

Certificate of Analysis

Sodium Chloride Injection, USP 0.9%

Product Code	: 918610	Manufacturing Date	: 17 Sep 2022
Batch Number	: 6028843	Expiration Date	: Sep 2024

Test	Method	Specification	Result
Assay (9 mg/mL)	03-08-07-0043	95.0% - 105.0% of Label Claim	100.6 %
Color of Solution	03-08-07-0057		
Color of Solution		Compares to Standard	Compares to Standard
Color of Solution/Value		NMT 50 dAPHA	0
Identification: Chloride	10-08-05-6034	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.	Complies
Identification: Sodium	10-08-05-6034	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.	Complies
Iron	10-08-05-6033	NMT 2 ppm	Not more than 2 ppm
pH	10-08-05-6001	4.5 - 7.0	5.8
Visual Inspection	10-08-05-6005		
Clarity		Clear	Clear
Particulate Matter		Essentially free from visible particulate matter	Essentially free from visible particulate matter
Container/Closure		Container is intact	Container is intact
Volume in Container	03-08-03-0002	NLT 10 mL	Not less than 10 mL
10 mL Label Claim			
Particulate Matter - Beginning	03-10-02-0002		
Particulate Matter >= 10 µm		Does not exceed 6000 particles greater than or equal to 10 microns per container.	4 Particles/Container
Particulate Matter >= 25 µm		Does not exceed 600 particles greater than or equal to 25 microns per container.	0 Particles/Container
Particulate Matter - Middle	03-10-02-0002		
Particulate Matter >= 10 µm		Does not exceed 6000 particles greater than or equal to 10 microns per container.	A: 1 B: 1 C: 3 D: 3 E: 1 Particles/Container



**FRESENIUS
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Particulate Matter >= 25 µm		Does not exceed 600 particles greater than or equal to 25 microns per container.	A: 1 B: 0 C: 0 D: 0 E: 0 Particles/Container
Particulate Matter - End	03-10-02-0002		
Particulate Matter >= 10 µm		Does not exceed 6000 particles greater than or equal to 10 microns per container.	2 Particles/Container
Particulate Matter >= 25 µm		Does not exceed 600 particles greater than or equal to 25 microns per container.	0 Particles/Container
Sterility	03-10-07-0001	Sterile	Sterile
Bacterial Endotoxins	03-10-08-0005	NMT 0.5 EU/mL	<0.3 EU/mL
Other Requirements	USP <1>		
Sterility- FP Spec		Meets the requirements under Injection USP <1>	Complies
Volume In Container- FP Spec		Meets the requirements under Injection USP <1>	Complies
Foreign Matter/Particulate Matter- 100% Visual Inspection		Meets Requirement USP <1>	Complies
Particulate Matter- FP Spec		Meets the requirements under Injection USP <1>	Complies
Vehicles and Added Substances		Vehicles and Added Substances are specified per approved master formula.	Complies
Labels and Labeling		Labels and Labeling are specified per approved labeling material represented in batch record.	Complies
Containers and Closures		Containers, including closures, are defined by approved master component specifications.	Complies
Packaging and Storage		Packaging and Storage are defined by approved product material.	Complies
Labeling	USP	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.	Complies



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Statement of Compliance to USP <467>	USP <467>	This finished drug product complies to the USP <467> General Chapter for Residual Solvents per Option 1	Complies
Statement of Compliance to USP <232> and ICH Q3D	USP <232> and ICH Q3D	This finished drug product complies to USP <232> General Chapter and ICH Q3D for Elemental Impurities.	Complies

This product conforms to the specifications established by Fresenius Kabi USA, LLC.

This is an electronic signature

Quality Management : Michelle Webb **Release Date** : 31 Oct 2022
PRODUCT RELEASE SPECIALIST