



D-Glucose anhydrous

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

Product Code: TC130M Product Description :

Molecular Weight: 180.16 Molecular Formula: C₆H₁₂O₆ CAS No.: 50-99-7 Synonym : Dextrose

Quality Control:

Appearance (EP, BP)

White or almost white, crystalline powder Appearance (JP) White crystals or crystalline powder Appearance (IP) A white crystalline powder Appearance (USP) Colorless crystals or white, crystalline or granular powder Solubility (EP, BP) Freely soluble in water, very slightly soluble in ethanol (96%) Solubility (JP) Freely soluble in water, slightly soluble in ethanol (95%) and practically insoluble in diethyl ether Solubility (IP) Freely soluble in water, sparingly soluble in ethanol (95%) Solubility (USP) Very soluble in boiling water; freely soluble in water; soluble in boiling alcohol; slightly soluble in alcohol Identification A : FTIR (USP) Matches with the standard pattern **Identification A (IP)** Complies **Identification (JP)** A red precipitate is produced Identification A : specific rotation, anhydrous substance : (EP, BP) $+52.50^{\circ}$ to $+53.30^{\circ}$ (c= Dissolve 10.0 gm of sample in 80 mL of water R, add 0.2 mL of dilute ammonia Rl, allow to stand for 30 min and dilute to 100.0 mL with water at $20 \pm 0.5^{\circ}$ C) Identification B : HPLC (USP)

The principal peak from the sample solution is similar in retention time and size to the principal peak from standard solution A

Identification B : HPLC (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 B (IP)

A copious red precipitate is formed. **Identification C : Water (K.F.) : (USP)** <= 1.0%

Identification C : TLC : System suitability (EP, BP) The chromatogram shows 4 clearly separated spots **Identification C, TLC : (EP, BP)**

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

Identification D (EP, BP) A red precipitate is formed Identification E : Water (K.F.) : (EP, BP) <= 1.0% Appearance of solution (IP)

The solution is clear and not more intensely coloured than reference solution BYS7

Appearance of solution (EP, BP) Solution of 10g dissolved in 15 mL water is clear and not more intensely coloured than reference solution BY7 Colour and clarity of solution (USP)

Solution of 10g dissolved in 15 mL water is clear and not more intensely coloured than the reference solution **Colour and clarity of solution (JP)**

The solution of 25g dissolved in 50 mL water is clear and has no more colour than the control solution

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Specific rotation, anhydrous substance (EP, BP)
+52.50^{\circ} to +53.30^{\circ} (c = Dissolve 10.0 gm of sample in 80 mL of
water R, add 0.2 mL of dilute ammonia Rl, allow to stand for
30 min and dilute to 100.0 mL with water at 20 \pm 0.5^{\circ}C)
Specific rotation (IP)
+52.50° to +53.30° (c = Dissolve 10.0 gm of sample in 80 mL of
water, add 0.2 mL of 5M ammonia, allow to stand for 30 min.
and dilute to 100.0 mL with water)
Arsenic (IP)
<= 0.0001\%
Arsenic (JP)
<= 0.00013%
Chloride (JP)
<= 0.018%
Chloride (IP)
<= 0.0125%
Heavy metals (IP)
<= 0.0005%
Heavy metals (JP)
<= 0.0004\%
Sulphate (JP)
<= 0.024%
Sulphate (IP)
<= 0.020\%
Sulphite (IP)
The absorbance at 583 nm is not more than that of the
standard solution.
Residue on ignition (JP)
<= 0.1%
Conductivity (USP, EP, BP)
<= 20 µs.cm-1 (at 25°C)
Barium (IP)
Complies
Foreign sugars, soluble starch and dextrins (IP)
The appearance of solution does not change on cooling
Acidity (JP)
A red colour develops
Acidity or alkalinity (IP)
<= 0.15 mL of 0.1M NaOH is required to change the colour of
solution to pink.
Dextrin (USP, EP, BP, JP)
The sample dissolves completely when 1g is refluxed with 20
mL of alcohol
Soluble starch, sulfites (USP, EP, BP)
<= 0.0015%
Sulphated ash (IP)
<= 0.10%
Soluble starch and sulfite (JP)
A yellow colour develops
Related substances and assay, system suitability, HPLC:
resolution (USP)
\geq 1.3, between maltotriose and maltose
Related substances 1, Maltose and isomaltose : HPLC (USP)
<= 0.40\%
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Related substances 2, Maltriose : HPLC (USP) <= 0.20%Related substances 3, Fructose : HPLC (USP) <= 0.15%Related substances 4, unspecified impurities : HPLC (USP) <= 0.10% Related substances 5, total impurities : HPLC (USP) <= 0.50% Related substances, system suitability, HPLC : resolution (EP, BP) >= 1.3 between the peaks due to impurities C and A Related substances, sum of impurities A and B, HPLC: (EP, BP) <= 0.4%Related substances, impurities C, HPLC : (EP, BP) <= 0.2% Related substances, impurity D, HPLC: (EP, BP) <= 0.15%Related substances, unspecified impurities, HPLC: (EP, BP) <= 0.10% Related substances, total impurities, HPLC : (EP, BP) <= 0.50% Water (K.F.) (EP, BP, USP, IP) <= 1.0% Loss on drying : (JP) <= 1.0% (at 105°C, 6hr) Assay (HPLC, anhydrous basis) : (USP, EP, BP) 97.50 - 102.00% Assay (Optical rotation, dried substance) (JP) min. 99.50%

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: 04/2023

Disclaimer :

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