

Sodium Phosphate, Dibasic, 7-Hydrate
U.S.P.



Material No.: 3803-01
Batch No.: 0000173609
Manufactured Date: 2015/11/19
Retest Date: 2020/11/17

Certificate of Analysis

Meets U.S.P Requirements,
GMP Manufactured Product

| Test | Specification | Result |
|---|----------------|---------|
| Appearance (Colorless or translucent crystals or granules) | Passes Test | PT |
| USP – Assay (Na ₂ HPO ₄) (dried basis) | 98.0 – 100.5 % | 99.5 |
| USP – Arsenic (As) | <= 16 ppm | < 16 |
| USP – Chloride (Cl) | <= 0.06 % | < 0.06 |
| USP – Endotoxin Concentration (EU/g) | <= 2.5 | < 2.5 |
| USP – Heavy Metals (as Pb) | <= 0.002 % | < 0.002 |
| USP – Identification | Passes Test | PT |
| USP – Insoluble Substances | <= 0.4 % | < 0.1 |
| USP – Loss on Drying | 43.0 – 50.0 % | 47.2 |
| USP – Sulfate (SO ₄) | <= 0.2 % | < 0.2 |
| EP – Identification A | Passes Test | PT |
| EP – Identification C | Passes Test | PT |
| EP – Identification D | Passes Test | PT |
| EP – Reducing Substances | Passes Test | PT |
| EP – Monosodium Phosphate | <= 2.5 % | < 0.1 |
| EP – Arsenic (As) | <= 2 ppm | < 2 |
| EP – Chloride (Cl) | <= 200 ppm | < 200 |
| EP – Sulfate (SO ₄) | <= 500 ppm | < 500 |
| EP – Heavy Metals (as Pb) | <= 10 ppm | < 10 |
| EP – Appearance of Solution | Passes Test | PT |
| EP – Iron (Fe) | <= 20 ppm | < 20 |

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 - Assay (anhydrous basis) | 98.0 - 101.0 % | 99.8 |
| JP - Arsenic (As) | <= 2 ppm | < 2 |
| JP - Assay (Na ₂ HPO ₄) (dried basis) | 98.0 - 101.0 % | 100.0 |
| JP - Carbonate (CO ₃) | Passes Test | PT |
| JP - Chloride (Cl) | <= 0.014 % | < 0.014 |
| JP - Clarity and Color of Solution | Passes Test | PT |
| JP - Heavy Metals | <= 10 ppm | < 10 |
| JP - Identification | Passes Test | PT |
| JP - pH (1 in 50) | 9.0 - 9.4 | 9.4 |
| JP - Sulfate (SO ₄) | <= 0.038 % | < 0.038 |

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.

The EP results are derived from testing Sodium Phosphate, Dibasic, 7-Hydrate, U.S.P. to the EP chemical specifications derived from Disodium Phosphate Dihydrate and Disodium Phosphate Dodecahydrate.

The JP results are derived from testing Sodium Phosphate, Dibasic, 7-Hydrate, U.S.P. to the JP chemical specifications derived from Dibasic Sodium Phosphate Hydrate.

Country of Origin: US
 Packaging Site: Paris Mfg Ctr & DC
 Manufacturer: PBG
 Manufacturer source batch: 0000127880

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

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 Vice President Global Quality

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