



A Company of the Fresenius Kabi Group

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

Certificate of Analysis Finished Product

Product Name:	Sodium Chloride Injection, USP		
Product Code:	918620	Lot Number:	6005452
Manufacture Date:	01-17-13		
Release Date:	08-18-13	Expiration Date:	01/15

Analysis	Specifications	Results	Conforms												
Assay (9mg/mL)	95.0 – 105.0% of Label Claim	Method No.: 1 100.0%	✓												
Color of Solution	Compares to Standard	Compares to Standard: 2	✓												
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	✓ ✓												
Iron	NMT 2 ppm	NMT 2 ppm	✓												
pH	4.5 – 7.0	5.1	✓												
Visual Inspection 1. Clarity 2. Particulate Matter 3. Container/Closure	1. Clear 2. Essentially free from visible particles 3. Container is intact	1. Clear 2. Essentially free from visible particles 3. Container is intact	✓ ✓ ✓												
Volume in Container 20mL Label Claim	NLT Label Claim	NLT 20mL	✓												
Labeling	The label states the total osmolar concentration is mOsmol per L. Where the contents are less than 100mL, 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	✓												
Sterility	Sterile	Sterile	✓												
Bacterial Endotoxins	NMT 0.5 EU/mL	<0.3 EU/mL	✓												
Particulate Matter	1. Does not exceed 6000 particles ≥ 10 microns per container 2. Does not exceed 600 particles ≥ 25 microns per container	<table><tr><td></td><td>Beg.</td><td>Mid.</td><td>End</td></tr><tr><td>1.</td><td>61</td><td>84</td><td>53</td></tr><tr><td>2.</td><td>0</td><td>1</td><td>0</td></tr></table>		Beg.	Mid.	End	1.	61	84	53	2.	0	1	0	✓ ✓
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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**



Product Release Management