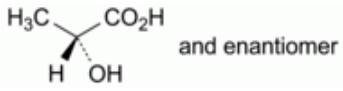
Edition: BP 2025 (Ph. Eur. 11.6 update)

# Lactic Acid

General Notices

*(Ph. Eur. monograph 0458)*




$C_3H_6O_3$ 90.1

**Preparations**

Sodium Lactate Infusion

Compound Sodium Lactate Infusion

Lactic Acid Pessaries

Ph Eur

## DEFINITION

Mixture of 2-hydroxypropanoic acid, its condensation products, such as lactoyl-lactic acid and polylactic acids, and water. The equilibrium between lactic acid and polylactic acids depends on the concentration and temperature. It is usually the racemate ((*RS*)-lactic acid).

### Content

88.0 per cent *m/m* to 92.0 per cent *m/m* of $C_3H_6O_3$.

## CHARACTERS

### Appearance

Colourless or slightly yellow, syrupy liquid.

### Solubility

Miscible with water and with ethanol (96 per cent).

## IDENTIFICATION

A. Dissolve 1 g in 10 mL of *water R*. The solution is strongly acidic (*2.2.4*).
B. Relative density (*2.2.5*): 1.20 to 1.21.
C. It gives the reaction of lactates (*2.3.1*).

## TESTS

### Solution S

Dissolve 5.0 g in 42 mL of *1 M sodium hydroxide* and dilute to 50 mL with *distilled water R*.

### Appearance

The substance to be examined is not more intensely coloured than reference solution $Y_6$ (*2.2.2, Method II*).

### Ether-insoluble substances

Dissolve 1.0 g in 25 mL of *ether R*. The solution is not more opalescent than the solvent used for the test.

### Sugars and other reducing substances

To 1 mL of solution S add 1 mL of *1 M hydrochloric acid*, heat to boiling, allow to cool and add 1.5 mL of *1 M sodium hydroxide* and 2 mL of *cupri-tartaric solution R*. Heat to boiling. No red or greenish precipitate is formed.

### Methanol (*2.4.24*)

Maximum 50 ppm, if intended for use in the manufacture of parenteral preparations.

### Citric, oxalic and phosphoric acids

To 5 mL of solution S add *dilute ammonia R1* until slightly alkaline (*2.2.4*). Add 1 mL of *calcium chloride solution R*. Heat on a water-bath for 5 min. Both before and after heating, any opalescence in the solution is not more intense than that in a mixture of 1 mL of *water R* and 5 mL of solution S.

### Sulfates (*2.4.13*)

Maximum 200 ppm.

Dilute 7.5 mL of solution S to 15 mL with *distilled water R*.

### Calcium (*2.4.3*)

Maximum 200 ppm.

Dilute 5 mL of solution S to 15 mL with *distilled water R*.

**Sulfated ash** (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

**Bacterial endotoxins** (*2.6.14*)

Less than 5 IU/g, if intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins. Before use, neutralise the test solution to pH 7.0-7.5 with *strong sodium hydroxide solution R* and shake vigorously.

## ASSAY

Place 1.000 g in a ground-glass-stoppered flask and add 10 mL of *water R* and 20.0 mL of *1 M sodium hydroxide*. Close the flask and allow to stand for 30 min. Using 0.5 mL of *phenolphthalein solution R* as indicator, titrate with *1 M hydrochloric acid* until the pink colour is discharged.

1 mL of *1 M sodium hydroxide* is equivalent to 90.1 mg of $C_3H_6O_3$.

## LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of parenteral preparations.

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