

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-5D18F662-DDB7-4A0C-9C09-CDF5D3FF7629_3_en-US
DOI: https://doi.org/10.31003/USPNF_M29136_03_01
DOI Ref: o8y8e

© 2025 USPC
Do not distribute

Multiple Electrolytes and Dextrose Injection Type 2

DEFINITION

Multiple Electrolytes and Dextrose Injection Type 2 is a sterile solution of Dextrose and suitable salts in Water for Injection to provide sodium, potassium, magnesium, calcium, and chloride ions. In addition, the salts provide ions of acetate, or acetate and citrate, or acetate and lactate, or gluconate and sulfate. It contains NLT 90.0% and NMT 110.0% of the labeled amounts of sodium (Na), potassium (K), magnesium (Mg), calcium (Ca), acetate ($C_2H_3O_2$), citrate ($C_6H_5O_7$), lactate ($C_3H_5O_3$), gluconate ($C_6H_{11}O_7$), and sulfate (SO_4); NLT 90.0% and NMT 120.0% of the labeled amount of chloride (Cl); and NLT 90.0% and NMT 105.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$). It may contain Hydrochloric Acid or Sodium Hydroxide used to adjust the pH. It contains no antimicrobial agents.

IDENTIFICATION

• A.

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

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. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Magnesium](#) and [Chloride](#):** Meets the requirements
- **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.]
- **E. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Calcium](#):** Meets the requirements of test A
- **F.** Where acetate is purported to be present, the retention time of the acetate peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay for Acetate.
- **G.** Where citrate is purported to be present, the retention time of the citrate peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay for Citrate.
- **H.** Where lactate is purported to be present, 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.
- **I.** Where gluconate is purported to be present, the retention time of the gluconate peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay for Gluconate.
- **J. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Sulfate](#):** Where sulfate is purported to be present, it meets the requirements of test A.

ASSAY

• ACETATE (if present)

Mobile phase: 0.05 N sulfuric acid

Standard solution: 1.2 mg/mL of sodium acetate trihydrate (0.0088 mEq/mL of acetate) in water

Sample solution: Nominally 0.0088 mEq/mL of acetate from a volume of Injection in water

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Columns

Guard: 4.6-mm × 3-cm; packing L17

Analytical: 7.8-mm × 30-cm; packing L17

Column temperature: 60°

Flow rate: 0.8 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of acetate ($C_2H_3O_2$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of acetate from the *Sample solution*

r_S = peak response of acetate from the *Standard solution*

C_S = concentration of acetate in the *Standard solution* (mEq/mL)

C_U = nominal concentration of acetate in the *Sample solution* (mEq/mL)

Acceptance criteria: 90.0%–110.0%

• 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.

Solution B: Mix 678 mL of hydrochloric acid with water to make 3000 mL.

Standard stock solution: 1000 µg/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 *Solution B*, and swirl to dissolve the calcium carbonate. Dilute with water to volume.

Standard solutions: 10.0, 15.0, and 20.0 µg/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 *Standard stock solution*. Dilute the contents of each flask with *Solution B* to volume.

Sample solution: Transfer a volume of Injection, equivalent to 20 mg of calcium, to a 1000-mL volumetric flask containing 50.0 mL of *Solution A*. Dilute with *Solution B* to volume.

Blank: 5.0 mL of *Solution A* diluted with *Solution B* to 100.0 mL

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 µg/mL, of calcium, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration (C), in µg/mL, of calcium in the *Sample solution*.

Calculate the percentage of the labeled amount of calcium (Ca) in the portion of Injection taken:

$$\text{Result} = (C/C_U) \times 100$$

C = concentration of calcium in the *Sample solution* (µg/mL), interpolated from the graph obtained

C_U = nominal concentration of calcium in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

• CHLORIDE

Sample solution: Transfer a volume of Injection, equivalent to 55 mg of chloride (1.55 mEq), to a suitable conical flask, and add water, if necessary, to bring the volume to 10 mL. Add 10 mL of glacial acetic acid, 75 mL of methanol, and 0.5 mL 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 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: 90.0%–120.0%

• 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 polarimeter tube (see [Optical Rotation \(781\)](#).)

Calculate the percentage of the labeled amount of dextrose ($\text{C}_6\text{H}_{12}\text{O}_6 \cdot \text{H}_2\text{O}$) 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 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: 90.0%–105.0%

• CITRATE (if present)

Mobile phase and Chromatographic system: Proceed as directed in the [Assay for Citric Acid/Citrate and Phosphate \(345\)](#).

Standard solution: 0.3 mEq/L of citrate ($\text{C}_6\text{H}_5\text{O}_7$) from [USP Citric Acid RS](#) in freshly prepared 1 mM sodium hydroxide

Sample solution: Nominally 0.3 mEq/L of citrate in 1 mM sodium hydroxide from a volume of Injection diluted with freshly prepared sodium hydroxide

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in [\(345\)](#).

Calculate the percentage of the labeled amount of citrate ($\text{C}_6\text{H}_5\text{O}_7$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of citrate from the *Sample solution*

r_S = peak response of citrate from the *Standard solution*

C_S = concentration of citrate in the *Standard solution* (mEq/L)

C_U = nominal concentration of citrate in the *Sample solution* (mEq/L)