



A Company of the Fresenius Kabi Group

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Certificate of Analysis

Finished Product

Product Name:	Sodium Chloride Injection, USP		pg. 1 of 2
Product Code:	918602	Lot Number:	6008082
Manufacture Date:	06-26-14		
Release Date:	07-31-14	Expiration Date:	03/16

Analysis	Specifications	Results	Conforms
Visual Inspection			
1. Clarity	1. Clear	1. Clear	✓
2. Particulate Matter	2. Essentially free from visible particulate matter	2. Essentially free from visible particulate matter	✓
3. Container / Closure	3. Container is intact	3. Container intact	✓
pH	4.5 – 7.0	5.4	✓
Volume Check	NLT 2 mL	NLT 2 mL	✓
Color of Solution	Compares to Standard	Compares to Standard: 0	✓
Heavy Metals	NMT 0.001%	NMT 0.001%	✓
Iron	NMT 2 ppm	NMT 2 ppm	✓
Identification			
1. Chloride	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.	1. Meets specification	✓
2. Sodium	2. Add 15% potassium carbonate, no precipitate is formed. Add potassium pyroantimonate TS, a dense precipitate is formed. Sodium compounds impart an intense yellow color to a non-luminous flame.	2. Meets specification	✓
Assay (9 mg/mL)	95.0 – 105.0% of Label Claim	99.9%	✓
Labeling	The label states the total osmolar concentration in 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	✓
Particulate Matter			
	1. For particles $\geq 10 \mu\text{m}$, NMT 6,000 per container	Beg. Mid. End 1. 6 6 5	✓
	2. For particles $\geq 25 \mu\text{m}$, NMT 600 per container	2. 0 0 0	✓

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Analysis	Specifications	Results	Conforms
Sterility	Sterile	Sterile	✓
Bacterial Endotoxins	NMT 0.5 EU/mL	< 0.3 EU/mL	✓
Other Requirements	Meets the requirements under Injection <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
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**This product conforms to the specifications established by
APP Pharmaceuticals**

CA 07-31-14

Product Release Management