Colorless Liquid	Clear and Colorless Liquid
Conductivity (Packaged)	USP <645>	≤ 5.0 μS/cm	0.50 μS/cm
Endotoxin	USP <85>	< 0.25 EU/mL	< 0.005 EU/mL
Oxidizable Substances	USP	The Pink Color does not Completely Disappear	Pass
Particulate Matter	USP <788>	≤ 3 particles per mL that are ≥ 25 μm in size	0.07 particles/mL
Particulate Matter	USP <788>	≤ 25 particles per mL that are ≥ 10 μm in size	1.87 particles/mL
pH	USP <791>	5.0 - 7.0	5.99
Sterility	USP <71>	No Growth	No Growth
TOC (Before Packaging)	USP <643>	< 500 ppb	26.02 ppb

This lot has been produced using Current Good Manufacturing Practices (cGMP). The solution meets all requirements for residual solvents USP <467>.

This product is not of animal origin and does not contain, make use of or involve animal components during its manufacturing process.

No antimicrobial or other substance has been added.

STATEMENT FOR USE

This product is for further manufacturing, laboratory, or research use only.
Not intended for direct human or veterinary parenteral administration or where prohibited by law.

Approval

Quality Assurance – Print Name:	Quality Assurance – Sign Name:	Date:
Jessica Hymas		30 Apr 2021