

Dextrose
Anhydrous, U.S.P.



Material No.: 1920-05
Revision No.: 0

Product Specification

, 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
USP - Endotoxin Concentration (EU/g)	≤ 2.5
EP/BP - Identification A (Specific Rotation (+))	52.5 - 53.3 °
EP/BP - Identification B	Passes Test
EP/BP - Identification E	Passes Test
EP/BP - Assay (C ₆ H ₁₂ O ₆) (anhydrous substance)	97.5 - 102.0 %
EP/BP - Appearance of Solution	Passes Test
EP/BP - Conductivity, uS cm-1	≤ 20
EP/BP - Related Substances: sum of impurities A and B	≤ 0.4 %
EP/BP - Related Substances: impurity C	≤ 0.2 %
EP/BP - Related Substances: impurity D	≤ 0.15 %
EP/BP - Related Substances: unspecified impurities, each	≤ 0.10 %
EP/BP - Related Substances: total impurities	≤ 0.5 %
EP/BP - Dextrins	Passes Test
EP/BP - Soluble starch, sulfite	≤ 15 ppm
EP/BP - Water (H ₂ O)	≤ 1.0 %

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For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC
100 Mansford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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Test	Specification
JP - Identification 1	Passes Test
JP - Identification 2	Passes Test
JP - Water (H ₂ O)	≤ 1.0 %
JP - Assay (Anhydrous basis)	97.5 - 102.0 %
JP - Maltose and isomaltose	≤ 0.4 %
JP - Maltotriose	≤ 0.2 %
JP - Fructose	≤ 0.15 %
JP - Unspecified Impurities, each	≤ 0.10 %
JP - Total Impurities	≤ 0.5 %
JP - Color and Clarity of Solution	Passes Test
JP - Soluble Starch, Sulfites	≤ 15 ppm
JP - Conductivity (uS cm ⁻¹)	≤ 20 μS/cm
JP - Dextrin	Passes Test
JP - Heavy Metals (as Pb)	≤ 4 ppm

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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

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