

Dextrose, Anhydrous, Granular  
U.S.P.



Material No.: 4908-88

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 <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 - Soluble Starch, Sulfites	≤ 15 ppm
USP - Conductivity (uS cm-1)	≤ 20 μS/cm
USP - Dextrin	Passes Test
USP - Endotoxin Concentration (EU/g)	≤ 2.5
Solubility	Passes Test

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Appearance (white, granular powder)

Odorless

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

  
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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