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Sodium Citrate and Citric Acid Oral Solution

DEFINITION

Sodium Citrate and Citric Acid Oral Solution is a solution of Sodium 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), and NLT 6.11 g and NMT 6.75 g of citrate ($C_6H_5O_7$), equivalent to NLT 9.5 g and NMT 10.5 g of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$), and NLT 6.34 g and NMT 7.02 g of citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$).

IDENTIFICATION

- **A.** Sodium Citrate and Citric Acid Oral Solution imparts an intense yellow color to a nonluminous flame.
- **B.**

Sample solution: 2 mL of Oral Solution

Analysis: Add 2 mL of 15% [potassium carbonate TS](#) to the *Sample solution*, boil, and cool. Add 4 mL of [potassium pyroantimonate TS](#).

Acceptance criteria: A dense precipitate is formed (indicates the presence of sodium).

- **C.**

Sample solution: A dilution of 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 not formed immediately (indicates the absence of potassium).

- **D.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Citrate](#)

Sample solution: 3–5 drops of Oral Solution

Analysis: Add 20 mL of a mixture of [pyridine](#) and [acetic anhydride](#) (3:1) to the *Sample solution*.

Acceptance criteria: A light red color is produced.

ASSAY

- **SODIUM**

Sodium stock solution: 58.44 mg/mL of [sodium chloride](#) prepared as follows. Transfer 14.61 g of [sodium chloride](#), previously dried at 105° for 2 h, to a 250-mL volumetric flask. Dilute with [water](#) to volume.

Diluent: 1.04 mg/mL of [lithium nitrate](#) in [water](#) (equivalent to 15 mEq per 1000 mL of lithium) with a suitable nonionic surfactant

Standard stock solution: Pipet 50 mL of the *Sodium stock solution* into a 500-mL volumetric flask and dilute with [water](#) to volume.

Standard solution: Dilute 50 µL of the *Standard stock solution* with *Diluent* to 10 mL.

Sample stock solution: Transfer a volume of Oral Solution, equivalent to 1 g of sodium citrate dihydrate, to a 100-mL volumetric flask and dilute with [water](#) to volume.

Sample solution: Dilute 50 µL of the *Sample stock solution* with *Diluent* to 10 mL.

Blank: *Diluent*

Instrumental conditions

Mode: Flame photometry

Analytical wavelength: Sodium emission line at 589 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Adjust the flame photometer to read zero with the *Diluent*. Concomitantly determine the sodium flame emission readings for the *Standard solution* and the *Sample solution*.

Calculate the quantity (g) of sodium (Na) in 100 mL of Oral Solution taken:

$$\text{Result} = (R_{U, Na} / R_{S, Na}) \times (W/V) \times F \times (A_r/M_r) \times F_1$$

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

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

- W = weight of sodium chloride in the *Sodium stock solution* (g)
 V = volume of Oral Solution taken (mL)
 F = ratio of the dilution factor of the *Sample solution* to the *Standard solution*, 0.04
 A_r = atomic weight of sodium, 22.99
 M_r = molecular weight of sodium chloride, 58.44
 F_1 = conversion factor for each 100 mL of Oral Solution, 100 mL

Acceptance criteria: 2.23–2.46 g of sodium (Na) in each 100 mL of Oral Solution

• **SODIUM CITRATE**

Cation-exchange column: Mix 10 g of [styrene–divinylbenzene cation-exchange resin](#) with 50 mL of [water](#) in a suitable beaker. Allow the resin to settle and decant the supernatant until a slurry of resin remains. Pour the slurry into a 15-mm × 30-cm glass chromatographic tube (having a sealed-in, coarse-porosity fritted disk and fitted with a stopcock), and allow to settle as a homogeneous bed. Wash the resin bed with about 100 mL of [water](#), closing the stopcock when the [water](#) level is about 2 mm above the resin bed.

Sample solution: Transfer a volume of Oral Solution, equivalent to 1 g of sodium citrate dihydrate, to a 100-mL volumetric flask and dilute with [water](#) to volume.

Titrimetric system

Mode: Direct titration

Titrant: [0.02 N sodium hydroxide VS](#)

Endpoint detection: Visual

Analysis

Sample: *Sample solution*

Pipet 5 mL of the *Sample solution* carefully onto the top of the resin bed in the *Cation-exchange column*. Place a 250-mL conical flask below the column, open the stopcock, and allow to flow until the solution has entered the resin bed. Elute the column with 60 mL of [water](#) at a flow rate of about 5 mL/min, collecting about 65 mL of the eluate. Add 5 drops of [phenolphthalein TS](#) to the eluate, swirl the flask, and titrate with *Titrant*. Record the buret reading and calculate the volume of *Titrant* consumed.

Calculate the quantity (g) of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$) in 100 mL of the Oral Solution taken:

$$\text{Result} = \{[V \times N \times F \times (D/V_s)] - [(M_{r1}/M_{r2}) \times C]\} \times F_1 \times F_2$$

- V = volume of *Titrant* consumed by the *Sample solution* (mL)
 N = actual normality of the *Titrant* (mEq/mL)
 F = equivalency factor, 98.05 mg/mEq for sodium citrate dihydrate
 D = dilution factor of the *Sample solution*, 20
 V_s = volume of Oral Solution taken (mL)
 M_{r1} = molecular weight of sodium citrate dihydrate, 294.10
 M_{r2} = molecular weight of citric acid monohydrate, 210.14
 C = concentration of citric acid monohydrate in the *Sample solution*, as obtained in the Assay for *Citric Acid* (mg/mL)
 F_1 = conversion factor from mg to g, 0.001
 F_2 = conversion factor for each 100 mL of Oral Solution, 100 mL

Acceptance criteria: 9.5–10.5 g of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$) in each 100 mL of Oral Solution

• **CITRIC ACID**

Sample solution: Transfer a volume of Oral Solution, equivalent to 0.67 g of citric acid monohydrate, to a 100-mL volumetric flask and dilute with [water](#) to volume.

Titrimetric system

Mode: Direct titration

Titrant: [0.02 N sodium hydroxide VS](#)

Endpoint detection: Visual