

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

Certificate of Analysis

Finished Product

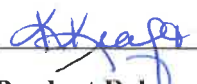
Product Name:	Sterile Water for Injection, USP		
Product Code:	918510	Lot Number:	6007073
Manufacture Date:	11-15-13		
Release Date:	12-29-13	Expiration Date:	11/16

Analysis	Specifications	Results	Conforms
Color of Solution	Compares to Standard	Compares to Standard: 0	✓
Oxidizable Substances	The pink color does not completely disappear	Meets Specifications	✓
Visual Inspection: A. Description B. Clarity C. Particulate Matter D. Color	A. Solution in a 10 cc Plastic vial B. Clear C. Essentially free from visible particulate D. Colorless	A. Solution in a 10 cc Plastic vial B. Clear C. Meets Specifications D. Colorless	✓ ✓ ✓ ✓
Volume Check	NLT 10 mL	NLT 10 mL	✓
Conductivity	NMT 25 μS/cm	2 μS/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 its first having been made approximately isotonic by the addition of a suitable solute	Meets Specification	✓
Particulate Matter	1. For particles ≥ 10 μm, NMT 6,000 per container	1. Beg. 175 Mid. 58 End 213	✓
	2. For particles ≥ 25 μm, NMT 600 per container	2. 0 0 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

This product conforms to the specifications established by
APP Pharmaceuticals

 12-29-13
 Product Release Management