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

Sodium (*S*)-Lactate Solution

General Notices

(Ph. Eur. monograph 2033)

Ph Eur

DEFINITION

Content

Minimum 50.0 per cent *m/m* of sodium (2*S*)-2-hydroxypropanoate ($C_3H_5NaO_3$; M_r 112.1); 96.0 per cent to 104.0 per cent of the content of sodium lactate stated on the label, not less than 95.0 per cent of which is the (*S*)-enantiomer.

CHARACTERS

Appearance

Clear, colourless, slightly syrupy liquid.

Solubility

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

IDENTIFICATION

A. To 0.1 mL add 10 mL of *water R*. 5 mL of the solution gives the reaction of lactates (*2.3.1*).
B. It gives reaction (a) of sodium (*2.3.1*).
C. It complies with the limits of the assay.

TESTS

Solution S

Dilute a quantity of the substance to be examined corresponding to 40.0 g of sodium lactate to 200 mL with *distilled water R*.

Appearance of solution

The substance to be examined is clear (*2.2.1*) and not more intensely coloured than reference solution BY_7 (*2.2.2, Method II*).

pH (*2.2.3*)

6.5 to 9.0 for the substance to be examined.

Reducing sugars and sucrose

To 5 mL of the substance to be examined add 2 mL of *dilute sodium hydroxide solution R* and 0.2 mL of *copper sulfate solution R*. The solution is clear and blue and remains so on boiling. Add to the hot solution 4 mL of *hydrochloric acid R*. Boil for 1 min. Add 6 mL of *strong sodium hydroxide solution R* and heat to boiling again. The solution is clear and blue.

Methanol

Gas chromatography (*2.4.24*).

Limit:

— *methanol*: maximum 50 ppm, calculated with reference to sodium lactate, if intended for use in the manufacture of parenteral preparations, dialysis, haemodialysis or haemofiltration solutions.

Chlorides (*2.4.4*)

Maximum 50 ppm calculated with reference to sodium lactate.

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

Oxalates and phosphates

To 1 mL of the substance to be examined add 15 mL of *ethanol (96 per cent) R* and 2 mL of *calcium chloride solution R*. Heat at 75 °C for 5 min. Any opalescence in the solution is not more intense than that of a standard prepared at the same time and in the same manner using a mixture of 1 mL of the substance to be examined, 15 mL of *ethanol (96 per cent) R* and 2 mL of *water R*.

Sulfates (*2.4.13*)

Maximum 100 ppm calculated with reference to sodium lactate.

To 7.5 mL of solution S, add 1.9 mL of *hydrochloric acid R1* and dilute to 15 mL with *distilled water R*. The solution complies with the limit test for sulfates without addition of 0.5 mL of *acetic acid R*. Acidify the standard solution with 0.05 mL of *hydrochloric acid R1* instead of 0.5 mL of *acetic acid R*.

Aluminium

Maximum 0.1 ppm, if intended for use in the manufacture of parenteral preparations, dialysis, haemodialysis or haemofiltration solutions.

Atomic absorption spectrometry (*2.2.23, Method I*). For the preparation of the solutions, use equipment that is aluminium-free or that will not release aluminium under the conditions of use (glass, polyethylene, etc).

Modifier solution Dissolve 100.0 g of *ammonium nitrate R* in a mixture of 50 mL of *water R* and 4 mL of *nitric acid R* and dilute to 200 mL with *water R*.

Blank solution Dilute 2.0 mL of the modifier solution to 25.0 mL with *water R*.

Test solution To 5.0 g add 2.0 mL of the modifier solution and dilute to 25.0 mL with *water R*.

Reference solutions Prepare the reference solutions immediately before use (0.010 ppm to 0.050 ppm of aluminium) using *aluminium standard solution (200 ppm Al) R*.

Source Aluminium hollow-cathode lamp.

Wavelength 309.3 nm.

Atomisation device Graphite furnace.

Carrier gas argon R.

Conditions The device is equipped with a non-specific absorption correction system. Heat the oven to 120 °C for as many seconds as there are microlitres of solution introduced into the apparatus, then heat at 1000 °C for 30 s and finally at 2700 °C for 6 s.

Iron (2.4.9)

Maximum 10 ppm calculated with reference to sodium lactate.

Dilute 5 mL of solution S to 10 mL with water R.

ASSAY

Dissolve a quantity of the substance to be examined corresponding to 75.0 mg of sodium lactate in a mixture of 10 mL of glacial acetic acid R and 20 mL of acetic anhydride R. Allow to stand for 15 min. Add 1 mL of naphtholbenzein solution R and titrate with 0.1 M perchloric acid.

1 mL of 0.1 M perchloric acid is equivalent to 11.21 mg of $C_3H_5NaO_3$.

(*S*)-enantiomer

Transfer a quantity of the substance to be examined corresponding to 2.50 g of sodium lactate into a 50 mL volumetric flask, dilute with about 30 mL of water R and add 5.0 g of ammonium molybdate R. Dissolve and dilute with water R to 50.0 mL. Measure the angle of optical rotation (2.2.7). Calculate the percentage content of (*S*)-enantiomer using the expression:

α	=	angle of optical rotation (absolute value);
m	=	mass of the substance to be examined, in grams;
c	=	percentage content *m/m* of $C_3H_5NaO_3$ in the substance to be examined.

The complex of sodium (*S*)-lactate formed under these test conditions is laevorotatory.

LABELLING

The label states:

— where applicable, that the substance is suitable for use in the manufacture of dialysis, haemodialysis and haemofiltration solutions;

— where applicable, that the substance is suitable for use in the manufacture of parenteral preparations;

— the declared content of sodium lactate.