



# Certificate of Analysis

## Water for Injection, EP/USP Sterile Grade

Product Number: WFI-EPZ-2XL

Lot Number: 31204211  
Date of Manufacture: 2021-04-12  
Expiration Date: 2024-04-12  
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	0.74 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	0.07 particles/mL
Particulate Matter	USP/EP	≤ 25 particles per mL that are ≥ 10 μm in size	1.13 particles/mL
pH	USP/EP	5.0 - 7.0	5.93
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	0.04 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		30 Apr 2021

### Intermountain Life Sciences

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