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Potassium Chloride in Dextrose and Sodium Chloride Injection

DEFINITION

Potassium Chloride in Dextrose and Sodium Chloride Injection is a sterile solution of Potassium Chloride, Dextrose, and Sodium Chloride in Water for Injection. It contains NLT 95.0% and NMT 110.0% of the labeled amounts of potassium (K) and chloride (Cl) and NLT 95.0% and NMT 105.0% of the labeled amounts of dextrose ($C_6H_{12}O_6 \cdot H_2O$) and sodium (Na). It contains no antimicrobial agents.

IDENTIFICATION

• A. The sample imparts an intense yellow color to a nonluminous flame.

• B.

Analysis: To 2 mL of Injection, add 5 mL of sodium cobaltinitrite TS.

Acceptance criteria: A yellow precipitate is formed immediately. If necessary, centrifuge the solution and examine the precipitate (presence of potassium).

• C. **IDENTIFICATION TESTS—GENERAL (191), Chloride:** Meets the requirements

• D.

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

• CHLORIDE

Sample solution: Transfer a volume of Injection, equivalent to 55 mg of chloride, to a suitable conical flask. Add 10 mL of glacial acetic acid, 75 mL of methanol, and 3 drops of eosin Y TS.

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N silver nitrate VS

Endpoint detection: Visual

Analysis

Sample: *Sample solution*

Titrate, with shaking, with *Titrant* to a pink endpoint. Each mL of *Titrant* is equivalent to 3.545 mg of chloride (Cl). Each mg of chloride is equivalent to 0.0282 mEq of chloride (Cl).

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

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

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

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

F = equivalency factor, 35.45 mg/mEq

W = nominal amount of chloride in the *Sample solution* (mg)

Acceptance criteria: 95.0%–110.0%

• DEXTROSE

Sample solution: Nominally 20–50 mg/mL of dextrose from Injection 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.

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* ($^{\circ}$)

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%

• **POTASSIUM AND SODIUM**

Internal standard solution: 1.04 mg/mL of lithium nitrate in water prepared as follows. Transfer 1.04 g of lithium nitrate to a 1000-mL volumetric flask, add a suitable nonionic surfactant, and dilute with water to volume.

Potassium stock solution: 74.56 mg/mL of potassium chloride (equivalent to 1 mEq/mL of potassium) prepared as follows. Transfer 18.64 g of potassium chloride, previously dried at 105° for 2 h, to a 250-mL volumetric flask. Dilute with water to volume.

Sodium stock solution: 58.44 mg/mL of sodium chloride (equivalent to 1 mEq/mL of sodium) prepared as follows. Transfer 14.61 g of sodium chloride, previously dried at 105° for 2 h, to a 250-mL volumetric flask. Dilute with water to volume.

Standard stock solution: 0.0391J mg/mL of potassium (K) from the *Potassium stock solution* and 0.02299J' mg/mL of sodium (Na) from the *Sodium stock solution* prepared as follows. Transfer 0.1J mL of the *Potassium stock solution* and 0.1J' mL of the *Sodium stock solution* to a 100-mL volumetric flask, where J and J' are the labeled amounts in (mEq/L) of potassium and sodium, respectively, in the Injection. Dilute with water to volume.

Standard solution: Transfer 5.0 mL of the *Standard stock solution* to a 500-mL volumetric flask, and dilute with the *Internal standard solution* to volume.

Sample solution: Transfer 5.0 mL of Injection to a 500-mL volumetric flask, and dilute with the *Internal standard solution* to volume.

Instrumental conditions

Mode: Flame photometer

Analytical wavelengths

Potassium: 766 nm

Sodium: 589 nm

Lithium: 671 nm

Blank: *Internal standard solution*

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Use the *Blank* to zero the instrument. Concomitantly determine the flame emission readings for the *Standard solution* and the *Sample solution*.

Calculate the percentage of the labeled amount of potassium (K) in the portion of Injection taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = emission reading ratio of potassium to lithium from the *Sample solution*

R_S = emission reading ratio of potassium to lithium from the *Standard solution*

C_S = concentration of potassium (K) in the *Standard stock solution* (mg/mL)

C_U = nominal concentration of potassium (K) in the *Sample solution* (mg/mL)

[NOTE—Each mg of potassium is equivalent to 0.02558 mEq of potassium.]

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

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = emission reading ratio of sodium to lithium from the *Sample solution*

R_s = emission reading ratio of sodium to lithium from the *Standard solution*

C_s = concentration of sodium (Na) in the *Standard stock solution* (mg/mL)

C_u = nominal concentration of sodium (Na) in the *Sample solution* (mg/mL)

[NOTE—Each mg of sodium is equivalent to 0.04350 mEq of sodium.]

Acceptance criteria

Potassium: 95.0%–110.0%

Sodium: 95.0%–105.0%

IMPURITIES

• 5-HYDROXYMETHYLFURFURAL AND RELATED SUBSTANCES

Sample solution: Nominally 2.0 mg/mL of dextrose from Injection in water

Instrumental conditions

Analytical wavelength: 284 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Sample solution* and *Blank*

Acceptance criteria: NMT 0.25

SPECIFIC TESTS

• **BACTERIAL ENDOTOXINS TEST (85):** NMT 0.5 USP Endotoxin Units/mL

• **pH (791):** 3.5–6.5

• **OTHER REQUIREMENTS:** It meets the requirements under *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.

• **LABELING:** The label states the potassium, sodium, and chloride contents in terms of mEq in a given volume. The label also states the total osmolar concentration in mOsmol/L. Where the contents are less than 100 mL, 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
POTASSIUM CHLORIDE IN DEXTROSE AND SODIUM CHLORIDE 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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