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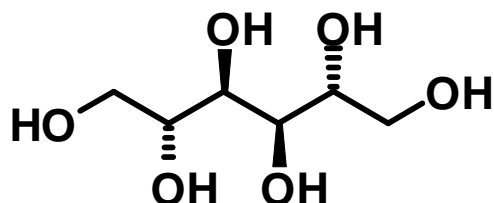
Product Specifications

D-Mannitol (tested to USP, EP)

CAS 69-65-8

Syn: Mannite

Structure:

Mol. Formula
Source $C_6H_{14}O_6$
D-(+)-Glucose

Mol. Wt.

182.17

<i>Test</i>	<i>Specification</i>
Identity (EP<2.2.24>) (USP<197K>)	IR
Identity (EP<2.2.27>)	TLC
Identity (EP<2.2.7>)	Sp. Rot., $[\alpha]_D$: +23° to +25°
Identity (EP<2.2.14>) (USP<741>)	MP: 165-170 °C
Appearance	White microcryst. solid
Solubility	Freely soluble in water, practically insoluble in Ethanol (96%)
Appearance of solution (EP) (USP)	Clear (2.2.1), colorless (2.2.2, Method II) solution
Conductivity (EP<2.2.38>) (USP)	$\leq 20 \mu\text{Scm}^{-1}$
Assay (EP<2.2.29>) (USP)	97%-102%
Related Substances (EP<2.2.29>) (USP)	
Impurity A (D-Sorbitol)	$\leq 2\%$
Impurity B (D-Maltitol) + Impurity C (D-Glucitol + Isomalt)	$\leq 2\%$
Unknown impurities	$\leq 0.1\%$
Total impurities	$\leq 2\%$

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<i>Test</i>	<i>Specification</i>
Reducing Sugars	USP, EP
LOD (EP<2.2.32>) (USP<731>)	≤ 0.5%
Residual Solvents (USP)	Meets USP <467> specifications
Heavy metals (Pb) (EP)	≤ 5 ppm
Ni (EP<2.4.15>) (AAS : USP<852>)	≤ 1.0 ppm
<u>Microbiological Specifications</u>	
Total Aerobic (EP<2.6.12>) (USP<62>)	≤ 100 CFU/g
<i>E. Coli</i>	Negative
<i>Salmonella</i>	Negative
Mold and Yeast (EP<2.6.13>) (USP<62>)	≤100 CFU/g
Endotoxin Level* (EP <2.6.14>) (USP<85>) [†]	≤ 4 IU/ g
Endotoxin Level* (EP <2.6.14>) (USP<85>) [‡]	≤ 2.5 IU/ g

Storage: Maintain in cool, dry containment.

* If intended for use in the manufacture of parenteral dosage forms without a further appropriate procedure for the removal of bacterial endotoxins.

[†] For parenteral dosage forms having a concentration of 100 g/L or less of Mannitol

[‡] For parenteral dosage forms having a concentration of more than 100 g/L of Mannitol.