IDENTIFICATION

A. Solution S (see Tests) gives the reactions of iodides (*2.3.1*).

B. Solution S gives the reactions of sodium (*2.3.1*).

TESTS

Solution S. Dissolve 10.0 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 100 mL with the same solvent.

Appearance of solution. Solution S is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

Alkalinity. To 12.5 mL of solution S add 0.1 mL of *bromothymol blue solution R1*. Not more than 0.7 mL of *0.01 M hydrochloric acid* is required to change the colour of the indicator.

Iodates. To 10 mL of solution S add 0.25 mL of *iodide-free starch solution R* and 0.2 mL of *dilute sulfuric acid R* and allow to stand protected from light for 2 min. No blue colour develops.

Sulfates (*2.4.13*): maximum 150 ppm.

Dilute 10 mL of solution S to 15 mL with *distilled water R*.

Thiosulfates. To 10 mL of solution S add 0.1 mL of *starch solution R* and 0.1 mL of *0.005 M iodine*. A blue colour is produced.

Iron (*2.4.9*): maximum 20 ppm.

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

Heavy metals (*2.4.8*): maximum 10 ppm.

12 mL of solution S complies with test A. Prepare the reference solution using *lead standard solution (1 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 3.0 per cent, determined on 1.00 g by drying in an oven at 105 °C for 3 h.

ASSAY

Dissolve 1.300 g in *water R* and dilute to 100.0 mL with the same solvent. To 20.0 mL of the solution add 40 mL of *hydrochloric acid R* and titrate with *0.05 M potassium iodate* until the colour changes from red to yellow. Add 5 mL of *chloroform R* and continue the titration, shaking vigorously, until the chloroform layer is decolorised.

1 mL of *0.05 M potassium iodate* is equivalent to 14.99 mg of NaI.

STORAGE

Protected from light.

01/2011:1151

SODIUM LACTATE SOLUTION

Natrii lactatis solutio

DEFINITION

Solution of a mixture of the enantiomers of sodium 2-hydroxypropanoate in approximately equal proportions.

Content: minimum declared content 50 per cent *m/m* of sodium 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.

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*).

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 0.2 mL of *copper sulfate solution R* and 2 mL of *dilute sodium hydroxide 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*. The solution complies with the test for chlorides.

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 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 4 mL of *nitric acid R* and 50 mL of *water R* and dilute to 200 mL with *water R*.

Blank solution. Dilute to 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: a 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.

Barium. To 10 mL of solution S add 10 mL of *calcium sulfate solution R*. Allow to stand for 30 min. Any opalescence (*2.2.1*) 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 10 mL of solution S and 10 mL of *distilled water R*.

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*. The solution complies with the test for iron.

Heavy metals (*2.4.8*): maximum 10 ppm calculated with reference to sodium lactate.

12 mL of solution S complies with test A. Prepare the reference solution using *lead standard solution (2 ppm Pb) R*.

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.

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 $C_3H_5NaO_3$.

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.

01/2008:2033

SODIUM (*S*)-LACTATE SOLUTION

Natrii (*S*)-lactatis solutio

DEFINITION

Content: minimum 50.0 per cent *m/m* of sodium (*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 alcohol.

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*. The solution complies with the limit test for chlorides.

Oxalates and phosphates. To 1 mL of the substance to be examined add 15 mL of *alcohol 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 *alcohol 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 1.25 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: a 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.

Barium. To 10 mL of solution S add 10 mL of *calcium sulfate solution R*. Allow to stand for 30 min. Any opalescence (*2.2.1*) 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 10 mL of solution S and 10 mL of *distilled water R*.

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*. The solution complies with the limit test for iron.

Heavy metals (*2.4.8*): maximum 10 ppm calculated with reference to sodium lactate.

12 mL of solution S complies with limit test A. Prepare the standard using *lead standard solution (2 ppm Pb) R*.