

Dextrose, Anhydrous, U.S.P.
Multi-Compendial

(Glucose)



Material No.: 1920-05
Batch No.: 0000256454
Manufactured Date: 2020/02/25
Retest Date: 2025/02/23
Release Date: 2020/04/25
Revision No: 1

Certificate of Analysis

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	Result
USP – Identification A	Passes Test	PT
USP – Identification B	Passes Test	PT
USP – Identification C: Water (H ₂ O)	<= 1.0 %	< 0.1
USP – Assay (Anhydrous basis)	97.5 – 102.0 %	100.4
USP – Related substances: Maltose and isomaltose	<= 0.4 %	< 0.4
USP – Related substances: Maltotriose	<= 0.2 %	< 0.2
USP – Related substances: Fructose	<= 0.15 %	< 0.15
USP – Related substances: Unspecified impurities, each	<= 0.10 %	< 0.10
USP – Related substances: Total Impurities	<= 0.5 %	< 0.5
USP – Color and Clarity of Solution	Passes Test	PT
USP – Dextrin	Passes Test	PT
USP – Soluble Starch, Sulfites	<= 15 ppm	< 15
USP – Conductivity (uS cm ⁻¹)	<= 20 µS/cm	2
USP – Endotoxin Concentration (EU/g)	<= 2.5	< 0.1
EP/BP – Identification A (Specific Rotation (+))	52.5 – 53.3 Degree	52.9
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification E	Passes Test	PT
EP/BP – Assay (C ₆ H ₁₂ O ₆) (anhydrous substance)	97.5 – 102.0 %	100.4
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Conductivity, uS cm ⁻¹	<= 20	2
EP/BP – Related Substances: sum of impurities A and B	<= 0.4 %	< 0.4

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC
100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone: 610.386.1700

Test	Specification	Result
EP/BP – Related Substances: impurity C	<= 0.2 %	< 0.2
EP/BP – Related Substances: impurity D	<= 0.15 %	< 0.15
EP/BP – Related Substances: unspecified impurities, each	<= 0.10 %	< 0.10
EP/BP – Related Substances: total impurities	<= 0.5 %	0.5
EP/BP – Dextrins	Passes Test	PT
EP/BP – Soluble starch, sulfite	<= 15 ppm	< 15
EP/BP – Water (H ₂ O)	<= 1.0 %	< 0.1
JP – Identification 1	Passes Test	PT
JP – Identification 2	Passes Test	PT
JP – Water (H ₂ O)	<= 1.0 %	< 0.1
JP – Assay (Anhydrous basis)	97.5 – 102.0 %	100.4
JP – Maltose and isomaltose	<= 0.4 %	< 0.4
JP – Maltotriose	<= 0.2 %	< 0.2
JP – Fructose	<= 0.15 %	< 0.15
JP – Unspecified Impurities, each	<= 0.10 %	< 0.10
JP – Total Impurities	<= 0.5 %	< 0.5
JP – Color and Clarity of Solution	Passes Test	PT
JP – Soluble Starch, Sulfites	<= 15 ppm	< 15
JP – Conductivity (uS cm ⁻¹)	<= 20 uS/cm	2
JP – Dextrin	Passes Test	PT
JP – Heavy Metals (as Pb)	<= 4 ppm	< 4

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.

Storage Conditions: Preserve in well-closed containers.

Country of Origin: US

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0003001

Manufacturer source batch: 1000056300



Jamie Ethier
 Vice President Global Quality

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