

Product Specification

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

Test	Specification
Appearance (White crystals or granules)	Passes Test
USP – Assay (anhydrous basis)	98.0 – 103.0 %
USP – Aluminum, Calcium, and Related Elements	Passes Test
USP – Arsenic (As)	≤ 8 ppm
USP – Chloride (Cl)	≤ 0.014 %
USP – Identification A	Passes Test
USP – Identification B	Passes Test
USP – Insoluble Substances	≤ 0.2 %
USP – pH (1 in 20)	4.1 – 4.5
USP – Sulfate (SO ₄)	≤ 0.15 %
USP – Water (H ₂ O)	10.0 – 15.0 %
EP – Identification A	Passes Test
EP – Identification B	Passes Test
EP – Identification C	Passes Test
EP – Assay (anhydrous basis)	98.0 – 100.5 %
EP – Chloride (Cl)	≤ 200 ppm
EP – Sulfate (SO ₄)	≤ 300 ppm
EP – Reducing Substances	Passes Test
Endotoxin Concentration (EU/g)	≤ 2.5
EP – Iron (Fe)	≤ 10 ppm
EP – Appearance of Solution	Passes Test
EP – pH	4.2 – 4.5
BP – Identification A	Passes Test
BP – Identification B	Passes Test
BP – Identification C	Passes Test
BP – Identification D	Passes Test
BP – Acidity	4.2 – 4.5
BP – Clarity and Color of Solution	Passes Test

>>> Continued on page 2 >>>

Test	Specification
BP – Arsenic (As)	≤ 2 ppm
BP – Iron (Fe)	≤ 10 ppm
BP – Chloride (Cl)	≤ 200 ppm
BP – Sulfate (SO ₄)	≤ 300 ppm
BP – Reducing Substances	Passes Test
BP – Loss on Drying at 130°C	11.5 – 14.5 %
BP – Assay (dried basis)	98.0 – 100.5 %
JPE – Assay (dried basis)	≥ 98.0 %
JPE – Identification	Passes Test
JPE – pH	4.1 – 4.7
JPE – Clarity and Color of Solution	Passes Test
JPE – Chloride (Cl)	≤ 0.005 %
JPE – Sulfate (SO ₄)	≤ 0.019 %
JPE – Heavy Metals	≤ 10 ppm
JPE – Arsenic (As)	≤ 2 ppm

>>> Continued on page 3 >>>

Sodium Phosphate, Monobasic, Monohydrate, U.S.P.
Multi-Compendial



Material No.: 3802-05

Test

Specification

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

For EP notated requirements, results are derived from testing Sodium Phosphate, Monobasic Monohydrate, U.S.P. to the EP Chemical

specifications for Sodium Dihydrogen Phosphate Dihydrate.

For JPE notated requirements, results are derived from testing Sodium Phosphate, Monobasic Monohydrate, U.S.P. to the JPE Chemical specifications for Sodium Dihydrogen Phosphate Dihydrate.

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

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

Jamie Ethier
Vice President Global Quality

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC

100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700