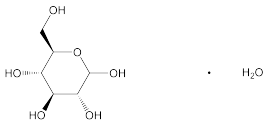
Dextrose

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 (*USP39*)
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 L19[1]
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.

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*)