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

(Glucose)



Material No.: 1920-06 Batch No.: 0000273349

Manufactured Date: 2020/09/22 Retest Date: 2025/09/21

Release Date: 2020/12/21 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 (H2O)	<= 1.0 %	0.1
USP – Assay (Anhydrous basis)	97.5 - 102.0 %	99.7
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)	$<= 20 \ \mu S/cm$	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 <sub>6</sub> H <sub>12</sub> O <sub>6</sub> ) (anhydrous substance)	97.5 - 102.0 %	99.7
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

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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 <sub>2</sub> O)	<= 1.0 %	< 0.1
P – Identification 1	Passes Test	PT
P – Identification 2	Passes Test	PT
P – Water (H <sub>2</sub> O)	<= 1.0 %	< 0.1
P – Assay (Anhydrous basis)	97.5 - 102.0 %	99.7
IP – Maltose and isomaltose	<= 0.4 %	< 0.4
P – Maltotriose	<= 0.2 %	< 0.2
P – Fructose	<= 0.15 %	< 0.15
P – Unspecified Impurities, each	<= 0.10 %	< 0.10
P – Total Impurities	<= 0.5 %	< 0.5
P – Color and Clarity of Solution	Passes Test	PT
P – Soluble Starch, Sulfites	<= 15 ppm	< 15
P – Conductivity (uS cm–1)	$<= 20 \ \mu S/cm$	2
IP – 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: 1000266300

