

Material No.: 3302-28 Revision No.: 0

## **Product Specification**

Meets F.C.C. Requirements, Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification
USP - Identification A	Passes Test
USP - Identification B	Passes Test
USP - Acidity or Alkalinity	Passes Test
USP – Appearance of Solution	Passes Test
USP – Aluminum (Al)	≤ 0.2 ppm
USP – Arsenic (As)	≤ 1 ppm
USP - Barium (Ba)	Passes Test
USP – Bromide (Br)	≤ 100 ppm
USP - Ferrocyanide	Passes Test
USP – Iodides (I)	Passes Test
USP – Iron (Fe)	≤ 2 ppm
USP – Loss on Drying at 105°C	≤ 0.5 %
USP - Magnesium and Alkaline Earth Metals (as Ca)	≤ 100 ppm
USP - Nitrite (NO <sub>2</sub> ) (Absorbance Value)	≤ 0.01
USP – Phosphate (PO <sub>4</sub> )	≤ 25 ppm
USP – Potassium (K)	≤ 500 ppm
USP – Sulfate (SO <sub>4</sub> )	≤ 200 ppm
USP - Assay (NaCl) (dried basis)	99.0 – 100.5 %
FCC - Assay (as NaCl) (FCC) (ignited basis)	99.0 – 100.5 %
FCC - Identification A	Passes Test
FCC - Identification B	Passes Test
FCC – Arsenic (As)	≤ 1 ppm
FCC - Calcium and Magnesium	≤ 0.35 %
FCC - Heavy Metals (as Pb)	≤ 2 ppm
FCC – Loss on Drying at 105°C	≤ 0.5 %
Endotoxin Concentration (EU/g)	≤ 5.0

Sodium Chloride U.S.P. – F.C.C.



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Test Specification

GMP Manufactured Product
Food GMP Manufactured Product
Bulk Food Chemical
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.

Packaging Site: Paris Mfg Ctr & DC

