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Dextrose Injection

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-dextrose-inj-20220429.

DEFINITION

Dextrose Injection is a sterile solution of Dextrose in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$). Dextrose Injection contains no antimicrobial agents.

IDENTIFICATION

• **A.**

Sample solution: Nominally 50 mg/mL of dextrose from a suitable volume of Injection in water

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.

ASSAY

Change to read:

• **Procedure**

Sample solution: Nominally 20–50 mg/mL of dextrose prepared as follows. Transfer a volume of Injection containing 2–5 g of dextrose to a 100-mL volumetric flask. Add 0.2 mL of 6 N ammonium hydroxide, and dilute with water to volume. ▲[Note—Ammonium hydroxide may be omitted for finished products containing up to 10% of dextrose and that have been terminally heat sterilized.]▲ (RB 1-Jun-2022)

Analysis

Sample: *Sample solution*

Determine the angular rotation in a suitable polarimeter tube (see *Optical Rotation* ⟨781⟩).

Calculate the percentage of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken:

$$\text{Result} = [(100 \times a)/(l \times \alpha)] \times (1/C_U) \times (M_{r1}/M_{r2}) \times 100$$

a = observed angular rotation of the *Sample solution* (°)

l = length of the polarimeter tube (dm)

α = midpoint of the specific rotation range for anhydrous dextrose, 52.9°

C_U = nominal concentration of dextrose in the *Sample solution* (g/100 mL)

M_{r1} = molecular weight of dextrose monohydrate, 198.17

M_{r2} = molecular weight of anhydrous dextrose, 180.16

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• **Limit of 5-Hydroxymethylfurfural and Related Substances**

Sample solution: Nominally 4 mg/mL of dextrose ($C_6H_{12}O_6 \cdot H_2O$) from a volume of Injection equivalent to 1.0 g of dextrose in water

Instrumental conditions

Mode: UV

Analytical wavelength: 284 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Sample solution* and *Blank*

Acceptance criteria: The absorbance of the *Sample solution* is NMT 0.25.

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: Dilute a suitable volume of Injection, if necessary, with water to NMT 5% of dextrose.

Analysis: Add 0.30 mL of saturated potassium chloride to 100 mL of *Sample solution*, and measure the pH.

Acceptance criteria: 3.2–6.5

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements

• **Bacterial Endotoxins Test ⟨85⟩**

[Note—Before analysis, dilute Injections containing more than 10% of dextrose to a concentration of 10% of dextrose.]

Acceptance criteria: NMT 0.5 USP Endotoxin Units/mL for Injection containing less than 5% dextrose; NMT 10.0 USP Endotoxin Units/g for Injection containing 5%–70% dextrose

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass. Store at room temperature.

• **Labeling:** The label states the total osmolar concentration in mOsmol/L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol/mL.

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

Topic/Question	Contact	Expert Committee
DEXTROSE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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