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# Ringer's and Dextrose Injection

## DEFINITION

Ringer's and Dextrose Injection is a sterile solution of Sodium Chloride, Potassium Chloride, Calcium Chloride, and Dextrose in Water for Injection. It contains, in each 100 mL, NLT 323.0 mg and NMT 354.0 mg of sodium (Na) [equivalent to NLT 820.0 mg and NMT 900.0 mg of sodium chloride (NaCl)], NLT 14.9 mg and NMT 16.5 mg of potassium (K) [equivalent to NLT 28.5 mg and NMT 31.5 mg of potassium chloride (KCl)], NLT 8.20 mg and NMT 9.80 mg of calcium (Ca) [equivalent to NLT 30.0 mg and NMT 36.0 mg of calcium chloride ($CaCl_2 \cdot 2H_2O$)], and NLT 523.0 mg and NMT 608.5 mg of chloride (Cl) [as sodium chloride (NaCl), potassium chloride (KCl), and calcium chloride ($CaCl_2 \cdot 2H_2O$)]. It contains 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.

[NOTE—The potassium, calcium, sodium, and chloride ion contents of Ringer's and Dextrose Injection are approximately 4, 4.5, 147.5, and 156 mEq/L, respectively.]

## IDENTIFICATION

• **A.**

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

**Analysis:** Add a few drops of *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.

**Acceptance criteria:** A copious red precipitate of cuprous oxide is formed.

• **B. IDENTIFICATION TESTS—GENERAL⟨191⟩:** Meets the requirements of test *A* under *Calcium*, and test *A* under *Chloride*.

• **C. SODIUM:** The sample imparts an intense yellow color to a nonluminous flame.

• **D. POTASSIUM:** The sample imparts a violet color to a nonluminous flame. Because the presence of small quantities of sodium masks the color, screen out the yellow color produced by sodium by viewing through a blue filter that blocks the 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.]

## ASSAY

• **CALCIUM**

[NOTE—Concentrations of the *Standard solution* and the *Sample solution* may be modified to fit the linear or working range of the atomic absorption spectrophotometer.]

**Lanthanum chloride solution:** 88.45 g/L of lanthanum chloride prepared as follows. Transfer a suitable quantity of lanthanum chloride to an appropriate volumetric flask. Add 50% of the final flask volume of water. Carefully add 25% of the final flask volume of hydrochloric acid. Mix, and allow to cool. Dilute with water to volume.

**Calcium stock solution:** 1 mg/mL of calcium (Ca) prepared as follows. Transfer 499.5 mg of primary standard calcium carbonate to a 200-mL volumetric flask, and add 10 mL of water. Carefully add 5 mL of diluted hydrochloric acid, and swirl to dissolve the calcium carbonate. Dilute with water to volume.

**Standard solutions:** 0.010, 0.015, and 0.020 mg/mL of calcium (Ca) prepared as follows. To three separate 100-mL volumetric flasks, each containing 5.0 mL of *Lanthanum chloride solution*, add 1.0, 1.5, and 2.0 mL, respectively, of *Calcium stock solution*. Dilute the contents of each flask with water to volume.

**Sample solution:** Transfer 20.0 mL of Injection to a 100-mL volumetric flask containing 5.0 mL of *Lanthanum chloride solution*. Dilute with water to volume.

**Blank:** Transfer 5.0 mL of *Lanthanum chloride solution* to a 100-mL volumetric flask and dilute with water to volume.

**Instrumental conditions**

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

**Mode:** Atomic absorption spectrophotometry

**Analytical wavelength:** Calcium emission line at 422.7 nm

**Lamp:** Calcium hollow-cathode

**Flame:** Air–acetylene

**Analysis**

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

Plot the absorbances of the *Standard solutions* versus the concentration, in mg/mL, of calcium, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration ($C$), in mg/mL, of calcium in the *Sample solution*.

Calculate the quantity (mg) of calcium (Ca) in each 100 mL of Injection taken:

$$\text{Result} = C \times D \times F$$

$C$ = concentration of calcium in the *Sample solution*, as determined from the graph (mg/mL)

$D$ = dilution factor of the *Sample solution*, 5

$F$ = conversion factor for each 100 mL of Injection, 100 mL

**Acceptance criteria:** 8.20–9.80 mg of calcium (Ca) in each 100 mL

• **Chloride**

**Sample solution:** Transfer 10 mL of Injection into a 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. Calculate the amount, in mg, of chloride (Cl) in each 100 mL of Injection taken:

$$\text{Result} = V \times N \times D \times F$$

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

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

$D$ = dilution factor of the *Sample solution*, 10

$F$ = equivalency factor, 35.45 mg/mEq

**Acceptance criteria:** 523.0–608.5 mg of chloride (Cl) in each 100 mL

• **Dextrose**

**Sample solution:** 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**

**Solution A:** Suitable nonionic wetting agent (1 in 500)

**Solution B:** 10.93 mg/mL of sodium chloride in water

**Standard stock solution:** 100 µg/mL of potassium in water prepared as follows. Dissolve 190.7 mg of potassium chloride, previously dried at 105° for 2 h, in 50 mL of water. Transfer the resulting solution to a 1-L volumetric flask, and dilute with water to volume.

