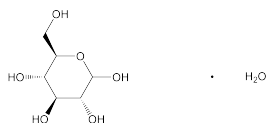


Dextrose

Add the following:

- 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. ■_{2S} (*USP39*)

Change to read:



$C_6H_{12}O_6 \cdot H_2O$	198.17
$C_6H_{12}O_6$	180.16
D-Glucose monohydrate ■[77938-63-7] ■ _{2S} (<i>USP39</i>)	
Anhydrous [50-99-7].	

DEFINITION

Change to read:

- 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%, calculated on the anhydrous basis. ■_{2S} (*USP39*)

IDENTIFICATION

Delete the following:

- A.**
Sample solution: 1 in 20
Analysis: Add a few drops of the *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.
Acceptance criteria: A copious red precipitate of cuprous oxide is formed. ■_{2S} (*USP39*)

Add the following:

- ♦**A. INFRARED ABSORPTION** (197) ♦ ■_{2S} (*USP39*)

Add the following:

- B.**
Analysis: Examine the chromatograms obtained in the *Assay*.
Acceptance criteria: The principal peak obtained with the *Sample solution* is similar in retention time and size to the principal peak obtained with *Standard solution A*. ■_{2S} (*USP39*)

Add the following:

- C. WATER DETERMINATION** (921)
Sample
Anhydrous: 0.50 g
Monohydrate: 0.25 g
Acceptance criteria
Anhydrous: NMT 1.0%
Monohydrate: 7.5%–9.5% ■_{2S} (*USP39*)

ASSAY

Add the following:

- 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 L19¹
Temperatures
Detector: 40°
Column: 85 ± 1°
Flow rate: 0.3 mL/min
Injection volume: 20 μL
Run time: 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 requirements
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*, based on the anhydrous basis (mg/mL)

Acceptance criteria: 97.5%–102.0% on the anhydrous basis ■_{2S} (*USP39*)

IMPURITIES

Add the following:

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

¹ Aminex HPX-87C from Biorad is suitable.

2 Dextrose

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.

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

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 requirements

Resolution: NLT 1.3 between maltotriose and maltose

Analysis

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

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

Acceptance criteria

Maltose and isomaltose: NMT 0.4%. The sum is NMT the area of the principal peak obtained with *Standard solution B*.

Maltotriose: NMT 0.2%. NMT 0.5 times the area of the principal peak obtained with *Standard solution B*.

Fructose: NMT 0.15%. NMT 3 times the area of the principal peak obtained with *Standard solution C*.

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

Total impurities: NMT 0.5%. NMT 1.25 times the area of the principal peak obtained with *Standard solution B*.^{■2S (USP39)}

Delete the following:

- **RESIDUE ON IGNITION (281):** NMT 0.1%.^{■2S (USP39)}

Delete the following:

- **CHLORIDE AND SULFATE (221), Chloride**
Control: 0.50 mL of 0.020 N hydrochloric acid
Sample: 2.0 g
Acceptance criteria: 0.018%; the *Sample* shows no more chloride than the *Control*.^{■2S (USP39)}

Delete the following:

- **CHLORIDE AND SULFATE (221), Sulfate**
Control: 0.50 mL of 0.020 N sulfuric acid
Sample: 2.0 g
Acceptance criteria: 0.025%; the *Sample* shows no more sulfate than the *Control*.^{■2S (USP39)}

Delete the following:

- **ARSENIC (211), Method I:** NMT 1 µg/g.^{■2S (USP39)}

Delete the following:

- **HEAVY METALS (231)**
Test preparation: 4.0 g of Dextrose in water to make 25 mL

Acceptance criteria: NMT 5 µg/g.^{● (Official 1-Jan-2018)}

SPECIFIC TESTS

Add the following:

■ **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 *Spectrophotometry and Light-Scattering (851)*, *Visual Comparison*).

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*.^{■2S (USP39)}

Delete the following:

■ **COLOR OF SOLUTION**

Control: Mix 1.0 mL of cobaltous chloride CS, 3.0 mL of ferric chloride CS, and 2.0 mL of cupric sulfate CS with water to make 10 mL, and dilute 3 mL of this solution with water to 50 mL.

Sample solution: 25 g of Dextrose in water to make 50.0 mL

Analysis: Make the comparison by viewing the solutions downward in matched color-comparison tubes against a white surface.

Acceptance criteria: The *Sample solution* has no more color than the *Control*.^{■2S (USP39)}

Delete the following:

■ **ACIDITY**

Sample solution: Dissolve 5.0 g in 50 mL of carbon dioxide-free water. Add phenolphthalein TS.

Analysis: Titrate with 0.020 N sodium hydroxide to the production of a distinct pink color.

Acceptance criteria: NMT 0.30 mL^{■2S (USP39)}

Delete the following:

- **WATER DETERMINATION (921), Method III**
Analysis: Dry at 105° for 16 h.
Acceptance criteria
Hydrous form: 7.5%–9.5%
Anhydrous form: NMT 0.5%^{■2S (USP39)}

Delete the following:

- **OPTICAL ROTATION (781S), Specific Rotation**
Sample solution: 100 mg/mL of Dextrose in 0.012 N ammonium hydroxide
Acceptance criteria: +52.6° to +53.2°^{■2S (USP39)}

Add the following:

- **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°^{■2S (USP39)}
- **DEXTRIN**
Sample: 1 g, finely powdered
Analysis: Reflux the *Sample* with 20 mL of alcohol.
Acceptance criteria: The *Sample* dissolves completely.

Change to read:

- **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).^{■2S (USP39)}

ADDITIONAL REQUIREMENTS

Change to read:

- ^{■2S (USP39)} **PACKAGING AND STORAGE:** Preserve in well-closed containers.^{■2S (USP39)}

Change to read:

- ^{■2S (USP39)} **LABELING:** Label to indicate whether it is hydrous or anhydrous.^{■2S (USP39)}

Add the following:

- **USP REFERENCE STANDARDS (11)**
USP Dextrose RS
USP Fructose RS
USP Maltose Monohydrate RS
USP Maltotriose RS[◆]
^{■2S (USP39)}