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## Potassium Chloride in Dextrose Injection

### DEFINITION

Potassium Chloride in Dextrose Injection is a sterile solution of Potassium Chloride and Dextrose in Water for Injection. It contains NLT 95.0% and NMT 110.0% of the labeled amount of potassium chloride (KCl) and NLT 95.0% and NMT 105.0% of the labeled amount of dextrose ( $C_6H_{12}O_6 \cdot H_2O$ ). 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.

• **B.** The sample imparts a violet color to a nonluminous flame. Since the presence of small quantities of sodium masks the color, screen out the yellow color produced by the sodium by viewing through a blue filter that blocks emission at 589 nm (sodium) but is transparent to emission at 404 nm (potassium). [NOTE—Traditionally, cobalt glass has been used, but other suitable filters are commercially available.]

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

### ASSAY

#### • 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* (°)

$l$  = length of the polarimeter tube (dm)

$\alpha$  = 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 CHLORIDE

**Sample solution:** Transfer a volume of Injection, equivalent to 75–150 mg of potassium chloride, to a conical flask. Add water, if necessary, to bring the volume to 10 mL, and 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

**Indicator:** Eosin Y TS

#### Analysis

**Sample:** *Sample solution*

Titrate, with shaking, with *Titrant* to a pink endpoint.

Calculate the percentage of the labeled amount of potassium chloride (KCl) 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, 74.55 mg/mEq

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

**Acceptance criteria:** 95.0%–110.0%

## IMPURITIES

### • LIMIT OF 5-HYDROXYMETHYLFURFURAL AND RELATED SUBSTANCES

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

#### Instrumental conditions

**Mode:** UV

**Analytical wavelength:** 284 nm

**Cell:** 1 cm

**Blank:** Water

#### Analysis

**Samples:** *Sample solution* and *Blank*

Determine the absorbance of the *Sample solution*.

**Acceptance criteria:** NMT 0.25

## SPECIFIC TESTS

• [BACTERIAL ENDOTOXINS TEST \(85\)](#): NMT 0.5 USP Endotoxin Units/mL

• [pH \(791\)](#).

**Sample solution:** Nominally 5% of dextrose from a portion of Injection in water

**Acceptance criteria:** 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 Type I or Type II.

• **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. The content of potassium, in mEq, is prominently displayed on the label.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
POTASSIUM CHLORIDE IN DEXTROSE INJECTION	<a href="#">Documentary Standards Support</a>	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM52020 Small Molecules 5

**Chromatographic Database Information:** [Chromatographic Database](#)

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