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

Partially Dehydrated Liquid Sorbitol

General Notices

(Sorbitol, Liquid, Partially Dehydrated, Ph. Eur. monograph 2048)

Action and use

Excipient.

Ph Eur

DEFINITION

Partially dehydrated liquid sorbitol is obtained by acid-catalysed partial internal dehydration of liquid sorbitol. It contains not less than 68.0 per cent *m/m* and not more than 85.0 per cent *m/m* of anhydrous substances, composed of a mixture of mainly D-sorbitol and 1,4-sorbitan, with mannitol, hydrogenated oligo- and disaccharides, and sorbitans.

Content

(nominal value):

— 1,4-sorbitan ($C_6H_{12}O_5$): minimum 15.0 per cent (anhydrous substance);

— D-sorbitol ($C_6H_{14}O_6$): minimum 25.0 per cent (anhydrous substance).

The contents of 1,4-sorbitan and D-sorbitol are within 95.0 per cent to 105.0 per cent of the nominal values.

CHARACTERS

Appearance

Clear, colourless, syrupy liquid.

Solubility

Miscible with water, practically insoluble in mineral oils and vegetable oils.

IDENTIFICATION

Examine the chromatograms obtained in the assay.

Results The 2 principal peaks in the chromatogram obtained with the test solution are similar in retention time and size to the peaks in the chromatogram obtained with reference solution (a).

TESTS

Solution S

Dilute the substance to be examined with *carbon dioxide-free water R* prepared from *distilled water R* to obtain a solution containing 50.0 per cent *m/m* of anhydrous substance.

Appearance of solution

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

Conductivity (*2.2.38*)

Maximum 20 $\mu S \cdot cm^{-1}$.

Measure the conductivity of solution S, while gently stirring with a magnetic stirrer.

Reducing sugars

Maximum 0.3 per cent, calculated as glucose (anhydrous substance).

To an amount of the substance to be examined equivalent to 3.3 g of anhydrous substance, add 3 mL of *water R*, 20.0 mL of *cupri-citric solution R* and a few glass beads. Heat so that boiling begins after 4 min. Maintain boiling for 3 min. Cool rapidly and add 100 mL of a 2.4 per cent *V/V* solution of *glacial acetic acid R* and 20.0 mL of *0.025 M iodine*. With continuous shaking, add 25 mL of a mixture of 6 mL of *hydrochloric acid R* and 94 mL of *water R*. When the precipitate has dissolved, titrate the excess of iodine with *0.05 M sodium thiosulfate* using 2 mL of *starch solution R*, added towards the end of the titration, as indicator. Not less than 12.8 mL of *0.05 M sodium thiosulfate* is required.

Water (*2.5.12*)

15.0 per cent to 32.0 per cent, determined on 0.100 g.

Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

Absence of *Escherichia coli* (*2.6.13*).

Absence of *Salmonella* (*2.6.13*).

ASSAY

Liquid chromatography (*2.2.29*).

Test solution Dissolve 0.400 g of the substance to be examined in *water R* and dilute to 20.0 mL with the same solvent.

Reference solution (a) Dissolve 50.0 mg of *sorbitol CRS* and 20.0 mg of *1,4-sorbitan CRS* in *water R* and dilute to 5.0 mL with the same solvent.

Reference solution (b) Dissolve 0.100 g of *mannitol R* and 0.100 g of *sorbitol R* in *water R* and dilute to 10 mL with the same solvent.

Column:

— *size*: *l* = 0.3 m, Ø = 7.8 mm;

— *stationary phase*: *strong cation-exchange resin (calcium form) R* (9 µm);

— *temperature*: 55 ± 5 °C.

Mobile phase Degassed *water for chromatography R*.

Flow rate 0.5 mL/min.

Detection Differential refractometer maintained at a constant temperature (e.g. 30-35 °C).

Injection 20 µL.

Relative retention With reference to D-sorbitol (retention time = about 30 min): 1,4-sorbitan = about 0.5; mannitol = about 0.8.

System suitability Reference solution (b):

— *resolution*: minimum 2.0 between the peaks due to mannitol and D-sorbitol.

Calculate the percentage contents of 1,4-sorbitan ($C_6H_{12}O_5$) and D-sorbitol ($C_6H_{14}O_6$) taking into account the assigned contents of *1,4-sorbitan CRS* and *sorbitol CRS*.

LABELLING

The label states the content of D-sorbitol and the content of 1,4-sorbitan (= nominal values).

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