

Material No.: 1919-09

Revision No.: 0

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 ₂ 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-1)	≤ 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

