Dextrose Excipient

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Expert Committee	Excipient Monographs1
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Excipient Monographs 1 Expert Committee has revised the Dextrose Excipient monograph. The purpose for the revision is to widen the *Acceptance criteria* in the *Related Substances* test as follows:

- For *Maltose and isomaltose*, change NMT 0.4% to NMT 0.6%
- For *Total impurities*, change NMT 0.5% to NMT 0.7%

The Dextrose Excipient Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Galina Holloway, Senior Scientific Liaison (301-816-8133 or gvh@usp.org).

Revision Bulletin
Official: September 1, 2020

Dextrose Excipient

$C_6H_{12}O_6 \cdot H_2O$ 198.17
D-Glucose, monohydrate;
D-Glucose monohydrate [77938-63-7].

DEFINITION

Dextrose Excipient is a sugar usually obtained by hydrolysis of starch. It contains 1 molecule of water of hydration. It contains NLT 97.5% and NMT 102.0% of dextrose ($C_6H_{12}O_6$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K
  Sample: Dry a test specimen per the conditions specified in the test for *Water Determination*.
  Acceptance criteria: Meets the requirements
- **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*.
- **C.** Meets the requirements for the water content in the test for *Water Determination*.

ASSAY

- **Procedure**
  Mobile phase: Water
  System suitability solution: 0.1 mg/mL each of USP Maltose Monohydrate RS, USP Maltotriose RS, and USP Fructose RS
  Standard solution A: 30 mg/mL of USP Dextrose RS
  Sample solution: Equivalent to 30 mg/mL of anhydrous dextrose
  Chromatographic system
  (See *Chromatography ⟨621⟩, System Suitability*.)
  Mode: LC
  Detector: Refractive index
  Column: 7.8-mm × 30-cm; 9-µm packing L19
  Temperatures
  Column: 85 ± 1°
  Detector: 40°
  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 of dextrose ($C_6H_{12}O_6$) in the portion of Dextrose Excipient taken:

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

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

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

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

C_U = concentration of Dextrose Excipient in the *Sample solution* (mg/mL)

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

IMPURITIES

Change to read:

- **Related Substances**

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

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: Equivalent to 30 mg/mL of anhydrous 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 B*, *Standard solution C*, and *Sample solution*

The reporting threshold is 0.05%. Disregard any peak with an area less than the principal peak from *Standard solution C*.

Acceptance criteria

Maltose and isomaltose: NMT ▲0.6%;▲ (RB 1-Sep-2020) the sum is NMT ▲1.5 times▲ (RB 1-Sep-2020) the area of the principal peak from *Standard solution B*.

Maltotriose: NMT 0.2%; NMT 0.5 times the area of the principal peak from *Standard solution B*

Fructose: NMT 0.15%; NMT 3 times the area of the principal peak from *Standard solution C*

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

Total impurities: NMT ▲0.7%;▲ (RB 1-Sep-2020) NMT ▲1.75▲ (RB 1-Sep-2020) times the area of the principal peak from *Standard solution B*

- **Residue on Ignition** ⟨281⟩**:** NMT 0.1%

- **Soluble Starch, Sulfites**

Sample solution: 1 g of Dextrose Excipient in 10 mL of water

Analysis: To the *Sample solution* add 1 drop of iodine TS.

Acceptance criteria: The liquid is colored yellow.

SPECIFIC TESTS

- **Water Determination** ⟨921⟩, *Method III*

Analysis: Dry under vacuum at 70° to constant weight.

Acceptance criteria: 7.5%–9.5%

- **Color of Solution**

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

Control solution: 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. Dilute 3 mL of this solution with water to 50 mL.

Analysis: Make the comparison by viewing the *Sample solution* and *Control solution* downward in matched color-comparison tubes against a white surface.

Acceptance criteria: The *Sample solution* has no more color than the *Control solution*.

- **Acidity**

Sample solution: 100 mg/mL in carbon dioxide-free water

Analysis: Add phenolphthalein TS to 50 mL of the *Sample solution*, and titrate with 0.020 N sodium hydroxide to the production of a distinct pink color.

Acceptance criteria: NMT 0.30 mL

- **Chloride and Sulfate ⟨221⟩, *Chloride***

Standard solution: 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 *Standard solution*.

- **Chloride and Sulfate ⟨221⟩, *Sulfate***

Standard solution: 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 *Standard solution*.

- **Arsenic ⟨211⟩, *Procedures, Method 1*:** NMT 1 ppm

- **Dextrin**

Sample: 1 g of finely powdered Dextrose Excipient

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

Acceptance criteria: It dissolves completely.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.

- **Labeling:** Label it to indicate that it is not intended for parenteral use. Label it to indicate that it is dextrose monohydrate.

- **USP Reference Standards ⟨11⟩**

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

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