Certificate of Analysis

Water for Injection, EP/USP Sterile Grade

Product Number: **WFI-EPZ-2XL**

Lot Number: **30504211**
Date of Manufacture: **2021-04-05**
Expiration Date: **2024-04-05**
Storage Temperature: **2 - 30 °C**

BASIS FOR RELEASE

Test	Method	Specification	Result
Acidity-Alkalinity	EP	Conforms	Pass
Ammonium	EP	≤ 0.2 ppm	Pass
Appearance	Visual	Clear and Colorless Liquid	Clear and Colorless Liquid
Calcium and Magnesium	EP	A Blue Color is Produced	Pass
Chlorides	EP	No Change in Appearance	Pass
Conductivity (Packaged)	USP/EP	≤ 5.0 µS/cm	0.44 µS/cm
Endotoxin	USP/EP	< 0.25 EU/mL	< 0.005 EU/mL
Nitrates	EP	≤ 0.2 ppm	Pass
Oxidizable Substances	USP/EP	The Solution Remains Faintly Pink	Pass
Particulate Matter	USP/EP	≤ 3 particles per mL that are ≥ 25 µm in size	0.00 particles/mL
Particulate Matter	USP/EP	≤ 25 particles per mL that are ≥ 10 µm in size	0.87 particles/mL
pH	USP/EP	5.0 - 7.0	5.65
Residue on Evaporation	EP	≤ 3.0 mg (0.003%)	Pass
Sterility	USP/EP	No Growth	No Growth
Sulfates	EP	No Change in Appearance	Pass
TOC (Before Packaging)	USP/EP	≤ 0.5 mg/L	0.05 mg/L

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		23 Apr 2021

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