

## 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:                                                          | 6035261                |
| Date of manufacture:                                                   | 05/01/2024             |
| Expiry date:                                                           | 05/31/2027             |
| Amount released:                                                       | 81,700.000             |

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: 1851612

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 sales and distribution.

06/13/2024

Cindy Wojtowicz

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** : 01 May 2024  
**Batch Number** : 6035261 **Expiration Date** : May 2027

| Test                                                      | Method                                                                  | Specification                                            | Result                          |
|-----------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------|
| <b>Color of Solution</b>                                  | 03-08-07-0057                                                           |                                                          |                                 |
| Color of Solution                                         |                                                                         | Compares To Standard                                     | Complies                        |
| dAPHA                                                     |                                                                         | NMT 50 dAPHA                                             | 1                               |
| <b>Total Organic Carbon</b>                               | 10-08-03-7299                                                           |                                                          |                                 |
| Total Organic Carbon                                      |                                                                         |                                                          | 1.10 ppm                        |
| Total Organic Carbon- USP                                 |                                                                         | Meets the USP requirements                               | Meets Specification             |
| <b>Visual Inspection</b>                                  | 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                       |
| <b>Volume Check</b>                                       | 03-08-03-0002                                                           | NLT 20 mL                                                | NLT 20 mL                       |
| <b>Identification</b>                                     | Add 1 drop of product to 5.0 mL of Karl Fleher ® reagent to a test tube | Solution becomes light yellow                            | Meets Specification             |
| <b>Conductivity</b>                                       | 03-08-07-0054                                                           | NMT 5 µS/cm                                              | 1 µS/cm                         |
| <b>Particulate Matter in Injections</b>                   | 03-10-02-0002                                                           |                                                          |                                 |
| - Beginning                                               |                                                                         |                                                          |                                 |
| Particulate Matter >= 10 µm                               |                                                                         | For particles ≥ 10 µm: NMT 6,000 particles per container | 124 Particles/Container         |
| Particulate Matter >= 25 µm                               |                                                                         | For particles ≥ 25 µm: NMT 600 particles per container   | 0 Particles/Container           |
| <b>Particulate Matter in Injections</b>                   | 03-10-02-0002                                                           |                                                          |                                 |
| - Middle                                                  |                                                                         |                                                          |                                 |
| Particulate Matter >= 10 µm                               |                                                                         | For particles ≥ 10 µm: NMT 6,000 particles per container | 85 Particles/Container          |
| Particulate Matter >= 25 µm                               |                                                                         | For particles ≥ 25 µm: NMT 600 particles per container   | 0 Particles/Container           |
| <b>Particulate Matter in Injections</b>                   | 03-10-02-0002                                                           |                                                          |                                 |
| - End                                                     |                                                                         |                                                          |                                 |
| Particulate Matter >= 10 µm                               |                                                                         | For particles ≥ 10 µm: NMT 6,000 particles per container | 88 Particles/Container          |
| Particulate Matter >= 25 µm                               |                                                                         | For particles ≥ 25 µm: NMT 600 particles per container   | 0 Particles/Container           |
| <b>Other Requirements:</b>                                | 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                        |



**FRESENIUS  
KABI**

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+01 (716) 773-0800

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**Product Code** : 918520 **Manufacturing Date** : 01 May 2024  
**Batch Number** : 6035261 **Expiration Date** : May 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** : Cindy Wojtowicz **Release Date** : 13 Jun 2024