

Sodium Chloride, Granular
USP – GenAR®
Intended for Hemodialysis Use



Material No.: 7713-06
Batch No.: 0000192115
Manufactured Date: 2017/12/20
Retest Date: 2022/12/19
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Assay (NaCl)(USP) (dried basis)	99.0 – 100.5 %	99.3
USP – Appearance of Solution	Passes Test	PT
USP – Identification A	Passes Test	PT
USP – Identification B	Passes Test	PT
USP – Acidity or Alkalinity	Passes Test	PT
USP – Bromide (Br)	<= 100 ppm	< 100
USP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
USP – Iodide (I)	Passes Test	PT
USP – Aluminum (Al)	<= 0.2 ppm	< 0.2
USP – Magnesium and Alkaline Earth Metals (as Ca)	<= 100 ppm	< 100
USP – Arsenic (As)	<= 1 ppm	< 1
USP – Barium (Ba)	Passes Test	PT
USP – Ferrocyanide	Passes Test	PT
USP – Sulfate (SO ₄)	<= 200 ppm	< 200
USP – Iron (Fe)	<= 2 ppm	< 2
USP – Nitrite (NO ₂) (Absorbance Value)	<= 0.01	0.01
USP – Phosphate (PO ₄)	<= 25 ppm	< 25
USP – Potassium (K)	<= 500 ppm	85
EP/BP – Assay (NaCl) (dried basis)	99.0 – 100.5 %	99.3
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Acidity or Alkalinity	Passes Test	PT
EP/BP – Bromide (Br)	<= 100 ppm	< 100

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor Performance Materials, LLC.
3477 Corporate Parkway. Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

Test	Specification	Result
EP/BP – Ferrocyanide	Passes Test	PT
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Iodide (I)	Passes Test	PT
EP/BP – Nitrite (NO ₂)	<= 0.01	< 0.01
EP/BP – Phosphate (PO ₄)	<= 25 ppm	< 25
EP/BP – Sulfate (SO ₄)	<= 200 ppm	< 200
EP/BP – Aluminum (Al)	<= 0.2 ppm	< 0.2
EP/BP – Arsenic (As)	<= 1 ppm	< 1
EP/BP – Barium (Ba)	Passes Test	PT
EP/BP – Iron (Fe)	<= 2 ppm	< 2
EP/BP – Magnesium and Alkaline Earth Metals (as Ca)	<= 100 ppm	< 100
EP/BP – Potassium (K)	<= 500 ppm	85
EP/BP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
EP/BP – Endotoxin Concentration, <5 IU/g	Passes Test	PT
Endotoxin Concentration (EU/g)	<= 2.5	< 1.0
JP – Assay	99.0 – 100.5 %	99.3
JP – Identification A	Passes Test	PT
JP – Identification B	Passes Test	PT
JP – Acidity or Alkalinity	Passes Test	PT
JP – Clarity and Color of Solution	Passes Test	PT
JP – Bromide (Br)	Passes Test	PT
JP – Iodide (I)	Passes Test	PT
JP – Ferrocyanide	Passes Test	PT
JP – Iron (Fe)	Passes Test	PT
JP – Heavy Metals (as Pb)	<= 3 ppm	< 3
JP – Barium (Ba)	Passes Test	PT
JP – Magnesium and Alkaline Earth Metals	Passes Test	PT
JP – Phosphate (PO ₄)	Passes Test	PT
JP – Sulfates (as SO ₄)	Passes Test	PT
JP – Arsenic (As)	<= 2 ppm	< 2
JP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
FCC – Assay (as NaCl) (FCC) (ignited basis)	99.0 – 100.5 %	99.8
FCC – Arsenic (As)	<= 1 ppm	< 1
FCC – Calcium and Magnesium (FCC)	<= 0.35 %	< 0.35
FCC – Heavy Metals (as Pb)(FCC)	<= 2 mg/kg	< 2

Test	Specification	Result
FCC – Identification A	Passes Test	PT
FCC – Identification B	Passes Test	PT
FCC – Loss on Drying at 105°C	<= 0.5 %	< 0.1

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.

Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0002001
Manufacturer source batch: RI17354001



Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000
Paris, KY 9001:2008
Mexico City, Mexico 9001:2008
Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003
Gliwice, Poland 9001:2008, 13485:2012
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008
Panoli, India 9001:2008

James Ethier
Jamie Ethier
Vice President Global Quality

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