



Mannitol, Powder, U.S.P. Multi-Compendial

Product No. 2553
Specifications current as of: Feb 28 2017

TEST	SPECIFICATION
GMP Manufactured Product	
Meets B.P. Chemical Specifications	
Meets E.P. Chemical Specifications	
Meets J.P. Chemical Specifications	
Meets U.S.P Requirements	
CAUTION: For Manufacturing, processing or repackaging	
Bulk Pharmaceutical Chemical	
USP - Assay (dried basis)	97.0 - 102.0 %
USP - Identification	Passes Test
USP - Related Substances: Sorbitol	<= 2.0 %
USP - Related Substances: Sum of isomalt& maltitol	<= 2.0 %
USP - Related Substances: Unspecified impurities	<= 0.10 %
USP - Related Substances: Total impurities	<= 2.0 %
USP - Loss on Drying at 105°C	<= 0.5 %
USP - Melting Point	165 - 170 °C
USP - Reducing Sugars	<= 0.1 %
USP - Nickel (Ni)	<= 1 ppm
USP - Appearance of Solution	Passes Test
USP - Conductivity (uS cm-1)	<= 20 µS/cm
USP - Total Aerobic Microbial Count	<= 100 cfu/g
USP - Total Yeast and Mold Count	<= 100 cfu/g
USP - Escherichia coli	Passes Test
USP - Bacterial Endotoxins, IU/g	<= 2.5
EP/BP - Assay (as HOCH ₂ (CHOH) ₄ CH ₂ OH) (dried basis)	97.0 - 102.0 %
EP/BP - Identification C	Passes Test
EP/BP - Melting Point	165 - 170 °C
EP/BP - Appearance of Solution	Passes Test
EP/BP - Conductivity, uS cm-1	<= 20
EP/BP - Reducing Sugars	<= 0.1 %
EP/BP - Related Substances: Impurity A	<= 2.0 %
EP/BP - Related Substances: Sum of Impurities B & C	<= 2.0 %
EP/BP - Related Substances: Unspecified Impurities, each	<= 0.10 %
EP/BP - Related Substances: Total Impurities	<= 2.0 %

EP/BP - Heavy Metals (as Pb)	<= 5 ppm
EP/BP - Nickel (Ni)	<= 1 ppm
EP/BP - Loss on Drying	<= 0.5 %
EP/BP - Escherichia coli	None Detected
EP/BP - Salmonella	None Detected
EP/BP - Total Yeast and Mold Count	<= 100 cfu/g
EP/BP - Total Aerobic Microbial Count	<= 100 cfu/g
EP/BP Endotoxin Concentration, <2.5 IU/g	Passes Test
JP - Assay (dried basis)	97.0 - 102.0 %
JP - Identification	Passes Test
JP - Related Substances: Sorbitol	<= 2.0 %
JP - Related Substances: Sum of isomalt & maltitol	<= 2.0 %
JP - Related Substances: Unspecified impurities	<= 0.10 %
JP - Related Substances: Total impurities	<= 2.0 %
JP - Heavy Metals (as Pb)	<= 5 ppm
JP - Loss on Drying at 105°C	<= 0.5 %
JP - Melting Point	165 - 170 °C
JP - Glucose	<= 0.1 %
JP - Nickel (Ni)	<= 1 ppm
JP - Clarity and Color of Solution	Passes Test
JP - Conductivity (uS cm-1)	<= 20 µS/cm
Suitable for use in the manufacture of parenteral dosage forms.	
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.	
Metallic Residues: Only residual nickel may be present at values <1ppm.	