



D-(-)-Sorbitol

Meets USP-NF, EP, BP, JP and IP testing specifications

Product Code: TC170M

Product Description :

Molecular weight: 182.17Molecular formula: $C_6H_{14}O_6$ CAS No.: 50-70-4

Quality Control:

Appearance (USP) White granules, powder, or crystalline masses

Appearance (EP, BP) White or almost white, crystalline powder

Appearance (JP) White, granules, powder, or crystalline masses

Appearance (IP) A white crystalline powder

Solubility (USP) Very soluble in water, sparingly soluble in alcohol; and practically insoluble in ethyl ether.

Solubility (EP, BP) Very soluble in water, practically insoluble in ethanol (96%)

Solubility (JP) Very soluble in water, sparingly soluble in ethanol (95%), and practically insoluble in diethyl ether

Solubility (IP)

Very soluble in water, sparingly soluble in ethanol (95%), and practically insoluble in chloroform and in ether

pH (USP)

3.50 - 7.00 (10% w/w solution in carbon dioxide free water)

Clarity and colour of solution (USP) 10% solution in carbon dioxide-free water is clear and colourless

Clarity and colour of solution (JP) 25% solution in warm water is Clear and colourless

Acidity or alkalinity (JP)

25% solution in warm water is neutral **Acidity or alkalinity 1 (IP)**

<= 0.2 mL of 0.01 M sodium hydroxide is required to change the colour of the solution to pink

Acidity or alkalinity 2 (IP) <= 0.3 mL of 0.01M hydrochloric acid is required to change the colour of the solution to red

Appearance of solution (EP, BP, IP)

10% solution in water is clear and colourless

Identification A (USP) A deep pink or wine-red color appears

Identification A (EP, BP)

The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a)

Identification A (IP)

The principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with reference solution (a)

Identification 1 (JP)

A blue-green color develops, but no turbidity is produced

Identification B (USP)

The retention time of the major peak of the sample solution corresponds to that from the standard solution, as obtained in the assay

Identification B (EP, BP)

The precipitate, recrystallized from a small volume of ethanol (96%)R and dried in vacuo, melts at 98°C to 104°C

Identification B (IP)

A pink colour is produced

Identification 2 (JP)

A reddish purple to red-purple color immediately develops

Identification Test C : TLC (EP, BP)

The principal spot in the chromatogram obtained with the test solution is similar in positon, colour and size to the principal spot in the chromatogram obtained with reference solution (a)

Identification C (IP)

The residue, after washing rapidly with 5 mL of mixture of equal volumes of methanol and water and drying in a current of air, melts at about 175°

Identification 3 : (JP)

The precipitate, recrystallized from a small volume of ethanol (96%)R and dried in vacuo, melts at 97°C to 101°C

Identification D : (EP, BP)

+4.00° to +7.00° (c = 5gm substance and 6.4 gm of disodium tetraborate in 40 mL of water R. Allow to stand for 1 h and dilute to 50 mL with water R, at 20 ± 0.5 °C, anhydrous basis)

Specific rotation (EP, BP)

+4.00° to +7.00° (c = 5gm substance and 6.4 gm of disodium tetraborate in 40 mL of water R. Allow to stand for 1 h and dilute to 50 mL with water R, at 20 ± 0.5 °C, anhydrous basis)

Specific rotation (IP)

 $+4.00^{\circ}$ to $+7.00^{\circ}$ (c = 5gm substance and 6.4 gm of borax in 40 mL of water, allow to stand for 1 h, shaking dilute to 50 mL with water and filter if necessary

Limit of Nickel (USP) <= 0.0001%

Nickel (IP) <= 0.0001%

Nickel (JP) No red color develops

Chloride (USP, JP, IP) <= 0.0050%

Sulfate (JP) <= 0.006%

Sulfate (USP) <= 0.01%

Sulfate (IP) <= 0.0125%

Heavy metals (JP) <= 0.0005%

Heavy metals (IP) <= 0.001%

Residue on ignition (USP) <= 0.10%

Residue on ignition (JP) <= 0.02%

Arsenic (JP) <= 0.00013%

Arsenic (IP) <= 0.0002%

Water (USP, EP, BP, IP) <= 1.50%

Conductivity (EP, BP) <= 20 µs.cm-1

Reducing sugars (USP) <= 0.3%

Reducing sugars (EP, BP, IP) NLT 12.8 mL of 0.05M sodium thiosulfate is required

Glucose (JP) NMT 6.3 mL of volume for titration consumed Sugars (JP) Complies

Sulphated ash (IP) <= 0.10%

Loss on drying (JP) <= 2.00% (0.5g in vacuum, phosphorus (V)oxide, 80°C, 3 hr)

Related substances, system suitability, HPLC : Resolution : (EP, BP, IP)

min. 2.00 between the peaks due to impurity A and sorbitol

Related substances, any impurity, HPLC : (EP, BP, IP) <=2.00%

Related substances, total impurity, HPLC : (EP, BP, IP) <= 3.00%

System suitability, assay, HPLC : Resolution : (USP) >= 2.0 between sorbitol and mannitol

System suitability, assay, HPLC : RSD : (USP) <= 2.00%

Assay (HPLC, on anhydrous basis) : (USP) 91.00 - 100.50%

Assay (HPLC, on anhydrous basis) : (EP, BP) 97.00 - 102.00%

Assay (HPLC, on anhydrous basis) : (IP) 98.00 - 101.00%

Assay (Iodometry, dried sample) : (JP)

>= 97.00%

Microbial contamination (TAMC) : (USP, EP, BP) <= 1000 cfu/g

Microbial contamination (TYMC) : (USP, EP, BP) <= 100 cfu/g

Microbial contamination (Pathogen, E.Coli, Salmonella) : (EP, BP)

Absent

Bacterial endotoxins, <100 g/L sorbitol : (USP, EP, BP) NMT 4 IU/g

Bacterial endotoxins, 100 g/L or more of sorbitol : (USP, EP, BP) NMT 2.5 IU/g

Bacterial endotoxins, <10% w/v of sorbitol : (IP) NMT 4 EU/g Bacterial endotoxins, 10% W/V or more of sorbitol : (IP) NMT 2.5 EU/g

Storage and Shelf Life:

Store below 30°C away from bright light. Shelf life is 48 months. Use before expiry date given on the product label.

Revision : 05/2023

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia[™] publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia[™] Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic , research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HIMEDIA

HiMedia Laboratories Pvt. Ltd.

Plot No. C40, Road No. 21Y, MIDC, Wagle Industrial Area, Thane (West) 400604, Maharashtra, India.Tel No.022-69034800 Email: atc@himedialabs.com Website: www.himedialabs.com.