

## Product Specification

Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification
USP – Identification A	Passes Test
USP – Identification B	Passes Test
USP – Identification C: Water (H <sub>2</sub> O)	≤ 1.0 %
USP – Assay (Anhydrous basis)	97.5 – 102.0 %
USP – Related substances: Maltose and isomaltose	≤ 0.4 %
USP – Related substances: Maltotriose	≤ 0.2 %
USP – Related substances: Fructose	≤ 0.15 %
USP – Related substances: Unspecified impurities, each	≤ 0.10 %
USP – Related substances: Total Impurities	≤ 0.5 %
USP – Color and Clarity of Solution	Passes Test
USP – Dextrin	Passes Test
USP – Soluble Starch, Sulfites	≤ 15 ppm
USP – Conductivity (uS cm <sup>-1</sup> )	≤ 20 μS/cm

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) – 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



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