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Lactic Acid

Propanoic acid, 2-hydroxy-;
Lactic acid
CAS RN®: 50-21-5.

DEFINITION

Lactic Acid is a mixture of lactic acid ($C_3H_6O_3$) and lactic acid lactate ($C_6H_{10}O_5$), equivalent to a total of NLT 88.0% and NMT 92.0%, by weight, of lactic acid ($C_3H_6O_3$). It is obtained by the lactic fermentation of sugars or is prepared synthetically. Lactic Acid obtained by fermentation of sugars is levorotatory, whereas that prepared synthetically is racemic.

[NOTE—Lactic Acid prepared by fermentation becomes dextrorotatory on dilution, which hydrolyzes L-(−)-lactic acid lactate to L-(+)-lactic acid.]

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, *Lactate*⟨191⟩:** Meets the requirements

ASSAY

- **PROCEDURE**

Sample: 2.5 mL, accurately weighed

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 1 N sodium hydroxide VS

Back-titrant: 1 N sulfuric acid VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a tared 250-mL flask, add 50.0 mL of *Titrant*, and boil the mixture for 20 min. Add phenolphthalein TS, and titrate the excess alkali in the hot solution with *Back-titrant*. Perform a blank determination. Each mL of *Titrant* is equivalent to 90.08 mg of lactic acid ($C_3H_6O_3$).

Acceptance criteria: 88.0%–92.0% (w/w)

IMPURITIES

- **CHLORIDE**

Sample solution: 1 in 100

Analysis: To 10 mL of the *Sample solution* acidified with nitric acid add a few drops of silver nitrate TS.

Acceptance criteria: No opalescence is produced immediately.

- **SULFATE**

Sample solution: 1 in 100

Analysis: To 10 mL of the *Sample solution* add 2 drops of hydrochloric acid and 1 mL of barium chloride TS.

Acceptance criteria: No turbidity is produced.

- **RESIDUE ON IGNITION** ⟨281⟩

Sample: 5 mL, accurately weighed

Acceptance criteria: NMT 3 mg (0.05%)

- **LIMIT OF CITRIC, OXALIC, PHOSPHORIC, OR TARTARIC ACID**

Sample solution: 1 in 10

Analysis: To 10 mL of the *Sample solution* add 40 mL of calcium hydroxide TS, and boil for 2 min.

Acceptance criteria: No turbidity is produced.

SPECIFIC TESTS

- **READILY CARBONIZABLE SUBSTANCES**

Sample: 5 mL

Analysis: Rinse a test tube with sulfuric acid, and allow to drain for 10 min. Add 5 mL of sulfuric acid to the test tube, carefully overlay it with the *Sample*, and maintain the tube at 15°.

Acceptance criteria: No dark color develops at the interface of the two acids within 15 min.

- **Optical Rotation, *Angular Rotation*⟨781A⟩:** −0.05° to +0.05° for racemic Lactic Acid
- **Sugars**

  Sample: 5 drops

  Analysis: To 10 mL of hot alkaline cupric tartrate TS add the *Sample*.

  Acceptance criteria: No red precipitate is formed.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **Labeling:** Label it to indicate whether it is levorotatory or racemic.

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

Topic/Question	Contact	Expert Committee
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