

Product Specification

Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification
USP – Assay (Na ₂ HPO ₄) (dried basis)	98.0 – 100.5 %
USP – Arsenic (As)	≤ 16 ppm
USP – Chloride (Cl)	≤ 0.06 %
USP – Identification	Passes Test
USP – Insoluble Substances	≤ 0.4 %
USP – Loss on Drying at 130°C	43.0 – 50.0 %
USP – Sulfate (SO ₄)	≤ 0.2 %

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: Paris Mfg Ctr & DC



Jamie Ethier
Vice President Global Quality