FRESENIUS KABI

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:	918510
Name of product:	Water Sterile 10mL SDV
Destination / Importing country / countries:	USA
Marketing Authorization number or Clinical Trial Authorization number:	N/A
Strength / Potency:	NA
Dosage form:	Liquid
Packaging size and type:	1 X 25 X 10ML
Batch number:	6033058
Date of manufacture:	08/06/2023
Expiry date:	08/31/2026
Amount released:	654,000.000

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: 1666373, 1645698

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.

10/23/2023	Cindy Wojtowicz
Date	Authorized Person for Batch / Product Release

FRESENIUS KABI

Fresenius Kabi USA, LLC
3159 Staley Road
Grand Island, New York 14072
+01 (716) 773-0800

Certificate of Analysis

Sterile Water For Injection, USP

Product Code	: 918510	**Manufacturing Date**	: 06 Aug 2023
Batch Number	: 6033058	**Expiration Date**	: Aug 2026

Test	Method	Specification	Result
Color of Solution	03-08-07-0057		
Color of Solution		Compares to Standard	Complies
dAPHA		NMT 50 dAPHA	1
Total Organic Carbon	10-08-03-7299		
Total Organic Carbon			1.43 ppm
Total Organic Carbon- USP		Meets the USP requirements	Meets Specification
Visual Inspection:	10-08-05-6005		
Description		Solution in a 10cc Plastic Vial	Solution in a 10cc Plastic Vial
Clarity		Clear	Clear
Particulate Matter		Essentially free from visible particulate matter	Meets Specification
Color		Colorless	Colorless
Identification	Add 1 drop of product to 5.0 mL of Karl Fisher ® reagent to a test tube	Solution becomes light yellow	Meets Specification
Volume Check	03-08-03-0002	NLT 10 mL	Not less than 10 mL
Conductivity	03-08-07-0054	NMT 25 µS/cm	1 µS/cm
Particulate Matter in Injections - Beginning	03-10-02-0002		
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	31 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container
Particulate Matter in Injections - Middle	03-10-02-0002		
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	A: 25 B: 37 C: 28 D: 16 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	A: 1 B: 1 C: 0 D: 0 Particles/Container
Particulate Matter in Injections - End	03-10-02-0002		
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	16 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container

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Test	Method	Specification	Result
Other Requirements:	USP <1>		
Sterility- FP Spec		Meets requirements of USP <1>	Complies
Volume In Container- FP Spec		Meets requirements of USP <1>	Complies
Foreign Matter/Particulate Matter- 100% Visual Inspection		Meets requirements	Complies
Particulate Matter- FP Spec		Meets requirements of 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 on batch record pages R6, R8, and R9.	Complies
Containers and Closures		Containers, including closures, are defined by approved master component specifications.	Complies
Packaging and Storage		Packaging and Storage defined by approved product material.	Complies
Labeling	USP	Label it to indicate that no antimicrobial or other subetance has been added, and that it is not suitable for intravascular injection without first having been made approximately isotonic by the addition of a suitable solute.	Complies
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 the USP <232> General Chapter and ICH Q3D for Elemental Impurities	Complies
Sterility	03-10-07-0001	Sterile	Sterile
Bacterial Endotoxins	03-10-08-0005	<0.25 EU/mL	<0.05 EU/mL

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

This is an electronic signature

Quality Management	: Cindy Wojtowicz	**Release Date**	: 23 Oct 2023