

Material No.: 3627-01 Batch No.: 24G1261020

Manufactured Date: 2024-02-26 Retest Date: 2029-02-24

> Release Date: 2024-08-05 Revision No.: 0

## Certificate of Analysis

Meets U.S.P Requirements, Meets B.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets E.P. Chemical Specifications, GMP Manufactured Product

Test	Specification	Result
USP – Identification A	Passes Test	Passes Test
USP – Identification B	Passes Test	Passes Test
USP – Acidity or Alkalinity	Passes Test	Passes Test
USP - Appearance of Solution	Passes Test	Passes Test
USP – Aluminum (Al)	≤ 0.2 ppm	< 0.1 ppm
USP – Arsenic (As)	≤ 1 ppm	< 1 ppm
USP – Barium (Ba)	Passes Test	Passes Test
USP – Bromide (Br)	≤ 100 ppm	< 100 ppm
USP – Ferrocyanide	Passes Test	Passes Test
USP – lodides (I)	Passes Test	Passes Test
USP – Iron (Fe)	≤ 2 ppm	< 2 ppm
USP – Loss on Drying at 105°C	<b>≤ 0.5 %</b>	< 0.1 %
USP – Magnesium and Alkaline Earth Metals (as Ca)	≤ 100 ppm	< 100 ppm
USP – Nitrite (NO2) (Absorbance Value)	≤ 0.01	< 0.01
USP – Phosphate (PO <sub>4</sub> )	≤ 25 ppm	< 25 ppm
USP – Potassium (K)	≤ 500 ppm	< 50 ppm
USP – Sulfate (SO <sub>4</sub> )	≤ 200 ppm	< 200 ppm
USP - Assay (NaCl) (dried basis)	99.0 - 100.5 %	99.6 %
EP/BP - Identification A	Passes Test	Passes Test
EP/BP – Identification B	Passes Test	Passes Test
EP/BP – Aluminum (Al)	≤ 0.2 ppm	< 0.1 ppm
EP/BP - Appearance of Solution	Passes Test	Passes Test
EP/BP – Acidity or Alkalinity	Passes Test	Passes Test
EP/BP – Bromide (Br)	≤ 100 ppm	< 100 ppm
EP/BP – Ferrocyanide	Passes Test	Passes Test
EP/BP – lodide (I)	Passes Test	Passes Test
EP/BP - Nitrite (NO <sub>2</sub> )	≤ 0.01	< 0.01
EP/BP - Phosphate (PO <sub>4</sub> )	≤ 25 ppm	< 25 ppm

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Test	Specification	Result
EP/BP - Sulfate (SO <sub>4</sub> )	≤ 200 ppm	< 200 ppm
EP/BP – Arsenic (As)	≤ 1 ppm	< 1 ppm
EP/BP - Barium (Ba)	Passes Test	Passes Test
EP/BP - Iron (Fe)	≤ 2 ppm	< 2 ppm
EP/BP - Magnesium and Alkaline Earth Metals	≤ 100 ppm	< 100 ppm
EP/BP – Loss on Drying at 105°C	≤ 0.5 %	< 0.1 %
EP/BP - Potassium (K)	≤ 500 ppm	< 50 ppm
EP/BP - Assay (NaCl) (dried basis)	99.0 - 100.5 %	99.6 %
EP/BP – Endotoxin Concentration, IU/g	≤ 2.5	< 1.0
JP – Assay (NaCl) (dried basis)	99.0 - 100.5 %	99.6 %
JP – Identification A	Passes Test	Passes Test
JP – Identification B	Passes Test	Passes Test
JP – Acidity or Alkalinity	Passes Test	Passes Test
JP – Clarity and Color of Solution	Passes Test	Passes Test
JP – Bromide (Br)	Passes Test	Passes Test
JP – Ferrocyanide	Passes Test	Passes Test
JP – lodide (l)	Passes Test	Passes Test
JP – Iron (Fe)	Passes Test	Passes Test
JP – Magnesium and Alkaline Earth Metals	Passes Test	Passes Test
JP – Phosphate (PO4)	Passes Test	Passes Test
JP – Sulfates (SO <sub>4</sub> )	Passes Test	Passes Test
JP – Barium (Ba)	Passes Test	Passes Test
JP – Arsenic (As)	≤ 2 ppm	< 2 ppm
JP – Loss on Drying	≤ 0.5 %	< 0.1 %
Total Aerobic Microbial Count, For Information Only		< 10 CFU/g
Total Yeasts and Molds Count, For Information Only		< 10 CFU/g

Sodium Chloride, Granular, U.S.P. Multi-Compendial



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Specification Result Test

**GMP Manufactured Product Bulk Pharmaceutical Chemical** CAUTION: For Manufacturing, processing or repackaging No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product. Must be subjected to further processing during the preparation of injectable dosage forms Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Country of Origin: USA

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0002001

Manufacturer source batch: RI24057001



Michelle Bales Sr. Manager, Quality Assurance