

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



Material No.: 3802-01
Batch No.: 0000172025
Manufactured Date: 2017/04/01
Retest Date: 2022/03/31

Certificate of Analysis

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

Test	Specification	Result
Appearance (White crystals or granules)	Passes Test	PT
USP – Assay (anhydrous basis)	98.0 – 103.0 %	100.4
USP – Aluminum, Calcium, and Related Elements	Passes Test	PT
USP – Arsenic (As)	<= 8 ppm	< 8
USP – Chloride (Cl)	<= 0.014 %	< 0.014
USP – Heavy Metals (as Pb)	<= 0.002 %	< 0.002
USP – Identification A	Passes Test	PT
USP – Identification B	Passes Test	PT
USP – Insoluble Substances	<= 0.2 %	< 0.1
USP – pH (1 in 20)	4.1 – 4.5	4.4
USP – Sulfate (SO ₄)	<= 0.15 %	< 0.15
USP – Water (H ₂ O)	10.0 – 15.0 %	11.7
EP – Identification A	Passes Test	PT
EP – Identification B	Passes Test	PT
EP – Identification C	Passes Test	PT
EP – Assay (anhydrous basis)	98.0 – 100.5 %	99.7
EP – Chloride (Cl)	<= 200 ppm	< 200
EP – Sulfate (SO ₄)	<= 300 ppm	< 300
EP – Arsenic (As)	<= 2 ppm	< 2
EP – Reducing Substances	Passes Test	PT
EP – Heavy Metals (as Pb)	<= 10 ppm	< 10
Endotoxin Concentration (EU/g)	<= 2.5	< 2.5
EP – Iron (Fe)	<= 10 ppm	< 10

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 – Appearance of Solution	Passes Test	PT
EP – pH	4.2 – 4.5	4.3
BP – Identification A	Passes Test	PT
BP – Identification B	Passes Test	PT
BP – Identification C	Passes Test	PT
BP – Identification D	Passes Test	PT
BP – Acidity	4.2 – 4.5	4.3
BP – Clarity and Color of Solution	Passes Test	PT
BP – Arsenic (As)	<= 2 ppm	< 2
BP – Heavy Metals (as Pb)	<= 10 ppm	< 10
BP – Iron (Fe)	<= 10 ppm	< 10
BP – Chloride (Cl)	<= 200 ppm	< 200
BP – Sulfate (SO ₄)	<= 300 ppm	< 300
BP – Reducing Substances	Passes Test	PT
BP – Loss on Drying at 130°C	11.5 – 14.5 %	11.5
BP – Assay (dried basis)	98.0 – 100.5 %	99.7
JPE – Assay (dried basis)	>= 98.0 %	99.9
JPE – Identification	Passes Test	PT
JPE – pH	4.1 – 4.7	4.6
JPE – Clarity and Color of Solution	Passes Test	PT
JPE – Chloride (Cl)	<= 0.005 %	< 0.005
JPE – Sulfate (SO ₄)	<= 0.019 %	< 0.019
JPE – Heavy Metals	<= 10 ppm	< 10
JPE – Arsenic (As)	<= 2 ppm	< 2

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.

Country of Origin: US
 Packaging Site: Paris Mfg Ctr & DC
 Manufacturer: PBG
 Manufacturer source batch: 0000169809

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

Jamie Ethier
 Vice President Global Quality

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