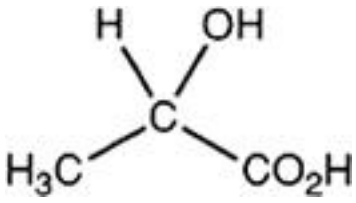
Lactic acid (Acidum lacticum)



$C_3H_6O_3$

Relative molecular mass. 90.08

Chemical name. Lactic acid; 2-hydroxypropanoic acid; CAS Reg. No. 50-21-5.

Description. A colourless or slightly yellow, clear, syrupy, caustic liquid; odourless or with a slight characteristic odour.

Miscibility. Miscible with water, ethanol (~750 g/l) TS, and ether R.

Category. Used in the preparation of sodium lactate solution as electrolyte.

Storage. Lactic acid should be kept in a tightly closed container.

Additional information. Lactic acid as described is not suitable for parenteral administration (haemodialysis). Lactic acid is usually a racemate (*RS*), but the (+)-(*S*)-isomer may predominate; it is hygroscopic.

Requirements

Definition. Lactic acid is a mixture of lactic acid, its condensation products, and water, the equilibrium between the components being dependent on the concentration and temperature.

Lactic acid contains not less than **88.0% *m/m*** and not more than the equivalent of **92.0% *m/m*** of $C_3H_6O_3$.

Identity tests

A. To 5 mL of a solution containing 5 mg of Lactic acid, add 1 mL of bromine TS1 and 0.5 mL of sulfuric acid (~100 g/l) TS and heat on a water-bath until the colour is discharged, while stirring occasionally with a glass rod (an odour of acetaldehyde is perceptible). Add 4 g of ammonium sulfate R, mix, and add, drop by drop without mixing, 0.2 mL of a solution containing 10 mg of sodium nitroprusside R per mL of sulfuric acid (~100 g/l) TS. Without prior mixing add 1 mL of ammonia (~260 g/l) TS and allow to stand for 30 minutes; a dark green ring is produced at the interface of the two liquids.

B. A mixture of 1 mL and 9 mL of water shows an acid reaction with pH-indicator paper R.

C. Relative density, d_{20}^{20} = 1.20 - 1.21.

Heavy metals. Use 1.0 g for the preparation of the test solution as described under 2.2.3 Limit test for heavy metals, Procedure 1; determine the heavy metals content according to Method A; not more than 10 µg/g.

Iron. Use 1.0 g; the solution complies with the 2.2.4 Limit test for iron; not more than 40 µg/g.

Calcium. Dissolve 5 g in 42 mL of sodium hydroxide (1 mol/l) VS and dilute to 50 mL with distilled water. Dilute 5 mL to 15 mL with distilled water. (Keep the remaining solution for the "Chlorides" and "Sugars and other reducing substances" tests.)

To 0,2 mL of ethanolic calcium standard (100 µg/mL Ca) TS add 1 mL of ammonium oxalate (50 g/l) TS and allow to stand for 1 minute. Add 1 mL of acetic acid (~60 g/l) TS and the above-prepared 15 mL of test solution. Similarly, prepare a reference solution but using 10 mL of calcium standard (10 µg/mL) TS and 5 mL of water. Allow both solutions to stand for 15 minutes. Any opalescence observed in the test solution is not more intense than that of the reference solution (200 µg/g).

Chlorides. Dissolve 0.1 g in 10 mL of water, acidify with nitric acid (~130 g/l) TS, and add a few drops of silver nitrate (40 g/l) TS; no opalescence is immediately produced.

Sulfates. Take 25 mL of the solution prepared for the "Calcium" test and proceed as described under 2.2.2 Limit test for sulfates; the sulfate content is not more than 200 µg/g.

Sugars and other reducing substances. To 1 mL of the solution prepared for the "Calcium" test add 1 mL of hydrochloric acid (1 mol/l) VS, heat to boiling, cool, and add 1.5 mL of sodium hydroxide (1 mol/l) VS and 2 mL of potassio-cupric tartrate TS. Heat to boiling; no red or greenish precipitate is produced.

Volatile fatty acids. Heat 5 g cautiously in a glass-stoppered flask at 50 °C for 10 minutes; on opening of the flask no unpleasant

odour resembling that of the lower fatty acids is noticed.

Methanol and methyl esters. Place 2 g in a round-bottomed flask and add 10 mL of water. Cool in ice, add cautiously a mixture of 7.5 mL of water with 22.5 mL of potassium hydroxide (~400 g/l) TS, and cool in ice for a further 10-15 minutes. Connect to a suitable condenser and steam distil. Collect the distillate in a 10-mL graduated flask containing 1 mL of ethanol (~750 g/l) TS and distil until a volume of at least 9.5 mL is obtained. Dilute to 10 mL with water and to 1 mL add 5 mL of potassium permanganate/phosphoric acid TS and mix. After 15 minutes add 2 mL of oxalic acid/sulfuric acid TS, stir with a glass rod until the solution is colourless, and then add 5 mL of decolorized fuchsin TS. Allow to stand for 2 hours. The solution is not more intensely coloured than a reference solution prepared similarly, but using instead of the distillate 1.0 mL of a solution containing 100 µg of methanol R and 0.1 mL of ethanol (~750 g/l) TS per mL (500 µg/g of methanol).

Citric, oxalic, phosphoric, and tartaric acid. To 1 g dissolved in 10 mL of water add 40 mL of calcium hydroxide TS and boil for 2 minutes; no turbidity is produced.

Ether-insoluble substances. Dissolve 1 g in 25 mL of ether R and compare it with 25 mL of ether R; both solutions are equally clear.

Colour. Lactic acid is not more intensely coloured than standard colour solution Yw2 when compared as described under 1.11 Colour of liquids.

Sulfated ash. Not more than 1.0 mg/g.

Assay. Place about 1 g, accurately weighed, in a glass-stoppered flask, and add 10 mL of water and 20 mL of sodium hydroxide (1 mol/l) VS. Stopper the flask and allow to stand for 30 minutes. Back-titrate with hydrochloric acid (1 mol/l) VS, using 0.5 mL of phenolphthalein/ethanol TS as indicator.

Each mL of sodium hydroxide (1 mol/l) VS is equivalent to 90.08 mg of $C_3H_6O_3$.

Additional requirements for Lactic acid for parenteral use

Complies with the monograph for "Parenteral preparations".

Bacterial endotoxins. Carry out the test as described under 3.4 Test for bacterial endotoxins; contains not more than 83.3 IU of endotoxin RS per mg.