

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:	918520
Name of product:	Water Sterile 20mL 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 20ML
Batch number:	6032768
Date of manufacture:	07/12/2023
Expiry date:	07/31/2026
Amount released:	83,400.000

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: N/A

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.

08/08/2023

Cindy Wojtowicz

Date

Authorized Person for Batch / Product Release