



A Company of the Fresenius Kabl Group

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

Certificate of Analysis

Finished Product

Product Name:	Sodium Chloride Injection, USP		
Product Code:	918610	Lot Number:	6006469
Manufacture Date:	07-20-13		
Release Date:	09-04-13	Expiration Date:	07/15

Analysis	Specifications	Results	Conforms												
Assay (9mg/mL)	95.0 – 105.0% of Label Claim	99.6%	✓												
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, 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.	1. Meets Specification 2. Meets Specification	✓ ✓												
Iron	NMT 2 ppm	NMT 2 ppm	✓												
Labeling	The label states the total osmolar concentration in 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	✓												
pH	4.5 – 7.0	5.1	✓												
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 10 mL	✓												
Sterility	Sterile	Sterile	✓												
Particulate Matter	1. Does not exceed 6000 particles $\geq$ 10 microns per container 2. Does not exceed 600 particles $\geq$ 25 microns per container	<table> <tr> <td></td><td>Beg</td><td>Mid</td><td>End</td></tr> <tr> <td>1.</td><td>74</td><td>91</td><td>75</td></tr> <tr> <td>2.</td><td>0</td><td>0</td><td>1</td></tr> </table>		Beg	Mid	End	1.	74	91	75	2.	0	0	1	✓ ✓
	Beg	Mid	End												
1.	74	91	75												
2.	0	0	1												
Bacterial Endotoxins	NMT 0.5 EU/mL	NMT 0.3 EU/mL	✓												
Other Requirements	Meets the requirements under Injections USP <1>	Meets USP requirements	✓												

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


 Product Release Management