

Dextrose, Monohydrate, U.S.P.
Multi-Compendial
(glucose, monohydrate)



Material No.: 1913-01
Revision No.: 0

Product Specification

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets J.P. Chemical Specifications, 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)	7.5 – 9.5 %
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
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)	7.5 – 9.5 %

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Test	Specification
JP – Identification 1	Passes Test
JP – Identification 2	Passes Test
JP – Water (H ₂ O)	7.5 – 9.5 %
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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Test	Specification
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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, 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

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

Avantor Performance Materials, LLC

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