



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: 6010583	
Manufacture Date: 10-04-15			
Release Date: 10-31-15		Expiration Date: 10/17	
Analysis	Specifications	Results	Conforms
Assay (9mg/mL)	95.0% - 105.0% of Label Claim	98.9%	✓
Color of Solution	Compares to Standard	Compares to Standard, 0	✓
Heavy Metals	NMT 0.001%	NMT 0.001%	✓
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 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.	2. Meets Specification	✓
Iron	NMT 2 ppm	NMT 2 ppm	✓
pH	4.5 - 7.0	5.1	✓
Visual Inspection 1. Clarity	1. Clear	1. Clear	✓
2. Particulate Matter	2. Essentially free from visible particles	2. Essentially no visible particles	✓
3. Container/Closure	3. Container is intact	3. Container is intact	✓
Volume in Container 20 mL Label Claim	NLT Label Claim	NLT 20 mL	✓
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	✓
Sterility	Sterile	Sterile	✓
Bacterial Endotoxins	NMT 0.5 EU/mL	< 0.3 EU/mL	✓

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Particulate Matter	<table border="1"> <thead> <tr> <th></th> <th>Beg</th> <th>Mid</th> <th>End</th> <th></th> </tr> </thead> <tbody> <tr> <td>1. Does not exceed 6,000 particles greater than or equal to 10 microns per container</td> <td>233</td> <td>121</td> <td>193</td> <td>✓</td> </tr> <tr> <td>2. Does not exceed 600 particles greater than or equal to 25 microns per container</td> <td>0</td> <td>0</td> <td>3</td> <td>✓</td> </tr> </tbody> </table>		Beg	Mid	End		1. Does not exceed 6,000 particles greater than or equal to 10 microns per container	233	121	193	✓	2. Does not exceed 600 particles greater than or equal to 25 microns per container	0	0	3	✓
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Other Requirements	Meets the requirements under Injection <1>															

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

 10-31-15
Product Release Management