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Half-Strength Lactated Ringer's and Dextrose Injection

DEFINITION

Half-Strength Lactated Ringer's and Dextrose Injection is a sterile solution of Calcium Chloride, Potassium Chloride, Sodium Chloride, Sodium Lactate, and Dextrose in Water for Injection. It contains, in each 100 mL, NLT 142.5 and NMT 157.5 mg of sodium (Na) [as sodium chloride (NaCl) and sodium lactate ($C_3H_5NaO_3$)], NLT 7.08 and NMT 8.65 mg of potassium (K) [equivalent to NLT 13.5 and NMT 16.5 mg of potassium chloride (KCl)], NLT 2.45 and NMT 3.00 mg of calcium (Ca) [equivalent to NLT 9.0 and NMT 11.0 mg of calcium chloride ($CaCl_2 \cdot 2H_2O$)], NLT 184.0 and NMT 214.0 mg of chloride (Cl) [as sodium chloride (NaCl), potassium chloride (KCl), and calcium chloride ($CaCl_2 \cdot 2H_2O$)], and NLT 115.5 and NMT 130.5 mg of lactate ($C_3H_5O_3$) [equivalent to NLT 145.0 and NMT 165.0 mg of sodium lactate ($C_3H_5NaO_3$)]. It contains NLT 90.0% 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 calcium, potassium, and sodium contents of Half-Strength Lactated Ringer's and Dextrose Injection are approximately 1.4, 2, and 65 mEq/L, respectively.]

IDENTIFICATION

• A.

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

Change to read:

• **B. IDENTIFICATION TESTS—GENERAL (191), [Chemical Identification Tests, Chloride](#) and [Calcium](#):** Meets the requirements of the test ▲ (USP 1-May-2021) under *Chloride* and test A under *Calcium*

• **C. 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.]

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

• **E.** The retention time of the lactate peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay for *Lactate*.

ASSAY

• CALCIUM

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

Solution A: 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, 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 [dilute 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, prepared as follows. To three separate 100-mL volumetric flasks, each containing 5.0 mL of *Solution A*, 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: Nominally 0.014 mg/mL of calcium, prepared as follows. Transfer 50.0 mL of Injection, equivalent to 1.4 mg of calcium, to a 100-mL volumetric flask containing 5.0 mL of *Solution A*, and dilute with [water](#) to volume.

Blank: 5.0 mL of *Solution A* diluted with [water](#) to 100.0 mL

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometer

Analytical wavelength: Calcium emission line at 422.7 nm

Lamp: Calcium hollow-cathode

Flame: Air–acetylene

Analysis

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

Concomitantly determine the absorbances of the *Standard solutions* and the *Sample solution*. 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 this graph, calculate the concentration of calcium in each 100 mL of Injection taken:

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

C = concentration of calcium in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*, 2

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

Acceptance criteria: 2.45–3.00 mg of calcium (Ca) in each 100 mL

• POTASSIUM

Solution A: Suitable nonionic wetting solution (1 in 500)

Solution B: 10.93 mg/mL of [sodium chloride](#)

Standard stock solution: 0.100 mg/mL of potassium, prepared as follows. Transfer 190.7 mg of [potassium chloride](#), previously dried at 105° for 2 h, 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. To four separate 100-mL volumetric flasks, each containing 10.0 mL of *Solution A* and 10 mL of *Solution B*, add 5.0, 10.0, 15.0, and 20.0 mL, respectively, of *Standard 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, add 10.0 mL of *Solution A*, and dilute with [water](#) to volume.

Blank: Transfer 10.0 mL of *Solution A* and 10 mL of *Solution B* to a 100-mL volumetric flask. Dilute with [water](#) to volume.

Instrumental conditions

Mode: Flame photometry

Analytical wavelength: Maximum transmittance at 766 nm

Analysis

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

Set the flame photometer for maximum transmittance. 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 of the *Standard solutions* versus the concentration, in mg/mL, of potassium. Draw the straight line best fitting the four plotted points.

From this graph, calculate the concentration of potassium in each 100 mL of Injection taken:

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

C = concentration of potassium in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*, 5

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

Acceptance criteria: 7.08–8.65 mg of potassium (K) in each 100 mL

• SODIUM

Solution A: Suitable nonionic wetting solution (1 in 500)

Standard stock solution: 0.100 mg/mL of sodium, prepared as follows. Dissolve 254.2 mg of [sodium chloride](#), previously dried at 105° for 2 h, in 50 mL of [water](#). Transfer this solution to a 100-mL 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. To four separate 100-mL volumetric flasks, each containing 10.0 mL of *Solution A*, add 5.0, 10.0, 15.0, and 20.0 mL, respectively, of *Standard stock solution*. Dilute the contents of each flask with [water](#) to volume.

Sample solution: Transfer 10 mL of Injection to a 1-L volumetric flask containing 100.0 mL of *Solution A*. Dilute with [water](#) to volume.

Blank: Transfer 10.0 mL of *Solution A* to a 100-mL volumetric flask. Dilute with [water](#) to volume.

Instrumental conditions

Mode: Flame photometry