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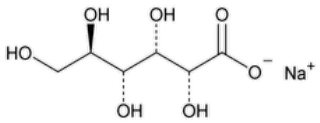
Sodium Gluconate



$C_6H_{11}NaO_7$ 218.14

D-Gluconic acid, monosodium salt;

Monosodium D-gluconate CAS RN®: 527-07-1; UNII: R6Q3791S76.

DEFINITION

Sodium Gluconate contains NLT 98.0% and NMT 102.0% of sodium gluconate ($C_6H_{11}NaO_7$).

IDENTIFICATION

- **A. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium***

  Sample solution: 1 in 20

  Acceptance criteria: Meets the requirements

- **B. Thin-Layer Chromatography**

  Standard solution: 10 mg/mL of USP Potassium Gluconate RS in water. [Note—Heat in a water bath at 60° to dissolve, if necessary.]

  Sample solution: 10 mg/mL of Sodium Gluconate in water. [Note—Heat in a water bath at 60° to dissolve, if necessary.]

  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 in the *Developing solvent system* until the solvent front has moved 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 10 min.

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

ASSAY

- **Procedure**

  Sample: 150 mg

  Analysis: Transfer the *Sample* to a suitable conical flask and dissolve in 75 mL of glacial acetic acid, warming to dissolve, if necessary. Cool, add quinaldine red TS, and titrate with 0.1 N perchloric acid VS to a colorless endpoint. Each milliliter of 0.1 N perchloric acid is equivalent to 21.81 mg of sodium gluconate ($C_6H_{11}NaO_7$).

  Acceptance criteria: 98.0%–102.0%

IMPURITIES

Change to read:

- **Chloride and Sulfate ⟨221⟩, *Chloride***

  Sample: 1.0 g

Acceptance criteria: ▲The turbidity produced in the *Sample* does not exceed that produced in▲ (USP 1-May-2022) 1 mL of 0.02 N hydrochloric acid (NMT 0.07%).

Change to read:

• **Chloride and Sulfate ⟨221⟩, *Sulfate***

Sample: 2.0 g, dissolved in boiling water

Acceptance criteria: ▲The turbidity produced in the *Sample* does not exceed that produced in▲ (USP 1-May-2022) 1 mL of 0.020 N sulfuric acid (NMT 0.05%).

Delete the following:

▲• **Lead ⟨251⟩**

Test preparation: 1.0 g in 25 mL of water

Acceptance criteria: NMT 10 ppm▲ (USP 1-May-2022)

• **Reducing Substances**

Sample: 1.0 g

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 0.1 N iodine VS, and 10 mL of 3 N hydrochloric acid, and then titrate with 0.1 N sodium thiosulfate VS, adding 3 mL of starch TS as the endpoint is approached. Perform a blank determination, omitting the specimen, and note the difference in volumes required (see *Titrimetry* ⟨541⟩). Each milliliter of the difference in volume of 0.1 N sodium thiosulfate consumed is equivalent to 2.7 mg of reducing substances (as dextrose).

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed 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
SODIUM GLUCONATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(5)

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