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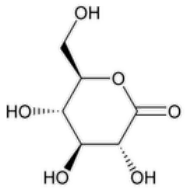
Gluconolactone



$C_6H_{10}O_6$ 178.14

D-Gluconic acid δ-lactone;

Glucono δ-lactone CAS RN®: 90-80-2.

DEFINITION

Gluconolactone contains NLT 99.0% and NMT 101.0% of gluconolactone ($C_6H_{10}O_6$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197K

ASSAY

• **Procedure**

Sample: 600 mg

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 0.1 N sodium hydroxide VS

Back-titrant: 0.1 N hydrochloric acid VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 100 mL of water in a 300-mL conical flask, add 50.0 mL of *Titrant*, and allow to stand for 15 min. Add phenolphthalein TS. Titrate excess alkali with *Back-titrant*. Perform a blank determination. Each milliliter of *Titrant* is equivalent to 17.81 mg of gluconolactone ($C_6H_{10}O_6$).

Acceptance criteria: 99.0%–101.0%

IMPURITIES

Delete the following:

▲• **Lead ⟨251⟩**

Test preparation: Prepare as directed in the chapter.

Analysis: Use 10 mL of *Diluted standard lead solution* (10 µg of lead) for the procedure.

Acceptance criteria: NMT 10 ppm▲ (USP 1-Dec-2021)

• **Reducing Substances**

Sample solution: Transfer 10.0 g to a 400-mL beaker, add 40 mL of water, and swirl to dissolve. Add 2 drops of phenolphthalein TS, and neutralize with sodium hydroxide solution (1 in 2). Dilute with water to 50 mL, and add 50 mL of alkaline cupric tartrate TS. Heat so that the solution begins to boil in 4 min, and allow boiling to continue for 120 s. Pass the suspension through a filtering crucible of medium pore size, and wash the filter with three 5-mL portions of water. Place the crucible in an upright position in the original beaker, add 5 mL of water and 3 mL of nitric acid to the crucible, mix with a glass rod to ensure complete solution of the cuprous oxide, and wash the solution from the crucible into a beaker with the aid of 5 mL of water. Add bromine TS, usually 5–10 mL, until the solution becomes yellow in color, and

dilute with water to 75 mL. Add a few glass beads, boil until the bromine has been driven off, and cool. Slowly add ammonium hydroxide until a deep blue color appears, then adjust with glacial acetic acid to a pH of 4, and add water to make 100 mL.

Analysis: Add 4 g of potassium iodide to the *Sample solution*, and titrate with 0.1 N sodium thiosulfate VS, adding starch TS just before the endpoint is reached.

Acceptance criteria: NMT 16.1 mL of 0.1 N sodium thiosulfate is consumed.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

  USP Gluconolactone RS

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

Topic/Question	Contact	Expert Committee
GLUCONOLACTONE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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