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Potassium Chloride Oral Solution

DEFINITION

Potassium Chloride Oral Solution contains NLT 95.0% and NMT 105.0% of the labeled amount of potassium chloride (KCl). It may contain alcohol.

IDENTIFICATION

• **A. Identification Tests—General, *Potassium*⟨191⟩**

Sample solution: Carefully evaporate 5 mL to dryness, and ignite the residue at dull-red heat to remove all organic matter. Cool, dissolve the residue in 10 mL of water, and filter.

Acceptance criteria: Meets the requirements

• **B. Identification Tests—General, *Chloride*⟨191⟩**

Sample solution: Carefully evaporate 5 mL to dryness, and ignite the residue at dull-red heat to remove all organic matter. Cool, dissolve the residue in 10 mL of water, and filter.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Standard stock solution: 19.07 µg/mL of potassium chloride, previously dried at 105° for 2 h, in water. This solution contains 10 µg/mL of potassium.

Standard solutions: To separate 100-mL volumetric flasks transfer 10.0, 15.0, and 20.0 mL, respectively, of *Standard stock solution*. To each flask add 2.0 mL of sodium chloride solution (200 mg/mL) and 1.0 mL of hydrochloric acid, and dilute with water to volume. The *Standard solutions* contain, respectively, 1.0, 1.5, and 2.0 µg/mL of potassium.

Sample stock solution: Transfer a volume of Oral Solution, equivalent to 600 mg of potassium chloride, to a 500-mL volumetric flask, and dilute with water to volume. Transfer 5.0 mL of the solution to a 100-mL volumetric flask, and dilute with water to volume.

Sample solution: Transfer 5.0 mL of *Sample stock solution* to a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (200 mg/mL) and 1.0 mL of hydrochloric acid, and dilute with water to volume.

Instrumental conditions

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

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Potassium emission line at 766.5 nm

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Blank: Water

Analysis

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

Plot the absorbance of the *Standard solutions* versus the concentration of potassium, in µg/mL, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration of potassium in the *Sample solution* (µg/mL).

Calculate the percentage of the labeled amount of potassium chloride (KCl) in the portion of Oral Solution taken:

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

C = concentration of potassium in the *Sample solution* as determined in this test (µg/mL)

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

M_r = molecular weight of potassium chloride, 74.55

A_r = atomic weight of potassium, 39.10

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• **Alcohol Determination,** *Method II* ⟨611⟩(if present)**:** NLT 90.0% and NMT 115.0% of the labeled amount, the labeled amount being NMT 7.5% of C_2H_5OH, acetone being used as the internal standard

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

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

Topic/Question	Contact	Expert Committee
POTASSIUM CHLORIDE ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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