Standard preparation—Transfer 5.0 mL of *Stock standard preparation* to a 500-mL volumetric flask, dilute with *Internal standard solution* to volume, and mix.

Assay preparation—Transfer 5.0 mL of Injection to a 500-mL volumetric flask, dilute with *Internal standard solution* to volume, and mix.

Procedure—Using a suitable flame photometer, adjusted to read zero with *Internal standard solution*, concomitantly determine the flame emission readings for the *Standard preparation* and the *Assay preparation* at the wavelengths of maximum emission for potassium, sodium, and lithium (766 nm, 589 nm, and 671 nm, respectively). Calculate the quantity, in mg, of K in each mL of the Injection taken by the formula:

$$C(R_{U,766} / R_{U,671})(R_{S,671} / R_{S,766})$$

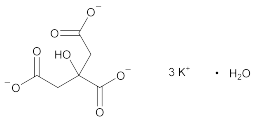
in which C is the concentration, in mg per mL, of potassium in the *Stock standard preparation*, $R_{U,766}$ and $R_{U,671}$ are the emission readings at the wavelengths identified by the subscript numbers obtained from the *Assay preparation*, and $R_{S,671}$ and $R_{S,766}$ are the emission readings at the wavelengths identified by the subscript numbers obtained from the *Standard preparation*. Each mg of potassium is equivalent to 0.02558 mEq of potassium. Calculate the quantity, in mg, of Na in each mL of the Injection taken by the formula:

$$C(R_{U,589} / R_{U,671})(R_{S,671} / R_{S,589})$$

in which C is the concentration, in mg per mL, of sodium in the *Stock standard preparation*, $R_{U,589}$ and $R_{U,671}$ are the emission readings at the wavelengths identified by the subscript numbers obtained for the *Assay preparation*, and $R_{S,671}$ and $R_{S,589}$ are the emission readings at the wavelengths identified by the subscript numbers obtained from the *Standard preparation*. Each mg of sodium is equivalent to 0.04350 mEq of sodium.

Assay for chloride—Transfer an accurately measured volume of Injection, equivalent to about 55 mg of chloride, to a conical flask, and add 10 mL of glacial acetic acid, 75 mL of methanol, and 3 drops of eosin Y TS. Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of Cl. Each mg of chloride is equivalent to 0.0282 mEq of Cl.

Potassium Citrate



$C_6H_5K_3O_7 \cdot H_2O$ 324.41

$C_6H_5K_3O_7$ 306.40

1,2,3-Propanetricarboxylic acid, 2-hydroxy-, tripotassium salt, monohydrate;
Tripotassium citrate monohydrate [6100-05-6].
Anhydrous [866-84-2].

DEFINITION

Potassium Citrate contains NLT 99.0% and NMT 100.5% of potassium citrate ($C_6H_5K_3O_7$), calculated on the dried basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL,** *Potassium* ⟨**191**⟩ and *Citrate* ⟨**191**⟩**:** A 100-mg/mL solution meets the requirements.

ASSAY

- **PROCEDURE**

Sample: 200 mg of Potassium Citrate
Blank: 25 mL of glacial acetic acid
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.1 N perchloric acid VS
Endpoint detection: Visual
Analysis: Dissolve the *Sample* in 25 mL of glacial acetic acid, add 2 drops of crystal violet TS, and titrate with the *Titrant* to a green endpoint. Perform a *Blank* determination.
Calculate the percentage of potassium citrate ($C_6H_5K_3O_7$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)
V_B = *Titrant* volume consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F = equivalency factor, 102.1 mg/mEq
W = *Sample* weight (mg)
Acceptance criteria: 99.0%–100.5% on the dried basis

IMPURITIES

- **HEAVY METALS,** *Method I* ⟨**231**⟩

Test preparation: Dissolve 2 g in 25 mL of water, and proceed as directed in the chapter, except use glacial acetic acid to adjust the pH.
Acceptance criteria: NMT 10 ppm

- **TARTRATE**

Sample: 1 g of Potassium Citrate
Analysis: Dissolve the *Sample* in 1.5 mL of water in a test tube, add 1 mL of 6 N acetic acid, and scratch the walls of the test tube with a glass rod.
Acceptance criteria: No crystalline precipitate is formed.

SPECIFIC TESTS

- **ALKALINITY**

Sample solution: Dissolve 1 g of Potassium Citrate in 20 mL of water.
Analysis: To the *Sample solution* add 0.20 mL of 0.10 N sulfuric acid, and add 1 drop of phenolphthalein TS.
Acceptance criteria: The *Sample solution* is alkaline to litmus. No pink color is produced after the addition of phenolphthalein TS.

- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample at 180° for 4 h: it loses 3.0%–6.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

Potassium Citrate Extended-Release Tablets

» Potassium Citrate Extended-Release Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of potassium citrate ($C_6H_5K_3O_7$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Citric Acid RS

Identification—

A: Powder 5 Tablets, mix with 20 mL of water, and filter: the filtrate responds to the tests for *Potassium* ⟨191⟩.

B: A portion of powdered Tablets containing about 50 mg of potassium citrate responds to the test for *Citrate* ⟨191⟩, 20 mL of the mixture of pyridine and acetic anhydride being used.