



Specification

D-Mannitol USP/EP

Catalog Number: MN1001
CAS Number: 69-65-8
Synonym(s): Mannite
Molecular Formula: $C_6H_{14}O_6$
Molecular Weight: 182.17
Storage: 15°C – 30°C
Retest Period: Two years from the date of manufacture

Test	Specification
Appearance ²	White crystalline powder
Assay (HPLC) ^{1,2}	97.0 – 102.0%
Identification A: Specific Rotation ² B: Melting Point ^{1,2} C: FTIR ^{1,2} D: TLC ²	+23.0° to +25.0° 165°C - 170°C To match reference spectra To match standard
Appearance of Solution ^{1,2}	Clear & colorless in comparison to standard solution
Conductivity ^{1,2}	≤ 20μS/cm
Moisture (LOD) ^{1,2}	≤ 0.5%
Reducing Sugars ^{1,2}	≤ 0.1%
Related Substances (HPLC) Sorbitol ^{1,2} Maltitol & Isomalt ^{1,2} Unspecified Impurities ^{1,2} Total Impurities ^{1,2}	≤ 2.0% ≤ 2.0% ≤ 0.1% ≤ 2.0%
Lead	≤ 0.5ppm
Nickel ^{1,2}	≤ 1ppm
Aerobic Microbial Count ^{1,2}	≤ 100CFU/g
Yeast & Mold Count ^{1,2}	≤ 100CFU/g
<i>E. coli</i> ^{1,2}	Negative
<i>Salmonella</i> ²	Negative
Bacterial Endotoxin ^{1,2}	≤ 2.5IU/g
Residual Solvents: Raw materials, manufacturing process and the product do not contain residual solvents.	
This batch meets the specifications for USP38 ¹ & EP8.0 ² .	

Approved:

Date: July 16, 2018

John Grubb, PhD



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