



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

Product No. 1913
Specifications current as of: Feb 28
2017

TEST	SPECIFICATION
GMP Manufactured Product	
Meets B.P. Chemical Specifications	
Meets E.P. Chemical Specifications	
Meets JPE Specifications	
Meets U.S.P Requirements	
CAUTION: For Manufacturing, processing or repackaging	
Bulk Pharmaceutical Chemical	
USP - Identification A	Passes Test
USP - Identification B	Passes Test
USP - Identification C: Water (H ₂ O)	7.5 - 9.5 %
USP - Specific Rotation $[\alpha]^{25}_D$ (calculated on dried basis)(+)	52.6 - 53.2 Degree
USP - Assay (Anhydrous basis)	97.5 - 102.0 %
USP - Related substances: Maltose and isomaltose	\leq 0.4 %
USP - Related substances: Maltotriose	\leq 0.2 %
USP - Related substances: Fructose	\leq 0.15 %
USP - Related substances: Unspecified impurities, each	\leq 0.10 %
USP - Related substances: Total Impurities	\leq 0.5 %
USP - Color and Clarity of Solution	Passes Test
USP - Soluble Starch, Sulfites	\leq 15 ppm
USP - Conductivity (uS cm ⁻¹)	\leq 20 μ S/cm
USP - Heavy Metals (as Pb)	\leq 5 ppm
USP - Dextrin	Passes Test
USP - Endotoxin Concentration (EU/g)	\leq 2.5
EP/BP - Identification A (Specific Rotation (+))	52.5 - 53.3 Degree
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	\leq 20
EP/BP - Related Substances: sum of impurities A and B	\leq 0.4 %
EP/BP - Related Substances: impurity C	\leq 0.2 %
EP/BP - Related Substances: impurity D	\leq 0.15 %
EP/BP - Related Substances: unspecified impurities, each	\leq 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)	7.0 - 9.5 %
JPE - Identification	Passes Test
JPE - Clarity and Color of Solution	Passes Test
JPE - Acid	Passes Test
JPE - Optical Rotation [α] _D ²⁰ (+)	52.2 - 53.2 Degree
JPE - Chloride (Cl)	<= 0.018 %
JPE - Sulfate (SO ₄)	<= 0.024 %
JPE - Arsenic (As)	<= 1.3 ppm
JPE - Heavy Metals (as Pb)	<= 4 ppm
JPE - Soluble Starch, Sulfites	Passes Test
JPE - Loss on Drying	<= 10.0 %
JPE - Residue on Ignition	<= 0.10 %

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.