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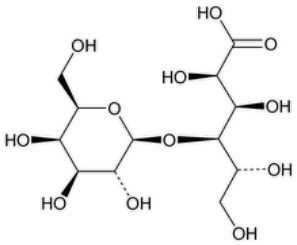
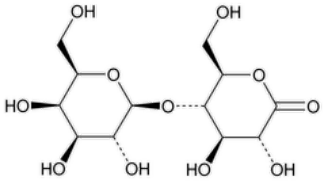
Lactobionic Acid



$C_{12}H_{22}O_{12}$(acid form) 358.30 CAS RN®: 96-82-2.



$C_{12}H_{20}O_{11}$(δ-lactone) 340.28 CAS RN®: 5965-65-1.
4-*O*-β-Galactopyranosyl-D-gluconic acid.

DEFINITION

Lactobionic Acid is a mixture in variable proportions of 4-*O*-β-D-galactopyranosyl-D-gluconic acid and 4-*O*-β-D-galactopyranosyl-D-glucono-1,5-lactone. It contains NLT 98.0% and NMT 102.0%, on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K.**▲ (CN 1-May-2020) [Note—If the spectra obtained show differences, dissolve the test substance and USP Lactobionic Acid RS separately in water, dry at 105°, and record new spectra using the residues.]

• **B.** Thin-Layer Chromatography ⟨621⟩

Standard solution: 10 mg/mL of USP Lactobionic Acid RS

Sample solution: 10 mg/mL of Lactobionic Acid

Adsorbent: Chromatographic silica gel mixture with an average particle size of 10–15 µm (TLC plates)

Developing solvent: Methanol, ethyl acetate, ammonium hydroxide, and water (2:1:1:1)

Application volume: 5 µL

Spray reagent: Slowly add 10 mL of sulfuric acid to about 40 mL of water. Mix, and allow to cool. Dilute with water to 100 mL, and mix. Add 2.5 g of ammonium molybdate and 1 g of ceric sulfate, and shake for 15 min to dissolve.

Analysis: Develop the chromatograms until the solvent front has moved about three-fourths the length of the plate, and allow to dry. Spray the plate with *Spray reagent*, and allow to dry. Repeat two more times, heat at 110° for 15 min, and examine.

Acceptance criteria: The principal spot from the *Sample solution* is similar in position and color to the principal spot from the *Standard solution*.

ASSAY

• **Procedure**

Sample: 0.350 g of Lactobionic Acid

Analysis: Dissolve the *Sample* in 50 mL of carbon dioxide-free water, previously heated to 30°. Immediately titrate with 0.1 N sodium hydroxide, and determine the two equivalence points potentiometrically. (See Titrimetry ⟨541⟩.)

Each mL of 0.1 N sodium hydroxide consumed to the first equivalency point is equivalent to 35.83 mg of $C_{12}H_{22}O_{12}$ (corresponds to the acid form), and each mL of 0.1 N sodium hydroxide consumed between the first and second equivalency points is equivalent to 34.03 mg of $C_{12}H_{20}O_{11}$ (corresponds to the δ-lactone form).

Calculate the content, expressed as a percentage, of the lactobionic acid as the sum of both results.

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

SPECIFIC TESTS

- **Water Determination,** *Method Ia* ⟨921⟩

  Sample solution: 0.50 g in a mixture of methanol and formamide (2:1)

  Acceptance criteria: NMT 5.0%

- **Appearance of Solution**

  Sample solution: 120 mg/mL of Lactobionic Acid

  Standard stock solution: Pipet 24.0 mL of ferric chloride CS and 6.0 mL of cobaltous chloride CS into a 100-mL volumetric flask. Dilute with 1% (w/v) hydrochloric acid to volume.

  Reference solution: Pipet 12.5 mL of the *Standard stock solution* into a 100-mL volumetric flask. Dilute with 1% (w/v) hydrochloric acid to volume.

  Acceptance criteria: The *Sample solution* is clear and not more intensely colored than the *Reference solution*.

- **Optical Rotation,** *Specific Rotation* ⟨781S⟩

  Sample solution: 10 mg/mL of Lactobionic Acid. Allow to stand for 24 h.

  Acceptance criteria: +23.0° to +29.0° (anhydrous substance)

- **Reducing Sugars**

  Sample solution: Dissolve 5.0 g of Lactobionic Acid in 25 mL of water with the aid of gentle heat, and cool.

  Analysis: To the *Sample solution* add 20 mL of cupric citrate TS and a few glass beads. Heat so that boiling begins after 4 min, and maintain boiling for 3 min. Cool rapidly, and add 100 mL of a 2.4% solution of glacial acetic acid and 20.0 mL of 0.025 M iodine VS. With continuous shaking, add 25 mL of a mixture of 6 mL of hydrochloric acid and 94 mL of water. When the precipitate has dissolved, titrate the excess iodine with 0.05 M sodium thiosulfate VS using 1 mL of starch TS, added toward the end of the titration as an indicator.

  Acceptance criteria: NLT 12.8 mL of 0.05 M sodium thiosulfate VS is required, corresponding to NMT 0.2% of reducing sugars, as glucose.

- **Articles of Botanical Origin,** *Total Ash* ⟨561⟩**:** NMT 0.2%

ADDITIONAL REQUIREMENTS

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

  USP Lactobionic Acid RS

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

Topic/Question	Contact	Expert Committee
LACTOBIONIC ACID	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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