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Dextrose

Portions of this monograph that are national USP text, and are not part of the harmonized text, are marked with symbols (◆▲) to specify this fact.

Change to read:

▲

▲ (USP 1-Aug-2024)

$C_6H_{12}O_6 \cdot H_2O$ 198.17

$C_6H_{12}O_6$ 180.16

D-Glucose monohydrate CAS RN®: 77938-63-7.

▲D-Glucose▲ (USP 1-Aug-2024) anhydrous CAS RN®: 50-99-7.

DEFINITION

Dextrose is (+)-D-glucopyranose and is derived from starch. It contains one molecule of water of hydration or is anhydrous. It contains NLT 97.5% and NMT 102.0% of dextrose, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **◆A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K ▲or 197A▲ (USP 1-Aug-2024)

Sample: Dry at 70° under vacuum for at least 2 h to constant weight.

Acceptance criteria: Meets the requirements◆

• **B.**

Analysis: Examine the chromatograms from the *Assay*.

Acceptance criteria: The principal peak from the *Sample solution* is similar in retention time and size to the principal peak from *Standard solution A*.

• **C. Water Determination ⟨921⟩, *Method I***

Samples

Anhydrous: 0.50 g

Monohydrate: 0.25 g

Acceptance criteria

Anhydrous: NMT 1.0%

Monohydrate: 7.5%–9.5%

ASSAY

• **Procedure**

Mobile phase: Water

System suitability solution: Dissolve 5 mg of USP Maltose Monohydrate RS, 5 mg of USP Maltotriose RS, and 5 mg of USP Fructose RS in water and dilute with water to 50.0 mL.

Standard solution A: 30 mg/mL of USP Dextrose RS

Sample solution: 30 mg/mL, determined on the anhydrous basis

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 30-cm; 9-µm packing L19[1]

Temperatures

Column: 85 ± 1°

Detector: 40°

Flow rate: 0.3 mL/min

Injection volume: 20 µL

Run time: About 1.5 times the retention time of dextrose

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for maltotriose, maltose, isomaltose, dextrose, and fructose are 0.7, 0.8, 0.8, 1.0, and 1.3, respectively. The retention time for dextrose is about 21 min.]

Suitability requirement

Resolution: NLT 1.3 between maltotriose and maltose

Analysis

Samples: *Standard solution A* and *Sample solution*

Calculate the percentage, on the anhydrous basis, of dextrose ($C_6H_{12}O_6$) in the portion of Dextrose taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of dextrose from the *Sample solution*

r_S = peak response of dextrose from *Standard solution A*

C_S = concentration of USP Dextrose RS in *Standard solution A* (mg/mL)

C_U = concentration of the *Sample solution* on the anhydrous basis (mg/mL)

Acceptance criteria: 97.5%–102.0% on the anhydrous basis

IMPURITIES

• **RELATED SUBSTANCES**

Mobile phase, System suitability solution, Standard solution A, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sample solution: 30 mg/mL, determined on the anhydrous basis

Standard solution B: Dilute 1.0 mL of the *Sample solution* with water to 250.0 mL.

Standard solution C: Dilute 25.0 mL of *Standard solution B* with water to 200.0 mL.

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for maltotriose, maltose, isomaltose, dextrose, and fructose are 0.7, 0.8, 0.8, 1.0, and 1.3, respectively. The retention time for dextrose is about 21 min.]

Suitability requirement

Resolution: NLT 1.3 between maltotriose and maltose

Analysis

Samples: *Standard solution A*, *Sample solution*, *Standard solution B*, and *Standard solution C*

Disregard any peak with an area less than the principal peak from *Standard solution C* (0.05%).

Acceptance criteria

For maltose and isomaltose: NMT 0.4%. The sum is NMT the area of the principal peak from *Standard solution B*.

For maltotriose: NMT 0.2%. NMT 0.5 times the area of the principal peak from *Standard solution B*.

For fructose: NMT 0.15%. NMT 3 times the area of the principal peak from *Standard solution C*.

Unspecified: NMT 0.10%. NMT twice the area of the principal peak from *Standard solution C*.

Total impurities: NMT 0.5%. NMT 1.25 times the area of the principal peak from *Standard solution B*.

SPECIFIC TESTS

• **COLOR AND CLARITY OF SOLUTION**

Reference solution: To 2.5 mL of cobaltous chloride CS, 6.0 mL of ferric chloride CS, and 1.0 mL of cupric sulfate CS add hydrochloric acid [10 g/L of hydrogen chloride (HCl)] to make 1000.0 mL.

Hydrazine sulfate solution: Dissolve 1.0 g of hydrazine sulfate in water and dilute to 100.0 mL. Allow to stand for 4–6 h.

Hexamethylenetetramine solution: In a 100-mL ground-glass-stoppered flask, dissolve 2.5 g of hexamethylenetetramine in 25.0 mL of water.

Primary opalescent suspension: To the *Hexamethylenetetramine solution* in the flask add 25.0 mL of the *Hydrazine sulfate solution*. Mix and allow to stand for 24 h. This suspension is stable for 2 months, provided it is stored in a glass container free from surface defects. The suspension must not adhere to the glass and must be well mixed before use.

Standard of opalescence: Dilute 15.0 mL of the *Primary opalescent suspension* with water to 1000.0 mL. This suspension is freshly prepared and may be stored for up to 24 h.

Reference suspension: To 5.0 mL of *Standard of opalescence* add 95.0 mL of water. Mix and shake before use.

Sample solution: Dissolve 10.0 g in 15 mL of water using a bath of boiling water. Allow to cool.

Analysis: Make the comparison by viewing the solutions downward in matched color–comparison tubes against a white surface (see *Visual Comparison ⟨630⟩*).

Acceptance criteria: The *Sample solution* is clear (its clarity is the same as that of water or its opalescence is not more pronounced than that of the *Reference suspension*) and not more intensely colored than the *Reference solution*.

- **Conductivity**

Sample solution: Dissolve 20.0 g in carbon dioxide-free water prepared from distilled water and dilute with the same solvent to 100.0 mL.

Analysis: Measure the conductivity of the solution while gently stirring with a magnetic stirrer.

Acceptance criteria: NMT 20 µS/cm at 25°

- **Dextrin**

Sample: 1 g, finely powdered

Analysis: Reflux the *Sample* with 20 mL of alcohol.

Acceptance criteria: The *Sample* dissolves completely.

- **Soluble Starch, Sulfites**

Sample solution: Dissolve the Dextrose sample (6.7 g of anhydrous or 7.4 g of monohydrate) in 15 mL of water using a bath of boiling water. Allow to cool.

Analysis: To the *Sample solution* add 25 µL of iodine TS.

Acceptance criteria: The resulting solution is yellow (NMT 15 ppm).

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** Label to indicate whether it is hydrous or anhydrous.
- **USP Reference Standards ⟨11⟩**

USP Dextrose RS
USP Fructose RS
USP Maltose Monohydrate RS
USP Maltotriose RS

[1] Aminex HPX-87C from Biorad is suitable.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DEXTROSE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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