



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

Certificate of Analysis

Finished Product

Product Name: Sterile Water for Injection, USP		Lot Number: 6010670	
Product Code: 918510		Manufacture Date: 10-20-15	
Release Date: 11-18-15		Expiration Date: 10/18	
Analysis	Specifications	Results	Conforms
Color of Solution	Compares to Standard	Compares to standard, 0	✓
Oxidizable Substances	The pink color does not completely disappear	Meets Specification	✓
Visual Inspection			
1. Description	1. Solution in a 10 cc Plastic Vial	1. Solution in a 10cc Plastic Vial	✓
2. Clarity	2. Clear	2. Clear	✓
3. Particulate Matter	3. Essentially free from visible particulate	3. Meets Specification	✓
4. Color	4. Colorless	4. Colorless	✓
Volume Check	NLT 10 mL	NLT 10 mL	✓
Conductivity	NMT 25 μ S/cm	2 μ S/cm	✓
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	✓
Particulate Matter	1. $\geq 10\mu$ m: NMT 6,000 particles per container 2. $\geq 25\mu$ m: NMT 600 particles per container	Beg Mid End	
		1. 121 98 126	✓
		2. 0 1 1	✓
Sterility	Sterile	Sterile	✓
Bacterial Endotoxins	< 0.25 EU/mL	< 0.05 EU/mL	✓

Statement of Compliance to USP <467>	This finished drug product complies to the USP <467> General Chapter for Residual Solvents per Option 1.
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This product conforms to the specifications established by
Fresenius Kabi USA, LLC

Product Release Management

11-18-15