FRESENIUS KABI

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:	6011521
Manufacture Date:	02-26-16		
Release Date:	04-08-16	Expiration Date:	02/19

Analysis	Specifications	Results	Conforms
Visual Inspection 1. Appearance 2. Particulate Matter 3. Clarity 4. Color 5. Container/Closure	 1. Clear solution in a vial 2. Essentially free from visible particulate matter 3. Clear 4. Colorless 5. Container is intact	 1. Clear solution in a vial 2. Meets Specification 3. Clear 4. Colorless 5. Container is intact	 ✓ ✓ ✓ ✓ ✓
Conductivity	NMT 5 µS/cm	2 µS/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	✓
Particulate Matter	1. For particles ≥ 10µm: NMT 6,000 particles per vial 2. For particles ≥ 25µm: NMT 600 particles per vial	Pt1/Pt2 Beg Mid End 1.700/340 700/227 1213/560 2. 0/1 20/0 0/0	✓ ✓
Sterility Test	Sterile	Sterile	✓
Bacterial Endotoxins Test	Less than 0.25 EU per mL	<0.05 EU/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

04-08-16

Product Release Management