

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) | ≤ 3 ppm |
| USP – Chloride (Cl) | ≤ 0.06 % |
| USP – Identification A | Passes Test |
| USP – Identification B | Passes Test |
| USP – Insoluble Matter | ≤ 0.2 % |
| USP – Loss on Drying at 130°C | ≤ 5.0 % |
| USP – Sulfate (SO ₄) | ≤ 0.2 % |

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

(Suitable for Buffer Solutions)

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