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Potassium Citrate Tablets

DEFINITION

Potassium Citrate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of potassium (K).

IDENTIFICATION

- **A.** The *Sample solution* for *Strength* produces line emissions or absorptions at the characteristic wavelengths for potassium.
- **B.** [IDENTIFICATION TESTS—GENERAL, Citrate\(191\)](#)

Analysis: Grind a Tablet to a fine powder in a mortar. Transfer the powder to a centrifuge tube, add 2–5 mL of water, sonicate for 1 min, shake, and centrifuge.

Acceptance criteria: The supernatant meets the requirements for the test.

STRENGTH

• CONTENT OF POTASSIUM, PROCEDURE 1

[NOTE—A standard stock solution is commercially available at different potassium concentrations, which may be used for preparation of the *Standard stock solution*. Necessary volumetric adjustment can be made in the *Standard solution*. Concentrations of the *Standard solution* and the *Sample solution* may be modified to fit the linear or working range of the instrument.]

Standard stock solution: Solution of potassium chloride, previously dried at 105° for 2 h, in water containing 1000 mg/L of potassium.

Standard solution: To a 50-mL volumetric flask add 20 mL of water and 1 mL of nitric acid, and mix thoroughly. Pipet 10.0 mL of the *Standard stock solution* into a volumetric flask, and dilute with water to volume to obtain a solution having a known concentration of about 200 µg/mL of potassium.

Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer an accurately weighed portion of the powdered Tablets, equivalent to about 0.1 g of potassium, to a 50-mL flask. Add 10 mL of nitric acid, and heat the solution to a gentle boil, during which fuming evolves. Boil the solution for an additional 30 min with constant swirling, during which time no fuming should be observed. Cool the solution to room temperature. Quantitatively transfer all of the solution to a 500-mL volumetric flask, dilute with water to volume, mix, and filter.

Inductively coupled plasma system

(See [Plasma Spectrochemistry \(730\)](#).)

Mode: Atomic emission spectroscopy

Analytical wavelength: 766.49 nm. [NOTE—The operating conditions may be developed and optimized based on the manufacturer's recommendation. A typical setting includes radio frequency (RF) power of about 1300 watts, argon torch flow of about 15 L/min, argon auxiliary flow of about 0.2 L/min, and a nebulizer flow rate of about 0.8 L/min.]

Blank: 2% nitric acid solution

Analysis

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

Calculate the percentage of the labeled amount of potassium (K) in the portion of Tablets taken:

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

r_U = response from the *Sample solution*

r_S = response from the *Standard solution*

C_S = concentration of potassium in the *Standard solution* (µg/mL)

C_U = nominal concentration of potassium in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of potassium

• CONTENT OF POTASSIUM, PROCEDURE 2

Standard stock solution A: 100 µg/mL of potassium chloride, previously dried at 105° for 2 h, in water



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Standard stock solution B: 10 µg/mL of potassium from *Standard stock solution A* in 0.125 N hydrochloric acid

Standard solutions: Transfer 5.0, 10.0, 15.0, 20.0, and 25.0 mL of *Standard stock solution B* to separate 100-mL volumetric flasks. Dilute the contents of each flask with 0.125 N hydrochloric acid to volume to obtain solutions containing 0.5, 1.0, 1.5, 2.0, and 2.5 µg/mL of potassium.

Sample solution: Finely powder NLT 20 Tablets. Transfer an equivalent to 5 Tablets to a porcelain crucible. Heat the crucible in a muffle furnace maintained at 550° for 6–12 h, and cool. Add 60 mL of hydrochloric acid, and boil gently on a hot plate or steam bath for 30 min, intermittently rinsing the inner surface of the crucible with 6 N hydrochloric acid. Cool, and quantitatively transfer the contents of the crucible to a 100-mL volumetric flask. Rinse the crucible with small portions of 6 N hydrochloric acid, and add the rinsings to the flask. Dilute with water to volume, and filter, discarding the first 5 mL of the filtrate. Dilute this solution quantitatively with 0.125 N hydrochloric acid to obtain a nominal concentration of 2 µg/mL of potassium.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 766.5 nm

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Blank: 0.125 N hydrochloric acid

Analysis

Samples: *Standard solutions* and *Sample solution*

Determine the absorbances of the solutions, using the *Blank*. Plot the absorbances of the *Standard solutions* versus concentration, in µg/mL, and draw the straight line best fitting the five plotted points. From the graph so obtained, determine the concentration, *C*, in µg/mL of potassium in the *Sample solution*.

Calculate the percentage of the labeled amount of potassium (K) in the portion of Tablets taken:

$$\text{Result} = (C/C_U) \times 100$$

C = determined concentration of potassium in the *Sample solution* interpolated from the graph (µg/mL)

C_U = nominal concentration of potassium in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0% of the label claim

SPECIFIC TESTS

- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic microbial count does not exceed 10³ cfu/g, and the total combined yeast and mold count does not exceed 10² cfu/g.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): Meet the requirement of the test for absence of *Escherichia coli*

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION \(2040\)](#)

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Analysis: Proceed as directed in *Content of Potassium, Procedure 1* or *Procedure 2*, for *Strength*, making any necessary volumetric adjustments.

Sample solution: If *Content of Potassium, Procedure 1* is used, pipet 10.0 mL of the filtered pooled solution under test to a 50-mL volumetric flask, and dilute with 2% nitric acid solution to 50 mL. If *Content of Potassium, Procedure 2* is used, dilute the filtered pooled solution under test with 0.125 N hydrochloric acid to a concentration falling within the range of the *Standard solutions*.

Calculate the percentage of the labeled amount of potassium (K) dissolved:

$$\text{Result} = (C \times D \times V/L) \times 100$$

C = measured concentration of potassium in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% of the labeled amount of K is dissolved.