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Potassium Gluconate Tablets

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

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020) **:** The IR absorption spectrum of potassium gluconate extracted from finely powdered Tablets exhibits maxima only at the same wavelengths as those of a similar preparation of USP Potassium Gluconate RS.

• **B.**

Sample solution: Triturate a portion of powdered Tablets with a few milliliters of water, and filter.

Acceptance criteria: The *Sample solution* imparts a violet color to a nonluminous flame; the presence of small quantities of sodium masks the color, unless the yellow color produced by sodium is screened out by viewing through a blue filter that blocks the emission at 589 nm (sodium); it is transparent to the emission at 404 nm (potassium). [Note—Traditionally, cobalt glass has been used, but other suitable filters are commercially available.]

ASSAY

• **Procedure**

Standard stock solution: 19.07 µg/mL of potassium chloride in water (equivalent to 10 µg/mL of potassium), prepared from potassium chloride previously dried at 105° for 2 h

Standard solutions: 1.0, 1.5, and 2.0 µg/mL of potassium from suitably diluted *Standard stock solution*, in a solution containing 4 mg/mL of sodium chloride and 1 mL of hydrochloric acid per 100 mL

Sample stock solution: Filtered water solution containing 0.18 mg/mL of potassium gluconate from NLT 20 finely powdered Tablets

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

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*, 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 Tablets taken:

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

C = 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%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 100 rpm

Time: 45 min

Sample solution: Filtered portion of the solution under test, suitably diluted with *Medium* if necessary

Analysis: Proceed as directed in the *Assay*.

Calculate the percentage of the labeled amount of potassium gluconate ($C_6H_{11}KO_7$) dissolved:

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

C = determined 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)

M_r = molecular weight of potassium gluconate, 234.25

A_r = atomic weight of potassium, 39.10

Tolerances: NLT 75% (Q) of the labeled amount of potassium gluconate ($C_6H_{11}KO_7$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Potassium Gluconate RS

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

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

Chromatographic Database Information: Chromatographic Database

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