

# Specification

**Formula Hill:** C<sub>6</sub>H<sub>14</sub>O<sub>6</sub>  
**Molar Mass:** 182,17 g/mol  
**CAS N°:** 69-65-8

Print Date: 20 March 2024

108185 D(-)-Mannitol, Ph. Eur., for parenteral use

|                                      | Specifications |
|--------------------------------------|----------------|
| Assay (HPLC, dried basis)            | 97,0 - 102,0 % |
| Identity                             | conforms       |
| Appearance                           |                |
| - White or almost white              | conforms       |
| - Powder or crystals                 | conforms       |
| Appearance of solution               | conforms       |
| Conductivity                         | ≤ 20 μS/cm     |
| Melting range                        | 165 - 170 °C   |
| 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)      | ≤ 0,10 %       |
| Loss on drying (105°C)               | ≤ 0,5 %        |
| Bacterial endotoxins                 | ≤ 2,5 IU/g     |
| TAMC (Total aerobic microbial count) | ≤ 100 cfu/g    |
| TYMC (Total yeast & mould count)     | ≤ 100 cfu/g    |
| Escherichia coli                     |                |
| - Negative in 1 g                    | conforms       |
| Salmonella                           |                |
| - Negative in 10g                    | conforms       |

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

Conforms to: Ph. Eur. specification