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Tricitrates Oral Solution

DEFINITION

Tricitrates Oral Solution is a solution of Sodium Citrate, Potassium Citrate, and Citric Acid in a suitable aqueous medium. It contains, in each 100 mL, NLT 2.23 g and NMT 2.46 g of sodium (Na), equivalent to NLT 9.5 g and NMT 10.5 g of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$); NLT 3.78 g and NMT 4.18 g of potassium (K), equivalent to NLT 10.45 g and NMT 11.55 g of potassium citrate monohydrate ($C_6H_5K_3O_7 \cdot H_2O$); NLT 12.20 g and NMT 13.48 g of citrate ($C_6H_5O_7$) as sodium citrate and potassium citrate; and NLT 6.34 g and NMT 7.02 g of citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$). [NOTE—The sodium and potassium ion contents of Tricitrates Oral Solution are each approximately 1 mEq/mL.]

IDENTIFICATION

- **A. Identification Tests—General, (191)**

  Sample: 2 mL Oral Solution

  Acceptance criteria: Meets the requirements for test *A* under *Sodium*

- **B.**

  Sample solution: Oral Solution (1 in 20)

  Analysis: Add 5 mL of sodium cobaltinitrite TS to 2 mL of *Sample solution*.

  Acceptance criteria: A yellow precipitate is formed immediately (presence of potassium).

- **C.** The retention time of the citrate peak of the *Sample solution* corresponds to that of *Standard solution 1*, as obtained in the *Assay* for *Citric Acid*.

ASSAY

- **Sodium and Potassium**

  Sodium stock solution: Transfer 14.61 g of sodium chloride, previously dried at 105° for 2 h, to a 250-mL volumetric flask, and dilute with water to volume.

  Potassium stock solution: Transfer 18.64 g of potassium chloride, previously dried at 105° for 2 h, to a 250-mL volumetric flask, and dilute with water to volume.

  Diluent: Transfer 1.04 g of lithium nitrate to a 1000-mL volumetric flask, add a suitable nonionic surfactant, then add water to volume. This solution contains 15 mEq of Li/1000 mL.

  Standard solution: Pipet 50 mL of *Sodium stock solution* and 50 mL of *Potassium stock solution* into a 500-mL volumetric flask, and dilute with water to volume. Each mL of this solution contains 0.1 mEq of sodium (Na) and 0.1 mEq of potassium (K). Transfer 50 µL of this solution to a 10-mL volumetric flask, and dilute with *Diluent* to volume.

  Sample solution: Transfer a volume of Oral Solution, equivalent to 2 g of combined citrates, to a 100-mL volumetric flask, and dilute with water to volume. Transfer 50 µL of this solution to a 10-mL volumetric flask, and dilute with *Diluent* to volume.

  Instrumental conditions

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

  Mode: Atomic absorption spectrophotometry

  Analytical wavelengths

  Sodium emission line: 589 nm

  Potassium emission line: 766 nm

  Blank: *Diluent*

  Analysis

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

  Calculate the quantity, in g, of sodium (Na) in the portion of Oral Solution taken:

$$\text{Result} = (A_r/M_r) \times (R_{U,Na}/R_{S,Na}) \times (W/F)$$

  A_r = atomic weight of sodium, 22.99

M_r = molecular weight of sodium chloride, 58.44

$R_{U,Na}$ = sodium emission reading from the *Sample solution*

$R_{S,Na}$ = sodium emission reading from the *Standard solution*

W = weight of sodium chloride in the *Sodium stock solution*, 14.61 g

F = conversion factor, 25

Calculate the quantity, in g, of potassium (K) in the portion of Oral Solution taken:

$$\text{Result} = (A_r/M_r) \times (R_{U,K}/R_{S,K}) \times (W/F)$$

A_r = atomic weight of potassium, 39.10

M_r = molecular weight of potassium chloride, 74.55

$R_{U,K}$ = potassium emission reading from the *Sample solution*

$R_{S,K}$ = potassium emission reading from the *Standard solution*

W = weight of potassium chloride in the *Potassium stock solution*, 18.64 g

F = conversion factor, 25

Acceptance criteria: 2.23–2.46 g/100 mL of sodium and 9.5–10.5 g/100 mL of potassium

• **Citrate**

Mobile phase, Standard solution 1, Chromatographic system, and **System suitability:** Proceed as directed in *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩.

Sample solution: Transfer an appropriate volume of Oral Solution into a suitable volumetric flask, and proceed as directed in *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩, *Sample solution (for the assay of citric acid/citrate)*.

Analysis: Proceed as directed in *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩, *Procedure*.

Calculate the concentration, in g/100 mL, of citrate ($C_6H_5O_7$) in the portion of Oral Solution taken:

$$\text{Result} = [(r_U/r_S) \times (C_S/C_U) - A(M_{r1}/M_{r2})] \times L$$

r_U = citrate peak area from the *Sample solution*

r_S = citrate peak area from *Standard solution 1*

C_S = concentration of citrate in *Standard solution 1* (µg/mL)

C_U = nominal concentration of *Sample solution*

A = concentration of citric acid monohydrate determined in the *Assay* for *Citric Acid* (mg/mL)

M_{r1} = molecular weight of citrate, 189.10

M_{r2} = molecular weight of citric acid monohydrate, 210.14

L = Oral Solution label claim (g/100 mL)

Acceptance criteria: 12.20–13.48 g/100 mL as sodium citrate and potassium citrate

• **Citric Acid**

Sample solution: Transfer 15 mL of Oral Solution into a 250-mL volumetric flask, and dilute with water to volume.

Analysis: Transfer 5 mL of the *Sample solution* into a suitable flask, and add 25 mL of water and 5 drops of phenolphthalein TS. Titrate with 0.02 N sodium hydroxide VS to a pink endpoint. Each mL of 0.02 N sodium hydroxide is equivalent to 1.401 mg of citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$).

Acceptance criteria: 6.34–7.02 g/100 mL

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.9–5.4

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩
  USP Citric Acid RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TRICITRATES ORAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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