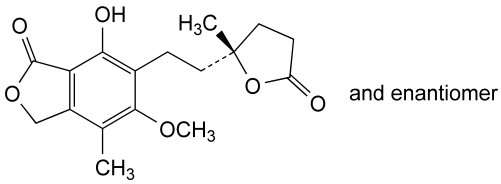

and enantiomer

H. 7-hydroxy-5-methoxy-4-methyl-6-[2-[(2*RS*)-2-methyl-5-oxotetrahydrofuran-2-yl]ethyl]isobenzofuran-1(3*H*)-one.

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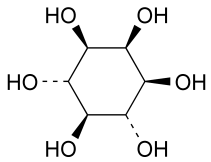
myo-INOSITOL

myo-Inositolum



$C_6H_{12}O_6$ M_r 180.2

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 μS·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* and 0.5 g of *mannitol 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*: 85 °C.

Mobile phase: *water R*.

Flow rate: 0.5 ml/min.

Detection: refractometer maintained at a constant temperature (at about 30-35 °C for example).

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 17.5 min): impurity A = about 1.3; impurity B = about 1.4.

System suitability: reference solution (c):

– *resolution*: minimum 4 between the peaks due to *myo*-inositol 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).

Barium. To 10 ml of solution S add 1 ml of *dilute sulphuric acid R*. When examined immediately, and after 1 h, any opalescence in the solution is not more intense than that in a mixture of 1 ml of *distilled water R* and 10 ml of solution S.

Lead (*2.4.10*): maximum 0.5 ppm.

Prepare the test solution by dissolving 20.0 g of the substance to be examined in 100 ml of *water R*, heating if necessary, and diluting to 200.0 ml with *dilute acetic acid R*.

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 $C_6H_{12}O_6$ from the declared content of *myo-inositol CRS*.

IMPURITIES

Specified impurities: A, B.

A. mannitol,

B. glycerol.