

Specification

Formula Hill: C₆H₁₄O₆
Molar Mass: 182,17 g/mol
CAS N°: 69-65-8

Print Date: 20 March 2024

108182 D(-)-Mannitol, Ph.Eur., USP

Specifications

Assay (HPLC, dried basis)	97,0 - 102,0 %
Identity	conforms
Appearance	
- White or almost white	conforms
- Crystalline powder	conforms
Appearance of solution	conforms
Conductivity	≤ 20,0 μS/cm
Melting point	165 - 170 °C
Nickel (Ni)	≤ 1 ppm
Reducing sugars (as glucose)	≤ 0,1 %
Related substances	
- Impurity A	≤ 2,0 %
- Sum of impurities B and C	≤ 2,0 %
- Total of all impurities	≤ 2,0 %
- Unspecified impurities (each)	≤ 0,1 %
Loss on drying (105°C)	≤ 0,5 %
TAMC (Total aerobic microbial count)	≤ 1.000 cfu/g
TYMC (Total yeast & mould count)	≤ 100 cfu/g
Escherichia coli	
- Negative in 1g	conforms
Salmonella	
- Negative in 10g	conforms

The product cannot be considered as an Active Pharmaceutical Ingredient (API)

Conforms to: Ph. Eur., USP specification