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



Material No.: 3803-07

Revision No.: 0

## **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 (CI)	≤ 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 (CI)	≤ 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 (Na₂HPO₄) (dried basis)	98.0 - 101.0 %	
JP - Carbonate (CO₃)	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 %	

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Test Specification

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

