



3159 Staley Road, Grand Island, NY 14072, (716) 773-0800

Certificate of Analysis

Finished Product

Product Name: Sterile Water for Injection, USP			
Product Code: 185100	Lot Number: 6011518		
Manufacture Date: 02-24-16			
Release Date: 03-31-16	Expiration Date: 02/19		
Analysis	Specifications	Results	Conforms
Visual Inspection			
1. Appearance	1. Clear solution in a vial	1. Clear solution in a vial	✓
2. Particulate Matter	2. Essentially free from visible particulate matter	2. Meets Specification	✓
3. Clarity	3. Clear	3. Clear	✓
4. Color	4. Colorless	4. Colorless	✓
5. Container/Closure	5. Container is intact	5. Container is intact	✓
Conductivity	NMT 5 μ S/cm	2 μ S/cm	✓
Oxidizable Substances	The pink color does not completely disappear	Meets Specification	✓
Volume in Container 100 mL Label Claim	NLT 100 mL/vial	NLT 100 mL	✓
Container/Closure Integrity Green Dye Immersion	The absorbance of the sample is less than or equal to 0.000, or the absorbance difference between the test sample and the negative control is NMT 0.002.	Meets Specification	✓
Container/Closure Integrity Wilcomat - Differential Pressure (DP) Test	Sample DP values are lower than the self test DP values.	Meets Specification	✓
Particulate Matter	1. For particles $\geq 10\mu$ m: NMT 6,000 particles per vial 2. For particles $\geq 25\mu$ m: NMT 600 particles per vial	Beg Mid End 1. 600 467 413	✓
		2. 0 0 7	✓
Sterility Test	Sterile	Sterile	✓
Bacterial Endotoxins Test	Less than 0.25 EU per mL	< 0.05 EU per mL	✓
Other Requirements	Meets requirements of USP <1>	Meets Specification	✓
Labeling	Label it to indicate that no antimicrobial or other substance has been added, and that it is not suitable for intravascular injection without first having been made approximately isotonic by the addition of a suitable solute.	Meets Specification	✓

Statement of Compliance to USP <467>

This finished product complies to the USP <467> General Chapter for Residual Solvents per Option 1.

This product conforms to the specifications established by
Fresenius Kabi USA, LLC

[Signature] 03-31-16
Product Release Management