
Release Certificate

- ☐ Pre-release
☒ Release
☐ Reject

Address of Production Unit: Fresenius Kabi USA, LLC
3159 Staley Road
Grand Island, NY 14072

No. of Manufacturing License:	3001833549
GMP certificate or, if available, EudraGMP reference number:	N/A
Material number:	918610
Name of product:	Sodium Chloride 0.9% 90mg 10mL SDV
Destination / Importing country / countries:	USA
Marketing Authorization number or Clinical Trial Authorization number:	N/A
Strength / Potency:	90 mg
Dosage form:	Liquid
Packaging size and type:	1 X 25 X 10ML
Batch number:	6034296
Date of manufacture:	01/03/2024
Expiry date:	01/31/2026
Amount released:	808,525.000

Name, address and number of Manufacturing license, GMP certificate or, if available, EudraGMP reference number of all manufacturing and testing sites other than the production unit mentioned above:

Not Required.

Results of analysis incl. methods
☒ see attachment

Remarks, deviations: 1757737, 1752314, 1769409, 1773749

Certification Statement:**Pharmaceutical Product / Bulk Product:**

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labeling and quality control at the above-mentioned site in full compliance with the GMP requirements of the destination country and the specifications in the respective Marketing Authorization or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

The batch / product is released for sales and distribution.

02/13/2024

Cindy Wojtowicz

Date

Authorized Person for Batch / Product Release



Certificate of Analysis

Sodium Chloride Injection, USP 0.9%

Product Code : 918610 **Manufacturing Date** : 03 Jan 2024
Batch Number : 6034296 **Expiration Date** : Jan 2026

Test	Method	Specification	Result
Assay (9 mg/mL)	03-08-07-0043	95.0% - 105.0% of Label Claim	100.7 %
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.	Complex
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.	Complex
Iron	10-08-05-6033	NMT 2 ppm	Not more than 2 ppm
pH	10-08-05-6001	4.5 - 7.0	6.1
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.	14 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: 3 B: 9 C: 7 D: 10 E: 3 Particles/Container



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Test	Method	Specification	Result
Particulate Matter $\geq 25 \mu\text{m}$		Does not exceed 600 particles greater than or equal to 25 microns per container.	A: 0 B: 0 C: 0 D: 0 E: 0 Particles/Container
Particulate Matter - End	03-10-02-0002		
Particulate Matter $\geq 10 \mu\text{m}$		Does not exceed 6000 particles greater than or equal to 10 microns per container.	7 Particles/Container
Particulate Matter $\geq 25 \mu\text{m}$		Does not exceed 600 particles greater than or equal to 25 microns per container.	1 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 Labelling		Labels and Labelling are specified per approved labelling 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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Test	Method	Specification	Result
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 : Cindy Wojtowicz **Release Date** : 13 Feb 2024