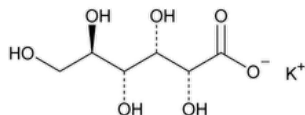


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Potassium Gluconate



$C_6H_{11}KO_7$ 234.25

$C_6H_{11}KO_7 \cdot H_2O$ 252.26

D-Gluconic acid, monopotassium salt;

Monopotassium D-gluconate.

Anhydrous CAS RN®: 299-27-4; UNII: 12H3K5QKN9.

Monohydrate CAS RN®: 35398-15-3; UNII: 8UXL786OWP.

DEFINITION

Potassium Gluconate is anhydrous or contains one molecule of water of hydration. It contains NLT 97.0% and NMT 103.0% of anhydrous potassium gluconate ($C_6H_{11}KO_7$), calculated on the dried basis.

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197M**

• **B.** Potassium Gluconate imparts a violet color to a nonluminous flame. Because the presence of small quantities of sodium masks the color, screen out the yellow color produced by sodium 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.]

• **C. THIN-LAYER CHROMATOGRAPHY**

Standard solution: 10 mg/mL of [USP Potassium Gluconate RS](#)

Sample solution: 10 mg/mL of Potassium Gluconate

Chromatographic system

(See [Chromatography \(621\), Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 µL

Developing solvent system: [Alcohol](#), [ethyl acetate](#), [ammonium hydroxide](#), and [water](#) (50:10:10:30)

Spray reagent: Dissolve 2.5 g of [ammonium molybdate](#) in 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask, add 1.0 g of [ceric sulfate](#), swirl to dissolve, and dilute with 2 N sulfuric acid to volume.

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry at 110° for 20 min. Allow to cool, and spray with the *Spray reagent*. Heat the plate at 110° for about 10 min.

Acceptance criteria: The principal spot of the *Sample solution* corresponds in color, size, and R_f to that of the *Standard solution*.

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. Add 2.0 mL of a 200-mg/mL [sodium chloride](#) solution and 1.0 mL of [hydrochloric acid](#) to each flask. Dilute with [water](#) to volume and mix. The *Standard solutions* contain 1.0, 1.5, and 2.0 µg/mL of potassium, respectively.

Sample stock solution: 0.18 mg/mL of Potassium Gluconate in [water](#). Filter the solution.

Sample solution: Transfer 5.0 mL of the filtrate from the *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_K , in µg/mL, of potassium in the *Sample solution*.

Calculate the percentage of potassium gluconate ($C_6H_{11}KO_7$) in the portion of Potassium Gluconate 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 = 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: 97.0%–103.0% on the dried basis

IMPURITIES

Change to read:

• REDUCING SUBSTANCES

Sample: 1.0 g of Potassium Gluconate

Blank: 10 mL of water

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Residual titration

Titrant: ▲ [0.1 N Iodine VS](#) ▲ (ERR 1-Sep-2022)

Back-titrant: ▲ [0.1 N Sodium Thiosulfate VS](#) ▲ (ERR 1-Sep-2022)

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 250-mL conical flask, dissolve in 10 mL of [water](#), and add 25 mL of [alkaline cupric citrate TS](#). Cover the flask, boil gently for 5 min, accurately timed, and cool rapidly to room temperature. Add 25 mL of 0.6 N [acetic acid](#), 10.0 mL of *Titrant*, and 10 mL of 3 N [hydrochloric acid](#), and titrate with *Back-titrant*, adding 3 mL of [starch TS](#) as the endpoint is approached. Perform the blank determination.

Calculate the percentage of reducing substances (as dextrose) in the portion of the *Sample* taken:

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

V_B = *Back-titrant* volume consumed by the *Blank* (mL)

V_S = *Back-titrant* volume consumed by the *Sample* (mL)

N_A = actual *Back-titrant* normality (mEq/mL)

F = equivalency factor, 27 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: NMT 1.0%