



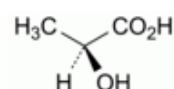
Edition: BP 2025 (Ph. Eur. 11.6 update)

(S)-Lactic Acid



[General Notices](#)

(Ph. Eur. monograph 1771)



$C_3H_6O_3$ 90.1

Ph Eur

DEFINITION

Mixture of (S)-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.

Content

88.0 per cent *m/m* to 92.0 per cent *m/m* of $C_3H_6O_3$, not less than 95.0 per cent of which is the (S)-enantiomer.

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](#)).
- D. It complies with the limits of the assay.

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 Y₆ ([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 $C_3H_6O_3$.

(S)-enantiomer

Transfer an amount of the substance to be examined equivalent to 2.00 g of lactic acid into a round-bottomed flask, add 25 mL of [1 M sodium hydroxide](#) and boil gently for 15 min. Cool down and adjust to pH 7.0 using [1 M hydrochloric acid](#). Add 5.0 g of [ammonium molybdate R](#), dissolve and dilute to 50.0 mL with [water R](#). Filter and measure the angle of optical rotation ([2.2.7](#)). Calculate the percentage content of (S)-enantiomer using the expression:

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α	=	angle of optical rotation (absolute value),
m	=	mass of the substance to be examined, in grams,
c	=	percentage content of $C_3H_6O_3$ in the substance to be examined.

The complex of (S)-lactic acid formed under these test conditions is laevorotatory.

LABELLING

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

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