

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:	Not Applicable
Material number:	918520
Name of product:	Water Sterile 20mL SDV
Destination / Importing country / countries:	Not Applicable
Marketing Authorization number or Clinical Trial Authorization number:	Not Applicable
Strength / Potency:	NA
Dosage form:	Liquid
Packaging size and type:	1 X 25 X 20ML
Batch number:	6034489
Date of manufacture:	01/24/2024
Expiry date:	01/31/2027
Amount released:	82,200.000

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: Non Applicable

Note: Event records are stored in the original electronic format in KabiTrack.

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 further processing.

02/22/2024

Corinne Law

Date

Authorized Person for Batch / Product Release
SAP is the original source record of the electronic signature



Certificate of Analysis

Sterile Water For Injection, USP

Product Code : 918520 **Manufacturing Date** : 24 Jan 2024
Batch Number : 6034489 **Expiration Date** : Jan 2027

Test	Method	Specification	Result
Color of Solution	03-08-07-0057		
Color of Solution		Compares To Standard	Complies
dAPHA		NMT 50 dAPHA	7
Total Organic Carbon	10-08-03-7299		
Total Organic Carbon			0.93 ppm
Total Organic Carbon- USP		Meets the USP requirements	Meets Specification
Visual Inspection	10-08-05-6005		
Description		Solution in a 20cc Plastic Vial	Solution in a 20cc Plastic Vial
Clarity		Clear	Clear
Particulate Matter		Essentially free from visible particulate matter	Meets Specification
Color		Colorless	Colorless
Volume Check	03-08-03-0002	NLT 20 mL	NLT 20 mL
Identification	Add 1 drop of product to 5.0 mL of Karl Fisher ® reagent to a test tube	Solution becomes light yellow	Meets Specification
Conductivity	03-08-07-0054	NMT 5 µS/cm	1 µS/cm
Particulate Matter in Injections	03-10-02-0002		
- Beginning			
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	25 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container
Particulate Matter in Injections	03-10-02-0002		
- Middle			
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	53 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container
Particulate Matter in Injections	03-10-02-0002		
- End			
Particulate Matter >= 10 µm		For particles ≥ 10 µm: NMT 6,000 particles per container	48 Particles/Container
Particulate Matter >= 25 µm		For particles ≥ 25 µm: NMT 600 particles per container	0 Particles/Container
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



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Sterile Water For Injection, USP

Product Code : 918520 **Manufacturing Date** : 24 Jan 2024
Batch Number : 6034489 **Expiration Date** : Jan 2027

Test	Method	Specification	Result
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 substance 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 : Corinne Law **Release Date** : 22 Feb 2024
Supervisor, MQA Disposition