



**FRESENIUS  
KABI**

Fresenius Kabi USA, LLC  
3159 Staley Road  
Grand Island, New York 14072  
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## Certificate of Analysis

### Sodium Chloride Injection, USP

|                     |           |                           |               |
|---------------------|-----------|---------------------------|---------------|
| <b>Product Code</b> | : 918610  | <b>Manufacturing Date</b> | : 30 Sep 2018 |
| <b>Batch Number</b> | : 6017997 | <b>Expiration Date</b>    | : Sep 2020    |

| Test                                  | Method        | Specification                                                                                                                                                                                                                                 | Result                                           |
|---------------------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Assay (9 mg/mL)</b>                | 03-08-07-0043 | 95.0% - 105.0% of Label Claim                                                                                                                                                                                                                 | 99.8 %                                           |
| <b>Color of Solution</b>              | 03-08-07-0057 | Compares to Standard                                                                                                                                                                                                                          | Compares to Standard                             |
| <b>Identification: Chloride</b>       | 10-08-05-6034 | Solutions of chlorides yield with silver nitrate TS a white, curdy precipitate that is insoluble in nitric acid but is soluble in a slight excess of 6N ammonium hydroxide.                                                                   | Complies                                         |
| <b>Identification: Sodium</b>         | 10-08-05-6034 | Add 15% potassium carbonate and heat to boiling, no precipitate is formed. Add potassium pyroantimonate TS and heat to boiling, cool, a dense precipitate is formed. Sodium compounds impart an intense yellow color to a non-luminous flame. | Complies                                         |
| <b>Iron</b>                           | 10-08-05-6033 | NMT 2 ppm                                                                                                                                                                                                                                     | Not more than 2 ppm                              |
| <b>pH</b>                             | 10-08-05-6001 | 4.5 - 7.0                                                                                                                                                                                                                                     | 5.3                                              |
| <b>Visual Inspection</b>              | 10-08-05-6005 |                                                                                                                                                                                                                                               |                                                  |
| Clarity                               |               | Clear                                                                                                                                                                                                                                         | Clear                                            |
| Particulate Matter                    |               | Essentially free from visible particulate matter                                                                                                                                                                                              | Essentially free from visible particulate matter |
| Container/Closure                     |               | Container is intact                                                                                                                                                                                                                           | Container is intact                              |
| <b>Volume in Container</b>            | 03-08-03-0002 | NLT 10 mL                                                                                                                                                                                                                                     | Not less than 10 mL                              |
| <b>10 mL Label Claim</b>              |               |                                                                                                                                                                                                                                               |                                                  |
| <b>Particulate Matter - Beginning</b> | 03-10-02-0002 |                                                                                                                                                                                                                                               |                                                  |
| Particulate Matter >= 10 µm           |               | Does not exceed 6000 particles greater than or equal to 10 microns per container.                                                                                                                                                             | 32 Particles/Container                           |
| Particulate Matter >= 25 µm           |               | Does not exceed 600 particles greater than or equal to 25 microns per container.                                                                                                                                                              | 1 Particles/Container                            |
| <b>Particulate Matter - Middle</b>    | 03-10-02-0002 |                                                                                                                                                                                                                                               |                                                  |
| Particulate Matter >= 10 µm           |               | Does not exceed 6000 particles greater than or equal to 10 microns per container.                                                                                                                                                             | 51 Particles/Container                           |
| Particulate Matter >= 25 µm           |               | Does not exceed 600 particles greater than or equal to 25 microns per container.                                                                                                                                                              | 1 Particles/Container                            |
| <b>Particulate Matter - End</b>       | 03-10-02-0002 |                                                                                                                                                                                                                                               |                                                  |
| Particulate Matter >= 10 µm           |               | Does not exceed 6000 particles greater than or equal to 10 microns per container.                                                                                                                                                             | 57 Particles/Container                           |
| Particulate Matter >= 25 µm           |               | Does not exceed 600 particles greater than or equal to 25 microns per container.                                                                                                                                                              | 0 Particles/Container                            |
| <b>Sterility</b>                      | 03-10-07-0001 | Sterile                                                                                                                                                                                                                                       | Complies                                         |
| <b>Bacterial Endotoxins</b>           | 03-10-08-0005 | NMT 0.5 EU/mL                                                                                                                                                                                                                                 | <0.3 EU/mL                                       |



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| Test                                              | Method                                           | Specification                                                                                                                                                                                                                                                                                            | Result   |
|---------------------------------------------------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| <b>Other Requirements</b>                         | USP <1>                                          |                                                                                                                                                                                                                                                                                                          |          |
| Sterility- FP Spec                                |                                                  | Meets the requirements under Injection USP <1>                                                                                                                                                                                                                                                           | Complies |
| Volume in Container- FP Spec                      |                                                  | Meets the requirements under Injection USP <1>                                                                                                                                                                                                                                                           | Complies |
| Foreign Matter/Particulate                        |                                                  | Meets the requirements under Injection USP <1>                                                                                                                                                                                                                                                           | Complies |
| Matter 100% Visual Inspection                     |                                                  | Meets the requirements under Injection USP <1>                                                                                                                                                                                                                                                           | Complies |
| Particulate Matter- FP Spec                       |                                                  | Meets the requirements under Injection 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 in batch record.                                                                                                                                                                                                            | Complies |
| Containers and Closures                           |                                                  | Containers, including closures, are defined by approved master component specifications.                                                                                                                                                                                                                 | Complies |
| Packaging and Storage                             |                                                  | Packaging and Storage are defined by approved product material.                                                                                                                                                                                                                                          | Complies |
| <b>Labeling</b>                                   | USP                                              | The label states the total osmolar concentration is mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL. | Complies |
| <b>Statement of Compliance to USP &lt;467&gt;</b> | USP <467>                                        | This finished drug product complies to the USP <467> General Chapter for Residual Solvents per Option 1                                                                                                                                                                                                  | Complies |
| <b>Elemental Impurities Statement</b>             | Statement of Compliance to USP <232> and ICH Q3D | This finished drug product complies to USP <232> General Chapter and ICH Q 3D for Elemental Impurities.                                                                                                                                                                                                  | Complies |

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

This is an electronic signature

**Quality Management** : Katherine Kraft  
Sr. Quality Assurance Manager

**Release Date** : 03 Feb 2019