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Potassium Gluconate Oral Solution

DEFINITION
Potassium Gluconate Oral Solution contains NLT 95.0% and NMT 105.0% of the labeled amount of potassium gluconate ($C_6H_{11}KO_7$).

IDENTIFICATION

• **A.** Oral Solution imparts a violet color to a nonluminous flame. The presence of small quantities of sodium can mask the color unless the yellow color produced by sodium is screened out by viewing through a blue filter that blocks emission at 589 nm (sodium), but is transparent to emission at 404 nm (potassium). [NOTE—Traditionally, cobalt glass has been used, but other suitable filters are commercially available.]

• **B.**

Analysis: Evaporate 5 mL on a steam bath to dryness.

Acceptance criteria: A mineral oil dispersion of the residue exhibits an IR absorption maximum in the spectral region of 6.2–6.25 µm (carboxylic acid salt).

ASSAY

• **PROCEDURE**

Standard stock solution: Transfer 190.7 mg of potassium chloride, previously dried at 105° for 2 h, to a 1000-mL volumetric flask, add sufficient water to dissolve, and dilute with water to volume. Transfer 100.0 mL of this solution to a 1000-mL volumetric flask, and dilute with water to volume. This solution contains 10 µg/mL of potassium (equivalent to 19.07 µg/mL of potassium chloride).

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

Sample solution: Transfer an accurately measured volume of Oral Solution, equivalent to 1.8 g of potassium gluconate, to a 1000-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of the solution to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (1 in 5) and 1.0 mL of hydrochloric acid, dilute with water to volume, and mix.

Blank: Water

Instrumental conditions

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

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 766.5 nm

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Analysis

Samples: *Standard solutions* and *Sample solution*

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

Calculate the percentage of the labeled amount of potassium gluconate ($C_6H_{11}KO_7$) in the portion of Oral Solution taken:

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

C_K = determined concentration of potassium in the *Sample solution*, (µg/mL)

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

M_r = molecular weight of potassium gluconate, 234.25

A_r = atomic weight of potassium, 39.10

Acceptance criteria: 95.0%–105.0%

Change to read:

SPECIFIC TESTS

• **Alcohol Determination** ⟨611⟩, *▲Method I▲ (ERR-1-Feb-2023) —Distillation Method*: 4.5%–5.5% of alcohol (C_2H_5OH)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

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

Topic/Question	Contact	Expert Committee
POTASSIUM GLUCONATE ORAL SOLUTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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