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Dextrose and Sodium Chloride Injection

DEFINITION

Dextrose and Sodium Chloride Injection is a sterile solution of Dextrose and Sodium Chloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$) and of sodium chloride (NaCl). It 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.

Add the following:

▲• **B. Sodium:** The sample imparts an intense yellow color to a nonluminous flame.▲ (USP 1-May-2023)

Change to read:

• ▲**C.**▲ (USP 1-May-2023) **Identification Tests—General** ⟨191⟩, *Chemical Identification Tests,* ▲*Chloride* (USP 1-May-2023)**:** Meets the requirements

ASSAY

Change to read:

• **Dextrose**

Sample solution: Nominally 2–5 g of dextrose per 100 mL, 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% dextrose that have been terminally heat sterilized.]▲ (USP 1-May-2023)

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 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%

Change to read:

• **Sodium Chloride**

▲**Sample solution:** A volume of Injection equivalent to 1.5–110 mg of sodium chloride. Add NLT 0.2 mL of diluted nitric acid and 35–100 mL of water. [Note—A protective colloid, such as polyvinyl alcohol, may be added to avoid coagulation of the silver chloride precipitate.]

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.1 N silver nitrate VS

Endpoint detection: Potentiometric

Analysis

Sample: *Sample solution*

Titrate, with stirring, with *Titrant* and determine the endpoint potentiometrically.

Calculate the percentage of the labeled amount of sodium chloride (NaCl) in the portion of Injection taken:

$$\text{Result} = V \times N \times (F/W) \times 100$$

V = volume of *Titrant* consumed by the *Sample solution* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 58.44 mg/mEq

W = nominal amount of sodium chloride in the *Sample solution* (mg)▲ (USP 1-May-2023)

Acceptance criteria: 95.0%–105.0%

IMPURITIES

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

Sample solution: Nominally 2 mg/mL of dextrose ($C_6H_{12}O_6 \cdot H_2O$) prepared from a volume of Injection containing the equivalent of 1.0 g of dextrose and 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

Change to read:

• **pH** ⟨791⟩

Sample solution: Nominally, ▲NMT▲ (USP 1-May-2023) 5% dextrose prepared by diluting, if necessary, a suitable volume of Injection with water

Acceptance criteria: 3.2–6.5

• **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 10.0 USP Endotoxin Units/g of dextrose.

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

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass. ▲Protect from freezing. Store at controlled room temperature.▲ (USP 1-May-2023)

Change to read:

• **Labeling:** ▲Label to indicate▲ (USP 1-May-2023) 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, ▲alternatively label to indicate▲ (USP 1-May-2023) 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 AND SODIUM CHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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