

Material No.: 3627-01
Batch No.: 0000247574
Manufactured Date: 2019/11/07
Retest Date: 2024/11/05
Release Date: 2020/01/14
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Identification A	Passes Test	PT
USP – Identification B	Passes Test	PT
USP – Acidity or Alkalinity	Passes Test	PT
USP – Appearance of Solution	Passes Test	PT
USP – Aluminum (Al)	<= 0.2 ppm	< 0.2
USP – Arsenic (As)	<= 1 ppm	< 1
USP – Barium (Ba)	Passes Test	PT
USP – Bromide (Br)	<= 100 ppm	< 100
USP – Ferrocyanide	Passes Test	PT
USP – Iodides (I)	Passes Test	PT
USP – Iron (Fe)	<= 2 ppm	< 2
USP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
USP – Magnesium and Alkaline Earth Metals (as Ca)	<= 100 ppm	< 100
USP – Nitrite (NO ₂) (Absorbance Value)	<= 0.01	< 0.01
USP – Phosphate (PO ₄)	<= 25 ppm	< 25
USP – Potassium (K)	<= 500 ppm	73
USP – Sulfate (SO ₄)	<= 200 ppm	< 200
USP – Assay (NaCl) (dried basis)	99.0 – 100.5 %	99.7
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Aluminum (Al)	<= 0.2 ppm	< 0.2
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Acidity or Alkalinity	Passes Test	PT

Test	Specification	Result
EP/BP – Bromide (Br)	<= 100 ppm	< 100
EP/BP – Ferrocyanide	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 – 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	<= 100 ppm	< 100
EP/BP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
EP/BP – Potassium (K)	<= 500 ppm	73
EP/BP – Assay (NaCl) (dried basis)	99.0 – 100.5 %	99.7
EP/BP – Endotoxin Concentration, IU/g	<= 2.5	< 1.0
JP – Assay (NaCl) (dried basis)	99.0 – 100.5 %	99.7
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 – Ferrocyanide	Passes Test	PT
JP – Iodide (I)	Passes Test	PT
JP – Iron (Fe)	Passes Test	PT
JP – Magnesium and Alkaline Earth Metals	Passes Test	PT
JP – Phosphate (PO ₄)	Passes Test	PT
JP – Sulfates (SO ₄)	Passes Test	PT
JP – Heavy Metals (as Pb)	<= 3 ppm	< 3
JP – Barium (Ba)	Passes Test	PT
JP – Arsenic (As)	<= 2 ppm	< 2
JP – Loss on Drying	<= 0.5 %	< 0.1
Total Aerobic Microbial Count, For Information Only	cfu/g	< 10
Total Yeasts and Molds Count, For Information Only	cfu/g	< 10

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

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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: R119313567



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Vice President Global Quality

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