



Certificate of Analysis

D-Mannitol USP/EP

Catalog Number: MN1001
Lot Number: 0625802
CAS Number: 69-65-8
Synonym(s): Mannite
Molecular Formula: C₆H₁₄O₆
Molecular Weight: 182.17
Storage: 15°C – 30°C
Date of Manufacture: March 20, 2018
Retest Date: March 19, 2020

| Test | Specification | Result |
|---|----------------------------|-------------------|
| Appearance | White crystalline powder | Conforms |
| Assay (HPLC) | 97.0 – 102.0% | 99.9% |
| Identification | | |
| A: Specific Rotation | +23.0° to +25.0° | 23.4° |
| B: Melting Point | 165°C - 170°C | 166.0°C – 168.0°C |
| C: FTIR | To match reference spectra | Conforms |
| D: TLC | To match standard | Conforms |
| Appearance of Solution | Clear & colorless | Conforms |
| Particle Size | 90% thru 80mesh | Conforms |
| Conductivity | ≤ 20μS/cm | 1.9μS/cm |
| Moisture (LOD) | ≤ 0.5% | 0.1% |
| Reducing Sugars | ≤ 0.1% | < 0.1% |
| Related Substances | | |
| Sorbitol | ≤ 2.0% | < 2.0% |
| Maltitol | ≤ 2.0% | < 2.0% |
| Isomalt | ≤ 2.0% | < 2.0% |
| Unspecified Impurities | ≤ 0.1% | < 0.1% |
| Total Impurities | ≤ 2.0% | < 2.0% |
| Lead | ≤ 0.5ppm | < 0.5ppm |
| Nickel | ≤ 1ppm | < 1ppm |
| Aerobic Microbial Count | ≤ 100CFU/g | 10CFU/g |
| Yeast & Mold Count | ≤ 100CFU/g | < 10CFU/g |
| <i>E. coli</i> | Negative | Negative |
| <i>Salmonella</i> | Negative | Negative |
| Bacterial Endotoxin | ≤ 2.5IU/g | < 2.5IU/g |
| Residual Solvents: Raw materials, manufacturing process and the product do not contain residual solvents. | | |
| This batch meets the specifications for USP39. | | |



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Approved by:

Date: July 18, 2018

A handwritten signature in blue ink that reads "John Grubb". The signature is written in a cursive, flowing style.

John Grubb, PhD
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