
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: 918610

Name of product: Sodium Chloride 0.9% 90mg 10mL SDV

Destination / Importing country / countries: Not Applicable

Marketing Authorization number or Clinical Trial Authorization number: Not Applicable

Strength / Potency: 90 mg

Dosage form: Liquid

Packaging size and type: 1 X 25 X 10ML

Batch number: 6028843

Date of manufacture: 09/17/2022

Expiry date: 09/30/2024

Amount released: 817,150.000

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: 1413911

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.

10/31/2022

Date

Michelle Webb

Authorized Person for Batch / Product Release