APP®
A Company of the Fresenius Kabi Group

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Certificate of Analysis
Finished Product

Product Name:	Sodium Chloride Injection, USP		
Product Code:	918610	**Lot Number:**	6007948
Manufacture Date:	05-23-14		
Release Date:	06-27-14	**Expiration Date:**	05/16

Analysis	Specifications	Results	Conforms
Assay (9mg/mL)	95.0% – 105.0% of Label Claim	Method No.: 1 100.1%	✓
Color of Solution	Compares to Standard	Compares to Standard, 0	✓
Heavy Metals	NMT 0.001%	NMT 0.001%	✓
Identification 1. Chloride 2. Sodium	1. Solutions of chlorides yield with silver nitrate TS a white, curdy precipitate that is insoluble in nitric acid but is soluble in a slight excess of 6 *N* ammonium hydroxide. 2. Add 15% potassium carbonate and heat to boiling, no precipitate is formed. Add potassium pyroantimonate TS and heat to boiling, cool, a dense precipitate is formed. Sodium compounds impart an intense yellow color to a non-luminous flame.	1. Meets Specification 2. Meets Specification	✓ ✓
Labeling	The label states the total osmolar concentration is mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL.	Meets Specification	✓
Iron	NMT 2 ppm	NMT 2ppm	✓
pH	4.5 – 7.0	5.2	✓
Visual Inspection 1. Clarity 2. Particulate Matter 3. Container/Closure	1. Clear 2. Essentially no visible particles 3. Container is intact	1. Clear 2. Essentially no visible particles 3. Container is intact	✓ ✓ ✓
Volume in Container 10 mL Label Claim	NLT Label Claim	NLT 10mL	✓
Sterility	Sterile	Sterile	✓
Bacterial Endotoxins	NMT 0.5 EU/mL	<0.3EU/mL	✓
Particulate Matter	1. Does not exceed 6000 particles ≥ 10 microns per container 2. Does not exceed 600 particles ≥ 25 microns per container	Beg. Mid. End 1. 65 24 68 2. 0 0 1	✓ ✓
Other Requirements	Meets the requirements under Injections USP <1>	Meets Specifications	✓

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

Mmm 06-27-14

Product Release Management