

## D-Mannitol

Meets USP 41-NF 36, EP 9.0, JP 17, BP 2016 and IP 2018 testing specifications

### Product Code: TC513M

Molecular weight: 182.172

Molecular formula: C<sub>6</sub>H<sub>14</sub>O<sub>6</sub>

CAS No.: 69-65-8

### Quality Control

#### Appearance (USP, IP)

White crystalline powder or free-flowing granules.

#### Appearance (EP, BP)

White or almost white crystals or powder

#### Appearance (JP)

White crystals or powder or grain

#### Solubility (USP)

Freely soluble in water, soluble in alkaline solutions; slightly soluble in pyridine; very slightly soluble in alcohol; practically insoluble in ether.

#### Solubility (EP, BP)

Freely soluble in water, practically insoluble in 96% ethanol

#### Solubility (JP)

It is freely soluble in water, practically insoluble in ethanol (99.5%). It dissolves in sodium hydroxide TS.

#### Solubility (IP)

Freely soluble in water, slightly soluble in pyridine; very slightly soluble in ethanol (95%); insoluble in chloroform and in ether

#### Identification, FTIR (JP)

Matches with the standard pattern

#### Identification A, FTIR (USP, IP)

Matches with the standard pattern

#### Identification A, Specific rotation (EP, BP)

+23.00° to +25.00° (c = 2g sample + 2.6 g of disodium tetraborate + 20 mL of water, shake for 15-30 min., dilute the solution to 25 mL with water at 25°C)

#### Identification B (IP)

A clear solution is obtained which remains clear on the further addition of sodium hydroxide solution.

#### Identification B, Melting range (EP, BP)

165 - 170°C

#### Identification C (IP)

A pink colour is produced.

#### Identification C, FTIR (EP, BP)

Matches with the standard pattern

#### Identification D, Melting range (IP)

165 - 170°C

#### Identification D, TLC (EP, BP)

The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution

#### Appearance of solution (USP, EP, BP, IP)

The solution is clear and colourless

#### Clarity and colour of solution (JP)

10% solution is clear and its colour is not more intense than the control solution

#### Specific rotation (EP, BP, IP)

+23.00° to +25.00° (c = 2g sample + 2.6 g of disodium tetraborate + 20 mL of water, shake for 15-30 min., dilute the solution to 25 mL with water at 25°C)

#### Melting range (USP, EP, BP, JP)

165 - 170°C

#### Nickel (USP, EP, BP, JP)

<= 0.0001%

#### Heavy metals (BP, JP)

<= 0.0005%

#### Arsenic (IP)

<= 0.0002%

#### Acidity or alkalinity (IP)

<= 0.3 ml of 0.01M HCl is required to change the colour of the solution to red

#### Chloride (IP)

<= 0.005%

#### Sulphate (IP)

<= 0.01%

#### Glucose : KMnO<sub>4</sub> titration (JP)

<= 0.1%

#### Conductivity (USP, EP, BP, JP)

<= 20 μS.cm<sup>-1</sup> at 25°C

**Reducing sugar (USP, EP, BP)**

<= 0.1%

**Reducing sugar (IP)**

>= 12.8 ml of 0.05m sodium thiosulphate is required

**Sorbitol : TLC (IP)**

Any spot corresponding to sorbitol in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution

**Related substance : system suitability : Resolution : solution A : HPLC (USP, EP, BP)**

>= 2.0

**Related substance : system suitability : Resolution : solution B : HPLC (USP, EP, BP)**

>= 2.0

**Related substance : system suitability : Relative standard deviation : HPLC (JP)**

<= 1.0%

**Related substance, Impurity A : D-Sorbitol (USP, EP, BP, JP)**

<= 2.0%

**Related substance, Sum of impurity B (D-mannitol) and impurity C (Isomalt) (USP, EP, BP, JP)**

<= 2.0%

**Related substance, Unspecified impurities (USP, EP, BP, JP)**

<= 0.10%

**Related substance, Total impurity (USP, EP, BP, JP)**

<= 2.0%

**Sulphated ash (IP)**

<= 0.1%

**Loss on drying (at 105°C, 4 hr) (USP, EP, BP, JP, IP)**

<= 0.50%

**Bacterial endotoxin : 100g/l or less of mannitol (USP, EP, BP, IP)**

<= 4 IU/g

**Bacterial endotoxin : more than 100g/l of mannitol (USP, EP, BP, IP)**

<= 2.5 IU/g

**Microbial contamination : TAMC (USP, BP, EP)**

<= 100 CFU/g

**Microbial contamination : TYMC (USP, BP, EP)**

<= 100 CFU/g

**Assay (HPLC, on dry basis) (USP, EP, BP, JP, IP)**

97.0 - 102.0%

**Storage and Shelf Life:**

Store below 30°C

Shelf life is 48 months.

Use before expiry date given on the product label.

Revision: 03/2022

**Disclaimer :**

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