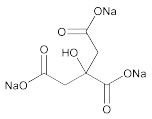
Sodium Citrate



$C_6H_5Na_3O_7$ 258.07
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, trisodium salt; Trisodium citrate (anhydrous) [68-04-2].

$C_6H_5Na_3O_7 \cdot 2H_2O$ 294.10
Trisodium citrate dihydrate [6132-04-3].

DEFINITION
Sodium Citrate is anhydrous or contains two molecules of water of hydration. It contains NLT 99.0% and NMT 100.5% of $C_6H_5Na_3O_7$, calculated on the anhydrous basis.

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Sodium* ⟨**191**⟩
  Sample solution: 50 mg/mL
  Acceptance criteria: Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL,** *Citrate* ⟨**191**⟩
  Sample solution: 50 mg/mL
  Acceptance criteria: Meets the requirements
- **C.** Upon ignition, it yields an alkaline residue that effervesces when treated with 3 N hydrochloric acid.

ASSAY
- **PROCEDURE**
  Sample: Add 100 mL of glacial acetic acid to 350 mg of Sodium Citrate (previously dried at 180° for 18 h) in a 250-mL beaker. Stir until completely dissolved.
  Analysis: Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N perchloric acid is equivalent to 8.602 mg of $C_6H_5Na_3O_7$.
  Acceptance criteria: 99.0%–100.5% on the anhydrous basis

IMPURITIES
- **HEAVY METALS** ⟨**231**⟩
  [NOTE—Use 50-mL color comparison tubes for preparing the *Standard preparation*, *Test preparation*, and *Monitor preparation*.]
  Standard preparation: 1.0 mL of *Standard Lead Solution* and 11 mL of water
  Test stock preparation: 88 mg/mL of anhydrous sodium citrate in water
  Test preparation: 12 mL of the *Test stock preparation*
  Monitor preparation: 11 mL of the *Test stock preparation* and 1.0 mL of *Standard Lead Solution*
  Analysis: Proceed as directed in the chapter for *Procedure*, omitting the dilution to 50 mL.
  Acceptance criteria: NMT 10 ppm
- **TARTRATE**
  Analysis: To a solution of 1 g in 2 mL of water in a test tube add 1 mL of potassium acetate TS and 1 mL of 6 N acetic acid. Rub the wall of the tube with a glass rod.
  Acceptance criteria: No crystalline precipitate is formed.

SPECIFIC TESTS
- **ALKALINITY**
  Sample solution: 1.0 g in 20 mL of water
  Acceptance criteria: The *Sample solution* is alkaline to litmus paper, but after the addition of 0.20 mL of 0.10 N sulfuric acid, no pink color is produced by 1 drop of phenolphthalein TS.
- **WATER DETERMINATION,** *Method III* ⟨**921**⟩**:** Dry a sample at 180° for 18 h: the anhydrous form loses NMT 1.0% of its weight; the hydrous form loses 10.0%–13.0% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Label it to indicate whether it is anhydrous or hydrous.

Sodium Citrate and Citric Acid Oral Solution

» 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, not less than 2.23 g and not more than 2.46 g of sodium (Na), and not less than 6.11 g and not more than 6.75 g of citrate ($C_6H_5O_7$), equivalent to not less than 9.5 g and not more than 10.5 g of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$); and not less than 6.34 g and not more than 7.02 g of citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$).

Packaging and storage—Preserve in tight containers.

Identification—

A: It meets the requirements of the flame test for *Sodium* ⟨191⟩.

B: Add 2 mL of 15% potassium carbonate TS to 2 mL of Oral Solution, boil, and cool. Add 4 mL of potassium pyroantimonate TS: a dense precipitate is formed *(presence of sodium).*

C: To 2 mL of a dilution of Oral Solution (1 in 20) add 5 mL of sodium cobaltinitrite TS: a yellow precipitate is not formed immediately *(absence of potassium).*

D: It meets the requirements of the tests for *Citrate* ⟨191⟩, 3 to 5 drops of Oral Solution and 20 mL of the mixture of pyridine and acetic anhydride being used.

Uniformity of dosage units ⟨905⟩**—**

FOR ORAL SOLUTION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩**—**

FOR ORAL SOLUTION PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

pH ⟨791⟩**:** between 4.0 and 4.4.

Assay for sodium—

Potassium stock solution, Sodium stock solution, Lithium diluent solution, and *Standard preparation*—Prepare as directed in the *Assay for sodium and potassium* under *Tricitrates Oral Solution.*

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 1 g of sodium citrate dihydrate, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 50 µL of this solution to a 10-mL volumetric flask, dilute with *Lithium diluent solution* to volume, and mix.

Procedure—Using a suitable flame photometer, adjusted to read zero with *Lithium diluent solution,* concomitantly determine the sodium flame emission readings for the *Standard preparation* and the *Assay preparation* at the wavelength of maximum emission at about 589 nm. Calculate the quantity, in g, of Na in each mL of Oral Solution taken by the formula:

$$(14.61/25V)(22.99/58.44)(R_{U,Na} / R_{S,Na})$$

in which 14.61 is the weight, in g, of sodium chloride in the *Sodium stock solution; V* is the volume, in mL, of Oral Solution taken, 22.99 is the atomic weight of sodium; 58.44 is the molecular weight of sodium chloride; and $R_{U,Na}$ and $R_{S,Na}$ are the sodium emission readings obtained for the *Assay preparation* and the *Standard preparation,* respectively.