

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



Material No.: 3802-60  
Batch No.: 0000272894  
Manufactured Date: 2020/11/30  
Retest Date: 2025/11/29  
Release Date: 2021/01/05  
Revision No: 1

## 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 %	100.1
USP – Aluminum, Calcium, and Related Elements	Passes Test	PT
USP – Arsenic (As)	<= 8 ppm	< 8
USP – Chloride (Cl)	<= 0.014 %	< 0.014
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 <sub>4</sub> )	<= 0.15 %	< 0.15
USP – Water (H <sub>2</sub> O)	10.0 – 15.0 %	12.6
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 %	100.3
EP – Chloride (Cl)	<= 200 ppm	< 200
EP – Sulfate (SO <sub>4</sub> )	<= 300 ppm	< 300
EP – Arsenic (As)	<= 2 ppm	< 2
EP – Reducing Substances	Passes Test	PT
Endotoxin Concentration (EU/g)	<= 2.5	< 2.5
EP – Iron (Fe)	<= 10 ppm	< 10
EP – Appearance of Solution	Passes Test	PT
EP – pH	4.2 – 4.5	4.4

For questions on this Certificate of Analysis 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

Test	Specification	Result
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	4.4
BP – Clarity and Color of Solution	Passes Test	PT
BP – Arsenic (As)	<= 2 ppm	< 2
BP – Iron (Fe)	<= 10 ppm	< 10
BP – Chloride (Cl)	<= 200 ppm	< 200
BP – Sulfate (SO <sub>4</sub> )	<= 300 ppm	< 300
BP – Reducing Substances	Passes Test	PT
BP – Loss on Drying at 130°C	11.5 – 14.5 %	12.8
BP – Assay (dried basis)	98.0 – 100.5 %	100.3
JPE – Assay (dried basis)	>= 98.0 %	100.1
JPE – Identification	Passes Test	PT
JPE – pH	4.1 – 4.7	4.5
JPE – Clarity and Color of Solution	Passes Test	PT
JPE – Chloride (Cl)	<= 0.005 %	< 0.005
JPE – Sulfate (SO <sub>4</sub> )	<= 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.

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: Phillipsburg Mfg Ctr & DC  
Manufacturer: PBG  
Manufacturer source batch: 0000272894

  
Jamie Ethier  
Vice President Global Quality