

## Product Specification

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

Test	Specification
USP – Assay ( $\text{Na}_2\text{HPO}_4$ ) (dried basis)	98.0 – 100.5 %
USP – Identification	Passes Test
USP – Loss on Drying at 130°C	$\leq 5.0$ %
USP – Insoluble Substances	$\leq 0.4$ %
USP – Chloride (Cl)	$\leq 0.06$ %
USP – Sulfate ( $\text{SO}_4$ )	$\leq 0.2$ %
USP – Arsenic (As)	$\leq 16$ ppm
USP – Endotoxin Concentration (2.5 EU/g)	Passes Test
JPE – Assay (dried basis)	$\geq 99.0$ %
JPE – Identification	Passes Test
JPE – Arsenic (As)	$\leq 2$ ppm
JPE – Carbonate	Passes Test
JPE – Chloride (Cl)	$\leq 0.011$ %
JPE – Clarity and Color of Solution	Passes Test
JPE – Heavy Metals	$\leq 10$ ppm
JPE – pH (1–100)	9.0 – 9.4
JPE – Sulfate ( $\text{SO}_4$ )	$\leq 0.038$ %
JPE – Loss on Drying	$\leq 2.0$ %
EP – Assay ( $\text{Na}_2\text{HPO}_4$ ) (dried basis)	98.0 – 101.0 %
EP – Appearance of Solution	Passes Test
EP – Identification A	Passes Test
EP – Identification B	Passes Test
EP – Identification C	Passes Test
EP – Identification D	Passes Test
EP – Reducing Substances	Passes Test
EP – Chloride (Cl)	$\leq 200$ ppm
EP – Iron (Fe)	$\leq 20$ ppm
EP – Loss on Drying	$\leq 1.0$ %

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Sodium Phosphate, Dibasic, Anhydrous, U.S.P.  
Multi-Compendial



Material No.: 3804-08

Test	Specification
EP – Monosodium Phosphate	$\leq 2.5 \%$
EP – Sulfate (SO <sub>4</sub> )	$\leq 500 \text{ ppm}$

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.

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: Phillipsburg 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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