U.S. PHARMACOPEIA

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Lactic Acid

Propanoic acid, 2-hydroxy-.
Lactic acid [*50-21-5*].

» 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 not less than 88.0 percent and not more than 92.0 percent, by weight, of $C_3H_6O_3$. It is obtained by the lactic fermentation of sugars or is prepared synthetically. Lactic Acid obtained by fermentation of sugars is levorotatory, while 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.]

Packaging and storage— Preserve in tight containers.

Labeling— Label it to indicate whether it is levorotatory or racemic.

Identification— It meets the requirements of the test for *Lactate* ⟨ 191 ⟩.

Specific rotation ⟨ 781A ⟩: between −0.05° and +0.05°, for racemic Lactic Acid.

Readily carbonizable substances— Rinse a test tube with sulfuric acid TS, and allow to drain for 10 minutes. Add 5 mL of sulfuric acid TS to the test tube, carefully overlay it with 5 mL of Lactic Acid, and maintain the tube at a temperature of 15°: no dark color develops at the interface of the two acids within 15 minutes.

Residue on ignition ⟨ 281 ⟩: not more than 3 mg, from a 5-mL portion (0.05%).

Sugars— To 10 mL of hot alkaline cupric tartrate TS add 5 drops of Lactic Acid: no red precipitate is formed.

Chloride— To 10 mL of a solution (1 in 100) acidified with nitric acid add a few drops of silver nitrate TS: no opalescence is produced immediately.

Sulfate— To 10 mL of a solution (1 in 100) add 2 drops of hydrochloric acid and 1 mL of barium chloride TS: no turbidity is produced.

Heavy metals, *Method II* ⟨ 231 ⟩: 0.001%.

Limit of citric, oxalic, phosphoric, or tartaric acid— To 10 mL of a solution (1 in 10) add 40 mL of calcium hydroxide TS, and boil for 2 minutes: no turbidity is produced.

Residual solvents ⟨ 467 ⟩**:** meets the requirements.
(Official January 1, 2007)

Assay— To about 2.5 mL of Lactic Acid, accurately weighed in a tared 250-mL flask, add 50.0 mL of 1 N sodium hydroxide VS, and boil the mixture for 20 minutes. Add phenolphthalein TS, and titrate the excess alkali in the hot solution with 1 N sulfuric acid VS. Perform a blank determination (see *Residual Titrations* under *Titrimetry* ⟨ 541 ⟩). Each mL of 1 N sodium hydroxide is equivalent to 90.08 mg of $C_3H_6O_3$.

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