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Multiple Electrolytes Injection Type 1

DEFINITION

Multiple Electrolytes Injection Type 1 is a sterile solution of suitable salts in Water for Injection to provide sodium, potassium, magnesium, and chloride ions. In addition, the salts provide ions of acetate, acetate and gluconate, or acetate, gluconate, and phosphate. It contains NLT 90.0% and NMT 110.0% of the labeled amounts of sodium (Na), potassium (K), magnesium (Mg), chloride (Cl), acetate ($C_2H_3O_2$), gluconate ($C_6H_{11}O_7$), and phosphate (PO_4). It may contain Hydrochloric Acid or Sodium Hydroxide used to adjust the pH. It contains no antimicrobial agents.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL (191), Magnesium and Chloride:** Meets the requirements
- **B. SODIUM:** The sample imparts an intense yellow color to a nonluminous flame.
- **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.** The retention time of the acetate peak of the *Sample solution* corresponds to that of the *Standard solution*, obtained as directed in the Assay for Acetate.
- **E.** 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*, obtained as directed in the Assay for Gluconate.
- **F.** Where phosphate is purported to be present, proceed as follows.

Sample solution: Add 5 mL of Injection and 1 mL of ammonium molybdate TS to a test tube and mix.

Acceptance criteria: A yellow precipitate, which is soluble in 6 N ammonium hydroxide, is formed.

ASSAY

• ACETATE

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%

• **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%–110.0%

• **GLUCONATE** (if present)

Mobile phase: 0.05 N sulfuric acid

Standard solution: 1 mg/mL of [USP Potassium Gluconate RS](#) (0.0043 mEq/mL of gluconate) in water

Sample solution: Nominally 0.004 mEq/mL of gluconate 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

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 gluconate ($C_6H_{11}O_7$) in the portion of Injection taken:

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

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