

## Product Specification

Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification
Appearance (Colorless or translucent crystals or granules)	Passes Test
USP – Assay (Na <sub>2</sub> HPO <sub>4</sub> ) (dried basis)	98.0 – 100.5 %
USP – Arsenic (As)	≤ 16 ppm
USP – Chloride (Cl)	≤ 0.06 %
USP – Endotoxin Concentration (EU/g)	≤ 2.5
USP – Identification	Passes Test
USP – Insoluble Substances	≤ 0.4 %
USP – Loss on Drying	43.0 – 50.0 %
USP – Sulfate (SO <sub>4</sub> )	≤ 0.2 %
EP – Identification A	Passes Test
EP – Identification C	Passes Test
EP – Identification D	Passes Test
EP – Reducing Substances	Passes Test
EP – Monosodium Phosphate	≤ 2.5 %
EP – Chloride (Cl)	≤ 200 ppm
EP – Sulfate (SO <sub>4</sub> )	≤ 500 ppm
EP – Appearance of Solution	Passes Test
EP – Iron (Fe)	≤ 20 ppm
EP – Assay (anhydrous basis)	98.0 – 101.0 %
JP – Arsenic (As)	≤ 2 ppm
JP – Assay (Na <sub>2</sub> HPO <sub>4</sub> ) (dried basis)	98.0 – 101.0 %
JP – Carbonate (CO <sub>3</sub> )	Passes Test
JP – Chloride (Cl)	≤ 0.014 %
JP – Clarity and Color of Solution	Passes Test
JP – Heavy Metals	≤ 10 ppm
JP – Identification	Passes Test
JP – pH (1 in 50)	9.0 – 9.4
JP – Sulfate (SO <sub>4</sub> )	≤ 0.038 %

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



Material No.: 3803-QM

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Test

Specification

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GMP Manufactured Product

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.

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

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