**Standard solutions:** 0.005, 0.010, 0.015, and 0.020 mg/mL of potassium prepared as follows. Transfer 10 mL of *Solution B* to each of four 100-mL volumetric flasks containing 10.0 mL of *Solution A*. To each flask add 5.0, 10.0, 15.0, and 20.0 mL of *Standard stock solution*, respectively, and dilute with water to volume.

**Sample solution:** Transfer 10 mL of Injection to a 100-mL volumetric flask. Add 10.0 mL of *Solution A*. Dilute with water to volume.

**Blank:** Transfer 10 mL of *Solution B* to a 100-mL volumetric flask containing 10.0 mL of *Solution A*. Dilute with water to volume.

**Instrumental conditions**

**Mode:** Atomic emission spectrophotometry

**Emission wavelength:** 766 nm

**Analysis**

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

Set a suitable flame photometer for maximum transmittance at a wavelength of 766 nm. Adjust the instrument to zero transmittance with the *Blank*. Adjust the instrument to 100% transmittance with the most concentrated of the *Standard solutions*. Read the percentage transmittance of the other *Standard solutions*, and plot transmittances versus concentration of potassium. From the graph so obtained, read the percentage transmittance of the *Sample solution*.

Calculate the quantity (mg) of potassium (K) in each 100 mL of Injection taken:

$$\text{Result} = C \times D \times F$$

$C$ = concentration of potassium in the *Sample solution*, as determined from the graph (mg/mL)

$D$ = dilution factor of the *Sample solution*, 10

$F$ = conversion factor for each 100 mL of Injection, 100 mL

**Acceptance criteria:** 14.9–16.5 mg of potassium (K) in each 100 mL

- **Sodium**

**Solution A:** Suitable nonionic wetting agent (1 in 500)

**Standard stock solution:** 100 µg/mL of sodium in water prepared as follows. Dissolve 254.2 mg of sodium chloride, previously dried at 105° for 2 h, in 50 mL of water. Transfer the resulting solution to a 1-L volumetric flask, and dilute with water to volume.

**Standard solutions:** 0.005, 0.010, 0.015, and 0.020 mg/mL of sodium prepared as follows. Transfer 10 mL of *Solution A* to each of four 100-mL volumetric flasks. To each flask add 5.0, 10.0, 15.0, and 20.0 mL of *Standard stock solution*, respectively, and dilute with water to volume.

**Sample solution:** Transfer 5 mL of Injection to a 1-L volumetric flask containing 100 mL of *Solution A*. Dilute with water to volume.

**Blank:** Transfer 10 mL of *Solution A* to a 100-mL volumetric flask. Dilute with water to volume.

**Instrumental conditions**

**Mode:** Atomic emission spectrophotometry

**Emission wavelength:** 589 nm

**Analysis**

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

Set a suitable flame photometer for maximum transmittance at a wavelength of 589 nm. Adjust the instrument to zero transmittance with the *Blank*. Adjust the instrument to 100% transmittance with the most concentrated of the *Standard solutions*. Read the percentage transmittance of the other *Standard solutions*, and plot transmittances versus concentration of sodium. From the graph so obtained, read the percentage transmittance of the *Sample solution*.

Calculate the quantity (mg) of sodium (Na) in each 100 mL of Injection taken:

$$\text{Result} = C \times D \times F$$

$C$ = concentration of sodium in the *Sample solution*, as determined from the graph (mg/mL)

$D$ = dilution factor of the *Sample solution*, 200

$F$ = conversion factor for each 100 mL of Injection, 100 mL

**Acceptance criteria:** 323.0–354.0 mg of sodium (Na) in each 100 mL

**IMPURITIES**

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

**Sample solution:** Nominally 2.0 mg/mL of dextrose ($C_6H_{12}O_6 \cdot H_2O$) from Injection in water

**Instrumental conditions**

**Mode:** UV-Vis

**Analytical wavelength:** 284 nm

**Cell:** 1 cm

**Blank:** Water

**Analysis**

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

Determine the absorbance of the *Sample solution* with a suitable spectrophotometer.

**Acceptance criteria:** The absorbance is 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 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.
- **Labeling:** The label 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.

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