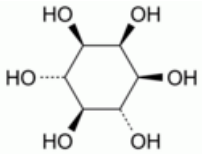
Edition: BP 2025 (Ph. Eur. 11.6 update)

myo-Inositol

General Notices

(Ph. Eur. monograph 1805)



$C_6H_{12}O_6$ 180.2 *87-89-8*

Action and use

Vasodilator.

Ph Eur

DEFINITION

Cyclohexane-1,2,3,5/4,6-hexol.

Content

97.0 per cent to 102.0 per cent (anhydrous substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Very soluble in water, practically insoluble in ethanol (96 per cent).

IDENTIFICATION

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison *myo-inositol CRS*.

B. Examine the chromatograms obtained in the assay.

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

TESTS

Solution S

Dissolve 10.0 g in *distilled water R* and dilute to 100.0 mL with the same solvent.

Appearance of solution

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

Conductivity (*2.2.38*)

Maximum 30 $\mu S \cdot cm^{-1}$.

Dissolve 10.0 g in *carbon dioxide-free water R* prepared from *distilled water R*, with gentle warming if necessary, and dilute to 50.0 mL with the same solvent. Measure the conductivity of the solution while gently stirring with a magnetic stirrer.

Related substances

Liquid chromatography (*2.2.29*).

Test solution Dissolve 0.500 g of the substance to be examined in *water R* and dilute to 10.0 mL with the same solvent.

Reference solution (a) Dissolve 0.500 g of *myo-inositol CRS* in *water R* and dilute to 10.0 mL with the same solvent.

Reference solution (b) Dilute 2.0 mL of the test solution to 100.0 mL with *water R*. Dilute 5.0 mL of this solution to 100.0 mL with *water R*.

Reference solution (c) Dissolve 0.5 g of *myo-inositol R*, 2 mg of *mannitol R* (impurity A) and 2 mg of *glycerol R* (impurity B) 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*: 85 ± 2 °C.

Mobile phase *water for chromatography R*.

Flow rate 0.5 mL/min.

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

Injection 20 µL of the test solution and reference solutions (b) and (c).

Run time Twice the retention time of *myo*-inositol.

Relative retention With reference to *myo*-inositol (retention time = about 16 min): impurity B = about 1.2; impurity A = about 1.3.

System suitability Reference solution (c):

— *resolution*: minimum 1.5 between the peaks due to impurity B and impurity A.

Limits:

— *impurities A, B*: for each impurity, not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent);

— *unspecified impurities*: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.10 per cent);

— *total*: not more than 10 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent);

— *disregard limit*: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Water (*2.5.12*)

Maximum 0.5 per cent, determined on 1.00 g.

ASSAY

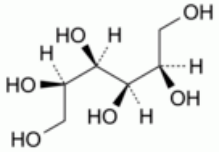
Liquid chromatography (*2.2.29*) as described in the test for related substances with the following modification.

Injection Test solution and reference solution (a).

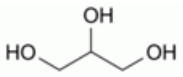
Calculate the percentage content of $C_6H_{12}O_6$ taking into account the assigned content of *myo-inositol CRS*.

IMPURITIES

Specified impurities *A, B.*



A. D-mannitol,



B. propane-1,2,3-triol (glycerol).